



Australian Government

Department of Health
Therapeutic Goods Administration

POISONS STANDARD 2015

I, ANTHONY GILL, a delegate of the Secretary to the Department of Health for the purposes of paragraph 52D(2)(b) of the *Therapeutic Goods Act 1989* (the Act) and acting in accordance with the Secretary's power under that paragraph of the Act, prepare this new Poisons Standard, in substitution for the current Poisons Standard.

(Signed by)

ANTHONY GILL
Delegate of the Secretary to the Department of Health

Dated this 5 February 2015

1. Citation

This instrument is the *Poisons Standard 2015*.

2. The New Poisons Standard

The Poisons Standard 2015 consists of the Standard for the Uniform Scheduling of Medicines and Poisons No. 6 (the SUSMP6) as set out in Schedule 1.

3. Commencement

The Poisons Standard 2015 commences on the day after registration.

Schedule 1-Standard for the Uniform Scheduling of Medicines and Poisons No. 6

Poisons Standard 2015

**STANDARD FOR THE UNIFORM SCHEDULING OF
MEDICINES AND POISONS
No. 6**

February 2015

Poisons Standard 2015

Reasons for scheduling delegates' final decisions can be accessed from the TGA website, at <https://www.tga.gov.au/reasons-scheduling-delegates-final-decisions>

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Contents

INTRODUCTION	ii
CLASSIFICATION	iii
PRINCIPLES OF SCHEDULING	iii
READING THE SCHEDULES	iv
PART 1	2
INTERPRETATION	2
PART 2	10
CONTROL ON MEDICINES AND POISONS	10
SECTION ONE LABELS	10
SECTION TWO CONTAINERS	20
PART 3	28
MISCELLANEOUS REGULATIONS	28
SECTION ONE ADVERTISING	28
SECTION TWO SALE OR SUPPLY	28
SECTION 3 STORAGE	29
PART 4	31
THE SCHEDULES	31
SCHEDULE 1	32
SCHEDULE 2	33
SCHEDULE 3	48
SCHEDULE 4	54
SCHEDULE 5	131
SCHEDULE 6	158
SCHEDULE 7	196
SCHEDULE 8	207
SCHEDULE 9	210
SCHEDULE 10	216
PART 5	221
THE APPENDICES	221
APPENDIX A	222
APPENDIX B	225
APPENDIX C (see SCHEDULE 10)	234
APPENDIX D	235
APPENDIX E	237
APPENDIX F	252
APPENDIX G	276
APPENDIX H	277
APPENDIX I	278
APPENDIX J	279
APPENDIX K	282
APPENDIX L	285

INTRODUCTION

The Poisons Standard 2015, which, under section 2 above consists of the *Standard for the Uniform Scheduling of Medicines and Poisons* (the Standard, or the SUSMP), is made under paragraph 52D(2)(b) of the *Therapeutic Goods Act 1989*, and is a compilation of the decisions made under section 52D of the same Act. The SUSMP should be read in conjunction with the *Scheduling Policy Framework* (SPF) of the Australian Health Ministers' Advisory Council. Further information on the scheduling amendments and the SPF can be accessed at www.tga.gov.au. Refer to Part 1, Interpretation, on page 2 below for definitions of specific terms used in this document including “medicine” and “poison” (noting that the definition of poison includes medicine).

The SUSMP serves two key purposes.

Firstly, the SUSMP contains the decisions of the Secretary of the Department of Health or the Secretary's delegates regarding the classification of poisons into Schedules, as recommendations to Australian States and Territories. The scheduling classification sets the level of control on the availability of poisons. The scheduling of poisons is implemented through relevant State and Territory legislation. Certain advertising, labelling and packaging requirements may also be a consequence of scheduling, but are the subject of other Commonwealth registration schemes.

Secondly, the SUSMP includes model provisions for labelling, containers, storage and possession of poisons in general, which are intended to be adopted for use in each jurisdiction of Australia, according to local requirements and local law. Other government agencies may also impose controls on certain products, for example cosmetics.

The requirements for labelling and containers in the SUSMP are intended to integrate with existing legislative instruments for labelling and containers. Advertising, labelling and packaging of therapeutic goods and agricultural and veterinary chemicals are also dealt with through the respective product registration schemes provided for in Commonwealth legislation.

Poisons which are packed and sold solely for industrial, manufacturing, laboratory or dispensary use are exempt from all labelling requirements included in the SUSMP as they are covered by Safe Work Australia's *National Code of Practice for the Labelling of Workplace Substances* [NOHSC: 2012(1994)]. Note, however that this exemption does not extend to controls on supply of these poisons.

The SUSMP is presented with a view to promoting uniform:

- scheduling of poisons throughout Australia;
- signal headings on labels for poisons throughout Australia;
- labelling and packaging requirements for poisons throughout Australia;
- additional controls on the availability and use of poisons in Australia.

The various Commonwealth Acts, legislative instruments and other documents which integrate with the SUSMP include:

- the *Agricultural and Veterinary Chemicals Code Act 1994*
- the *Agricultural and Veterinary Chemicals Code Regulations 1995*
- the *Therapeutic Goods Act 1989*
- Therapeutic Goods Order 69 – *General requirements for labels for medicines*
- Therapeutic Goods Order 80 – *Child-Resistant Packaging Requirements for Medicines*
- the *Required Advisory Statements for Medicine Labels* (RASML).

CLASSIFICATION

Poisons are classified according to the Schedules in which they are included. The following is a general description of the Schedules. For the legal definitions, however, it is necessary to check with each relevant State or Territory authority.

- Schedule 1.** This Schedule is intentionally blank.
- Schedule 2. Pharmacy Medicine** – Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.
- Schedule 3. Pharmacist Only Medicine** – Substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription.
- Schedule 4. Prescription Only Medicine, or Prescription Animal Remedy** – Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.
- Schedule 5. Caution** – Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.
- Schedule 6. Poison** – Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.
- Schedule 7. Dangerous Poison** – Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.
- Schedule 8. Controlled Drug** – Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.
- Schedule 9. Prohibited Substance** – Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.
- Schedule 10/
Appendix C. Substances of such danger to health as to warrant prohibition of sale, supply and use** - Substances which are prohibited for the purpose or purposes listed for each poison.

PRINCIPLES OF SCHEDULING

Poisons are not scheduled on the basis of a universal scale of toxicity. Although toxicity is one of the factors considered, and is itself a complex of factors, the decision to include a substance in a particular Schedule also takes into account many other criteria such as the purpose of use, potential for abuse, safety in use and the need for the substance.

This Standard lists poisons in nine Schedules according to the degree of control recommended to be exercised over their availability to the public.

Poisons for therapeutic use (medicines) are mostly included in Schedules 2, 3, 4 and 8 with progression through these Schedules signifying increasingly restrictive regulatory controls.

For some medicines and agricultural, domestic and industrial poisons, Schedules 5, 6 and 7 represent increasingly stricter container and labelling requirements with special regulatory controls over the availability of the poisons listed in Schedule 7. Products for domestic use must not include poisons listed in Schedule 7.

Schedule 9 contains substances that should be available only for teaching, training, medical or scientific research including clinical trials conducted with the approval of Commonwealth and/or State and Territory health authorities. Although appearing as a Schedule in this Standard, the method by which it is implemented in the States and Territories may vary.

Schedule 10/Appendix C contains a list of substances or preparations, the sale, supply or use of which should be prohibited because of their known dangerous properties.

Substances in products which have been considered for scheduling, but have been exempted from this Standard, may be listed in either Appendix A (general exemptions) or Appendix B (substances considered not to require control by scheduling).

READING THE SCHEDULES

Schedule entries have been designed to be as simple as possible while retaining readability, legal integrity and as much freedom from ambiguity and contradiction as possible. As a result, they are expressed in a number of ways, though this number has been kept to a minimum. It is necessary to keep this variety of expression in mind when searching or interpreting Schedule entries.

Firstly, poisons are scheduled individually using their approved names wherever practicable although exceptions are necessary in some cases. Some of those are mentioned overleaf. Older group entries are revised and replaced by individual entries as time permits, although in some of these cases a group term has also been retained to deal with any members of the group or class that may have escaped attention but should be scheduled.

Secondly, Schedule entries have been expressed in either positive or negative terms and care must be taken to distinguish between the two different forms of expression. Thus, selenium is in Schedule 6 only when one of the clauses in this Schedule entry applies, while fluorides are in Schedule 6 unless one of the exempting clauses applies.

Where exceptions are included in an entry, these have been emphasised by printing the word “except” in bold type.

Where the Schedule entries for a poison make a specific exclusion or exemption, the requirements of this Standard do not apply to that poison within the constraints of that exclusion or exemption although controls under other legislation, such as pesticide registration, may apply.

Where a Schedule entry for a poison requires a specific statement to be included on a label as a condition for a product to qualify for an exemption (‘reverse scheduling’), then in cases where it is impracticable for a supplier to use the exact wording of such a statement, its wording may be varied provided that the full intent and meaning of the statement is not changed.

Where a poison has been included in more than one Schedule, the principal entry, where practicable, has been included in the most restrictive Schedule with references to the other Schedule(s) involved.

It is important to remember that a Schedule entry includes preparations containing the poison in any concentration and all salts and derivatives of the poison unless it specifically states otherwise. (See Part 1, Interpretation, subparagraph 1(2)).

It is important to note that a substance is not classed as a derivative on the basis of a single, prescriptive set of criteria. Classification of a substance as a derivative of a scheduled poison relies on a balanced consideration of factors to decide if a substance has a similar nature (e.g. structurally, pharmacologically, toxicologically) to a scheduled poison or is readily converted (either physically or chemically) to a scheduled poison. However, a substance is only considered a derivative of a scheduled poison if it is not individually listed elsewhere in the

Schedules, or captured by a more restrictive group or class entry. Additionally, some entries specifically exclude derivatives. Once a substance is determined to be a derivative of a scheduled poison, the same scheduling requirements as the scheduled poison, including limits on access, supply and availability, will apply.

Finally, when using this Standard to determine the scheduling status of a poison, it may be necessary to search each relevant Schedule as well as Appendices A and B, the Index and the Cross Reference Index. In this process, if the poison is not found under its “approved name” it may be shown under a group term such as:

Group	Example
the parent acid of salts	“oxalic acid” to find sodium oxalate
the radical of a salt	“chromates” to find potassium chromate
the element	“arsenic” to find arsenic trioxide
a chemical group with similar toxicological or pharmacological activity	“hydrocarbons, liquid” to find kerosene
a pharmacological group	“anabolic steroidal agents” to find “androsterone”

Availability of poisons

The purpose of classification is to group substances into Schedules that require similar regulatory controls over their availability.

These Schedules have been developed over a long period and contain poisons that may be obsolete for various reasons. Also, as part of the move to harmonise the Australian and New Zealand classifications, many substances have been added to the Schedules for that purpose, irrespective of their availability in either country.

Inclusion of a poison in a Schedule indicates the degree of control required if it is marketed. It does not indicate:

- that the poison is available; nor
- that it has been approved or is efficacious for any use that may be specified in a Schedule; nor
- does it negate any obligation for registration of a therapeutic good, or agricultural or veterinary chemical product containing that poison.

Preparations containing poisons listed in two or more Schedules

If a preparation contains two or more poisons, the provisions relating to each of the Schedules in which those poisons are included apply.

Where it is not possible to comply both with a provision relating to one of those Schedules and with a provision relating to another of those Schedules, the provision of the more restrictive Schedule applies, unless a contrary intention is indicated in the Schedules or relevant legislation.

The Schedules listed in order of greatest to least restriction on access and availability are 9, 10, 8, 4, 7, 3, 2, 6, 5.

Schedule 1 is not currently in use.

Some substances in certain circumstances are also subject to exemptions or additional restrictions as described in the Appendices of this Standard. The table below summarises the purpose of each of the Appendices and the controls imposed on substances included in them.

Appendix	Title	Purpose/ controls imposed
Appendix A	General exemptions	List of classes of products or uses exempted from this Standard.
Appendix B	Substances considered not to require control by scheduling	List of poisons exempted from scheduling.
Appendix C	Appendix is intentionally left blank	
Appendix D	Additional controls on possession or supply of poisons included in Schedule 4 or 8	List of poisons included in Schedule 4 or 8 where additional specified controls apply on possession or supply.
Appendix E	First aid instructions for poisons	First aid instructions for poisons (other than agricultural and veterinary chemicals and chemicals packed and sold solely for industrial, dispensary, manufacturing or laboratory use).
Appendix F	Warning statements and general safety directions for poisons	Warning statements and general safety directions for poisons (other than human medicines, agricultural and veterinary chemicals and chemicals packed and sold solely for industrial, dispensary, manufacturing or laboratory use).
Appendix G	Dilute preparations	Concentration cut-offs for specified poisons, below which the requirements of the Standard do not apply
Appendix H	Schedule 3 medicines permitted to be advertised	List of medicines included in Schedule 3 that are permitted to be advertised to the public.
Appendix I	Appendix is intentionally left blank	
Appendix J	Conditions for availability and use of Schedule 7 poisons	List of poisons included in Schedule 7 where additional specified conditions apply to their availability and use.
Appendix K	Human medicines required to be labelled with a sedation warning	List of human medicines required to be labelled with a warning regarding their sedation potential.
Appendix L	Requirements for dispensing labels for medicines	Requirements applying to labels attached to medicines at the time of dispensing.

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PART 1

INTERPRETATION

1. (1) In this Standard, unless the contrary intention appears —

“**Agricultural chemical**” means a substance that is represented, imported, manufactured, supplied or used as a means of directly or indirectly:

- (a) destroying, stupefying, repelling, inhibiting the feeding of, or preventing infestation by or attacks of, any pest in relation to a plant, a place or a thing;
- (b) destroying a plant;
- (c) modifying the physiology of a plant or pest so as to alter its natural development, productivity, quality or reproductive capacity;
- (d) modifying an effect of another agricultural chemical;
- (e) attracting a pest for the purpose of destroying it; or
- (f) any active ingredient included in a product declared by regulation under the *Agricultural and Veterinary Chemicals Code Act 1994* to be an agricultural chemical product;

but does not include:

- (g) a veterinary chemical.

“**Agricultural chemical product**” has the meaning defined in the *Agricultural and Veterinary Chemicals Code Act 1994*.

“**Animal**” means any animal (other than a human being), whether vertebrate or not, and whether a food producing species or not, and includes mammals, birds, bees, reptiles, amphibians, fish, crustaceans and molluscs.

“**Animal feed premix**” means a concentrated preparation, containing one or more poisons, for mixing with food ingredients to produce a bulk feed for a group of animals (including fish or birds), but does not include a preparation for mixing with an individual animal’s food.

“**Appropriate authority**” means:

- (a) in the Australian Capital Territory, ACT Government Health Directorate;
- (b) for the purpose of providing an exemption from all or part of paragraphs 2 to 12 in Part 2 of this Standard by the Australian Pesticides and Veterinary Medicines Authority, the Chief Executive Officer or their delegate;
- (c) in New South Wales, the Director-General of the NSW Ministry of Health;
- (d) in the Northern Territory, the Chief Health Officer of the Department of Health;
- (e) in Queensland, the Chief Executive of Queensland Health;
- (f) in South Australia, the Chief Executive of the Department for Health and Ageing;
- (g) in Tasmania, the Secretary of the Department of Health and Human Services;
- (h) for the purpose of providing an exemption from all or part of Section 1.1 to Section 1.5.3 of this Standard by the Therapeutic Goods Administration, the National Manager or their delegate;

PART 1, INTERPRETATION - continued

- (i) in Victoria, the Secretary to the Department of Health;
- (j) in Western Australia, the Chief Executive Officer of the Department of Health.

“Approved name” means:

- (a) in relation to a poison that is for human therapeutic use, the name approved for use by the Therapeutic Goods Administration;
- (b) in relation to a poison that is for animal or agricultural use, the name approved for use by the Australian Pesticides and Veterinary Medicines Authority;
- (c) in relation to all other poisons:
 - (i) the name used in an entry in these Schedules; or, if no such name is given,
 - (ii) the English name recommended by Standards Australia as the common name for the poison; or, if no such name is given,
 - (iii) the English name given to the poison by the International Organization for Standardization; or, if no such name is given,
 - (iv) the English name given to the poison by the British Standards Institution; or, if no such name is given,
 - (v) the name that would comply with the requirements of part (a) or (b) of this definition, or, if no such name is given,
 - (vi) the English name given to the poison by the European Committee for Standardization (CEN); or, if no such name is given,
 - (vii) the international non-proprietary name recommended for the poison by the World Health Organization; or, if no such name is given,
 - (viii) the International Nomenclature Cosmetic Ingredient name for the poison listed in the *International Cosmetic Ingredient Dictionary & Handbook* published by the Personal Care Products Council of America; or, if no such name is given,
 - (ix) the accepted scientific name or the name descriptive of the true nature and origin of the poison.

“Australian Code for the Transport of Dangerous Goods by Road and Rail” means the seventh edition of the document of that name.

“Authorised prescriber” means a registered medical, dental or veterinary practitioner or such other person authorised by the appropriate authority.

“Blood” means whole blood extracted from human donors.

“Blood components” means therapeutic components that have been manufactured from blood (including red cells, white cells, stem cells, platelets and plasma), except for products derived through fractionation of plasma.

“Child-resistant closure” means:

- (a) a closure that complies with the requirements for a child-resistant closure in the Australian Standard AS 1928-2007 entitled *Child-resistant packaging – Requirements and testing procedures for reclosable packages* (ISO 8317:2003, MOD);
- (b) a closure approved by an order made under subsection 10(3) of the Commonwealth *Therapeutic Goods Act 1989*; or

PART 1, INTERPRETATION - continued

- (c) in the case of a can fitted with a press-on lid, a lid of the design known as “double tight” or “triple tight”.

See also "Non-access packaging".

“Child-resistant packaging” means packaging that:

- (a) complies with the requirements of the Australian Standard AS 1928-2007 entitled *Child resistant packaging – Requirements and testing procedures for reclosable packages* (ISO 8317:2003, MOD);
- (b) is reclosable and complies with the requirements of at least one of the following Standards:
- (i) the International Organization for Standardization Standard ISO 8317:2003 entitled *Child-resistant packaging – Requirements and testing procedures for reclosable packages*;
 - (ii) the British Standards Institution Standard BS EN ISO 8317:2004 entitled *Child-resistant packaging. Requirements and testing procedures for reclosable packages*;
 - (iii) the Canadian Standards Association Standard CSA Z76.1-06 entitled *Reclosable Child-Resistant Packages*;
 - (iv) the United States Code of Federal Regulations, Title 16, Section 1700.15, entitled *Poison prevention packaging standards* and Section 1700.20, entitled *Testing procedure for special packaging*;
- (c) is approved as child-resistant by any order made under subsection 10(3) of the Commonwealth *Therapeutic Goods Act 1989*; or
- (d) is in the form of blister or strip packaging in which a unit of use is individually protected until the time of release and that complies with Section 3 (Requirements for non-reclosable packages) of Australian Standard AS 1928-2001 entitled *Child-resistant packages*.

See also "Non-access packaging".

“Compounded” in relation to a substance means combined with one or more other therapeutically active substances in such a way that it cannot be separated from them by simple dissolution or other simple physical means.

“Cosmetic” means:

- (a) a substance or preparation intended for placement in contact with any external part of the human body, including:
- (i) the mucous membranes of the oral cavity; and
 - (ii) the teeth;
- with a view to:
- (iii) altering the odours of the body; or
 - (iv) changing its appearance; or
 - (v) cleansing it; or
 - (vi) maintaining it in good condition; or
 - (vii) perfuming it; or

PART 1, INTERPRETATION - continued

(viii) protecting it.

“**Debitterised neem seed oil**” means highly purified oil from the neem seed containing only fatty acids and glycerides of fatty acids.

“**Dermal use**” means application to the skin primarily for localised effect.

“**Designated solvent**” means the following:

acetone
dimethylformamide
N-(N-dodecyl)-2-pyrrolidone
hydrocarbons, liquid
methanol when included in Schedule 5
methyl ethyl ketone
methyl isoamyl ketone
methyl isobutyl ketone
N-methyl-2-pyrrolidone
N-(N-octyl)-2-pyrrolidone
phenyl methyl ketone
styrene
tetrachloroethylene
1,1,1-trichloroethane

“**Dispensing label**” means the label attached to the immediate container of a substance for therapeutic use at the time of dispensing.

“**Distributor**” means a person who imports, sells or otherwise supplies a poison.

“**Divided preparation**” means a preparation manufactured and packed as discrete pre-measured dosage units prior to sale or supply, and includes tablets, capsules, cachets, single dose powders or single dose sachets of powders or granules.

“**Dosage unit**” means an individual dose of a poison for therapeutic use and includes a tablet, capsule, cachet, single dose powder or single dose sachet of powders or granules.

“**Drug**” means a poison intended for human or animal therapeutic use.

“**Essential oils**” means products obtained from natural raw materials either by distillation with water or steam or from the epicarp of citrus fruits by a mechanical process, or by dry distillation. For scheduling purposes it also means:

- (a) oils of equivalent composition derived through synthetic means; or
- (b) prepared mixtures of oils of equivalent composition comprising a mixture of synthetic and natural components.

“**External**” in relation to the use of a poison means application in the ears, eyes or nose or to a body surface other than in the mouth, rectum, vagina, urethra or other body orifice.

“**First Schedule Paint**” means a paint containing the specified proportion of any substance in the First Group to Part 2 of this Standard.

“**Free formaldehyde**” includes all hydrated and non-hydrated formaldehyde present in aqueous solution, including methylene glycol.

“**Graphic material**” means the material which is to be deposited on another material by a graphic instrument during writing, drawing or marking and includes cores of pencils, school pastels or crayons, blackboard chalks, finger or showcard colours, poster paints and watercolour blocks.

“**Height**” in relation to letters used for words, expressions or statements on labels means the height of capital letters or lower case letters having an ascender or a descender.

PART 1, INTERPRETATION - continued

“Hemp seed oil” means the oil obtained by cold expression from the ripened fruits (seeds) of *Cannabis sativa*.

“Immediate container” includes all forms of containers in which a poison is directly packed but does not include any such container intended for consumption or any immediate wrapper.

“Immediate wrapper” means metal foil, plastic foil, waxed paper, or any other such material not intended for consumption, when used as the first wrapper for a dosage unit or dressing.

“Internal use” means administration:

- (a) orally, except for topical effect in the mouth; or
- (b) for absorption and the production of a systemic effect;
 - (i) by way of a body orifice other than the mouth; or
 - (ii) parenterally, other than by application to unbroken skin.

“Label” means:

- (a) a written statement on a container of a poison; and
- (b) in relation to a therapeutic good, includes a display of printed information about the product:
 - (i) on, or attached to, the good;
 - (ii) on, or attached to, a container or primary pack in which the good is supplied; or
 - (iii) supplied with such a container or pack.

“Main label” means, where there are two or more labels on a container or a label is divided into two or more portions:

- (a) the part of a label that is most likely to be displayed, presented, shown, or examined under ordinary or customary conditions of display; and
- (b) where there are two or more labels or two or more portions of a single label – that label or portion of the label where the product name is more or most conspicuously shown; or
- (c) where the product name is equally conspicuous on two or more labels or portions of a label – each such label or portion.

“Manufacturer” means a person who manufactures, produces, or packs a poison.

“Measure pack” means a sealed container which contains a measured quantity of poison for use on one occasion as a pesticide or domestic product and one or more of which is enclosed in a primary pack.

“Medicine” means any poison for therapeutic use.

Note: To be preceded by “human” or “veterinary” where restriction of the “medicine” to human or animal use is intended.

“Name and address” means the name and address, in Australia, of the manufacturer or distributor of a poison but does not include a post office, cable, telegraphic or code address. Where such manufacturer or distributor is a company incorporated in accordance with the appropriate law of any State or Territory of the Commonwealth of Australia or a firm registered under the Business Names Act of any State or Territory, the inclusion in the label of the registered name of the corporation or firm or its branch or its division and the city or town in which a registered office is situated shall be deemed to comply with the requirements.

“Non-access packaging” is packaging that complies with the requirements of Australian Standard

PART 1, INTERPRETATION - continued

AS4710-2001 entitled *Packages for chemicals not intended for access or contact with their contents by humans*, in relation to products that are not intended for human therapeutic use.

See also "Child-resistant closure" and "Child-resistant packaging".

“Non-volatile content” in relation to a paint or tinted means that portion of a paint or tinted determined to be the non-volatile content by Method 301.1 of Australian Standard AS 1580-301.1-2005 entitled *Paints and related materials – Methods of test – Non-volatile content by mass*.

“Oromucosal use” means administration to the oral mucosa, specifically the oral cavity and/or the pharynx.

“Paint”, without limiting the ordinary meaning, includes any substance used or intended to be used for application as a colouring or protective coating to any surface but does not include graphic material or paints for therapeutic use.

“Pesticide” means any substance or mixture of substances used or intended to be used:

- (a) for preventing, destroying, repelling, attracting, inhibiting or controlling any insects, rodents, birds, nematodes, bacteria, fungi, weeds or other forms of plant or animal life or viruses, which are pests; or
- (b) as a plant regulator, promoter, defoliant or desiccant for food storage, household, industrial, commercial, agricultural and non-agricultural application, but does not include veterinary drugs, stock medicines, stock feeds, stock feed additives, drugs for human use, food additives or fertilisers.

“Poison” means any substance or preparation included in a Schedule to this Standard.

“Primary pack” means the pack in which a poison and its immediate container or immediate wrapper or measure pack are presented for sale or supply.

“Required Advisory Statements for Medicine Labels” means the document made under subsection 3(5A) of the *Therapeutic Goods Act 1989* by the Therapeutic Goods Administration.

“Restricted flow insert” means a restriction fitted, or moulded, in the neck of a container which:

- (a) cannot readily be removed from the container by manual force; and
- (b) limits the delivery of the contents to drops each of which is not more than 200 microlitres.

“Second Schedule Paint” means a paint containing the specified proportion of any substance in the Second Group to Part 2 Section 7 of this Standard.

“Selected container” means:

- (a) an injection vial having a nominal capacity of ten millilitres or less;
- (b) a single use syringe; or
- (c) any other container for substances for therapeutic use having a nominal capacity of ten millilitres or less.

“Solid” is considered to include “powder” for the purposes of scheduling.

“Therapeutic good” has the meaning defined in the *Commonwealth Therapeutic Goods Act 1989*.

PART 1, INTERPRETATION - continued

“Therapeutic use” means use in or in connection with:

- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in human beings or animals;
- (b) influencing, inhibiting or modifying a physiological process in human beings or animals;
- (c) testing the susceptibility of human beings or animals to a disease or ailment;
- (d) influencing, controlling or preventing conception in persons or animals;
- (e) testing for pregnancy in persons or animals; or
- (f) the replacement or modification of parts of the anatomy in persons or animals.

“Tinter” means any pigment or admixture of pigment with other substances, in powder, semi-solid or liquid form, sold or supplied for the purpose of adding to paint in order to change the colour of the paint.

“Topical use” means application of a poison for the purpose of producing a localised effect on the surface of the organ or within the tissue to which it is applied.

“Toy” means an object or number of objects manufactured, designed, labelled or marketed as a plaything for a child or children up to the age of fourteen years.

“Transdermal use” means application to the skin primarily for systemic effect.

“Veterinary chemical” means a substance that is represented as being suitable for, or is manufactured, supplied or used for, administration or application to an animal by any means, or consumption by an animal, as a way of directly or indirectly:

- (a) preventing, diagnosing, curing or alleviating a disease or condition in the animal or an infestation of the animal by a pest;
- (b) curing or alleviating an injury suffered by the animal;
- (c) modifying the physiology of the animal:
 - (i) so as to alter its natural development, productivity, quality or reproductive capacity; or
 - (ii) so as to make it more manageable;
- (d) modifying the effect of another veterinary chemical
- (e) any vitamin, mineral substance, or additive, if, and only if, the vitamin, substance or additive is used for a purpose mentioned in paragraph (a), (b), (c) or (d); or
- (f) any active ingredient included in a product declared by regulation under the *Agricultural and Veterinary Chemicals Code Act 1994* to be an veterinary chemical product;

but does not include:

- (g) an agricultural chemical.

“Veterinary chemical product” has the meaning defined in the *Agricultural and Veterinary Chemicals Code Act 1994*.

“Writing” includes the visible representation or reproduction of words or figures in any form, and “to write” and “written” have corresponding meanings.

PART 1, INTERPRETATION - continued

- (2) Unless the contrary intention appears a reference to a substance in a Schedule or an Appendix to this Standard includes:
- (a) that substance prepared from natural sources or artificially; and
 - (b) where the substance is a plant (other than a plant included in Schedule 8 or 9), that plant or any part of that plant when packed or prepared for therapeutic use; and
 - (c) every salt, active principle or derivative of the substance, including esters and ethers, and every salt of such an active principle or derivative; and
 - (d) every alkaloid of the substance and every salt of such an alkaloid; and
 - (e) every stereoisomer of the substance and every salt of such a stereoisomer; and
 - (f) every recombinant form of the substance; and
 - (g) a preparation or admixture containing any proportion of the substance,
- but does not include:
- (h) a preparation or product included in Appendix A, or a substance and the reason for its entry in Appendix B; or
 - (i) a substance included in Appendix G at a concentration not exceeding the concentration specified in column 2 of that Appendix in respect of that substance; or
 - (j) any other substance included in Schedules 1 to 6, at a concentration not exceeding 10 mg per litre or 10 mg per kilogram, unless that substance is also included in Schedule 7 or 8; or
 - (k) any substance present as an impurity in a pesticide, at a concentration at or below the maximum content for that substance, specified for the pesticide in the *Standards for Active Constituents*, as published by the Australian Pesticides and Veterinary Medicines Authority.
- (3) Unless the contrary intention appears where a concentration, strength or quantity is specified in a Schedule or an Appendix to this Standard in respect of a substance:
- (a) if the substance is present as a salt, active principle or derivative (including an ester or ether), the concentration, strength or quantity is calculated as the equivalent amount of the substance that is listed in the Schedule or Appendix; and
 - (b) the expression “one per cent” means:
 - (i) in the case of a liquid preparation, 1 gram of the substance per 100 millilitres of the preparation; or
 - (ii) in the case of a solid, semi-solid or pressurised spray aerosol preparation, 1 gram of the substance per 100 grams of the preparation; and
 - (iii) any expression of greater or lesser percentages shall have a corresponding meaning; and
 - (c) in the case of codeine, such concentration, strength or quantity is calculated as anhydrous codeine.
- (4) A reference to a boiling or distillation temperature in the Schedules means that temperature at an atmospheric pressure of 101.325 kPa (760 millimetres of mercury).

PART 2

CONTROL ON MEDICINES AND POISONS

SECTION ONE

LABELS

1.1 General requirements

- (1) A person must not sell or supply a poison unless it is labelled in accordance with Part 2 Section 1 of this Standard .
- (2) Any word, expression or statement required by this Standard to be written on a label or container must be written:
 - (a) on the outside face of the label or container; and
 - (b) in the English language; and
 - (c) in durable characters; and
 - (d) in a colour or colours to provide a distinct contrast to the background colour; and
 - (e) in letters at least 1.5 millimetres in height.
- (3) Section 1.1(2)(e) does not apply to a word, expression or statement on a container which has a capacity of 20 millilitres or less, or on the label of such a container if:
 - (a) an appropriate authority approves the use of smaller letters; and
 - (b) the letters are at least 1 millimetre in height.
- (4) The label must be printed on, or securely attached to:
 - (a) the outside of the immediate container; and
 - (b) if the immediate container is enclosed in a primary pack, the outside of that primary pack.

1.2 Immediate wrapper

- (1) A poison enclosed in an immediate wrapper must be contained in a primary pack labelled in accordance with Section 1.3 of this Standard; and
- (2) the immediate wrapper must be conspicuously labelled with:
 - (a) the name of the manufacturer or distributor or the brand name or trade name used exclusively by the manufacturer or distributor for that poison; and
 - (b) the approved name of the poison; and
 - (c) a statement of the quantity or strength of the poison in accordance with Section 1.4 of this Standard.

1.3 Primary packs and immediate containers

- (1) The primary pack and immediate container of a poison must be labelled as follows:
 - (a) with the signal word or words relating to the Schedule in which the poison is included and the purpose for which it is to be used, as shown in the following table:

PART 2, CONTROLS ON MEDICINES AND POISONS – continued

Schedule	Purpose	Signal words required
2	for any purpose	PHARMACY MEDICINE
3	for any purpose	PHARMACIST ONLY MEDICINE
4	for human use	PRESCRIPTION ONLY MEDICINE
4	for animal use	PRESCRIPTION ANIMAL REMEDY
5	for any purpose	CAUTION
6	for any purpose	POISON
7	for any purpose	DANGEROUS POISON
8	for any purpose	CONTROLLED DRUG

written:

- (i) on the first line or lines of the main label; and
- (ii) in bold-face sans serif capital letters of uniform thickness; and
- (iii) in letters at least half the height of the largest letter or numeral on the label but need not be larger than:
 - (A) 6 millimetres on labels for packages having a nominal capacity of 2 litres or less; or
 - (B) 15 millimetres on labels for packages having a nominal capacity of more than 2 litres; and
- (iv) if the poison:
 - (A) is a Schedule 5 poison, with nothing, other than a Class label as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail* or a statement of the principal hazard of the poison, written on that line; or
 - (B) is not a Schedule 5 poison, with nothing, other than a Class label as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail*, written on that line;
- (b) if the poison is a Schedule 8 poison, with the cautionary statement –

POSSESSION WITHOUT AUTHORITY ILLEGAL

written:

- (i) on a separate line or lines immediately below the signal words required by Section 1.3(1)(a); and
- (ii) in bold-face sans serif capital letters of uniform thickness; and
- (iii) in letters at least four-tenths the height of the letters used for the signal words; and
- (iv) with no other statement written on the same line;
- (c) with the cautionary statement –

KEEP OUT OF REACH OF CHILDREN

written:

- (i) on a separate line or lines:
 - (A) immediately below the signal word or words required by Section 1.3(1)(a); or
 - (B) where the cautionary statement “POSSESSION WITHOUT AUTHORITY ILLEGAL” is required by Section 1.3(1)(b), on the line immediately below that statement; and
 - (ii) in bold-face sans serif capital letters of uniform thickness; and
 - (iii) in letters at least four-tenths the height of the letters used for the signal word or words; and
 - (iv) with nothing, other than a Class label as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail*, written on the same line;
- (d) if the poison is a dry chlorinating compound containing more than 10 per cent of available chlorine, **except** for preparations certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5, Division 5.1: Oxidising substances, as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail*, with the cautionary statement –

FIRE AND EXPLOSION HAZARD

written:

- (i) on a separate line or lines immediately below the cautionary statement “KEEP OUT OF REACH OF CHILDREN” as required by Section 1.3(1)(c); and
 - (ii) in bold-face sans serif capital letters of uniform thickness; and
 - (iii) in letters at least four-tenths the height of the letters used for the signal word or words; and
 - (iv) with nothing, other than a Class label as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail*, written on the same line;
- (e) if the poison is an alkaline salt in a dishwashing machine product, with the cautionary statement –

BURNS SKIN AND THROAT

written:

- (i) on a separate line or lines immediately below the cautionary statement “KEEP OUT OF REACH OF CHILDREN” as required by Section 1.3(1)(c); and
 - (ii) in bold-face sans serif capital letters of uniform thickness; and
 - (iii) in letters at least four-tenths the height of the letters used for the signal word; and
 - (iv) with nothing, other than a Class label as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail*, written on the same line of the main label;
- (f) if the poison is an aqueous solution of paraquat, with the cautionary statements –

**CAN KILL IF SWALLOWED
DO NOT PUT IN DRINK BOTTLES
KEEP LOCKED UP**

PART 2, CONTROLS ON MEDICINES AND POISONS – continued

written:

- (i) on separate lines immediately below the cautionary statement “KEEP OUT OF REACH OF CHILDREN” as required by Section 1.3(1)(c); and
 - (ii) in bold-face sans serif capital letters of uniform thickness; and
 - (iii) in letters at least four-tenths the height of the letters used for the signal words; and
 - (iv) with nothing, other than a Class label as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail*, written on the same lines of the main label;
- (g) for any poison other than a poison for human therapeutic use labelled in accordance with the *Required Advisory Statements for Medicine Labels*, if safety directions are required on the label by Section 1.3(1)(n), with the cautionary statement –

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

or with the cautionary statement –

READ SAFETY DIRECTIONS

written:

- (i) on a separate line or lines;
 - (A) immediately below the cautionary statement “KEEP OUT OF REACH OF CHILDREN” as required by Section (1)(c); or
 - (B) if one or more other cautionary statements is required to be on the line immediately below “KEEP OUT OF REACH OF CHILDREN”, immediately below that statement or those statements; and
 - (ii) in bold-face sans serif capital letters of uniform thickness; and
 - (iii) in letters at least four-tenths the height of the letters used for the signal word or words; and
 - (iv) with nothing, other than a Class label as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail*, written on the same line;
- (h) if the poison meets the criteria for a ‘flammable liquid’ in the *Australian Code for the Transport of Dangerous Goods by Road and Rail*, with the cautionary statement –

FLAMMABLE

written on the main label in bold-face sans serif capital letters of uniform thickness, unless already present in accordance with the requirements of the *Australian Code for the Transport of Dangerous Goods by Road and Rail*;

- (i) if the poison is for the treatment of animals, with the cautionary statement –

FOR ANIMAL TREATMENT ONLY

written on the main label in bold-face sans serif capital letters of uniform thickness;

- (j) if the poison is a Schedule 5 poison intended for any purpose other than internal or pesticidal use, with the cautionary statement –

DO NOT SWALLOW

PART 2, CONTROLS ON MEDICINES AND POISONS – continued

written in sans serif capital letters on the main label or as part of the directions for use;

- (k) with the approved name of the poison and a statement of the quantity, proportion or strength of the poison in accordance with Section 1.4:
- (i) if the poison is for human therapeutic use, written in accordance with orders made under subsection 10(3) of the Commonwealth *Therapeutic Goods Act, 1989*; or
 - (ii) if the poison is not for human therapeutic use, written in bold-face sans serif capital letters on the main label, unless:
 - (A) a list of approved names is required; and
 - (B) it is impractical to include the list on the main label; and
 - (C) an appropriate authority has authorised its inclusion on another part of the label; or
 - (iii) if the poison is a Schedule 5 poison referred to in column 1 of the following table the appropriate name opposite thereto in column 2 may be used as the approved name:

TABLE

Column 1	Column 2
Alkaline salts	Alkaline salts
Amines for use as curing agents for epoxy resins (unless separately specified in the Schedules)	Aliphatic amines or aromatic amines
Epoxy resins, liquid	Liquid epoxy resins
Hydrocarbons, liquid	Liquid hydrocarbons
Quaternary ammonium compounds	Quaternary ammonium compound(s)

- (iv) if a poison contains a mixture of designated solvents in excess of 25 per cent of the total volume of the poison but the proportion of one or more individual designated solvents in the mixture is equal to or less than 25 per cent, the approved names of those solvents may be expressed as follows:
- (A) where the designated solvent is a liquid hydrocarbon as “liquid hydrocarbons”; or
 - (B) where the designated solvent is a ketone as “ketones”; or
 - (C) in any other case as “solvents” or “other solvents”;
- (l) if the poison is an organophosphorus compound or carbamate for pesticidal use or for the treatment of animals, with the following expression written immediately below the approved name or the list of declared contents –

AN ANTICHOLINESTERASE COMPOUND

- (i) the requirements of Section 1.3(1)(l) do not apply to:
 - (A) dazomet, mancozeb, metiram, propineb, thiram, tri-allate, zineb or ziram; or
 - (B) an organophosphorus compound or carbamate contained in impregnated plastic resin strips, medallions or granules; or

PART 2, CONTROLS ON MEDICINES AND POISONS – continued

- (C) an organophosphorus compound or carbamate contained in a pressurised spray pack for household use;
- (m) for any poison other than a poison for human therapeutic use labelled in accordance with Therapeutic Goods Order 69 *General requirements for labels for medicines* or in an agricultural or veterinary chemical product labelled in compliance with the *Agricultural and Veterinary Chemicals Code Act 1994*, if the poison is prepared, packed or sold for a specific purpose, with clear and adequate directions for use unless:
 - (i) the poison is included in Schedule 4 or Schedule 8; or
 - (ii) it is impractical to include such directions on the label and:
 - (A) the primary pack and the immediate container are labelled with the statement “DIRECTIONS FOR USE: See package insert”; and
 - (B) an appropriate authority has authorised the directions for use to be written on a package insert instead of the label; and
 - (C) the insert is enclosed in the primary pack;
- (n) for any poison other than a poison for human therapeutic use labelled in accordance with the *Required Advisory Statements for Medicine Labels*, if use of the poison may be harmful to the user, with appropriate safety directions (see Appendix F), grouped together as a distinct section of the label and prefaced by the words –

SAFETY DIRECTIONS

written in bold-face capital letters;

- (o) for any poison other than a poison for human therapeutic use labelled in accordance with the *Required Advisory Statements for Medicine Labels*, if any warning statement or statements are required for the poison (see Appendix F), with that warning statement or those statements grouped together:
 - (i) if safety directions are included on the label, immediately after the words “SAFETY DIRECTIONS”; or
 - (ii) if there are no safety directions, immediately preceding the directions for use;
- (p) if the poison is not for human internal use and is not a Schedule 3, Schedule 4 or Schedule 8 poison, with appropriate first aid instructions (see Appendix E):
 - (i) grouped together and prefaced by the words –

FIRST AID

written in bold-face capital letters; or

- (ii) if a primary pack contains two or more immediate containers of poisons each requiring different first aid instructions:
 - (A) written on each immediate container as specified in Section 1.3(1)(p)(i); and
 - (B) replaced on the primary pack with the statement –

FIRST AID: See inner packs;
- (q) with the name and address of the manufacturer or distributor.

PART 2, CONTROLS ON MEDICINES AND POISONS – continued

- (2) For the purposes of Section 1.3(1)(a)(iii) the term “largest letter or numeral” does not include:
- (a) a single letter or numeral which is larger than other lettering on the label; or
 - (b) an affix forming part of the trade name; or
 - (c) in the case of a poison for therapeutic use, numerals used to distinguish the strength of a preparation from the strengths of other preparations of the same poison.

1.4 Statements of quantity, proportion or strength

- (1) The statement of the quantity, proportion or strength of a poison must be expressed in the most appropriate of the following forms:
- (a) if the poison is for human therapeutic use, in the manner prescribed by orders made under subsection 10(3) of the Commonwealth *Therapeutic Goods Act 1989*;
 - (b) if the poison is for a purpose or purposes other than human therapeutic use and:
 - (i) if the poison is in a pressurised spray aerosol preparation, as the mass of the poison per stated mass of the preparation;
 - (ii) if the poison is a liquid in a liquid preparation, as the mass or volume of the poison per stated volume of the preparation;
 - (iii) if the poison is a liquid in a solid or semi-solid preparation, as the mass or volume of the poison per stated mass of the preparation;
 - (iv) if the poison is a solid or semi-solid in a liquid preparation, as the mass of the poison per stated volume of the preparation;
 - (v) if the poison is a solid or semi-solid in a solid or semi-solid preparation, as the mass of the poison per stated mass of the preparation;
 - (vi) if the poison is a gas in a liquid preparation, as the mass of the poison per stated volume of the preparation;
 - (vii) if the poison is a gas in a solid or semi-solid preparation, as the mass of the poison per stated mass of the preparation;
 - (viii) if the poison is a gas in a gaseous preparation, as the mass of the poison per stated mass of the preparation;
 - (c) if the poison is a solution of a mineral acid, the proportion of the acid (un-neutralised by any bases present in the preparation) in a preparation may be expressed as the un-neutralised mass of the acid per stated mass of the preparation;
 - (d) if the poison is an inorganic pigment, the proportion may be expressed as a percentage of the metal present using one of the following expressions as appropriate:
 - contains not more than 10 per cent of (*insert name of the metal*); or
 - contains not more than 30 per cent of (*insert name of the metal*); or
 - contains more than 30 per cent of (*insert name of the metal*);
 - (e) if the poison is included in a paint, other than a paint for therapeutic or cosmetic use, the proportion may be expressed as a range provided that the limits of the range do not differ by more than 5 per cent of the product;
 - (f) if the poison is a lead-based pigment included in automotive paint, the proportion may be expressed as

PART 2, CONTROLS ON MEDICINES AND POISONS – continued

the maximum content of the lead that may be present in the non-volatile content of the paint;

- (g) if a preparation contains more than one derivative of a poison, the quantity or proportion of the poison may be expressed as the equivalent quantity or proportion of one of the derivatives present which it would contain if all of the derivatives were that derivative.
- (h) For the purposes of Section 1.4(1)(g) “derivative” includes alkaloid.

1.5 Exemptions

1.5.1 Selected containers and measure packs

(1) The requirements of Section 1.3 do not apply to an immediate container that is a measure pack or a selected container (other than an ampoule, a pre-filled syringe or an injection vial to which Section 1.5.2 (1) and (2) apply) when:

(a) the immediate container is for a therapeutic good and is labelled in the manner prescribed by orders made under subsection 10(3) of the Commonwealth *Therapeutic Goods Act 1989*; or

(b) the immediate container is:

(i) packed in a primary pack labelled in accordance with Section 1.3; and

(ii) labelled with:

(A) the signal word or words relating to the Schedule in which the poison is included and the purpose for which it is to be used, as shown in the table to Section 1.3(1)(a); and

(B) the approved name of the poison and the quantity, proportion or strength of the poison in accordance with Section 1.4; and

(C) the name of the manufacturer or distributor or the brand name or trade name used exclusively by the manufacturer or distributor for the poison; and

(D) if the poison is for the treatment of animals, with the cautionary statement –

FOR ANIMAL TREATMENT ONLY

written in sans serif capital letters.

1.5.2 Ampoules, pre-filled syringes and injection vials

(1) The requirements of Section 1.3 do not apply to a selected container, or an ampoule (other than an ampoule to which Section 1.5.2(2) applies) when:

(a) the selected container or ampoule is for a therapeutic good and is labelled in the manner prescribed by orders made under subsection 10(3) of the Commonwealth *Therapeutic Goods Act 1989*; or

(b) the selected container or ampoule is:

(i) packed in a primary pack labelled in accordance with Section 1.3; and

(ii) labelled with:

(A) the approved name of the poison and the quantity, proportion or strength of the poison in accordance with Section 1.4; and

(B) with the name of the manufacturer or distributor or the brand name or trade name used exclusively by the manufacturer or distributor for the poison; and

PART 2, CONTROLS ON MEDICINES AND POISONS – continued

(C) if the poison is for the treatment of animals, with the cautionary statement –

FOR ANIMAL TREATMENT ONLY

written in sans serif capital letters.

- (2) The requirements of Section 1.3 do not apply to a selected container that is a plastic ampoule that is continuous with a strip of the same material and opens as it is detached from the strip when:
- (a) the selected container is a plastic ampoule that is continuous with a strip of the same material and opens as it is detached from the strip, is for a therapeutic good and is labelled in the manner prescribed by orders made under subsection 10(3) of the Commonwealth *Therapeutic Goods Act 1989*; or
 - (b) the selected container is a plastic ampoule that is continuous with a strip of the same material and opens as it is detached from the strip, is:
 - (i) packed in a primary pack labelled in accordance with Section 1.3; and
 - (ii) the strip is labelled in accordance with Section 1.5.2; and
 - (iii) the ampoule is labelled with:
 - (A) the approved name of the poison or the trade name of the product; and
 - (B) the quantity, proportion or strength of the poison in accordance with Section 1.4.

1.5.3 Transport containers and wrappings

- (1) The labelling requirements of this Standard do not apply to a transparent cover, or to any wrapper, hamper, packing case, crate or other cover used solely for the purposes of transport or delivery.

1.5.4 Dispensary, industrial, laboratory and manufacturing poisons

- (1) The labelling requirements of this Standard do not apply to a poison that:
- (a) is packed and sold solely for dispensary, industrial, laboratory or manufacturing purposes; and
 - (b) is labelled in accordance with Safe Work Australia's *National Code of Practice for the Labelling of Workplace Substances* [NOHSC: 2012(1994)].

1.5.5 Exemptions from label requirements in certain circumstances

- (1) The labelling requirements of Sections 1.3 to 1.5.3 do not apply to a poison where an appropriate authority has granted a labelling exemption in whole or in part for these sections for a specified product; and
- (2) the labelling exemption from an appropriate authority referred to in Section 1.5.5(1) is limited to no more than 12 months from the effective date of the decision for retail supply of the product; and
- (3) for the avoidance of doubt this paragraph does not apply to exemptions issued under Section 1.3(1)(m)(ii)(B) of this Standard.

1.5.6 Dispensed medicines

- (1) Unless otherwise specified by regulation:
- (a) The labelling requirements of this Standard do not apply to a medicine that:
 - (i) is supplied by an authorised prescriber or other person authorised to supply and is labelled in accordance with the requirements of Appendix L Part 1 of this Standard; or
 - (ii) is supplied on and in accordance with a prescription written by an authorised prescriber and is

PART 2, CONTROLS ON MEDICINES AND POISONS – continued

labelled in accordance with the requirements of Appendix L Part 1 of this Standard; or

(iii) is prepared and supplied by a pharmacist for an individual patient and is labelled in accordance with the requirements of Appendix L Part 1 of this Standard.

(b) A person must not supply a dispensed medicine for human use containing:

(i) a poison listed in column 1 of the table at Appendix L Part 2 of this Standard unless it is clearly labelled with the warning statement(s) specified in column 2 of that table; or

(ii) a poison listed in Appendix K unless it is clearly labelled with a sedation warning (being statement 39, 40 or 90 as specified in Appendix F Part 1 of this Standard).

1.5.7 Gas cylinders

(1) The requirements of Sections 1.3(1)(a)(iv), 1.3(1)(c)(iv), and 1.3(1)(g)(iv) do not apply to a cylinder containing a poison that is a compressed gas.

1.5.8 Paints

(1) The requirements of Section 1.3 do not apply to:

(a) paint (other than a paint for therapeutic or cosmetic use) which:

(i) contains only Schedule 5 poisons; or

(ii) is a First Group or Second Group paint that is labelled with:

(A) the word “WARNING”, written in bold-face sans serif capital letters, the height of which is not less than 5 mm, on the first line of the main label with no other words written on that line; and

(B) the expression “KEEP OUT OF REACH OF CHILDREN”, written in bold-face sans serif capital letters, the height of which is not less than 2.5 mm, on a separate line immediately below the word “WARNING”; and

(C) the appropriate warnings specified for the paint in Appendix F, written immediately below the expression “KEEP OUT OF REACH OF CHILDREN”; and

(D) the name and proportion of the First Group or Second Group poisons it contains, provided that where the substance is a metal or metal salt the proportion is expressed as the metallic element present “calculated on the non-volatile content” or “in the dried film” of the paint; or

(b) a tinter which contains:

(a) only Schedule 5 poisons; or

(b) a poison included in the First Group or Second Group in Part 2 Section 7, provided that it is labelled with the name and proportion of that poison, and where the poison is a metal or metal salt, the proportion is expressed as the metallic element present as “calculated on the non-volatile content” or “in the dried film”.

1.5.9 Camphor and naphthalene

(1) The labelling requirements of Section 1.1(2)(d) and Section 1.3 do not apply to a device that contains camphor or naphthalene in block, ball, disc, pellet or flake form if the device:

(1) complies with Section 2.7; and

(2) is sold or supplied in a primary pack labelled in accordance with Section 1.1 and Section 1.3.

1.6 Prohibitions

- (1) A label used in connection with any poison must not include:
- (a) any reference to this Standard, or any comment on, reference to, or explanation of any expression required by this Standard that directly or by implication contradicts, qualifies or modifies such expression; or
 - (b) any expression or device suggesting or implying that the poison is safe, harmless, non-toxic, non-poisonous, or is recommended or approved by the Government or any government authority unless required by legislation; or
 - (c) any expression or device which is false or misleading in any particular concerning the safety of the poison or any of its ingredients; or
 - (d) any trade name or description that:
 - (i) represents any single constituent of a compound preparation; or
 - (ii) misrepresents the composition or any property or quality of the poison; or
 - (iii) gives any false or misleading indication of origin or place of manufacture of the poison.
- (2) A label must not be attached to the immediate container or primary pack used in connection with any poison in such a manner as to obscure:
- (a) any expression required by this Standard to be written or embossed on the container or pack; or
 - (b) any of the ribs or embossed or printed words required by paragraph 21, 22 or 23 as appropriate.

SECTION TWO CONTAINERS

2.1 Containers for poisons other than Schedule 5 poisons

- (1) A person must not sell or supply a poison unless the immediate container complies with the requirements of Sections 2.1 and 2.3 to 2.7 of this Standard.
- (2) If a poison, other than a Schedule 5 poison, is sold or supplied in a container with a nominal capacity of 2 litres or less, the container must comply with Australian Standard AS 2216-1997, entitled *Packaging for poisonous substances*.
- (3) Notwithstanding Section 2.1(2), a poison which is in Schedule 6 and is an essential oil may be packed in an amber glass container which does not comply with the tactile identification requirements of Australian Standard AS 2216-1997, entitled *Packaging for poisonous substances*, if:
- (a) the other safety factors are not diminished; and
 - (b) the container has a restricted flow insert and a child-resistant closure.
- (4) If a poison, other than a Schedule 5 poison, is sold or supplied in a container with a nominal capacity of more than 2 litres, the container must:
- (a) comply with subsection 1.4 (General Requirements) of Australian Standard AS 2216-1997 entitled *Packaging for poisonous substances*; and
 - (b) have the word “POISON”:
 - (ia) in sans serif capital letters the height of which is at least one thirty second part of the length, height or width of the container, whichever is the greatest:

PART 2, CONTROLS ON MEDICINES AND POISONS – continued

- (A) embossed; or
- (B) indelibly written in a colour in distinct contrast to the background colour;

(ii) on the side or shoulder of the container.

2.2 Containers for Schedule 5 poisons

- (1) The container in which any Schedule 5 poison is sold or supplied must:
- (a) comply with the container requirements of Sections 2.1(2) or 2.1(4); or
 - (b) be readily distinguishable from a container in which food, wine or other beverage is sold; and
 - (i) comply with subsection 1.4 (General Requirements) of Australian Standard AS 2216-1997 entitled *Packaging for poisonous substances*, excluding paragraph 1.4.3;
 - (ii) be securely closed and, except when containing a preparation for use on one occasion only, be capable of being re-closed to prevent spillage of its contents; and
 - (iii) have the expression “POISON”, “NOT TO BE TAKEN” or “NOT TO BE USED AS A FOOD CONTAINER” embossed or indelibly written thereon, or printed on a permanent adhesive label designed to adhere to a substrate without lifting and which cannot be removed without damaging either the label or the substrate.

(2) Notwithstanding Section 2.2(1), the following Schedule 5 poisons namely:

- (a) methylated spirit(s);
- (b) liquid hydrocarbons when packed as kerosene, lamp oil, mineral turpentine, thinners, reducers, white petroleum spirit or dry cleaning fluid;
- (c) petrol;
- (d) toluene; or
- (e) xylene,

must not be sold or supplied in a bottle or jar having a nominal capacity of 2 litres or less, unless the immediate container complies with the container requirements specified in Section 2.1(2).

2.3 Approved containers

- (1) Notwithstanding subparagraphs 21, 22 and 23 a poison may be packed in a container that does not comply with the tactile identification requirements of Australian Standard AS2216-1997 entitled *Packaging for poisonous substances* or the requirements of Section 2.1(4)(b) or Section 2.2(1)(b)(iii) if:
- (a) the other safety factors are not diminished;
 - (b) the container is for a specific purpose; and
 - (c) an appropriate authority has approved the use of the container for that purpose.

2.4 Child-resistant closures

- (1) If a poison, other than a poison included in a therapeutic good packaged in a manner compliant with orders made under subsection 10(3) of the Commonwealth *Therapeutic Goods Act 1989*, listed in column 1 of the following table is sold or supplied in a container having a nominal capacity specified for that poison in column 2, it must be closed with a child-resistant closure.

PART 2, CONTROLS ON MEDICINES AND POISONS – continued

Column 1 Name of the poison	Column 2 Nominal capacity
Alkaline salts included in Schedule 5, when packed and labelled as dishwashing machine tablets.	All sizes
Alkaline salts included in Schedule 5, when packed and labelled as dishwashing machine liquids, solids or gels.	5 litres /kilograms or less
Alkaline salts included in Schedule 5, when packed and labelled as a food additive.	2.5 litres or less
Anise oil when included in Schedule 5.	200 millilitres or less
Basil oil when included in Schedule 5.	200 millilitres or less
Bay oil when included in Schedule 6.	200 millilitres or less
Cajuput oil when included in Schedule 6.	200 millilitres or less
Cassia oil when included in Schedule 5.	200 millilitres or less
Cineole when included in Schedule 6.	2 litres or less
Cinnamon bark oil when included in Schedule 5.	200 millilitres or less
Cinnamon leaf oil when included in Schedule 6.	200 millilitres or less
Clove oil when included in Schedule 6.	200 millilitres or less
Essential oils when included in Schedule 6 because of their natural camphor component.	200 millilitres or less
Ethylene glycol when included in Schedule 6.	5 litres or less
Ethylene glycol when included in Schedule 5 in preparations containing more than 50 per cent of ethylene glycol.	5 litres or less
Eucalyptus oil when included in Schedule 6.	2 litres or less
Eugenol when included in Schedule 6.	200 millilitres or less
Hydrocarbons, liquid, when packed as kerosene, lamp oil, mineral turpentine, thinners, reducers, white petroleum spirit or dry cleaning fluid.	5 litres or less
Hydrochloric acid when included in Schedule 6.	5 litres or less
<i>Leptospermum scoparium</i> oil (manuka oil) when included in Schedule 6	200 millilitres or less
Marjoram oil when included in Schedule 5.	200 millilitres or less

PART 2, CONTROLS ON MEDICINES AND POISONS – continued

Column 1 Name of the poison	Column 2 Nominal capacity
Melaleuca oil (tea-tree oil) when included in Schedule 6.	200 millilitres or less
Methylated spirit excluding preparations or admixtures.	5 litres or less
Methyl salicylate and preparations containing more than 50 per cent of methyl salicylate.	200 millilitres or less
Nutmeg oil when included in Schedule 5.	200 millilitres or less
Oil of turpentine.	5 litres or less
Pennyroyal oil when included in Schedule 6.	200 millilitres or less
Potassium hydroxide as such.	2.5 litres or less
Potassium hydroxide in oven, hot plate or drain cleaners when included in Schedule 6 except when in pressurised spray packs.	5 litres or less
d-Pulegone when included in Schedule 6.	200 millilitres or less
Sage oil (Dalmatian) when included in Schedule 6.	200 millilitres or less
Sodium hydroxide as such.	2.5 litres or less
Sodium hydroxide in oven, hot plate or drain cleaners when included in Schedule 6 except when in pressurised spray packs.	5 litres or less
Thujone when included in Schedule 6.	200 millilitres or less
Thyme oil when included in Schedule 5.	200 millilitres or less
(2) The manufacturer or packer of a poison must ensure that the child-resistant closure is appropriate for the container and the poison and that it retains its child-resistant properties for the expected life of the poison.	

2.5 Schedule 8 poisons

- (1) A person who supplies any Schedule 8 poison must ensure that the Schedule 8 poison is packaged in such a way that its primary pack is so sealed that, when the seal is broken, it is readily distinguishable from other sealed primary packs.
- (2) This paragraph does not apply to the supply of a Schedule 8 poison by an:
 - (a) authorised prescriber or other authorised supplier;
 - (b) pharmacist on the prescription of an authorised prescriber;
 - (c) pharmacist employed at a hospital, on the written requisition of a medical practitioner, a dentist or the nurse or midwife in charge of the ward in which the Schedule 8 poison is to be used or stored; or

PART 2, CONTROLS ON MEDICINES AND POISONS – continued

(d) nurse or midwife on the direction in writing of an authorised prescriber.

2.6 Exemptions

- (1) Section 2.1(2), Section 2.1(4) and Section 2.2 do not apply to the immediate container of a poison prepared, packed and sold:
 - (a) for human internal or animal internal use; or
 - (b) as a solid or semi-solid preparation for human external or animal external use; or
 - (c) as a paint, other than a paint for therapeutic or cosmetic use; or
 - (d) in containers having a nominal capacity of 15 millilitres or less; or
 - (e) for use in automatic photographic or photocopy processing machines if the container is specifically designed to fit into the machines; or
 - (f) solely for dispensary, industrial, laboratory or manufacturing purposes.
- (2) Section 2.4 does not apply to a poison prepared, packed and sold solely for dispensary, industrial, laboratory or manufacturing purposes.
- (3) The tactile identification or embossing required by Section 2.1(2), Section 2.1(4) and Section (2.2) of this Standard or Australian Standard AS 2216-1997 entitled Packaging for poisonous substances do not apply to a container that is an aerosol container, a collapsible tube, or a measure pack which is a flexible sachet.

2.7 Camphor and naphthalene

- (1) The container requirements of Section 2.1(2) do not apply to a device that contains only camphor or naphthalene in block, ball, disc, pellet or flake form for domestic use, if the device:
 - (a) in normal use, prevents removal or ingestion of its contents; and
 - (b) is incapable of reacting with the poison; and
 - (c) is sufficiently strong to withstand the ordinary risks of handling, storage or transport; and
 - (d) has the word “POISON” and the approved name of the poison embossed or indelibly printed on it.
- (2) A person must not sell or supply camphor or naphthalene in ball, block, disc, pellet or flake form for domestic use unless the balls, blocks, discs, pellets or flakes are enclosed in a device which prevents removal or ingestion of its contents.

2.8 Prohibitions

- (1) A person must not sell or supply a poison in a container which has the name of another poison embossed or indelibly marked thereon.
- (2) A person must not sell any poison which is for internal use or any food, drink or condiment in a container prescribed by Sections 2.1(2), 2.1(4) and Section 2.2 of this Standard.
- (3) A person must not sell any poison in a container that is not readily distinguishable from a container in which food, alcohol, other beverage or condiment is sold..

PART 2, LABELS AND CONTAINERS – continued

SECTION THREE STORAGE

3.1 General requirements

- (1) A person who sells or supplies Schedule 6 poisons by way of retail sale must keep those poisons in such a way as to prevent access by children.
- (2) A person who sells or supplies Schedule 7 poisons must not keep those poisons for retail sale in any areas or in any area or in any manner that allows physical access by any person unless they are:
 - (a) the owner of the retail establishment; or
 - (b) an employee of the owner; or
 - (c) legally permitted to purchase the substance and are under the supervision of the owner or an employee of the owner.
- (3) Controls on storage of Schedule 2, 3, 4 and 8 poisons require referral to Part 3 of this Standard and relevant legislation.

SECTION FOUR DISPOSAL

4.1 General requirements

- (1) A person must not dispose of or cause to be disposed of a Schedule 5, Schedule 6 or Schedule 7 poison in any place or manner that constitutes or is likely to constitute a risk to public health or safety.
- (2) Controls on disposal of Schedule 2, 3, 4 and 8 poisons require referral to relevant legislation.

SECTION FIVE RECORD KEEPING

5.1 General Requirements

- (1) A person who sells or supplies Schedule 7 poisons must keep a record of:
 - (a) Name and address of seller or supplier and purchaser; and
 - (b) Date of order and supply; and
 - (c) Approved name or trade name that identifies the poison to be supplied or sold; and
 - (d) Quantity supplied or sold; and
 - (e) Proof of purchaser authorisation must be recorded in jurisdictions where an authorisation is required for purchase.
- (2) Records for sale or supply of Schedule 7 poisons must be kept for a minimum period of five years.
- (3) Controls on record keeping for sale or supply of Schedule 2, 3, 4 and 8 poisons require referral to relevant legislation.

SECTION SIX SALE, SUPPLY, POSSESSION, or USE

6.1 General Requirements for Schedule 5 and Schedule 6 Product samples

- (1) A person must not sell or supply or distribute free a product sample containing a Schedule 5 or Schedule 6 poison in any manner unless the recipient has the opportunity to refuse at the time of sale or supply.
- (2) A person must not sell or supply or distribute free a product sample containing a Schedule 5 or Schedule 6 poison in an unsolicited manner for example via the post / mailbox or attached to any other product.

PART 2, LABELS AND CONTAINERS – continued

- (3) A person must not sell or supply a Schedule 5 or Schedule 6 poison product sample in a manner that does not promote disposal in accordance with section four.

6.2 Schedule 7 Poisons

- (1) A person must not possess or use a Schedule 7 poison for domestic or domestic garden purposes.
- (2) A person must not sell or supply:
 - (a) a Schedule 7 poison for domestic or domestic garden purposes; or
 - (b) a Schedule 7 poison being a liquid preparation containing paraquat unless it is coloured blue or green and contains sufficient stenching agent to produce an offensive smell; or
 - (c) a Schedule 7 poison for which an authorisation to purchase, possess or use is required by the appropriate authority unless the purchaser produces his or her authorisation.
- (3) A person must not sell, supply or distribute free product samples containing Schedule 7 poisons.

6.3 Schedule 10/Appendix C poisons

- (1) A person must not knowingly have in his or her possession or sell, supply or use a poison listed in Schedule 10/Appendix C of this Standard for the purpose or purposes indicated in relation to that poison in Schedule 10/Appendix C;

6.4 Hawking

- (1) A person must not sell by way of hawking a Schedule 7 poison.
- (2) Controls on sale or supply or sale by way of hawking of Schedule 2, 3, 4 and 8 poisons require referral to Part 3 of this Standard and relevant legislation.

SECTION SEVEN/Appendix I

PAINT OR TINTERS

7.1 General Requirements

- (1) A person must not manufacture, sell, supply or use a First Group Paint for application to:
 - (a) a roof or any surface to be used for the collection or storage of potable water; or
 - (b) furniture; or
 - (c) any fence, wall, post, gate or building (interior or exterior) other than a building which is used exclusively for industrial purposes or mining or any oil terminal; or
 - (d) any premises used for the manufacture, processing, preparation, packing or serving of products intended for human or animal consumption.
- (2) A person must not manufacture, sell, supply or use a paint or tinter containing more than 0.1% Lead (the proportion of Lead for the purposes of this section is calculated as a percentage of the element present in the non-volatile content of the paint).
- (3) A person must not manufacture, sell, supply or use a paint for application to toys unless the paint complies with the specification for coating materials contained in Australian/New Zealand Standard AS/NZS ISO 8124.3:2012 entitled *Safety of toys Part 3: Migration of certain elements* (ISO 8124-03:2010, MOD).
- (4) A person must not manufacture, sell, supply, or use a paint or tinter containing a pesticide except a fungicide, algicide, bactericide or antifouling agent.

PART 2, LABELS AND CONTAINERS – continued

The First Group

The proportion of a substance for the purposes of this Group is calculated as a percentage of the element present in the non-volatile content of the paint.

Substance	Proportion
ANTIMONY or antimony compounds other than antimony titanate pigments	more than 5 per cent
BARIUM salts except barium sulfate or barium metaborate	more than 5 per cent
CADMIUM or cadmium compounds	more than 0.1 per cent
CHROMIUM as chromates of ammonia, barium, potassium sodium, strontium or zinc	more than 5 per cent
SELENIUM or selenium compounds	more than 0.1 per cent

The Second Group

Substance	Proportion
DICHLOROMETHANE (methylene chloride)	more than 5 per cent by wt
ETHYLENE GLYCOL MONOALKYL ETHERS and their acetates	more than 10 per cent by vol
TOLUENE	more than 50 per cent by vol
XYLENE	more than 50 per cent by vol

PART 3

MISCELLANEOUS REGULATIONS

(It is recommended that the States and Territories implement regulations which provide controls similar to those included in this Part of the Standard.)

SECTION ONE ADVERTISING

3.1 General requirements

- (1) A person must not include any reference to a poison included in:
 - (a) Schedule 3 unless included in Appendix H; or
 - (b) Schedule 4 or Schedule 8,of this Standard in any advertisement except in genuine professional or trade journals or other publications intended for circulation only within the medical, nursing, veterinary, dental or pharmaceutical professions or the wholesale drug industry.
- (2) A person must not include any reference to a poison included in Schedule 9 or Schedule 10/Appendix C of this Standard in any advertisement.

SECTION TWO SALE OR SUPPLY

3.2 Schedule 2 poisons

- (1) A person, other than a pharmacist (or an assistant under the direction of a pharmacist) or a medical, dental or veterinary practitioner in the lawful practice of their professions, must not sell or supply a Schedule 2 poison unless licensed to do so.
- (2) A person is not eligible to be granted a licence to sell a Schedule 2 poison by way of retail sale unless:
 - (a) he or she is carrying on the business of selling goods by retail; and
 - (b) the premises from which the poison will be sold is more than 25 kilometres by the shortest practical route from the nearest pharmacy; and
 - (c) he or she produces such evidence, as may be required, that he or she is a fit and proper person to be so licensed.

3.3 Schedule 3 poisons

- (1) A person, other than a pharmacist, or a medical, dental or veterinary practitioner, in the lawful practice of his or her profession, must not sell or supply a Schedule 3 poison.
- (2) The person who sells or supplies a Schedule 3 poison must:
 - (a) provide adequate instructions for use, either written or verbal, at the time of supply or sale; and
 - (b) label the container with his or her name or the name of the pharmacy and the address from which it was sold or supplied; and
 - (c) if required by regulation, make a record of the transaction in a prescription book or other approved recording system.

PART 3, MISCELLANEOUS REGULATIONS –continued

3.4 Schedule 4 poisons

- (1) A person, other than a medical, dental or veterinary practitioner in the ordinary course of their professions or a pharmacist dispensing a legal prescription must not sell or supply a Schedule 4 poison.
- (2) Section 3.4(1) does not apply to a pharmacist who sells or supplies a Schedule 4 poison, other than a poison excepted by regulation from this provision, without a prescription if:
 - (a) the patient is under medical treatment with the poison and continuation of medication is essential; and
 - (b) the quantity sold or supplied does not exceed 3 days' medication; and
 - (c) the pharmacist is satisfied that an emergency exists.
- (3) Section 3.2(1), Sections 3.3(1) and (2) and Section 3.4(1) do not apply to sale by way of wholesale dealing to a pharmacist, medical practitioner, veterinary practitioner, dentist or a person licensed or otherwise authorised to possess, sell or supply such poisons.

3.5 Prohibitions on sale, prescribing and possession

- (1) A person must not:
 - (a) sell or supply, other than by way of wholesale dealing, or prescribe a poison listed in Appendix D paragraphs 1, 2, 3 or 4 except in accordance with the provisions indicated for that poison in Appendix D; or
 - (b) knowingly have in his or her possession a poison listed in Appendix D paragraph 5 without authority.

SECTION 3 STORAGE

- 3.6 A person who sells or supplies Schedule 2 poisons must keep those poisons in such a way that public access to advice from a pharmacist is available if required.
- 3.7 A person who sells or supplies Schedule 3 or Schedule 4 poisons must keep those poisons in a part of the premises to which the public does not have access.

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PART 4
THE SCHEDULES

SCHEDULE 1

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SCHEDULE 2

(Substances marked are listed in Appendix C)

ACETIC ACID (excluding its salts and derivatives) and preparations containing more than 80 per cent of acetic acid (CH₃COOH) for therapeutic use.

ACETYLCYSTEINE in preparations for oral use **except** when labelled with a recommended daily dose of 1 g or less of acetylcysteine.

ACONITUM spp. for therapeutic use in adults:

- (a) in preparations for oral use in packs each containing 0.2 mg or less of total alkaloids **except** in packs containing 0.02 mg or less of total alkaloids; or
- (b) in preparations for dermal use containing 0.02 per cent or less of total alkaloids, in packs each containing 0.2 mg or less of total alkaloids **except** in packs containing 0.02 mg or less of total alkaloids.

ALOXIPRIN.

AMETHOCAINE in preparations for topical use other than eye drops, containing 10 per cent or less of total local anaesthetic substances **except** in dermal preparations containing 2 per cent or less of total local anaesthetic substances.

AMOROLFINE in preparations for topical use **except** in preparations for the treatment of tinea pedis.

ANTAZOLINE in eye drops.

ASPIRIN **except**:

- (a) when included in Schedule 4, 5 or 6;
- (b) in individually wrapped powders or sachets of granules each containing 650 mg or less of aspirin as the only therapeutically active constituent other than an effervescent agent when:
 - (i) enclosed in a primary pack that contains 12 or less such powders or sachets of granules; and
 - (ii) compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (c) in tablets or capsules each containing no other therapeutically active constituent other than an effervescent agent when:
 - (i) packed in blister or strip packaging or in a container with a child-resistant closure;
 - (ii) in a primary pack of not more than 25 tablets or capsules, each containing 325 mg or less of aspirin, or in a primary pack of not more than 16 tablets or capsules, each containing 500 mg or less of aspirin; and
 - (iii) compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (d) in tablets or capsules each containing no other therapeutically active constituent other than an effervescent agent when:
 - (i) packed in blister or strip packaging or in a container with a child-resistant closure;

SCHEDULE 2 – continued

- (ii) in a primary pack containing 100 or less tablets or capsules, each containing 100 mg or less of aspirin when packed and labelled for the prevention of cardiovascular disease or for the inhibition of platelet aggregation; and
- (iii) compliant with the requirements of the *Required Advisory Statements for Medicine Labels*.

ATROPA BELLADONNA (belladonna):

- (a) for external use in preparations containing 0.03 per cent or less of total solanaceous alkaloids; or
- (b) for oral use:
 - (i) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
 - (ii) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit, when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

ATROPINE (excluding atropine methonitrate) for oral use:

- (a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
- (b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

AZELAIC ACID in dermal preparations.

AZELASTINE:

- (a) in preparations for nasal use; or
- (b) in topical eye preparations containing 0.05 per cent or less of azelastine.

BECLOMETHASONE in aqueous nasal sprays delivering 50 micrograms or less of beclomethasone per actuation when the maximum recommended daily dose is no greater than 400 micrograms and when packed in a primary pack containing 200 actuations or less, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.

BENZOCAINE in preparations for topical use other than eye drops:

- (a) containing 10 per cent or less of total local anaesthetic substances, **except** in dermal preparations containing 2 per cent or less of total local anaesthetic substances; or
- (b) in divided preparations containing 200 mg or less of total local anaesthetic substances per dosage unit, **except** in lozenges containing 30 mg or less of total local anaesthetic substances per dosage unit.

BENZOYL PEROXIDE in preparations for human external therapeutic use containing 10 per cent or less of benzoyl peroxide **except** in preparations containing 5 per cent or less of benzoyl peroxide.

BENZYDAMINE in preparations for topical use, **except** in preparations for dermal use.

BEPHENIUM SALTS.

SCHEDULE 2 – continued

BIFONAZOLE in preparations for dermal use **except**:

- (a) in preparations containing 1 per cent or less of bifonazole for the treatment of the scalp; or
- (b) in preparations for the treatment of tinea pedis.

BROMHEXINE.

BROMPHENIRAMINE when combined with one or more other therapeutically active substances in oral preparations when:

- (a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- (b) in a day-night pack containing brompheniramine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

BUDESONIDE in aqueous nasal sprays delivering 50 micrograms or less of budesonide per actuation when the maximum recommended daily dose is no greater than 400 micrograms and when packed in a primary pack containing 200 actuations or less, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.

CARBETAPENTANE **except** in preparations containing 0.5 per cent or less of carbetapentane.

CARBOCISTEINE.

CETIRIZINE in preparations for oral use **except** in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

- (a) in a primary pack containing not more than 5 days' supply; and
- (b) labelled with a recommended daily dose not exceeding 10 mg of cetirizine.

CHLOPHEDIANOL.

CHLORBUTOL for human use in topical preparations containing 5 per cent or less of chlorbutol **except** in preparations containing 0.5 per cent or less of chlorbutol.

CHLOROFORM in preparations for therapeutic use **except**:

- (a) when included in Schedule 4; or
- (b) in preparations containing 0.5 per cent or less of chloroform.

CHLORPHENIRAMINE when combined with one or more other therapeutically active substances in oral preparations when:

- (a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- (b) in a day-night pack containing chlorpheniramine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

CICLOPIROX:

- (a) in preparations for dermal use containing 2 per cent or less of ciclopirox **except** in preparations for the treatment of tinea pedis; or

SCHEDULE 2 – continued

- (b) in preparations for application to the nails containing 8 per cent or less of ciclopirox.

CINCHOCAINE in preparations for topical use other than eye drops, containing 0.5 per cent or less of total local anaesthetic substances.

CINNAMEDRINE.

CLOTRIMAZOLE for human use in dermal preparations and for application to the nails **except** in preparations for the treatment of tinea pedis.

CODEINE in preparations for the treatment of coughs and colds when:

- (a) not combined with any other opiate substance;
- (b) compounded with one or more other therapeutically active substances, of which at least one is phenylephrine and not more than one is an analgesic substance:
 - (i) in divided preparations containing 10 mg or less of codeine per dosage unit; or
 - (ii) in undivided preparations containing 0.25 per cent or less of codeine;
- (c) labelled with a recommended daily dose not exceeding 60 mg of codeine; and
- (d) in packs containing not more than 6 days' supply at the maximum dose recommended on the label.

CREOSOTE derived from wood other than beechwood for human therapeutic use, **except** in preparations containing 10 per cent or less of creosote derived from wood other than beechwood.

DATURA spp. for oral use:

- (a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids, or
 - (b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids,
- except** when separately specified in these Schedules.

DATURA STRAMONIUM (stramonium) for oral use when:

- (a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
 - (b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids,
- except** for smoking or burning.

DATURA TATULA (stramonium) for oral use:

- (a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
- (b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids,

SCHEDULE 2 – continued

except for smoking or burning.

DELPHINIUM STAPHISAGRIA **except** in preparations containing 0.2 per cent or less of *Delphinium staphisagria*.

DESLORATADINE in preparations for oral use.

DEXCHLORPHENIRAMINE when combined with one or more other therapeutically active substances in oral preparations when:

- (a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- (b) in a day-night pack containing dexchlorpheniramine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

DEXTROMETHORPHAN (excluding its stereoisomers) when supplied in a pack containing 600 mg or less of dextromethorphan and with a recommended daily dose of 120 mg or less of dextromethorphan.

DIBROMOPROPAMIDINE for ophthalmic use.

DICLOFENAC when:

- (a) in divided preparations for oral use containing 12.5 mg or less of diclofenac per dosage unit in a pack containing 20 or less dosage units and labelled with a recommended daily dose of 75 mg or less of diclofenac;
- (b) in preparations for dermal use containing 4 per cent or less of diclofenac **except** in preparations for dermal use containing 1 per cent or less of diclofenac or for the treatment of solar keratosis; or
- (c) in transdermal preparations for topical use containing 140 mg or less of diclofenac.

DIHYDROCODEINE when compounded with aspirin and no other therapeutically active substance in divided preparations:

- (a) containing 5 mg or less of dihydrocodeine per dosage unit;
- (b) packed in blister or strip packaging or in a container with a child-resistant closure;
- (c) enclosed in primary packs containing 25 or less dosage units; and
- (d) labelled with a recommended dose not exceeding 10 mg of dihydrocodeine.

DIMENHYDRINATE in primary packs of 10 doses or less for the prevention or treatment of motion sickness, **except** in preparations for the treatment of children under 2 years of age.

DIPHENHYDRAMINE in oral preparations:

- (a) in a primary pack containing 10 dosage units or less for the prevention or treatment of motion sickness; or
- (b) when combined with one or more other therapeutically active substances when:
 - (i) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
 - (ii) in a day-night pack containing diphenhydramine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

SCHEDULE 2 – continued

except in preparations for the treatment of children under 2 years of age.

DOXYLAMINE when combined with one or more other therapeutically active substances in oral preparations when:

- (a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- (b) in a day-night pack containing doxylamine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

DUBOISIA LEICHHARDTII for oral use:

- (a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
- (b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

DUBOISIA MYOPOROIDES for oral use:

- (a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
- (b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

ECONAZOLE for human use in dermal preparations **except** in preparations for the treatment of tinea pedis.

ETAFEDRINE.

ETHER for therapeutic use **except**:

- (a) when included in Schedule 4; or
- (b) in preparations containing 10 per cent or less of ether.

ETHYLMORPHINE when:

- (a) compounded with one or more other therapeutically active substances:
 - (i) in divided preparations containing 10 mg or less of ethylmorphine per dosage unit; or
 - (ii) in undivided preparations containing 0.25 per cent or less of ethylmorphine;
- (b) labelled with a recommended dose not exceeding 15 mg of ethylmorphine.

ETOFENAMATE in preparations for external use.

FAMOTIDINE when sold in the manufacturer's original pack containing not more than 14 days' supply.

FELBINAC in preparations for external use.

FEXOFENADINE in preparations for oral use **except** in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

SCHEDULE 2 – continued

- (a) in a primary pack containing 10 dosage units or less and not more than 5 days' supply; and
- (b) labelled with a recommended daily dose not exceeding 120 mg of fexofenadine.

FLUORIDES for human use:

- (a) in preparations for ingestion containing 0.5 mg or less of fluoride ion per dosage unit; or
- (b) in liquid preparations for topical use containing 1000 mg/kg or less of fluoride ion, in a container with a child-resistant closure:
 - (i) for therapeutic use when compliant with the requirements of the *Required Advisory Statements for Medicine Labels* **except** in preparations containing 220 mg/kg or less of fluoride ion, in packs containing not more than 120 mg total fluoride when fitted with a child-resistant closure and compliant with the requirements of *Required Advisory Statements for Medicine Labels*; or
 - (ii) for non-therapeutic use when labelled with warnings to the following effect:
 - (A) Do not swallow; and
 - (B) Do not use [this product/name of product] in children six years of age or less, **except** in preparations containing 220 mg/kg or less of fluoride ion, in packs containing not more than 120 mg total fluoride, when fitted with a child-resistant closure and labelled with warnings to the following effect:
 - (A) Do not swallow; and
 - (B) Do not use [this product/name of product] in children six years of age or less, **except** in preparations containing 15 mg/kg or less of fluoride ion or preparations for supply to registered dental professionals or by approval of an appropriate authority.

FLURBIPROFEN in preparations for topical oral use when:

- (a) in divided preparations containing 10 mg or less of flurbiprofen per dosage unit; or
- (b) in undivided preparations containing 0.25 per cent or less, or 10 mg or less per dose, of flurbiprofen.

FLUTICASONE in aqueous nasal sprays delivering 50 micrograms or less of fluticasone per actuation when the maximum recommended daily dose is no greater than 400 micrograms and when packed in a primary pack containing 200 actuations or less, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.

FOLIC ACID for human therapeutic use **except**:

- (a) when included in Schedule 4; or
- (b) in preparations containing 500 micrograms or less of folic acid per recommended daily dose.

FOLINIC ACID for human therapeutic use **except**:

- (a) when included in Schedule 4; or
- (b) in preparations containing 500 micrograms or less of folinic acid per recommended daily dose.

FORMALDEHYDE (excluding its derivatives) for human therapeutic use **except**:

SCHEDULE 2 – continued

- (a) in oral hygiene preparations containing 0.1 per cent or less of free formaldehyde; or
- (b) in other preparations containing 0.2 per cent or less of free formaldehyde.

GUAIPHENESIN in a modified release dosage form of 1200 mg or less of guaiphenesin with a recommended daily dose of 2400 mg or less when not labelled for the treatment of children under 12 years of age.

GELSEMIUM SEMPERVIRENS.

GLUTARALDEHYDE for human therapeutic use.

HEXACHLOROPHANE in preparations for human use containing 3 per cent or less of hexachlorophane **except**:

- (a) in preparations containing 0.75 per cent or less of hexachlorophane; or
- (b) in preparations for use on infants, as specified in Schedule 4.

HYDROCORTISONE and HYDROCORTISONE ACETATE, but excluding other salts and derivatives, in preparations for human therapeutic use containing 0.5 per cent or less of hydrocortisone:

- (a) for dermal use, in packs containing 30 g or less of such preparations, containing no other therapeutically active constituent other than an antifungal substance; or
- (b) for rectal use when combined with a local anaesthetic substance but no other therapeutically active constituent **except** unscheduled astringents:
 - (i) in undivided preparations in packs of 35 g or less; or
 - (ii) in packs containing 12 or less suppositories.

HYDROQUINONE (excluding monobenzone and alkyl ethers of hydroquinone included in Schedule 4) in preparations for human external therapeutic or cosmetic use containing 2 per cent or less of hydroquinone **except**:

- (a) in hair preparations containing 0.3 per cent or less of hydroquinone; or
- (b) in cosmetic nail preparations containing 0.02 per cent or less of hydroquinone.

8-HYDROXYQUINOLINE and its non-halogenated derivatives for human therapeutic use, **except** in preparations for external use containing 1 per cent or less of such substances.

HYOSCINE (excluding hyoscine butylbromide):

- (a) for transdermal use in preparations containing 2 mg or less of total solanaceous alkaloids per dosage unit; or
- (b) for oral use:
 - (i) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids, when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
 - (ii) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

HYOSCINE BUTYLBROMIDE as the only therapeutically active substance, in divided preparations for oral use, containing 20 mg or less of hyoscine butylbromide per dosage unit in a pack containing 200 mg or less of hyoscine butylbromide.

SCHEDULE 2 – continued

HYOSCYAMINE:

- (a) for external use in preparations containing 0.03 per cent or less of total solanaceous alkaloids; or
- (b) for oral use:
 - (i) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids, when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
 - (ii) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less total solanaceous alkaloids.

HYOSCYAMUS NIGER for oral use:

- (a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
- (b) in divided preparations containing 0.3 mg of total solanaceous alkaloids or less per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids,
except in a pack containing 0.03 mg or less of total solanaceous alkaloids.

IBUPROFEN in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen:

- (a) in liquid preparations when sold in the manufacturer's original pack containing 8 grams or less of ibuprofen; or
- (b) in divided preparations, each containing 200 mg or less of ibuprofen, in packs of not more than 100 dosage units **except** when:
 - (i) as the only therapeutically active constituent (other than phenylephrine or when combined with an effervescent agent);
 - (ii) packed in blister or strip packaging or in a container with a child-resistant closure;
 - (iii) in a primary pack containing not more than 25 dosage units;
 - (iv) compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
 - (v) not labelled for the treatment of children 6 years of age or less; and
 - (vi) not labelled for the treatment of children under 12 years of age when combined with phenylephrine.

INDANAZOLINE.

INDOMETHACIN in preparations for external use containing 1 per cent or less of indomethacin.

IODINE:

SCHEDULE 2 – continued

- (a) in preparations for human internal therapeutic use containing 300 micrograms or more of iodine per recommended daily dose; or
- (b) in preparations for human external therapeutic use containing more than 2.5 per cent of available iodine (excluding salts, derivatives or iodophors),

except in oral preparations for use in prophylaxis and treatment in the event of radioactive iodine exposure under an emergency plan approved by an appropriate authority.

IPRATROPIUM in preparations for nasal use.

IRON COMPOUNDS (excluding iron oxides when present as an excipient, in divided preparations containing 10 mg or less of total iron oxides per dosage unit or in undivided preparations containing 1 per cent or less of total iron oxides) for human internal use **except**:

- (a) when included in Schedule 4; or
- (b) when labelled with a recommended daily dose of 24 mg or less of iron:
 - (i) in undivided preparations supplied in packs each containing 750 mg or less of iron; or
 - (ii) in divided preparations:
 - (A) containing more than 5 mg of iron per dosage unit in packs each containing 750 mg or less of iron; or
 - (B) containing 5 mg or less of iron per dosage unit.

ISOCONAZOLE for human use in dermal preparations.

ISOPROPAMIDE in preparations for dermal use containing 2 per cent or less of isopropamide.

KETOCONAZOLE in preparations for dermal use **except**:

- (a) in preparations containing 1 per cent or less of ketoconazole for the treatment of the scalp; or
- (b) in preparations for the treatment of tinea pedis.

KETOTIFEN for ophthalmic use in preparations containing 0.025 per cent or less of ketotifen.

LEVOCABASTINE in topical eye or nasal preparations.

LIGNOCAINE in preparations for topical use other than eye drops:

- (a) containing 10 per cent or less of total local anaesthetic substances, **except** in dermal preparations containing 2 per cent or less of total local anaesthetic substances; or
- (b) in divided preparations containing 200 mg or less of total local anaesthetic substances per dosage unit, **except** in lozenges containing 30 mg or less of total local anaesthetic substances per dosage unit.

LINDANE in preparations for human external therapeutic use containing 2 per cent or less of lindane.

LITHIUM in preparations for dermal use containing 1 per cent or less of lithium **except**:

- (a) when present as an excipient at 0.25 per cent or less of lithium; or
- (b) in preparations containing 0.01 per cent or less of lithium.

SCHEDULE 2 – continued

LOBELIA INFLATA **except** for smoking or burning.

LOBELINE **except** in preparations for smoking or burning.

LODOXAMIDE in preparations for ophthalmic use.

LOPERAMIDE in divided preparations for oral use in packs of 20 dosage units or less **except** in preparations containing 2 mg or less of loperamide per dosage unit, in a primary pack containing 8 dosage units or less.

LORATADINE in preparations for oral use **except** in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

- (a) in a primary pack containing 5 dosage units or less; and
- (b) labelled with a recommended daily dose not exceeding 10 mg of loratadine.

MACROGOLS in preparations for oral use as a liquid concentrate for laxative use.

MEBENDAZOLE for human therapeutic use.

MECLOZINE in primary packs containing 12 or less tablets or capsules of meclizine for the prevention or treatment of motion sickness, **except** in preparations for the treatment of children under 2 years of age.

MEFENAMIC ACID in divided preparations for oral use in packs of 30 or less dosage units for the treatment of dysmenorrhoea.

MEPYRAMINE for dermal use.

MERCUROCHROME in preparations for external use containing 2 per cent or less of mercurochrome **except** when included in Schedule 6.

MERCURY for external use in preparations containing 0.5 per cent or less of mercury.

METHOXAMINE in preparations for external use **except** in preparations containing 1 per cent or less of methoxamine.

METHOXYPHENAMINE.

METHYLEPHEDRINE.

MICONAZOLE for human use in dermal preparations and for application to the nails **except** in preparations for the treatment of tinea pedis.

MINOXIDIL in preparations for dermal use containing 5 per cent or less of minoxidil.

MOMETASONE in aqueous nasal sprays delivering 50 micrograms or less of mometasone per actuation when the maximum recommended daily dose is no greater than 200 micrograms for the prophylaxis or treatment of allergic rhinitis for up to six months in adults and children 12 years of age and over.

NAPHAZOLINE.

NAPROXEN in divided preparations containing 250 mg or less of naproxen per dosage unit in packs of 30 or less dosage units.

NICLOSAMIDE for human therapeutic use.

NIZATIDINE when sold in the manufacturer's original pack containing not more than 14 days' supply.

SCHEDULE 2 – continued

NOSCAPINE.

NYSTATIN in dermal preparations.

OXETACAINE (oxethazaine) in preparations for internal use.

OXICONAZOLE for dermal use **except** in preparations for the treatment of tinea pedis.

OXYMETAZOLINE.

PAPAVERINE **except** when included in Schedule 4.

PARACETAMOL for therapeutic use **except**:

- (a) when included in Schedule 4;
- (b) in individually wrapped powders or sachets of granules each containing 1000 mg or less of paracetamol as the only therapeutically active constituent (other than phenylephrine and/or guaiphenesin or when combined with effervescent agents) when:
 - (i) enclosed in a primary pack that contains not more than 10 such powders or sachets of granules;
 - (ii) compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
 - (iii) not labelled for the treatment of children 6 years of age or less; and
 - (iv) not labelled for the treatment of children under 12 years of age when combined with phenylephrine and/or guaiphenesin; or
- (c) in tablets or capsules each containing 500 mg or less of paracetamol as the only therapeutically active constituent (other than phenylephrine and/or guaiphenesin or when combined with effervescent agents) when:
 - (i) packed in blister or strip packaging or in a container with a child-resistant closure;
 - (ii) in a primary pack containing not more than 20 tablets or capsules;
 - (iii) compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
 - (iv) not labelled for the treatment of children 6 years of age or less; and
 - (v) not labelled for the treatment of children under 12 years of age when combined with phenylephrine and/or guaiphenesin.

PARAFORMALDEHYDE (excluding its derivatives) for human therapeutic use **except**:

- (a) in oral hygiene preparations containing 0.1 per cent or less of free formaldehyde; or
- (b) in other preparations containing 0.2 per cent or less of free formaldehyde.

PENCICLOVIR for external use for the treatment of herpes labialis.

PHEDRAZINE.

PHENAZONE for human external use.

PHENIRAMINE:

- (a) in eye drops; or

SCHEDULE 2 – continued

- (b) when combined with one or more other therapeutically active substances in oral preparations when:
 - (i) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
 - (ii) in a day-night pack containing pheniramine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

PHENOL, or any homologue boiling below 220°C, for human therapeutic use **except**:

- (a) when included in Schedule 4; or
- (b) in preparations for external use containing 3 per cent or less of such substances.

PHENYLEPHRINE **except**:

- (a) when included in Schedule 4;
- (b) in oral preparations containing 50 mg or less of phenylephrine per recommended daily dose in packs containing 250 mg or less of phenylephrine; or
- (c) in topical eye or nasal preparations containing 1 per cent or less of phenylephrine.

PHOLCODINE:

- (a) in liquid preparations containing 0.5 per cent or less of pholcodine and with a recommended dose not exceeding 25 mg of pholcodine; or
- (b) when compounded with one or more other therapeutically active substances in divided preparations containing 10 mg or less of pholcodine per dosage unit and with a recommended dose not exceeding 25 mg of pholcodine.

PIPERAZINE for human therapeutic use.

PODOPHYLLOTOXIN in preparations containing 0.5 per cent or less of podophyllotoxin for human use for the treatment of warts other than anogenital warts.

PODOPHYLLUM EMODI (podophyllin) in preparations containing 10 per cent or less of podophyllin for human use for the treatment of warts other than anogenital warts.

PODOPHYLLUM PELTATUM (podophyllin) in preparations containing 10 per cent or less of podophyllin for human use for the treatment of warts other than anogenital warts.

POTASSIUM CHLORATE for therapeutic use **except** in preparations containing 10 per cent or less of potassium chlorate.

PRILOCAINE in preparations for dermal use containing 10 per cent or less of total local anaesthetic substances.

PROCYCLIDINE in preparations containing 5 per cent or less of procyclidine for dermal use.

PROMETHAZINE in oral preparations:

- (a) in a primary pack containing 10 dosage units or less for the prevention or treatment of motion sickness; or
- (b) when combined with one or more other therapeutically active substances when:

Poisons Standard 2015

SCHEDULE 2 – continued

- (i) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- (ii) in a day-night pack containing promethazine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

PROPAMIDINE for ophthalmic use.

PYRANTEL for human therapeutic use.

PYRETHRINS, naturally occurring, being pyrethrolone, cinerolone or jasmolone esters of chrysanthemic or pyrethic acids, for human therapeutic use in preparations containing more than 10 per cent of such substances.

PYRITHIONE ZINC for human therapeutic use, **except** in preparations for the treatment of the scalp containing 2 per cent or less of pyrithione zinc when compliant with the requirements of the *Required Advisory Statements for Medicine Labels*.

RANITIDINE in preparations supplied in the manufacturer's original pack containing not more than 14 days' supply **except** in divided preparations for oral use containing 150 mg or less of ranitidine per dosage unit in the manufacturer's original pack containing not more than 14 dosage units.

SALICYLAMIDE **except** when included in Schedule 4.

SELENIUM in preparations for human therapeutic use **except**:

- (a) for topical use containing 3.5 per cent or less of selenium sulfide;
- (b) when included in Schedule 4; or
- (c) for oral use with a recommended daily dose of 150 micrograms or less.

SILVER for therapeutic use **except**:

- (a) in solutions for human oral use containing 0.3 per cent or less of silver when compliant with the requirements of the *Required Advisory Statements for Medicine Labels*; or
- (b) in other preparations containing 1 per cent or less of silver.

SODIUM CROMOGLYCATE in preparations for nasal or ophthalmic use.

SODIUM NITRITE for therapeutic use (excluding when present as an excipient).

SQUILL **except** in preparations containing 1 per cent or less of squill.

SULCONAZOLE in preparations for dermal use.

TERBINAFINE for dermal use **except** in preparations for the treatment of tinea pedis.

TETRACHLOROETHYLENE for human therapeutic use.

TETRAHYDROZOLINE.

THIABENDAZOLE for human therapeutic use.

TIOCONAZOLE in preparations for dermal use **except** in preparations for the treatment of tinea pedis.

TRAMAZOLINE.

SCHEDULE 2 – continued

TRIAMCINOLONE in aqueous nasal sprays delivering 55 micrograms or less of triamcinolone per actuation when the maximum recommended daily dose is no greater than 220 micrograms, for prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.

TRIMEPRAZINE when combined with one or more other therapeutically active substances in solid oral preparations when:

- (a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- (b) in a day-night pack containing trimeprazine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

TRIPROLIDINE when combined with one or more other therapeutically active substances in oral preparations when:

- (a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- (b) in a day-night pack containing triprolidine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

TUAMINOHEPTANE.

TYMAZOLINE.

XYLOMETAZOLINE.

ZINC CHLORIDE for human dermal use **except** in preparations containing 5 per cent or less of zinc chloride.

SCHEDULE 3

ADRENALINE in preparations containing 1 per cent or less of adrenaline **except** in preparations containing 0.02 per cent or less of adrenaline unless packed and labelled for injection.

ALCLOMETASONE as the only therapeutically active substance in preparations for dermal use containing 0.05 per cent or less of alclometasone in packs containing 30 g or less of the preparation.

AMINOPHYLLINE in liquid oral preparations containing 2 per cent or less of aminophylline.

AZATADINE in oral preparations.

BROMPHENIRAMINE in oral preparations **except**:

- (a) when included in Schedule 2; or
- (b) for the treatment of children under 2 years of age.

BUCLIZINE in oral preparations.

BUTOCONAZOLE in preparations for vaginal use.

CHLORAMPHENICOL for ophthalmic use only.

CHLORBUTOL in preparations for human use **except**:

- (a) when included in Schedule 2; or
- (b) in preparations containing 0.5 per cent or less of chlorbutol.

CHLORPHENIRAMINE in oral preparations **except**:

- (a) when included in Schedule 2; or
- (b) for the treatment of children under 2 years of age.

CICLOPIROX in preparations for dermal use and for application to the nails **except**:

- (a) when included in Schedule 2; or
- (b) in preparations for the treatment of tinea pedis.

CIMETIDINE in a primary pack containing not more than 14 days' supply.

CLEMASTINE in preparations for oral use.

CLOBETASONE (clobetasone-17-butyrate) as the only therapeutically active substance in preparations for dermal use containing 0.05 per cent or less of clobetasone in packs containing 30 g or less of the preparation.

CLOTRIMAZOLE in preparations for vaginal use.

CODEINE when:

- (a) not combined with any other opiate substance;
- (b) compounded with one or more other therapeutically active substances, of which not more than one is an analgesic substance:
 - (i) in divided preparations containing 12 mg or less of codeine per dosage unit; or

SCHEDULE 3 – continued

- (ii) in undivided preparations containing 0.25 per cent or less of codeine;
- (c) labelled with a recommended daily dose not exceeding 100 mg of codeine; and
- (d) in packs containing not more than 5 days' of supply at the maximum dose recommended on the label,

except when included in Schedule 2.

CYCLIZINE in preparations for oral use.

CYPROHEPTADINE in oral preparations.

DEXCHLORPHENIRAMINE in oral preparations **except**:

- (a) when included in Schedule 2; or
- (b) for the treatment of children under 2 years of age.

DICLOFENAC in divided preparations for oral use containing 25 mg or less of diclofenac per dosage unit in a pack containing 30 or less dosage units **except** when included in Schedule 2.

DIHYDROCODEINE when compounded with one or more other therapeutically active substances:

- (a) in divided preparations containing 10 mg or less per dosage unit and with a recommended dose not exceeding 15 mg of dihydrocodeine; or
- (b) in undivided preparations containing 0.25 per cent or less of dihydrocodeine with a recommended dose not exceeding 15 mg of dihydrocodeine,

except when included in Schedule 2.

DI-IODOHYDROXYQUINOLINE (iodoquinol) for vaginal use.

DIMENHYDRINATE in oral preparations **except** when included in Schedule 2.

DIMETHINDENE in oral preparations.

DIPHENHYDRAMINE in oral preparations **except**:

- (a) when included in Schedule 2; or
- (b) for the treatment of children under 2 years of age.

DIPHENOXYLATE in packs of 8 or less dosage units, each dosage unit containing 2.5 mg or less of diphenoxylate and a quantity of atropine sulfate equivalent to at least 1 per cent of the dose of diphenoxylate.

DITHRANOL for therapeutic use.

DOXYLAMINE in oral preparations **except**:

- (a) when included in Schedule 2; or
- (b) for the treatment of children under 2 years of age.

ECONAZOLE in preparations for vaginal use.

ERYTHRITYL TETRANITRATE for therapeutic use.

SCHEDULE 3 – continued

ESOMEPRAZOLE in oral preparations containing 20 mg or less per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days supply.

FAMCICLOVIR for oral use, in divided preparations containing a total dose of 1500 mg or less of famciclovir for the treatment of herpes labialis (cold sores).

FLAVOXATE.

FLUCONAZOLE in single-dose oral preparations containing 150 mg or less of fluconazole for the treatment of vaginal candidiasis.

FLUORIDES for human topical use:

- (a) in liquid preparations containing 5500 mg/kg or less of fluoride ion, in a container with a child-resistant closure **except** when included in or expressly excluded from Schedule 2; or
- (b) in non-liquid preparations containing 5500 mg/kg or less of fluoride ion **except**:
 - (i) in preparations for therapeutic use containing 1500 mg/kg or less of fluoride ion and, when containing more than 1000 mg/kg fluoride ion, compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
 - (ii) in preparations for non-therapeutic use containing 1500 mg/kg or less of fluoride ion and, when containing more than 1000 mg/kg fluoride ion, labelled with warnings to the following effect:
 - (A) Do not swallow; and
 - (B) Do not use [this product/name of product] in children six years of age or less; or
 - (iii) in preparations for supply to registered dental professionals or by approval of an appropriate authority.

GLUCAGON.

GLYCERYL TRINITRATE:

- (a) in preparations for oral use; or
- (b) in preparations for rectal use.

GLYCOPYRRONIUM **except** when included in Schedule 4.

HYDROCORTISONE and HYDROCORTISONE ACETATE, but excluding other salts and derivatives, in preparations for human therapeutic use containing 1 per cent or less of hydrocortisone:

- (a) for dermal use, in packs containing 30 g or less of such preparations, containing no other therapeutically active constituent other than an antifungal substance; or
- (b) for rectal use when combined with a local anaesthetic substance but no other therapeutically active constituent **except** unscheduled astringents:
 - (i) in undivided preparations, in packs of 35 g or less; or
 - (ii) in packs containing 12 or less suppositories,

SCHEDULE 3 – continued

except when included in Schedule 2.

IBUPROFEN in divided preparations, each containing 400 mg or less of ibuprofen in a primary pack containing not more than 50 dosage units when labelled:

- (a) with a recommended daily dose of 1200 mg or less of ibuprofen; and
- (b) not for the treatment of children under 12 years of age,

except when included in or expressly excluded from Schedule 2.

INOSITOL NICOTINATE.

ISOCONAZOLE in preparations for vaginal use.

ISOSORBIDE DINITRATE in oral preparations containing 10 mg or less of isosorbide dinitrate per dosage unit.

KETOPROFEN in divided preparations for oral use containing 25 mg or less of ketoprofen per dosage unit in a pack containing 30 or less dosage units.

LANSOPRAZOLE in oral preparations containing 15 mg or less of lansoprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply.

LEVONORGESTREL for emergency post-coital contraception.

MACROGOLS in preparations for oral use for bowel cleansing prior to diagnostic, medical or surgical procedures.

MAGNESIUM SULFATE for human therapeutic use in divided oral preparations **except** when containing 1.5 g or less of magnesium sulfate per recommended daily dose.

MALATHION in preparations for human external use **except** in preparations containing 2 per cent or less of malathion.

MANNITYL HEXANITRATE for therapeutic use.

MEPYRAMINE in oral preparations.

METHDILAZINE in oral preparations.

METOCLOPRAMIDE when combined with paracetamol in divided preparations, packed and labelled only for the treatment of nausea associated with migraine, in packs containing not more than 10 dosage units.

MICONAZOLE for human use in topical preparations:

- (a) for the treatment of oral candidiasis; or
- (b) for vaginal use.

NAPROXEN in a modified release dosage form of 600 mg or less of naproxen per dosage unit in packs of 16 or less dosage units when labelled not for the treatment of children under 12 years of age.

NICOTINIC ACID for human therapeutic use in divided preparations containing 250 mg or less of nicotinic acid per dosage unit **except**:

- (a) in preparations containing 100 mg or less of nicotinic acid per dosage unit; or
- (b) nicotinamide.

SCHEDULE 3 – continued

NICOTINYL ALCOHOL **except** in preparations containing 100 mg or less of nicotiny alcohol per dosage unit.

NYSTATIN in preparations for topical use **except** when included in Schedule 2.

OMEPRAZOLE in oral preparations containing 20 mg or less of omeprazole per dosage unit for the relief of heartburn and other gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply.

ORLISTAT in oral preparations for weight-control purposes containing 120 mg or less of orlistat per dosage unit.

OXICONAZOLE in preparations for vaginal use.

PANTOPRAZOLE in oral preparations containing 20 mg or less of pantoprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply.

PARACETAMOL when combined with ibuprofen in a primary pack containing 30 dosage units or less.

PHENIRAMINE in oral preparations **except**:

- (a) when included in Schedule 2; or
- (b) for the treatment of children under 2 years of age.

PODOPHYLLOTOXIN in preparations containing 1 per cent or less of podophyllotoxin for human use for the treatment of warts other than anogenital warts **except** when included in Schedule 2.

PODOPHYLLUM EMODI (podophyllin) in preparations containing 20 per cent or less of podophyllin for human use for the treatment of warts other than anogenital warts **except** when included in Schedule 2.

PODOPHYLLUM PELTATUM (podophyllin) in preparations containing 20 per cent or less of podophyllin for human use for the treatment of warts other than anogenital warts **except** when included in Schedule 2.

PROCHLORPERAZINE in divided preparations for oral use in packs containing not more than 10 dosage units for the treatment of nausea associated with migraine.

PROMETHAZINE in oral preparations **except**:

- (a) when included in Schedule 2; or
- (b) in preparations for the treatment of children under 2 years of age.

PSEUDOEPHEDRINE (other than preparations for stimulant, appetite suppression or weight-control purposes) when supplied in a primary pack:

- (a) in liquid preparations containing 800 mg or less of pseudoephedrine hydrochloride (or its equivalent); or
- (b) in other preparations containing 720 mg or less of pseudoephedrine hydrochloride (or its equivalent).

RABEPRAZOLE in oral preparations containing 10 mg or less of rabeprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply.

SALBUTAMOL as the only therapeutically active substance:

SCHEDULE 3 – continued

- (a) in metered aerosols delivering 100 micrograms or less of salbutamol per metered dose; or
- (b) in dry powders for inhalation delivering 200 micrograms or less of salbutamol per dose.

SALICYLIC ACID in preparations for dermal use **except** in preparations containing 40 per cent or less of salicylic acid.

SANTONIN.

SODIUM PHOSPHATE in preparations for oral use for bowel cleansing prior to diagnostic medical and surgical procedures.

SODIUM PICOSULFATE in preparations for oral use for bowel cleansing prior to diagnostic medical or surgical procedures.

SULFACETAMIDE in preparations for ophthalmic use containing 10 per cent or less of sulfacetamide.

TERBUTALINE as the only therapeutically active substance:

- (a) in metered aerosols delivering 250 micrograms or less of terbutaline per metered dose; or
- (b) in dry powders for inhalation delivering 500 micrograms or less of terbutaline per dose.

THEOPHYLLINE in liquid oral preparations containing 2 per cent or less of theophylline.

TIOCONAZOLE in preparations for vaginal use.

TRIAMCINOLONE for buccal use in preparations containing 0.1 per cent or less of triamcinolone in a pack of 5 g or less.

TRIMEPRAZINE:

- (a) in solid oral preparations **except** when included in Schedule 2; or
- (b) in liquid oral preparations containing 10 mg or less of trimeprazine per 5 mL,
except in preparations for the treatment of children under 2 years of age.

TRIPROLIDINE in oral preparations **except**:

- (a) when included in Schedule 2; or
- (b) for the treatment of children under 2 years of age.

VITAMIN D for human internal therapeutic use in preparations containing 175 micrograms or less of vitamin D per recommended single weekly dose **except** in preparations containing 25 micrograms or less of vitamin D per recommended daily dose.

SCHEDULE 4

(Substances marked # are listed in Appendix D)

ABACAVIR.

ABATACEPT.

ABIRATERONE ACETATE.

ABCIXIMAB.

ACAMPROSATE CALCIUM.

ACARBOSE.

ACEBUTOLOL.

ACEPROMAZINE.

ACETANILIDE and alkyl acetanilides (excluding when present as an excipient) for human therapeutic use.

ACETARSOL.

ACETAZOLAMIDE.

ACETOHEXAMIDE.

ACETYL ISOVALERYLTYSOSIN.

ACETYLCARBROMAL.

ACETYLCHOLINE.

ACETYLCYSTEINE **except:**

- (a) when included in Schedule 2; or
- (b) in preparations for oral use when labelled with a recommended daily dose of 1 g or less of acetylcysteine.

ACETYLDIGITOXIN.

ACETYLMETHYLDIMETHYLOXIMIDOPHENYLHYDRAZINE.

ACETYLSTROPHANTHIDIN.

ACICLOVIR **except** in preparations containing 5 per cent or less of aciclovir for the treatment of herpes labialis in packs containing 10 g or less.

ACIPIMOX.

ACITRETIN.

ACLIDINIUM BROMIDE.

ACOKANTHERA OUABAIO.

ACOKANTHERA SCHIMPERI.

ACONITUM spp. **except:**

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

- (a) when included in Schedule 2;
- (b) in preparations for oral use in adults in packs containing 0.02 mg or less of total alkaloids; or
- (c) in preparations for dermal use in adults containing 0.02 per cent or less of total alkaloids in packs containing 0.02 mg or less of total alkaloids.

ACRIVASTINE.

ADALIMUMAB.

ADAPALENE.

ADEFOVIR.

ADENOSINE for human therapeutic use in preparations for injection.

ADIPHENINE.

ADONIS VERNALIS.

ADRAFINIL.

ADRENALINE. **except:**

- (a) when included in Schedule 3; or
- (b) in preparations containing 0.02 per cent or less of adrenaline unless packed and labelled for injection.

ADRENOCORTICAL HORMONES **except** when separately specified in these Schedules.

AFAMELANOTIDE.

AFATINIB DIMALEATE.

AFLIBERCEPT.

AGALSIDASE.

AGLEPRISTONE.

AGOMELATINE.

ALATROFLOXACIN MESYLATE.

ALBENDAZOLE **except:**

- (a) when included in Schedule 5 or 6; or
- (b) in intraruminal implants each containing 3.85 g or less of albendazole for the treatment of animals.

ALCLOFENAC.

ALCLOMETASONE **except** when included in Schedule 3.

ALCURONIUM.

ALDESLEUKIN.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

ALDOSTERONE.

ALEFACEPT.

ALEMTUZUMAB.

ALENDRONIC ACID.

ALFACALCIDOL.

ALFUZOSIN.

ALGLUCERASE.

ALGLUCOSIDASE.

ALISKIREN.

ALLERGENS.

ALLOPURINOL.

ALLYLOESTRENOL.

ALOGLIPTIN.

ALOSETRON.

ALPHA1-PROTEINASE INHIBITOR (HUMAN).

ALPHADOLONE.

ALPHAXALONE.

ALPRENOLOL.

ALPROSTADIL.

ALSEROXYLON.

ALTEPLASE.

ALTRENOGEST.

ALTRETAMINE (hexamethylmelamine).

AMANTADINE.

AMBENONIUM CHLORIDE.

AMBRISENTAN.

AMBUCETAMIDE.

AMBUTONIUM BROMIDE.

AMCINONIDE.

AMETHOCAINE **except:**

Poisons Standard 2015

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

- (a) when included in Schedule 2; or
- (b) in dermal preparations containing 2 per cent or less of total local anaesthetic substances.

AMIFOSTINE.

AMIKACIN.

AMILORIDE.

AMINOCAPROIC ACID.

AMINOGLUTETHIMIDE.

5-AMINOLEVULINIC ACID.

AMINOMETRADINE.

AMINOPHENAZONE (amidopyrine) and derivatives for the treatment of animals.

AMINOPHYLLINE **except** when included in Schedule 3.

AMINOPTERIN.

4-AMINOPYRIDINE for therapeutic use.

AMINOREX.

AMINOSALICYLIC ACID.

AMIODARONE.

AMIPHENAZOLE.

AMISOMETRADINE.

AMISULPRIDE.

AMITRIPTYLINE.

AMLODIPINE.

AMMI VISNAGA.

AMMONIUM BROMIDE for therapeutic use.

AMODIAQUINE.

AMOROLFINE **except**:

- (a) when included in Schedule 2; or
- (b) in preparations for the treatment of tinea pedis.

AMOXAPINE.

AMOXYCILLIN.

AMPHOMYCIN.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

AMPHOTERICIN.

AMPICILLIN.

AMPRENAVIR.

AMRINONE.

AMSACRINE.

AMYL NITRITE.

AMYLOBARBITONE when packed and labelled for injection.

AMYLOCAINE.

ANABOLIC STEROIDAL AGENTS.

ANAGRELIDE.

ANAKINRA.

ANASTROZOLE.

ANCESTIM.

ANCROD and its immunoglobulin antidote.

ANECORTAVE.

ANDROGENIC STEROIDAL AGENTS.

ANDROISOXAZOLE.

ANDROSTANOLONE.

ANDROSTENEDIOL.

ANDROSTENEDIONE.

ANGIOTENSIN AMIDE.

ANIDULAFUNGIN.

ANISTREPLASE.

ANTAZOLINE **except** when included in Schedule 2.

ANTIBIOTIC SUBSTANCES **except**:

- (a) when separately specified in these Schedules; or
- (b) nisin.

ANTIGENS for human therapeutic use **except** when separately specified in this Schedule.

ANTIHISTAMINES **except**:

- (a) when included in Schedule 2 or 3; or

Poisons Standard 2015

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

(b) when separately specified in this Schedule.

ANTIMONY for therapeutic use **except** when separately specified in these Schedules.

ANTISERA (immunoser) for human use by injection **except** when separately specified in these Schedules.

APIXABAN.

APOCYNUM spp.

APOMORPHINE.

APRACLONIDINE.

APRAMYCIN.

APREPITANT.

APRONAL.

APROTININ.

ARECOLINE.

ARIPIRAZOLE.

ARSENIC for human therapeutic use **except** when separately specified in these Schedules.

ARTEMETHER.

ARTICAINE.

ASENAPINE.

ASPIRIN:

(a) when combined with caffeine, paracetamol or salicylamide or any derivative of these substances;
or

(b) for injection.

ASTEMIZOLE.

ATAMESTANE.

ATAZANAVIR.

ATENOLOL.

ATIPAMEZOLE.

ATOMOXETINE.

ATORVASTATIN.

ATOSIBAN.

ATOVAQUONE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

ATRACURIUM BESYLATE.

ATROPA BELLADONNA (belladonna) **except** when included in Schedule 2.

ATROPINE **except** when included in Schedule 2.

ATROPINE METHONITRATE.

AURANOFIN.

AUROTHIOMALATE SODIUM.

AVILAMYCIN **except**:

- (a) in animal feed premixes containing 15 per cent or less of avilamycin activity; or
- (b) in animal feeds containing 50 mg/kg or less of avilamycin activity.

AVIPTADIL.

AXITINIB.

AVOPARCIN.

AZACITIDINE.

AZACYCLONOL.

AZAPERONE.

AZAPROPAZONE.

AZARIBINE.

AZATADINE **except** when included in Schedule 3.

AZATHIOPRINE.

AZELAIC ACID **except**:

- (a) when included in Schedule 2; or
- (b) in preparations containing 1 per cent or less of azelaic acid for non-human use.

AZELASTINE **except** when included in Schedule 2.

AZITHROMYCIN.

AZLOCILLIN.

AZTREONAM.

BACAMPICILLIN.

BACITRACIN.

BACLOFEN.

BALSALAZIDE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

BAMBERMYCIN (flavophospholipol) **except**:

- (a) when included in Schedule 6; or
- (b) in animal feeds for growth promotion containing 50 mg/kg or less of antibiotic substances.

BAMBUTEROL.

BAMETHAN.

BAMIPINE.

BARBITURATES **except** when separately specified in these Schedules.

BASILIXIMAB.

BAZEDOXIFENE.

BECAPLERMIN.

BECLAMIDE.

BECLOMETHASONE **except** when included in Schedule 2.

BELATACEPT.

BELIMUMAB.

BEMEGRIDE.

BENACTYZINE.

BENZAEPRIIL.

BENDAMUSTINE.

BENDROFLUAZIDE.

BENETHAMINE PENICILLIN.

BENORYLATE.

BENOXAPROFEN.

BENPERIDOL.

BENSERAZIDE.

BENZATHINE PENICILLIN.

BENZHEXOL.

BENZILONIUM.

BENZOCAINE **except**:

- (a) when included in Schedule 2;
- (b) in dermal preparations containing 2 per cent or less of total local anaesthetic substances; or

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

(c) in lozenges containing 30 mg or less of total local anaesthetic substances per dosage unit.

BENZODIAZEPINE derivatives **except** when separately specified in these Schedules.

BENZOYL PEROXIDE in preparations for human therapeutic use **except**:

(a) when included in Schedule 2; or

(b) in preparations for external use containing 5 per cent or less of benzoyl peroxide.

BENZPHETAMINE.

BENZTHIAZIDE.

BENZTROPINE (benzatropine).

BENZYDAMINE **except**:

(a) when included in Schedule 2; or

(b) in preparations for dermal use.

BENZYL PENICILLIN.

BEPRIDIL.

BERACTANT.

BESIFLOXACIN.

BETAHISTINE.

BETAMETHASONE.

BETAXOLOL.

BETHANECHOL CHLORIDE.

BETHANIDINE.

BEVACIZUMAB.

BEVANTOLOL.

BEXAROTENE.

BEZAFIBRATE.

BICALUTAMIDE.

BIFONAZOLE **except**:

(a) when included in Schedule 2;

(b) in preparations for dermal use containing 1 per cent or less of bifonazole for the treatment of the scalp; or

(c) in preparations for dermal use for the treatment of tinea pedis.

BIMATOPROST.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

BIPERIDEN.

BISMUTH COMPOUNDS for cosmetic use, **except**:

- (a) bismuth citrate when incorporated in hair colourant preparations in concentrations of 0.5 per cent or less; or
- (b) bismuth oxychloride.

BISMUTH COMPOUNDS for human therapeutic use, **except** bismuth formic iodide or bismuth subiodide in dusting powders containing 3 per cent or less of bismuth.

BISOPROLOL.

BIVALIRUDIN.

BLEOMYCIN.

BOCEPREVIR.

BOLANDIOL.

BOLASTERONE.

BOLAZINE.

BOLDENONE (dehydrotestosterone).

BOLENOL.

BOLMANTALATE.

BORON, including boric acid and borax, for human therapeutic use **except**:

- (a) in preparations for internal use containing 6 mg or less of boron per recommended daily dose;
- (b) in preparations for dermal use containing 0.35 per cent or less of boron, which are not for paediatric or antifungal use; or
- (c) when present as an excipient.

BORTEZOMIB.

BOSENTAN.

BOSUTINIB.

BOTULINUM TOXINS for human use **except** when separately specified in these Schedules.

BRENTUXIMAB VEDOTIN.

BRETYLIUM TOSYLATE.

BRIMONIDINE.

BRINZOLAMIDE.

BROMAZEPAM.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

BROMIDES, inorganic, for therapeutic use **except** when separately specified in these Schedules.

BROMOCRIPTINE.

BROMOFORM for therapeutic use.

BROMPHENIRAMINE **except** when included in Schedule 2 or 3.

BROMVALESTONE.

BRUGMANSIA spp.

BUCLIZINE **except** when included in Schedule 3.

BUDESONIDE **except** when included in Schedule 2.

BUFEXAMAC **except**:

- (a) in preparations for dermal use containing 5 per cent or less of bufexamac; or
- (b) in suppositories.

BUMETANIDE.

BUPHENINE.

BUPIVACAINE **except** when included in Schedule 5.

BUPROPION.

BUSERELIN.

BUSPIRONE.

BUSULPHAN.

BUTACAINE.

BUTOCONAZOLE **except** when included in Schedule 3.

BUTRACONAZOLE.

BUTYL AMINOBENZOATE **except** in dermal preparations containing 2 per cent or less of total local anaesthetic substances.

BUTYLCHLORAL HYDRATE.

BUTYL NITRITE.

CABAZITAXEL.

CABERGOLINE.

CADMIUM COMPOUNDS for human therapeutic use.

CALCIPOTRIOL.

CALCITONIN.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

CALCITRIOL.

CALCIUM CARBIMIDE for therapeutic use.

CALCIUM HYDROXYLAPATITE in preparations for injection or implantation:

(a) for tissue augmentation; or

(b) for cosmetic use.

CALCIUM POLYSTYRENE SULPHONATE.

CALOTROPIS GIGANTEA.

CALOTROPIS PROCERA.

CALUSTERONE.

CAMPHORATED OIL for therapeutic use.

CAMPHOTAMIDE.

CANAGLIFLOZIN.

CANAKINUMAB.

CANDESARTAN CILEXETIL.

CANDICIDIN.

CANINE TICK ANTI-SERUM.

CANTHARIDIN.

CAPECITABINE.

CAPREOMYCIN.

CAPTODIAME.

CAPTOPRIL.

CAPURIDE.

CARAMIPHEN.

CARBACHOL.

CARBAMAZEPINE.

CARBARYL for human therapeutic use.

CARBAZOCHROME.

CARBENICILLIN.

CARBENOXOLONE for internal use.

CARBETOCIN.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

CARBIDOPA.
CARBIMAZOLE.
CARBOCROMEN.
CARBOPLATIN.
CARBOPROST.
CARBROMAL.
CARBUTAMIDE.
CARBUTEROL.
CARGLUMIC ACID (N-carbomoyl-L-glutamic acid)
CARINDACILLIN.
CARISOPRODOL.
CARMUSTINE.
CARNIDAZOLE.
CARPROFEN.
CARVEDILOL.
CASPOFUNGIN.
CATHINE.
CATUMAXOMAB.
CEFACETRILE.
CEFACLOR.
CEFADROXIL.
CEFALORIDINE.
CEFAMANDOLE.
CEFAPIRIN.
CEFAZOLIN.
CEFEPIME.
CEFETAMET.
CEFIXIME.
CEFODIZIME.
CEFONICID.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

CEFOPERAZONE.

CEFOTAXIME.

CEFOTETAN.

CEFOTIAM.

CEFOVECIN for veterinary use.

CEFOXITIN.

CEFPIROME.

CEFPODOXIME.

CEFQUINOME.

CEFTAROLINE FOSAMIL.

CEFSULODIN.

CEFTAZIDIME.

CEFTIBUTEN.

CEFTIOFUR.

CEFTRIAXONE.

CEFUROXIME.

CELECOXIB.

CELIPROLOL.

CEPHAELIS ACUMINATA (ipecacuanha) **except** in preparations containing 0.2 per cent or less of emetine.

CEPHAELIS IPECACUANHA **except** in preparations containing 0.2 per cent or less of emetine.

CEPHALEXIN.

CEPHALONIUM.

CEPHALOTHIN.

CEPHRADINE.

CERIVASTATIN.

CERTOLIZUMAB PEGOL.

CERULETIDE.

CETIRIZINE **except**

(a) when included in Schedule 2; or

(b) in divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

children 12 years of age and over when:

- (i) in a primary pack containing not more than 5 days' supply; and
- (ii) labelled with a recommended daily dose not exceeding 10 mg of cetirizine.

CETRORELIX.

CETUXIMAB.

CHENODEOXYCHOLIC ACID.

CHLORAL FORMAMIDE.

CHLORAL HYDRATE **except** in preparations for topical use containing 2 per cent or less of chloral hydrate.

CHLORALOSE **except** when included in Schedule 6.

CHLORAMBUCIL.

CHLORAMPHENICOL **except** when included in Schedule 3.

CHLORANDROSTENOLONE.

CHLORAZANIL.

CHLORCYCLIZINE.

CHLORDIAZEPOXIDE.

CHLORMERODRIN.

CHLORMETHIAZOLE.

CHLORMEZANONE.

CHLOROFORM for use in anaesthesia.

4-CHLOROMETHANDIENONE.

2-(4-CHLOROPHENYL)-(1,2,4)TRIAZOLO[5,1-A]ISOQUINOLINE.

CHLOROQUINE.

CHLOROTHIAZIDE.

CHLOROTRIANISENE.

CHLOROXYDIENONE.

CHLORPHENIRAMINE **except** when included in Schedule 2 or 3.

CHLORPHENTERMINE.

CHLORPROMAZINE.

CHLORPROPAMIDE.

CHLORPROTHIXENE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

CHLORQUINALDOL for human topical use.

CHLORTETRACYCLINE **except** when included in Schedule 5.

CHLORTHALIDONE.

CHLORZOXAZONE.

CHOLERA VACCINE.

CHOLESTYRAMINE (colestyramine) for human therapeutic use.

CHYMOPAPAIN for human therapeutic use.

CICLACILLIN.

CICLESONIDE.

CICLOPIROX **except**:

- (a) when included in Schedule 2 or 3; or
- (b) in preparations for the treatment of tinea pedis.

CIDOFOVIR.

CILASTATIN.

CILAZAPRIL.

CILOSTAZOL.

CIMETIDINE **except** when included in Schedule 3.

CINACALCET.

CINCHOCAINE **except** when included in Schedule 2.

CINOXACIN.

CIPROFLOXACIN.

CISAPRIDE.

CISATRACURIUM BESYLATE.

CISPLATIN.

CITALOPRAM.

CLADRIBINE.

CLANOBUTIN.

CLARITHROMYCIN.

CLAVULANIC ACID.

CLEMASTINE **except** when included in Schedule 3.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

CLEMIZOLE.

CLENBUTEROL.

CLEVIDIPINE.

CLIDINIUM BROMIDE.

CLINDAMYCIN.

CLIOQUINOL and other halogenated derivatives of 8-hydroxyquinoline for human topical use **except** when separately specified in this Schedule.

CLOBAZAM.

CLOBETASOL.

CLOBETASONE (clobetasone-17-butyrate) **except** when included in Schedule 3.

CLOCORTOLONE.

CLODRONIC ACID (includes sodium clodronate).

CLOFARABINE.

CLOFAZIMINE.

CLOFENAMIDE.

CLOFIBRATE.

CLOMIPHENE.

CLOMIPRAMINE.

CLOMOCYCLINE.

CLONAZEPAM.

CLONIDINE.

CLOPAMIDE.

CLOPIDOGREL.

CLOPROSTENOL.

CLORAZEPATE.

CLOREXOLONE.

CLORPRENALINE.

CLOSTEBOL (4-chlorotestosterone).

CLOTRIMAZOLE **except**:

(a) when included in Schedule 2, 3 or 6; or

(b) in preparations for dermal use for the treatment of tinea pedis.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

CLOXACILLIN.

CLOZAPINE.

COBALT for human therapeutic use **except** as dicobalt edetate in preparations for the treatment of cyanide poisoning.

COBICISTAT.

CODEINE when compounded with one or more other therapeutically active substances:

- (a) in divided preparations containing 30 mg or less of codeine per dosage unit; or
- (b) in undivided preparations containing 1 per cent or less of codeine,
except when included in Schedule 2 or 3.

CO-DERGOCRINE.

COLASPASE.

COLCHICINE.

COLCHICUM AUTUMNALE.

COLESTIPOL.

COLFOSCERIL PALMITATE for human therapeutic use.

COLISTIN.

COLLAGEN in preparations for injection or implantation:

- (a) for tissue augmentation; or
- (b) for cosmetic use.

COLLAGENASE CLOSTRIDIUM HISTOLYTICUM.

CONVALLARIA KEISKI.

CONVALLARIA MAJALIS.

COPPER COMPOUNDS for human use **except**:

- (a) when separately specified in these Schedules;
- (b) in preparations for human internal use containing 5 mg or less of copper per recommended daily dose; or
- (c) in other preparations containing 5 per cent or less of copper compounds.

CORIFOLLITROPIN ALFA.

CORONILLA spp.

CORTICOSTERONE.

CORTICOTROPHIN.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

CORTISONE.

CO-TRIMOXAZOLE.

COUMARIN for therapeutic use (excluding when present as an excipient).

CRIZOTINIB.

CROFELEMER.

CRYSTAL VIOLET for human use **except** when used as a dermal marker.

CUPRIMYXIN.

CURARE.

CYCLANDELATE.

CYCLIZINE **except** when included in Schedule 3.

CYCLOBENZAPRINE.

CYCLOFENIL.

CYCLOHEXIMIDE.

CYCLOPENTHIAZIDE.

CYCLOPENTOLATE.

CYCLOPHOSPHAMIDE.

CYCLOPROPANE for therapeutic use.

CYCLOSERINE.

CYCLOSPORIN.

CYCLOTHIAZIDE.

CYCRIMINE.

CYMARIN.

CYPROHEPTADINE **except** when included in Schedule 3.

CYPROTERONE.

CYSTEAMINE for human therapeutic use.

CYTARABINE.

DABRAFENIB MESILATE.

DABIGATRAN.

DACARBAZINE.

DACLIZUMAB.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

DACTINOMYCIN.

DALFOPRISTIN.

DALTEPARIN (includes dalteparin sodium).

DANAPAROID (includes danaparoid sodium).

DANAZOL.

DANTHRON for human use.

DANTROLENE.

DAPAGLIFLOZIN.

DAPOXETINE.

DAPSONE.

DAPTOMYCIN.

DARBEPOETIN.

DARIFENACIN.

DARUNAVIR.

DATURA spp. **except:**

- (a) when included in Schedule 2; or
- (b) when separately specified in this Schedule.

DASATINIB.

DATURA STRAMONIUM (stramonium) **except:**

- (a) when included in Schedule 2; or
- (b) for smoking or burning.

DATURA TATULA (stramonium) **except:**

- (a) when included in Schedule 2; or
- (b) for smoking or burning.

DAUNORUBICIN.

DEANOL for therapeutic use.

DEBRISOQUINE.

DECAMETHONIUM.

DEFERASIROX.

DEFERIPRONE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

DEFLAZACORT.

DEGARELIX.

DEHYDROCHLOROMETHYLTTESTOSTERONE.

DEHYDROCORTICOSTERONE.

DELAVIDINE (includes delavirdine mesylate).

DEMBREXINE **except** when included in Schedule 5.

DEMECARIUM.

DEMECLOCYCLINE.

DENOSUMAB.

DEOXYCORTONE.

DEOXYRIBONUCLEASE **except**:

- (a) when separately specified in this Schedule; or
- (b) for external use.

DERACOXIB.

DEFERRIOXAMINE.

DESFLURANE.

DESIPRAMINE.

DESIRUDIN.

DESLANOSIDE.

DESLORATADINE **except** when included in Schedule 2.

DESLORELIN.

DESMOPRESSIN (D.D.A.V.P.).

DESOGESTREL.

DESONIDE.

DESOXYMETHASONE.

DESVENLAFAXINE.

DETOMIDINE.

DEXAMETHASONE.

DEXCHLORPHENIRAMINE **except** when included in Schedule 2 or 3.

DEXFENFLURAMINE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

DEXMEDETOMIDINE.

DEXTROMETHORPHAN (excluding its stereoisomers) **except** when included in Schedule 2.

DEXTROPROPOXYPHENE:

- (a) in divided preparations containing 135 mg of dextropropoxyphene or less per dosage unit; or
- (b) liquid preparations containing 2.5 per cent or less of dextropropoxyphene.

DEXTRORPHAN (excluding its stereoisomers).

DIAMTHAZOLE.

DIAYERIDINE.

DIAZEPAM.

DIAZOXIDE.

DIBENZEPIN.

DIBOTERMIN.

DIBROMOPROPAMIDINE for therapeutic use **except** when included in Schedule 2.

DICHLORALPHENAZONE.

DICHLOROPHEN for human therapeutic use.

DICHLORPHENAMIDE.

DICLOFENAC **except:**

- (a) when included in Schedule 2 or 3; or
- (b) in preparations for dermal use unless:
 - (i) for the treatment of solar keratosis; or
 - (ii) containing more than 4 per cent of diclofenac.

DICLOXACILLIN.

DICYCLOMINE.

DIDANOSINE.

DIENESTROL.

DIENOGEST.

DIETHAZINE.

DIETHYLCARBAMAZINE for human therapeutic use.

DIETHYLPROPION.

DIFENOXIN in preparations containing, per dosage unit, 0.5 mg or less of difenoxin and a quantity of atropine

Poisons Standard 2015

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

sulfate equivalent to at least 5 per cent of the dose of difenoxin.

DIFLORASONE.

DIFLOXACIN.

DIFLUCORTOLONE.

DIFLUNISAL.

DIGITALIS LANATA.

DIGITALIS PURPUREA.

DIGITOXIN.

DIGOXIN.

DIGOXIN-SPECIFIC ANTIBODY FRAGMENT F (Ab).

DIHYDRALAZINE.

DIHYDROCODEINE when compounded with one or more other therapeutically active substances:

- (a) in divided preparations containing not more than 100 mg of dihydrocodeine per dosage unit; or
- (b) in undivided preparations with a concentration of not more than 2.5 per cent of dihydrocodeine, **except** when included in Schedule 2 or 3.

DIHYDROERGOTOXINE.

DIHYDROLONE.

DIHYDROSTREPTOMYCIN.

DIHYDROTACHYSTEROL.

DI-IODOHYDROXYQUINOLINE (iodoquinol) **except**:

- (a) when included in Schedule 3; or
- (b) for human internal use.

DIISOPROPYLAMINE DICHLOROACETATE.

DILTIAZEM.

DIMENHYDRINATE **except** when included in Schedule 2 or 3.

DIMERCAPROL.

DIMETHANDROSTANOLONE.

DIMETHAZINE.

DIMETHINDENE **except** when included in Schedule 3.

DIMETHOTHIAZINE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

DIMETHOXANATE.

DIMETHYL FUMARATE.

DIMETHYL SULFOXIDE (excluding dimethyl sulfone) for therapeutic use **except**:

- (a) when included in Schedule 6; or
- (b) in *in vitro* test kits.

DIMETRIDAZOLE.

2,4-DINITROCHLOROBENZENE for therapeutic use.

DINITROCRESOLS for therapeutic use **except** when separately specified in these Schedules.

DINITRONAPHTHOLS for therapeutic use **except** when separately specified in these Schedules.

DINITROPHENOLS for therapeutic use.

DINITROTHYMOLS for therapeutic use **except** when separately specified in these Schedules.

DINOPROST.

DINOPROSTONE.

DIPERODON.

DIPHEMANIL **except** in preparations for dermal use.

DIPHENHYDRAMINE **except** when included in Schedule 2 or 3.

DIPHENIDOL.

DIPHENOXYLATE in preparations containing, per dosage unit, 2.5 mg or less of diphenoxylate and a quantity of atropine sulfate equivalent to at least 1 per cent of the dose of diphenoxylate **except** when included in Schedule 3.

DIPHENYLPYRALINE.

DIPHThERIA TOXOID.

DIPIVEFRIN.

DIPYRIDAMOLE.

DIRITHROMYCIN.

DIRLOTAPIDE.

DISOPHENOL.

DISOPYRAMIDE.

DISTIGMINE.

DISULFIRAM for therapeutic use.

DISULPHAMIDE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

DITHIAZANINE **except** when included in Schedule 6.

DITIOCARB.

DOBUTAMINE.

DOCETAXEL.

DOFETILIDE.

DOLASETRON.

DOLUTEGRAVIR.

DOMPERIDONE.

DONEPEZIL.

DOPAMINE.

DOPEXAMINE.

DORIPENEM.

DORNASE.

DORZOLAMIDE.

DOTHIEPIN.

DOXANTRAZOLE.

DOXAPRAM.

DOXAZOSIN.

DOXEPIN.

DOXORUBICIN.

DOXYCYCLINE.

DOXYLAMINE **except** when included in Schedule 2 or 3.

DRONEDARONE.

DROPERIDOL.

DROSPIRENONE.

DROSTANOLONE.

DROTRECOGIN.

DUBOISIA LEICHHARDTII **except** when included in Schedule 2.

DUBOISIA MYOPOROIDES **except** when included in Schedule 2.

DULOXETINE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

DUTASTERIDE.

DYDROGESTERONE.

ECONAZOLE **except**:

- (a) when included in Schedule 2, 3 or 6; or
- (b) in preparations for dermal use for the treatment of tinea pedis.

ECOTHIOPATE (includes ecothiopate iodide).

ECTYLUREA.

ECULIZUMAB.

EDETIC ACID for human therapeutic use **except**:

- (a) in preparations containing 0.25 per cent or less of edetic acid;
- (b) as dicobalt edetate in preparations for the treatment of cyanide poisoning; or
- (c) in contact lens preparations.

EDOXUDINE.

EDROPHONIUM.

EFALIZUMAB.

EFAVIRENZ.

EFLORNITHINE.

EFORMOTEROL.

ELETRIPTAN.

ELOSULFASE ALFA.

ELTENAC.

ELTROMBOPAG.

ELVITEGRAVIR.

EMEPRONIUM.

EMETINE **except** in preparations containing 0.2 per cent or less of emetine.

EMPAGLIFLOZIN.

EMTRICITABINE.

ENALAPRIL.

ENESTEBOL.

ENFLURANE for therapeutic use.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

ENFUVRTIDE.

ENOBOSARM.

ENOXACIN.

ENOXAPARIN.

ENOXIMONE.

ENPROSTIL.

ENROFLOXACIN.

ENTACAPONE.

ENTECAVIR.

EPHEDRA spp. **except** in preparations containing 0.001 per cent or less of ephedrine.

EPHEDRINE.

EPICILLIN.

EPINASTINE.

EPIRUBICIN.

EPITIOSTANOL.

EPLERENONE.

EPOETINS.

EPOPROSTENOL.

EPROSARTAN.

EPTIFIBATIDE.

ERGOMETRINE.

ERGOT.

ERGOTAMINE.

ERGOTOXINE.

ERIBULIN MESYLATE.

ERLOTINIB.

ERTAPENEM.

ERYSIMUM spp.

ERYTHROMYCIN.

ERYTHROPOIETIN.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

ERYTHROPOIETINS **except** when separately specified in these Schedules.

ESCITALOPRAM.

ESMOLOL.

ESOMEPRAZOLE **except** when included in Schedule 3.

ESTRAMUSTINE.

ESTROPIPATE (piperazine oestrone sulfate).

ETANERCEPT.

ETHACRYNIC ACID.

ETHAMBUTOL.

ETHAMIVAN.

ETHANOLAMINE in preparations for injection.

ETHCHLORVYNOL.

ETHER for use in anaesthesia.

ETHINAMATE.

ETHINYLOESTRADIOL.

ETHIONAMIDE.

ETHISTERONE.

ETHOGLUCID.

ETHOHEPTAZINE.

ETHOPROPAZINE.

ETHOSUXIMIDE.

ETHOTOIN.

ETHOXZOLAMIDE.

ETHYL CHLORIDE for human therapeutic use.

ETHYLDIENOLONE.

ETHYLHEXANEDIOL for animal use.

ETHYLMORPHINE when compounded with one or more other therapeutically active substances:

- (a) in divided preparations containing not more than 100 mg of ethylmorphine per dosage unit; or
 - (b) in undivided preparations with a concentration of not more than 2.5 per cent of ethylmorphine;
- except** when included in Schedule 2.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

ETHYLOESTRENOL.

ETHYNODIOL.

ETIDOCAINE.

ETIDRONIC ACID (includes disodium etidronate):

(a) for internal use; or

(b) in topical preparations **except** in preparations containing 1 per cent or less of etidronic acid.

ETILEFRIN.

ETIPROSTON.

ETODOLAC.

ETOFENAMATE **except** when included in Schedule 2.

ETONOGESTREL.

ETOPOSIDE.

ETORICOXIB.

ETRAVIRINE.

ETRETINATE.

EVEROLIMUS.

EXEMESTANE.

EXENATIDE.

EZETIMIBE.

FAMCICLOVIR **except** when included in Schedule 3.

FAMOTIDINE **except** when included in Schedule 2.

FEBUXOSTAT.

FELBINAC **except** when included in Schedule 2.

FELODIPINE.

FELYPRESSIN.

FENBUFEN.

FENCAMFAMIN.

FENCLOFENAC.

FENFLURAMINE.

FENOFIBRATE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

FENOLDOPAM.

FENOPROFEN.

FENOTEROL.

FENPIPRAMIDE.

FENPIPRANE.

FENPROPOREX.

FENPROSTALENE.

FEXOFENADINE *except*:

- (a) when included in Schedule 2; or
- (b) in divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:
 - (i) in a primary pack containing 10 dosage units or less and not more than 5 days' supply; and
 - (ii) labelled with a recommended daily dose not exceeding 120 mg of fexofenadine.

FIBRINOLYSIN **except** for external use.

FIDAXOMICIN.

FILGRASTIM.

FINASTERIDE.

FINGOLIMOD.

FIROCOXIB.

FLECAINIDE.

FLEROXACIN.

FLOCTAFENINE.

FLORFENICOL.

FLUANISONE.

FLUCLOROLONE.

FLUCLOXACILLIN.

FLUCONAZOLE **except** when included in Schedule 3.

FLUCYTOSINE.

FLUDARABINE.

FLUDROCORTISONE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

FLUFENAMIC ACID.

FLUMAZENIL.

FLUMETHASONE.

FLUMETHIAZIDE.

FLUNISOLIDE.

FLUNIXIN MEGLUMINE.

FLUOCINOLONE.

FLUOCINONIDE.

FLUOCORTIN.

FLUOCORTOLONE.

FLUORESCEIN in preparations for injection.

FLUORIDES in preparations for human use **except** when included in or expressly excluded from
Schedule 2 or 3.

FLUOROMETHOLONE.

FLUOROURACIL.

FLUOXETINE.

FLUOXYMESTERONE.

FLUPENTHIXOL.

FLUPHENAZINE.

FLUPROSTENOL.

FLURANDRENOLONE.

FLURAZEPAM.

FLURBIPROFEN **except** when included in Schedule 2.

FLUROXENE for human therapeutic use.

FLUSPIRILENE.

FLUTAMIDE.

FLUTICASONE **except** when included in Schedule 2.

FLUVASTATIN.

FLUVOXAMINE.

FOLIC ACID in preparations for human use for injection.

FOLINIC ACID in preparations for human use for injection.

Poisons Standard 2015

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

FOLLICLE-STIMULATING HORMONE except when separately specified in this Schedule.

FOLLISTATIN.

FOLLITROPIN ALPHA.

FOLLITROPIN BETA.

FOMIVIRSEN.

FONDAPARINUX.

FORMEBOLONE.

FORMESTANE.

FOSAMPRENAVIR.

FOSAPREPITANT.

FOSCARNET.

FOSFESTROL (diethylstilboestrol diphosphate).

FOSINOPRIL.

FOSPHENYTOIN.

FOTEMUSTINE.

FRAMYCETIN.

FULVESTRANT.

FURALTADONE.

FURAZABOL.

FURAZOLIDONE.

FUROSEMIDE (frusemide).

FUSIDIC ACID.

GABAPENTIN.

GALANTAMINE.

GALANTHUS spp.

GALLAMINE.

GALSULFASE.

GANCICLOVIR.

GANIRELIX.

GATIFLOXACIN.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

GEFITINIB.

GEMCITABINE.

GEMEPROST.

GEMFIBROZIL.

GEMIFLOXACIN.

GEMTUZUMAB OZOGAMICIN.

GENTAMICIN.

GESTODENE.

GESTONORONE.

GESTRINONE.

GHRH INJECTABLE PLASMID.

GITALIN.

GLATIRAMER ACETATE.

GLIBENCLAMIDE.

GLIBORNURIDE.

GLICLAZIDE.

GLIMEPIRIDE.

GLIPIZIDE.

GLISOXEPIDE.

GLUTATHIONE for parenteral use.

GLUTETHIMIDE.

GLYCERYL TRINITRATE **except** when included in Schedule 3.

GLYCOPYRRONIUM in preparations for injection.

GLYMIDINE.

GnRH VACCINE.

GOLIMUMAB.

GONADORELIN.

GONADOTROPHIC HORMONES **except** when separately specified in this Schedule.

GOSERELIN.

GRAMICIDIN.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

GRANISETRON.

GREPAFLOXACIN.

GRISEOFULVIN.

GUAIPHENESIN for human therapeutic use **except**:

- (a) when included in Schedule 2;
- (b) in oral liquid preparations containing 2 per cent or less of guaiphenesin; or
- (c) in divided preparations containing 200 mg or less of guaiphenesin per dosage unit.

GUANABENZ.

GUANACLINE.

GUANETHIDINE.

GUANIDINE for therapeutic use.

HACHIMYCIN.

HAEMATIN.

HAEMOPHILUS INFLUENZAE VACCINE.

HALCINONIDE.

HALOFANTRINE.

HALOFENATE.

HALOFUGINONE in preparations containing 0.1 per cent or less of halofuginone for the treatment of animals.

HALOPERIDOL.

HALOTHANE for therapeutic use.

HEMEROCALLIS (*Hemerocallis flava*).

HEPARINS for internal use **except** when separately specified in this Schedule.

HEPATITIS A VACCINE.

HEPATITIS B VACCINE.

HETACILLIN.

HEXACHLOROPHANE:

- (a) in preparations for use on infants; or
- (b) in other preparations **except**:
 - (i) when included in Schedule 2 or 6; or
 - (ii) in preparations containing 0.75 per cent or less of hexachlorophane.

Poisons Standard 2015

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

HEXAMETHONIUM.

HEXETIDINE for human internal use.

HEXOBENDINE.

HEXOCYCLIUM.

HEXOPRENALINE.

HISTAMINE for therapeutic use **except** in preparations containing 0.5 per cent or less of histamine.

HMG-CoA REDUCTASE INHIBITORS (including "statins") **except** when separately specified in these Schedules.

HOMATROPINE.

HUMAN CHORIONIC GONADATROPHIN **except** in pregnancy test kits.

HUMAN PAPILLOMAVIRUS VACCINE.

HYALURONIC ACID AND ITS POLYMERS in preparations for injection or implantation:

- (a) for tissue augmentation;
- (b) for cosmetic use; or
- (c) for the treatment of animals.

HYDRALAZINE.

HYDRARGAPHEN.

HYDROCHLOROTHIAZIDE.

HYDROCORTISONE:

- (a) for human use **except** when included in Schedule 2 or 3; or
- (b) for the treatment of animals.

HYDROCYANIC ACID for therapeutic use.

HYDROFLUMETHIAZIDE.

HYDROQUINONE (other than its alkyl ethers separately specified in this Schedule) in preparations for human therapeutic or cosmetic use **except**:

- (a) when included in Schedule 2; or
- (b) in hair preparations containing 0.3 per cent or less of hydroquinone; or
- (c) in cosmetic nail preparations containing 0.02 per cent or less of hydroquinone.

HYDROXYCHLOROQUINE.

HYDROXYEPHEDRINE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

HYDROXYPHENAMATE.

HYDROXYPROGESTERONE.

HYDROXYSTENOZOL.

HYDROXYUREA.

HYDROXYZINE.

HYGROMYCIN.

HYOSCINE **except** when included in Schedule 2.

HYOSCYAMINE **except** when included in Schedule 2.

HYOSCYAMUS NIGER **except**:

- (a) when included in Schedule 2; or
- (b) in a pack containing 0.03 mg or less of total solanaceous alkaloids.

HYPOTHALAMIC RELEASING FACTORS **except** when separately specified in this Schedule.

HYPROMELLOSE in preparations for injection.

IBAFLOXACIN for veterinary use.

IBANDRONIC ACID.

IBOGAINE.

IBRITUMOMAB.

IBUFENAC.

IBUPROFEN **except**:

- (a) when included in or expressly excluded from Schedule 2 or 3; or
- (b) in preparations for dermal use.

IBUTEROL.

IBUTILIDE.

ICATIBANT.

IDARUBICIN.

IDOXURIDINE **except** in preparations containing 0.5 per cent or less of idoxuridine for dermal use.

IDURSULFASE.

IFOSFAMIDE.

ILOPROST.

IMATINIB.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

IMEPITOIN.

IMIDAPRIL.

IMIGLUCERASE.

IMIPENIM.

IMIPRAMINE.

IMIQUIMOD.

IMMUNOGLOBULINS for human parenteral use **except** when separately specified in these Schedules.

INDACATEROL.

INDAPAMIDE.

INDINAVIR.

INDOMETHACIN **except** when included in Schedule 2.

INDOPROFEN.

INDORAMIN.

INFLIXIMAB.

INFLUENZA AND CORYZA VACCINES:

(a) for parenteral use; or

(b) for nasal administration.

INGENOL MEBUTATE.

INSULIN GLARGINE.

INSULIN-LIKE GROWTH FACTOR I.

INSULIN-LIKE GROWTH FACTORS **except** when separately specified in this Schedule.

INSULINS.

INTERFERONS.

INTERLEUKINS **except** when separately specified in these Schedules.

IODOTHIOURACIL.

IPILIMUMAB.

IPRATROPIUM **except** when included in Schedule 2.

IPRIFLAVONE.

IPRINDOLE.

IPRONIAZID.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

IRBESARTAN.

IRINOTECAN.

IRON COMPOUNDS in injectable preparations for human use.

ISOAMINILE.

ISOAMYL NITRITE.

ISOBUTYL NITRITE.

ISOCARBOXAZID.

ISOCONAZOLE **except** when included in Schedule 2, 3 or 6.

ISOETARINE.

ISOFLURANE for therapeutic use.

ISOMETHEPTENE.

ISONIAZID.

ISOPRENALINE.

ISOPRINOSINE.

ISOPROPAMIDE **except** when included in Schedule 2.

ISOSORBIDE DINITRATE **except** when included in Schedule 3.

ISOSORBIDE MONONITRATE.

ISOTRETINOIN.

ISOXICAM.

ISOXSUPRINE.

ISRADIPINE.

ITRACONAZOLE.

IVABRADINE.

IVACAFTOR.

IVERMECTIN:

(a) for human use; or

(b) for the treatment of mange in dogs.

IXABEPILONE.

JAPANESE ENCEPHALITIS VACCINE.

KANAMYCIN.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

KETANSERIN **except** in topical veterinary preparations containing 0.5 per cent or less of ketanserin.

KETAZOLAM.

KETOCONAZOLE **except**:

- (a) when included in Schedule 2;
- (b) in preparations for dermal use containing 1 per cent or less of ketoconazole for the treatment of the scalp; or
- (c) in preparations for dermal use for the treatment of tinea pedis.

KETOPROFEN **except**:

- (a) in preparations for dermal use; or
- (b) when included in Schedule 3.

KETOROLAC (includes ketoralac trometamol).

KETOTIFEN **except** when included in Schedule 2.

KHELLIN.

KITASAMYCIN **except**:

- (a) when included in Schedule 5 ; or
- (b) in animal feeds for growth promotion containing 100 mg/kg or less of antibiotic substances.

LABETALOL.

LACIDIPINE.

LACOSAMIDE.

LAMIVUDINE.

LAMOTRIGINE.

LANATOSIDES.

LANREOTIDE.

LANSOPRAZOLE **except** when included in Schedule 3.

LANTHANUM for therapeutic use.

LAPATINIB.

LARONIDASE.

LAROPIPRANT.

LATAMOXEF.

LATANOPROST.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

LAUDEXIUM.

LAUROMACROGOLS in preparations for injection **except**:

- (a) when present as an excipient; or
- (b) when separately specified in these Schedules.

LEAD for human therapeutic use.

LEFETAMINE.

LEFLUNOMIDE.

LENALIDOMIDE.

LENOGRASTIM.

LEPIRUDIN.

LEPTAZOL.

LERCANIDIPINE.

LETROZOLE.

LEUPRORELIN.

LEVALLORPHAN.

LEVAMISOLE:

- (a) for human therapeutic use; or
- (b) in preparations for the prevention or treatment of heartworm in dogs.

LEVETIRACETAM.

LEVOBUNOLOL.

LEVOBUPIVACAINE.

LEVOCABASTINE **except** when included in Schedule 2.

LEVODOPA.

LEVOMEPRMAZINE.

LEVONORGESTREL **except** when included in Schedule 3.

LEVOSIMENDAN.

LIDOFLAZINE.

LIGNOCAINE **except**:

- (a) when included in Schedules 2 or 5;
- (b) in dermal preparations containing 2 per cent or less of total local anaesthetic substances per dosage unit; or

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

- (c) in lozenges containing 30 mg or less of total anaesthetic substances per dosage unit.

LINAGLIPTIN.

LINCOMYCIN.

LINDANE for human therapeutic use **except** when included in Schedule 2.

LINEZOLID.

LIOTHYRONINE.

LIRAGLUTIDE.

LISINOPRIL.

LISURIDE.

LITHIUM for therapeutic use **except**:

- (a) when included in Schedule 2;
- (b) when present as an excipient in preparations for dermal use containing 0.25 per cent or less of lithium; or
- (c) in preparations containing 0.01 per cent or less of lithium.

LIXISENATIDE.

LODOXAMIDE **except** when included in Schedule 2.

LOFEXIDINE.

LOGIPARIN for internal use.

LOMEFLOXACIN.

LOMUSTINE.

LOPERAMIDE **except**:

- (a) when included in Schedule 2; or
- (b) in divided oral preparations containing 2 mg or less of loperamide per dosage unit, in a primary pack containing 8 dosage units or less.

LOPINAVIR.

LOPRAZOLAM.

LORACARBEF.

LORATADINE **except**:

- (a) when included in Schedule 2; or
- (b) in divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

Poisons Standard 2015

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

- (i) in a primary pack containing 5 dosage units or less; and
- (ii) labelled with a recommended daily dose not exceeding 10 mg of loratadine.

LORAZEPAM.

LORMETAZEPAM.

LOSARTAN.

LOTEPREDNOL.

LOXAPINE.

LUMEFANTRINE.

LUMIRACOXIB.

LURASIDONE.

LUTEINISING HORMONE except in ovulation test kits.

LYMECYCLINE.

MACITENTAN for human use.

MAFENIDE **except** when included in Schedule 6.

MANDRAGORA OFFICINARUM.

MANNOMUSTINE.

MAPROTILINE.

MARAVIROC.

MARBOFLOXACIN.

MAROPITANT.

MAVACOXIB.

MAZINDOL.

MEASLES VACCINE.

MEBANAZINE.

MEBEVERINE.

MEBHYDROLIN.

MEBOLAZINE.

MEBUTAMATE.

MECAMYLAMINE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

MECASERMIN.

MECILLINAM.

MECLOCYCLINE.

MECLOFENAMATE.

MECLOFENOXATE.

MECLOZINE **except** when included in Schedule 2.

MEDAZEPAM.

MEDETOMIDINE.

MEDIGOXIN (methyl digoxin).

MEDROXYPROGESTERONE.

MEDRYSONE.

MEFENAMIC ACID **except** when included in Schedule 2.

MEFENOREX.

MEFLOQUINE.

MEFRUSIDE.

MEGESTROL.

MELAGATRAN.

MELATONIN for human use.

MELENGESTROL **except** when included in Schedule 6.

MELOXICAM.

MELPHALAN.

MEMANTINE.

MENINGOCOCCAL VACCINE.

MENOTROPHIN.

MEPACRINE.

MEPENZOLATE.

MEPHENESIN.

MEPHENTERMINE.

MEPINDOLOL.

MEPITIOSTANE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

MEPIVACAINE.

MEPROBAMATE.

MEPTAZINOL.

MEPYRAMINE **except** when included in Schedule 2 or 3.

MEQUITAZINE.

MERCAPTOMERIN.

MERCAPTOPURINE.

MERCUROCHROME **except** when included in Schedule 2 or 6.

MERCURY for cosmetic or therapeutic use **except**:

- (a) when separately specified in these Schedules; or
- (b) in a sealed device which prevents access to the mercury.

MEROPENEM.

MERSALYL.

MESABOLONE.

MESALAZINE.

MESNA.

MESTANOLONE (androstalone).

MESTEROLONE.

MESTRANOL.

METANDIENONE.

METARAMINOL.

METENOLONE.

METERGOLINE.

METFORMIN.

METHACHOLINE.

METHACYCLINE.

METHALLENOESTRIL.

METHANDRIOL.

METHANTHELINIUM.

METHAZOLAMIDE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

METHDILAZINE **except** when included in Schedule 3.

METHENOLONE.

METHICILLIN.

METHIMAZOLE.

METHISAZONE.

METHIXENE.

METHOCARBAMOL.

METHOHEXITONE.

METHOIN.

METHOTREXATE.

METHOXAMINE **except:**

(a) when included in Schedule 2; or

(b) in preparations for external use containing 1 per cent or less of methoxamine.

METHOXSALEN.

METHOXYFLURANE.

METHSUXIMIDE.

METHYCLOTHIAZIDE.

METHYL AMINOLEVULINATE.

#METHYLANDROSTANOLONE.

METHYLCLOSTEBOL.

METHYLDOPA.

METHYLENE BLUE in preparations for injection.

METHYLERGOMETRINE.

METHYL MERCURY for therapeutic use.

METHYLNALTREXONE.

METHYLPENTYNOL.

METHYLPHENOBARBITONE.

METHYLPREDNISOLONE.

METHYL SALICYLATE in preparations for internal therapeutic use.

METHYLTESTOSTERONE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

METHYLTHIOURACIL.

METHYLTRIENOLONE.

METHYPRYLONE.

METHYSERGIDE.

METOCLOPRAMIDE **except** when included in Schedule 3.

METOLAZONE.

METOPROLOL.

METRIBOLONE.

METRIFONATE (trichlorfon) for human therapeutic use.

METRONIDAZOLE.

METYRAPONE.

MEXILETINE.

MEZLOCILLIN.

MIANSERIN.

MIBEFRADIL.

MIBOLERONE.

MICAFUNGIN.

MICONAZOLE **except**:

- (a) when included in Schedule 2, 3 or 6; or
- (b) in preparations for dermal use for the treatment of tinea pedis.

MIDAZOLAM.

MIDODRINE.

MIFEPRISTONE.

MIGLITOL.

MIGLUSTAT.

MILBEMYCIN OXIME **except** when included in Schedule 5.

MILRINONE.

MINOCYCLINE.

MINOXIDIL **except** when included in Schedule 2.

MIRABEGRON.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

MIRTAZAPINE.

MISOPROSTOL.

MITOBRONITOL.

MITOMYCIN.

MITOTANE.

MITOXANTRONE.

MITRATAPIDE.

MIVACURIUM CHLORIDE.

MOCLOBEMIDE.

MODAFINIL.

MOLGRAMOSTIM.

MOLINDONE.

MOMETASONE **except** when included in Schedule 2.

MONENSIN **except**:

- (a) when included in Schedule 5 or 6; or
- (b) in animal feeds containing 360 mg/kg or less of antibiotic substances.

MONOBENZONE and alkyl ethers of hydroquinone for human therapeutic use or cosmetic use **except** in cosmetic nail preparations containing 0.02 per cent or less of monobenzene or alkyl ethers of hydroquinone.

MONOCLONAL ANTIBODIES for therapeutic use **except**:

- (a) in diagnostic test kits; or
- (b) when separately specified in these Schedules.

MONTELUKAST.

MOPERONE.

MORAZONE.

MORICIZINE.

MOTRAZEPAM.

MOTRETINIDE.

MOXIDECTIN in preparations for injection containing 10 per cent or less of moxidectin **except** when included in Schedule 5.

MOXIFLOXACIN.

MOXONIDINE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

MUMPS VACCINE.

MUPIROCIN.

MURAGLITAZAR.

MUROMONAB.

MUSTINE (nitrogen mustard).

MYCOPHENOLIC ACID (includes mycophenolate mofetil).

NABUMETONE.

NADOLOL.

NADROPARIN.

NAFARELIN.

NAFTIDROFURYL.

NALBUPHINE.

NALIDIXIC ACID.

NALMEFENE.

NALORPHINE.

NALOXONE.

NALTREXONE.

NANDROLONE.

NAPROXEN **except** when included in Schedule 3 or in Schedule 2.

NARASIN **except**:

- (a) when included in Schedule 6; or
- (b) in animal feeds containing 100 mg/kg or less of antibiotic substances.

NARATRIPTAN.

NATALIZUMAB.

NATAMYCIN **except** for use as a food additive.

NATEGLINIDE.

NEBACUMAB.

NEBIVOLOL.

NEDOCROMIL.

NEFAZODONE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

NEFOPAM.

NELFINAVIR (includes nelfinavir mesylate).

NEOMYCIN.

NEOSTIGMINE.

NEPAFENAC.

NERIUM OLEANDER.

NESIRITIDE.

NETILMICIN.

NEVIRAPINE.

NIALAMIDE.

NICARDIPINE.

NICERGOLINE.

NICOFURANOSE.

NICORANDIL.

NICOTINE in preparations for human therapeutic use **except** for use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use.

NICOTINIC ACID for human therapeutic use **except**:

- (a) when separately specified in these Schedules;
- (b) in preparations containing 100 mg or less of nicotinic acid per dosage unit; or
- (c) nicotinamide.

NICOUMALONE.

NIFEDIPINE.

NIFENAZONE.

NIKETHAMIDE.

NILOTINIB.

NILUTAMIDE.

NIMESULIDE.

NIMODIPINE.

NIMORAZOLE.

NIRIDAZOLE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

NISOLDIPINE.

NITISINONE.

NITRAZEPAM.

NITRENDIPINE.

NITRIC OXIDE for human therapeutic use.

NITROFURANTOIN.

NITROFURAZONE.

NITROUS OXIDE for therapeutic use.

NITROXOLINE.

NIZATIDINE **except** when included in Schedule 2.

NOMEGESTROL.

NOMIFENSINE.

NORADRENALINE.

19-NORANDROSTENEDIOL.

19-NORANDROSTENEDIONE.

NORANDROSTENOLONE.

NORBOLETHONE.

NORCLOSTEBOL.

NORELGESTROMIN.

NORETHANDROLONE.

NORETHISTERONE.

NORFLOXACIN.

NORGESTREL.

NORIBOGAINE.

NORMAL HUMAN IMMUNOGLOBULIN.

NORMETHANDRONE.

NORTRIPTYLINE.

NOVOBIOCIN.

NOXIPTYLINE.

NYSTATIN **except** when included in Schedule 2 or 3.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

OCLACITNIB.

OCRIPLASMIN.

OCTAMYLAMINE.

OCTATROPINE.

OCTREOTIDE.

OCTYL NITRITE.

OESTRADIOL **except** when included in Schedule 5.

OESTRIOL.

OESTROGENS **except** when separately specified in these Schedules.

OESTRONE.

OFATUMUMAB.

OFLOXACIN.

OLANZAPINE.

OLEANDOMYCIN **except**:

- (a) when included in Schedule 5; or
- (b) in animal feeds for growth promotion containing 50 mg/kg or less of antibiotic substances.

OLEANDRIN.

OLMESARTAN.

OLODATEROL.

OLOPATADINE.

OLSALAZINE.

OMALIZUMAB.

OMEGA-3-ACID ETHYL ESTERS (excluding salts and derivatives) for human therapeutic use, for the treatment of post-myocardial infarction and/or hypertriglyceridaemia.

OMEPRAZOLE **except** when included in Schedule 3.

ONDANSETRON.

OPIPRAMOL.

ORBIFLOXACIN.

ORCIPRENALINE.

ORGANOPHOSPHORUS COMPOUNDS with anticholinesterase activity for human therapeutic use **except**:

- (a) when separately specified in these Schedules; or

Poisons Standard 2015

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

(b) in preparations containing 2 per cent or less of malathion for external use.

ORLISTAT **except** when included in Schedule 3.

ORNIDAZOLE.

ORNIPRESSIN.

ORPHENADRINE.

ORTHOPTERIN.

OSELTAMIVIR.

OUABAIN.

OVANDROTONE.

OXABOLONE.

OXACILLIN.

OXALIPLATIN.

OXANDROLONE.

OXAPROZIN.

OXAZEPAM.

OXCARBAZEPINE.

OXEDRINE for human internal use **except** in preparations labelled with a recommended daily dose of 30 mg or less of oxedrine.

OXETACAINE (oxethazaine) **except** when included in Schedule 2.

OXICONAZOLE **except**:

(a) when included in Schedule 2 or 3; or

(b) in preparations for the treatment of tinea pedis.

OXITROPIUM.

OXOLAMINE.

OXOLINIC ACID.

XPENTIFYLLINE (pentoxifylline).

OXPRENOLOL.

OXYBUPROCAINE.

OXYBUTYNIN.

OXYMESTERONE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

OXYMETHOLONE.

OXYPHENBUTAZONE.

OXYPHENCYCLIMINE.

OXYPHENONIUM.

OXYTETRACYCLINE **except** when included in Schedule 5.

OXYTOCIN.

PACLITAXEL.

PALIFERMIN.

PALIPERIDONE.

PALIVIZUMAB.

PALONOSETRON.

PAMAQUIN.

PAMIDRONIC ACID (includes disodium pamidronate).

PANCREATIC ENZYMES **except**:

- (a) in preparations containing 20,000 BP units or less of lipase activity per dosage unit; or
- (b) when separately specified in these Schedules.

PANCURONIUM.

PANITUMUMAB.

PANTOPRAZOLE **except** when included in Schedule 3.

PAPAVERINE in preparations for injection.

PARACETAMOL:

- (a) when combined with aspirin or salicylamide or any derivative of these substances **except** when separately specified in these Schedules;
- (b) when combined with ibuprofen in a primary pack containing more than 30 dosage units;
- (c) in slow release tablets or capsules containing more than 665 mg of paracetamol;
- (d) in non-slow release tablets or capsules containing more than 500 mg of paracetamol;
- (e) in individually wrapped powders or sachets of granules each containing more than 1000 mg of paracetamol; or
- (f) for injection.

PARALDEHYDE.

PARAMETHADIONE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

PARAMETHASONE.

PARECOXIB.

PARICALCITOL.

PAROMOMYCIN.

PAROXETINE.

PASIREOTIDE.

PAZOPANIB.

PECAZINE.

PEFLOXACIN.

PEGAPTANIB.

PEGFILGRASTIM.

PEGINTERFERON.

PEGVISOMANT.

PEMETREXED.

PEMOLINE.

PEMPIDINE.

PENBUTOLOL.

PENCICLOVIR **except** when included in Schedule 2.

PENETHAMATE.

PENICILLAMINE.

PENTAERYTHRITYL TETRANITRATE.

PENTAGASTRIN.

PENTAMETHONIUM.

PENTAMIDINE (includes pentamidine isethionate).

PENTHIENATE.

PENTOBARBITONE when packed and labelled for injection.

PENTOLINIUM.

PENTOSAN POLYSULFATE SODIUM.

PERAMPANEL.

PERGOLIDE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

PERHEXILINE.

PERICYAZINE.

PERINDOPRIL.

PERMETHRIN for human therapeutic use **except** in preparations containing 5 per cent or less of permethrin.

PERPHENAZINE.

PERTUSSIS ANTIGEN.

PERTUZUMAB.

PHENACEMIDE.

PHENACETIN for therapeutic use (excluding when present as an excipient).

PHENAGLYCODOL.

PHENAZONE **except** when included in Schedule 2 or 5.

PHENAZOPYRIDINE.

PHENELZINE.

PHENETICILLIN.

PHENFORMIN.

PHENGLUTARIMIDE.

PHENINDIONE.

PHENIRAMINE **except** when included in Schedule 2 or 3.

PHENISATIN.

PHENOBARBITONE.

PHENOL in preparations for injection.

PHENOLPHTHALEIN for human therapeutic use.

PHENOXYBENZAMINE.

PHENOXYMETHYLPENICILLIN.

PHENSUXIMIDE.

PHENTERMINE.

PHENTHIMENTONIUM.

PHENTOLAMINE.

PHENYLBUTAZONE.

PHENYLEPHRINE:

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

- (a) in preparations for injection; or
- (b) in preparations for human ophthalmic use containing 5 per cent or more of phenylephrine.

PHENYLPROPANOLAMINE.

PHENYLTOLOXAMINE.

PHENYTOIN.

PHOLCODINE:

- (a) in divided preparations containing 100 mg or less of pholcodine per dosage unit; or
- (b) in undivided preparations containing 2.5 per cent or less of pholcodine,
except when included in Schedule 2.

PHOSPHODIESTERASE TYPE 5 INHIBITORS **except**:

- (a) when separately specified in these Schedules; or
- (b) when present as an unmodified, naturally occurring substance.

PHTHALYLSULFATHIAZOLE.

PHYSOSTIGMINE.

PICROTOXIN.

PILOCARPINE **except** in preparations containing 0.025 per cent or less of pilocarpine.

PIMECROLIMUS.

PIMOBENDAN.

PIMOZIDE.

PINACIDIL.

PINDOLOL.

PIOGLITAZONE.

PIPECURONIUM.

PIPEMIDIC ACID.

PIPENZOLATE.

PIPER METHYSTICUM (kava) in preparations for human use **except** when included on the Australian Register of Therapeutic Goods in preparations:

- (a) for oral use when present in tablet, capsule or teabag form that is labelled with a recommended maximum daily dose of 250 mg or less of kavalactones and:
 - (i) the tablet or capsule form contains 125 mg or less of kavalactones per tablet or capsule; or
 - (ii) the amount of dried whole or peeled rhizome in the teabag does not exceed 3 g;

Poisons Standard 2015

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

and, where containing more than 25 mg of kavalactones per dose, compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;

- (b) in topical preparations for use on the rectum, vagina or throat containing dried whole or peeled rhizome or containing aqueous dispersions or aqueous extracts of whole or peeled rhizome; or
- (c) in dermal preparations.

PIPERACILLIN.

PIPERIDINE.

PIPERIDOLATE.

PIPOBROMAN.

PIPOTHIAZINE.

PIPRADROL.

PIRACETAM.

PIRBUTEROL.

PIRENOXINE (catalin).

PIRENZEPINE.

PIRETANIDE.

PIROXICAM **except** in preparations for dermal use.

PIRPROFEN.

PITAVASTATIN.

PITUITARY HORMONES **except** when separately specified in these Schedules.

PIVAMPICILLIN.

PIZOTIFEN.

PLICAMYCIN.

PLERIXAFOR.

PNEUMOCOCCAL VACCINE.

PODOPHYLLOTOXIN for human use:

- (a) internally;
- (b) in preparations for the treatment of anogenital warts; or
- (c) in other preparations **except** when included in Schedule 2 or 3.

PODOPHYLLUM EMODI (podophyllin) for human use:

- (a) internally;

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

- (b) in preparations for the treatment of anogenital warts; or
- (c) in other preparations **except** when included in Schedule 2 or 3.

PODOPHYLLUM PELTATUM (podophyllin) for human use:

- (a) internally;
- (b) in preparations for the treatment of anogenital warts; or
- (c) in other preparations **except** when included in Schedule 2 or 3.

POLIDEXIDE.

POLIOMYELITIS VACCINE.

POLYACRYLAMIDE in preparations for injection or implantation:

- (a) for tissue augmentation; or
- (b) for cosmetic use.

POLYCAPROLACTONE in preparations for injection or implantation:

- (a) for tissue augmentation; or
- (b) for cosmetic use.

POLYESTRADIOL.

POLYLACTIC ACID in preparations for injection or implantation:

- (a) for tissue augmentation; or
- (b) for cosmetic use.

POLYMYXIN.

POLYSULFATED GLYCOSAMINOGLYCANS in preparations for injection, **except** when separately specified in these Schedules.

POLYTHIAZIDE.

PORACTANT.

POSACONAZOLE.

POTASSIUM BROMIDE for therapeutic use.

POTASSIUM CHLORIDE in oral preparations for human therapeutic use **except**:

- (a) when containing less than 550 mg of potassium chloride per dosage unit;
- (b) in preparations for oral rehydration therapy;
- (c) in preparations for oral use for bowel cleansing prior to diagnostic medical and surgical procedures; or
- (d) in preparations for enteral feeding.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

POTASSIUM PERCHLORATE for therapeutic use.

PRACTOLOL.

PRADOFLOXACIN.

PRALATREXATE.

PRALIDOXIME.

PRAMIPEXOLE.

PRAMOCAINE.

PRAMPINE.

PRASTERONE (dehydroepiandrosterone, dehydroisoandrosterone).

PRASUGREL.

PRAVASTATIN.

PRAZEPAM.

PRAZQUANTEL for human therapeutic use.

PRAZOSIN.

PREDNISOLONE.

PREDNISON.

PREGABALIN.

PREGNENOLONE.

PRENALTEROL.

PRENYLAMINE.

PRILOCAINE **except** when included in Schedule 2.

PRIMAQUINE.

PRIMIDONE.

PROBENECID.

PROBUCOL.

PROCAINAMIDE.

PROCAINE.

PROCAINE PENICILLIN.

PROCARBAZINE.

PROCHLORPERAZINE **except** when included in Schedule 3.

Poisons Standard 2015

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

PROCYCLIDINE **except** when included in Schedule 2.

PROGESTERONE **except** when included in Schedule 5.

PROGESTOGENS **except** when separately specified in these Schedules.

PROGLUMIDE.

PROGUANIL.

PROLINTANE.

PROMAZINE.

PROMETHAZINE **except** when included in Schedule 2 or 3.

PROMOXOLANE.

PROPAFENONE.

PROPAMIDINE for therapeutic use **except** when included in Schedule 2.

PROPANIDID.

PROPANTHELINE.

PROPENTOFYLLINE.

PROPETANDROL.

PROPIONIBACTERIUM ACNES for therapeutic use.

PROPOFOL.

PROPRANOLOL.

PROPYLHEXEDRINE.

PROPYLTHIOURACIL.

PROPYPHENAZONE.

PROQUAZONE.

PROSCILLARIDIN.

PROSTAGLANDINS **except** when separately specified in this Schedule.

PROSTIANOL.

PROTAMINE.

PROTHIONAMIDE.

PROTHIPENDYL.

PROTIRELIN.

PROTOVERATRINES.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

PROTRIPTYLINE.

PROXYMETACAINE.

PRUCALOPRIDE.

PSEUDOEPHEDRINE **except** when included in Schedule 3.

PYRAZINAMIDE.

PYRIDINOLCARBAMATE.

PYRIDOSTIGMINE.

PYRIDOXINE, PYRIDOXAL OR PYRIDOXAMINE for human therapeutic use **except**:

- (a) in oral preparations containing 200 mg or less but more than 50 mg of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose when compliant with the requirements of the *Required Advisory Statements for Medicine Labels*; or
- (b) in oral preparations containing 50 mg or less of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose.

PYRIMETHAMINE.

PYROVALERONE.

PYRVINIUM.

QUAZEPAM.

QUETIAPINE.

QUINAGOLIDE.

QUINAPRIL.

QUINBOLONE.

QUINETHAZONE.

QUINIDINE.

QUININE for human therapeutic use **except** when the maximum recommended daily dose is 50 mg or less of quinine.

QUINISOCAINE (dimethisoquin).

QUINUPRISTIN.

RABEPRAZOLE **except** when included in Schedule 3.

RABIES VACCINE.

RACTOPAMINE **except** when included in Schedule 5.

RALOXIFENE.

RALTEGRAVIR.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

RALTITREXED.

RAMIPRIL.

RANIBIZUMAB.

RANITIDINE **except:**

- (a) when included in Schedule 2; or
- (b) in divided preparations for oral use containing 150mg or less of ranitidine per dosage unit when supplied in the manufacturer's original pack containing not more than 14 dosage units.

RAPACURONIUM.

RASAGILINE.

RASBURICASE.

RAUWOLFIA SERPENTINA.

RAUWOLFIA VOMITORIA.

RAZOXANE.

REBOXETINE.

RED YEAST RICE for human therapeutic use.

REGORAFENIB.

REMOXIPRIDE.

REPAGLINIDE.

RESERPINE.

RETAPAMULIN.

RETEPLASE.

RETIGABINE.

RIBAVIRIN.

RIDAFOROLIMUS.

RIFABUTIN.

RIFAMPICIN.

RIFAMYCIN.

RIFAPENTINE.

RIFAXIMIN.

RILPIVIRINE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

RILUZOLE.
RIMEXOLONE.
RIMITEROL.
RIMONABANT.
RIOCIGUAT.
RISEDRONIC ACID.
RISPERIDONE.
RITODRINE.
RITONAVIR.
RITUXIMAB.
RIVAROXABAN.
RIVASTIGMINE.
RIZATRIPTAN.
ROBENACOXIB.
ROCURONIUM.
ROFECOXIB.
ROFLUMILAST.
ROLITETRACYCLINE.
ROMIDEPSIN.
ROMIFIDINE.
ROMIPLOSTIM.
RONIDAZOLE.
ROPINIROLE.
ROPIVACAINE.
ROSIGLITAZONE.
ROSOXACIN.
ROSUVASTATIN.
ROTIGOTINE.
ROXIBOLONE.
ROXITHROMYCIN.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

RUBELLA VACCINE.

RUBOXISTAURIN.

RUPATADINE.

RUXOLITINIB.

SALBUTAMOL **except** when included in Schedule 3.

SALCATONIN.

SALICYLAMIDE when combined with aspirin, caffeine or paracetamol or any derivative of these substances.

SALINOMYCIN **except**:

- (a) when included in Schedule 6; or
- (b) in animal feeds containing 60 mg/kg or less of antibiotic substances.

SALMETEROL.

SAPROPTERIN.

SAQUINAVIR.

SAXAGLIPTIN.

SCHOENOCAULON OFFICINALE (sabadilla) **except** in preparations containing 10 mg/kg or 10 mg/L or less of total alkaloids of *Schoenocaulon officinale*.

SCOPOLIA CARNIOLICA for therapeutic use.

SELECTIVE ANDROGEN RECEPTOR MODULATORS (SARM).

SELEGILINE.

SELENIUM:

- (a) for human oral use with a recommended daily dose of more than 300 micrograms; or
- (b) for the treatment of animals **except**:
 - (i) when included in Schedule 6 or 7;
 - (ii) in solid, slow release bolus preparations each weighing 100 g or more and containing 300 mg or less of selenium per dosage unit;
 - (iii) in other divided preparations containing 30 micrograms or less of selenium per dosage unit;
 - (iv) as elemental selenium, in pellets containing 100 g/kg or less of selenium; or
 - (v) in feeds containing 1 g/tonne or less of selenium.

SERELAXIN.

SERMORELIN.

SERTINDOLE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

SERTRALINE.

SEVELAMER.

SEVOFLURANE.

SEX HORMONES and all substances having sex hormonal activity **except** when separately specified in these Schedules.

SIBUTRAMINE.

SILANDRONE.

SILDENAFIL.

SILICONES for intra-ocular use.

SILVER SULFADIAZINE.

SIMEPREVIR.

SIMVASTATIN.

SIROLIMUS.

SISOMICIN (sisomycin).

SITAGLIPTIN.

SITAXENTAN.

SODIUM BROMIDE for therapeutic use.

SODIUM CELLULOSE PHOSPHATE for human internal use.

SODIUM CROMOGLYCATE **except** when included in Schedule 2.

SODIUM MORRHUATE in preparations for injection.

SODIUM NITROPRUSSIDE for human therapeutic use.

SODIUM PHOSPHATE in preparations for oral laxative use.

SODIUM POLYSTYRENE SULPHONATE for human therapeutic use.

SODIUM SALICYLATE in preparations for injection for the treatment of animals.

SODIUM TETRADECYLSULFATE in preparations for injection.

SOFOSBUVIR.

SOLASODINE.

SOLIFENACIN.

SOMATOSTATIN.

SOMATOTROPIN EQUINE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

SOMATROPIN (human growth hormone).

SONTOQUINE.

SORAFENIB.

SOTALOL.

SPARFLOXACIN.

SPARTEINE.

SPECTINOMYCIN.

SPIRAMYCIN.

SPIRAPRIL.

SPIRONOLACTONE.

STANOLONE.

STANOZOLOL.

STAVUDINE.

STENBOLONE.

STEROID HORMONES except when separately specified in these Schedules.

STILBOESTROL (diethylstilboestrol).

STREPTODORNASE.

STREPTOKINASE.

STREPTOMYCIN.

STRONTIUM RANELATE.

STROPHANTHINS.

STROPHANTHUS spp.

STRYCHNINE in preparations containing 1.5 per cent or less of strychnine for the treatment of animals.

STRYCHNOS spp. **except** in preparations containing 1 mg or less per litre or per kilogram of strychnine.

STYRAMATE.

SUCCIMER.

SUGAMMADEX.

SULBACTAM.

SULCONAZOLE **except** when included in Schedule 2.

SULFACETAMIDE **except** when included in Schedule 3 or 5.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

SULFADIAZINE **except** when included in Schedule 5.

SULFADIMETHOXINE.

SULFADIMIDINE **except** when included in Schedule 5.

SULFADOXINE.

SULFAFURAZOLE.

SULFAGUANIDINE.

SULFAMERAZINE **except** when included in Schedule 5.

SULFAMETHIZOLE.

SULFAMETHOXAZOLE.

SULFAMETHOXYDIAZINE.

SULFAMETHOXPYRIDAZINE.

SULFAMETROLE.

SULFAMONOMETHOXINE.

SULFAMOXOLE.

SULFAPHENAZOLE.

SULFAPYRIDINE.

SULFAQUINOXALINE.

SULFASALAZINE.

SULFATHIAZOLE **except** when included in Schedule 5.

SULFATROXAZOLE.

SULFINPYRAZONE.

SULFOMYXIN.

SULFONAMIDES **except**:

- (a) when separately specified in this Schedule;
- (b) when included in Schedule 3, 5 or 6; or
- (c) when packed and labelled solely for use as a herbicide.

SULFONMETHANE (sulfonal and alkyl sulfonals).

SULINDAC.

SULTAMICILLIN.

SULTHIAME.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

SUMATRIPTAN.

SUNITINIB.

SUPROFEN.

SUTILAINS.

SUXAMETHONIUM.

SUXETHONIUM.

SUVOREXANT.

TACRINE.

TACROLIMUS.

TADALAFIL.

TAFLUPROST.

TALIGLUCERASE ALFA.

TAMOXIFEN.

TAMSULOSIN.

TANACETUM VULGARE **except** in preparations containing 0.8 per cent or less of oil of tansy.

TASONERMIN.

TAZAROTENE.

TAZOBACTAM.

T-CELL RECEPTOR ANTIBODY.

TEGAFUR.

TEGASEROD.

TELAPREVIR.

TELITHROMYCIN.

TEICOPLANIN.

TELBIVUDINE.

TELMISARTAN.

TEMAZEPAM.

TEMOZOLOMIDE.

TEMSIROLIMUS.

TENECTEPLASE.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

TENIPOSIDE.

TENOFOVIR.

TENOXICAM.

TEPOXALIN.

TERAZOSIN.

TERBINAFINE **except**:

- (a) when included in Schedule 2; or
- (b) in preparations for dermal use for the treatment of tinea pedis.

TERBUTALINE **except** when included in Schedule 3.

TERFENADINE.

TERIFLUNOMIDE.

TERIPARATIDE.

TERLIPRESSIN.

TERODILINE.

TEROPTERIN.

TESTOLACTONE.

TESTOSTERONE **except** when included in Schedule 6.

TETANUS ANTITOXIN **except** when used for short-term protection or treatment of tetanus in animals.

TETANUS TOXOID for human use.

TETRABENAZINE.

TETRACOSACTRIN.

TETRACYCLINE **except** when included in Schedule 5.

TETRAETHYLAMMONIUM.

TETROXOPRIM.

THALIDOMIDE.

THENYLDIAMINE.

THEOPHYLLINE **except** when included in Schedule 3.

THEVETIA PERUVIANA.

THEVETIN.

THIACETARSAMIDE in preparations for the prevention or treatment of heartworm in dogs.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

THIAMBUTOSINE.

THIAZOSULFONE.

THIETHYLPERAZINE.

THIOACETAZONE.

THIOCARLIDE.

THIOGUANINE.

THIOMESTERONE (tiomesterone).

THIOPENTONE.

THIOPROPAZATE.

THIOPROPERAZINE.

THIORIDAZINE.

THIOSTREPTON.

THIOTEPA.

THIOTHIXENE.

THIOURACIL.

THIOUREA for therapeutic use **except** in preparations containing 0.1 per cent or less of thiourea.

THYMOXAMINE (includes thymoxamine hydrochloride).

THYROID **except** when separately specified in this Schedule.

THYROTROPHIN.

THYROXINE (includes thyroxine sodium).

TIAGABINE.

TIAMULIN.

TIAPROFENIC ACID.

TIARAMIDE.

TIBOLONE.

TICAGRELOR.

TICARCILLIN.

TICLOPIDINE.

TIEMONIUM.

TIENILIC ACID.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

TIGECYCLINE.

TIGLOIDINE.

TILDIPIROSIN.

TILETAMINE.

TILMICOSIN.

TILUDRONIC ACID (includes disodium tiludronate).

TIMOLOL.

TINIDAZOLE.

TINZAPARIN (includes tinzaparin sodium).

TIOCONAZOLE **except:**

- (a) when included in Schedule 2 or 3; or
- (b) in preparations for dermal use for the treatment of tinea pedis.

TIOTROPIUM.

TIPEPIDINE.

TIPRANAVIR.

TIRILAZAD.

TIROFIBAN.

TOBRAMYCIN.

TOCAINIDE.

TOCERANIB.

TOCILIZUMAB.

TOLAZAMIDE.

TOLAZOLINE.

TOLBUTAMIDE.

TOLCAPONE.

TOLFENAMIC ACID.

TOLMETIN.

TOLONIUM.

TOLPROPAMINE.

TOLRESTAT.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

TOLTERODINE.

TOLVAPTAN.

TOPIRAMATE.

TOPOTECAN.

TORASEMIDE.

TOREMIFENE.

TOXOIDS for human parenteral use **except** when separately specified in these Schedules.

TRAMADOL.

TRANDOLAPRIL.

TRAMETINIB DIMETHYL SULFOXIDE.

TRANEXAMIC ACID **except** in preparations containing 3 per cent or less of cetyl tranexamate hydrochloride for dermal cosmetic use.

TRANLYCYPROMINE.

TRASTUZUMAB.

TRASTUZUMAB EMTANSINE.

TRAVOPROST.

TRAZODONE.

TRENBOLONE (trienbolone, trienolone) **except** when included in Schedule 5.

TREOSULPHAN.

TREPROSTINIL.

TRESTOLONE.

TRETAMINE.

TRETINOIN.

TRIACETYLOLEANDOMYCIN.

TRIAMCINOLONE **except** when included in Schedule 2 or 3.

TRIAMTERENE.

TRIAZQUONE.

TRIAZOLAM.

TRICHLORMETHIAZIDE.

TRICHLOROACETIC ACID for human dermal use **except** when in preparations containing 12.5 per cent or less of trichloroacetic acid for the treatment of warts other than anogenital warts.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

TRICHLOROETHYLENE for therapeutic use.

TRICLOFOS.

TRICYCLAMOL.

TRIDIHEXETHYL.

TRIETHANOLAMINE when in preparations for tattoo removal.

TRIFLUOPERAZINE.

TRIFLUPERIDOL.

TRIFLUPROMAZINE.

TRILOSTANE.

TRIMEPRAZINE **except** when included in Schedule 2 or 3.

TRIMETAPHAN.

TRIMETHOPRIM.

TRIMIPRAMINE.

TRIMUSTINE.

TRINITROPHENOL (excluding its derivatives) in preparations for human therapeutic use.

TRIOXYSALEN.

TRIPELENNAMINE.

TRIPLE ANTIGEN VACCINE.

TRIPROLIDINE **except** when included in Schedule 2 or 3.

TRIPTORELIN.

TROGLITAZONE.

TROMETAMOL in preparations for injection **except** in preparations containing 3 per cent or less of trometamol.

TROPICAMIDE.

TROPISETRON.

TROVAFLOXACIN.

TROXIDONE.

TRYPTOPHAN for human therapeutic use **except** in preparations labelled with a recommended daily dose of 100 mg or less of tryptophan.

TUBERCULIN.

TUBOCURARINE.

TULATHROMYCIN.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

TULOBUTEROL.

TYLOSIN.

TYPHOID VACCINE.

UMECLIDINIUM.

UNOPROSTONE.

URACIL.

URAPIDIL.

URETHANE (excluding its derivatives) for therapeutic use.

UROFOLLITROPIN.

UROKINASE.

URSODEOXYCHOLIC ACID.

USTEKINUMAB.

VACCINES for human therapeutic use **except** when separately specified in this Schedule.

VACCINES, veterinary live virus except:

- (a) poultry vaccines;
- (b) pigeon pox vaccine; or
- (c) scabby mouth vaccine.

VACCINIA VIRUS VACCINE.

VALACICLOVIR.

VALDECOXIB.

VALGANCICLOVIR.

VALNOCTAMIDE.

VALPROIC ACID.

VALSARTAN.

VANCOMYCIN.

VANDETANIB.

VARDENAFIL.

VARENICLINE.

VARICELLA VACCINE.

VASOPRESSIN.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

VECURONIUM.

VEDAPROFEN.

VEDOLIZUMAB.

VELAGLUCERASE ALFA.

VEMURAFENIB.

VENLAFAXINE.

VERAPAMIL.

VERATRUM spp. **except** when separately specified in this Schedule.

VERNAKALANT.

VERTEPORFIN.

VIDARABINE.

VIGABATRIN.

VILANTEROL.

VILDAGLIPTIN.

VILOXAZINE.

VINBLASTINE.

VINCAMINE.

VINCRISTINE.

VINDESINE.

VINFLUNINE.

VINORELBINE.

VINYL ETHER for therapeutic use.

VIRGINIAMYCIN **except** when included in Schedule 5.

VISMODEGIB.

VISNADINE.

VITAMIN A for human therapeutic or cosmetic use **except**:

- (a) in preparations for topical use containing 1 per cent or less of Vitamin A;
- (b) in preparations for internal use containing 3000 micrograms retinol equivalents or less of Vitamin A per daily dose; or
- (c) in preparations for parenteral nutrition replacement.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

VITAMIN D for human internal therapeutic use **except**:

- (a) in preparations containing 25 micrograms or less of vitamin D per recommended daily dose ; or
- (b) when included in Schedule 3.

VORICONAZOLE.

VORINOSTAT.

VORTIOXETINE.

WARFARIN for therapeutic use.

XAMOTEROL.

XANTHINOL NICOTINATE.

XIMELAGATRAN.

XIPAMIDE.

XYLAZINE.

YOHIMBINE.

ZAFIRLUKAST.

ZALCITABINE.

ZALEPLON.

ZANAMIVIR.

ZERANOL **except** when included in Schedule 6.

ZIDOVUDINE.

ZILPATEROL.

ZIMELDINE.

ZINC COMPOUNDS for human internal use **except**:

- (a) in preparations with a recommended daily dose of 25 mg or less of zinc; or
- (b) in preparations with a recommended daily dose of more than 25 mg but not more than 50 mg of zinc when compliant with the requirements of the *Required Advisory Statements for Medicine Labels*.

ZIPRASIDONE.

ZOLAZEPAM.

ZOLEDRONIC ACID.

ZOLMITRIPTAN.

ZOLPIDEM.

SCHEDULE 4 – continued
(Substances marked # are listed in Appendix D)

ZONISAMIDE.

ZOPICLONE.

ZOXAZOLAMINE.

ZUCLOPENTHIXOL.

SCHEDULE 5

ABAMECTIN in preparations, for internal use for the treatment of animals, containing 1 per cent or less of abamectin.

ABSCISIC ACID.

ACETIC ACID (excluding its salts and derivatives) in preparations containing more than 30 per cent of acetic acid (CH₃COOH) **except**:

- (a) when included in Schedule 2 or 6; or
- (b) for therapeutic use.

ACETONE **except** in preparations containing 25 per cent or less of designated solvents.

ACRIFLAVINE in preparations for veterinary use containing 2.5 per cent or less of acriflavine.

AFOXOLANER for the treatment and prevention of flea infestations and control of ticks in dogs in oral divided preparations each containing 140 mg or less of afoxolaner per dosage unit.

AKLOMIDE.

ALBENDAZOLE for the treatment of animals, in preparations containing 12.5 per cent or less of albendazole **except** in intraruminal implants each containing 3.85 g or less of albendazole.

ALKALINE SALTS, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination:

- (a) in solid orthodontic device cleaning preparations, the pH of which as an “in-use” aqueous solution is more than 11.5;
- (b) in solid automatic dishwashing preparations, the pH of which in a 500 g/L aqueous solution or mixture is more than 11.5 but less than or equal to 12.5;
- (c) in other solid preparations, the pH of which in a 10 g/L aqueous solution is more than 11.5; or
- (d) in liquid or semi-solid preparations, the pH of which is more than 11.5, unless:
 - (i) in food additive preparations for domestic use; or
 - (ii) in automatic dish washing preparations for domestic use with a pH of more than 12.5,

except when separately specified in these Schedules.

ALKOXYLATED FATTY ALKYLAMINE POLYMER in preparations containing 50 per cent or less of alkoxyated fatty alkylamine polymer **except** in preparations containing 20 per cent or less of alkoxyated fatty alkylamine polymer.

ALLETHRIN in preparations containing 10 per cent or less of allethrin **except**:

- (a) in insecticidal mats; or
- (b) in other preparations containing 1 per cent or less of allethrin.

ALLOXYDIM.

ALPHA-CYPERMETHRIN:

SCHEDULE 5— continued

- (a) in aqueous preparations containing 3 per cent or less of alpha-cypermethrin; or
- (b) in other preparations containing 1.5 per cent or less of alpha-cypermethrin.

AMETRYN.

AMINACRINE in preparations for veterinary use containing 2.5 per cent or less of aminacrine.

AMINES for use as curing agents for epoxy resins **except** when separately specified in these Schedules.

AMINOPYRALID in water soluble gel formulations containing 0.5 per cent or less of aminopyralid.

AMITROLE.

AMINOCYCLOPYRACHLOR.

AMMONIA (excluding its salts and derivatives other than ammonium hydroxide) in preparations containing 5 per cent or less of ammonia **except**:

- (a) in preparations for human internal therapeutic use;
- (b) in preparations for inhalation when absorbed in an inert solid material; or
- (c) in preparations containing 0.5 per cent or less of free ammonia.

AMMONIUM THIOCYANATE **except** in preparations containing 10 per cent or less of ammonium thiocyanate.

ANHYDRIDES, ORGANIC ACID for use as curing agents for epoxy resins **except** when separately specified in these Schedules.

ANISE OIL **except**:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert, and labelled with the warning:

KEEP OUT OF REACH OF CHILDREN; or

- (c) in preparations containing 50 per cent or less of anise oil.

ASPIRIN for the treatment of animals, in divided preparations when packed in blister or strip packaging or in a container with a child-resistant closure.

ATRAZINE.

AZADIRACHTA INDICA EXTRACTS (neem extracts), extracted from neem seed kernels using water, methanol or ethanol, in preparations containing 5 per cent or less of total limonoids, for agricultural use.

AZOXYSTROBIN.

BACILLUS THURINGIENSIS DELTA ENDOTOXIN encapsulated in killed *Pseudomonas fluorescens*.

BARIUM SILICOFLUORIDE when coated on paper in an amount not exceeding 8 mg of barium silicofluoride per sq. cm.

SCHEDULE 5– continued

BASIL OIL **except:**

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert, and labelled with the warning:

KEEP OUT OF REACH OF CHILDREN; or

- (c) in preparations containing 5 per cent or less of methyl chavicol.

BEAUVERIA BASSIANA in preparations containing 1×10^8 Colony Forming Units (CFU)/mL or less of *Beauveria bassiana*.

BENALAXYL.

BENDIOCARB in preparations containing 2 per cent or less of bendiocarb.

BENTAZONE.

BENZALKONIUM CHLORIDE in preparations containing 10 per cent or less of benzalkonium chloride **except** in preparations containing 5 per cent or less of benzalkonium chloride.

BENZOFENAP.

BENZOYL PEROXIDE **except:**

- (a) when included in Schedule 2 or 4; or
- (b) in preparations containing 5 per cent or less of benzoyl peroxide.

BERGAMOT OIL **except:**

- (a) when steam distilled or rectified;
- (b) in preparations for internal use;
- (c) in preparations containing 0.4 per cent or less of bergamot oil;
- (d) in soaps or bath or shower gels that are washed off the skin;
- (e) in medicines for human therapeutic use when compliant with the requirements of the *Required Advisory Statements for Medicine Labels*; or
- (f) in other preparations when packed in containers labelled with the statement:
Application to the skin may increase sensitivity to sunlight.

BETACYFLUTHRIN:

- (a) in aqueous preparations containing 2.5 per cent or less of betacyfluthrin; or
- (b) in solid preparations containing 8 per cent or less of betacyfluthrin in a plastic matrix.

BIFLUORIDES (including ammonium, potassium and sodium salts), in preparations containing 0.3 per cent or less of total bifluorides.

SCHEDULE 5– continued

BIOALLETHRIN in preparations containing 10 per cent or less of bioallethrin **except** in preparations containing 1 per cent or less of bioallethrin.

BIORESMETHRIN **except** in preparations containing 10 per cent or less of bioresmethrin.

BISPYRIBAC **except** in preparations containing 10 per cent or less of bispyribac.

BORIC ACID (excluding its salts) and BORAX **except**:

- (a) when included in Schedule 4;
- (b) in preparations, other than insect baits, containing 1 per cent or less of boron; or
- (c) in hand cleaning preparations.

BORON TRIFLUORIDE in preparations containing 0.1 per cent or less of boron trifluoride (BF₃).

BROMUCONAZOLE in preparations containing 20 per cent or less of bromuconazole.

BUPIVACAINE in aqueous gel preparations containing 0.5 per cent or less of bupivacaine, for the dermal spray-on treatment of wounds associated with 'mulesing' of sheep.

BUPROFEZIN **except** in preparations containing 40 per cent or less of buprofezin.

BUTHIDAZOLE.

BUTOXYCARBOXIM in solid preparations containing 10 per cent or less of butoxycarboxim.

BUTRALIN.

BUTROXYDIM.

CAMPHOR as a natural component in essential oils containing 10 per cent or less of camphor **except**:

- (a) in medicines for human therapeutic use, in essential oils when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in preparations other than medicines for human therapeutic use, in essential oils when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert, and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN;

- (c) in rosemary oil, sage oil (Spanish), or lavandin oils; or
- (d) in preparations containing 2.5 per cent or less of camphor.

CARBAMIDE PEROXIDE in preparations containing 18 per cent or less of carbamide peroxide **except** in preparations containing 9 per cent or less of carbamide peroxide.

CARBARYL:

- (a) in preparations containing 10 per cent or less of carbaryl **except** when included in Schedule 4; or
- (b) when impregnated into plastic resin material containing 20 per cent or less of carbaryl.

CASSIA OIL **except**:

SCHEDULE 5– continued

- (a) in food additives;
- (b) in preparations for dermal use as a rubefacient containing 5 per cent or less of cassia oil; or
- (c) in other preparations containing 2 per cent or less of cassia oil.

CHLORFENAC.

CHLORFENAPYR. in preparations containing 0.5 per cent or less of chlorfenapyr.

CHLORFENSON.

CHLORHEXIDINE in preparations containing 3 per cent or less of chlorhexidine **except**:

- (a) in preparations containing 1 per cent or less of chlorhexidine; or
- (b) when in solid preparations.

CHLORINATING COMPOUNDS containing 20 per cent or less of available chlorine, **except**:

- (a) when separately specified in these Schedules;
- (b) sodium hypochlorite preparations with a pH of less than 11.5;
- (c) liquid preparations containing not less than 2 per cent but not more than 4 per cent of available chlorine when labelled with the statements:

WARNING – Ensure adequate ventilation when using. Vapour may be harmful. May give off dangerous gas if mixed with other products;

- (d) liquid preparations containing less than 2 per cent of available chlorine; or
- (e) other preparations containing 4 per cent or less of available chlorine.

CHLORNIDINE.

CHLOROCRESOL **except** in preparations containing 3 per cent or less of chlorocresol.

CHLORPROPHAM.

CHLORPYRIFOS:

- (a) in aqueous preparations containing 20 per cent or less of microencapsulated chlorpyrifos;
- (b) in controlled release granular preparations containing 10 per cent or less of chlorpyrifos; or
- (c) in other preparations containing 5 per cent or less of chlorpyrifos,

except in prepared potting or soil mixes containing 100 g or less of chlorpyrifos per cubic metre.

CHLORSULFURON.

CHLORTETRACYCLINE in preparations:

- (a) for topical application to animals for ocular use only; or
- (b) containing 40 per cent or less of chlortetracycline, when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

CHLORTHAL-DIMETHYL.

SCHEDULE 5– continued

CINMETHYLIN.

CINNAMON BARK OIL **except:**

- (a) in food additives; or
- (b) in preparations containing 2 per cent or less of cinnamon bark oil.

CLETHODIM.

CLIMBAZOLE in preparations containing 40 per cent or less of climbazole **except** in preparations containing 2 per cent or less of climbazole.

CLOFENTEZINE.

CLOPYRALID.

CLOQUINTOCET-MEXYL.

CLORSULON.

CLOTHIANIDIN in preparations containing 20 per cent or less of clothianidin.

CLOVE OIL for topical use in the mouth in a pack containing 5 mL or less of clove oil **except** in preparations containing 25 per cent or less of clove oil.

COPPER ACETATE in preparations containing 20 per cent or less of copper acetate **except** in preparations containing 5 per cent or less of copper acetate.

COPPER COMPOUNDS in animal feed additives containing 5 per cent or less of copper **except** in preparations containing 1 per cent or less of copper.

COPPER HYDROXIDE in preparations containing 50 per cent or less of copper hydroxide **except** in preparations containing 12.5 per cent or less of copper hydroxide.

COPPER OXIDES in preparations containing 25 per cent or less of copper oxides **except:**

- (a) in preparations for internal use;
- (b) in marine paints; or
- (c) in other preparations containing 5 per cent or less of copper oxides.

COPPER OXYCHLORIDE in preparations containing 50 per cent or less of copper oxychloride **except** in preparations containing 12.5 per cent or less of copper oxychloride.

COPPER SULFATE in preparations containing 15 per cent or less of copper sulfate **except:**

- (a) in preparations for internal use; or
- (b) in other preparations containing 5 per cent or less of copper sulfate.

COUMATETRALYL in rodenticides containing 0.05 per cent or less of coumatetralyl.

4-CPA.

CYANATRYN.

CYANOACRYLATE ESTERS in contact adhesives **except:**

- (a) when labelled with the warning:

Poisons Standard 2015

SCHEDULE 5– continued

KEEP OUT OF REACH OF CHILDREN. Avoid contact with skin and eyes and avoid breathing vapour. Bonds on contact. Should fingers stick together apply a solvent such as acetone to contact areas then wash off with water. Do not use solvents near eyes or open wounds. In case of eye contact immediately flush with water; or

- (b) when packed in sealed measure packs each containing 0.5 g or less of cyanoacrylate esters:
 - (i) labelled with the approved name or trade name of the poison, the quantity and the warning:
Can cause eye injury. Instantly bonds skin; and
 - (ii) enclosed in a primary pack labelled with the warning:

KEEP OUT OF REACH OF CHILDREN. Avoid contact with skin and eyes and avoid breathing vapour. Bonds on contact. Should fingers stick together apply a solvent such as acetone to contact areas then wash off with water. Do not use solvents near eyes or open wounds. In case of eye contact immediately flush with water.

CYANURIC ACID (excluding its salts and derivatives).

CYANTRANILIPROLE.

CYAZOFAMID.

CYCLOHEXANONE PEROXIDE.

CYCLOPROTHRIN **except** in preparations containing 10 per cent or less of cycloprothrin.

CYCLOXYDIM.

CYFLUFENAMID.

CYFLUTHRIN:

- (a) in wettable powders containing 10 per cent or less of cyfluthrin;
- (b) in emulsifiable concentrates containing 2 per cent or less of cyfluthrin; or
- (c) in emulsions containing 5 per cent or less of cyfluthrin.

CYHALOFOP-BUTYL.

CYMIAZOLE.

CYPERMETHRIN in preparations containing 10 per cent or less of cypermethrin.

CYPHENOTHRIN in preparations containing 10 per cent or less of cyphenothrin.

CYPROCONAZOLE **except** in preparations containing 10 per cent or less of cyproconazole.

CYPRODINIL.

CYSTEAMINE in cosmetic preparations containing 6 per cent or less of cysteamine **except** in preparations containing 1 per cent or less of cysteamine.

CYTHIOATE for the treatment of animals:

- (a) in divided preparations containing 30 mg or less of cythioate per dosage unit when packed in blister or strip packaging or in a container with a child-resistant closure; or

SCHEDULE 5– continued

(b) in undivided preparations containing 5 per cent or less of cythioate.

2,4-D in preparations containing 20 per cent or less of 2,4-D.

DAMINOZIDE.

2,4-DB.

DECOQUINATE:

DELTAMETHRIN:

- (a) when impregnated in plastic resin strip material containing 4 per cent or less of deltamethrin;
- (b) in aqueous preparations containing 5 per cent or less of deltamethrin when no organic solvent other than a glycol is present;
- (c) in wettable granular preparations containing 25 per cent or less of deltamethrin when packed in child-resistant packaging each containing 3 grams or less of the formulation;
- (d) in water-dispersible tablets each containing 500 mg or less of deltamethrin in child-resistant packaging; or
- (e) in other preparations containing 0.5 per cent or less of deltamethrin,

except:

- (a) in factory prepared mosquito nets containing 1 per cent or less deltamethrin; or
- (b) in preparations containing 0.1 per cent or less of deltamethrin.

DEMBREXINE in oral preparations for the treatment of animals.

2,4-DES.

DIAFENTHIURON.

N,N-DIALLYLDICHLOROACETAMIDE **except** in preparations containing 10 per cent or less of N,N-diallyldichloroacetamide.

DIAZINON in dust preparations containing 2 per cent or less of diazinon.

DICAMBA (including its salts and derivatives) in preparations containing 20 per cent or less of dicamba.

DICHLONE.

para-DICHLOROBENZENE.

DICHLOROISOCYANURIC ACID containing 40 per cent or less of available chlorine, **except** in:

- (a) liquid preparations containing not less than 2 per cent but not more than 4 per cent of available chlorine when labelled with the statements:

WARNING – Ensure adequate ventilation when using. Vapour may be harmful. May give off dangerous gas if mixed with other products;

- (b) liquid preparations containing less than 2 per cent of available chlorine; or
- (c) other preparations containing 4 per cent or less of available chlorine.

DICHLOROMETHANE (methylene chloride) **except:**

Poisons Standard 2015

SCHEDULE 5– continued

- (a) in preparations in pressurised spray packs labelled as degreasers, decarbonisers or paint strippers and containing 10 per cent or less of dichloromethane;
- (b) in other preparations in pressurised spray packs; or
- (c) in paints and tinters containing 5 per cent or less of dichloromethane.

DICHLOROPHEN for the treatment of animals.

DICHLORVOS:

- (a) when impregnated in plastic resin strip material containing 20 per cent or less of dichlorvos;
- (b) in sustained release resin pellets containing 20 per cent or less of dichlorvos for the treatment of animals; or
- (c) in pressurised spray packs containing 10 grams or less of dichlorvos.

DICLOBUTRAZOL.

DICLORAN.

DICOFOL.

DIETHANOLAMINE (excluding its salts and derivatives) in preparations containing 20 per cent or less of diethanolamine **except** in preparations containing 5 per cent or less of diethanolamine.

DIETHYLENE GLYCOL (excluding its salts and derivatives) in preparations containing not less than 10 mg/kg of denatonium benzoate as a bittering agent **except**:

- (a) in paints or paint tinters;
- (b) in toothpastes or mouthwashes containing more than 0.25 per cent of diethylene glycol; or
- (c) in other preparations containing 2.5 per cent or less of diethylene glycol.

DIETHYLENE GLYCOL MONOBUTYL ETHER **except** in preparations containing 10 per cent or less of diethylene glycol monobutyl ether.

DIETHYLTOLUAMIDE (DEET) **except**:

- (a) in medicines for human therapeutic use containing 20 per cent or less of diethyltoluamide, when compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in preparations for human use, other than medicines, containing 20 per cent or less of diethyltoluamide, when labelled with the warning statement:

WARNING: May be dangerous, particularly to children, if you use large amounts on the skin, clothes or bedding or on large areas of the body, especially if you keep using it for a long time; or

- (c) in preparations other than for human use containing 20 per cent or less of diethyltoluamide.

DIFENOCONAZOLE.

DIFLUBENZURON.

DIMETHICODIETHYLBENZALMALONATE **except** when included in preparations containing 10 per cent or less of dimethicodiethylbenzalmalonate.

DIMETHIRIMOL.

SCHEDULE 5— continued

DIMETHOMORPH **except** in preparations containing 10 per cent or less of dimethomorph.

DIMETHYLACETAMIDE in preparations containing 20 per cent or less of dimethylacetamide.

DIMETHYLFORMAMIDE in preparations containing 10 per cent or less of dimethylformamide **except** in silicone rubber mastic containing 2 per cent or less of dimethylformamide.

DINICONAZOLE.

DI-N-PROPYL ISOCINCHOMERONATE **except** in preparations containing 25 per cent or less of di-N-propyl isocinchomeronate.

DIPHENAMID.

DITHIOPYR.

N-(N-DODECYL)-2-PYRROLIDONE in preparations containing 50 per cent or less of N-(N-dodecyl)-2-pyrrolidone or preparations containing 50 per cent or less of a mixture of any two or more of N-(N-dodecyl)-2-pyrrolidone, N-methyl-2-pyrrolidone or N-(N-octyl)-2-pyrrolidone **except** in preparations containing 25 per cent or less of designated solvents.

DORAMECTIN for internal use for the treatment of animals, in preparations containing 2 per cent or less of doramectin.

EMAMECTIN in preparations containing 2 per cent or less of emamectin.

EMODEPSIDE in preparations:

- (a) containing 2.5 per cent or less of emodepside for the external treatment of animals; or
- (b) containing 30 mg or less of emodepside per dosage unit for the oral treatment of animals.

EPOXICONAZOLE.

EPOXY RESINS, LIQUID.

EPRINOMECTIN in preparations containing 0.5 per cent or less of eprinomectin.

ESBIOTHRIN in preparations containing 10 per cent or less of esbiothrin **except** in pressurised spray packs containing 1 per cent or less of esbiothrin.

ESFENVALERATE in preparations containing 0.1 per cent or less of esfenvalerate.

1,2-ETHANEDIAMINE POLYMER WITH (CHLOROMETHYL)OXIRANE AND N-METHYLMETHANAMINE.

ETHANOLAMINE (excluding its salts and derivatives) in preparations containing 20 per cent or less of ethanolamine **except**:

- (a) when included in Schedule 4; or
- (b) in preparations containing 5 per cent or less of ethanolamine.

ETHER in preparations containing more than 10 per cent of ether for use in internal combustion engines.

ETHOFUMESATE.

ETHOXYQUIN **except** in preparations containing 10 per cent or less of ethoxyquin.

ETHOXYSULFURON.

SCHEDULE 5— continued

ETHYLENE GLYCOL (excluding its salts and derivatives) in preparations containing not less than 10 mg/kg of denatonium benzoate as a bittering agent **except**:

- (a) in paints or paint tinters;
- (b) in toothpastes or mouthwashes containing more than 0.25 per cent of ethylene glycol; or
- (c) in other preparations containing 2.5 per cent or less of ethylene glycol.

ETHYL METHACRYLATE (excluding its derivatives) for cosmetic use **except** in preparations containing 1 per cent or less of ethyl methacrylate as residual monomer in a polymer.

ETRIDIAZOLE.

EUGENOL for topical use in the mouth in a pack containing 5 mL or less of eugenol **except** in preparations containing 25 per cent or less of eugenol.

EXTRACT OF LEMON EUCALYPTUS, being acid modified oil of lemon eucalyptus (*Corymbia citriodora*), **except** in preparations containing 40 per cent or less of extract of lemon eucalyptus.

FENARIMOL.

FENBENDAZOLE for the treatment of animals.

FENBUCONAZOLE.

FENCHLORAZOLE-ETHYL.

FENOPROP.

FENOXAPROP-ETHYL.

FENOXAPROP-P-ETHYL.

FENSON.

FENTHION:

- (a) in preparations containing 25 per cent or less of fenthion when packed in single-use containers having a capacity of 2 mL or less; or
- (b) in preparations containing 10 per cent or less of fenthion.

FIPRONIL in preparations containing 10 per cent or less of fipronil **except** in preparations containing 0.05 per cent or less of fipronil.

FLAMPROP-METHYL.

FLAMPROP-M-METHYL.

FLAZASULFURON.

FLORASULAM.

FLUAZURON.

FLUBENDAZOLE for the treatment of animals.

FLUBENDIAMIDE.

SCHEDULE 5— continued

FLUCHLORALIN.

FLUDIOXONIL **except** in preparations containing 10 per cent or less of fludioxonil.

FLUMETHRIN:

- (a) when impregnated in plastic resin strip material containing 3 per cent or less of flumethrin; or
- (b) in oil based preparations containing 1 per cent or less of flumethrin.

FLUMICLORAC PENTYL.

FLUORIDES in preparations containing 3 per cent or less of fluoride ion **except**:

- (a) in preparations for human use; or
- (b) in preparations containing 15 mg/kg or less of fluoride ion.

FLURALANER for the treatment and prevention of flea infestations and control of ticks in dogs in oral divided preparations each containing 1400 mg or less of fluralaner per dosage unit.

FLUVALINATE in aqueous preparations containing 25 per cent or less of fluvalinate.

FLUXAPYROXAD.

FORAMSULFURON.

FORMIC ACID (excluding its salts and derivatives) **except** in preparations containing 0.5 per cent or less of formic acid.

FOSPIRATE when impregnated in plastic resin strip material containing 20 per cent or less of fospirate.

FURALAXYL.

FURATHIOCARB in microencapsulated suspensions containing 50 per cent or less of furathiocarb.

GAMMA-CYHALOTHRIN in aqueous preparations containing 15 per cent or less of microencapsulated gamma-cyhalothrin.

GLUFOSINATE-AMMONIUM.

GLUTARALDEHYDE in preparations containing 5 per cent or less of glutaraldehyde **except**:

- (a) when included in Schedule 2; or
- (b) in preparations containing 0.5 per cent or less of glutaraldehyde when labelled with the statements:
IRRITANT; and
Avoid contact with eyes.

GLYPHOSATE.

HALOSULFURON-METHYL.

HEXACONAZOLE **except** in preparations containing 5 per cent or less of hexaconazole.

HEXAZINONE in preparations containing 25 per cent or less of hexazinone.

HYDRAMETHYLNON in solid baits containing 2 per cent or less of hydramethylnon in welded plastic labyrinths.

SCHEDULE 5– continued

HYDROCARBONS, LIQUID, including kerosene, diesel (distillate), mineral turpentine, white petroleum spirit, toluene, xylene and light mineral and paraffin oils (but excluding their derivatives), **except**:

- (a) toluene and xylene when included in Schedule 6;
- (b) benzene and liquid aromatic hydrocarbons when included in Schedule 7;
- (c) food grade and pharmaceutical grade white mineral oils;
- (d) in solid or semi-solid preparations;
- (e) in preparations containing 25 per cent or less of designated solvents;
- (f) in preparations packed in pressurised spray packs;
- (g) in adhesives packed in containers each containing 50 grams or less of adhesive;
- (h) in writing correction fluids and thinners for writing correction fluids packed in containers having a capacity of 20 mL or less; or
- (i) in other preparations when packed in containers with a capacity of 2 mL or less.

HYDROCHLORIC ACID (excluding its salts and derivatives) in preparations containing 10 per cent or less of hydrochloric acid (HCl) **except**:

- (a) in preparations containing 0.5 per cent or less of hydrochloric acid (HCl); or
- (b) for therapeutic use.

HYDROFLUORIC ACID (excluding its salts and derivatives) and admixtures that generate hydrofluoric acid, in preparations containing 0.1 per cent or less of hydrogen fluoride.

HYDROGEN PEROXIDE (excluding its salts and derivatives):

- (a) in hair dye preparations containing 12 per cent or less of hydrogen peroxide **except** in hair dyes containing 6 per cent or less of hydrogen peroxide; or
- (b) in other preparations containing 6 per cent (20 volume) or less of hydrogen peroxide **except** in preparations containing 3 per cent (10 volume) or less of hydrogen peroxide.

HYDROSILICOFLUORIC ACID (excluding its salts and derivatives) in preparations containing 0.1 per cent or less of hydrosilicofluoric acid (H₂SiF₆).

IMAZALIL.

IMAZAMOX **except** in preparations containing 25 per cent or less of imazamox.

IMAZAPIC **except** in preparations containing 25 per cent or less of imazapic.

IMAZAPYR **except** in preparations containing 25 per cent or less of imazapyr.

IMAZETHAPYR **except** in preparations containing 25 per cent or less of imazethapyr.

IMIDACLOPRID in preparations containing 20 per cent or less of imidacloprid **except** in preparations containing 5 per cent or less of imidacloprid.

IMIPROTHRIN in preparations containing 50 per cent or less of imiprothrin **except** in preparations containing 10 per cent or less of imiprothrin.

SCHEDULE 5– continued

INDOXACARB (includes the R and S enantiomers) in preparations containing 1 per cent or less of indoxacarb.

3-iodo-2-propynyl butyl carbamate (Iodocarb)) in preparations containing 10 per cent or less of 3-iodo-2-propynyl butyl carbamate **except**:

- (a) in aqueous preparations not for cosmetic use containing 10 per cent or less 3-iodo-2-propynyl butyl carbamate; or
- (b) in cosmetic preparations (other than aerosolised preparations) containing 0.1 per cent or less of 3-iodo-2-propynyl butyl carbamate.

IODOSULFURON-METHYL-SODIUM.

IPCONAZOLE in preparations containing 2 per cent or less of ipconazole.

IRON COMPOUNDS:

- (a) for the treatment of animals (excluding up to 1 per cent of iron oxides when present as an excipient):
 - (i) in preparations for injection containing 20 per cent or less of iron **except** in preparations containing 0.1 per cent or less of iron; or
 - (ii) in other preparations containing 4 per cent or less of iron **except**:
 - (A) in liquid or gel preparations containing 0.1 per cent or less of iron; or
 - (B) in animal feeds or feed premixes; or
- (b) in garden preparations **except** in preparations containing 4 per cent or less of iron.

ISOEUGENOL in preparations containing 25 per cent or less of isoeugenol **except** in preparations containing 10 per cent or less of isoeugenol.

ISOPHORONE.

ISOXABEN.

ISOXAFLUTOLE.

IVERMECTIN for use in animals:

- (a) in preparations for the prophylaxis of heartworm in cats and dogs;
- (b) in intraruminal implants containing 160 mg or less of ivermectin;
- (c) in preparations containing 3.5 per cent or less of ivermectin when packed in child-resistant packaging or in packaging approved by the relevant registration authority; or
- (d) in other preparations containing 2 per cent or less of ivermectin.

KITASAMYCIN in animal feed premixes for growth promotion containing 2 per cent or less of antibiotic substances.

LAMBDA-CYHALOTHRIN:

- (a) in aqueous preparations containing 1 per cent or less of lambda- cyhalothrin; or
- (b) in aqueous preparations containing 2.5 per cent or less of microencapsulated lambda-cyhalothrin.

SCHEDULE 5— continued

LEAD COMPOUNDS in preparations for use as hair cosmetics.

LEMON OIL **except:**

- (a) when steam distilled or rectified;
- (b) in preparations for internal use;
- (c) in preparations containing 0.05 per cent or less of lemon oil;
- (d) in soaps or bath or shower gels that are washed off the skin;
- (e) in medicines for human therapeutic use, when compliant with the requirements of the *Required Advisory Statements for Medicine Labels*; or
- (f) in other preparations when packed in containers labelled with the statement:
Application to the skin may increase sensitivity to sunlight.

LEVAMISOLE in preparations containing 15 per cent or less of levamisole for the treatment of animals **except:**

- (a) when included in Schedule 4; or
- (b) in preparations for the treatment of ornamental birds or ornamental fish, in packs containing 10 mg or less of levamisole.

LIGNOCAINE in aqueous gel preparations containing 4.5 per cent or less of lignocaine, for the dermal spray-on treatment of wounds associated with 'mulesing' of sheep.

LIME OIL **except:**

- (a) when steam distilled or rectified;
- (b) in preparations for internal use;
- (c) in preparations containing 0.5 per cent or less of lime oil;
- (d) in soaps or bath or shower gels that are washed off the skin;
- (e) in medicines for human therapeutic use, when compliant with the requirements of the *Required Advisory Statements for Medicine Labels*; or
- (f) in other preparations when packed in containers labelled with the statement:
Application to the skin may increase sensitivity to sunlight.

LINDANE in preparations containing 10 per cent or less of lindane **except** when included in Schedule 2 or 4.

LUFENURON **except:**

- (a) in divided preparations each containing 500 mg or less of lufenuron for the treatment of animals;
or
- (b) in single use syringes each containing 500 mg or less of lufenuron for the treatment of animals.

MADURAMICIN in animal feed premixes containing 1 per cent or less of antibiotic substances.

MAGNESIUM CHLORATE **except** in preparations containing 10 per cent or less of magnesium chlorate.

MALACHITE GREEN in preparations for veterinary use containing 10 per cent or less of malachite green.

SCHEDULE 5— continued

MALATHION in preparations containing 10 per cent or less of malathion **except**:

- (a) for human therapeutic use; or
- (b) in dust preparations containing 2 per cent or less of malathion.

MANCOZEB.

MANDIPROPAMID.

MARJORAM OIL **except**:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert, and labelled with the warning:

KEEP OUT OF REACH OF CHILDREN; or
- (c) in preparations containing 50 per cent or less of marjoram oil.

MCPA:

- (a) in preparations containing 25 per cent or less of MCPA (acid); or
- (b) in preparations containing 50 per cent or less of the salts and esters of MCPA.

MCPB.

MEBENDAZOLE for the treatment of animals:

- (a) in divided preparations each containing 300 mg or less of mebendazole per dosage unit; or
- (b) in undivided preparations containing 25 per cent or less of mebendazole.

MECLOFENAMIC ACID for the treatment of animals.

MECOPROP in preparations containing 2 per cent or less of mecoprop.

MEFENPYR-DIETHYL.

MEPIQUAT.

MESOTRIONE.

METAFLUMIZONE.

METALAXYL in preparations containing 35 per cent or less of metalaxyl.

METALDEHYDE in preparations containing 2 per cent or less of metaldehyde.

METHABENZTHIAZURON.

METHANOL (excluding its derivatives) in preparations containing 10 per cent or less of methanol **except** in preparations containing 2 per cent or less of methanol.

METHIOCARB in pelleted preparations containing 2 per cent or less of methiocarb.

SCHEDULE 5– continued

METHOXYCHLOR.

METHYLATED SPIRIT(S) (being ethanol denatured with denatonium benzoate, methyl isobutyl ketone and fluorescein) **except**:

- (a) when included in preparations or admixtures; or
- (b) when packed in containers having a capacity of more than 5 litres.

METHYLENE BLUE in preparations for veterinary use containing 50 per cent or less of methylene blue.

METHYL ETHYL KETONE **except** in preparations containing 25 per cent or less of designated solvents.

METHYL ETHYL KETONE PEROXIDE.

METHYL ISOAMYL KETONE **except** in preparations containing 25 per cent or less of designated solvents.

METHYL ISOBUTYL KETONE **except** in preparations containing 25 per cent or less of designated solvents.

N-METHYL-2-PYRROLIDONE:

- (a) when packed in single use containers having a capacity of 2 mL or less; or
- (b) in preparations containing 50 per cent or less of N-methyl-2-pyrrolidone or preparations containing 50 per cent or less of a mixture of any two or more of N-methyl-2-pyrrolidone, N-(N-octyl)-2-pyrrolidone or N-(N-dodecyl)-2-pyrrolidone **except** in preparations containing 25 per cent or less of designated solvents.

METHYL SALICYLATE in preparations containing 25 per cent or less of methyl salicylate **except**:

- (a) in preparations for therapeutic use; or
- (b) in preparations containing 5 per cent or less of methyl salicylate.

2-METHYLTHIO-4-(2-METHYLPROP-2-YL) AMINO-6-CYCLOPROPYLAMINO-5- TRIAZINE.

METIRAM.

METHOFLUTHRIN in impregnated fabric mosquito repellent preparations for use in a vaporiser containing 15 mg or less of metofluthrin per disk.

METOLACHLOR.

METRAFENONE in preparations containing 50 per cent or less of metrafenone.

MILBEMECTIN in preparations containing 1 per cent or less of milbemectin.

MILBEMYCIN OXIME for the prophylaxis of heartworm in dogs and cats.

MONENSIN in intraruminal implants for cattle, each containing 35 g or less of monensin.

MONEPANTEL.

MORANTEL in preparations containing 25 per cent or less of morantel **except** in preparations containing 10 per cent or less of morantel.

MOXIDECTIN:

- (a) in preparations for external use for the treatment of animals other than cats and dogs, containing 0.5 per cent or less of moxidectin;

SCHEDULE 5— continued

- (b) in preparations for external use for the treatment of cats and dogs, containing 2.5 per cent or less of moxidectin packed in single dose tubes with a volume of 1 mL or less; or
- (c) for internal use for the treatment of animals:
 - (i) in divided preparations for dogs, containing 250 micrograms or less of moxidectin per dosage unit in a pack containing six or less dosage units; or
 - (ii) in other preparations containing 2 per cent or less of moxidectin.

MYCLOBUTANIL.

NAA **except** in preparations containing 25 per cent or less of NAA.

NALED when impregnated in plastic resin strip material containing 20 per cent or less of naled.

NAPTALAM.

NETOBIMIN for the treatment of animals, in preparations containing 12.5 per cent or less of netobimin.

NITRIC ACID (excluding its salts and derivatives) in preparations containing 10 per cent or less of nitric acid (HNO₃) **except** in preparations containing 0.5 per cent or less of nitric acid.

NITROSCANATE for the treatment of animals.

NONOXINOL 9 in preparations containing 25 per cent or less of nonoxinol 9 **except**:

- (a) when labelled with the statements:
 - IRRITANT; and
 - Avoid contact with eyes;
- (b) in preparations containing 12.5 per cent or less of nonoxinol 9; or
- (c) in preparations for human use.

NORBORMIDE.

NUTMEG OIL **except**:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert, and labelled with the warning:
 - KEEP OUT OF REACH OF CHILDREN; or
- (c) in preparations containing 50 per cent or less of nutmeg oil.

N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE **except** in preparations containing 10 per cent or less of N-octyl bicycloheptene dicarboximide.

N-(N-OCTYL)-2-PYRROLIDONE in preparations containing 50 per cent or less of:

- (a) N-(N-octyl)-2-pyrrolidone or preparations containing 50 per cent or less of a mixture of any two or more of N-(N-octyl)-2-pyrrolidone, N-methyl-2-pyrrolidone or
- (b) N-(N-dodecyl)-2-pyrrolidone **except** in preparations containing 25 per cent or less of designated

SCHEDULE 5– continued

solvents.

OESTRADIOL in implant preparations for growth promotion in animals.

OLEANDOMYCIN in animal feed premixes for growth promotion.

OMETHOATE in pressurised spray packs containing 0.2 per cent or less of omethoate.

ORANGE OIL (BITTER) **except**:

- (a) when steam distilled or rectified;
- (b) in preparations for internal use;
- (c) in preparations containing 1.4 per cent or less of orange oil (bitter);
- (d) in soaps or bath or shower gels that are washed off the skin;
- (e) in medicines for human therapeutic use, when compliant with the requirements of the *Required Advisory Statements for Medicine Labels*; or
- (f) in other preparations when packed in containers labelled with the statement:

Application to the skin may increase sensitivity to sunlight.

OXADIARGYL.

OXADIXYL.

OXANTEL EMBONATE for the treatment of animals.

OXFENDAZOLE for the treatment of animals.

OXIBENDAZOLE for the treatment of animals.

OXYCARBOXIN.

OXYTETRACYCLINE in preparations:

- (a) for topical application to animals for ocular use only; or
- (b) containing 40 per cent or less of oxytetracycline per dose, when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

OXYTHIOQUINOX.

PACLOBUTRAZOL.

PENCONAZOLE.

PENDIMETHALIN.

PENFLUFEN.

PENTHIOPYRAD **except** in preparations containing 20 per cent or less of penthiopyrad.

PERACETIC ACID in concentrations of 10 per cent or less of peracetic acid.

PERMETHRIN (excluding preparations for human therapeutic use):

- (a) in preparations containing 25 per cent or less of permethrin; or

SCHEDULE 5— continued

- (b) in preparations for external use, for the treatment of dogs, containing 50 per cent or less of permethrin when packed in single use containers having a capacity of 4 mL or less,

except in preparations containing 2 per cent or less of permethrin.

PETROL **except** preparations containing 25 per cent or less of petrol.

PHENAZONE for the external treatment of animals.

PHENISOPHAM.

PHENOL, including cresols and xylenols and any other homologue of phenol boiling below 220°C, when in animal feed additives containing 15 per cent or less of such substances, **except** in preparations containing 3 per cent or less of such substances.

PHENYL METHYL KETONE **except** in preparations containing 25 per cent or less of designated solvents.

ortho-PHENYLPHENOL **except** in preparations containing 5 per cent or less of o-phenylphenol.

PHOSPHONIC ACID (excluding its salts and derivatives) **except** in preparations containing 10 per cent or less of phosphonic acid (H₃PO₃).

PHOSPHORIC ACID (excluding its salts and derivatives) in preparations containing 35 per cent or less of phosphoric acid (H₃PO₄) **except**:

- (a) in preparations containing 15 per cent or less of phosphoric acid (H₃PO₄);
- (b) in solid or semi-solid preparations; or
- (c) in professional dental kits.

ortho-PHTHALALDEHYDE in preparations containing 1 per cent or less of ortho-phthalaldehyde.

PICARIDIN **except** in preparations containing 20 per cent or less of picaridin.

PINE OILS in preparations containing 25 per cent or less of pine oils when packed and labelled as a herbicide.

PINOXADEN in preparations containing 10 per cent or less of pinoxaden.

PIPERAZINE for animal use.

PIRIMICARB in preparations containing 0.5 per cent or less of pirimicarb.

POLIHEXANIDE **except** in preparations containing 5 per cent or less of polihexanide.

POLIXETONIUM SALTS in preparations containing 60 per cent or less of polixetonium salts **except** in preparations containing 1 per cent or less of polixetonium salts.

POLYETHANOXY (15) TALLOW AMINE.

POLY(OXY-1,2-ETHANEDIYL), α -[2-[(2-HYDROXYETHYL)AMINO]-2-OXOETHYL]- α -HYDROXY-, MONO-C₁₃₋₁₅-ALKYL ETHERS.

POTASSIUM CHLORATE **except**:

- (a) when included in Schedule 2; or
- (b) in preparations containing 10 per cent or less of potassium chlorate.

POTASSIUM HYDROXIDE (excluding its salts and derivatives) in preparations containing 5 per cent or less of

SCHEDULE 5— continued

potassium hydroxide being:

- (a) solid preparations, the pH of which in a 10 g/L aqueous solution is more than 11.5; or
- (b) liquid or semi-solid preparations, the pH of which is more than 11.5 **except** in food additive preparations for domestic use.

POTASSIUM METABISULPHITE when packed for domestic use **except** in preparations containing 10 per cent or less of potassium metabisulphite.

POTASSIUM NITRITE in preparations containing 1 per cent or less of potassium nitrite **except**:

- (a) in preparations containing 0.5 per cent or less of potassium nitrite;
- (b) when present as an excipient in preparations for therapeutic use; or
- (c) in aerosols.

POTASSIUM PEROXOMONOSULFATE TRIPLE SALT in preparations containing 5 per cent or less of potassium peroxomonosulfate triple salt being:

- (a) solid preparations, the pH of which in a 10 g/L aqueous solution is less than 2.5; or
- (b) liquid or semi-solid preparations, the pH of which is less than 2.5.

POTASSIUM SULFIDE in preparations for metal treatment in containers each containing 50 g or less of potassium sulfide.

PRALLETHRIN (cis:trans=20:80) in preparations containing 10 per cent or less of prallethrin **except** in insecticidal mats containing 1 per cent or less of prallethrin.

PROFOXYDIM **except** in preparations containing 20 per cent or less of profoxydim.

PROGESTERONE:

- (a) in implant preparations or controlled release pessaries for synchronisation of oestrus in cattle, sheep or goats; or
- (b) in implant preparations for growth promotion in cattle.

PROHEXADIONE CALCIUM.

PROMETRYN.

PROPAMOCARB.

PROPANIL.

PROPAQUIZAFOP.

PROPICONAZOLE in preparations containing 20 per cent or less of propiconazole.

PROPIONIC ACID (excluding its salts and derivatives) in preparations containing 80 per cent or less of propionic acid, **except**:

- (a) in preparations containing 30 per cent or less of propionic acid; or
- (b) for therapeutic use.

PROPOXUR:

SCHEDULE 5– continued

- (a) when impregnated in plastic resin strip material containing 10 per cent or less of propoxur;
- (b) in dust preparations containing 3 per cent or less of propoxur;
- (c) in granular sugar-based fly baits containing 1 per cent or less of propoxur, a dark colouring agent and a separate bittering agent;
- (d) in pressurised spray packs containing 2 per cent or less of propoxur; or
- (e) in printed paper sheets for pest control containing 0.5 per cent or less of propoxur and in any case not more than 100 mg of propoxur per sheet.

PROPYZAMIDE.

PROTHIOCONAZOLE-DESCHLORO **except** in preparations containing 0.5 per cent or less of prothioconazole-deschloro.

PROTHIOCONAZOLE-TRIAZOLIDINETHIONE **except** in preparations containing 0.5 per cent or less of prothioconazole-triazolidinethione.

PYMETROZINE.

PYRACLOSTROBIN.

PYRAFLUFEN-ETHYL.

PYRASULFOTOLE.

PYRETHRINS, naturally occurring, being pyrethrolone, cinerolone or jasmolone esters of chrysanthemic or pyrethric acids **except**:

- (a) in preparations for human therapeutic use; or
- (b) in preparations containing 10 per cent or less of such substances.

PYRIDABEN in preparations containing 25 per cent or less of pyridaben.

PYRIFENOX.

PYRITHIOBAC SODIUM.

PYRITHIONE ZINC in paints containing 0.5 per cent or less of pyrithione zinc calculated on the non-volatile content of the paint **except** in paints containing 0.1 per cent or less of pyrithione zinc calculated on the non-volatile content of the paint.

QUATERNARY AMMONIUM COMPOUNDS in preparations containing 20 per cent or less of quaternary ammonium compounds **except**:

- (a) when separately specified in these Schedules;
- (b) dialkyl or dialkoyl quaternary ammonium compounds where the alkyl or alkoyl groups are derived from tallow or hydrogenated tallow or similar chain length (C16/C18) sources; or
- (c) in preparations containing 5 per cent or less of such quaternary ammonium compounds.

QUINCLORAC.

QUININE in preparations for veterinary use containing 1 per cent or less of quinine.

QUINTOZENE.

SCHEDULE 5– continued

QUIZALOFOP-P-ETHYL in aqueous preparations containing 40 per cent or less of quizalofop-p-ethyl.

RACTOPAMINE in animal feed premixes containing 10 per cent or less of ractopamine.

RESMETHRIN in preparations containing 10 per cent or less of resmethrin.

RIMSULFURON.

ROBENIDINE **except** in preparations containing 20 per cent or less of robenidine.

SAFLUFENACIL in water dispersible granule preparations.

SALICYLANILIDE.

SEDAXANE.

SELAMECTIN **except** in preparations containing 12 per cent or less of selamectin.

SETHOXYDIM.

SIDURON.

SILICOFLUORIDES in preparations containing 3 per cent or less of fluoride ion **except**:

- (a) barium silicofluoride when separately specified in this Schedule; or
- (b) in preparations containing 15 mg/kg or less of fluoride ion.

SINBIOALLETHRIN in preparations containing 10 per cent or less of sinbioallethrin **except** in preparations containing 1 per cent or less of sinbioallethrin.

SODIUM CHLORATE **except** in preparations containing 10 per cent or less of sodium chlorate.

SODIUM DIACETATE **except** in preparations containing 60 per cent or less of sodium diacetate.

SODIUM DODECYLBENZENE SULFONATE **except** in preparations containing 30 per cent or less of sodium dodecylbenzene sulfonate.

SODIUM HYDROGEN SULFATE **except** in preparations containing 10 per cent or less of sodium hydrogen sulfate.

SODIUM HYDROSULFITE when packed for domestic use **except** in preparations containing 10 per cent or less of sodium hydrosulfite.

SODIUM HYDROXIDE (excluding its salts and derivatives) in preparations containing 5 per cent or less of sodium hydroxide being:

- (a) solid preparations, the pH of which in a 10 g/L aqueous solution is more than 11.5; or
- (b) liquid or semi-solid preparations, the pH of which is more than 11.5 **except** in food additive preparations for domestic use.

SODIUM LAURETH-6 CARBOXYLATE **except** in preparations containing 1 per cent or less of sodium laureth-6 carboxylate.

SODIUM METABISULPHITE when packed for domestic use **except** in preparations containing 10 per cent or less of sodium metabisulphite.

SODIUM NITRITE in preparations containing 1 per cent or less of sodium nitrite **except**:

SCHEDULE 5– continued

- (a) in preparations containing 0.5 per cent or less of sodium nitrite;
- (b) when present as an excipient in preparations for therapeutic use; or
- (c) in aerosols.

SODIUM PERCARBONATE (CAS No. 15630-89-4) in preparations containing 35 per cent or less of sodium percarbonate **except** in preparations containing 15 per cent or less of sodium percarbonate.

SODIUM POLYSTYRENE SULPHONATE in preparations for cosmetic use **except** in preparations containing 10 per cent or less of sodium polystyrene sulphonate.

SODIUM STANNATE **except** in preparations for cosmetic use containing 1 per cent or less of sodium stannate.

SODIUM SULFIDE in preparations for metal treatment in containers each containing 50 g or less of sodium sulfide.

SPINETORAM.

SPINOSAD **except** in aqueous suspensions containing 25 per cent or less of spinosad.

STAR ANISE OIL **except**:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert, and labelled with the warning:

KEEP OUT OF REACH OF CHILDREN; or

- (c) in preparations containing 50 per cent or less of star anise oil.

STYRENE (excluding its derivatives).

SULFACETAMIDE when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

SULFADIAZINE when packed and labelled for treatment of ornamental caged birds or ornamental fish only.

SULFADIMIDINE when packed and labelled for treatment of ornamental caged birds or ornamental fish only.

SULFAMERAZINE when packed and labelled for treatment of ornamental caged birds or ornamental fish only.

SULFAMIC ACID (excluding its salts and derivatives) in preparations containing 10 per cent or less of sulfamic acid (H₃NO₃S).

SULFATHIAZOLE when packed and labelled for treatment of ornamental caged birds or ornamental fish only.

SULFOMETURON-METHYL.

SULFOXAFLOLOR in preparations containing 25 per cent or less of sulfoxafloL.

SYMPHYTUM spp. (Comfrey) for dermal use.

2,3,6-TBA.

TDE (1,1-dichloro-2,2-bis[4-chlorophenyl]ethane) in preparations containing 10 per cent or less of TDE.

SCHEDULE 5– continued

TEBUCONAZOLE.

TEBUFENOZIDE.

TEFLUTHRIN in preparations containing 2 per cent or less of tefluthrin.

TEMEPHOS:

- (a) in liquid preparations containing 10 per cent or less of temephos;
- (b) in powders containing 2 per cent or less of temephos; or
- (c) in preparations containing 40 per cent or less of temephos when packed in single use containers having a capacity of 2 mL or less.

TEPRALOXYDIM.

TERBUTRYN.

1,3,5,7-TETRAAZATRICYCLO[3.3.1.1^{3,7}] DECANE in cosmetic preparations, **except** in preparations containing 0.15 per cent or less of 1, 3, 5, 7-tetraazatricyclo [3.3.1.1^{3,7}] decane.

TETRACHLOROETHYLENE in preparations containing 5 per cent or less of tetrachloroethylene **except**:

- (a) when included in Schedule 2;
- (b) in preparations for the treatment of animals; or
- (c) when absorbed into an inert solid.

TETRACHLORVINPHOS **except** in animal feeds containing 0.2 per cent or less of tetrachlorvinphos.

TETRACONAZOLE in preparations containing 20 per cent or less of tetraconazole.

TETRACYCLINE in preparations:

- (a) for topical application to animals for ocular use only; or
- (b) containing 40 per cent or less of tetracycline when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

TETRAMETHRIN [(R, cis): (R, trans) = 20:80] **except** in pressurised spray packs.

THIABENDAZOLE:

- (a) for the treatment of animals; or
- (b) when packed and labelled for use as a fungicide **except** in preparations containing 50 per cent or less of thiabendazole.

THIAMETHOXAM in preparations containing 60 per cent or less of thiamethoxam.

THIAZOPYR.

THIFENSULFURON.

THIOBENCARB.

THIODICARB in pelleted preparations containing 1.5 per cent or less of thiodicarb.

THIOPHANATE-METHYL in preparations containing 25 per cent or less of thiophanate-methyl.

SCHEDULE 5– continued

THYME OIL except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert, and labelled with the warning:

KEEP OUT OF REACH OF CHILDREN; or

- (c) in preparations containing 50 per cent or less of thyme oil.

TIOCARBAZIL.

TOLCLOFOS-METHYL.

TOLTRAZURIL.

TRALKOXYDIM.

TRENBOLONE in implant preparations for growth promotion in animals.

TRIADIMEFON in wettable powders containing 25 per cent or less of triadimefon.

TRIADIMENOL.

TRI-ALLATE.

TRIBENURON-METHYL.

TRICHLOROACETIC ACID, alkali salts of.

1,1,1-TRICHLOROETHANE except:

- (a) in preparations packed in pressurised spray packs;
- (b) in preparations containing 25 per cent or less of designated solvents;
- (c) in preparations, other than writing correction fluids or thinners for writing correction fluids in containers having a capacity of 50 mL or less; or
- (d) in writing correction fluids or thinners for writing correction fluids, in containers having a capacity of 50 mL or less labelled with:
 - (i) the word “Trichloroethane” written in letters not less than 1 mm in height and in distinct contrast to the background; and
 - (ii) the expression:

WARNING – DO NOT DELIBERATELY SNIFF THIS PRODUCT. SNIFFING MIGHT HARM OR KILL YOU;

written in bold face sans serif capital letters not less than 1 mm in height and in distinct contrast to the background.

TRIDIPHANE.

SCHEDULE 5– continued

TRIETAZINE.

TRIETHANOLAMINE (excluding its salts and derivatives) **except:**

- (a) when in Schedule 4; or
- (b) in preparations containing 5 per cent or less of triethanolamine.

TRIFLOXYSTROBIN.

TRIFLUMIZOLE.

TRIFLUMURON.

TRIISOPROPANOLAMINE LAURYL ETHER SULFATE **except** in preparations containing 30 per cent or less of triisopropanolamine lauryl ether sulfate when labelled with the statements:

Avoid contact with eyes and skin; and

Wash hands after handling.

TRINEXAPAC-ETHYL **except:**

- (a) when packed in a sealed water-soluble measure pack; or
- (b) in solid preparations containing 25 per cent or less of trinexapac-ethyl in packs of 50 g or less.

3,6,9-TRIOXAUNDECANEDIOIC ACID **except** in preparations containing 5 per cent or less of 3,6,9-trioxaundecanedioic acid, the pH of which is 3.5 or greater.

TRITICONAZOLE.

TURPENTINE OIL **except** in preparations containing 25 per cent or less of turpentine oil.

VIRGINIAMYCIN in animal feed additives containing 1 per cent or less of virginiamycin for the prevention of laminitis in horses when in a pack of 5 kg or less.

VERNOLATE.

WARFARIN in rodent baits containing 0.1 per cent or less of warfarin.

ZINEB.

SCHEDULE 6

ABAMECTIN:

- (a) in preparations for pesticidal use containing 4 per cent or less of abamectin **except** when included in Schedule 5; or
- (b) in slow-release plastic matrix ear tags for livestock use containing 1 g or less of abamectin.

ACEPHATE.

ACETAMIPRID **except** in preparations containing 1 per cent or less of acetamiprid.

ACETIC ACID (excluding its salts and derivatives) and preparations containing more than 80 per cent of acetic acid (CH₃COOH) **except** when included in Schedule 2.

ACETIC ANHYDRIDE excluding its derivatives.

ACIFLUORFEN.

ACINITRAZOLE **except** in preparations containing 20 per cent or less of acinitrazole.

ALBENDAZOLE for the treatment of animals **except**:

- (a) when included in Schedule 5; or
- (b) in intraruminal implants each containing 3.85 g or less of albendazole.

ALDRIN.

ALKALINE SALTS, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination for non-domestic use:

- (a) in solid automatic dishwashing preparations, the pH of which in a 500 g/L aqueous solution or mixture is more than 12.5; or
- (b) in liquid or semi-solid automatic dishwashing preparations, the pH of which is more than 12.5.

ALKOXYLATED FATTY ALKYLAMINE POLYMER **except**:

- (a) when included in Schedule 5; or
- (b) in preparations containing 20 per cent or less of alkoxyated fatty alkylamine polymer.

ALLETHRIN **except**:

- (a) when included in Schedule 5;
- (b) in insecticidal mats containing 20 per cent or less of allethrin; or
- (c) in other preparations containing 1 per cent or less of allethrin.

SCHEDULE 6 continued

ALPHA-CYPERMETHRIN:

- (a) in aqueous preparations containing 25 per cent or less of alpha-cypermethrin; or
- (b) in other preparations containing 10 per cent or less of alpha-cypermethrin,
except when included in Schedule 5.

AMICARBAZONE.

AMIDITHION.

AMINOCARB in preparations containing 25 per cent or less of aminocarb.

AMINOETHOXYVINYLGLYCINE **except** in preparations containing 15 per cent or less of aminoethoxyvinylglycine.

1-AMINOMETHANAMIDE DIHYDROGEN TETRAOXOSULFATE.

AMINOPYRALID **except** when included in Schedule 5.

AMITRAZ.

AMMONIA (excluding its salts and derivatives other than ammonium hydroxide) **except**:

- (a) when included in Schedule 5;
- (b) in preparations for human internal therapeutic use;
- (c) in preparations for inhalation when absorbed in an inert solid material; or
- (d) in preparations containing 0.5 per cent or less of ammonia.

AMMONIUM PERSULFATE in hair preparations.

ANILINE (excluding its salts and derivatives) **except** in preparations containing 1 per cent or less of aniline.

ANTIMONY COMPOUNDS **except**:

- (a) when included in Schedule 4;
- (b) antimony chloride in polishes;
- (c) antimony titanate pigments in paint; or
- (d) in paints or tinters containing 5 per cent or less of antimony calculated on the non-volatile content of the paint or tinter.

ARSENIC:

- (a) in ant poisons containing 0.4 per cent or less of arsenic;
- (b) in animal feed premixes containing 4 per cent or less of arsenic; or
- (c) in preparations for the treatment of animals **except** thiacetarsamide when included in Schedule 4,
except when separately specified in this Schedule.

ASPIRIN for the treatment of animals **except** when included in Schedule 4 or 5.

SCHEDULE 6 continued

AZACONAZOLE **except** in preparations containing 1 per cent or less of azaconazole.

AZADIRACHTA INDICA (Neem) including its extracts and derivatives **except**:

- (a) when included in Schedule 5;
- (b) in preparations for human internal use;
- (c) debitterised neem seed oil;
- (d) in preparations for human dermal therapeutic use containing cold pressed neem seed oil, when in a container fitted with a child-resistant closure and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*; or
- (e) in preparations for dermal use containing 1 per cent or less of cold pressed neem seed oil.

AZAMETHIPHOS.

AZOBENZENE.

BAMBERMYCIN (flavophospholipol) in animal feed premixes for growth promotion containing 2 per cent or less of antibiotic substances.

BARIUM SALTS **except**:

- (a) when included in Schedule 5;
- (b) barium sulfate; or
- (c) in paints or tinters containing 5 per cent or less of barium calculated on the non-volatile content of the paint or tinter.

BASIC ORANGE 31 (2-[(4-aminophenyl)azo]-1,3-dimethyl-1H-imidazolium chloride) **except**:

- (a) in preparations for skin colouration and dyeing of eyelashes or eyebrows; or
- (b) in hair dye preparations containing 1 per cent or less of Basic Orange 31 when the immediate container and primary pack are labelled with the following statements:

KEEP OUT OF REACH OF CHILDREN;

If in eyes wash out immediately with water; and

WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5 mm in height.

BAY OIL **except**:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with

SCHEDULE 6 continued

the requirements of the *Required Advisory Statements for Medicine Labels*;

- (c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN;

- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN; or

- (e) in preparations containing 25 per cent or less of bay oil.

BEAUVERIA BASSIANA **except** when included in Schedule 5.

BENDIOCARB:

- (a) in wettable powders containing 80 per cent or less of bendiocarb when packed in containers or primary packs containing not less than 100 g of bendiocarb;
- (b) in wettable powders containing 20 per cent or less of bendiocarb and not less than 0.002 per cent of denatonium benzoate when packed in containers or primary packs containing not less than 48 g of bendiocarb and labelled for use as a fly control preparation;
- (c) in insoluble granular preparations containing 5 per cent or less of bendiocarb; or
- (d) when impregnated in plastic resin strip material containing 10 per cent or less of bendiocarb,

except when included in Schedule 5.

BENQUINOX.

BENSULIDE.

BENZALKONIUM CHLORIDE **except**:

- (a) when included in Schedule 5; or
- (b) in preparations containing 5 per cent or less of benzalkonium chloride.

1,2-BENZENEDIOL.

6-BENZYLADENINE **except** in preparations containing 2 per cent or less of 6-benzyladenine.

BERYLLIUM.

BETACYFLUTHRIN in preparations containing 12.5 per cent or less of betacyfluthrin **except** when included in Schedule 5.

BETA-CYPERMETHRIN.

BHC (excluding lindane).

SCHEDULE 6 continued

BIFENTHRIN in preparations containing 25 per cent or less of bifenthrin **except** in preparations containing 0.5 per cent or less of bifenthrin.

BIFLUORIDES (including ammonium, potassium and sodium salts) in preparations containing 3 per cent or less of total bifluorides **except** when included in Schedule 5.

BIOALLETHRIN **except**:

- (a) when included in Schedule 5; or
- (b) in preparations containing 1 per cent or less of bioallethrin.

N,N-BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE-2,5-DIMETHANAMINE **except** in preparations containing 1 per cent or less of N,N-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,5-dimethanamine, or a combination of N,N-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,5-dimethanamine and N,N-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,6-dimethanamine, when labelled with statements to the effect of:

IRRITANT;

REPEATED EXPOSURE MAY CAUSE SENSITISATION;

Avoid contact with eyes;

Avoid contact with skin;

Wear protective gloves when mixing or using; and

Ensure adequate ventilation when using.

N,N-BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE-2,6-DIMETHANAMINE **except** in preparations containing 1 per cent or less of N,N-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,6-dimethanamine, or a combination of N,N-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,5-dimethanamine and N,N-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,6-dimethanamine, when labelled with statements to the effect of:

IRRITANT;

REPEATED EXPOSURE MAY CAUSE SENSITISATION;

Avoid contact with eyes;

Avoid contact with skin;

Wear protective gloves when mixing or using; and

Ensure adequate ventilation when using.

BITHIONOL for treatment of animals.

BORON TRIFLUORIDE in preparations containing 1 per cent or less of boron trifluoride (BF₃) **except** when included in Schedule 5.

BRODIFACOUM in preparations containing 0.25 per cent or less of brodifacoum.

BROMADIOLONE in preparations containing 0.25 per cent or less of bromadiolone.

BROMETHALIN in rodent baits containing 0.01 per cent or less of bromethalin.

BROMOFORM **except** when included in Schedule 4.

BROMOPHOS.

SCHEDULE 6 continued

BROMOPHOS-ETHYL.

BROMOXYNIL.

BROMUCONAZOLE **except** when included in Schedule 5.

BROTIANIDE.

BUNAMIDINE.

BUTACARB.

BUTOXYCARBOXIM **except** when included in Schedule 5.

2-BUTOXYETHANOL and its ACETATES **except** in preparations containing 10 per cent or less of such substances.

2-BUTOXY-2'-THIOCYANODIETHYL ETHER.

BUTYRIC ACID in preparations for use as insect lures.

CACODYLIC ACID:

- (a) in animal feed premixes containing 4 per cent or less of arsenic; or
- (b) in herbicide or defoliant preparations containing 10 per cent or less of cacodylic acid.

CADMIUM COMPOUNDS **except**:

- (a) when included in Schedule 4; or
- (b) in paints or tinters containing 0.1 per cent or less of cadmium calculated on the non-volatile content of the paint or tinter.

CADUSAFOS in aqueous preparations containing 20 per cent or less of microencapsulated cadusafos.

CAJUPUT OIL **except**:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN;

- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

SCHEDULE 6 continued

NOT TO BE TAKEN;

- (e) in preparations containing 25 per cent or less of cajuput oil; or
- (f) in oils containing 25 per cent or less of cajuput oil.

CALCIFEROL in rodent baits containing 0.1 per cent or less of calciferol.

CAMBENDAZOLE.

CAMPBOR **except:**

- (a) when included in Schedule 4 or 5;
- (b) when enclosed in an inhaler device which prevents ingestion of its contents;
- (c) in solid or semi-solid preparations containing 12.5 per cent or less of camphor;
- (d) in liquid preparations containing 2.5 per cent or less of camphor;
- (e) in essential oils when the camphor is present as a natural component of the oil:
 - (i) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
 - (ii) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
 - (iii) in essential oils other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN; or

- (iv) in essential oils other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN; or

- (f) in rosemary oil, sage oil (Spanish), or lavandin oil as such.

CAPTAN.

CARBARYL **except** when included in Schedule 4 or 5.

CARBON DISULFIDE.

CARBAMIDE PEROXIDE **except:**

- (a) when included in Schedule 5; or

SCHEDULE 6 continued

- (b) in other preparations containing 9 per cent or less of carbamide peroxide.

CASTOR OIL, MONOMALEATE (excluding its salts and derivatives) in preparations for cosmetic use **except** in wash-off preparations containing 1 per cent or less of castor oil, monomaleate.

CHLORALOSE (alpha-CHLORALOSE) when packed and labelled for use as a pesticide.

CHLORDANE.

CHLORFENAPYR in preparations containing 36 per cent or less of chlorfenapyr **except** when included in Schedule 5.

CHLORFENETHOL.

CHLORHEXIDINE in preparations containing 7 per cent or less of chlorhexidine **except**:

- (a) when included in Schedule 5;
- (b) in preparations containing 1 per cent or less of chlorhexidine; or
- (c) when in solid preparations.

CHLORINATING COMPOUNDS **except**:

- (a) when included in Schedule 5;
- (b) when separately specified in these Schedules;
- (c) sodium hypochlorite preparations with a pH of less than 11.5;
- (d) in liquid preparations containing not less than 2 per cent but not more than 4 per cent of available chlorine when labelled with the statements:

WARNING – Ensure adequate ventilation when using. Vapour may be harmful. May give off dangerous gas if mixed with other products;
- (e) in liquid preparations containing less than 2 per cent of available chlorine; or
- (f) in other preparations containing 4 per cent or less of available chlorine.

CHLORMEQUAT.

CHLOROFORM **except**:

- (a) when included in Schedule 2 or 4; or
- (b) in preparations containing 10 per cent or less of chloroform.

ALPHA-CHLOROHYDRIN.

CHLOROPHACINONE.

(E)-(S)-1-(4-CHLOROPHENYL)-4,4-DIMETHYL-2-(1H-1,2,4-TRIAZOL-1-YL)PENT-1-EN-3-OL (uniconazole-p) **except** in preparations containing 5 per cent or less of (E)-(S)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1-yl)pent-1-en-3-ol.

CHLOROPICRIN in preparations containing 5 per cent or less of chloropicrin.

SCHEDULE 6 continued

CHLOROTHALONIL **except** in water-based paint containing 0.5 per cent or less of chlorothalonil.

2-CHLORO-6-(TRICHLOROMETHYL)-PYRIDINE.

CHLORPYRIFOS **except**:

- (a) when included in Schedule 5; or
- (b) in prepared potting or soil mixes containing 100 g or less of chlorpyrifos per cubic metre.

CHLORPYRIFOS-METHYL.

CHLORTHIAMID.

CHROMATES (including dichromates) **except** in paints or tinters containing 5 per cent or less of chromium as the ammonium, barium, calcium, iron, potassium, sodium, strontium or zinc chromate calculated on the non-volatile content of the paint or tinter.

CHROMIUM TRIOXIDE (excluding its salts and derivatives).

CINEOLE **except**:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN;

- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN;

- (e) in preparations containing 25 per cent or less of cineole;
- (f) in oils containing 25 per cent or less of cineole; or
- (g) in rosemary oil or camphor oil (white).

CINNAMON LEAF OIL **except**:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of

SCHEDULE 6 continued

25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;

- (c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN;

- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN; or

- (e) in preparations containing 25 per cent or less of cinnamon leaf oil.

CLIMBAZOLE except:

- (a) when included in Schedule 5; or
(b) in preparations containing 2 per cent or less of climbazole.

CLODINAFOP-PROPARGYL.

CLOMAZONE.

CLOSANTEL.

CLOTHIANIDIN except when included in Schedule 5.

CLOTRIMAZOLE for external treatment of animals.

CLOVE OIL except:

- (a) when included in Schedule 5;
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (c) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:
- KEEP OUT OF REACH OF CHILDREN; and
- NOT TO BE TAKEN;
- (e) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure

SCHEDULE 6 continued

and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN; or

- (f) in preparations containing 25 per cent or less of clove oil.

N-COCO-1,3-DIAMINOPROPANE.

COCOYL GLYCINATE in cosmetic preparations **except**:

- (a) in leave-on preparations containing 5 per cent or less of cocoyl glycinate; or
- (b) in wash-off preparations containing 30 per cent or less of cocoyl glycinate and, when containing more than 5 per cent of cocoyl glycinate labelled with a warning to the following effect:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER.

COPPER ACETATE **except**:

- (a) when included in Schedule 5; or
- (b) in preparations containing 5 per cent or less of copper acetate.

COPPER COMPOUNDS **except**:

- (a) when separately specified in these Schedules;
- (b) in preparations for human internal use containing 5 mg or less of copper per recommended daily dose;
- (c) pigments where the solubility of the copper compound(s) in water is 1 gram per litre or less;
- (d) in feed additives containing 1 per cent or less of copper; or
- (e) in other preparations containing 5 per cent or less of copper compounds.

COPPER HYDROXIDE **except**:

- (a) when included in Schedule 5; or
- (b) in preparations containing 12.5 per cent or less of copper hydroxide.

COPPER NITRATE in preparations containing copper chloride for the treatment of footrot in sheep.

COPPER OXIDES **except**:

- (a) when included in Schedule 5;
- (b) in preparations for internal use;
- (c) in marine paints; or
- (d) in other preparations containing 5 per cent or less of copper oxides.

COPPER OXYCHLORIDE **except**:

SCHEDULE 6 continued

- (a) when included in Schedule 5; or
- (b) in preparations containing 12.5 per cent or less of copper oxychloride.

COPPER SULFATE **except:**

- (a) when included in Schedule 5;
- (b) in preparations for internal use; or
- (c) in other preparations containing 5 per cent or less of copper sulfate.

COUMAPHOS:

- (a) in slow-release plastic matrix ear tags for livestock use containing 6 g or less of coumaphos; or
- (b) in other preparations containing 5 per cent or less of coumaphos.

COUMATETRALYL in rodenticides containing 1 per cent or less of coumatetralyl **except** when included in Schedule 5.

CREOSOTE derived from wood other than beechwood **except:**

- (a) when included in Schedule 2;
- (b) in preparations for human therapeutic use containing 10 per cent or less of creosote derived from wood other than beechwood; or
- (c) in other preparations containing 3 per cent or less of phenols and homologues of phenol boiling below 220°C.

CROTOXYPHOS.

CRUFOMATE.

CYANAMIDE.

CYANAZINE.

CYCLANILIDE.

N-CYCLOHEXYLDIAZENIUMDIOXY-POTASSIUM.

CYFLUTHRIN **except:**

- (a) when included in Schedule 5; or
- (b) in pressurised spray packs containing 1 per cent or less of cyfluthrin.

CYOMETRINIL.

CYPERMETHRIN **except** when included in Schedule 5.

CYPHENOTHHRIN **except** when included in Schedule 5.

CYSTEAMINE for cosmetic use **except:**

- (a) when included in Schedule 5; or

SCHEDULE 6 continued

- (b) in preparations containing 1 per cent or less of cysteamine.

CYTHIOATE **except** when included in Schedule 5.

2,4-D **except** when included in Schedule 5.

DAZOMET.

DELTAMETHRIN:

- (a) in aqueous preparations containing 25 per cent or less of deltamethrin, when no organic solvent, other than 10 per cent or less of a glycol, is present;
- (b) in wettable granular preparations containing 25 per cent or less of deltamethrin;
- (c) in water-dispersible tablets each containing 500 mg or less of deltamethrin;
- (d) in emulsifiable concentrates containing 11 per cent or less of deltamethrin in a solvent containing 40 per cent or less of acetophenone and 45 per cent or less of liquid hydrocarbons; or
- (e) in other preparations containing 3 per cent or less of deltamethrin,

except:

- (a) when included in Schedule 5;
- (b) in factory prepared mosquito nets containing 1 per cent or less of deltamethrin; or
- (c) in preparations containing 0.1 per cent or less of deltamethrin.

DERQUANTEL.

DIAZINON **except** when included in Schedule 5.

DICAMBA (including its salts and derivatives) **except** when included in Schedule 5.

DICHLOBENIL.

DICHLOFENTHION.

DICHLOFLUANID.

ortho-DICHLOROBENZENE.

DICHLOROETHYL ETHER.

DICHLOROISOCYANURIC ACID **except:**

- (a) when included in Schedule 5;
- (b) in liquid preparations containing not less than 2 per cent but not more than 4 per cent of available chlorine when labelled with the statements:

WARNING – Ensure adequate ventilation when using. Vapour may be harmful. May give off dangerous gas if mixed with other products;
- (c) in liquid preparations containing less than 2 per cent of available chlorine; or

SCHEDULE 6 continued

- (d) in other preparations containing 4 per cent or less of available chlorine.

4,5-DICHLORO-2-N-OCTYL-3(2H)-ISOTHIAZOLONE.

DICHLOROPHEN **except**:

- (a) when included in Schedules 4 or 5; or
- (b) in fabrics other than when:
- (i) for human therapeutic use; or
 - (ii) as part of a registered pesticidal product.

1,2-DICHLOROPROPANE.

2,4-DICHLORPROP (including the R and S enantiomers).

DICHLORVOS in preparations containing 50 per cent or less of dichlorvos **except** when included in Schedule 5.

DICLOFOP-METHYL.

DICYCLANIL **except** in preparations containing 5 per cent or less of dicyclanil.

DIDECYLDIMETHYLAMMONIUM SALTS **except** in preparations containing 1 per cent or less of didecyldimethylammonium salts labelled with the statement:

Avoid contact with eyes.

DIELDRIN.

DIETHANOLAMINE (excluding its salts and derivatives) **except**:

- (a) when included in Schedule 5; or
- (b) in preparations containing 5 per cent or less of diethanolamine.

DIETHYLENE GLYCOL (excluding its salts and derivatives) **except**:

- (a) when included in Schedule 5;
- (b) in paints or paint tinters;
- (c) in toothpastes or mouthwashes containing more than 0.25 per cent of diethylene glycol; or
- (d) in other preparations containing 2.5 per cent or less of diethylene glycol.

DIFENACOUM in preparations containing 0.25 per cent or less of difenacoum.

DIFENZOQUAT.

DIFETHIALONE in rodent baits containing 0.0025 per cent or less of difethialone.

5,6-DIHYDROXYINDOLINE.

DIMETHENAMID-P.

DIMETHIPIN.

SCHEDULE 6 continued

DIMETHOATE.

DIMETHYLACETAMIDE **except** when included in Schedule 5.

DIMETHYLFORMAMIDE **except**:

- (a) when included in Schedule 5; or
- (b) in silicone rubber mastic containing 2 per cent or less of dimethylformamide.

DIMETHYL SULFOXIDE (excluding dimethyl sulfone):

- (a) when not for therapeutic use; or
- (b) for the treatment of animals:
 - (i) when combined with no other therapeutic substance(s);
 - (ii) in liquid preparations containing copper salicylate and 1 per cent or less of methyl salicylate as the only other therapeutic substances; or
 - (iii) in clay poultices containing 2 per cent or less of dimethyl sulfoxide.

DINITROCRESOLS and their homologues in preparations containing 5 per cent or less of such compounds **except**:

- (a) when included in Schedule 4; or
- (b) when separately specified in this Schedule.

DINITROPHENOLS and their homologues in preparations containing 5 per cent or less of such compounds **except**:

- (a) when included in Schedule 4; or
- (b) when separately specified in this Schedule.

DIOXACARB.

DIOXANE.

DIPHACINONE.

DIQUAT in preparations containing 20 per cent or less of diquat.

DISULFIRAM **except** when included in Schedule 4.

DISULFOTON in granular preparations containing 5 per cent or less of disulfoton.

DITHIANON.

DITHIAZANINE in preparations containing 2 per cent or less of dithiazanine for the treatment of animals.

DIUREDOSAN.

N-(N-DODECYL)-2-PYRROLIDONE **except**:

- (a) when included in Schedule 5; or

SCHEDULE 6 continued

- (b) in preparations containing 25 per cent or less of designated solvents.

DODINE.

DORAMECTIN for external use for the treatment of animals, in preparations containing 2 per cent or less of doramectin.

DSMA in herbicide or defoliant preparations containing 10 per cent or less of DSMA.

ECONAZOLE for external treatment of animals.

EMAMECTIN in preparations containing 5 per cent or less of emamectin **except** when included in Schedule 5.

EMODEPSIDE for the treatment of animals **except** when included in Schedule 5.

ENDOSULFAN in aqueous preparations containing 33 per cent or less of microencapsulated endosulfan.

ENDOTHAL in preparations containing 20 per cent or less of endothal.

EPTC.

ESBIOTHRIN **except**:

- (a) when included in Schedule 5; or
(b) in pressurised spray packs containing 1 per cent or less of esbiothrin.

ESFENVALERATE **except** when included in Schedule 5.

ETHANOLAMINE (excluding its salts and derivatives) **except**:

- (a) when included in Schedule 4 or 5; or
(b) in preparations containing 5 per cent or less of ethanolamine.

ETHEPHON (excluding its salts and derivatives).

ETHER **except**:

- (a) when included in Schedule 2, 4 or 5; or
(b) in preparations containing 10 per cent or less of ether.

ETHIOFENCARB.

ETHOATE-METHYL.

ETHOPROPHOS in granular formulations containing 10 per cent or less of ethoprophos and 2 per cent of linseed oil.

ETHYL BROMIDE.

ETHYL FORMATE when packed and labelled for use as a fumigant.

ETHYLENE CHLOROXYDRIN.

ETHYLENE DICHLORIDE.

ETHYLENE GLYCOL (excluding its salts and derivatives) **except**:

Poisons Standard 2015

SCHEDULE 6 continued

- (a) when included in Schedule 5;
- (b) in paints or paint tinters;
- (c) in toothpastes or mouthwashes containing more than 0.25 per cent of ethylene glycol; or
- (d) in other preparations containing 2.5 per cent or less of ethylene glycol.

ETHYLENE GLYCOL MONOALKYL ETHERS and their ACETATES, **except:**

- (a) when separately specified in these Schedules; or
- (b) in preparations containing 10 per cent or less of such substances.

ETRIMFOS.

EUCALYPTUS OIL **except:**

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN;
- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN; or
- (e) in preparations containing 25 per cent or less of eucalyptus oil.

EUGENOL **except:**

- (a) when included in Schedule 5;
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (c) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the

SCHEDULE 6 continued

warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN;

- (e) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN; or

- (f) in preparations containing 25 per cent or less of eugenol.

FAMPHUR in preparations containing 20 per cent or less of famphur.

FEBANTEL **except:**

- (a) in divided preparations containing 1000 mg or less of febantel per dosage unit; or

- (b) in undivided preparations containing 10 per cent or less of febantel.

FENAMIPHOS in granular preparations containing 5 per cent or less of fenamiphos.

FENAZAFLOR.

FENBUTATIN OXIDE.

FENCHLORPHOS.

FENITROTHION.

FENOXACRIM in preparations for the treatment of carpets during manufacture.

FENPYROXIMATE.

FENTHION in preparations containing 60 per cent or less of fenthion **except** when included in Schedule 5.

FENVALERATE.

FIPRONIL **except:**

- (a) when included in Schedule 5; or

- (b) in preparations containing 0.05 per cent or less of fipronil.

FLOCOUMAFEN in preparations containing 0.005 per cent or less of flocoumafen.

FLONICAMID.

FLUAZIFOP-BUTYL.

FLUAZIFOP-P-BUTYL.

FLUAZINAM.

FLUCOFURON in preparations for the treatment of carpets during manufacture.

SCHEDULE 6 continued

FLUENSULFONE.

FLUMETHRIN **except** when included in Schedule 5.

FLUMIOXAZIN when contained in water soluble bags individually packed in sealed sachets.

FLUORIDES **except**:

- (a) when included in Schedule 5;
- (b) in preparations for human use; or
- (c) in preparations containing 15 mg/kg or less of fluoride ion.

FLUPROPANATE.

FLUQUINCONAZOLE.

FLUSILAZOL.

FLUTRIAFOL **except** in fertilisers containing 0.5 per cent or less of flutriafol.

FLUVALINATE **except** when included in Schedule 5.

FORMALDEHYDE (excluding its derivatives) in preparations containing 0.05 per cent or more of free formaldehyde **except**:

- (a) for human therapeutic use;
- (b) in oral hygiene preparations;
- (c) in nail hardener cosmetic preparations containing 5 per cent or more of free formaldehyde;
- (d) in nail hardener cosmetic preparations containing 0.2 per cent or less of free formaldehyde when labelled with the statement:
PROTECT CUTICLES WITH GREASE OR OIL;
- (e) in all other cosmetic preparations; or
- (f) in other preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement:
CONTAINS FORMALDEHYDE.

FORMOTHION.

FOSPIRATE **except** when included in Schedule 5.

FUMAGILLIN.

FURFURAL **except** in preparations containing 0.1 per cent or less of furfural.

GLUTARALDEHYDE **except**:

- (a) when included in Schedule 2 or 5; or
- (b) in preparations containing 0.5 per cent or less of glutaraldehyde when labelled with the statements:

SCHEDULE 6 continued

IRRITANT; and

Avoid contact with eyes.

GLYCERYL THIOGLYCOLLATE in hair waving preparations **except** when labelled with directions for use that include the statement:

Wear protective gloves when using. Keep out of eyes.

GLYCOLIC ACID (including its salts and esters) in cosmetic products or when packed and labelled for use as an agricultural chemical **except**:

- (a) in cosmetic preparations for salon use only, when labelled in accordance with Safe Work Australia's *National Code of Practice for the Labelling of Workplace Substances* [NOHSC:2012(1994)];
- (b) in preparations containing 5 per cent or less of glycolic acid; or
- (c) in preparations containing 20 per cent or less of glycolic acid with a pH of 3.5 or greater.

GUANIDINE **except**:

- (a) when included in Schedule 4; or
- (b) in preparations containing 1 per cent or less of guanidine.

GUAZATINE.

HALOXON.

HALOXYFOP.

HEPTACHLOR.

HEXACHLOROPHANE in preparations for the treatment of animals.

HEXAZINONE **except** when included in Schedule 5.

HEXYLOXYETHANOL **except** in preparations containing 10 per cent or less of hexyloxyethanol.

HYDRAMETHYLNON **except** when included in Schedule 5.

HYDRAZINE.

HYDROCHLORIC ACID (excluding its salts and derivatives) **except**:

- (a) when included in Schedule 5;
- (b) in preparations for therapeutic use; or
- (c) in preparations containing 0.5 per cent or less of hydrochloric acid (HCl).

HYDROFLUORIC ACID (excluding its salts and derivatives) and admixtures that generate hydrofluoric acid, in preparations containing 1 per cent or less of hydrogen fluoride **except** when included in Schedule 5.

HYDROGEN PEROXIDE (excluding its salts and derivatives) **except**:

- (a) when included in Schedule 5;

SCHEDULE 6 continued

- (b) in hair dye preparations containing 6 per cent (20 volume) or less of hydrogen peroxide; or
- (c) in other preparations containing 3 per cent (10 volume) or less of hydrogen peroxide.

HYDROQUINONE except:

- (a) when included in Schedule 2 or 4; or
- (b) in preparations containing 10 per cent or less of hydroquinone.

HYDROSILICOFLUORIC ACID (excluding its salts and derivatives) in preparations containing 1 per cent or less of hydrosilicofluoric acid (H_2SiF_6) **except** when included in Schedule 5.

IMIDACLOPRID except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 5 per cent or less of imidacloprid.

IMIDOCARB.

IMINOCTADINE TRIALBESILATE.

IMIPROTHRIN except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 10 per cent or less of imiprothrin.

INDAZIFLAM.

INDOXACARB (includes the R and S enantiomers) **except** when included in Schedule 5.

IODINE (excluding its salts, derivatives and iodophors) **except:**

- (a) when included in Schedule 2; or
- (b) in solid or semi-solid preparations containing 2.5 per cent or less of available iodine.

IODOPHORS except in preparations containing 1.5 per cent or less of available iodine.

3-iodo-2-propynyl butyl carbamate (Iodocarb) except:

- (a) when included in Schedule 5;
- (b) in aqueous preparations not for cosmetic use containing 10 per cent or less of 3-iodo-2-propynyl butyl carbamate (Iodocarb); or
- (c) in cosmetic preparations (other than aerosolised preparations) containing 0.1 per cent or less of 3-iodo-2-propynyl butyl carbamate.

IOXYNIL.

IPCONAZOLE except when included in Schedule 5.

IRON COMPOUNDS (excluding up to 1 per cent of iron oxides when present as an excipient) for the treatment of animals **except:**

- (a) when included in Schedule 5;

SCHEDULE 6 continued

- (b) in liquid or gel preparations containing 0.1 per cent or less of iron; or
- (c) in animal feeds or feed premixes.

ISOCONAZOLE for external treatment of animals.

ISOCYANATES, free organic, boiling below 300° C, **except** in:

- (a) viscous polyurethane adhesives; or
- (b) viscous polyurethane sealants;

containing not more than 0.7 per cent of free organic isocyanates boiling below 300°C.

ISOEUGENOL **except**:

- (a) when included in Schedule 5; or
- (b) in preparations containing 10 per cent or less of isoeugenol.

LAMBDA-CYHALOTHRIN:

- (a) in aqueous preparations containing 25 per cent or less of microencapsulated lambda-cyhalothrin; or
- (b) in other preparations containing 1.6 per cent or less of lambda-cyhalothrin

except when included in Schedule 5

LASALOCID **except** in animal feeds containing 100 mg/kg or less of antibiotic substances.

LAURETH CARBOXYLIC ACIDS (excluding its salts and derivatives) **except**:

- (a) in leave-on preparations containing 1.5 per cent or less of laureth carboxylic acids;
- (b) in wash-off preparations containing 30 per cent or less of laureth carboxylic acids and, if containing more than 5 per cent of laureth carboxylic acids, when labelled with a warning to the following effect:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER; or

- (c) in other preparations containing 30 per cent or less of laureth carboxylic acids and, if containing more than 5 per cent of laureth carboxylic acids, when labelled with warnings to the following effect:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER; and

IF SKIN OR HAIR CONTACT OCCURS, REMOVE CONTAMINATED CLOTHING AND FLUSH SKIN AND HAIR WITH RUNNING WATER.

LAURYL ISOQUINOLINIUM BROMIDE.

LEAD COMPOUNDS **except**:

- (a) when included in Schedule 4 or 5;
- (b) in paints, tinters, inks or ink additives;

SCHEDULE 6 continued

- (c) in preparations for cosmetic use containing 100 mg/kg or less of lead;
- (d) in pencil cores, finger colours, showcard colours, pastels, crayons, poster paints/colours or coloured chalks containing 100 mg/kg or less of lead; or
- (e) in ceramic glazes when labelled with the warning statement:

CAUTION – Harmful if swallowed. Do not use on surfaces which contact food or drink.

written in letters not less than 1.5 mm in height.

LEPTOSPERMUM SCOPARIUM OIL (manuka oil) **except**:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN;

- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings;

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN; or

- (e) in preparations containing 25 per cent or less of *Leptospermum scoparium* oil.

LEVAMISOLE for the treatment of animals **except**:

- (a) when included in Schedule 4 or 5; or
- (b) in preparations for the treatment of ornamental birds or ornamental fish, in packs containing 10 mg or less of levamisole.

LINDANE **except** when included in Schedule 2, 4 or 5.

MAFENIDE when packed and labelled for the treatment of ornamental fish only.

MALATHION **except**:

- (a) when included in Schedule 5;
- (b) for human therapeutic use; or
- (c) in dust preparations containing 2 per cent or less of malathion.

MCPA **except** when included in Schedule 5.

SCHEDULE 6 continued

MEBENDAZOLE for the treatment of animals **except** when included in Schedule 5.

MECOPROP **except** when included in Schedule 5.

MECOPROP-P.

MEFLUIDIDE.

MELALEUCA OIL (tea tree oil) **except**:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN;

- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN; or

- (e) in preparations containing 25 per cent or less of melaleuca oil.

MELENGESTROL ACETATE when used as an animal feed additive.

MENAZON.

2-MERCAPTOETHANOL in preparations for use as insect lures.

MERCURIC OXIDE for the treatment of animals, in preparations for ocular use.

MERCUROCHROME for the treatment of animals, in preparations for topical use.

METACRESOLSULPHONIC ACID AND FORMALDEHYDE CONDENSATION PRODUCT for the treatment of animals.

METALAXYL **except** when included in Schedule 5.

METALDEHYDE **except** when included in Schedule 5.

METHACRIFOS in preparations containing 60 per cent or less of methacrifos.

METHAM.

METHANOL (excluding its derivatives) **except**:

Poisons Standard 2015

SCHEDULE 6 continued

- (a) when included in Schedule 5; or
- (b) in preparations containing 2 per cent or less of methanol.

METHIOCARB in preparations containing 20 per cent or less of methiocarb **except** when included in Schedule 5.

METHOMYL in fly-baits containing 1 per cent or less of methomyl and not less than 0.002 per cent of denatonium benzoate as a bittering agent.

METHYLCYCLOPENTADIENYL MANGANESE TRICARBONYL in preparations containing 10 per cent or less of methylcyclopentadienyl manganese tricarbonyl when fitted with a child-resistant closure.

METHYLDIBROMO GLUTARONITRILE **except** in preparations intended to be in contact with the skin, including cosmetic use.

METHYLENE BISTHIOCYANATE **except** in preparations containing 1 per cent or less of methylene bithiocyanate.

METHYLEUGENOL **except** in preparations containing 1 per cent or less of methyleugenol.

METHYL ETHYL KETONE OXIME **except** in preparations containing 1 per cent or less of methyl ethyl ketone oxime.

METHYL ISOTHIOCYANATE.

METHYL METHACRYLATE (excluding its derivatives) **except**:

- (a) for cosmetic use; or
- (b) in preparations containing 1 per cent or less of methyl methacrylate as residual monomer in a polymer.

METHYL NEODECANAMIDE **except** in liquid preparations containing 2 per cent or less of methyl neodecanamide.

METHYLNORBORNYPYRIDINE.

N-METHYL-2-PYRROLIDONE **except**:

- (a) when included in Schedule 5; or
- (b) in preparations containing 25 per cent or less of designated solvents.

METHYL SALICYLATE **except**:

- (a) when included in Schedule 5;
- (b) in preparations for therapeutic use; or
- (c) in preparations containing 5 per cent or less of methyl salicylate.

METOFLUTHRIN **except** when included in Schedule 5.

METOSULAM.

METRAFENONE **except** when included in Schedule 5.

SCHEDULE 6 continued

METRIBUZIN.

MICONAZOLE for the external treatment of animals.

MILBEMECTIN **except** when included in Schedule 5.

MONENSIN:

- (a) in animal feed premixes containing 12.5 per cent or less of antibiotic substances; or
- (b) in stockfeed supplements, blocks or licks containing 0.75 per cent or less of antibiotic substances.

MORANTEL **except**:

- (a) when included in Schedule 5; or
- (b) in preparations containing 10 per cent or less of morantel.

MOXIDECTIN for external use:

- (a) in preparations containing 2.5 per cent or less of moxidectin when packed in single dose tubes for the treatment of cats and dogs; or
- (b) in preparations containing 2 per cent or less of moxidectin for the treatment of animals,
except when included in Schedule 5.

MSMA in herbicide or defoliant preparations containing 10 per cent or less of MSMA.

NALED **except** when included in Schedule 5.

NAPHTHALENE (excluding its derivatives) **except** in liquid hydrocarbons as an impurity.

NAPHTHALOPHOS in preparations containing 80 per cent or less of naphthalophos.

NARASIN in animal feed premixes containing 12 per cent or less of narasin.

NETOBIMIN for the treatment of animals **except** when included in Schedule 5.

NICKEL SULFATE.

NICOTINE in preparations containing 3 per cent or less of nicotine when labelled and packed for the treatment of animals.

NIMIDANE in preparations containing 25 per cent or less of nimidane.

NITENPYRAM **except** in divided preparations containing 100 mg or less of nitenpyram.

NITRIC ACID (excluding its salts and derivatives) **except**:

- (a) when included in Schedule 5; or
- (b) in preparations containing 0.5 per cent or less of nitric acid (HNO₃).

NITROBENZENE **except**:

- (a) in solid or semi-solid polishes;
- (b) in soaps containing 1 per cent or less of nitrobenzene; or

SCHEDULE 6 continued

- (c) in other preparations containing 0.1 per cent or less of nitrobenzene.

NITROPHENOLS, ortho, meta and para, **except** when separately specified in these Schedules.

NITROPRUSSIDES in preparations containing 2.5 per cent or less of nitroprussides **except** when included in Schedule 4.

NITROXYNIL.

NONOXINOL 9 **except**:

- (a) when included in Schedule 5;
- (b) in preparations containing 25 per cent or less of nonoxinol 9 when labelled with the statements:
IRRITANT; and
Avoid contact with eyes;
- (c) in preparations containing 12.5 per cent or less of nonoxinol 9; or
- (d) in preparations for human use.

1-OCTEN-3-OL **except** in preparations containing 5 per cent or less of 1-octen-3-ol.

OCTHILINONE **except** in paints, jointing compounds and sealants containing 1 per cent or less of octhilonone calculated on the non-volatile content.

N-(N-OCTYL)-2-PYRROLIDONE **except**:

- (a) when included in Schedule 5; or
- (b) in preparations containing 25 per cent or less of designated solvents.

OLAQUINDOX **except** in preparations containing 10 per cent or less of olaquinox.

N-OLEYL-1,3-DIAMINOPROPANE.

OMETHOATE in preparations containing 30 per cent or less of omethoate **except** when included in Schedule 5.

OXADIAZON.

OXALIC ACID **except** its derivatives and insoluble salts.

OXYCLOZANIDE.

PAECILOMYCES LILACINUS STRAIN 251.

PARAFORMALDEHYDE (excluding its derivatives) in preparations containing 0.05 per cent or more of free formaldehyde **except**:

- (a) for human therapeutic use;
- (b) in oral hygiene preparations;
- (c) in nail hardener cosmetic preparations containing 5 per cent or more of free formaldehyde;
- (d) in nail hardener cosmetic preparations containing 0.2 per cent or less of free formaldehyde when

SCHEDULE 6 continued

labelled with the statement:

PROTECT CUTICLES WITH GREASE OR OIL;

- (e) in all other cosmetic preparations; or
- (f) in other preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement:

CONTAINS FORMALDEHYDE.

PARATHION-METHYL in aqueous preparations containing 45 per cent or less of microencapsulated parathion-methyl.

PARBENDAZOLE.

PEBULATE.

PENNYROYAL OIL **except:**

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN; or

- (c) in preparations containing 4 per cent or less of d-pulegone.

PENTACHLOROPHENOL in preparations containing 1.5 per cent or less of pentachlorophenol.

PERACETIC ACID **except** when included in Schedule 5.

PERFLUIDONE.

PERMANGANATES **except** potassium permanganate in aqueous solutions containing 1 per cent or less of potassium permanganate.

PERMETHRIN **except:**

- (a) when included in Schedule 4 or 5;
- (b) in preparations for human therapeutic use containing 5 per cent or less of permethrin; or
- (c) in preparations containing 2 per cent or less of permethrin.

2-PHENOXYETHANOL **except:**

- (a) in cosmetic preparations containing 1 per cent or less of 2-phenoxyethanol; or
- (b) in other preparations containing 15 per cent or less of 2-phenoxyethanol.

PHENOL, including cresols and xyenols and any other homologue of phenol boiling below 220°C, **except:**

- (a) when separately specified in these Schedules;

SCHEDULE 6 continued

- (b) when included in Schedule 5; or
- (c) in preparations containing 3 per cent or less of such substances.

PHENOTHIAZINE (excluding its derivatives) **except** in preparations containing 10 per cent or less of phenothiazine.

PHENYLENEDIAMINES and alkylated phenylenediamines not elsewhere specified in these Schedules:

- (a) in preparations packed and labelled for photographic purposes;
- (b) in preparations packed and labelled for testing water **except** tablets containing 10 mg or less of diethyl-para-phenylenediamine or dimethyl-para-phenylenediamine in opaque strip packaging provided the directions for use include the statement, "Do not discard testing solutions into the pool";
- (c) in hair dye preparations **except** when the immediate container and primary pack are labelled with the following statements:

KEEP OUT OF REACH OF CHILDREN, and

WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5 mm in height; or

- (d) in eyelash and eyebrow tinting products when the immediate container and primary pack are labelled with the following statement:

WARNING – This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use.

written in letters not less than 1.5 mm in height.

PHOSALONE.

PHOSMET.

PHOSPHORIC ACID (excluding its salts and derivatives) **except**:

- (a) when included in Schedule 5;
- (b) in preparations containing 15 per cent or less of phosphoric acid (H_3PO_4);
- (c) in solid or semi-solid preparations; or
- (d) in professional dental kits.

PHOXIM.

ortho-PHTHALALDEHYDE **except** when included in Schedule 5.

PINDONE.

PINE OILs when packed and labelled as a herbicide **except** when included in Schedule 5.

SCHEDULE 6 continued

PINOXADEN **except** when included in Schedule 5.

PIPEROPHOS.

PIRIMICARB **except** when included in Schedule 5.

PIRIMIPHOS-ETHYL.

PIRIMIPHOS-METHYL.

POLIXETONIUM SALTS **except**:

- (a) when included in Schedule 5; or
- (b) in preparations containing 1 per cent or less of polixetonium salts.

POTASSIUM AZELOYL DIGLYCINATE **except** in preparations for cosmetic use containing 1 per cent or less of potassium azeloyl diglycinate.

POTASSIUM BROMATE **except** in preparations containing 0.5 per cent or less of potassium bromate.

POTASSIUM CYANATE.

POTASSIUM HYDROXIDE (excluding its salts and derivatives) **except**:

- (a) when included in Schedule 5;
- (b) in preparations containing 5 per cent or less of potassium hydroxide being:
 - (i) solid preparations, the pH of which in a 10 g/L aqueous solution is 11.5 or less; or
 - (ii) liquid or semi-solid preparations, the pH of which is 11.5 or less; or
- (c) in liquid or semi-solid food additive preparations, the pH of which is more than 11.5, for domestic use.

POTASSIUM NITRITE in preparations containing 40 per cent or less of potassium nitrite **except**:

- (a) when included in Schedule 5;
- (b) in preparations containing 0.5 per cent or less of potassium nitrite;
- (c) when present as an excipient in preparations for therapeutic use; or
- (d) in aerosols containing 2 per cent or less of potassium nitrite.

POTASSIUM PEROXOMONOSULFATE TRIPLE SALT **except**:

- (a) when included in Schedule 5;
- (b) in solid orthodontic device cleaning preparations, the pH of which as an “in-use” aqueous solution is 2.5 or more, but not more than 11.5; or
- (c) in preparations containing 5 per cent or less of potassium peroxomonosulfate triple salt being:
 - (i) solid preparations, the pH of which in a 10 g/L aqueous solution is 2.5 or more; or
 - (ii) liquid or semi-solid preparations, the pH of which is 2.5 or more.

SCHEDULE 6 continued

POTASSIUM PERSULFATE in hair preparations.

PRALLETHRIN (cis:trans=20:80) **except**:

- (a) when included in Schedule 5; or
- (b) in insecticidal mats containing 1 per cent or less of prallethrin.

PROCHLORAZ.

PROFENOFOS.

PROMACYL.

PROPACHLOR.

PROPARGITE.

PROPETAMPHOS.

PROPICONAZOLE **except** when included in Schedule 5.

PROPINEB.

PROPIONIC ACID (excluding its salts and derivatives) **except**:

- (a) when included in Schedule 5;
- (b) in preparations containing 30 per cent or less of propionic acid; or
- (c) for therapeutic use.

PROPOXUR **except** when included in Schedule 5.

PROQUINAZID.

PROSULFOCARB.

PROSULFURON.

PROTHIOFOS.

d-PULEGONE **except** in preparations containing 4 per cent or less of d- pulegone.

PYRACLOFOS.

PYRAZOPHOS.

PYRIDABEN **except** when included in Schedule 5.

PYRIDALYL.

PYRIDATE.

PYRIPROLE.

PYRITHIONE COPPER.

PYRITHIONE ZINC **except**:

SCHEDULE 6 continued

- (a) when included in Schedule 2 or 5;
- (b) for human use in preparations for the treatment of the scalp containing 2 per cent or less of pyrrithione zinc when compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (c) in semi-solid hair preparations for animal use;
- (d) in shampoos for animal use containing 2 per cent or less of pyrrithione zinc when labelled with the statements “Keep out of eyes” and “If in eyes rinse well with water”;
- (e) when immobilised in solid preparations containing 0.5 per cent or less of pyrrithione zinc; or
- (f) in paints, jointing materials or sealants containing 0.1 per cent or less of pyrrithione zinc calculated on the non-volatile content.

PYRIOFENONE.

PYROXASULFONE.

PYROXSULAM.

QUATERNARY AMMONIUM COMPOUNDS **except**:

- (a) when separately specified in these Schedules;
- (b) when included in Schedule 5;
- (c) dialkyl or dialkoyl quaternary ammonium compounds where the alkyl or alkoyl groups are derived from tallow or hydrogenated tallow or similar chain length (C16/C18) sources; or
- (d) in preparations containing 5 per cent or less of such quaternary ammonium compounds.

QUIZALOFOP ETHYL.

QUIZALOFOP-P-ETHYL **except** when included in Schedule 5.

QUIZALOFOP-P-TEFURYL.

RESMETHRIN **except** when included in Schedule 5.

ROTENONE **except** in solid or semi-solid preparations containing 2 per cent or less of rotenone.

SAFROLE **except**:

- (a) for internal use; or
- (b) in other preparations containing 1 per cent or less of saffrole.

SAGE OIL (Dalmatian) **except**:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:

SCHEDULE 6 continued

KEEP OUT OF REACH OF CHILDREN; and

NOT TO BE TAKEN; or

- (c) in preparations containing 4 per cent or less of thujone.

SALINOMYCIN in animal feed premixes containing 12 per cent or less of antibiotic substances.

SASSAFRAS OIL **except:**

- (a) for internal use; or
- (b) in other preparations containing 1 per cent or less of saffrole.

SELENIUM:

- (a) in preparations containing 2.5 per cent or less of selenium when packed and labelled:
 - (i) for the blueing of gun barrels;
 - (ii) for photographic purposes; or
 - (iii) for the colouring of lead or lead alloys;
- (b) in coated granules containing 1 per cent or less of selenium for application to pasture **except** in fertilisers containing 200 g/tonne or less of selenium; or
- (c) for the treatment of animals:
 - (i) in a drench, injection, paste, stocklick, vaccine or horse feed supplement containing 0.5 per cent or less of selenium;
 - (ii) in animal feed premixes containing 2 per cent or less of selenium for the preparation of feeds containing 1 g/tonne or less of selenium;
 - (iii) in controlled release bolus preparations containing 25 mg or less of selenium with a release rate not greater than 0.25 mg/day; or
 - (iv) as barium selenate in preparations for injection containing 5 per cent or less of selenium.

SEMDURAMICIN in animal feed premixes for coccidiosis prevention containing 5 per cent or less of antibiotic substances.

SILICOFLUORIDES **except:**

- (a) when included in Schedule 5; or
- (b) in preparations containing 15 mg/kg or less of fluoride ion.

SILVER NITRATE **except:**

- (a) when included in or expressly excluded from Schedule 2; or
- (b) in preparations containing 1 per cent or less of silver.

SINBIOALLETHRIN **except:**

SCHEDULE 6 continued

- (a) when included in Schedule 5; or
- (b) in preparations containing 1 per cent or less of sinbioallethrin.

SODIUM ALUMINATE (excluding its salts and derivatives) **except:**

- (a) in solid preparations, the pH of which in a 10 g/L aqueous solution is 11.5 or less; or
- (b) in liquid preparations, the pH of which is 11.5 or less.

SODIUM BROMATE **except** in preparations containing 0.5 per cent or less of sodium bromate.

SODIUM HYDROXIDE (excluding its salts and derivatives) **except:**

- (a) when included in Schedule 5;
- (b) in preparations containing 5 per cent or less of sodium hydroxide being:
 - (i) solid preparations, the pH of which in a 10 g/L aqueous solution is 11.5 or less; or
 - (ii) liquid or semi-solid preparations, the pH of which is 11.5 or less; or
- (c) liquid or semi-solid food additive preparations, the pH of which is more than 11.5, for domestic use.

SODIUM LAURYL SULFATE (excluding its salts and derivatives) **except:**

- (a) in wash-off preparations containing 30 per cent or less of sodium lauryl sulfate and, if containing more than 5 per cent of sodium lauryl sulfate, when labelled with a warning to the following effect:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER;
- (b) in leave-on preparations containing 1.5 per cent or less of sodium lauryl sulfate;
- (c) in toothpaste and oral hygiene preparations containing 5 per cent or less of sodium lauryl sulfate;
- (d) in other preparations for animal use containing 2 per cent or less of sodium lauryl sulfate; or
- (e) in other preparations containing 30 per cent or less of sodium lauryl sulfate and, if containing more than 5 per cent of sodium lauryl sulfate, when labelled with warnings to the following effect:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER; and

IF SKIN OR HAIR CONTACT OCCURS, REMOVE CONTAMINATED CLOTHING AND FLUSH SKIN AND HAIR WITH RUNNING WATER.

SODIUM NITRITE in preparations containing 40 per cent or less of sodium nitrite **except:**

- (a) when included in Schedule 2 or 5;
- (b) in preparations containing 0.5 per cent or less of sodium nitrite;
- (c) when present as an excipient in preparations for therapeutic use; or
- (d) in aerosols containing 2 per cent or less of sodium nitrite.

SODIUM PERCARBONATE (CAS No. 15630-89-4) **except:**

SCHEDULE 6 continued

- (a) when included in Schedule 5; or
- (b) in preparations containing 15 per cent or less of sodium percarbonate.

SODIUM PERSULFATE:

- (a) in hair preparations; or
- (b) in products for the treatment of water for swimming pools and spas.

SODIUM SULFIDE in preparations for use as insect lures.

SPIROTETRAMAT.

SPIROXAMINE.

SULCOFURON in preparations for the treatment of carpets during manufacture.

SULFAMIC ACID (excluding its salts and derivatives) **except** when included in Schedule 5.

SULFLURAMID.

SULFOXAFLOL **except** when included in Schedule 5.

SULFURIC ACID (excluding its salts and derivatives) **except**:

- (a) in fire extinguishers; or
- (b) in preparations containing 0.5 per cent or less of sulfuric acid (H₂SO₄).

SULFURYL FLUORIDE.

SULPROFOS.

2,4,5-T.

N-TALLOW ALKYL-1,3-PROPANEDIAMINE DIACETATE and TALLOW ALKYLAMINE ACETATES.

TAR ACIDS distilling within the range 230-290°C inclusive.

TCMTB (2-[thiocyanomethylthio]benzothiazole).

TDE (1,1-dichloro-2,2-bis[4-chlorophenyl]ethane) **except** when included in Schedule 5.

TEBUFENPYRAD.

TEBUTHIURON.

TEMEPHOS **except** when in Schedule 5.

TERBUTHYLAZINE **except** in preparations containing 5 per cent or less of terbuthylazine.

TERPENES, CHLORINATED.

TESTOSTERONE in implant preparations for use in animals.

TETRACHLOROETHYLENE **except**:

- (a) when included in Schedule 2 or 5;

SCHEDULE 6 continued

- (b) in preparations containing 6 per cent or less of tetrachloroethylene when absorbed into an inert solid; or
- (c) in preparations for the treatment of animals.

TETRACONAZOLE **except** when included in Schedule 5.

TETRADIFON.

2,2',6,6'-TETRAISOPROPYL-DIPHENYL-CARBODIIMIDE in amitraz formulations containing 2 per cent or less of 2,2',6,6'-tetrakisopropyl-diphenyl-carbodiimide.

TETRAMISOLE in preparations for the treatment of animals.

THIACLOPRID.

THIAMETHOXAM **except** when included in Schedule 5.

THIAZAFLURON.

THIODICARB **except** when included in Schedule 5.

THIOMETON.

THIOPHANATE-METHYL **except** when included in Schedule 5.

THIOUREA AND ALKYL THIOUREAS **except**:

- (a) when separately specified in these Schedules; or
- (b) for therapeutic use.

THIRAM **except** in paint containing 0.5 per cent or less of thiram.

THUJONE **except** in preparations containing 4 per cent or less of thujone.

THYMOL when packed and labelled for the control of *Varroa* mites in bee hives.

TOLUENE (excluding its derivatives) **except** in preparations containing 50 per cent or less of toluene or toluene and xylene.

TOLUENEDIAMINE not elsewhere specified in these Schedules:

- (a) in hair dye preparations **except** when the immediate container and primary pack are labelled with the following statements:

KEEP OUT OF REACH OF CHILDREN, and

WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5 mm in height; or

- (b) in eyelash and eyebrow tinting products when the immediate container and primary pack are labelled with the following statement:

SCHEDULE 6 continued

WARNING – This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use.

written in letters not less than 1.5 mm in height.

TOLYLFLUANID.

TRANSFLUTHRIN **except**:

- (a) in preparations containing 1 per cent or less of transfluthrin; or
- (b) in a cartridge for vaporiser use containing 600 mg or less of transfluthrin per cartridge.

TRIADIMEFON **except**:

- (a) when included in Schedule 5; or
- (b) in fertilisers containing 5 g/kg or less of triadimefon.

TRICHLORFON **except** metrifonate included in Schedule 4.

TRICHLOROACETIC ACID **except**:

- (a) when included in Schedule 4 or 5; or
- (b) in human dermal preparations containing 12.5 per cent or less of trichloroacetic acid for the treatment of warts other than anogenital warts.

TRICHLOROETHYLENE **except** when included in Schedule 4.

TRICHLOROPHENOL.

TRICLABENDAZOLE **except** in preparations containing 20 per cent or less of triclabendazole.

TRICLOPYR.

TRICLOSAN in cosmetic preparations for human use containing more than 0.3 per cent of triclosan.

TRIDEMORPH.

TRIETHYL PHOSPHATE.

TRIFLUOROMETHANESULFONIC ACID.

TRINITROPHENOL (excluding its derivatives) **except**:

- (a) in preparations for human therapeutic use; or
- (b) in preparations containing 5 per cent or less of trinitrophenol.

TRISODIUM NITRILOTRIACETATE **except** in preparations containing 20 per cent or less of trisodium nitrilotriacetate.

VAMIDOTHION.

WARFARIN **except** when included in Schedule 4 or 5.

XYLENE (excluding its derivatives) **except** in preparations containing 50 per cent or less of xylene or xylene

SCHEDULE 6 continued

and toluene.

ZERANOL in ear implants for use as a growth promotant in steer cattle.

ZETA-CYPERMETHRIN in preparations containing 10 per cent or less of zeta-cypermethrin.

ZINC BORATE (excluding its derivatives) for use as an agricultural chemical.

ZINC CHLORIDE **except:**

- (a) when included in Schedule 2; or
- (b) in preparations containing 5 per cent or less of zinc chloride.

ZINC para-PHENOLSULFONATE **except** in preparations containing 5 per cent or less of zinc para-phenolsulfonate.

ZINC SULFATE **except:**

- (a) when included in or expressly excluded from Schedule 4; or
- (b) in other preparations containing 5 per cent or less of zinc sulfate.

ZIRAM in granular preparations.

SCHEDULE 7

ABAMECTIN **except** when included in Schedule 5 or 6.

ACIBENZOLAR-S-METHYL.

ACRIFLAVINE for veterinary use **except** when in Schedule 5.

ACROLEIN.

ACRYLONITRILE.

ALACHLOR.

ALDICARB.

ALDOXYCARB.

ALLYL ALCOHOL.

ALPHA-CYPERMETHRIN **except** when included in Schedule 5 or 6.

AMINACRINE for veterinary use **except** when included in Schedule 5.

AMINOCARB **except** when included in Schedule 6.

4-AMINOPYRIDINE **except** when included in Schedule 4.

AMITON.

ARPRINOCID.

ARSENIC **except**:

- (a) when separately specified in this Schedule;
- (b) when included in Schedule 4 or 6;
- (c) as selenium arsenide in photocopier drums;
- (d) as 10,10'-oxydiphenoxarsine in silicone rubber mastic containing 120 mg/kg or less of arsenic;
- (e) as 10,10'-oxydiphenoxarsine contained in polyvinyl chloride and polyurethane extruded and moulded articles containing 160 mg/kg or less of arsenic other than when included in articles:
 - (i) in contact with food stuffs, animal feeds or potable water;
 - (ii) of clothing and footwear in contact with the skin;
 - (iii) used as infant wear; or
 - (iv) intended for use as packaging materials;
- (f) in animal feeds containing 75 g/tonne or less of arsenic; or
- (g) in paints containing 0.1 per cent or less of arsenic calculated on the non-volatile content of the paint.

SCHEDULE 7 – continued

AZAFENIDIN.

AZINPHOS-ETHYL.

AZINPHOS-METHYL.

AZOCYCLOTIN.

BENDIOCARB **except** when included in Schedule 5 or 6.

BENOMYL **except** in paints containing 0.5 per cent or less of benomyl.

BENZENE (excluding its derivatives) **except**:

- (a) preparations containing 15 mL/L or less of benzene; or
- (b) petrol containing 50 mL/L or less of benzene.

BENZIDINE-BASED AZO DYES being:

2,2'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[N-(4-chlorophenyl)-3-oxobutanamide]
CAS No. 94249-03-3

Acid Red 85 (Acid Fast Red A)

1,3-Naphthalenedisulfonic acid, 7-hydroxy-8-[[4'-[[4-[(4-methylphenyl)sulfonyl]oxy]phenyl]azo]][1,1'-biphenyl]-4-yl]azo]-, disodium salt
CAS No. 3567-65-5

Direct Black 38

2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diaminophenyl)azo]][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt
CAS No. 1937-37-7

Direct Blue 2

2,7-Naphthalenedisulfonic acid, 5-amino-3-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo]][1,1'-biphenyl]-4-yl]azo]-4-hydroxy-, trisodium salt
CAS No. 2429-73-4

Direct Blue 6

2,7-Naphthalenedisulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[5-amino-4-hydroxy-, tetrasodium salt
CAS No. 2602-46-2

Direct Brown 2

5-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo]][1,1'-biphenyl]-4-yl]azo]-2-hydroxy- benzoic acid disodium salt
CAS No. 2429-82-5

Direct Brown 95

Cuprate(2-), [5-[[4'-[[2,6-dihydroxy-3-[(2-hydroxy-5-sulfo)phenyl]azo]phenyl]azo]][1,1'-biphenyl]-4-yl]azo]-2-hydroxybenzoato(4-)-, disodium salt
CAS No. 16071-86-6

Direct Green 1

2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[[4'-[(4-hydroxyphenyl)azo]][1,1'-biphenyl]-4-yl]azo]-6-(phenylazo)-, disodium salt
CAS No. 3626-28-6

Direct Green 6

2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-6-[[4'-[(4-hydroxyphenyl)azo]][1,1'-biphenyl]-4-yl]azo]-3-[(4-nitrophenyl)azo]-, disodium salt
CAS No. 4335-09-5

SCHEDULE 7 – continued

Direct Red 28 (Congo Red)

1-Naphthalenesulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[4-amino-, disodium salt
CAS No. 573-58-0

Direct Red 37

1,3-Naphthalenedisulfonic acid, 8-[[4'-[(4-ethoxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-7-hydroxy-,
disodium salt
CAS No. 3530-19-6

BETACYFLUTHRIN **except** when included in Schedule 5 or 6.

BIFENTHRIN **except**:

- (a) when included in Schedule 6; or
- (b) in preparations containing 0.5 per cent or less of bifenthrin.

BIFLUORIDES (including ammonium, potassium and sodium salts) **except** when included in Schedule 5 or 6.

BORON TRIFLUORIDE **except** when included in Schedule 5 or 6.

BRODIFACOUM **except** when included in Schedule 6.

BROMADIOLONE **except** when included in Schedule 6.

BROMETHALIN **except** when included in Schedule 6.

BROMINE (excluding its salts and derivatives).

BRUCINE **except** in alcohol containing 0.02 per cent or less of brucine as a denaturant.

CACODYLIC ACID **except**:

- (a) when included in Schedule 6; or
- (b) in animal feeds containing 75 g/tonne or less of arsenic.

CADUSAFOS **except** when included in Schedule 6.

CALCIFEROL for use as a rodenticide **except** when included in Schedule 6.

CAPTAFOL.

CARBADOX.

CARBENDAZIM **except** in paints, jointing compounds and sealants containing 0.1 per cent or less of carbendazim.

CARBOFURAN.

CARBON TETRACHLORIDE **except** in chlorinated rubber based paint containing 1 per cent or less of carbon tetrachloride.

CARBONYL SULFIDE when packed and labelled for use as a fumigant.

CARBOPHENOTHION.

CARBOSULFAN.

CHLORDECONE.

CHLORDIMEFORM.

CHLORFENAPYR **except** when included in Schedule 5 or 6.

CHLORFENVINPHOS.

CHLORINE (excluding its salts and derivatives).

CHLORHEXIDINE **except**:

- (a) when included in Schedule 5 or 6;
- (b) in preparations containing 1 per cent or less of chlorhexidine; or
- (c) in solid preparations.

CHLOROMETHIURON.

5-CHLORO-3-METHYL-4-NITROPYRAZOLE.

4-CHLORO-o-TOLUIDINE.

CHLOROPICRIN **except** when included in Schedule 6.

CHLORTHIOPHOS.

COLECALCIFEROL for use as a rodenticide.

COUMAPHOS **except** when included in Schedule 6.

COUMATETRALYL **except** when included in Schedule 5 or 6.

CREOSOTE derived from coal.

CREOSOTE derived from beechwood.

CYANIDES, metallic **except**:

- (a) ferricyanides;
- (b) ferrocyanides; or
- (c) when separately specified in these Schedules.

CYANOGEN.

CYHALOTHRIN (aRS,1R,cis,Z):(aRS,1S,cis,Z) = 50:50.

CYHEXATIN.

DELTAMETHRIN **except**:

- (a) when included in Schedules 5 or 6; or
- (b) in factory prepared mosquito nets containing 1 per cent or less of deltamethrin; or
- (c) in preparations containing 0.1 per cent or less of deltamethrin.

DEMETON.

SCHEDULE 7 – continued

DEMETON-O-METHYL.

DEMETON-S-METHYL.

DIALIFOS.

4,4-DIAMINODIPHENYLMETHANE (Methylene dianiline).

1,2-DIBROMO-3-CHLOROPROPANE.

1,3-DICHLOROPROPENE.

DICHLORVOS **except** when included in Schedule 5 or 6.

DICROTOPHOS.

DIFENACOUM **except** when included in Schedule 6.

DIFETHIALONE **except** when included in Schedule 6.

DIMEFOX.

4-DIMETHYLAMINOAZOBENZENE (N,N-dimethyl-4-[phenylazo]-benzenamine).

DIMETHYL SULFATE.

DIMETILAN.

DINITROCRESOLS **except** when included in Schedule 4 or 6.

DINITROPHENOLS **except** when included in Schedule 4 or 6.

DINOCAP.

DINOSEB.

DIQUAT **except** when included in Schedule 6.

DISULFOTON **except** when included in Schedule 6.

DORAMECTIN **except** when included in Schedule 5 or 6.

DSMA **except** when included in Schedule 6.

EMAMECTIN **except** when included in Schedule 5 or 6.

ENDOSULFAN **except** when included in Schedule 6.

ENDOTHAL **except** when included in Schedule 6.

ENDRIN.

EPICHLOROHYDRIN.

EPIDERMAL GROWTH FACTOR **except** in preparations for human therapeutic use.

EPRINOMECTIN **except** when included in Schedule 5.

ETACONAZOLE.

ETHION.

SCHEDULE 7 – continued

ETHOPROPHOS **except** when included in Schedule 6.

ETHYLENE DIBROMIDE.

ETHYLENE OXIDE.

FAMPHUR **except** when included in Schedule 6.

FENAMIPHOS **except** when included in Schedule 6.

FENOXACRIM **except**:

- (a) when included in Schedule 6; or
- (b) in treated carpets.

FENSULFOTHION.

FENTHION **except** when included in Schedule 5 or 6.

FENTHION-ETHYL.

FLOCOUMAFEN **except** when included in Schedule 6.

FLUCOFURON **except**:

- (a) when included in Schedule 6; or
- (b) in treated carpets.

FLUCYTHRINATE.

FLUMIOXAZIN **except** when included in Schedule 6.

FLUOROACETAMIDE.

FLUOROACETIC ACID.

FOLPET.

FORMETANATE.

FOSTHIAZATE.

FURATHIOCARB **except** when included in Schedule 5.

GAMMA-CYHALOTHRIN **except** when included in Schedule 5.

HALOFUGINONE **except** when included in Schedule 4.

HALOGENATED DIBENZODIOXINS AND DIBENZOFURANS.

HCB.

HYDROCARBONS LIQUID AROMATIC (including aromatic extract oils), any fraction of which boils above 350°C **except**:

- (a) when in solid polymers;
- (b) when containing 1 per cent or less of total polycyclic aromatic compounds as measured by IP 346;

SCHEDULE 7 – continued

or

- (c) when having a Mutagenicity Index of zero as measured by ASTM E1687-95.

HYDROCYANIC ACID except:

- (a) when included in Schedule 4; or
(b) its salts and derivatives other than cyanides separately specified in this Schedule.

HYDROFLUORIC ACID (excluding its salts and derivatives) **except** when included in Schedule 5 or 6.

HYDROGEN SULFIDE.

HYDROSILICOFLUORIC ACID (excluding its salts and derivatives) **except** when included in Schedule 5 or 6.

IODOMETHANE.

ISOCARBOPHOS.

ISOFENPHOS.

ISOPROTURON.

IVERMECTIN except when included in Schedule 4 or 5.

LAMBDA-CYHALOTHRIN except when included in Schedule 5 or 6.

LEPTOPHOS.

LITHIUM PERFLUOROOCCTANE SULFONATE except in sealed bait stations containing 1 per cent or less of lithium perfluorooctane sulfonate.

MADURAMICIN except:

- (a) when included in Schedule 5; or
(b) in animal feeds containing 5 mg/kg or less of antibiotic substances.

MALACHITE GREEN for veterinary use **except** when included in Schedule 5.

MAZIDOX.

MECARBAM.

MERCURIC CHLORIDE when prepared for use for agricultural, industrial, pastoral or horticultural purposes.

MERCURY except:

- (a) when separately specified in this Schedule;
(b) when included in Schedule 2, 4 or 6;
(c) in preparations containing 0.01 per cent or less of mercury in organic form as a preservative;
(d) mercury (metallic) in scientific instruments;
(e) dental amalgams; or
(f) in a sealed device, for therapeutic use, which prevents access to the mercury.

SCHEDULE 7 – continued

METHACRIFOS **except** when included in Schedule 6.

METHAMIDOPHOS.

METHAPYRILENE.

METHAZOLE.

METHIDATHION.

METHIOCARB **except** when included in Schedule 5 or 6.

METHOMYL **except** when included in Schedule 6.

METHOXYETHYLMERCURIC ACETATE.

METHOXYETHYLMERCURIC CHLORIDE.

METHYL BROMIDE.

METHYLCYCLOPENTADIENYL MANGANESE TRICARBONYL **except**:

- (a) when included in Schedule 6;
- (b) when used in laboratory analysis; or
- (c) when packed for industrial use in containers with a nominal capacity of 100 L or more.

4,4'-METHYLENEBIS[2-CHLOROANILINE] (MOCA).

METHYLENE BLUE for veterinary use **except** when included in Schedules 4 or 5.

MEVINPHOS.

MIPAFOX.

MIREX.

MOLINATE.

MONOCROTOPHOS.

MOXIDECTIN **except** when included in Schedule 4, 5 or 6.

MSMA **except** when included in Schedule 6.

NAPHTHALOPHOS **except** when included in Schedule 6.

NICOTINE **except**:

- (a) when included in Schedule 6;
- (b) in preparations for human therapeutic use; or
- (c) in tobacco prepared and packed for smoking.

NIMIDANE **except** when included in Schedule 6.

NITROFEN.

SCHEDULE 7 – continued

NITROPRUSSIDES **except** when included in Schedule 4 or 6.

2-NITROTOLUENE.

OMETHOATE **except** when included in Schedule 5 or 6.

OXAMYL.

OXYDEMETON METHYL.

PARAQUAT.

PARATHION.

PARATHION-METHYL **except** when included in Schedule 6.

PENTACHLOROPHENOL **except** when included in Schedule 6.

PHENYLMERCURIC ACETATE **except** in preparations containing 0.01 per cent or less of mercury as a preservative.

PHORATE.

PHOSFOLAN.

PHOSPHIDES, METALLIC.

PHOSPHINE.

PHOSPHORUS, YELLOW (excluding its salts and derivatives).

POTASSIUM NITRITE **except**:

- (a) when included in Schedule 5 or 6;
- (b) in preparations containing 0.5 per cent or less of potassium nitrite;
- (c) when present as an excipient in preparations for therapeutic use; or
- (d) in aerosols containing 2 per cent or less of potassium nitrite.

PROCYMIDONE.

PROPYLENE OXIDE.

PYRINURON.

QUININE for veterinary use **except** when included in Schedule 5.

SAFLUFENACIL **except** when included in Schedule 5.

SCHRADAN.

SELENIUM **except**:

- (a) when included in Schedule 6;
- (b) as selenium arsenide in photocopier drums;
- (c) in preparations for therapeutic use other than:

SCHEDULE 7 – continued

- (i) drench concentrates containing 2.5 per cent or less of selenium; or
- (ii) pour-on preparations containing 0.5 per cent or less of selenium;
- (d) in paints or tinters containing 0.1 per cent or less of selenium calculated on the non-volatile content of the paint or tinter; or
- (e) in fertilisers containing 200 g/tonne or less of selenium.

SEMDURAMICIN **except**:

- (a) when included in Schedule 6; or
- (b) in animal feeds containing 25 mg/kg or less of antibiotic substances.

SODIUM NITRITE **except**:

- (a) when included in Schedule 2, 5 or 6;
- (b) in preparations containing 0.5 per cent or less of sodium nitrite;
- (c) when present as an excipient in preparations for therapeutic use; or
- (d) in aerosols containing 2 per cent or less of sodium nitrite.

STRYCHNINE **except** when included in Schedule 4.

SULCOFURON **except**:

- (a) when included in Schedule 6; or
- (b) in treated carpets.

SULFENTRAZONE.

SULFOTEP.

TEFLUTHRIN **except** when included in Schedule 5.

TEPP.

TERBUFOS.

TETRACHLOROETHANE.

2,2',6,6'-TETRAISOPROPYL-DIPHENYL-CARBODIIMIDE **except** when included in Schedule 6.

THALLIUM.

THIOFANOX.

TIN ORGANIC COMPOUNDS, being di-alkyl, tri-alkyl and tri-phenyl tin compounds where the alkyl group is methyl, ethyl, propyl or butyl **except**:

- (a) when separately specified in this Schedule;
- (b) in plastics;
- (c) in semi-solid sealants, adhesives or elastomers containing 1 per cent or less of the dialkyl, trialkyl or triphenyl tin component; or

SCHEDULE 7 – continued

- (d) in paint containing 1 per cent or less of such compounds calculated as tin in the non-volatile content of the paint.

ortho-TOLIDINE **except** in solid-state diagnostic therapeutic reagents.

TRIAMIPHOS.

TRIAZBUTIL.

TRIBUFOS (S,S,S-tributylphosphorotrithioate).

VINCLOZOLIN.

VINYL CHLORIDE.

ZETA-CYPERMETHRIN **except** when included in Schedule 6.

ZIRAM **except** when included in Schedule 6.

SCHEDULE 8

(Substances marked # are listed in Appendix D.)

ACETYLDIHYDROCODEINE.

ACETYLMETHADOL.

ACETYLMORPHINES.

ALFENTANIL.

ALPHACETYLMETHADOL.

ALPHAPRODINE.

ALPRAZOLAM.

AMPHETAMINE.

AMYLOBARBITONE **except** when included in Schedule 4.

ANILERIDINE.

BENZYL MORPHINE.

BEZITRAMIDE.

BUPRENORPHINE.

BUTOBARBITONE.

BUTORPHANOL.

CARFENTANYL.

COCAINE.

CODEINE **except** when included in Schedule 2, 3 or 4.

CODEINE-N-OXIDE.

CONCENTRATE OF POPPY STRAW (the material arising when poppy straw has entered into a process for concentration of its alkaloids).

4-CYANO-1-METHYL-4-PHENYLPIPERIDINE (Pethidine intermediate A).

CYCLOBARBITONE.

DEXAMPHETAMINE.

DEXTROMORAMIDE.

DEXTROPROPOXYPHENE **except** when included in Schedule 4.

DIFENOXIN **except** when included in Schedule 4.

DIHYDROCODEINE **except** when included in Schedule 2, 3 or 4.

DIHYDROMORPHINE.

SCHEDULE 8 – continued
(Substances marked # are listed in Appendix D.)

DIPHENOXYLATE **except** when included in Schedule 3 or 4.

DIPIPANONE.

DRONABINOL (*delta*-9-tetrahydrocannabinol) when prepared and packed for therapeutic use.

DROTEBANOL.

ETHYLAMPHETAMINE.

ETHYLMORPHINE **except** when included in Schedule 2 or 4.

FENTANYL.

FLUNITRAZEPAM.

HYDROCODONE.

HYDROMORPHINOL.

HYDROMORPHONE.

KETAMINE.

LEVAMPHETAMINE.

LEVOMETHAMPHETAMINE.

LEVOMORAMIDE.

LEVORPHANOL (excluding its stereoisomers).

LISDEXAMFETAMINE.

METHADONE.

METHYLAMPHETAMINE.

METHYLDIHYDROMORPHINE.

METHYLPHENIDATE.

1-METHYL-4-PHENYLPYPERIDINE-4-CARBOXYLIC ACID (Pethidine intermediate C).

MORPHINE.

MORPHINE METHOBROMIDE.

MORPHINE-N-OXIDE.

NABILONE.

NABIXIMOLS (botanical extract of *Cannabis sativa* which includes the following cannabinoids: tetrahydrocannabinol, cannabidiol, cannabinol, cannabigerol, cannabichromene, cannabidiolic acid, tetrahydrocannabinolic acid, tetrahydrocannabivarol, and cannabidivarol, where tetrahydrocannabinol and cannabidiol (in approximately equal proportions) comprise not less than 90 per cent of the total cannabinoid content) in a buccal spray for human therapeutic use.

NORCODEINE.

SCHEDULE 8 – continued
(Substances marked # are listed in Appendix D.)

NORMETHADONE.

OPIUM **except** the alkaloids noscapine in Schedule 2 and papaverine when included in Schedule 2 or 4.

OXYCODONE.

OXYMORPHONE.

PENTAZOCINE.

PENTOBARBITONE **except** when included in Schedule 4.

PETHIDINE.

PHENDIMETRAZINE.

PHENMETRAZINE.

PHENOPERIDINE.

4-PHENYLPYPERIDINE-4-CARBOXYLIC ACID ETHYL ESTER (Pethidine intermediate B).

PHOLCODINE **except** when included in Schedule 2 or 4.

PIRITRAMIDE.

PROPIRAM.

QUINALBARBITONE.

RACEMORAMIDE.

REMIFENTANIL.

SECBUTOBARBITONE.

SODIUM OXYBATE for human therapeutic use.

SUFENTANIL.

TAPENTADOL.

THEBACON.

THEBAINE.

TILIDINE.

SCHEDULE 9

(Trivial or unofficial names are marked *)

ACETORPHINE.

ACETYL-ALPHA-METHYLFENTANYL.

ALKOXYAMPHETAMINES and substituted alkoxyamphetamines **except** when separately specified in these Schedules.

ALKOXYPHENYLETHYLAMINES and substituted alkoxyphenylethylamines **except** when separately specified in these Schedules.

ALKYLTHIOAMPHETAMINES and substituted alkylthioamphetamines **except** when separately specified in these Schedules.

ALLYLPRODINE.

ALPHAMEPRODINE.

ALPHA-METHYLFENTANYL.

ALPHA-METHYLTHIOFENTANYL.

ALPHAMETHADOL.

2-AMINO-1-(2,5-DIMETHOXY-4-METHYL)PHENYLPROPANE *(STP or DOM).

5-(2-AMINOPROPYL)INDAN and substituted 5-(2-aminopropyl)indans **except** when separately specified in these Schedules.

BENZETHIDINE.

BENZOYLINDOLES **except** when separately specified in these Schedules.

BENZYLPIPERAZINE *(BZP).

BETACETYLMETHADOL.

BETA-HYDROXYFENTANYL.

BETA-HYDROXY-3-METHYLFENTANYL.

BETAMEPRODINE.

BETAMETHADOL.

BETAPRODINE.

1-(8-BROMOBENZO[1,2-B;4,5-B]DIFURAN-4-YL)-2-AMINOPROPANE *(Bromo-Dragonfly).

4-BROMO-2,5-DIMETHOXYPHENETHYLAMINE *(BDMPEA).

BUFOTENINE.

CANNABIS **except**:

- (a) when separately specified in these Schedules; or

SCHEDULE 9 – continued
(Trivial or unofficial names are marked *)

- (b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinol and products manufactured from such fibre.

CATHINONE.

CLONITAZENE.

COCA LEAF.

CODOXIME.

4-CYANO-2-DIMETHYLAMINO-4,4'-DIPHENYLBUTANE.

CYCLOHEXYLPHENOLS **except** when separately specified in these Schedules.

DESOMORPHINE.

DIAMPROMIDE.

DIBENZOPYRANS **except** when separately specified in these Schedules.

3,4-DICHLORO-N-{{1-(DIMETHYLAMINO)CYCLOHEXYL}METHYL}BENZAMIDE *(AH-7921).

DIETHYLTHIAMBUTENE.

N,N-DIETHYLTRYPTAMINE *(DET).

DIMENOXADOL.

DIMEPHEPTANOL.

2,5-DIMETHOXYAMPHETAMINE *(DMA).

2,5-DIMETHOXY-4-BROMOAMPHETAMINE *(DOB).

2,5-DIMETHOXY-4-ETHYL- α -AMPHETAMINE *(DOET).

2,5-DIMETHOXY-4-ETHYLTHIOPHENETHYLAMINE *(2C-T-2).

2,5-DIMETHOXY-4-IODOPHENETHYLAMINE *(2C-I).

2,5-DIMETHOXY-4-(N)-PROPYLTHIOPHENETHYLAMINE *(2C-T-7).

3-(2-DIMETHYLAMINOETHYL)-4-HYDROXYINDOLE *(PSILOCINE or PSILOTSIN).

3-(1,2-DIMETHYLHEPTYL)-1-HYDROXY-7,8,9,10-TETRAHYDRO-6,6,9-TRIMETHYL-6H-DIBENZO
(b,d) PYRAN *(DMHP).

N, α -DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE *(MDMA).

N,N-DIMETHYLAMPHETAMINE (Dimetamfetamine).

DIMETHYLTHIAMBUTENE.

N,N-DIMETHYLTRYPTAMINE *(DMT).

DIOXAPHETYL BUTYRATE.

ECGONINE.

SCHEDULE 9 – continued
(Trivial or unofficial names are marked *)

N-ETHYL- α -METHYL-3,4-(METHYLENEDIOXY)PHENETHYLAMINE *(N-ETHYL MDA).

ETHYLMETHYLTHIAMBUTENE.

ETICYCLIDINE *(PCE).

ETONITAZENE.

ETORPHINE.

ETOXERIDINE.

FENETYLLINE.

4-FLUORO-N-METHYLAMPHETAMINE.

1-(5-FLUOROPENTYL)-3-(2-IODOBENZOYL)INDOLE *(AM-694).

FURETHIDINE.

HARMALA ALKALOIDS **except** in herbs, or preparations, for therapeutic use:

- (a) containing 0.1 per cent or less of harmala alkaloids; or
- (b) in divided preparations containing 2 mg or less of harmala alkaloids per recommended daily dose.

HEROIN.

3-HEXYL-1-HYDROXY-7,8,9,10-TETRAHYDRO-6,6,9-TRIMETHYL-6H-DIBENZO (b,d) PYRAN
*(PARAHEXYL).

4-HYDROXYXBUTANOIC ACID and its salts **except** for sodium oxybate when in Schedule 8. *(GAMMA
HYDROXYBUTYRATE (GHB)).

2-[(1R,3S)-3-HYDROXYCYCLOHEXYL]-5-(2-METHYLNONAN-2-YL)PHENOL
*(Cannabicyclohexanol or CP 47,497 C8 homologue).

2-[(1R,3S)-3-HYDROXYCYCLOHEXYL]-5-(2-METHYLOCTAN-2-YL)PHENOL *(CP 47,497).

HYDROXPETHIDINE.

ISOMETHADONE.

KETOBEMIDONE.

LEVOMETHORPHAN (excluding its stereoisomers).

LEVOPHENACYLMORPHAN.

LYSERGIC ACID.

LYSERGIDE.

MECLOQUALONE.

METAZOCINE.

METHAQUALONE.

METHCATHINONE.

SCHEDULE 9 – continued
(Trivial or unofficial names are marked *)

5-METHOXY- α -METHYLTRYPTAMINE *(5-MeO-AMT).

5-METHOXY-3,4-METHYLENEDIOXYAMPHETAMINE *(MMDA).

4-METHOXY- α -METHYLPHENYLETHYLAMINE *(PMA).

2-(2-METHOXYPHENYL)-1-(1-PENTYLINDOL-3-YL)ETHANONE *(JWH-250).

METHYL (2*S*, 4*aR*, 6*aR*, 7*R*, 9*S*, 10*aS*, 10*bR*)-9-ACETOXY-6*a*,10*b*-DIMETHYL-4,10-DIOXO-DODECAHYDRO-2-(3-FURYL)-2*H*-NAPHTHO[2,1-*c*]PYRAN-7-CARBOXYLATE
*(SALVINORIN A).

4-METHYLAMINOREX.

METHYLDESORPHINE.

3,4-METHYLENEDIOXYAMPHETAMINE *(MDA).

3,4-METHYLENEDIOXYPYROVALERONE *(MDPV).

3-METHYLFENTANYL.

4-METHYLMETHCATHINONE *(MEPHEDRONE).

N- α -[METHYL-3,4-(METHYLENEDIOXY)PHENETHYL]HYDROXYLAMINE *(N-HYDROXY
MDA).

N-METHYL-1-(3,4-METHYLENEDIOXYPHENYL)-2-BUTANAMINE *(MBDB).

2-METHYL-3-MORPHOLINO-1, 1-DIPHENYLPROPANE CARBOXYLIC ACID (Moramide intermediate).

1-METHYL-4-PHENYL-4-PIPERIDINOL PROPIONATE *(MPPP).

4-METHYLTHIOAMPHETAMINE.

3-METHYLTHIOFENTANYL.

METOPON.

MITRAGYNA SPECIOSA.

MITRAGYNINE.

MORPHERIDINE.

(1-(2-MORPHOLIN-4-YLETHYL)INDOL-3-YL)-NAPHTHALEN-1-YLMETHANONE *(JWH-200).

MUSCIMOL.

MYROPHINE.

NAPHTHOYLINDOLES **except** when separately specified in these Schedules.

NAPHTHYLMETHYLINDOLES **except** when separately specified in these Schedules.

NAPHTHOYLPYRROLES **except** when separately specified in these Schedules.

NAPHTHYLMETHYLINDENES **except** when separately specified in these Schedules.

SCHEDULE 9 – continued
(Trivial or unofficial names are marked *)

NAPHTHALEN-1-YL-(1-BUTYLINDOL-3-YL)METHANONE *(JWH-073).

NICOCODINE.

NICODICODINE.

NICOMORPHINE.

NORACYMETHADOL.

NORLEVORPHANOL.

NORMORPHINE.

NORPIPANONE.

PARA-FLUOROFENTANYL.

1-PENTYL-3-(4-METHYL-1-NAPHTHOYL)INDOLE. *(JWH-122).

1-PENTYL-3-(1-NAPHTHOYL)INDOLE *(JWH-018).

PHENADOXONE.

PHENAMPROMIDE.

PHENAZOCINE.

PHENCYCLIDINE *(PCP).

N-PHENETHYL-4-PIPERIDONE.

PHENOMORPHAN.

PHENYLACETYLINDOLES **except** when separately specified in these Schedules.

1-PHENYLETHYL-4-PHENYL-4-PIPERIDINOL ACETATE *(PEPAP).

PIMINODINE.

PROHEPTAZINE.

PROPERIDINE.

PSILOCYBINE.

RACEMETHORPHAN.

RACEMORPHAN.

ROLICYCLIDINE *(PHP or PCPY).

SALVIA DIVINORUM.

TENOCYCLIDINE *(TCP).

SYNTHETIC CANNABINOMIMETICS **except** when separately specified in these Schedules.

TETRAHYDROCANNABINOLS and their alkyl homologues **except**:

SCHEDULE 9 – continued
(Trivial or unofficial names are marked *)

- (a) when separately specified in this Schedule;
- (b) when included in Schedule 8;
- (c) in hemp seed oil, containing 50 mg/kg or less of tetrahydrocannabinols when labelled with a warning statement:

Not for internal use; or

Not to be taken; or
- (d) in products for purposes other than internal human use containing 50 mg/kg or less of tetrahydrocannabinols.

THIOFENTANYL.

1-(3-TRIFLUOROMETHYLPHENYL)PIPERAZINE *(TFMPP).

TRIMEPERIDINE.

3,4,5-TRIMETHOXY- α -METHYLPHENYLETHYLAMINE *(TMA).

3,4,5-TRIMETHOXYPHENETHYLAMINE (mescaline) and other substances structurally derived from methoxy-phenylethylamine **except**:

- (a) methoxyphenamine; or
- (b) when separately specified in this Schedule.

1-(3,4,5-TRIMETHOXYPHENYL)-2-AMINOBTANE.

SCHEDULE 10/APPENDIX C

SCHEDULE 10/APPENDIX C

**SUBSTANCES OF SUCH DANGER TO HEALTH AS TO WARRANT
PROHIBITION OF SALE, SUPPLY AND USE**

ABRUS PRECATORIUS (Jequirity) seed or root for therapeutic use.

ACORUS CALAMUS (calamus) for human therapeutic use.

ALKALINE SALTS, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination for domestic use:

- (a) in liquid or semi-solid food additive preparations, the pH of which is more than 11.5;
- (b) in solid automatic dishwashing preparations, the pH of which in a 500 g/L aqueous solution or mixture is more than 12.5; or
- (c) in liquid or semi-solid automatic dishwashing preparations, the pH of which is more than 12.5;

except:

- (a) when in Schedule 5; or
- (b) when in Schedule 6.

ALLYLISOPROPYLACETYLUREA for therapeutic use.

AMINOPHENAZONE (amidopyrine) and its derivatives for human therapeutic use **except:**

- (a) when in Schedule 4; or
- (b) when in Schedule 6.

AMYGDALIN for therapeutic use.

ANCHUSA OFFICINALIS for therapeutic use.

ARISTOLOCHIA spp. for therapeutic use.

ARISTOLOCHIC ACID(S) for human therapeutic use.

ASARUM spp. containing aristolochic acid(s) for human therapeutic use.

AZADIRACHTA INDICA (neem) including its extracts and derivatives, in preparations for human internal use **except:**

- (a) 'de-bitterised neem seed oil'; or
- (b) when in Schedule 5; or
- (c) when in Schedule 6.

BASIC ORANGE 31 (2-[(4-aminophenyl)azo]-1,3-dimethyl-1H-imidazolium chloride) in preparations for skin colouration and dyeing of eyelashes or eyebrows **except** when in Schedule 6.

1,2-BENZENEDIAMINE in preparations for cosmetic use and skin colouration (including tattooing).

SCHEDULE 10/APPENDIX C - continued

1,3-BENZENEDIAMINE in preparations for cosmetic use and skin colouration (including tattooing).

BITHIONOL for human therapeutic use **except** when in Schedule 6.

BORAGO OFFICINALIS (Borage) for therapeutic use **except** the fixed oil derived from the seeds of *Borago officinalis*.

BRAGANTIA spp. containing aristolochic acid(s) for human therapeutic use.

BUCLOSAMIDE for therapeutic use.

BUNIODYL SODIUM for therapeutic use.

1,4-BUTANEDIOL (excluding its derivatives) in non-polymerised form in preparations for domestic use.

CACALIA spp. for therapeutic use.

CARBAMIDE PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 18 per cent of carbamide peroxide **except:**

- (a) in preparations manufactured for, and supplied solely by, registered dental practitioners as part of their dental practice; or
- (b) when in Schedule 5; or
- (c) when in Schedule 6.

CINCHOPHEN and its derivatives for therapeutic use.

CLIOQUINOL and other halogenated derivatives of 8-hydroxyquinoline for human internal use **except** when in Schedule 4 or when being used solely for experimental purposes in humans and where such use:

- (a) is in accordance with:
 - (i) an approval granted under paragraph 19(1)(b) of the *Therapeutic Goods Act 1989*, including any conditions specified in the notice of approval; and
 - (ii) any conditions specified in the *Therapeutic Goods Regulations 1990* for the purposes of subsection 19(1A) of the *Therapeutic Goods Act 1989*; and
 - (iii) any conditions specified in the *Therapeutic Goods Regulations 1990* for the purposes of subsection 19(4A) of the *Therapeutic Goods Act 1989*; or
- (b) is in accordance with the requirements of item 3 of Schedule 5A to the *Therapeutic Goods Regulations 1990*.

COAL TAR for cosmetic use other than in therapeutic goods.

CONIUM MACULATUM (coniine) for therapeutic use.

COTARNINE for therapeutic use.

CROTALARIA spp. for therapeutic use.

CROTON TIGLIUM for therapeutic use.

CYNOGLOSSUM spp. for therapeutic use.

DICOPHANE (DDT) for therapeutic use.

DIETHYLENE GLYCOL for use in toothpastes or mouthwashes **except:**

SCHEDULE 10/APPENDIX C - continued

- (a) in preparations containing 0.25 per cent or less of diethylene glycol; or
- (b) when in Schedule 5; or
- (c) when in Schedule 6

DIETHYLHEXYL PHTHALATE for cosmetic use.

DIETHYLPHthalate in sunscreens, personal insect repellents or body lotion preparations for human use **except** in preparations containing 0.5 per cent or less of diethylphthalate.

5,6-DIHYDROXYINDOLINE for cosmetic use in preparations containing more than 2 per cent of 5,6-dihydroxyindoline **except** when in Schedule 6.

1,3-DIMETHYLAMYLAMINE (DMAA).

DIMETHYLPHthalate in sunscreens, personal insect repellents or body lotion preparations for human use **except** in preparations containing 0.5 per cent or less of dimethylphthalate.

DULCIN for therapeutic use.

ETHYLENE GLYCOL for use in toothpastes or mouthwashes **except:**

- (a) in preparations containing 0.25 per cent or less of ethylene glycol; or
- (b) when in Schedule 5; or
- (c) when in Schedule 6.

ETHYLHEXANEDIOL for human use **except** when in Schedule 4.

EUPATORIUM CANNABINUM (Hemp Agrimony) for therapeutic use.

FARFUGIUM JAPONICUM for therapeutic use.

FORMALDEHYDE (excluding its derivatives):

- (a) in oral hygiene preparations containing more than 0.1 per cent of free formaldehyde;
- (b) in aerosol sprays for cosmetic use containing 0.005 per cent or more of free formaldehyde;
- (c) in nail hardener cosmetic preparations containing 5 per cent or more of free formaldehyde; or
- (d) in all other cosmetic preparations containing 0.05 per cent or more of free formaldehyde ;

except:

- (a) in preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement:
CONTAINS FORMALDEHYDE;
- (b) when in Schedule 2; or
- (c) when in Schedule 6.

HELIOTROPIUM spp. for therapeutic use.

HYDROGEN PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 6 per cent (20 volume) of hydrogen peroxide **except:**

- (a) in preparations manufactured for, and supplied solely by, registered dental practitioners as part of their dental practice;
- (b) when in Schedule 5; or

SCHEDULE 10/APPENDIX C - continued

(c) when in Schedule 6.

JUNIPERUS SABINE [savin(e)] for therapeutic use.

LEAD COMPOUNDS in paints, tinters, inks or ink additives **except**;

(a) in preparations containing 0.1 per cent or less of lead calculated on the non-volatile content of the paint, tinter, ink or ink additive;

(b) when in Schedule 4;

(c) when in Schedule 5; or

(d) when in Schedule 6.

LIGULARIA DENTATA for therapeutic use.

MELIA AZEDARACH including its extracts and derivatives.

METHYLDIBROMO GLUTARONITRILE in preparations intended to be in contact with the skin, including cosmetic use **except** when in Schedule 6.

METHYL METHACRYLATE for cosmetic use **except** in preparations containing 1 per cent or less of methyl methacrylate as residual monomer in a polymer **except** when in Schedule 6.

OXYPHENISATIN for therapeutic use.

PARAFORMALDEHYDE (excluding its derivatives):

(a) in oral hygiene preparations containing more than 0.1 per cent of free formaldehyde;

(b) in aerosol sprays for cosmetic use containing 0.005 per cent or more of free formaldehyde;

(c) in nail hardener cosmetic preparations containing 5 per cent or more of free formaldehyde; or

(d) in all other cosmetic preparations containing 0.05 per cent or more of free formaldehyde ;

except:

(a) in preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement:

CONTAINS FORMALDEHYDE;

(b) when in Schedule 2; or

(c) when in Schedule 6.

PETASITES spp. for therapeutic use.

PHENYLENEDIAMINES, including alkylated and arylated derivatives, in preparations for skin colouration and dyeing of eyelashes or eyebrows **except** when included in Schedule 6.

POTASSIUM HYDROXIDE (excluding its salts and derivatives), in liquid or semi-solid food additive preparations, for domestic use, the pH of which is more than 11.5 **except**:

(a) when in Schedule 5; or

(b) when in Schedule 6.

PTERIDIUM spp. for therapeutic use.

PULMONARIA spp. for therapeutic use.

SAFROLE for internal therapeutic use **except**

SCHEDULE 10/APPNEDIX C - continued

(a) in preparations containing 0.1 per cent or less of saffrole; or

(b) when in Schedule 6.

SENECIO spp. for therapeutic use.

SILICONES for injection or implantation **except** when included in Schedule 4.

SODIUM HYDROXIDE (excluding its salts and derivatives), in liquid or semi-solid food additive preparations, for domestic use, the pH of which is more than 11.5 **except**:

(a) when in Schedule 5; or

(b) when in Schedule 6.

SYMPHYTUM spp. (Comfrey) for therapeutic or cosmetic use **except** when included in Schedule 5.

2,4-TOLUENEDIAMINE in preparations for skin colouration (including tattooing) and dyeing of hair, eyelashes or eyebrows.

TOLUENEDIAMINE in preparations for skin colouration and dyeing of eyelashes or eyebrows **except** when included in Schedule 6.

1,1,1-TRICHLOROETHANE in pressurised spray packs for therapeutic use **except** when in Schedule 5.

TRICHODESMA AFRICANA for therapeutic use.

TRIPARANOL for therapeutic use.

TUSSILAGO FARFARA for therapeutic use.

PART 5
THE APPENDICES

APPENDIX A
GENERAL EXEMPTIONS

This Standard does not apply to a poison in any of the following products:

ALGICIDES, BACTERIOCIDES OR SLIMICIDES for industrial use that do not fit the definition of an agvet chemical product.

BACTERIAL CULTURE MEDIA containing antibiotics.

CERAMICS.

CHEMISTRY SETS for toy and educational use, when complying with the requirements of Australian Standard AS 8124.4-2003 *Safety of toys* entitled *Part 4: Experimental sets for chemistry and related activities*.

COPPER COMPOUNDS in paints.

DEXTRANS, GELATIN – SUCCINYLATED & ETHERIFIED STARCHES used as plasma substitutes/blood volume expanders.

ELECTRICAL ACCUMULATORS, BATTERIES, COMPONENTS or LAMPS.

ELECTRONIC COMPONENTS.

ENHANCING AGENTS for use in ultrasonic and magnetic resonance imaging.

EXPLOSIVES.

FOOD **except:**

- (a) food additives before incorporation into food; or
- (b) when used as a means of administering a poison for therapeutic use.

FRITTED GLAZING OR ENAMELLING PREPARATIONS in which the poison is confined as a non-migratory component of glassy solid flakes or granules.

GLASS (including CRYSTAL WARE).

GLAZED POTTERY.

HUMAN BLOOD PRODUCTS including:

- (a) whole blood;
- (b) blood components including red cells, white cells, platelets and plasma (including cryoprecipitate); and
- (c) the following plasma-derived therapeutic proteins; and their equivalent recombinant alternatives:
 - (i) albumin;
 - (ii) anticoagulation complex;
 - (iii) C1 esterase inhibitors;
 - (iv) clotting factors;

APPENDIX A – continued

- (v) fibrinogen;
- (vi) protein C;
- (vii) prothrombin complex concentrate (PCC) ; and
- (viii) thrombin.

IN VITRO DIAGNOSTIC AND ANALYTICAL PREPARATIONS containing 0.001 per cent or less of a poison included in Schedules 1 to 8.

INTRAOCULAR VISCOELASTIC PRODUCTS.

LUBRICANTS **except** soluble oils and solvent-deposited lubricating agents.

MATCHES.

MEDICAL AND VETERINARY ADHESIVES, GLUES AND CEMENTS.

MEDICAL DEVICES classified as Class III by the classification rules set out in Schedule 2 to the *Therapeutic Goods (Medical Devices) Regulation 2002*, **except**:

- (a) injectable tissue reconstructive, augmentation and restoration materials, including collagen;
- (b) medical devices which include anticoagulants;
- (c) artificial tears;
- (d) urinary catheters; or
- (e) intra-articular fluids.

MOTOR, HEATING or FURNACE FUELS **except**:

- (a) when the contrary intention appears in any Schedule;
- (b) when containing methanol;
- (c) toy or hobby fuels; or
- (d) petrol or kerosene when packed in containers having a capacity of 20 litres or less.

NUTRITION REPLACEMENT PREPARATIONS FOR PARENTERAL ADMINISTRATION.

PAPER **except**:

- (a) when prepared for pesticidal use; or
- (b) when containing a poison included in Schedule 8 or 9.

PHOTOGRAPHIC PAPER or FILM.

PIGMENTS when immobilised in a polymer.

PORCELAIN.

PRINTING INKS or INK ADDITIVES **except**:

- (a) when containing a pesticide; or

APPENDIX A – continued

- (b) preparations containing more than 0.1 per cent of lead calculated on the non-volatile content of the ink or ink additive.

RADIOGRAPHIC CONTRAST MEDIA (radiopaques) for therapeutic use.

RADIOISOTOPES for therapeutic use.

SEEDS treated with seed protectants.

SINGLE-USE TUBES for the estimation of alcohol content of breath.

TERMITE BARRIERS consisting of an active ingredient, other than arsenic, approved by the relevant registration authority, and laminated between impervious sheeting.

TIMBER or WALLBOARD.

VITREOUS ENAMELS.

WRITING CORRECTION PENS which do not allow ingestion of the contents and which contain no scheduled poison other than designated solvents included in Schedule 5.

APPENDIX B
SUBSTANCES CONSIDERED NOT TO REQUIRE CONTROL
BY SCHEDULING

(This Appendix should be read in conjunction with Appendix A.)

INTRODUCTION

Substances for which the available information suggests that inclusion in the Poisons Schedules is not necessary, or not the most appropriate means of controlling the risk to public health, have been considered at various times.

Listing in Appendix B indicates that a decision has been taken not to list substances anywhere in the Schedules, either for a specific purpose, or generally. It is an inclusive, but not an exhaustive, list i.e. there may be substances not included in the Schedules, and not included in Appendix B, which may be hazardous or non-hazardous, but have not been considered in relation to the need for scheduling.

Substances may be included in Appendix B because they have intrinsically low toxicity, or where other factors suggest that the potential public health risk would be minimal. Factors which are considered when determining an Appendix B entry include:

- the toxicology profile was adequately characterised and not consistent with inclusion in any of the Schedules;
- the use, purpose or product presentation minimised any hazard to the public such as to not require scheduling; or
- the public access was limited such that scheduling was inappropriate or unnecessary.

The list was developed from scheduling files and historical records. For transparency, where the reason for entry and/or purpose or use for the substance was apparent in the consideration, this has been included in the columns “Reason for Entry” and “Area of Use”.

Inclusion in Appendix B will not prevent reconsideration of the scheduling of a substance where adverse information becomes available about the Appendix B entry for that substance.

Applications are considered for scheduling. Applications for inclusion in Appendix B will not be accepted.

APPENDIX B

PART 1

REASONS FOR ENTRY

- a Low Toxicity.
- b Use pattern restricts hazard.
- c Presentation/packaging restricts hazard.
- d Industrial use only.

PART 2

AREAS OF USE

- 1. Agricultural
 - 1.1 Herbicide
 - 1.2 Insecticide
 - 1.2.1 Insecticide for codling moth
 - 1.2.2 Termiticide
 - 1.3 Fungicide
 - 1.3.1 On seed fungicide
 - 1.4 Bird Repellent
 - 1.5 Fertiliser
 - 1.6 Plant Growth Regulator
 - 1.7 Insect Pheromone
 - 1.8 Mushroom Bactericide
 - 1.9 Acaricide
 - 1.10 Biological control agent
- 2. Veterinary
 - 2.1 For animal use
 - 2.2 Treatment of mastitis in cows
 - 2.3 Coccidiostat
 - 2.4 Feed additive
 - 2.5 Antiseptic
 - 2.6 Scabicide
 - 2.7 Anthelmintic
 - 2.8 Vitamin/Mineral
 - 2.9 Growth Promotant
 - 2.10 Ectoparasiticide
- 3. Domestic
 - 3.1 Aromatherapy
 - 3.2 Food additive
 - 3.3 Cosmetic
 - 3.4 Human use
 - 3.5 Miticide
- 4. Industrial
 - 4.1 Water treatment
 - 4.2 Biological control agent
- 5. Environmental
 - 5.1 Mosquito control

APPENDIX B, PART 2 – continued

- 6. Human therapeutic use
 - 6.1 Diagnostic agent
 - 6.2 Medical device
 - 6.3 Antiseptic
 - 6.4 Sunscreen
 - 6.5 External use
 - 6.6 Laxative
 - 6.7 Antiseborrheic
 - 6.8 Cytoprotective
 - 6.9 Vitamin/Mineral
 - 6.10 Eye Drops
- 7. General
 - 7.1 Any use
 - 7.2 Excipient
 - 7.3 Synergist
 - 7.4 Flux
 - 7.5 Pesticide
 - 7.6 Insect repellent
 - 7.7 Solvent
 - 7.8 Disinfectant
 - 7.9 Preservative
 - 7.10 Antioxidant
 - 7.11 Resin activator/accelerant
 - 7.12 Sweetener artificial
 - 7.13 Food additive

APPENDIX B

PART 3

**SUBSTANCES CONSIDERED NOT TO REQUIRE CONTROL
BY SCHEDULING**

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
4-[4-(ACETYLOXY)PHENYL]-2-BUTANONE	Feb 2005	b	1.7
<i>AGROBACTERIUM RADIOBACTER</i>	Nov 1989	a	1
ALCOHOL, DEHYDRATED	Aug 2000	b	6
ALUM	May 1997	a	7.1
ALUMINIUM AMMONIUM SULFATE	May 1997	a	7.1
ALUMINIUM POTASSIUM SULFATE	May 1997	a	7.1
ALUMINIUM SILICATE	Nov 1974	a	7.1
ALUMINIUM tris (ETHYLPHOSPHONATE)	Aug 1986	a	1
AMETOCTRADIN	May 2012	a	1.3
AMMONIUM PHOSPHATE	Nov 1974	a	7.1
AMMONIUM THIOSULPHATE	Nov 1974	a	7.1
AMPROLIUM	Jun 1969	a	2.3
AMYL ACETATE	Nov 1974	a	7.1
α -AMYLASE derived from <i>Aspergillus niger</i>	Feb 2005	a	2.4
ANDROSTENEDIONE ALBUMEN CONJUGATE WITH DEA DEXTRAN ADJUNCT	Jun 2004	a	2.1
ASPARTIC ACID	-	a	6
ASULAM	May 1986	a	1
AZIMSULFURON	Jun 2003	a	1.1
<i>BACILLUS SPHAERICUS</i> STRAIN 2362	Feb 2003	a	5.1
<i>BACILLUS THURINGIENSIS</i> (excluding endotoxin)	May 1992 Jun 2003	a a	5.1 2.10
<i>BACILLUS TOYOI</i>	Aug 1980	a	2.9
BACULOVIRUS <i>CYDIA POMONELLA</i>	Jun 2006	a	1.2
BENFLURALIN	-	a	1.1
BENSULFURON-METHYL	Aug 1987	a	1
BENTONITE	Jun 2002	a	7.1
BENZYL BENZOATE	Aug 1989	a	1.3.4
BETAINE HYDROCHLORIDE	Nov 1974	a	7.1
BIFENAZATE	Oct 2002	a	1.9
BISMUTH SUBNITRATE	Nov 1999	b, c	2.1
BISTRIFLURON	Feb 2014	a	1.2.2
BIURET	Nov 1974	a	2.4
BOSCALID	June 2003	a	1.3
BOVINE SOMATOTROPHIN	May 1992	a	2
BROMACIL	Aug 1987	a	1

APPENDIX B, PART 3 – continued

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
BROMOPROPYLATE	Nov 1994	a	1
BUPIRIMATE	Nov 1990	a	1
BUTAFENACIL	May 2000	a	1
BUTOXPOLYPROPYLENE GYLCOL	Nov 1974	a	7.7
n-BUTYL BUTYRATE	-	a	7.1
n-BUTYL LACTATE	-	a	7.1
CARBETAMIDE	Aug 1991	a	1
CARBOXIN	Aug 1987	a	1
CARFENTRAZONE-ETHYL	Aug 1998	a	1
CELLULASE derived from <i>Aspergillus niger</i>	Feb 2005	a	2.4
CETYL ALCOHOL	Nov 1974	a	7.1
CHAMOMILE OIL	Feb 2000	a	3.1
CHINA CLAY	Nov 1974	a	7.1
CHLORANTRANILIPROLE	Sep 2008	a	1.2
CHLORFLUAZURON	Oct 2005	a	1.2.2
CHLORFLURENOL	Feb 1974	a	1.6
CHLORIDAZON	May 1988	a	1
CHLOROXYLENOLS	Feb 1975	a	7.8
CITRONELLA OIL	Feb 2000	a	7.1
CLARY SAGE OIL	Feb 2000	a	7.1
CLOPIDOL	Nov 1974	d	2.3
COBALT NAPHTHENATE	-	d	7.1
COLOPHONY	Feb 1997	b	7.4
CROSPVIDONE	Aug 1996	a	2
<i>CULICINOMYCES CLAVOSPORUS</i>	Nov 1982	a	5.1
CYCLAMIC ACID	Nov 1971	a	7.1
CYCLOHEXANE	Nov 1974	a	7.7
CYCLOHEXANOL ACETATE	-	a	7.7
CYROMAZINE	Nov 1980	a	2
DICLAZURIL	Nov 2001	a	2.3
DIETHYL CARBONATE	-	a	7.1
DIFLUFENICAN	Feb 1987	a	1
DIKEGULAC-SODIUM	Mar 1980	a	1.6
DIMETHICONE		a	7.1
DIMETHYL ETHER	Nov 1988	d	4
DIPHENYLAMINE	Feb 1988	a	1
DIPROPYLENE GLYCOL MONOMETHYL ETHER	Nov 1987	a	4
DIURON	Nov 1987	a	1
DOCUSATE SODIUM (DIOCTYL SODIUM SULFOSUCCINATE)	Feb 1970	a	7.1
2,2-DPA	Nov 1989	a	1
DROMETRIZOLE TRISILOXANE	Oct 2003	a	6.4
EPSIPRANTEL	Nov 1991	a	2

APPENDIX B, PART 3 – continued

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
ETHAMETSULFURON-METHYL	Nov 2000	a	1.1
ETHOPABATE	Jun 1969	d	2.3
ETHYL ACETATE	Nov 1974	a	7.1
ETHYL ALCOHOL	Nov 1974	a	7.1
ETHYLBUTYLACETYL-AMINOPROPIONATE	Aug 2000	a	3.4
ETHYL BUTYRATE	-	a	7.1
ETHYL LACTATE	-	a	7.1
ETOXAZOLE	Oct 2003	a	1.2
<i>EUBACTERIUM</i> sp. strain DSM11798	Sep 2013	a	2.4
FENFURAM	May 1977	a	1.3.1
FENHEXAMID	Feb 1999	a	1
FENOXYCARB	Feb 1988	a	1
FLUFENOXURON	Feb 1997	a	1
FLUMETSULAM	Feb 1992	a	1
FLUOMETURON	Aug 1989	a	1
FLUTOLANIL	Nov 2001	a	1.3
FLUROXYPYR	May 1986	a, c	1
FORCHLORFENURON	Feb 2005	a	1.6
FULLERS EARTH	Nov 1974	a	7.1
FUNGAL PROTEASE derived from <i>Aspergillus niger</i>	Feb 2005	a	2.4
GERANIUM OIL	Feb 2000	a	7.1
GIBBERELIC ACID	Nov 1974	a	1.6
□-GLUCANASE derived from <i>Aspergillus niger</i>	Feb 2005	a	2.4
HALAUXIFEN METHYL	Oct 2014	a	1, 1.1
HEXAFLURON	Nov 1988	a	1
HEXYL ACETATE	-	a	7.7
HEXYTHIAZOX	Feb 1988	a	1
HUMAN OSTEOGENIC PROTEIN-1 (OP-1)	Aug 2001	b	6.2
HYDROPRENE	Feb 1988	a	1
HYDROXYPROPYL CELLULOSE	Nov 1982	a	7.1
ICODEXTRIN	Nov 2000	b	6
INDOLE-3-ACETIC ACID	Feb 1985	b	1.6
ISOPRENE ALCOHOL	-	a	7.1
IPRODIONE	Feb 1997	a	1
ISOSTEARYL ALCOHOL ETHOXYLATE	Nov 1999	a	5.1
KAOLIN	Nov 1974	a	7.1
KRESOXIM-METHYL	Aug 1999	a	1
KUNZEA OIL	Feb 2000	a	7.1
LAURIC ACID	Oct 2005	a	7.1
LAURYL ALCOHOL (1-DODECANOL)	Nov 1974	a	7.1
LAVANDIN OIL	Feb 2000	a	7.1
LAVENDER OIL	Feb 2000	a	7.1

APPENDIX B, PART 3 – continued

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
LEAD METALLIC	-	a	7.1
LEMONGRASS OIL	Feb 2000	a	7.1
LEPIDOPTEROUS SEX PHEROMONES	Nov 1990	a	1
LIMONENE (DIPENTENE)	Jun 2002	a	7.1
LINOLEIC ACID	Oct 2005	a	7.1
LINSEED FATTY ACIDS	Aug 1990	a	2.1
LINURON	Feb 1990	a	1
LIQUORICE, DEGLYCYRRHISINISED	May 1999	a	7.1
MALEIC HYDRAZIDE	Nov 1992	a	1
MANGANESE DIOXIDE	May 1999	b	1
<i>MEGASPHERA ELSDENII</i> strain 41125	Sep 2013	a	2.4
MESOLSULFURON-METHYL	Feb 2002	a	1.1
<i>METARHIZIUM ANISOPLIAE</i>	Feb 2000	b	4.2
<i>METARHIZIUM ANISOPLIAE</i>	Jun 2003	a	1.10
METHOPRENE	Aug 1987	a	1
METHOXYFENOZIDE	Nov 2000	a	1
METHYL ACETATE	-	a	7.7
METHYL BENZOQUATE	Nov 1974	d	2.3
1-METHYLCYCLOPROPENE	Jun 2003	a	1.6
METHYL p-HYDROXYBENZOATE	Nov 1974	a	7.9
METSULFURONMETHYL	Nov 1985	a	1.1
MYRISTIC ACID	Oct 2005	a	7.1
NAPROPAMIDE	Aug 1987	a	1
NAPHTHYL ACETAMIDE	Nov 1974	a	1.6
NEROLI OIL	Feb 2000	a	7.1
NICARBAZIN	Jun 1969	d	2.3
NISIN	Jun 2003	a	3.2
NORFLURAZON	Nov 1983	a	1.1
NOVALURON	Nov 2000	a	1
NUCLEAR POLYHEDROSIS VIRUS of <i>Helicoverpa armigera</i> occlusion bodies	Feb 2004	a	1.2
OCTYL ALCOHOLS	Nov 1974	a	7.1
OLEIC ACID	Oct 2005	a	7.1
ORANGE OIL, SWEET	Aug 2000	a	7.1
OXABETRINIL	Feb 1987	a	1
OXYFLUORFEN	May 2001	a	1
PALMAROSA OIL	Feb 2000	a	7.1
PALMITIC ACID	Oct 2005	a	7.1
PATCHOULI OIL	Feb 2000	a	7.1
PECTINASE derived from <i>Aspergillus niger</i>	Feb 2005	a	2.4
PENCYCURON	Aug 1994	a	1
PENTADECANOIC ACID	Oct 2005	a	7.1
PEPPERMINT OIL	Feb 2000	a	7.1
PHENMEDIPHAM	May 1989	a	1.1

APPENDIX B, PART 3 – continued

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
d-PHENOTHRIN	Feb 1982	a	7.5, 1.2
PHYTASE	Feb 1996	a	2.4
PICLORAM	Aug 1987	a	1
PICOLINAFEN	May 2000	a	1
PIMELIC ACID	Oct 2005	a	7.1
PIPERONYL BUTOXIDE	Aug 1991	a	7.5
POLOXALENE	Nov 1974	a	7.1
POLY DIALLYL DIMETHYL AMMONIUM CHLORIDE (PolyDADMAC)	Nov 1997	a	4.1
POLYHEDROSIS VIRUS of <i>Helico zea</i> occlusion bodies	Nov 1996	a	1
POLY (GNRF) OVALBUMIN	Feb 1990	a	2
POLYSORBATE 20	May 2001	a	1
PORCINE SOMATOTROPHIN	Nov 1991	c	2
POTASSIUM SORBATE	Oct 2004	a	1.3
POTASSIUM BICARBONATE	Jun 2004	a	1
PROPYL ACETATES	-	a	7.1
PROPYLENE GLYCOL	Nov 1974	a	7.1
2-PROPYLENE GLYCOL 1-MONOMETHYL ETHER	Nov 1987	a	4
PROTHIOCONAZOLE	June 2005	a	1.3.1
<i>PSEUDOMONAS FLUORESCENS</i>	May 1985	a	1.8
PYRIMETHANIL	Feb 1996	a	1
PYRIPROXYFEN	Aug 1994	a	1
QUASSIA	Nov 1974	d	6, 2.1
QUINOXYFEN	Nov 2001	a	1.3
ROSEMARY OIL	Feb 2000	a	7.1
SAGE OIL (Spanish)	Feb 2000	a	7.1
SANDALWOOD OIL	Feb 2000	a	7.1
SEAWEED & UNFRACTIONED SEAWEED EXTRACTS	Feb 1985	d	1.5
SIMAZINE	Nov 1987	a	1.1
SODIUM BICARBONATE	Jun 2004	a	1
SODIUM PROPIONATE	Oct 2004	a	1.3
STERIC ACID	Oct 2005	a	7.1
SUCRALFATE	Aug 1982	a	6.8
SULESOMAB	Jun 2002	b	6.1
SULFOSULFURON	Feb 1998	a	1
SULPHATED POLYSACCHARIDES	-	a	7.1
TANNIC ACID	Dec 1965	a	7.1
TANNIC ACID/BENZYL ALCOHOL PRODUCT	Nov 1993	a	7.1
TERBACIL	Aug 1987	a	1
THAUMATIN	Nov 1990	a	3.2
THIDIAZURON	Nov 1989	a	1

APPENDIX B, PART 3 – continued

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
TRIASULFURON	Feb 1988	a	1
TRICHODERMA HARZIANUM	May 1996	a	1
(Z)-9-TRICOSENE	Aug 1991	a	1
TRIETHYLENE GLYCOL	Nov 1974	a	7.1
TRIFLOXYSULFURON	Feb 2002	a	1.1
TRIFLURALIN	Aug 1990	a	1
TRIFORINE	Aug 1987	a	1
ULOCLADIUM OUDEMANSII	Oct 2003	a	1.10
UREA	Nov 1974	a	7.1
¹³ C-UREA	May 2001	a	6.1
VETIVER OIL	Feb 2000	a	7.1
VINYL ETHER	Nov 1987	b	6
VITAMIN K	Jul 1963	a	6.9, 2.8
XANTHOPHYLL (lutein)	Nov 1974	a	7.1
XYLANASE derived from <i>Aspergillus niger</i>	Feb 2005	a	2.4
YLANG YLANG OIL	Feb 2000	a	7.1
ZINC NAPHTHENATE	-	a	1.3

APPENDIX C (see SCHEDULE 10)

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APPENDIX D

ADDITIONAL CONTROLS ON POSSESSION OR SUPPLY OF POISONS INCLUDED IN SCHEDULE 4 OR 8

(The following controls apply for the substances shown only when included in Schedule 4 or Schedule 8.)

1. Poisons available only from or on the prescription or order of an authorised medical practitioner.

CLOMIPHENE for human use.
CLOZAPINE for human use.
CORIFOLLITROPIN ALFA (recombinant follicle stimulant) for human use.
CYCLOFENIL for human use.
DINOPROST for human use.
DINOPROSTONE for human use.
FOLLITROPIN ALPHA (recombinant human follicle-stimulating hormone) for human use.
FOLLITROPIN BETA (recombinant human follicle-stimulating hormone) for human use.
LUTEINISING HORMONE for human use.
NABIXIMOLS.
SODIUM OXYBATE for human use.
TERIPARATIDE for human use.
UROFOLLITROPIN (human follicle-stimulating hormone) for human use.

2. Poisons available only from or on the prescription or order of a specialist physician or a dermatologist and for which the prescriber must, where the patient is a woman of child-bearing age:

- (1) ensure that the possibility of pregnancy has been excluded prior to commencement of treatment; and
- (2) if the drug is -
 - (a) acitretin or etretinate, advise the patient to avoid becoming pregnant during or for a period of 24 months after completion of treatment; or
 - (b) bexarotene, isotretinoin or thalidomide, advise the patient to avoid becoming pregnant during or for a period of 1 month after completion of treatment.

ACITRETIN for human use.
BEXAROTENE for human use.
ETRETINATE for human use.
ISOTRETINOIN for human oral use.
THALIDOMIDE for human use.

3. Poisons available only from or on the prescription or order of a medical practitioner authorised or approved by the Secretary of the Commonwealth Department of Health and Ageing under section 19 of the *Therapeutic Goods Act 1989*.

DRONABINOL (delta-9-tetrahydrocannabinol).

4. Poisons available only from or on the order of a specialist physician and for which the prescriber must, where the patient is a woman of child bearing age:

- (a) ensure that the possibility of pregnancy has been excluded prior to commencement of treatment; and
- (b) advise the patient to avoid becoming pregnant during or for a period of 1 month after completion of treatment.

LENALIDOMIDE.
RIOCIGUAT for human use.

TRETINOIN for human oral use.

5. Poisons for which possession without authority is illegal (e.g. possession other than in accordance with a legal prescription).

ANABOLIC STEROIDAL AGENTS, including those separately specified in Schedule 4.

ANDROGENIC STEROIDAL AGENTS, including those separately specified in Schedule 4.

BENZODIAZEPINE DERIVATIVES, including those separately specified in Schedule 4 and Schedule 8.

DARBEOETIN.

DEXTROPROPOXYPHENE.

EPHEDRINE.

EPOETINS.

ERYTHROPOIETIN.

ERYTHROPOIETINS **except** when separately specified in this Appendix.

FOLLISTATIN.

GLUTETHIMIDE.

INSULIN-LIKE GROWTH FACTORS.

PERAMPANEL for human use.

PHENTERMINE.

SELECTIVE ANDROGEN RECEPTOR MODULATORS (SARM), including those separately specified in Schedule 4.

SOMATROPIN (human growth hormone).

6. Poisons available only from or on the prescription or order of a specialist physician and for which the prescriber must, where the patient is a woman of child-bearing age:

(a) ensure that the possibility of pregnancy has been excluded prior to commencement of treatment; and

(b) advise the patient to avoid becoming pregnant during and for a period of 3 months after completion of treatment.

AMBRISENTAN for human use.

BOSENTAN for human use.

MACITENTAN for human use.

SITAXENTAN for human use.

7. Poisons available only from or on the prescription or order of a dermatologist.

ALEFACEPT for human use.

APPENDIX E

FIRST AID INSTRUCTIONS FOR POISONS

(other than agricultural and veterinary chemicals (including pesticides) registered by the Australian Pesticides and Veterinary Medicines Authority and medicines for human use when compliant with the requirements of the *Required Advisory Statements for Medicine Labels*)

INTRODUCTION

Directions for First Aid Attention

Under poisons legislation, scheduled substances and their preparations are required to be labelled with appropriate directions for first aid attention in case of poisoning. It is the responsibility of the manufacturer, packer and supplier of a drug or poison to ensure that the first aid instructions included on the label of a poison are appropriate for a specific product. The following code has been prepared as a guide for health authorities and manufacturers in drafting suitable first aid directions for this purpose. Standard statements specified in this Appendix may be varied provided that the intent is not changed.

The directions listed for any particular substance may require modification to take into account combination of that substance with other substances, both toxic and non toxic, in a formulation, as well as the physical form and presentation of the product. Any such modification should be concise and readily understood.

These First Aid Instructions include action to be taken in case of eye contamination from substances recognised as causing direct poisoning via the eye, causing severe eye damage or requiring prolonged flushing to free the absorbed substance from the eye tissue. However, it is recognised that many other substances or preparations will require a statement of varying nature depending on the detailed formulation. While the necessity to flush the eyes in case of accident will be so self-evident as not to justify label space in many instances, a statement such as "If in eyes rinse well with water" may be appropriate.

Modified First Aid Instruction on Primary Pack

Where a primary pack contains two or more immediate containers of poisons each requiring different first aid instructions:

- (a) each immediate container must be labelled with first aid instructions appropriate for its contents; and
- (b) the primary pack must be labelled with the statement:

FIRST AID: See inner packs.

Exempt Preparations

This Appendix applies only to scheduled poisons. The directions are for substances and their preparations at the concentrations at which the Schedules apply. If it is thought desirable to show first aid instructions for a substance exempted from the schedules, it is the responsibility of the manufacturer to ensure they are appropriate.

Poisons Information Centre Telephone Numbers

Companies should use the Poisons Information Centre telephone number(s) (Australia 13 11 26; New Zealand 0800 764 766) appropriate to the country(ies) of sale for the product.

Companies wishing to use a poisons information centre telephone number other than the national telephone numbers for Australia and New Zealand must meet the following criteria:

1. the poisons information service whose number is used must be attended by adequately trained staff for 24 hour emergency poisons information; and
2. calls must be logged and submitted for incorporation into the official collection of poisoning data.

APPENDIX E

PART 1

STANDARD STATEMENTS

To be grouped together and prefaced with the words “FIRST AID” (see subparagraph 7(p) of this Standard).

Basic

- A For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once).
- Z First aid is not generally required. If in doubt, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.

General

- G1 Urgent hospital treatment is likely to be needed.
(Note – the words ‘at once’ to be added to instruction A).
- G2 If swallowed, give activated charcoal if instructed.
(Note – the words ‘at once’ to be added to instruction A).
- G3 If swallowed, do NOT induce vomiting.
- G4 Immediately give a glass of water.
- G5 Avoid giving milk or oils.
- G6 If sprayed in mouth, rinse mouth with water.

Eyes

- E1 If in eyes wash out immediately with water.
- E2 If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor, or for at least 15 minutes.

Respiratory system

- R1 If inhaled, remove from contaminated area. Apply artificial respiration if not breathing.
- R2 If swallowed or inhaled, remove from contaminated area. Apply artificial respiration if not breathing. Do not give direct mouth-to-mouth resuscitation. To protect rescuer, use air-viva, oxy-viva or one-way mask. Resuscitate in a well-ventilated area.

Skin

- S1 If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.
- S2 If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water. Continue flushing with water until advised to stop by a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.
- S3 If on skin, remove any contaminated clothing, wash skin thoroughly with soap and water, then methylated spirit if available. Contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.

APPENDIX E, PART 1 – continued

- S4 If on skin, immediately remove any contaminated clothing, wash skin with methylated spirit or PEG (polyethylene glycol) 300 or 400 if available, then flush under running water until advised to stop by a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.
- S5 If skin contact occurs, immediately remove contaminated clothing. Flush skin under running water for 15 minutes. Then apply calcium gluconate gel. Contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766).

Special Purpose

- SP1 If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

APPENDIX E

PART 2

FIRST AID INSTRUCTIONS

Standard statements in this Appendix apply to poisons other than agricultural and veterinary chemicals (including pesticides) registered by the Australian Pesticides and Veterinary Medicines Authority. Labelling is not required at concentrations below scheduled levels (see the Introduction to this Appendix).

POISON	STANDARD STATEMENTS
ACETIC ACID	A,G3,E2,S1
ACETIC ANHYDRIDE	A,G3,E2,S1
ACETONE	A,G3
ACROLEIN	A,G1,G2,G3,E2,R2,S2
ALKALINE SALTS	A,G3,E2,S1
AMINES for use as curing agents	A,G3,E1,S1
4-AMINOPYRIDINE	A,G1,G2,E1,S1
AMMONIA	
• 5 per cent or less	A
• above 5 per cent	A,G3,E1,R1,S1
AMMONIUM PERSULFATE	A,G3,E2
AMMONIUM THIOCYANATE	A
ANHYDRIDES, organic acid, for use as curing agents for epoxy resins	A,G3,E1,S1
ANILINE	A,E2,R1,S1
ANISE OIL	A,G3
ANTIMONY CHLORIDE	A,E2,S2
ANTIMONY COMPOUNDS, except antimony chloride	A
AZADIRACHTA INDICA (neem) including its extracts and derivatives when included in Schedule 6.	A,E1
BARIUM SALTS, except barium sulfate	A
BASIL OIL	A,G3
BAY OIL	A,G3

POISON	STANDARD STATEMENTS
BENZALKONIUM CHLORIDE	
• when included in Schedule 5	A,G3,E2
• when included in Schedule 6	A,G3,E2,S1
BENZENE	A,G3,E1,R1,S1
1,2-BENZENEDIOL (Catechol)	A,E1,S1
BENZOYL PEROXIDE	
• above 20 per cent	A,E2,S1
• above 10 per cent up to 20 per cent	A,E1
• 10 per cent or less	A
BERGAMOT OIL	A,G3
BIFLUORIDES (including ammonium, potassium and sodium salts)	
• when included in Schedule 5	A
• when included in Schedule 6 or 7	A,G3,E2,S5
BORAX	A
BORIC ACID	A
BORON TRIFLUORIDE	
• when included in Schedule 5	A
• when included in Schedule 6 or 7	A,G3,E2,S5
BROMOFORM	A,G3,E2,R1,S2
BRUCINE	A,G1,G2,G3,R2
2-BUTOXYETHANOL and its acetates	A,E2,S1
CADMIUM COMPOUNDS	A
CAJUPUT OIL	A,G3
CAMPHOR	A,G1,G3,G5
CARBAMIDE PEROXIDE	
• more than 9 per cent up to 60 per cent	A,G3,E2,S1
• more than 60 per cent	A,G1,G3,G4,E2,S1
CARBON DISULFIDE	A,G3,E2,R1,S2

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
CARBON TETRACHLORIDE	A,G3,E1,R1,S1
CASSIA OIL	A,G3
CHLORINATING COMPOUNDS, except when separately specified, containing	
• above 4 per cent and below 10 per cent of available chlorine	A,G3,E1,S1
• 10 per cent or more of available chlorine	A,G3,E2,S1
CHLORIDE (gas)	A,E1,R1
CHLOROCRESOL	A,G3,E2,S2
CHLOROFORM	A,G3,E1,R1,S1
CHROMATES	A,G3,E2,S1
CHROMIUM TRIOXIDE	A,G3,E2,S1
CINEOLE	A,G1,G3
CINNAMON BARK OIL	A,G3
CINNAMON LEAF OIL	A,G3
CLIMBAZOLE	A
CLOVE OIL	A,G1,G3,E2
COCOYL GLYCINATE	E1
COPPER SULFATE	A,G3,E2,S1
CREOSOTE	A,G3,E2,S1
CRESOLS	A,G3,E2,S3
CRESOLS in pressurised spray packs	A,G6,E1,S1
CYANIDES	A,G1,E1,R2
CYANOACRYLIC ACID ESTERS	A
CYANURIC ACID	A
CYCLOHEXANONE PEROXIDE	A,G3,E2,S1
CYCTEAMINE	E1
ortho-DICHLOROBENZENE	A,G3,E1,S1
para-DICHLOROBENZENE (PDB)	A
DICHLOROETHYL ETHER	A,G3,E1,R1,S1

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
DICHLOROISOCYANURATES	A,G3,E1,S1
DICHLOROMETHANE (methylene chloride)	A,G3,G5,E1,R1,S1
• in pressurised spray packs	A,G6,S1
DICHROMATES	A,G1,G3,E2,S1
DIDECYLDIMETHYLAMMONIUM SALTS	A,G3
DIESEL (distillate)	A,G3
DIETHANOLAMINE	
• when included in Schedule 5	A,G3
• when included in Schedule 6	A,G3,E2,S1
5,6-DIHYDROXYINDOLINE	E1
DIMETHYLFORMAMIDE	
• less than 75 per cent	A
• 75 per cent or more	A,E1,R1,S1
DIMETHYL SULFOXIDE	A,G3,E1,S1
DINITROCRESOLS	A,G1,E1,S1
DINITROPHENOLS	A,G1,E1,S1
DIOXANE	A,G3,E1,R1,S1
DISTILLATE	A,G3
N-(N-DODECYL)-2-PYRROLIDONE	
• when included in Schedule 5	A,G3,E1
• when included in Schedule 6	A,G3,E2,S1
EPOXY RESINS liquid	A,G3,E2,S1
Essential oils containing CAMPHOR as natural component unless otherwise specified.	A,G3
ETHANOLAMINE	
• when included in Schedule 5	A,G3,E1
• when included in Schedule 6	A,G3,E2,S1
ETHER	A,G3,E1,R1
ETHYL BROMIDE	A,E2,S1,R1

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
ETHYLENE GLYCOL	A
ETHYLENE GLYCOL MONOALKYL ETHERS and their acetates, except when separately specified	A,G3,E2,S1
ETHYLENE OXIDE	A,E2,R1
EUCALYPTUS OIL	A,G1,G3
EUGENOL	A,G1,G3,E2
FLUORIDE except when separately specified	
• when included in Schedule 5	A
• when included in Schedule 6	A,G1,G3,E2,S1
FORMALDEHYDE (see also paraformaldehyde)	A,G3,E2,R1,S1
FORMIC ACID	A,G3,E2,S1
FURFURAL	A,E1,S1
GLUTARALDEHYDE	
• below 5 per cent	A,G3,E1
• 5 per cent or more	A,G3,E2,S1
GLYCOLIC ACID	A,G3,E2
GUANIDINE when included in Schedule 6	A,G3,E2,S1
HEXACHLOROPHANE when included in Schedule 6	A
HEXYLOXYETHANOL	A,G3,E2,S1
HYDRAZINE	A,G1,G3,E2,R1,S1
HYDROCARBONS, liquid	A,G3
HYDROCHLORIC ACID	A,G3,E2,S1
• when included in Schedule 5	A,G3
HYDROFLUORIC ACID and admixtures that generate hydrofluoric acid	
• when included in Schedule 5	A
• when included in Schedule 6 or 7	A,G3,E2,S5

POISON	STANDARD STATEMENTS
HYDROGEN PEROXIDE	
• more than 3 per cent up to 20 per cent	A,G3,E2,S1
• more than 20 per cent	A,G1,G3,G4,E2,S1
HYDROQUINONE	
• when included in Schedule 2	A
• when included in Schedule 4 or 6	A,G2,G3,E2,R2,S1
HYDROSILICOFLUORIC ACID	
• when included in Schedule 5	A
• when included in Schedule 6 or 7	A,G3,E2,S5
IODINE (excluding salts, derivatives and iodophors)	
• 2.5 per cent or more for human external use	A,E2
• 2.5 per cent or more for other uses	A,E2,S1
• below 2.5 per cent	A
IODOPHORS	A
ISOCYANATES, free organic	A,E2,S1
ISOPHORONE	A,G3,E2,S1
KEROSENE	A,G3
LAURETH CARBOXYLIC ACIDS	
• leave-on or wash-off preparations above 5 per cent	E1
• other preparations above 5 per cent	E1,S1
LAURYL ISOQUINOLINIUM BROMIDE	A,E1
LEAD COMPOUNDS	
• in hair cosmetics	A
• in other preparations	A,S1
LEMON OIL	A,G3
<i>LEPTOSPERMUM SCOPARIUM</i> OIL (manuka oil)	A,G1,G3
LIME OIL	A,G3
MAGNESIUM CHLORATE	A
MALATHION at 20 per cent or less	A

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
MARJORAM OIL	A,G3
MELALEUCA OIL	A,G1,G3
MERURIC CHLORIDE	
• for external therapeutic use	A
• for other uses	A,G1,G3,E2,R2,S1
MERCURIC IODIDE	A,G1,G3,E2,R2,S1
MERCURIC NIRATE	A,G1,G3,E2,R2,S1
MERCURIC OXIDE	A,G1,G3
MERCURIC POTASSIUM IODIDE	A,G1,G3,E2,R2,S1
MERCURIC THIOCYANATE	A,G1,G3,E2,R2,S1
MERCUROCHROME	A
MERCUROUS CHLORIDE	A
MERCURY metallic	A
MERCURY, organic compounds	A,S1
• in preparations for human external use	A
METALDEHYDE	A,E1,S1
METHANOL	
• above 10 per cent	A,G3
• 10 per cent or less	A
METHYLATED SPIRIT	A,G3
METHYL ETHYL KETONE	A,G3
METHYL ETHYL KETONE OXIME	A,E1,S1
METHYL ETHYL KETONE PEROXIDE	A,G3,E2,S1
METHYLEUGENOL	A
METHYL ISOAMYL KETONE	A,G3
METHYL ISOBUTYL KETONE	A,G3
N-METHYL-2-PYRROLIDONE	
• when included in Schedule 5	A,G3,E1

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
• when included in Schedule 6	A,G3,E2
METHYL SALICYLATE LIQUID when included in Schedule 5 or 6	A,G3,E1
NAPHTHALENE	A,G1,G3
NITRIC ACID	A,G3,E2,S1
NITROBENZENE	A,G3,E1,S1
NITROPHENOL	A,G3,E2,S1
NITROPRUSSIDES	
• in aerosols	A,G6,R1
• in other preparations	A,G3
NONOXINOL 9	A,E2
NUTMEG OIL	A,G3
2-OCTYL-4-ISOTHIAZOLIN-3-ONE (Ocithilinone)	A,G3,E2,S1
N-(N-OCTYL)-2-PYRROLIDONE	
• when included in Schedule 5	A,G3,E1
• when included in Schedule 6	A,G3,E2
ORANGE OIL (bitter)	A,G3
OXALIC ACID	A,G3,E2,S1
PARAFORMALDEHYDE	A,G3,E2,R1,S1
PENNYROYAL OIL	A,G3
PERACETIC ACID	
• when included in Schedule 5	A,G3,E1,S1
• when included in Schedule 6	A,G3,E2,S1
PETROL	A,G3,R1
2-PHENOXYETHANOL	A, E1
PHENOLS	
• 25 per cent and less	A,G3,E2,S3
• above 25 per cent	A,G3,E2,S4
PEHNOLS in pressurised spray packs	A,E1

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
PHENYLENEDIAMINES and ALKYLATED PHENYLENEDIAMINES	
• in hair dyes	A,E1
• in other preparations	A,G1,G3,E1,S1
PHENYL METHYL KETONE	
• as such, or in preparations of similar viscosity	A,G3,E1
N,N-BIS(PHENYLMETHYLENE)-BICYCLO -(2.2.1)HEPTANE-2,5-DIMETHANAMINE	A,E2,S1
N,N-BIS(PHENYLMETHYLENE)-BICYCLO- (2.2.1)HEPTANE-2,6-DIMETHANAMINE	A,E2,S1
ortho-PHENYLPHENOL	A,G3,E2,S1
• in pressurised spray packs	A,G6,E2,S1
PHOSPHONIC ACID	A,G3,E2,S1
• neutralised to pH 6 (approx)	A
• in spray packs	A,E2,S1
PHOSPHORIC ACID	A,G3,E2,S1
PHOSPHORUS, yellow	A,G1,G3,E2,R2,S2
ortho-PHTHALALDEHYDE	
• when included in Schedule 5	A,E1
• when included in Schedule 6	A,G3,E2,S1
PICRIC ACID	A,G1,G3,E2,R1,S1
POLYETHANOXY (15) TALLOW AMINE	A,E2,S1
POLY(OXY-1,2-ETHANEDIYL), A - [2-[(2-HYDROXYETHYL)AMINO]-2- OXOETHYL]- A -HYDROXY-,MONO-C ₁₃₋₁₅ - -ALKYL ETHERS	A,E1
POTASIUM BROMATE	A
POTASIUM CHLORATE	A
POTASSIUM CYANATE	A,E1,S1
POTASSIUM HYDROXIDE	A,G3,E2,S1
POTASSIUM METABISULPHITE	A
POTASSIUM NITRITE	

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
• when included in Schedule 7	A,G1,G3
• when included in Schedule 5 or 6	A,G3
POTASSIUM PEROXOMONOSULFATE TRIPLE SALT	
• when included in Schedule 5	A,G3,E1
• when included in Schedule 6	A,G3,E2,S1
POTASSIUM PERSULFATE	A,G3,E2
POTASSIUM SULFIDE	A,G3,E2,S1
PROPIONIC ACID	A,G3,E1,S1
d-PULEGONE	A,G3
PYRITHIONE ZINC	A,E1
QUATERNARY AMMONIUM COMPOUND	Error! Bookmark not defined. except
when separately specified	
• above 20 per cent	A,G3,E2
• 20 per cent and below	A,E2
• in pressurised spray packs	A,E2,G6
SALFROLE	A,G1,G3
SAGE OIL (Dalmatian)	A,G3
SASSAFRAS OIL	A,G1,G3
SELENIUM COMPOUNDS	A,G1,E1,S1
SILICOFLUORIDES	
• when included in Schedule 5	A
• when included in Schedule 6	A,G1,G3,E2,S1
SILVER SALTS	A,E2
SODIUM ALUMINATE	A,G3,E2,S1
SODIUM BROMATE	A,G1
SODIUM CHLORATE	A
SODIUM DIACETATE	A,G3,E2,S1
SODIUM DICHLOROISOCYANURATE	A,G3,E1,S1
SODIUM DODECYLBENZENE SULFONATE	A,G3,E2,S1

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
SODIUM HYDROGEN SULFATE	A,G3,E1,S1
SODIUMHYDROSULFITE	A,G3,E2,S1
SODIUM HYDROXIDE	A,G3,E2,S1
SODIUM LAURETH-6 CABOXYLATE	A
SODIUM LAURYL SULFATE	
• leave-on or wash-off preparations above 5 per cent	E1
• other preparations above 5 per cent	E1,S1
SODIUM METABISULPHITE	A, G3
SODIUM NITRITE	
• when included in Schedule 7	A,G1,G3
• when included in Schedule 5 or 6	A,G3
SODIUM PRECARBONATE	
• when included in Schedule 5	A,G3,S1
• when included in Schedule 6	A,G3,E2,S1
SODIUM PERSULFATE	A,G3,E2
SODIUM STANNATE	A,E1
SODIUM SULFIDE	A,G3,E2,S1
SODIUM TRICHLOROACETATE	A
STRCHNINE	A,G1,G2,G3,R2
STYRENE	A,G3,S1,E1
SULCOFURON	A
SULFAMIC ACID	A,G3,E2,S1
SULFURIC ACID	A,G3,E2,S1
TERPENES, chlorinated	A,G3
TETRACHLOROETHANE	A,G3,E1,R1,S1
TETRACHLOROETHYLENE	A,G3,E2,R1,S1
THIOUREA	A
THUJONE	A,G3
THYME OIL	A,G3

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
ortho-TOLIDINE	A
TOLUENE	
• above 75 per cent	A,G3,E1,R1,S1
• 75 per cent and below	A,G3
• in pressurised spray packs	A
TOLUENEDIAMINE	
• in hair dyes	A,E1
• in other preparations	A,G1,G3,E1,S1
TRICHLOROACETIC ACID	A,G3,E2,S1
TRICHLOROACETIC ACID ALKALI SALTS	A
1,1,1-TRICHLOROETHANE	A,G3,E1,R1,S1
TRICHLOROETHYLENE	A,G3,E1,R1,S1
TRICHLOROISOCYANURIC ACID	A,G3,E1,S1
TRIETHANOLAMINE	A,G3,E1,S1
TRIETHYL PHOSPHATE	A,E1
TRIFLUOROMETHANESULFONIC ACID	A,G3,E2
TRIIISOPROPANOLAMINE LAURYL ETHER SULFATE	A,E1,S1
TURPENTINE (mineral)	A,G3
TURPENTINE OIL (vegetable)	A,G3,E2
WHITE SPIRIT	A,G3
XYLENE	
• above 75 per cent	A,G3,E1,R1,S1
• 75 per cent and below	A,G3
• in pressurised spray packs	A,G6,E1,S1
XYLENOLS	A,G3,E2,S3
• in pressurised spray packs	A,E1
ZINC CHLORIDE	A,G3,E2,S1
ZINC SULFATE	A,G3,E2,S1

APPENDIX F

WARNING STATEMENTS AND GENERAL SAFETY DIRECTIONS FOR POISONS

(other than agricultural and veterinary chemicals (including pesticides) registered by the Australian Pesticides and Veterinary Medicines Authority and medicines for human use when compliant with the requirements of the *Required Advisory Statements for Medicine Labels*)

INTRODUCTION

Warning Statements and Safety Directions

It is the responsibility of the manufacturer, packer and supplier of a drug or poison to ensure that the purchaser or user of a product is given sufficient information to be able to use it correctly and safely.

Under poisons legislation, scheduled substances, which may be harmful to the user, must be labelled with appropriate warning statements and/or safety directions. The selection of warning statements and safety directions will depend on the formulation of the product, and the use for which it is sold or supplied. The following code has been prepared as a guide for this purpose.

The wording of warning statements and safety directions specified in this Appendix may be varied provided that the intent is not changed. Additional statements also may be added to ensure that the user of a product is sufficiently advised of its harmful nature and how to avoid any deleterious effects.

Poisons Information Centre Telephone Numbers

Companies should use the Poisons Information Centre telephone number(s) (Australia 13 11 26; New Zealand 0800 764 766) appropriate to the country(ies) of sale for the product.

Companies wishing to use a poisons information centre telephone number other than the national telephone numbers for Australia and New Zealand in warning statement No. 99 in Part 1 of this Appendix must meet the following criteria:

1. the poisons information service whose number is used must be attended by adequately trained staff for 24 hour emergency poisons information; and
2. calls must be logged and submitted for incorporation into the official collection of poisoning data.

APPENDIX F

PART 1

WARNING STATEMENTS

1. Highly corrosive.
2. Corrosive.
3. Corrosive liquid.
4. Strongly alkaline.
5. Irritant.
6. May cause cancer.
7. WARNING – Causes birth defects.
8. WARNING – May be fatal to children.
9. Can be fatal to children if sucked or swallowed.
10. May produce severe burns.
11. WARNING – Vapour may be harmful.
12. Vapour is harmful to health on prolonged exposure.
13. May be fatal if inhaled, swallowed or absorbed through skin.
14. Dust will irritate and burn eyes, nose and skin.
15. Liquid will cause burns.
16. Forms dangerous gas near radiators or naked flames.
17. Contact with eyes even for short periods can cause blindness.
18. Product will irritate the eyes, nose, throat and skin.
19. WARNING – Skin contact may be dangerous. Take every precaution to avoid contact - wash off after spillage and after use.
20. May give off dangerous gas if mixed with other products.
21. WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.
22. Highly reactive oxidising chlorine compound.
23. May cause fire or explosion.
24. For external washing only. Rinse skin thoroughly after use.
25. Do not use on broken skin. Wash hands thoroughly after use.

APPENDIX F, PART 1 – continued

26. (Powder) (and) (concentrated solutions) are dangerous if swallowed.
27. Not for therapeutic use.
28. (Over) (Repeated) exposure may cause sensitisation.
29. If congestion persists, consult your doctor or pharmacist.
30. WARNING – Do not use on face or on anal or genital areas.
31. WARNING – Do not use on face or on anal or genital areas except on doctor's advice.
32. This preparation should be part of an overall treatment plan regularly assessed with your doctor.
33. Do not take for periods longer than four weeks except on medical advice.
34. WARNING – This medication may be dangerous when used in large amounts or for a long time (period).
35. CAUTION – This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. Prolonged use without medical supervision could be harmful.

or

CAUTION – This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. Prolonged or excessive use without medical supervision could be harmful.
36. For use under medical supervision only.
37. Consult a doctor before giving this medication to children or teenagers with chicken pox, influenza or fever.
38. CAUTION – Do not use for children under 2 years old unless a doctor has told you to.
39. This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.
40. This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.
41. Do not give to children under 12 years of age. Do not use beyond 48 hours or in pregnancy or lactation except on doctor's advice.
42. WARNING – Overuse may stain the skin or mouth.
43. Use of this product is not necessary in areas supplied with fluoridated water.
44. WARNING – May be dangerous, particularly to children, if you use large amounts on the skin, clothes or bedding or on large areas of the body, especially if you keep using it for a long time.
45. WARNING – If a pigmented spot or mole has recently become darker, changed colour, become enlarged or itchy, or bleeds, do not use this product, see your doctor immediately. Do not use on children. Do not use near the eyes. Mild irritation may occur; stop use if it becomes severe. If fading is not evident in three months, seek doctor's advice.
46. WARNING – Contains (name of substance) which causes birth defects in laboratory animals. Women of child bearing age should avoid contact with (name of substance).
47. WARNING – This product contains (name of substance) which causes birth defects in certain laboratory animals. Women of child bearing age are advised not to mix, load or spray this product. They should keep out of crops being sprayed.

APPENDIX F, PART 1 – continued

48. WARNING – This product forms cyhexatin which causes birth defects in certain laboratory animals. Women of child bearing age are advised not to mix, load or spray this product. They should keep out of crops being sprayed.
49. WARNING – Do not mix with other medication except on veterinarian's advice.
50. Unless adequately fired, utensils glazed with this preparation must not be used as containers for food or beverages; to do so may cause lead poisoning.
51. Irritant to skin, eyes, mucous membranes and upper respiratory tract.
52. Breathing vapour or spray mist is harmful and may cause an asthma-like reaction.
53. CAUTION – (Name of substance) should not be used by pregnant women.
54. Seek medical advice before first course of treatment.
55. Keep from eyes, lips, mouth and sensitive areas of the neck. If excessive swelling, irritation, redness or peeling occurs, discontinue use. If these persist, consult a physician. Avoid excessive exposure to sunlight and other sources of ultra violet light.
56. WARNING – Can cause elevated blood pressure and interact adversely with other medication.
57. Not to be applied to infants under 12 months of age unless on doctor's advice.
58. Highly reactive oxidising bromine and chlorine compound.
59. May cause allergy.
60. Do not mix with detergents or other chemicals.
61. WARNING – Can react with other medicines. Ask your doctor or pharmacist before taking.
62. Do not use if pregnant.
63. See a doctor if you are pregnant or diabetic.
64. See a doctor (or) (*dentist*) if no better after (Insert number of days as per approved Product Information) days.
65. If getting better, keep using for (Insert number of days as per approved Product Information) days.
66. See a doctor if problem returns.
67. Do not use if pregnant or likely to become pregnant.
68. If symptoms persist beyond 5 days consult a doctor (or) (*dentist*).
69. If symptoms recur within two weeks of completing the course, consult a doctor.
70. Use only under medical supervision if you are taking other medicines.
71. Do not use during the last three months of pregnancy.
72. Do not use in the eyes.
73. Do not use for acne.
74. Do not use under waterproof bandages unless a doctor has told you to.

APPENDIX F, PART 1 – continued

75. Do not use for more than 7 days unless a doctor has told you to.
76. Do not become pregnant during use or within (*Insert number of months as per approved Product Information*) month(s) of stopping treatment.
77. WARNING – May cause birth defects.
78. Attacks skin and eyes.
79. Will irritate eyes.
80. (Intentionally blank)
81. (Intentionally blank)
82. (Intentionally blank)
83. This paint is dangerous to health, even when dry.
For industrial use only.
Do not use on toys or furniture.
Do not use on, in or around the home.
84. Breathing the vapour is dangerous.
Provide adequate ventilation during application.
Do not use in the presence of a naked flame.
Do not smoke.
85. This paint contains lead and is dangerous to health, even when dry.
For industrial use only.
Do not use on toys or furniture.
Do not use for painting any building or fixed structure.
Do not use where contact with food or drinking water is possible.
86. This tinter contains lead.
Do not add to any paint which is for application to any toy, furniture, building (interior or exterior), fixed structure or to anything which may contact food or drinking water.
87. (*Insert brand name*) remains in the body for many months after treatment has stopped. Do not become pregnant or father a child before consulting your doctor.
88. This product is not recommended for dyeing eyelashes or eyebrows. To do so may be injurious to the eye.
89. Application to skin may increase sensitivity to sunlight.
90. This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.
91. CAUTION – Total iodine intake may exceed recommended level when taking this preparation.
92. WARNING – Contains iodine - do not take when pregnant **except** on physician's advice.
93. Causes severe burns, which are not likely to be immediately painful or visible.
94. WARNING – Contains nitrite. Substitution for table or cooking salt may be dangerous, particularly for young children.
95. CAUTION – Do not use for children under 12 years old unless a doctor has told you to.
96. CAUTION – This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. If symptoms persist or recur within two weeks, consult a doctor.

APPENDIX F, PART 1 – continued

97. *Adults:* Keep to the recommended dose. Don't take this medicine for longer than a few days at a time unless advised to by a doctor.
98. *Children and adolescents:* Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor.
99. If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26; New Zealand 0800 764 766) or go to a hospital straight away even if you feel well because of the risk of delayed, serious liver damage.
100. Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.
101. Don't use [this product/name of the product]:
If you have a stomach ulcer
In the last 3 months of pregnancy [*This statement may be omitted in preparations used exclusively for the treatment of dysmenorrhoea.*]
If you are allergic to (name of substance) or anti-inflammatory medicines.
102. Unless a doctor has told you to, don't use [*this product/name of the product*]:
For more than a few days at a time
With other medicines containing aspirin or other anti-inflammatory medicines
If you have asthma
In children under 12 years of age
In children 12-16 years of age with or recovering from chicken pox, influenza or fever
If you are pregnant.
103. See a doctor before taking [this product/name of the product] for thinning the blood or for your heart. [*This statement may be omitted in products for inhibition of platelet aggregation or with additional active ingredients.*]
104. Unless a doctor has told you to, don't use [this product/name of the product]:
For more than a few days at a time
With other medicines containing (name of substance) or other anti-inflammatory medicines
If you have asthma
If you are pregnant [*This statement may be omitted in preparations used exclusively for the treatment of dysmenorrhoea.*]
105. Do not use on the bedding or clothing of infants or in the bedrooms of children 3 years of age or less.
106. Contains formaldehyde.

APPENDIX F

PART 2

SAFETY DIRECTIONS - GENERAL

To be grouped together and prefaced with the words "SAFETY DIRECTIONS" (see Part 2, Labels and Containers, subparagraph 7(n) to this Standard).

1. Avoid contact with eyes.
2. Attacks eyes – protect eyes when using.
3. Wear eye protection when mixing or using.
4. Avoid contact with skin.
5. Wear protective gloves when mixing or using.
6. Wash hands after use.
7. Wash hands thoroughly after use.
8. Avoid breathing dust (or) vapour (or) spray mist.
9. Use only in well ventilated area.
10. Ensure adequate ventilation when using.
11. No smoking.
12. Do not allow product to come into contact with other chemicals, especially acids.
13. Do not allow product to come into contact with combustible materials such as paper, fabric, sawdust or kerosene.
14. Do not allow to get damp.
15. Store under cover in a dry, clean, cool, well ventilated place away from sunlight.
16. Store and transport in an upright container.
17. Do not mix with other chemicals.
18. Do not mix with different types of chlorinating chemicals.
19. Use clean containers for dispensing.
20. Mix with water only.
21. Do not add water to product – add product to water, but in case of fire drench with water.
22. In case of spillage flush with large quantities of water.
23. Keep away from heat, sparks and naked flames.
24. Avoid contact of the crystals or strong solutions with the eyes, mouth, nose and other mucous membranes.
25. Avoid contact with food.

APPENDIX F, PART 2 – continued

26. Avoid contact with clothing.
27. Wear a positive-pressure air-supplied full-face respirator whilst spraying and until spray mist has been effectively dispersed.
28. Do not mix with hot water.
29. Obtain a supply of calcium gluconate gel.
30. (Intentionally blank.)
31. Do not use on broken skin.
32. Do not use under occlusive dressing.
33. Mix strictly according to instructions.
34. May cause fire if it comes into contact with other chemicals, paper or other flammable materials.
35. Wash gloves thoroughly, immediately after use.
36. Protect cuticles with grease or oil.

APPENDIX F

PART 3

**POISONS (other than agricultural and veterinary chemicals)
TO BE LABELLED WITH WARNING STATEMENTS
OR SAFETY DIRECTIONS**

(Where more than one statement or direction is required, they may be combined to form simple sentences where appropriate.)

POISON	WARNING STATEMENTS	SAFETY DIRECTION
ACETIC ACID in concentrations of 80 per cent or more except when in Schedule 2.	2	1,4,8
ACETIC ANHYDRIDE	2	1,4,8
ACETONE in concentrations greater than 75 per cent.		1,4,8
ACITRETIN		7,62,76
ADAPALENE for topical use.	62,77	
ALCLOMETASONE when included in Schedule 3.	38,72,73,74,75	
ALKALINE SALTS	4	1,4
AMBRISENTAN	7,62,76	
AMINES used as curing agents for epoxy resins.		1,3,4,5,8
AMMONIA/AMMONIUM HYDROXIDE in concentrations greater than 20 per cent ammonia except in smelling salts.	4	1,4,8
AMMONIUM PERSULFATE	5,21,25	1,5,23,33,34
ANHYDRIDES, organic acid, for use as curing agents for epoxy resins.		1,3,4,5,8
ANILINE	13	1,4,8
ANTI-HISTAMINES not separately specified in this Appendix except :	39 or 40	
(a) dermal, ocular, parenteral and paediatric preparations;		
(b) oral preparations of astemizole, desloratadine, fexofenadine, loratadine or terfenadine;		
(c) nasal preparations of azelastine; or		
(d) preparations for the treatment of animals.		

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
AROMATIC EXTRACT OILS		1,3,4,5,6
ASPIRIN		
(a) for inhibition of platelet aggregation.	36	
(b) in sustained release preparations containing 650 mg or more of aspirin.	36	
(c) in other preparations.	101,102,103	
ASTEMIZOLE		61
AZADIRACHTA INDICA including its extracts and derivatives when included in Schedule 6.	67	
AZOCYCLOTIN	48	
BENOMYL	46	
BENZENE	12	1,4,9
1,2-BENZENEDIOL (Catechol)	51,59	1,4,8
BENZOYL PEROXIDE when included in Schedule 2.	55	
BENZOYL PEROXIDE when included in Schedule 5.		1,4,8
BERGAMOT OIL	89	
BERYLLIUM		1,4,8
BEXAROTENE		
(a) for human use.	7,62,76	
(b) for topical use.	62,77	
BIFLUORIDES (including ammonium, potassium and sodium salts)		
(a) when included in Schedule 5.	2	1,4
(b) when included in Schedule 6 or 7.	1,17,93	1,3,4,5,8,29,35
BITHIONOL for the treatment of animals.		1,4,8
BORON TRIFLUORIDE (including mixtures that generate boron trifluoride)		
(a) when included in Schedule 5.	2	1,4
(b) when included in Schedule 6 or 7.	1,17,93	1,3,4,5,8,29,35
BOSENTAN		7,62,76

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
BROMOFORM		1,4,8
2-BUTOXY-2'-THIOCYANODIETHYL ETHER		1,4,8
2-BUTOXYETHANOL and its acetates		1,4,8
CAMPHOR		
(a) in block, ball, disc, pellet or flake form, enclosed in a device which, in normal use, prevents removal or ingestion of its contents.	9	
(b) in other forms.	9	1
CARAMIDE PEROXIDE		
(a) more than 9 per cent up to 30 per cent.	5	1
(b) more than 30 per cent up to 60 per cent.	5	2
(c) more than 60 per cent.	2	2,4
CARBON DISULFIDE	12	1,4,8,9,23
CARBON TETRACHLORIDE	12	1,4,8,9
CASSIA OIL		4
CHLORINATING COMPOUNDS		
(a) in household cleaning or bleaching preparations.	20	
(b) in preparations containing less than 10 per cent of available chlorine.	11	1,4,10
(c) in liquid preparations containing 10 per cent or more of available chlorine.	3,18	1,4,6,8,10, 15,16, 17,18, 19,20,22,26
(d) in dry preparations containing 10 per cent or more of available chlorine.	10,18,22,23	1,4,8,12,13, 14,15,16,17, 18, 19,20,21, 22,26
(e) in dry preparations containing 10 per cent or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5, Division 5.1:Oxidising substances, as specified in the <i>Australian Code for the Transport of Dangerous Goods by Road and Rail</i> .	10,18,22	1,4,8,12,13, 14,15,16,17, 18,19,20,21, 22,26
(f) in compressed block or tablets containing 10 per cent or more of available chlorine except in preparations for use in toilet cisterns only, containing 15 g or less of	10,22,23	12,13,14,15, 17,18,19,21

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
trichloroisocyanuric acid.		
(g) in other compressed blocks or tablets containing 10 per cent or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5, Division 5.1: Oxidising substances, as specified in the <i>Australian Code for the Transport of Dangerous Goods by Road and Rail</i> except in preparations for use in toilet cisterns only, containing 15 g or less of trichloroisocyanuric acid.	10,22	12,13,14,15, 17,18,19,21
CHLOROFORM when included in Schedule 6		1,4,8
alpha-CHLOROHYDRIN	13,51	1,4,8,9
CHROMATES (including dichromates) of alkali metals or ammonia		1,4,8
CHROMIUM TRIOXIDE	2,14,15,23	1,4,8,13
CIMETIDINE when included in Schedule 3	70,96	
CINNAMON BARK OIL		4
CLOBETASONE when included in Schedule 3.	72,73,74,75,95	
CLOTRIMAZOLE in vaginal preparations when included in Schedule 3.	54,63,64,66	
CLOVE OIL		1
CYANIDES when included in Schedule 7.	13	4,8
CYANURIC ACID		1,4,8
CYCLOHEXANONE PEROXIDE		1,4,8
CYCTEAMINE		1
4,4-DIAMINODIPHENYLMETHANE (methylene dianiline)		1,4,8
ortho-DICHLOROBENZENE		1,4,8
para-DICHLOROBENZENE		1,4
DICHLOROETHYLENE		1,4,8
DICHLOROETHYL ETHER		1,4,8
DICHLOROISOCYANURATES		
(a) in household cleaning or bleaching preparations.	20	
(b) in preparations containing less than	11	1,4,10

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
10 per cent of available chlorine.		
(c) in liquid preparations containing 10 per cent or more of available chlorine.	3,18	1,4,6,8,10, 15,16,17,18, 19,20,22,26
(d) in dry preparations containing 10 per cent or more of available chlorine.	10,18,22,23	1,4,8,12,13,14, 15,16,17,18,19, 20,21,22,26
(e) in dry preparations containing 10 per cent or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5, Division 5.1: Oxidising substances, as specified in <i>the Australian Code for the Transport of Dangerous Goods by Road and Rail</i> .	10,18,22	1,4,8,12,13,14, 15,16,17,18,19, 20,21,22,26
(f) in anti-bacterial tablets containing 2.5 g or less of sodium dichloroisocyanurate..	60	
(g) in other compressed blocks or tablets containing 10 per cent or more of available chlorine except in preparations containing 21 g or less of sodium dichloroisocyanurate for use in toilet cisterns only.	10,22,23	12,13,14,15, 17,18,19,21
(h) in other compressed blocks or tablets containing 10 per cent or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5, Division 5.1: Oxidising substances, as specified in <i>the Australian Code for the Transport of Dangerous Goods by Road and Rail</i> except in preparations containing 21 g less of sodium dichloroisocyanurate for use in toilet cisterns only.	10,22	12,13,14,15,17, 18,19,21
(i) in other compressed blocks or tablets containing 10 per cent or more of available chlorine in preparations containing 5 g or less of sodium dichloroisocyanurate for use in toilet bowls only:		
(i) during storage	10,22,23	12,13,14,15,17, 18,21
(ii) during use	5	1,4,7,12
(j) in other compressed blocks or tablets containing 10 per cent or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5, Division 5.1: Oxidising substances, as specified in the <i>Australian Code for the Transport of Dangerous Goods by Road and Rail</i> in preparations		

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
containing 5 g or less of sodium dichloroisocyanurate for use in toilet bowls only.		
(i) during storage	10,22	12,13,14,15,17,18,21
(ii) during use	5	1,4,7,12
DICHLORMETHANE (methylene chloride)		
(a) in paint or lacquer removers.	12,16	1,4,8,11
(b) other than in paint or lacquer removers		1,4,8,25
DICLOFENAC		101,104
DIENESTROL	67	
DIETHANOLAMINE when included in Schedule 5.	5	1,4
DIETHANOLAMINE when included in Schedule 6.	2,11,18	1,4,8
DIETHYLTOLUAMIDE for human use.	44	
5,6-DIHYDROXYINDOLINE	21,28	
DIMETHYLFORMAMIDE		1,4,8
DIMETHYL SULFATE	2	1,4,8
DIMETHYL SULFOXIDE		
(a) when not packed and labelled for therapeutic use.	27	1,4,5,8
(b) when packed and labelled for treatment of animals.	49	1,4,5,8
DINITROCRESOLS (and their homologues) except when for therapeutic use.		1,4,8
DINITROPHENOLS (and their homologues) except when for therapeutic use.		1,4,8
DINOCAP	47	
DIOXANE		1,4,8
DIPHENOXYLATE when included in Schedule 3.	39 or 40,41	
ECONAZOLE in vaginal preparations when included in Schedule 3.	54,63,64,66	
EPHEDRINE in nasal preparations for topical use.	29	
EPICHLOROHYDRIN	2	1,4,8
EPOXY RESINS, liquid.		1,3,4,5,8

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
ETHANOLAMINE when included in Schedule 5.	5	1,4
ETHANOLAMINE when included in Schedule 6.	2,11,18	1,4,8
ETHER when included in Schedule 5 or 6.		1,4,8
ETHOXYETHYLMERCURIC CHLORIDE		1,4
ETHYL BROMIDE		1,4,8
ETHYLENE CHLOROXYDRIN		1,4,8
ETHYLENE GLYCOL MONOALKYL ETHERS and their acetates except when separately specified.		1,4,8
ETHYLENE OXIDE		1,4,8
ETHYLMERCURIC CHLORIDE		1,4
ETHYL METHACRYLATE	28	4,9,23
ETRETINATE		7,62,76
EUGENOL		1
FAMOTIDINE when included in Schedule 2.	96	
FENTEROL in metered aerosols.	32	
FLUCONAZOLE in oral preparations when included in Schedule 3.	64	
FLUORIDES (including silicofluorides) when included in Schedule 5 or 6 except when separately specified.		1,4
FORMALDEHYDE		
(a) in nail hardener cosmetics.	106	1,4,8,36
(b) in other preparations.	106	1,4,8
FORMIC ACID		1,4,8
FURFURAL		5 1,4
Glazing preparations containing LEAD COMPOUNDS.	50	
GLUTARALDEHYDE except when in Schedule 2		
(a) 25 per cent or less.	5,59	1,4,5
(b) more than 25 per cent.	3,59	1,4,5,8
GLYCOLIC ACID	79	1,5,6,31

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
HEXACHLOROPHANE in preparations for skin cleansing purposes containing 3 per cent or less of hexachlorophane.	24	
HEXLOXYETHANOL	2	1,4,8
HYDRAZINE		1,4,8
HYDROCHLORIC ACID		
(a) 30 per cent or less of HCl.		1,4
(b) more than 30 per cent of HCl.		1,4,8
HYDROCORTISONE		
(a) for dermal use when included in Schedule 2 or 3.	38,72,73,74,75	
(b) for topical rectal use when included in Schedule 2 or 3.	38,75	
HYDROCYANIC ACID when included in Schedule 7.	13	4,8
HYDROFLUORIC ACID (including mixtures that generate hydrofluoric acid)		
(a) when included in Schedule 5.	2	1,4
(b) when included in Schedule 6 or 7.	1,17,93	1,3,4,5,8,29,35
HYDROGEN PEROXIDE		
(a) more than 3 per cent up to 10 per cent.	5	1
(b) more than 10 per cent up to 20 per cent.	5	2
(c) more than 20 per cent.	2	2,4
HYDROQUINONE		
(a) when in Schedule 2.	45	
(b) except when in Schedule 2 or 4.		1,4
HYDROSILICOFLUORIC ACID (including mixtures that generate hydrosilicofluoric acid)		
(a) when included in Schedule 5.	2	1,4
(b) when included in Schedule 6 or 7.	1,17,93	1,3,4,5,8,29,35
8-HYDROXYQUINOLINE (including salts and derivatives) when prepared for internal use.	33	

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
IBUPROFEN		101,104
IODINE		
(a) more than 20 per cent.		1,4,8
(b) in preparations for human internal therapeutic use containing 300 micrograms or more of iodine per recommended daily dose.	91,92	
IPRATROPIUM BROMIDE in metered aerosols.	32	
ISOCYANATES (free organic)		
(a) when in paint.	28,52	1,5,8,10,27
(b) other than in paint.	28,52	1,4,8
ISOPRENALINE in metered aerosols	32	
ISOTRETINOIN		
(a) for human oral use.	7,62,76	
(b) for topical use.	62,77	
LEAD COMPOUNDS		
(a) in hair cosmetics.	25	
(b) when in Schedule 6.		1,4,8
LEFLUNOMIDE	7,62,87	
LEMON OIL		89
LENALIDOMIDE	7,62,76	
LEVOCABASTINE		
(a) in eye or nasal preparations containing 0.5 mg/mL or less of levocabastine.	62	
(b) in other preparations.	62 and either 39 or 40	
LIME OIL	89	
LOPERAMIDE when in Schedule 2.	41	
MAGNESIUM CHLORATE		1,4
MEFENAMIC ACID	101,104	
MERCURIC THIOCYANATE		1,4
METACRESOLSULPHONIC ACID and formaldehyde		1,4

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
condensation product for the treatment of animals.		
METHANOL except in methylated spirit.		1,4,8
METHOXAMINE in nasal preparations for topical use.	29	
METHYL CHLORIDE		1,4,8
METHYL ETHYL KETONE	5	1,4,8
METHYL ETHYL KETONE OXIME	5,28	1,4
METHYL ETHYL KETONE PEROXIDE	2	2,3,4,6
METHYL ISOAMYL KETONE		1,4,8
METHYL ISOBUTYL KETONE		1,4,8
METHYL ISOTHIOCYANATE	5,12	1,4,8
METHYL METHACRYLATE	28	4,9,23
METHYLDIBROMO GLUTARONITRILE	28	1,4,7
METHYLENE BISTHIOCYANATE		1,4
METHYLEUGENOL		1,6
METHYLNORBORNANYLPYRIDINE	59	
1-(BETA-METHYL SULPHONAMIDOETHYL)- 2-AMINO-3-N,N-DIETHYLAMINOBENZENE		1,4,8
MICONAZOLE in vaginal preparations when included in Schedule 3.	54,63,64,66	
MISOPROSTOL	53	
NAPHAZOLINE in nasal preparations for topical use.	29	
NAPHTHALENE		
(a) in block, ball, disc, pellet or flake form, enclosed in a device which, in normal use, prevents removal or ingestion of its contents.	9,105	
(b) in other forms.	9,105	1
NAPROXEN		101,104
NICOTINE except when in tobacco or when included in Schedule 2.		1,4
NITRIC ACID		

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
(a) 75 per cent or less HNO ₃ .	2	1,4
(b) more than 75 per cent HNO ₃ .	2	1,4,8
NITROBENZENE		1,4,8
NITROPHENOLS		1,4
NITROPRUSSIDES in aerosols.	84	8
NIZATIDINE when included in Schedule 2.	96	
NORADRENALINE in metered aerosols.	32	
NYSTATIN in vaginal preparations when included in Schedule 3.	54,63,64,65,66	
ORANGE OIL (bitter)	89	
ORCIPRENALINE in metered aerosols.	32	
OXALATES, metallic		4,8
OXALIC ACID		2 4,8
OXYMETAZOLINE in nasal preparations for topical use.	29	
PAINT		
(a) First Schedule paints.	83	
(b) Second Schedule paints.	84	
PARACETAMOL	97 and/or 98,99,100	
PENTACHLOROPEHNOL		1,4,8
PERACETIC ACID	2	1,4,8
PERMANGANATES	2	24
2-PEHNOXYETHANOL	5	1
PHENOL and any other homologue of phenol.		1,4
PHENOLS		5
PHENYLENEDIAMINES AND ALKYLATED PHENYLENEDIAMINES		
(a) in hair dyes.	21	
(b) in preparations other than hair dyes.		1,4,8
PHENYLEPHRINE in nasal preparations	29	

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
for topical use.		
N,N-BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE-2,5-DIMETHANAMINE	5,28	1,4,5,10
N,N-BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE-2,6-DIMETHANAMINE	5,28	1,4,5,10
ortho-PHENYLPHENOL except when in antiseptics.		1,4
PHENYLPROPANOLAMINE	56	
PHENYTOIN in pastes for the treatment of horses.	9	
PHOSPHONIC ACID		1,4
PHOSPHORIC ACID		1,4
PHOSPHORUS (yellow)	2	1,4
ortho-PHTHALALDEHYDE		
(a) when included in Schedule 5.	51,52,59	1,4,5,8,10
(b) when included in Schedule 6.	51,52,59	2,4,5,8,10
PICRIC ACID (more than 20 per cent).		1,4
PODOPHYLLIN		
(a) in preparations specifically for use on anal or genital area.	36	
(b) in other liquid preparations when included in Schedule 2 or Schedule 3.	31	
(c) in other solid or semi-solid preparations when included in Schedule 2.	30	
PODOPHYLLOTOXIN		
(a) in preparations specifically for use on anal or genital area.	36	
(b) in other liquid preparations when included in Schedule 2 or Schedule 3.	31	
(c) in other solid or semi-solid preparations when included in Schedule 2.	30	
POLIHEXANIDE		1,4,8
POLYETHANOXY (15) TALLOW AMINE		1,4
POLY(OXY-1,2-ETHANEDIYL), A -[2-[(2-HYDROXYETHYL)AMINO]5,88		1,5

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
-2-OXOETHYL]- A -HYDROXY-,MONO-C ₁₃₋₁₅ -ALKYL ETHERS		
POTASSIUM HYDROXIDE		
(a) in preparations containing 0.5 per cent or less of potassium hydroxide.	5	1,4,6
(b) in solid preparations containing more than 0.5 per cent of potassium hydroxide.	2,10,78	3,5,28
(c) in liquid preparations containing more than 0.5 per cent of potassium hydroxide.	2,10,78	3,5
POTASSIUM METABISULPHITE	5,26	1,4
POTASSIUM NITRITE in pickling or curing salts.	94	
POTASSIUM PERSULFATE	5,21,25	1,5,23,33,34
POTASSIUM SULFIDE	2	1,4
PROPIONIC ACID when in Schedule 6.	2	1,4
RANITIDINE when included in Schedule 2.	96	
SAFROLE		
(a) in preparations for therapeutic use.		1
(b) other than for therapeutic use.		1,4
SALBUTAMOL in metered aerosols or in dry powder formulations.	32	
SALICYLAMIDE	34 or 35	
SASSAFRAS OIL		
(a) in preparations for therapeutic use.		1
(b) other than for therapeutic use.		1,4
SELENIUM COMPOUNDS except when for therapeutic use (human or animal).		1,4,8
SLIVER in smoking deterrents.	42	
SITAXENTAN		7, 62, 76
SODIUM ALUMINATE	2	1,4
SODIUM CHLORATE		1,4

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
SODIUM DODECYLBENZENE SULFONATE	79	1
SODIUM FLUORIDE in preparations for human ingestion when in Schedule 2.	43	
SODIUM HYDROGEN SULFATE		1,4,8
SODIUM HYDROSULFITE (more than 50 per cent)	5,26	1,4,8
SODIUM HYDROXIDE		
(a) in preparations containing 0.5 per cent or less of sodium hydroxide.	5	1,4,6
(b) in solid preparations containing more than 0.5 per cent of sodium hydroxide.	2,10,78	3,5,28
(c) in liquid preparations containing more than 0.5 per cent of sodium hydroxide.	2,10,78	3,5
SODIUM LAURETH-6 CARBOXYLATE	79	1
SODIUM METABISULPHITE (more than 50 per cent)	5,26	1,4
SODIUM NITRITE in pickling or curing salts	94	
SODIUM PERSULFATE	5,21,25	1,5,23,33,34
SODIUM SULFIDE	2	1,4
STYRENE		1,4,8
SULFAMIC ACID	2	1,4
SULFURIC ACID	2	1,4
SYMPHYTUM SPP. (Comfrey) when included in Schedule 5.		31,32
TAZAROTENE for topical use.	77,62	
TERBUTALINE in metered aerosols or in dry powder formulations.	32	
TERFENADINE		61
TERIFLUNOMIDE.		7,62,87
TERPENES, chlorinated		1,4,8
TETRACHLOROETHANE	12	8
TETRACHLOROETHYLENE when in Schedule 5 or 6.	12,16	1,4,8,11
TETRAHYDROZOLINE in nasal preparations for topical use.	29	

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
THALIDOMIDE	7,62,76	
THIOUREA		1,4
TOLUENE		1,4,8
TOLUENEDIAMINE		
(a) in hair dyes.	21	
(b) in preparations other than hair dyes.		1,4,8
TRAMAZOLINE in nasal preparations for topical use.	29	
TRETINOIN		
(a) for human oral use.	7,62,76	
(b) for topical use.	62,77	
TRIAMCINOLONE when in topical preparations for the treatment of mouth ulcers.	64 or 68	
TRICHLOROACETIC ACID except when for therapeutic use.	2	1,4
1,1,1-TRICHLOROETHANE		8,9
TRICHLOROETHYLENE except when for therapeutic use.	12	1,4,5,8,9
TRICHLOROPHENOL		1,4,8
TRIETHANOLAMINE	5	1,4
TRIETHYL PHOSPHATE		1,4,8
TRIFLUOROMETHANESULFONIC ACID		
(a) more than 10 per cent.	1,17	1,4,8
(b) 10 per cent or less.		1,4,8
TRISOPROPANOLAMINE LAURYL ETHER SULFATE		1,4,6
3,6,9-TRIOXAUNDECANEDIOIC ACID	5	1
TYMAZOLINE in nasal preparations for topical use.	29	
VINCLOZOLIN		46
XYLENE		1,4,8
XYLOMETAZOLINE in nasal preparations for topical use.	29	

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
ZINC CHLORIDE		1,4
ZINC SULFATE when in Schedule 6.		1,4

APPENDIX G

DILUTE PREPARATIONS

The requirements of this Standard do not apply to a poison listed in Column 1 of this Appendix at a concentration not more than that specified in Column 2 in respect of that poison.

Column 1 Poison	Column 2 Concentration (quantity per litre or kilogram)
ACETYLCHOLINE	1 mg
ALDOSTERONE	10 micrograms
ANTIMONY COMPOUNDS	1 mg
APOMORPHINE	1 mg
ARSENIC	1 mg
ATROPA BELLADONNA (belladonna)	300 micrograms
ATROPINE	300 micrograms
CANTHARIDIN	10 micrograms
CHLORINE	5 mg
CROTON TIGLIUM (croton oil)	1 mg
DIOXANE	100 mg
ERYSIMUM spp.	1 mg
FOLLICLE-STIMULATING HORMONE	100 micrograms
GELSEMIUM SEMPERVIRENS	1 mg
GLUCAGON	100 micrograms
GLYCERYL TRINITRATE	100 micrograms
GROWTH HORMONE	10 micrograms
HALOPERIDOL	1 mg
HYDROCYANIC ACID	1 microgram
HYOSCINE	300 micrograms
HYOSCYAMINE	300 micrograms
HYOSCYAMUS NIGER	300 micrograms
HYPOTHALAMIC RELEASING FACTORS	10 micrograms
INDOMETHACIN	1 mg
MERCURY	1 mg
METHYLMERCURY	300 micrograms
NAPHTHALENE	1 mg
NERIUM OLEANDER	1 mg
OESTRADIOL	10 micrograms
OESTRONE	100 micrograms
OXYTOCIN	1 microgram
PHOSPHORUS	1 mg
PODOPHYLLUM RESIN (podophyllin)	1 mg
PROGESTERONE	1 mg
PROPRANOLOL	1 mg
SELENIUM	100 micrograms
STROPHANTHUS spp.	1 mg
STRYCHNINE	1 mg
TESTOSTERONE	1 mg
THYROXINE	10 micrograms

APPENDIX H

SCHEDULE 3 POISONS PERMITTED TO BE ADVERTISED

BUTOCONAZOLE.

CLOTRIMAZOLE.

DICLOFENAC.

DIMENHYDRINATE for the prevention and relief of motion sickness.

DIPHENOXYLATE.

ECONAZOLE.

FLUCONAZOLE.

HYDROCORTISONE.

MICONAZOLE.

NYSTATIN.

APPENDIX I

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APPENDIX J
CONDITIONS FOR AVAILABILITY AND USE OF
SCHEDULE 7 POISONS

PART 1
CONDITIONS FOR AVAILABILITY AND USE

The following controls are recommended for poisons only when included in Schedule 7. These conditions for availability and use may be implemented through poisons controls or other State or Territory legislation.

1. Not to be available except to authorised or licensed persons.
2. Not to be used in printing inks.
3. Not to be used except by or in accordance with the directions of accredited government vermin control officers.
4. Not to be used in industries which handle, process or store foods, animal feeds or packaging materials.

APPENDIX J

PART 2

A poison listed in this Appendix is to be available only in accordance with the conditions specified beside it in the “Conditions” column. The conditions apply only when the poison is included in Schedule 7.

POISONS	CONDITIONS
ABAMECTIN	1
ACIBENZOLAR-S-METHYL	1
ACROLEIN	1
ACRYLONITRILE	1
ALACHLOR	1
ALLYL ALCOHOL	1
4-AMINOPYRIDINE	1
ARPINOCID	1
ARSENIC	1
AZOCYCLOTIN	1
BENZENE	1
BIFLUORIDE (including ammonium, potassium and sodium salts)	1
BORON TRIFLUORIDE	1
BRODIFACOUM	1
BROMADIOLENE	1
BROMINE	1
BRUCINE	1
CALCIFEROL	1
CAPTAFOL	1
CARBADOX	1
CARBON TETRACHLORIDE	1
CARBONYL SULFIDE	1
CHLORDECONE	1
CHLORDIMEFORM	1
CHLORINE	1
CHLOROMETHIURON	1
CHLOROPRIN	1
4-CHLORO-O-TOLURIDINE	1
COLECALCIFEROL	1
COUMATETRALYL	1
CYANOGEN	1
CYCHEXATIN	1
4,4-DIAMINODIPHENYLMETHANE (methylene dianiline)	1
1,2-DIBROMO-3-CHLOROPROPANE	1
1,3-DICHLOROPROPENE	1
DIFENACOUM	1
4-DIMETHYLAMINOAZOBENZENE	1
DINITROCRESOLS	1
DINITROPHENOLS	1
DINOSEB	1
EPICHLOROHYDRIN	1
EPIDERMAL GROWTH FACTOR	1
ETAACONAZOLE	1
ETHYLENE DIBROMIDE	1
ETHYLENE OXIDE	1
FLUROACETAMIDE	3
FLUROACETIC ACID	3
FOLPET	1

POISONS	CONDITIONS
HALOFUGINONE	1
HALOGENATED DIBENZODIOXINS AND DIBENZOFURANS	1
HCB	1
HYDROCYANIC ACID AND CYANIDES	1
HYDROFLUORIC ACID	1
HYDROSILICOFLUORIC ACID	1
IODOMETHANE	1
MADURAMICIN	1
MERCURY	1
METHACRIFOS	1
METHOXYETHYLMERCURIC ACETATE	1
METHOXYETHYLMERCURIC CHLORIDE	1
METHYL BROMIDE	1
4,4'-METHYLENEBIS[2-CHLOROANILINE]	1
MIREX	1
MOLINATE	1
NICOTINE	1
NITROFEN	1
PHENYLMERCURIC ACETATE	1
PHOSPHIDE, metallic	1
PHOSPHINE	1
PROPYLENE OXIDE	1
PYRINURON	1
STRYCHNINE	1
SULCOFURON	1
TETRACHLOROETHANE	1
2,2',6,6'-TETRAISOPROPYL-DIPHENYL-CARBODIMIDE	1
THALLIUM	3
ORTHO-TOLIDINE	1
TRICHLOROISOCYANURIC ACID	1
VINYL CHLORIDE	1

APPENDIX K

DRUGS REQUIRED TO BE LABELLED WITH A SEDATION WARNING

(see Part 2 – Controls on Medicines and Poisons, Section 1 – Labels, subsection 1.5.6)

ALPRAZOLAM
AMISULPRIDE
AMITRIPTYLINE
AMYLOBARBITONE
ARIPIPRAZOLE
ASENAPINE
AZATADINE
BACLOFEN
BENZTROPINE
BROMAZEPAM
BROMPHENIRAMINE
BUCLIZINE
BUPRENORPHINE
BUTOBARBITONE
CETIRIZINE
CHLORAL HYDRATE
CHLORDIAZEPOXIDE
CHLORMETHIAZOLE
CHLORPHENIRAMINE
CHLORPROMAZINE
CLEMASTINE
CLOMIPRAMINE
CLONAZEPAM
CLONIDINE
CLORAZEPATE
CLOZAPINE
CODEINE **except** when included in Schedule 2 or 3.
CYCLIZINE
CYCLOBARBITONE
CYCLOSERINE
CYPROHEPTADINE
CYSTEAMINE
DANTROLENE
DESIPRAMINE
DEXCHLORPHENIRAMINE
DEXTROMORAMIDE
DEXTROPROPOXYPHENE
DIAZEPAM
DIFENOXIN
DIHYDROCODEINE
DIMENHYDRINATE
DIMETHINDENE
DIPHENHYDRAMINE
DIPHENOXYLATE
DIPHENYLPYRALINE
DOTHIEPIN
DOXEPIN
DOXYLAMINE
DRONABINOL (*delta-9-TETRAHYDROCANNABINOL*)
DROPERIDOL
DULOXETINE
ETHYLMORPHINE
FENFLURAMINE
FLUNITRAZEPAM

APPENDIX K – continued

FLUPENTHIXOL
FLUPHENAZINE
FLURAZEPAM
GABAPENTIN
GEMCITABINE
GLUTETHIMIDE
HALOPERIDOL
HYDROCODONE
HYDROMORPHONE
HYDROXYZINE
IMIPRAMINE
LAMOTRIGINE
LEVETIRACETAM
LEVOCABASTINE
LORAZEPAM
LURASIDONE.
MAZINDOL
MEBHYDROLIN
MECLOZINE
MEDAZEPAM
MEPROBAMATE
MEPYRAMINE
METHADONE
METHDILAZINE
METHOCARBAMOL
METHYLPHENOBARBITONE
MIANSERIN
MIRTAZAPINE
MORPHINE
NABIXIMOLS .
NALBUPHINE
NITRAZEPAM
NORMETHADONE
NORTRIPTYLINE
OLANZAPINE
OPIUM in any form **except** the alkaloids noscapine and papaverine.
OXAZEPAM
OXYCODONE
PALIPERIDONE
PAPAVERETUM
PENTAZOCINE
PENTOBARBITONE
PERAMPANEL
PERICYAZINE
PERPHENAZINE
PETHIDINE
PHENELZINE
PHENIRAMINE
PHENOBARBITONE
PHENOPERIDINE
PHENYLTOLOXAMINE
PHOLCODINE
PIMOZIDE
PIZOTIFEN
PRAZEPAM
PREGABALIN
PROCHLORPERAZINE
PROMAZINE
PROMETHAZINE
PROTRIPTYLINE

APPENDIX K – continued

QUETIAPINE
QUINALBARBITONE
RETIGABINE
RISPERIDONE
ROTIGOTINE
RUPATADINE
SECBUTOBARBITONE
SUVOREXANT
TAPENTADOL
TEMAZEPAM
THENYLDIAMINE
THIETHYLPERAZINE
THIOPROPAZATE
THIORIDAZINE
THIOTHIXENE
TRAMADOL
TRANLYCYPROMINE
TRIFLUOPERAZINE
TRIMEPRAZINE
TRIMIPRAMINE
TRIPROLIDINE
ZIPRASIDONE
ZOLPIDEM
ZONISAMIDE
ZOPICLONE

APPENDIX L

REQUIREMENTS FOR DISPENSING LABELS FOR HUMAN AND VETERINARY MEDICINES

PART 1

GENERAL REQUIREMENTS FOR DISPENSING LABELS

(see Part 2, Labels and Containers, subparagraph 14(1))

- (1) All details, words and other required information on a label on a container of a substance for therapeutic use must be in the English language in letters at least 1.5 millimetres in height.
- (2) All symbols, numbers and words on a label must be in durable characters.
- (3) The label on a container of a substance for therapeutic use must contain the following details:
 - (a) the name, address and telephone number of the dispenser supplying the substance;
 - (b) the approved name of the substance and/or its proprietary name (unless it is a preparation compounded in accordance with the dispenser's own formula);
 - (c) adequate directions for use;
 - (d) the strength and form of the substance;
 - (e) the total quantity of the goods in the container;
 - (f) the words "KEEP OUT OF REACH OF CHILDREN" in red on a white background;
 - (g) if the substance is intended for external use only, the word "POISON", or the words "FOR EXTERNAL USE ONLY", in red on a white background;
 - (h) if the substance is a medicine, the name of the person for whom it was dispensed; and
 - (i) if the substance is a veterinary chemical, the species of animal, the name of the animal's owner and the words "FOR ANIMAL TREATMENT ONLY".
- (4) The label on a container of a medicine or veterinary chemical that is supplied on prescription must also include:
 - (a) the prescription reference number;
 - (b) the date on which the prescription was supplied (unless that date is clear from the prescription reference number); and
 - (c) the directions for use set out in the prescription.

APPENDIX L

PART 2

ADDITIONAL LABELLING REQUIREMENTS FOR CERTAIN HUMAN MEDICINES

(see Part 2, Labels and Containers, subparagraph 14(2))

Medicines required to be labelled with certain warning statements A substance listed in Column 1 of the following table must be labelled with the warning statement in Appendix F, Part 1, as specified opposite in Column 2.

Column 1 Substance	Column 2 Warning statement
ACITRETIN:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
ADAPALENE:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
AMBRISENTAN.	7, 62 and 76
BEXAROTENE:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
BOSENTAN.	7, 62 and 76
DIENESTROL.	67
ETRETINATE:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
FINGOLIMOD.	76
ISOTRETINOIN:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
LEFLUNOMIDE.	7, 62 and 76
LENALIDOMIDE:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
LEVOCABASTINE.	62
MACITENTAN.	7, 62 and 76
MISOPROSTOL.	53
RIOCIGUAT.	7, 62 and 76
SITAXENTAN.	7, 62 and 76

Column 1 Substance	Column 2 Warning statement
TERIFLUOMIDE.	7, 62 and 87
THALIDOMIDE:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
TRETINOIN:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77

INDEX

(

(1-(2-MORPHOLIN-4-YLETHYL)INDOL-3-YL)-NAPHTHALEN-1-YLMETHANONE	213
(E)-(S)-1-(4-CHLOROPHENYL)-4,4-DIMETHYL-2-(1H-1,2,4-TRIAZOL-1-YL)PENT-1-EN-3-OL.....	165
(Z)-9-TRICOSENE	233

1

1-(3,4,5-TRIMETHOXYPHENYL)-2-AMINOBTANE.....	215
1-(3-TRIFLUOROMETHYLPHENYL)PIPERAZINE	215
1-(5-FLUOROPENTYL)-3-(2-IODOBENZOYL)INDOLE	212
1-(8-BROMOBENZO[1,2-B;4,5-B]DIFURAN-4-YL)-2-AMINOPROPANE.....	210
1-(BETA-METHYL SULPHONAMIDOETHYL)- 2-AMINO-3-	269
1,1,1-TRICHLOROETHANE.....	156, 220, 251, 274
1,2-BENZENEDIAMINE	216
1,2-BENZENEDIOL.....	241, 261
1,2-DIBROMO-3-CHLOROPROPANE.....	200
1,2-DICHLOROPROPANE.....	171
1,2-ETHANEDIAMINE POLYMER WITH (CHLOROMETHYL)OXIRANE AND N-METHYLMETHANAMINE	140
1,3,5,7-TETRAAZATRICYLO[3.3.1.1 ^{3,7}] DECANE.....	155
1,3-BENZENEDIAMINE	217
1,3-DICHLOROPROPENE	200, 280
1,3-DIMETHYLAMYLAMINE	218
1,4-BUTANEDIOL.....	217
¹³ C-UREA	233
19-NORANDROSTENEDIOL	103
19-NORANDROSTENEDIONE	103
1-AMINOMETHANAMIDE DIHYDROGEN TETRAOXOSULFATE	159
1-METHYL-4-PHENYL-4-PIPERIDINOL PROPIONATE	213
1-METHYL-4-PHENYLPIPERIDINE-4-CARBOXYLIC ACID	208
1-METHYLCYCLOPROPENE.....	231
1-OCTEN-3-OL	184
1-PENTYL-3-(1-NAPHTHOYL)INDOLE.....	214
1-PENTYL-3-(4-METHYL-1-NAPHTHOYL)INDOLE	214
1-PHENYLETHYL-4-PHENYL-4-PIPERIDINOL ACETATE.....	214

2

2-(2-METHOXYPHENYL)-1-(1-PENTYLINDOL-3-YL)ETHANONE.....	213
2-(4-CHLOROPHENYL)-(1,2,4)TRIAZOLO[5,1-A]ISOQUINOLINE	68
2,2',6,6'-TETRAISOPROPYL-DIPHENYL-CARBODIIMIDE	193, 205, 281
2,2-DPA	229
2,3,6-TBA	154
2,4,5-T	192
2,4-D	138, 170
2,4-DB.....	138
2,4-DES.....	138
2,4-DICHLORPROP	171
2,4-DINITROCHLOROBENZENE.....	77
2,4-TOLUENEDIAMINE	220
2,5-DIMETHOXY-4-(N)-PROPYLTHIOPHENETHYLAMINE	211
2,5-DIMETHOXY-4-BROMOAMPHETAMINE	211
2,5-DIMETHOXY-4-ETHYL- α -AMPHETAMINE	211
2,5-DIMETHOXY-4-ETHYLTHIOPHENETHYLAMINE	211
2,5-DIMETHOXY-4-IODOPHENETHYLAMINE.....	211
2,5-DIMETHOXYAMPHETAMINE	211
2-[(1R,3S)-3-HYDROXYCYCLOHEXYL]-5-(2-METHYLNONAN-2-YL)PHENOL	212
2-[(1R,3S)-3-HYDROXYCYCLOHEXYL]-5-(2-METHYLOCTAN-2-YL)PHENOL	212
2-AMINO-1-(2,5-DIMETHOXY-4-METHYL)PHENYLPROPANE.....	210
2-BUTOXY-2'-THIOCYANODIETHYL ETHER.....	163, 262
2-BUTOXYETHANOL	163, 241, 262
2-CHLORO-6-(TRICHLOROMETHYL)-PYRIDINE.....	166
2-MERCAPTOETHANOL	181

2-METHYL-3-MORPHOLINO-1, 1-DIPHENYLPROPANE CARBOXYLIC ACID	213
2-METHYLTHIO-4-(2-METHYLPROP-2-YL) AMINO-6-CYCLOPROPYLAMINO-5- TRIAZINE	147
2-NITROTOLUENE	204
2-OCTYL-4-ISOTHIAZOLIN-3-ONE	247
2-PHENOXYETHANOL	185, 247, 270
2-PROPYLENE GLYCOL 1-MONOMETHYL	232

3

3-(1,2-DIMETHYLHEPTYL)-1-HYDROXY-7,8,9,10-TETRAHYDRO-6,6,9- TRIMETHYL-6H-DIBENZO (b,d) PYRAN	211
3-(2-DIMETHYLAMINOETHYL)-4-HYDROXYINDOLE	211
3,4,5-TRIMETHOXY- α -METHYLPHENYLETHYLAMINE	215
3,4,5-TRIMETHOXYPHENETHYLAMINE	215
3,4-DICHLORO-N- {[1- (DIMETHYLAMINO)CYCLOHEXYL]METHYL} BENZAMIDE	211
3,4-METHYLENEDIOXYAMPHETAMINE	213
3,4-METHYLENEDIOXYPYROVALERONE	213
3,6,9-TRIOXAUNDECANEDIOIC ACID	157, 274
3-HEXYL-1-HYDROXY-7,8,9,10-TETRAHYDRO-6,6,9-TRIMETHYL-6H-DIBENZO (b,d) PYRAN	212
3-iodo-2-propynyl butyl carbamate	144, 178
3-METHYLFENTANYL	213
3-METHYLTHIOFENTANYL	213

4

4,4'-METHYLENEBIS[2-CHLOROANILINE]	203, 281
4,4-DIAMINODIPHENYLMETHANE	200, 263, 280
4,5-DICHLORO-2-N-OCTYL-3(2H)-ISOTHIAZOLONE	171
4-[4-(ACETYLOXY)PHENYL]-2-	228
4-AMINOPYRIDINE	57, 196, 240, 280
4-BROMO-2,5-DIMETHOXYPHENETHYLAMINE	210
4-CHLOROMETHANDIENONE	68
4-CHLORO-O-TOLURIDINE	199, 280
4-CPA	136
4-CYANO-1-METHYL-4-PHENYLPYPERIDINE	207
4-CYANO-2-DIMETHYLAMINO-4,4'-DIPHENYLBUTANE	211
4-DIMETHYLAMINOAZOBENZENE	200, 280
4-FLUORO-N-METHYLAMPHETAMINE	212
4-HYDROXYBUTANOIC ACID	212
4-METHOXY- α -METHYLPHENYLETHYLAMINE	213
4-METHYLAMINOEX	213
4-METHYLMETHCATHINONE	213
4-METHYLTHIOAMPHETAMINE	213
4-PHENYLPYPERIDINE-4-CARBOXYLIC ACID ETHYL ESTER	209

5

5-(2-AMINOPROPYL)INDAN	210
5,6-DIHYDROXYINDOLINE	171, 218, 243, 265
5-AMINOLEVULINIC ACID	57
5-CHLORO-3-METHYL-4-NITROPYRAZOLE	199
5-METHOXY- α -METHYLTRYPTAMINE	213
5-METHOXY-3,4-METHYLENEDIOXYAMPHETAMINE	213

8

8-HYDROXYQUINOLINE	40, 267
--------------------------	---------

A

ABACAVIR	54
ABAMECTIN	131, 158, 196, 280
ABATACEPT	54
ABCIXIMAB	54
ABIRATERONE ACETATE	54
ABRUS PRECATORIUS	216

ABSCISIC ACID	131
ACAMPROSATE CALCIUM	54
ACARBOSE	54
ACEBUTOLOL	54
ACEPHATE	158
ACEPROMAZINE	54
ACETAMIPRID	158
ACETANILIDE	54
ACETARSOL	54
ACETAZOLAMIDE	54
ACETIC ACID	33, 131, 158, 240, 260
ACETIC ANHYDRIDE	158, 240, 260
ACETOHEXAMIDE	54
ACETONE	131, 240, 260
ACETORPHINE	210
ACETYL ISOVALERYLTYSOSIN	54
ACETYL-ALPHA-METHYLFENTANYL	210
ACETYLCARBROMAL	54
ACETYLCOLINE	54, 276
ACETYLCYSTEINE	33, 54
ACETYLDIGITOXIN	54
ACETYLDIHYDROCODEINE	207
ACETYLMETHADOL	207
ACETYLMETHYLDIMETHYLOXIMIDOPHENYLHYDRAZINE	54
ACETYLMORPHINES	207
ACETYLSTROPHANTHIDIN	54
ACIBENZOLAR-S-METHYL	196, 280
ACICLOVIR	54
ACIFLUORFEN	158
ACINITRAZOLE	158
ACIPIMOX	54
ACITRETIN	54, 235, 260, 286
ACLIDINIUM BROMIDE	54
ACOKANTHERA OUABAIO	54
ACOKANTHERA SCHIMPERI	54
ACONITUM spp.	33, 54
ACORUS CALAMUS	216
ACRIFLAVINE	131, 196
ACRIVASTINE	55
ACROLEIN	196, 240, 280
ACRYLONITRILE	196, 280
ADALIMUMAB	55
ADAPALENE	55, 260, 286
ADEFOVIR	55
ADENOSINE	55
ADIPHENINE	55
ADONIS VERNALIS	55
ADRAFINIL	55
ADRENALINE	48, 55
ADRENOCORTICAL HORMONES	55
AFAMELANOTIDE	55
AFATINIB DIMALEATE	55
AFLIBERCEPT	55
AFOXOLANER	131
AGALSIDASE	55
AGLEPRISTONE	55
AGOMELATINE	55
<i>AGROBACTERIUM RADIOBACTER</i>	228
AKLOMIDE	131
ALACHLOR	196, 280
ALATROFLOXACIN MESYLATE	55
ALBENDAZOLE	55, 131, 158
ALCLOFENAC	55
ALCLOMETASONE	48, 55, 260
ALCOHOL, DEHYDRATED	228
ALCURONIUM	55
ALDESLEUKIN	55

ALDICARB	196
ALDOSTERONE	56, 276
ALDOXYCARB	196
ALDRIN	158
ALEFACEPT	56, 236
ALEMTUZUMAB	56
ALENDRONIC ACID	56
ALFACALCIDOL	56
ALFENTANIL	207
ALFUZOSIN	56
ALGICIDES	222
ALGLUCERASE	56
ALGLUCOSIDASE	56
ALISKIREN	56
ALKALINE SALTS	131, 158, 216, 240, 260
ALKOXYAMPHETAMINES	210
ALKOXYLATED FATTY ALKYLAMINE POLYMER	131, 158
ALKOXYPHENYLETHYLAMINES	210
ALKYLATED PHENYLENEDIAMINES	248
ALKYLTHIOAMPHETAMINES	210
ALLERGENS	56
ALLETHRIN	131, 158
ALLOPURINOL	56
ALLOXYDIM	131
ALLYL ALCOHOL	196, 280
ALLYLISOPROPYLACETYLURE	216
ALLYLOESTRENOL	56
ALLYLPRODINE	210
ALOGLIPTIN	56
ALOSETRON	56
ALOXIPRIN	33
ALPHA1-PROTEINASE INHIBITOR (HUMAN)	56
ALPHACETYLMETHADOL	207
ALPHA-CHLOROHYDRIN	165, 263
ALPHA-CYPERMETHRIN	131, 159, 196
ALPHADOLONE	56
ALPHAMEPRODINE	210
ALPHAMETHADOL	210
ALPHA-METHYLFENTANYL	210
ALPHA-METHYLTHIOFENTANYL	210
ALPHAPRODINE	207
ALPHAXALONE	56
ALPRAZOLAM	207, 282
ALPRENOLOL	56
ALPROSTADIL	56
ALSEROXYLON	56
ALTEPLASE	56
ALTRENOGEST	56
ALTRETAMINE (hexamethylmelamine)	56
ALUM	228
ALUMINIUM AMMONIUM SULFATE	228
ALUMINIUM POTASSIUM SULFATE	228
ALUMINIUM SILICATE	228
ALUMINIUM tris (ETHYLPHOSPHONATE)	228
AMANTADINE	56
AMBENONIUM CHLORIDE	56
AMBRISENTAN	56, 236, 260
AMBRISENTAN	286
AMBUCETAMIDE	56
AMBUTONIUM BROMIDE	56
AMCINONIDE	56
AMETHOCAINE	33, 56
AMETOCTRADIN	228
AMETRYN	132
AMICARBAZONE	159
AMIDITHION	159
AMIFOSTINE	57

AMIKACIN	57
AMILORIDE	57
AMINACRINE	132, 196
AMINES	132, 240, 260
AMINOCAPROIC ACID	57
AMINOCARB	159, 196
AMINOCYCLOPYRACHLOR	132
AMINOETHOXYVINYLGLYCINE	159
AMINOGLUTETHIMIDE	57
AMINOMETRADINE	57
AMINOPHENAZONE	57, 216
AMINOPHYLLINE	48, 57
AMINOPTERIN	57
AMINOPYRALID	132, 159
AMINOREX	57
AMINOSALICYLIC ACID	57
AMIODARONE	57
AMIPHENAZOLE	57
AMISOMETRADINE	57
AMISULPRIDE	57, 282
AMITON	196
AMITRAZ	159
AMITRIPTYLINE	57, 282
AMITROLE	132
AMLODIPINE	57
AMMI VISNAGA	57
AMMONIA	132, 159, 240, 260
AMMONIUM BROMIDE	57
AMMONIUM HYDROXIDE	260
AMMONIUM PERSULFATE	159, 240, 260
AMMONIUM PHOSPHATE	228
AMMONIUM THIOCYANATE	132, 240
AMMONIUM THIOSULPHATE	228
AMODIAQUINE	57
AMOROLFINE	33, 57
AMOXAPINE	57
AMOXYCILLIN	57
AMPHETAMINE	207
AMPHOMYCIN	57
AMPHOTERICIN	58
AMPICILLIN	58
AMPRENAVIR	58
AMPROLIUM	228
AMRINONE	58
AMSACRINE	58
AMYGDALIN	216
AMYL ACETATE	228
AMYL NITRITE	58
α -AMYLASE derived from <i>Aspergillus niger</i>	228
AMYLOBARBITONE	58, 207, 282
AMYLOCAINE	58
ANABOLIC STEROIDAL AGENTS	58, 236
ANAGRELIDE	58
ANAKINRA	58
ANASTROZOLE	58
ANCESTIM	58
ANCHUSA OFFICINALIS	216
ANCROD	58
ANDROGENIC STEROIDAL AGENTS	58, 236
ANDROISOXAZOLE	58
ANDROSTANOLONE	58
ANDROSTENEDIOL	58
ANDROSTENEDIONE	58
ANDROSTENEDIONE ALBUMEN	228
ANECORTAVE	58
ANGIOTENSIN AMIDE	58
ANHYDRIDES	240, 260

ANHYDRIDES, ORGANIC ACID	132
ANIDULAFUNGIN	58
ANILERIDINE	207
ANILINE	159, 240, 260
ANISE OIL	132, 240
ANISTREPLASE	58
ANITMONY CHLORIDE	240
ANTAZOLINE	33, 58
ANTIBIOTIC SUBSTANCES	58
ANTIGENS	58
ANTIHISTAMINES	58, 260
ANTIMONY	59
ANTIMONY COMPOUNDS	159, 240, 276
ANTISERA	59
APIXABAN	59
APOCYNUM spp.	59
APOMORPHINE	59, 276
APRACLONIDINE	59
APRAMYCIN	59
APREPITANT	59
APRONAL	59
APROTININ	59
ARECOLINE	59
ARIPIRAZOLE	59, 282
ARISTOLOCHIA spp.	216
ARISTOLOCHIC ACID(S)	216
AROMATIC EXTRACT OILS	261
ARPINOCID	280
ARPRINOCID	196
ARSENIC	59, 159, 196, 276, 280
ARTEMETHER	59
ARTICAINE	59
ASARUM spp.	216
ASENAPINE	59, 282
ASPARTIC ACID	228
ASPIRIN	33, 59, 132, 159, 261
ASTEMIZOLE	59, 261
ASULAM	228
ATAMESTANE	59
ATAZANAVIR	59
ATENOLOL	59
ATIPAMEZOLE	59
ATOMOXETINE	59
ATORVASTATIN	59
ATOSIBAN	59
ATOVAQUONE	59
ATRACURIUM BESYLATE	60
ATRAZINE	132
ATROPA BELLADONNA (belladonna)	34, 60, 276
ATROPINE	34, 60, 276
ATROPINE METHONITRATE	60
AURANOFIN	60
AUROTHIOMALATE SODIUM	60
AVILAMYCIN	60
AVIPTADIL	60
AVOPARCIN	60
AXITINIB	60
AZACITIDINE	60
AZACONAZOLE	160
AZACYCLONOL	60
AZADIRACHTA INDICA	160, 216, 240, 261
AZADIRACHTA INDICA EXTRACTS	132
AZAFENIDIN	197
AZAMETHIPHOS	160
AZAPERONE	60
AZAPROPAZONE	60
AZARIBINE	60

AZATADINE.....	282
AZATADINE.....	48, 60
AZATHIOPRINE	60
AZELAIC ACID.....	34, 60
AZELASTINE	34, 60
AZIMSULFURON	228
AZINPHOS-ETHYL.....	197
AZINPHOS-METHYL.....	197
AZITHROMYCIN.....	60
AZLOCILLIN.....	60
AZOBENZENE	160
AZOCYCLOTIN	197, 261, 280
AZOXYSTROBIN.....	132
AZTREONAM.....	60

B

BACAMPICILLIN	60
<i>BACILLUS SPHAERICUS</i> STRAIN 2362.....	228
<i>BACILLUS THURINGIENSIS</i>	228
BACILLUS THURINGIENSIS DELTA ENDOTOXIN.....	132
<i>BACILLUS TOYOI</i>	228
BACITRACIN	60
BACLOFEN.....	60, 282
BACTERIAL CULTURE MEDIA	222
BACTERIOCIDES.....	222
BACULOVIRUS <i>CYDIA POMONELLA</i>	228
BALSALAZIDE	60
BAMBERMYCIN.....	61, 160
BAMBUTEROL	61
BAMETHAN.....	61
BAMIPINE	61
BARBITURATES.....	61
BARIUM SALTS.....	160, 240
BARIUM SILICOFLUORIDE	132
BASIC ORANGE 31	160, 216
BASIL OIL	133, 240
BASILIXIMAB.....	61
BAY OIL.....	160, 240
BAZEDOXIFENE	61
BEAUVERIA BASSIANA.....	133, 161
BECAPLERMIN.....	61
BECLAMIDE	61
BECLOMETHASONE	34, 61
BELATACEPT	61
BELIMUMAB	61
BEMEGRIDE.....	61
BENACTYZINE.....	61
BENALAXYL	133
BENAZEPRIL	61
BENDAMUSTINE.....	61
BENDIOCARB.....	133, 161, 197
BENDROFLUAZIDE.....	61
BENETHAMINE PENICILLIN	61
BENFLURALIN	228
BENOMYL	197, 261
BENORYLATE.....	61
BENOXAPROFEN.....	61
BENPERIDOL.....	61
BENQUINOX.....	161
BENSERAZIDE.....	61
BENSULFURON-METHYL.....	228
BENSULIDE	161
BENTAZONE.....	133
BENTONITE	228
BENZALKONIUM CHLORIDE.....	133, 161, 241
BENZATHINE PENICILLIN.....	61

BENZENE	197, 241, 261, 280
BENZETHIDINE	210
BENZHEXOL	61
BENZIDINE-BASED AZO DYES	197
BENZILONIUM	61
BENZOCAINE	34, 61
BENZODIAZEPINE DERIVATIVES	62, 236
BENZOFENAP	133
BENZOYL PEROXIDE	34, 62, 133, 241, 261
BENZOYLINDOLES	210
BENZPHETAMINE	62
BENZTHIAZIDE	62
BENZTROPINE	62, 282
BENZYDAMINE	34, 62
BENZYL BENZOATE	228
BENZYLMORPHINE	207
BENZYLPENICILLIN	62
BENZYLPIPERAZINE	210
BEPHENIUM SALTS	34
BEPRIDIL	62
BERACTANT	62
BERGAMOT OIL	133, 241, 261
BERYLLIUM	161, 261
BESIFLOXACIN	62
BETACETYLMETHADOL	210
BETACYFLUTHRIN	133, 161, 198
BETA-CYPERMETHRIN	161
BETAHISTINE	62
BETA-HYDROXY-3-METHYLFENTANYL	210
BETA-HYDROXYFENTANYL	210
BETAINE HYDROCHLORIDE	228
BETAMEPRODINE	210
BETAMETHADOL	210
BETAMETHASONE	62
BETAPRODINE	210
BETAXOLOL	62
BETHANECHOL CHLORIDE	62
BETHANIDINE	62
BEVACIZUMAB	62
BEVANTOLOL	62
BEXAROTENE	62, 235, 261, 286
BEZAFIBRATE	62
BEZITRAMIDE	207
BHC	161
BICALUTAMIDE	62
BIFENAZATE	228
BIFENTHRIN	162, 198
BIFLUORIDES	133, 162, 198, 241, 261, 280
BIFONAZOLE	35, 62
BIMATOPROST	62
BIOALLETHRIN	134, 162
BIORESMETHRIN	134
BIPERIDEN	63
BISMUTH COMPOUNDS	63
BISMUTH SUBNITRATE	228
BISOPROLOL	63
BISPYRIBAC	134
BISTRIFLURON	228
BITHIONOL	217, 261
BIURET	228
BIVALIRUDIN	63
BLEOMYCIN	63
BOCEPREVIR	63
BOLANDIOL	63
BOLASTERONE	63
BOLAZINE	63
BOLDENONE (dehydrotestosterone)	63

BOLENOL.....	63
BOLMANTALATE.....	63
BORAGO OFFICINALIS.....	217
BORAX.....	241
BORIC ACID.....	134, 241
BORON.....	63
BORON TRIFLUORIDE.....	134, 162, 198, 241, 261, 280
BORTEZOMIB.....	63
BOSCALID.....	228
BOSENTAN.....	63, 236, 261, 286
BOSUTINIB.....	63
BOTULINUM TOXINS.....	63
BOVINE SOMATOTROPHIN.....	228
BRAGANTIA spp.....	217
BRENTUXIMAB VEDOTIN.....	63
BRETYLIUM TOSYLATE.....	63
BRIMONIDINE.....	63
BRINZOLAMIDE.....	63
BRODIFACOUM.....	162, 198, 280
BROMACIL.....	228
BROMADIOLENE.....	280
BROMADIOLONE.....	162, 198
BROMAZEPAM.....	63, 282
BROMETHALIN.....	162, 198
BROMHEXINE.....	35
BROMIDES.....	64
BROMINE.....	198, 280
BROMOCRIPTINE.....	64
BROMOFORM.....	64, 162, 241, 262
BROMOPHOS.....	162
BROMOPHOS-ETHYL.....	163
BROMOPROPYLATE.....	229
BROMOXYNIL.....	163
BROMPHENIRAMINE.....	35, 48, 64, 282
BROMUCONAZOLE.....	134, 163
BROMVALETONE.....	64
BROTIANIDE.....	163
BRUCINE.....	198, 241, 280
BRUGMANSIA spp.....	64
BUCLIZINE.....	282
BUCLIZINE.....	48, 64
BUCLOSAMIDE.....	217
BUDESONIDE.....	35, 64
BUFEXAMAC.....	64
BUFOTENINE.....	210
BUMETANIDE.....	64
BUNAMIDINE.....	163
BUNIODYL SODIUM.....	217
BUPHENINE.....	64
BUPIRIMATE.....	229
BUPIVACAINE.....	64, 134
BUPRENORPHINE.....	207, 282
BUPROFEZIN.....	134
BUPROPION.....	64
BUSERELIN.....	64
BUSPIRONE.....	64
BUSULPHAN.....	64
BUTACAINE.....	64
BUTACARB.....	163
BUTAFENACIL.....	229
BUTHIDAZOLE.....	134
BUTOBARBITONE.....	207, 282
BUTOCONAZOLE.....	48, 64, 277
BUTORPHANOL.....	207
BUTOXYCARBOXIM.....	134, 163
BUTOXPOLYPROPYLENE GYLCOL.....	229
BUTRACONAZOLE.....	64

BUTRALIN	134
BUTROXYDIM	134
BUTYL AMINO BENZOATE	64
BUTYL NITRITE	64
BUTYLCHLORAL HYDRATE	64
BUTYRIC ACID	163

C

CABAZITAXEL	64
CABERGOLINE	64
CACALIA spp	217
CACODYLIC ACID	163, 198
CADMIUM COMPOUNDS	64, 163, 241
CADUSAFOS	163, 198
CAJUPUT OIL	163, 241
CALCIFEROL	164, 198, 280
CALCIPOTRIOL	64
CALCITONIN	64
CALCITRIOL	65
CALCIUM CARBIMIDE	65
CALCIUM HYDROXYLAPATITE	65
CALCIUM POLYSTYRENE SULPHONATE	65
CALOTROPIS GIGANTEA	65
CALOTROPIS PROCERA	65
CALUSTERONE	65
CAMBENDAZOLE	164
CAMPHOR	134, 164, 241, 262
CAMPHORATED OIL	65
CAMPHOTAMIDE	65
CANAGLIFLOZIN	65
CANAKINUMAB	65
CANDESARTAN CILEXETIL	65
CANDICIDIN	65
CANINE TICK ANTI-SERUM	65
CANNABIS	210
CANTHARIDIN	65, 276
CAPECITABINE	65
CAPREOMYCIN	65
CAPTAFOL	198, 280
CAPTAN	164
CAPTODIAME	65
CAPTOPRIL	65
CAPURIDE	65
CARAMIDE PEROXIDE	262
CARAMIPHEN	65
CARBACHOL	65
CARBADOX	198, 280
CARBAMAZEPINE	65
CARBAMIDE PEROXIDE	134, 164, 217, 241
CARBARYL	65, 134, 164
CARBAZOCHROME	65
CARBENDAZIM	198
CARBENICILLIN	65
CARBENOXOLONE	65
CARBETAMIDE	229
CARBETAPENTANE	35
CARBETOCIN	65
CARBIDOPA	66
CARBIMAZOLE	66
CARBOCISTEINE	35
CARBOCROMEN	66
CARBOFURAN	198
CARBON DISULFIDE	164, 241
CARBON TETRACHLORIDE	198, 242, 262, 280
CARBONYL SULFIDE	198
CARBOPHENOTHION	198

CARBOPLATIN.....	66
CARBOPROST.....	66
CARBOSULFAN.....	198
CARBOXIN.....	229
CARBROMAL.....	66
CARBUTAMIDE.....	66
CARBUTEROL.....	66
CARFENTANYL.....	207
CARFENTRAZONE-ETHYL.....	229
CARGLUMIC ACID.....	66
CARINDACILLIN.....	66
CARISOPRODOL.....	66
CARMUSTINE.....	66
CARNIDAZOLE.....	66
CARPROFEN.....	66
CARVEDILOL.....	66
CASPOFUNGIN.....	66
CASSIA OIL.....	134, 242, 262
CASTOR OIL, MONOMALEATE.....	165
CATHINE.....	66
CATHINONE.....	211
CATUMAXOMAB.....	66
CEFACETRILE.....	66
CEFACLOR.....	66
CEFADROXIL.....	66
CEFALORIDINE.....	66
CEFAMANDOLE.....	66
CEFAPIRIN.....	66
CEFAZOLIN.....	66
CEFEPIME.....	66
CEFETAMET.....	66
CEFIXIME.....	66
CEFODIZIME.....	66
CEFONICID.....	66
CEFOPERAZONE.....	67
CEFOTAXIME.....	67
CEFOTETAN.....	67
CEFOTIAM.....	67
CEFOVECIN.....	67
CEFOXITIN.....	67
CEFPIROME.....	67
CEFPODOXIME.....	67
CEFQUINOME.....	67
CEFSULODIN.....	67
CEFTAROLINE FOSAMIL.....	67
CEFTAZIDIME.....	67
CEFTIBUTEN.....	67
CEFTIOFUR.....	67
CEFTRIAZONE.....	67
CEFUROXIME.....	67
CELECOXIB.....	67
CELIPROLOL.....	67
CELLULASE.....	229
CEPHAELIS ACUMINATA.....	67
CEPHAELIS IPECACUANHA.....	67
CEPHALEXIN.....	67
CEPHALONIUM.....	67
CEPHALOTHIN.....	67
CEPHRADINE.....	67
CERAMICS.....	222
CERIVASTATIN.....	67
CERTOLIZUMAB PEGOL.....	67
CERULETIDE.....	67
CETIRIZINE.....	282
CETIRIZINE.....	35, 67
CETRORELIX.....	68
CETUXIMAB.....	68

CETYL ALCOHOL.....	229
CHAMOMILE OIL.....	229
CHEMISTRY SETS.....	222
CHENODEOXYCHOLIC ACID.....	68
CHINA CLAY.....	229
CHLOPHEDIANOL.....	35
CHLORAL FORMAMIDE.....	68
CHLORAL HYDRATE.....	68, 282
CHLORALOSE.....	68, 165
CHLORAMBUCIL.....	68
CHLORAMPHENICOL.....	48, 68
CHLORANDROSTENOLONE.....	68
CHLORANTRANILIPROLE.....	229
CHLORAZANIL.....	68
CHLORBUTOL.....	35, 48
CHLORCYCLIZINE.....	68
CHLORDANE.....	165
CHLORDECONE.....	198, 280
CHLORDIAZEPOXIDE.....	68, 282
CHLORDIMEFORM.....	199, 280
CHLORFENAC.....	135
CHLORFENAPYR.....	135, 165, 199
CHLORFENETHOL.....	165
CHLORFENSON.....	135
CHLORFENVINPHOS.....	199
CHLORFLUAZURON.....	229
CHLORFLURENOL.....	229
CHLORHEXIDINE.....	135, 165, 199
CHLORIDAZON.....	229
CHLORIDE.....	242
CHLORINATING COMPOUNDS.....	135, 165, 242, 262
CHLORINE.....	199, 276, 280
CHLORMEQUAT.....	165
CHLORMERODRIN.....	68
CHLORMETHIAZOLE.....	68, 282
CHLORMEZANONE.....	68
CHLORNIDINE.....	135
CHLOROCRESOL.....	135, 242
CHLOROFORM.....	35, 68, 165, 242, 263
CHLOROMETHIURON.....	199, 280
CHLOROPHACINONE.....	165
CHLOROPICRIN.....	165, 199
CHLOROPRCRIN.....	280
CHLOROQUINE.....	68
CHLOROTHALONIL.....	166
CHLOROTHIAZIDE.....	68
CHLOROTRIANISENE.....	68
CHLOROXYDIENONE.....	68
CHLOROXYLENOLS.....	229
CHLORPHENIRAMINE.....	35, 48, 68, 282
CHLORPHENTERMINE.....	68
CHLORPROMAZINE.....	68, 282
CHLORPROPAMIDE.....	68
CHLORPROPHAM.....	135
CHLORPROTHIXENE.....	68
CHLORPYRIFOS.....	135, 166
CHLORPYRIFOS-METHYL.....	166
CHLORQUINALDOL.....	69
CHLORSULFURON.....	135
CHLORTETRACYCLINE.....	69, 135
CHLORTHAL-DIMETHYL.....	135
CHLORTHALIDONE.....	69
CHLORTHIAMID.....	166
CHLORTHIOPHOS.....	199
CHLORZOXAZONE.....	69
CHOLERA VACCINE.....	69
CHOLESTYRAMINE.....	69

CHROMATES	166, 242, 263
CHROMIUM TRIOXIDE.....	166, 242, 263
CHYMOPAPAIN	69
CICLACILLIN.....	69
CICLESONIDE.....	69
CICLOPIROX.....	35, 48, 69
CIDOFOVIR.....	69
CILASTATIN	69
CILAZAPRIL.....	69
CILOSTAZOL.....	69
CIMETIDINE.....	48, 69, 263
CINACALCET.....	69
CINCHOCAINE.....	36, 69
CINCHOPHEN.....	217
CINEOLE.....	166, 242
CINMETHYLIN.....	136
CINNAMEDRINE.....	36
CINNAMON BARK OIL.....	136, 242, 263
CINNAMON LEAF OIL.....	166, 242
CINOXACIN.....	69
CIPROFLOXACIN.....	69
CISAPRIDE.....	69
CISATRACURIUM BESYLATE.....	69
CISPLATIN.....	69
CITALOPRAM.....	69
CITRONELLA OIL.....	229
CLADRIBINE.....	69
CLANOBUTIN.....	69
CLARITHROMYCIN.....	69
CLARY SAGE OIL.....	229
CLAVULANIC ACID.....	69
CLEMASTINE.....	282
CLEMASTINE.....	48, 69
CLEMIZOLE.....	70
CLENBUTEROL.....	70
CLETHODIM.....	136
CLEVIDIPINE.....	70
CLIDINIUM BROMIDE.....	70
CLIMBAZOLE.....	136, 167, 242
CLINDAMYCIN.....	70
CLIOQUINOL.....	70, 217
CLOBAZAM.....	70
CLOBETASOL.....	70
CLOBETASONE.....	48, 70, 263
CLOCORTOLONE.....	70
CLODINAFOP-PROPARGYL.....	167
CLODRONIC ACID.....	70
CLOFARABINE.....	70
CLOFAZIMINE.....	70
CLOFENAMIDE.....	70
CLOFENTEZINE.....	136
CLOFIBRATE.....	70
CLOMAZONE.....	167
CLOMIPHENE.....	70, 235
CLOMIPRAMINE.....	70, 282
CLOMOCYCLINE.....	70
CLONAZEPAM.....	70, 282
CLONIDINE.....	282
CLONIDINE.....	70
CLONITAZENE.....	211
CLOPAMIDE.....	70
CLOPIDOGREL.....	70
CLOPIDOL.....	229
CLOPROSTENOL.....	70
CLOPYRALID.....	136
CLOQUINTOCET-MEXYL.....	136
CLORAZEPATE.....	70, 282

CLOREXOLONE	70
CLORPRENALINE	70
CLORSULON	136
CLOSANTEL	167
CLOSTEBOL	70
CLOTHIANIDIN	136, 167
CLOTRIMAZOLE	36, 48, 70, 167, 263, 277
CLOVE OIL	136, 167, 242, 263
CLOXACILLIN	71
CLOZAPINE	71, 235, 282
COAL TAR	217
COBALT	71
COBALT NAPHTHENATE	229
COBICISTAT	71
COCA LEAF	211
COCAINE	207
COCOYL GLYCINATE	168, 242
CODEINE	36, 48, 71, 207, 282
CODEINE-N-OXIDE	207
CO-DERGOCRINE	71
CODOXIME	211
COLASPASE	71
COLCHICINE	71
COLCHICUM AUTUMNALE	71
COLECALCIFEROL	199, 280
COLESTIPOL	71
COLFOSCERIL PALMITATE	71
COLISTIN	71
COLLAGEN	71
COLLAGENASE CLOSTRIDIUM HISTOLYTICUM	71
COLOPHONY	229
CONCENTRATE OF POPPY STRAW	207
CONIUM MACULATUM	217
CONVALLARIA KEISKI	71
CONVALLARIA MAJALIS	71
COPPER ACETATE	136, 168
COPPER COMPOUNDS	71, 136, 168, 222
COPPER HYDROXIDE	136, 168
COPPER NITRATE	168
COPPER OXIDES	136, 168
COPPER OXYCHLORIDE	136, 168
COPPER SULFATE	136, 169, 242
CORIFOLLITROPIN ALFA	71, 235
CORONILLA spp.	71
CORTICOSTERONE	71
CORTICOTROPHIN	71
CORTISONE	72
COTARNINE	217
CO-TRIMOXAZOLE	72
COUMAPHOS	169, 199
COUMARIN	72
COUMATETRALYL	136, 169, 199, 280
CREOSOTE	36, 169, 199, 242
CRESOLS	242
CRIZOTINIB	72
CROFELEMER	72
CROSPVIDONE	229
CROTALARIA spp.	217
CROTON TIGLIUM	217, 276
CROTOXYPHOS	169
CRUFOMATE	169
CRYSTAL VIOLET	72
<i>CULICINOMYCES CLAVOSPORUS</i>	229
CUPRIMYXIN	72
CURARE	72
CYANAMIDE	169
CYANATRYN	136

CYANAZINE	169
CYANIDES	199, 242, 263
CYANOACRYLATE ESTERS	136
CYANOACRYLIC ACID ESTERS	242
CYANOGEN	199, 280
CYANTRANILIPROLE	137
CYANURIC ACID	137, 242, 263
CYAZOFAMID	137
CYCHEXATIN	280
CYCLAMIC ACID	229
CYCLANDELATE	72
CYCLANILIDE	169
CYCLIZINE	49, 72, 282
CYCLOBARBITONE	207, 282
CYCLOBENZAPRINE	72
CYCLOFENIL	72, 235
CYCLOHEXANE	229
CYCLOHEXANOL ACETATE	229
CYCLOHEXANONE PEROXIDE	137, 242, 263
CYCLOHEXIMIDE	72
CYCLOHEXYLPHENOLS	211
CYCLOPENTHAZIDE	72
CYCLOPENTOLATE	72
CYCLOPHOSPHAMIDE	72
CYCLOPROPANE	72
CYCLOPROTHRIN	137
CYCLOSERINE	72, 282
CYCLOSPORIN	72
CYCLOTHIAZIDE	72
CYCLOXYDIM	137
CYCRIMINE	72
CYCTEAMINE	242, 263
CYFLUFENAMID	137
CYFLUTHRIN	137, 169
CYHALOFOP-BUTYL	137
CYHALOTHRIN	199
CYHEXATIN	199
CYMARIN	72
CYMAZOLE	137
CYNOGLOSSUM spp	217
CYOMETRINIL	169
CYPERMETHRIN	137, 169
CYPHENOTHRIN	137, 169
CYPROCONAZOLE	137
CYPRODINIL	137
CYPROHEPTADINE	49, 72, 282
CYPROTERONE	72
CYROMAZINE	229
CYSTEAMINE	72, 137, 169, 282
CYTARABINE	72
CYTHIOATE	137, 170

D

DABIGATRAN	72
DABRAFENIB MESILATE	72
DACARBAZINE	72
DACLIZUMAB	72
DACTINOMYCIN	73
DALFOPRISTIN	73
DALTEPARIN	73
DAMINOZIDE	138
DANAPAROID	73
DANAZOL	73
DANTHRON	73
DANTROLENE	73, 282
DAPAGLIFLOZIN	73

DAPOXETINE	73
DAPSONE	73
DAPTOMYCIN	73
DARBEPOETIN	73, 236
DARIFENACIN	73
DARUNAVIR	73
DASATINIB	73
DATURA spp.	36, 73
DATURA STRAMONIUM	36, 73
DATURA TATULA	36, 73
DAUNORUBICIN	73
DAZOMET	170
DEANOL	73
DEBRISOQUINE	73
DECAMETHONIUM	73
DECOQUINATE	138
DEFERASIROX	73
DEFERIPRONE	73
DEFLAZACORT	74
DEGARELIX	74
DEHYDROCHLOROMETHYLTESTOSTERONE	74
DEHYDROCORTICOSTERONE	74
DELAVIRDINE	74
DELPHINIUM STAPHISAGRIA	37
DELTAMETHRIN	138, 170, 199
DEMBREXINE	74, 138
DEMECARIUM	74
DEMECLOCYCLINE	74
DEMETON	199
DEMETON-O-METHYL	200
DEMETON-S-METHYL	200
DENOSUMAB	74
DEOXYCORTONE	74
DEOXYRIBONUCLEASE	74
DERACOXIB	74
DERQUANTEL	170
DEFERRIOXAMINE	74
DESFLURANE	74
DESIPRAMINE	74, 282
DESIRUDIN	74
DESLANOSIDE	74
DESLORATADINE	37, 74
DESLORELIN	74
DESMOPRESSIN	74
DESOGESTREL	74
DESOMORPHINE	211
DESONIDE	74
DESOXYMETHASONE	74
DESVENLAFAXINE	74
DETOMIDINE	74
DEXAMETHASONE	74
DEXAMPHETAMINE	207
DEXCHLORPHENIRAMINE	37, 49, 74, 282
DEXFENFLURAMINE	74
DEXMEDETOMIDINE	75
DEXTRANS, GELATIN – SUCCINYLATED & ETHERIFIED STARCHES	222
DEXTROMETHORPHAN	37, 75
DEXTROMORAMIDE	207, 282
DEXTROPROPOXYPHENE	75, 207, 236, 282
DEXTRORPHAN	75
DIAFENTHIURON	138
DIALIFOS	200
DIAMPROMIDE	211
DIAMTHAZOLE	75
DIAVERIDINE	75
DIAZEPAM	75, 282
DIAZINON	138, 170

DIAZOXIDE.....	75
DIBENZEPIN.....	75
DIBENZOPYRANS.....	211
DIBOTERMIN.....	75
DIBROMOPROPAMIDINE.....	37, 75
DICAMBA.....	138, 170
DICHOLOBENIL.....	170
DICHOEOETHYL ETHER.....	263
DICHLOFENTHION.....	170
DICHOLOFLUANID.....	170
DICHLONE.....	138
DICHLORALPHENAZONE.....	75
DICHLORMETHANE.....	265
DICHLOROBENZENE.....	138, 170, 242
DICHLOROETHYL ETHER.....	170, 242
DICHLOROETHYLENE.....	263
DICHLOROISOCYANURATES.....	243, 263
DICHLOROISOCYANURIC ACID.....	138, 170
DICHLOROMETHANE.....	138, 243
DICHLOROPHEN.....	75, 139, 171
DICHLORPHENAMIDE.....	75
DICHLORVOS.....	139, 171, 200
DICHROMATES.....	243
DICLAZURIL.....	229
DICLOBUTRAZOL.....	139
DICLOFENAC.....	37, 49, 75, 265, 277
DICLOFOP-METHYL.....	171
DICLORAN.....	139
DICLOXACILLIN.....	75
DICOFOL.....	139
DICOPHANE.....	217
DICROTOPHOS.....	200
DICYCLANIL.....	171
DICYCLOMINE.....	75
DIDANOSINE.....	75
DIDECYLDIMETHYLAMMONIUM SALTS.....	171
DIELDRIN.....	171
DIENESTROL.....	75, 265, 286
DIENOGEST.....	75
DIESEL.....	243
DIETHANOLAMINE.....	139, 171, 243, 265
DIETHAZINE.....	75
DIETHYL CARBONATE.....	229
DIETHYL CARBAMAZINE.....	75
DIETHYLENE GLYCOL.....	139, 171, 217
DIETHYLENE GLYCOL MONOBUTYL ETHER.....	139
DIETHYLHEXYL PHTHALATE.....	218
DIETHYLPHTHALATE.....	218
DIETHYLPROPION.....	75
DIETHYLTHIAMBUTENE.....	211
DIETHYLTOLUAMIDE.....	265
DIETHYLTOLUAMIDE (DEET).....	139
DIFENACOUM.....	171, 200, 280
DIFENOCONAZOLE.....	139
DIFENOXIN.....	282
DIFENOXIN.....	75, 207
DIFENZOQUAT.....	171
DIFETHIALONE.....	171, 200
DIFLORASONE.....	76
DIFLOXACIN.....	76
DIFLUBENZURON.....	139
DIFLUCORTOLONE.....	76
DIFLUFENICAN.....	229
DIFLUNISAL.....	76
DIGITALIS LANATA.....	76
DIGITALIS PURPUREA.....	76
DIGITOXIN.....	76

DIGOXIN.....	76
DIGOXIN-SPECIFIC ANTIBODY FRAGMENT F (Ab)	76
DIHYDRALAZINE	76
DIHYDROCODEINE.....	37, 49, 76, 207, 282
DIHYDROERGOTOXINE.....	76
DIHYDROLONE.....	76
DIHYDROMORPHINE.....	207
DIHYDROSTREPTOMYCIN.....	76
DIHYDROTACHYSTEROL.....	76
DI-iodohydroxyquinoline.....	49, 76
DIISOPROPYLAMINE DICHLOROACETATE	76
DIKEGULAC-SODIUM.....	229
DILTIAZEM.....	76
DIMEFOX.....	200
DIMENHYDRINATE	37, 49, 76, 277, 282
DIMENOXADOL.....	211
DIMEPHEPTANOL.....	211
DIMERCAPROL.....	76
DIMETHANDROSTANOLONE.....	76
DIMETHAZINE.....	76
DIMETHENAMID-P.....	171
DIMETHICODIETHYLBENZALMALONATE	139
DIMETHICONE.....	229
DIMETHINDENE.....	49, 76, 282
DIMETHIPIN.....	171
DIMETHIRIMOL.....	139
DIMETHOATE.....	172
DIMETHOMORPH.....	140
DIMETHOTHIAZINE.....	76
DIMETHOXANATE.....	77
DIMETHYL ETHER.....	229
DIMETHYL FUMARATE.....	77
DIMETHYL SULFATE.....	200, 265
DIMETHYL SULFOXIDE.....	77, 172, 243, 265
DIMETHYLACETAMIDE.....	140, 172
DIMETHYLFORMAMIDE.....	140, 172, 243, 265
DIMETHYLPHTHALATE.....	218
DIMETHYLTHIAMBUTENE.....	211
DIMETILAN.....	200
DIMETRIDAZOLE.....	77
DINICONAZOLE.....	140
DINITROCRESOLS.....	77, 172, 200, 243, 280
DINITRONAPHTHOLS.....	77
DINITROPHENOLS.....	77, 172, 200, 243, 265, 280
DINITROTHYMOLS.....	77
DINOCAP.....	200, 265
DINOPROST.....	77, 235
DINOPROSTONE.....	77, 235
DINOSEB.....	200, 280
DI-N-PROPYL ISOCINCHOMERONATE.....	140
DIOXACARB.....	172
DIOXANE.....	172, 243, 265, 276
DIOXAPHETYL BUTYRATE.....	211
DIPERODON.....	77
DIPHACINONE.....	172
DIPHEMANIL.....	77
DIPHENAMID.....	140
DIPHENHYDRAMINE.....	37, 49, 77, 282
DIPHENIDOL.....	77
DIPHENOXYLATE.....	49, 77, 208, 265, 277, 282
DIPHENYLAMINE.....	229
DIPHENYLPYRALINE.....	77, 282
DIPHThERIA TOXOID.....	77
DIPIANONE.....	208
DIPIVEFRIN.....	77
DIPROPYLENE GLYCOL.....	229
DIPYRIDAMOLE.....	77

DIQUAT	172, 200
DIRITHROMYCIN	77
DIRLOTAPIDE	77
DISOPHENOL	77
DISOPYRAMIDE	77
DISTIGMINE	77
DISTILLATE	243
DISULFIRAM	77, 172
DISULFOTON	172, 200
DISULPHAMIDE	77
DITHIANON	172
DITHIAZANINE	78, 172
DITHIOPYR	140
DITHRANOL	49
DITIOCARB	78
DIUREDOSAN	172
DIURON	229
DOBUTAMINE	78
DOCETAXEL	78
DOCUSATE SODIUM	229
DODINE	173
DOFETILIDE	78
DOLASETRON	78
DOLUTEGRAVIR	78
DOMPERIDONE	78
DONEPEZIL	78
DOPAMINE	78
DOPEXAMINE	78
DORAMECTIN	140, 173, 200
DORIPENEM	78
DORNASE	78
DORZOLAMIDE	78
DOTHIEPIN	78, 282
DOXANTRAZOLE	78
DOXAPRAM	78
DOXAZOSIN	78
DOXEPIN	78, 282
DOXORUBICIN	78
DOXYCYCLINE	78
DOXYLAMINE	38, 49, 78, 282
d-PHENOTHRIN	232
d-PULEGONE	188, 249
DROMETRIZOLE TRISILOXANE	229
DRONABINOL	208, 235, 282
DRONEDARONE	78
DROPERIDOL	78, 282
DROSPIRENONE	78
DROSTANOLONE	78
DROTEBANOL	208
DROTRECOGIN	78
DSMA	173, 200
DUBOISIA LEICHHARDTII	38, 78
DUBOISIA MYOPOROIDES	38, 78
DULCIN	218
DULOXETINE	78, 282
DUTASTERIDE	79
DYDROGESTERONE	79

E

ECGONINE	211
ECONAZOLE	38, 49, 79, 173, 265, 277
ECOTHIOPATE	79
ECTYLUREA	79
ECULIZUMAB	79
EDETIC ACID	79
EDOXUDINE	79

EDROPHONIUM	79
EFALIZUMAB	79
EFAVIRENZ	79
EFLORNITHINE	79
EFORMOTEROL	79
ELECTRICAL ACCUMULATORS, BATTERIES, COMPONENTS or LAMPS	222
ELECTRONIC COMPONENTS	222
ELETRIPTAN	79
ELOSULFASE ALFA	79
ELTENAC	79
ELTROMBOPAG	79
ELVITEGRAVIR	79
EMAMECTIN	140, 173, 200
EMEPRONIUM	79
EMETINE	79
EMODEPSIDE	140, 173
EMPAGLIFLOZIN	79
EMTRICITABINE	79
ENALAPRIL	79
ENDOSULFAN	173, 200
ENDOTHAL	173, 200
ENDRIN	200
ENESTEBOL	79
ENFLURANE	79
ENFUVIRTIDE	80
ENHANCING AGENTS	222
ENOBOSARM	80
ENOXACIN	80
ENOXAPARIN	80
ENOXIMONE	80
ENPROSTIL	80
ENROFLOXACIN	80
ENTACAPONE	80
ENTECAVIR	80
EPHEDRA spp.	80
EPHEDRINE	80, 236, 265
EPICHLOROHYDRIN	200, 265, 280
EPICILLIN	80
EPIDERMAL GROWTH FACTOR	200, 280
EPINASTINE	80
EPIRUBICIN	80
EPITIOSTANOL	80
EPLERENONE	80
EPOETINS	80, 236
EPOPROSTENOL	80
EPOXICONAZOLE	140
EPOXY RESINS	243, 265
EPOXY RESINS, LIQUID	140
EPRINOMECTIN	140, 200
EPROSARTAN	80
EPSIPRANTEL	229
EPTC	173
EPTIFIBATIDE	80
ERGOMETRINE	80
ERGOT	80
ERGOTAMINE	80
ERGOTOXINE	80
ERIBULIN MESYLATE	80
ERLOTINIB	80
ERTAPENEM	80
ERYSIMUM spp.	80, 276
ERYTHRITYL TETRANITRATE	49
ERYTHROMYCIN	80
ERYTHROPOIETIN	80, 236
ERYTHROPOIETINS	81, 236
ESBIOTHRIN	140, 173
ESCITALOPRAM	81

ESFENVALERATE.....	140, 173
ESMOLOL.....	81
ESOMEPRAZOLE.....	50, 81
ESTRAMUSTINE.....	81
ESTROPIPATE.....	81
ETACONAZOLE.....	200, 280
ETAFEDRINE.....	38
ETANERCEPT.....	81
ETHACRYNIC ACID.....	81
ETHAMBUTOL.....	81
ETHAMETSULFURON-METHYL.....	230
ETHAMIVAN.....	81
ETHANOLAMINE.....	81, 140, 173, 243, 266
ETHCHLORVYNOL.....	81
ETHEPHON.....	173
ETHER.....	38, 81, 140, 173, 243, 266
ETHINAMATE.....	81
ETHINYLOESTRADIOL.....	81
ETHIOFENCARB.....	173
ETHION.....	200
ETHIONAMIDE.....	81
ETHISTERONE.....	81
ETHOATE-METHYL.....	173
ETHOFUMESATE.....	140
ETHOGLUCID.....	81
ETHOHEPTAZINE.....	81
ETHOPABATE.....	230
ETHOPROPAZINE.....	81
ETHOPROPHOS.....	173, 201
ETHOSUXIMIDE.....	81
ETHOTOIN.....	81
ETHOXYETHYLMERCURIC CHLORIDE.....	266
ETHOXYQUIN.....	140
ETHOXSULFURON.....	140
ETHOXZOLAMIDE.....	81
ETHYL ACETATE.....	230
ETHYL ALCOHOL.....	230
ETHYL BROMIDE.....	173, 243, 266
ETHYL BUTYRATE.....	230
ETHYL CHLORIDE.....	81
ETHYL FORMATE.....	173
ETHYL LACTATE.....	230
ETHYL METHACRYLATE.....	141, 266
ETHYLAMPHETAMINE.....	208
ETHYLBUTYLACETYL-.....	230
ETHYLDIENOLONE.....	81
ETHYLENE CHLOROXYDRIN.....	173, 266
ETHYLENE DIBROMIDE.....	201, 280
ETHYLENE DICHLORIDE.....	173
ETHYLENE GLYCOL.....	141, 173, 218, 244
ETHYLENE GLYCOL MONOALKYL ETHERS.....	174, 244, 266
ETHYLENE OXIDE.....	201, 244, 266, 280
ETHYLHEXANEDIOL.....	81, 218
ETHYLMERCURIC CHLORIDE.....	266
ETHYLMETHYLTHIAMBUTENE.....	212
ETHYLMORPHINE.....	38, 81, 208, 282
ETHYLOESTRENOL.....	82
ETHYNODIOL.....	82
ETICYCLIDINE.....	212
ETIDOCAINE.....	82
ETIDRONIC ACID.....	82
ETILEFRIN.....	82
ETIPROSTON.....	82
ETODOLAC.....	82
ETOFENAMATE.....	38, 82
ETONITAZENE.....	212
ETONOGESTREL.....	82

ETOPOSIDE	82
ETORICOXIB	82
ETORPHINE	212
ETOXAZOLE	230
ETOXERIDINE	212
ETRAVIRINE	82
ETRETINATE	82, 235, 266, 286
ETRIDIAZOLE	141
ETRIMFOS	174
<i>EUBACTERIUM</i> sp. strain DSM11798	230
EUCALYPTUS OIL	174, 244
EUGENOL	141, 174, 244, 266
EUPATORIUM CANNABINUM	218
EVEROLIMUS	82
EXEMESTANE	82
EXENATIDE	82
EXPLOSIVES	222
EXTRACT OF LEMON EUCALYPTUS	141
EZETIMIBE	82

F

FAMCICLOVIR	50, 82
FAMOTIDINE	38, 82, 266
FAMPHUR	175, 201
FARFUGIUM JAPONICUM	218
FEBANTEL	175
FEBUXOSTAT	82
FELBINAC	38, 82
FELODIPINE	82
FELYPRESSIN	82
FENAMIPHOS	175, 201
FENARIMOL	141
FENAZAFLOR	175
FENBENDAZOLE	141
FENBUCONAZOLE	141
FENBUFEN	82
FENBUTATIN OXIDE	175
FENCAMFAMIN	82
FENCHLORAZOLE-ETHYL	141
FENCHLORPHOS	175
FENCLOFENAC	82
FENETYLLINE	212
FENFLURAMINE	82, 282
FENFURAM	230
FENHEXAMID	230
FENITROTHION	175
FENOFIBRATE	82
FENOLDOPAM	83
FENOPROFEN	83
FENOPROP	141
FENOTEROL	83
FENOXACRIM	175, 201
FENOXAPROP-ETHYL	141
FENOXAPROP-P-ETHYL	141
FENOXYCARB	230
FENPIPRAMIDE	83
FENPIPRANE	83
FENPROPOREX	83
FENPROSTALENE	83
FENPYROXIMATE	175
FENSON	141
FENSULFOTHION	201
FENTANYL	208
FENTEROL	266
FENTHION	141, 175, 201
FENTHION-ETHYL	201

FENVALERATE	175
FEXOFENADINE	38, 83
FIBRINOLYSIN	83
FIDAXOMICIN	83
FILGRASTIM	83
FINASTERIDE	83
FINGOLIMOD	83, 286
FIPRONIL	141, 175
FIROCOXIB	83
FLAMPROP-METHYL	141
FLAMPROP-M-METHYL	141
FLAVOXATE	50
FLAZASULFURON	141
FLECAINIDE	83
FLEROXACIN	83
FLOCOUMAFEN	175, 201
FLOCTAFENINE	83
FLONICAMID	175
FLORASULAM	141
FLORFENICOL	83
FLUANISONE	83
FLUAZIFOP-BUTYL	175
FLUAZIFOP-P-BUTYL	175
FLUAZINAM	175
FLUAZURON	141
FLUBENDAZOLE	141
FLUBENDIAMIDE	141
FLUCHLORALIN	142
FLUCLOROLONE	83
FLUCLOXACILLIN	83
FLUCOFURON	175, 201
FLUCONAZOLE	50, 83, 266, 277
FLUCYTHRINATE	201
FLUCYTOSINE	83
FLUDARABINE	83
FLUDIOXONIL	142
FLUDROCORTISONE	83
FLUENSULFONE	176
FLUFENAMIC ACID	84
FLUFENOXURON	230
FLUMAZENIL	84
FLUMETHASONE	84
FLUMETHIAZIDE	84
FLUMETHRIN	142, 176
FLUMETSULAM	230
FLUMICLORAC PENTYL	142
FLUMIOXAZIN	176, 201
FLUNISOLIDE	84
FLUNITRAZEPAM	282
FLUNITRAZEPAM	208
FLUNIXIN MEGLUMINE	84
FLUOCINOLONE	84
FLUOCINONIDE	84
FLUOCORTIN	84
FLUOCORTOLONE	84
FLUOMETURON	230
FLUORESCEIN	84
FLUORIDES	39, 50, 84, 142, 176, 244, 266
FLUOROACETAMIDE	201
FLUOROACETIC ACID	201, 280
FLUOROMETHOLONE	84
FLUOROURACIL	84
FLUOXETINE	84
FLUOXYMESTERONE	84
FLUPENTHIXOL	84, 283
FLUPHENAZINE	84, 283
FLUPROPANATE	176

FLUPROSTENOL	84
FLUQUINCONAZOLE	176
FLURALANER	142
FLURANDRENOLONE	84
FLURAZEPAM	84, 283
FLURBIPROFEN	39, 84
FLUROACETAMIDE	280
FLUROXENE	84
FLUROXYPYR	230
FLUSILAZOL	176
FLUSPIRILENE	84
FLUTAMIDE	84
FLUTICASONE	39, 84
FLUTOLANIL	230
FLUTRIAFOL	176
FLUVALINATE	142, 176
FLUVASTATIN	84
FLUVOXAMINE	84
FLUXAPYROXAD	142
FOLIC ACID	39, 84
FOLINIC ACID	39, 84
FOLLICLE-STIMULATING HORMONE	85, 276
FOLLISTATIN	85, 236
FOLLITROPIN ALPHA	85, 235
FOLLITROPIN BETA	85, 235
FOLPET	201, 280
FOMIVIRSEN	85
FONDAPARINUX	85
FOOD	222
FORAMSULFURON	142
FORCHLORFENURON	230
FORMALDEHYDE	39, 176, 218, 244, 266
FORMALDEHYDE CONDENSATION PRODUCT	181
FORMEBOLONE	85
FORMESTANE	85
FORMETANATE	201
FORMIC ACID	142, 244, 266
FORMOTHION	176
FOSAMPRENAVIR	85
FOSAPREPITANT	85
FOSCARNET	85
FOSFESTROL	85
FOSINOPRIL	85
FOSPHENYTOIN	85
FOSPIRATE	142, 176
FOSTHIAZATE	201
FOTEMUSTINE	85
FRAMYCETIN	85
FRITTED GLAZING OR ENAMELLING PREPARATIONS	222
FULLERS EARTH	230
FULVESTRANT	85
FUMAGILLIN	176
FUNGAL PROTEASE derived from	230
FURALAXYL	142
FURALTADONE	85
FURATHIOCARB	142, 201
FURAZABOL	85
FURAZOLIDONE	85
FURETHIDINE	212
FURFURAL	176, 244, 266
FUROSEMIDE	85
FUSIDIC ACID	85

G

GABAPENTIN	85, 283
GALANTAMINE	85

GALANTHUS spp.....	85
GALLAMINE.....	85
GALSULFASE.....	85
GAMMA HYDROXYBUTYRATE.....	212
GAMMA-CYHALOTHRIN.....	142, 201
GANCICLOVIR.....	85
GANIRELIX.....	85
GATIFLOXACIN.....	85
GEFITINIB.....	86
GELSEMIUM SEMPERVIRENS.....	40, 276
GEMCITABINE.....	86, 283
GEMEPROST.....	86
GEMFIBROZIL.....	86
GEMIFLOXACIN.....	86
GEMTUZUMAB OZOGAMICIN.....	86
GENTAMICIN.....	86
GERANIUM OIL.....	230
GESTODENE.....	86
GESTONORONE.....	86
GESTRINONE.....	86
GHRH INJECTABLE PLASMID.....	86
GIBBERELIC ACID.....	230
GITALIN.....	86
GLASS.....	222
GLATIRAMER ACETATE.....	86
GLAZED POTTERY.....	222
GLIBENCLAMIDE.....	86
GLIBORNURIDE.....	86
GLICLAZIDE.....	86
GLIMEPIRIDE.....	86
GLIPIZIDE.....	86
GLISOXEPIDE.....	86
GLUCAGON.....	50, 276
□-GLUCANASE derived from <i>Aspergillus niger</i>	230
GLUFOSINATE-AMMONIUM.....	142
GLUTARALDEHYDE.....	40, 142, 176, 244, 266
GLUTATHIONE.....	86
GLUTETHIMIDE.....	86, 236, 283
GLYCERYL THIOGLYCOLLATE.....	177
GLYCERYL TRINITRATE.....	50, 86, 276
GLYCOLIC ACID.....	177, 244, 266
GLYCOPYRRONIUM.....	50, 86
GLYMIDINE.....	86
GLYPHOSATE.....	142
GnRH VACCINE.....	86
GOLIMUMAB.....	86
GONADORELIN.....	86
GONADOTROPHIC HORMONES.....	86
GOSERELIN.....	86
GRAMICIDIN.....	86
GRANISETRON.....	87
GREPAFLOXACIN.....	87
GRISEOFULVIN.....	87
GROWTH HORMONE.....	276
GUAIPHENESIN.....	40, 87
GUANABENZ.....	87
GUANACLINE.....	87
GUANETHIDINE.....	87
GUANIDINE.....	87, 177, 244
GUAZATINE.....	177

H

HACHIMYCIN.....	87
HAEMATIN.....	87
HAEMOPHILUS INFLUENZAE VACCINE.....	87
HALAUXIFEN METHYL.....	230

HALCINONIDE	87
HALOFANTRINE	87
HALOFENATE	87
HALOFUGINONE	87, 201, 281
HALOGENATED DIBENZODIOXINS AND DIBENZOFURANS	201, 281
HALOPERIDOL	87, 276, 283
HALOSULFURON-METHYL	142
HALOTHANE	87
HALOXON	177
HALOXYFOP	177
HARMALA ALKALOIDS	212
HCB	201, 281
HELIOTROPIUM spp.	218
HEMEROCALLIS	87
HEPARINS	87
HEPATITIS A VACCINE	87
HEPATITIS B VACCINE	87
HEPTACHLOR	177
HEROIN	212
HETACILLIN	87
HEXACHLOROPHANE	40, 87, 177, 244, 267
HEXAACONAZOLE	142
HEXAFLURON	230
HEXAMETHONIUM	88
HEXAZINONE	142, 177
HEXETIDINE	88
HEXLOXYETHANOL	267
HEXOBENDINE	88
HEXOCYCLIUM	88
HEXOPRENALINE	88
HEXYL ACETATE	230
HEXYLOXYETHANOL	177, 244
HEXYTHIAZOX	230
HISTAMINE	88
HMG-CoA REDUCTASE INHIBITORS	88
HOMATROPINE	88
HUMAN BLOOD PRODUCTS	222
HUMAN CHORIONIC GONADATROPHIN	88
HUMAN OSTEOGENIC PROTEIN-1 (OP-1)	230
HUMAN PAPILLOMAVIRUS VACCINE	88
HYALURONIC ACID AND ITS POLYMERS	88
HYDRALAZINE	88
HYDRAMETHYLNON	142, 177
HYDRARGAPHEN	88
HYDRAZINE	177, 244, 267
HYDROCARBONS	244
HYDROCARBONS LIQUID AROMATIC	201
HYDROCARBONS, LIQUID	143
HYDROCHLORIC ACID	143, 177, 244, 267
HYDROCHLOROTHIAZIDE	88
HYDROCODONE	208, 283
HYDROCORTISONE	40, 50, 88, 267, 277
HYDROCORTISONE ACETATE	40, 50
HYDROCYANIC ACID	88, 202, 267, 276
HYDROCYANIC ACID AND CYANIDES	281
HYDROFLUMETHIAZIDE	88
HYDROFLUORIC ACID	143, 177, 202, 281
HYDROGEN PEROXIDE	143, 177, 218, 245, 267
HYDROGEN SULFIDE	202
HYDROMORPHINOL	208
HYDROMORPHONE	208, 283
HYDROPRENE	230
HYDROQUINONE	40, 88, 178, 245, 267
HYDROSILICOFLUORIC ACID	143, 178, 202, 245, 267
HYDROXYCHLOROQUINE	88
HYDROXYEPHEDRINE	88
HYDROXYPETHIDINE	212

HYDROXYPHENAMATE	89
HYDROXYPROGESTERONE	89
HYDROXYPROPYL CELLULOSE	230
HYDROXYSTENOZOL	89
HYDROXYUREA	89
HYDROXYZINE	89, 283
HYGROMYCIN	89
HYOSCINE	40, 89, 276
HYOSCINE BUTYLBROMIDE	40
HYOSCYAMINE	41, 276
HYOSCYAMUS NIGER	41, 276
HYPOTHALAMIC RELEASING FACTORS	89, 276
HYPROMELLOSE	89

I

IBAFLOXACIN	89
IBANDRONIC ACID	89
IBOGAINE	89
IBRITUMOMAB	89
IBUFENAC	89
IBUPROFEN	41, 51, 89, 268
IBUTEROL	89
IBUTILIDE	89
ICATIBANT	89
ICODEXTRIN	230
IDARUBICIN	89
IDOXURIDINE	89
IDURSULFASE	89
IFOSFAMIDE	89
ILOPROST	89
IMATINIB	89
IMAZALIL	143
IMAZAMOX	143
IMAZAPIC	143
IMAZAPYR	143
IMAZETHAPYR	143
IMEPITOID	90
IMIDACLOPRID	143, 178
IMIDAPRIL	90
IMIDOCARB	178
IMIGLUCERASE	90
IMINOCTADINE TRIALBESILATE	178
IMIPENIM	90
IMIPRAMINE	90, 283
IMIPROTHRIN	143, 178
IMIQUIMOD	90
IMMUNOGLOBULINS	90
IN VITRO DIAGNOSTIC AND ANALYTICAL PREPARATIONS	223
INDACATEROL	90
INDANAZOLINE	41
INDAPAMIDE	90
INDAZIFLAM	178
INDINAVIR	90
INDOLE-3-ACETIC ACID	230
INDOMETHACIN	41, 90, 276
INDOPROFEN	90
INDORAMIN	90
INDOXACARB	144, 178
INFLIXIMAB	90
INFLUENZA AND CORYZA VACCINES	90
INGENOL MEBUTATE	90
INOSITOL NICOTINATE	51
INSULIN GLARGINE	90
INSULIN-LIKE GROWTH FACTOR I	90
INSULIN-LIKE GROWTH FACTORS	90, 236
INSULINS	90

INTERFERONS.....	90
INTERLEUKINS.....	90
INTRAOCULAR VISCOELASTIC PRODUCTS	223
IODINE.....	41, 178, 245, 268
IODOMETHANE	202, 281
IODOPHORS.....	178, 245
IODOSULFURON-METHYL-SODIUM	144
IODOTHIOURACIL	90
IOXYNIL.....	178
IPCONAZOLE.....	144, 178
IPILIMUMAB.....	90
IPRATROPIUM.....	42, 90
IPRATROPIUM BROMIDE	268
IPRIFLAVONE.....	90
IPRINDOLE	90
IPRODIONE	230
IPRONIAZID.....	90
IRBESARTAN	91
IRINOTECAN	91
IRON COMPOUNDS.....	42, 91, 144, 178
ISOAMINILE	91
ISOAMYL NITRITE	91
ISOBUTYL NITRITE.....	91
ISOCARBOPHOS	202
ISOCARBOXAZID	91
ISOCONAZOLE.....	42, 51, 91, 179
ISOCYANATES	179, 245, 268
ISOETARINE	91
ISOEUGENOL	144, 179
ISOFENPHOS	202
ISOFLURANE.....	91
ISOMETHADONE.....	212
ISOMETHEPTENE	91
ISONIAZID	91
ISOPHORONE	144, 245
ISOPRENALINE	91, 268
ISOPRENE ALCOHOL.....	230
ISOPRINOSINE	91
ISOPROPAMIDE	42, 91
ISOPROTURON.....	202
ISOSORBIDE DINITRATE	51, 91
ISOSORBIDE MONONITRATE	91
ISOSTEARYL ALCOHOL ETHOXYLATE	230
ISOTRETINOIN.....	91, 235, 268, 286
ISOXABEN	144
ISOXAFLUTOLE.....	144
ISOXICAM.....	91
ISOXSUPRINE.....	91
ISRADIPINE	91
ITRACONAZOLE.....	91
IVABRADINE.....	91
IVACAFTOR.....	91
IVERMECTIN	91, 144, 202
IXABEPILONE	91

J

JAPANESE ENCEPHALITIS VACCINE.....	91
JUNIPERUS SABINE	219

K

KANAMYCIN.....	91
KAOLIN	230
KEROSENE.....	245
KETAMINE.....	208
KETANSERIN.....	92

KETAZOLAM	92
KETOBEMIDONE	212
KETOCONAZOLE	42, 92
KETOPROFEN	51, 92
KETOROLAC	92
KETOTIFEN	42, 92
KHELLIN	92
KITASAMYCIN	92, 144
KRESOXIM-METHYL	230
KUNZEA OIL	230

L

LABETALOL	92
LACIDIPINE	92
LACOSAMIDE	92
LAMBDA-CYHALOTHRIN	144, 179, 202
LAMIVUDINE	92
LAMOTRIGINE	283
LAMOTRIGINE	92
LANATOSIDES	92
LANREOTIDE	92
LANSOPRAZOLE	51, 92
LANTHANUM	92
LAPATINIB	92
LARONIDASE	92
LAROPIPRANT	92
LASALOCID	179
LATAMOXEF	92
LATANOPROST	92
LAUDEXIUM	93
LAURETH CARBOXYLIC ACIDS	179, 245
LAURIC ACID	230
LAUROMACROGOLS	93
LAURYL ALCOHOL (1-DODECANOL)	230
LAURYL ISOQUINOLINIUM BROMIDE	179, 245
LAVANDIN OIL	230
LAVENDER OIL	230
LEAD	93
LEAD COMPOUNDS	145, 179, 219, 245, 266, 268
LEAD METALLIC	231
LEFETAMINE	93
LEFLUNOMIDE	93, 268, 286
LEMON OIL	145, 245, 268
LEMONGRASS OIL	231
LENALIDOMIDE	93, 235, 268, 286
LENOGRASTIM	93
LEPIDOPTEROUS SEX PHEROMONES	231
LEPIRUDIN	93
LEPTAZOL	93
LEPTOPHOS	202
LEPTOSPERMUM SCOPARIUM OIL	245
LEPTOSPERMUM SCOPARIUM OIL	180
LERCANIDIPINE	93
LETROZOLE	93
LEUPRORELIN	93
LEVALLORPHAN	93
LEVAMISOLE	93, 145, 180
LEVAMPHETAMINE	208
LEVETIRACETAM	93, 283
LEVOBUNOLOL	93
LEVOBUPIVACAINE	93
LEVOCABASTINE	42, 93, 268, 286, 283
LEVODOPA	93
LEVOMEPRMAZINE	93
LEVOMETHAMPHETAMINE	208
LEVOMETHORPHAN	212

LEVOMORAMIDE.....	208
LEVONORGESTREL.....	51, 93
LEVOPHENACYLMORPHAN.....	212
LEVORPHANOL.....	208
LEVOSIMENDAN.....	93
LIDOFLAZINE.....	93
LIGNOCAINE.....	42, 93, 145
LIGULARIA DENTATA.....	219
LIME OIL.....	145, 245, 268
LIMONENE.....	231
LINAGLIPTIN.....	94
LINCOMYCIN.....	94
LINDANE.....	42, 94, 145, 180
LINEZOLID.....	94
LINOLEIC ACID.....	231
LINSEED FATTY ACIDS.....	231
LINURON.....	231
LIOTHYRONINE.....	94
LIQUORICE, DEGLYCYRRHISINISED.....	231
LIRAGLUTIDE.....	94
LISDEXAMFETAMINE.....	208
LISINAPRIL.....	94
LISURIDE.....	94
LITHIUM.....	42, 94
LITHIUM PERFLUOROOCCTANE SULFONATE.....	202
LIXISENATIDE.....	94
LOBELIA INFLATA.....	43
LOBELINE.....	43
LODOXAMIDE.....	43, 94
LOFEXIDINE.....	94
LOGIPARIN.....	94
LOMEFLOXACIN.....	94
LOMUSTINE.....	94
LOPERAMIDE.....	43, 94, 268
LOPINA VIR.....	94
LOPRAZOLAM.....	94
LORACARBEF.....	94
LORATADINE.....	43, 94
LORAZEPAM.....	95, 283
LORMETAZEPAM.....	95
LOSARTAN.....	95
LOTEPREDNOL.....	95
LOXAPINE.....	95
LUBRICANTS.....	223
LUFENURON.....	145
LUMEFANTRINE.....	95
LUMIRACOXIB.....	95
LURASIDONE.....	95, 283
LUTEINISING HORMONE.....	95, 235
LYMECYCLINE.....	95
LYSERGIC ACID.....	212
LYSERGIDE.....	212

M

MACITENTAN.....	95, 236, 286
MACROGOLS.....	43, 51
MADURAMICIN.....	145, 202, 281
MAFENIDE.....	95, 180
MAGNESIUM CHLORATE.....	145, 245, 268
MAGNESIUM SULFATE.....	51
MALACHITE GREEN.....	145, 202
MALATHION.....	51, 146, 180, 245
MALEIC HYDRAZIDE.....	231
MANCOZEB.....	146
MANDIPROPAMID.....	146
MANDRAGORA OFFICINARUM.....	95

MANGANESE DIOXIDE	231
MANNITYL HEXANITRATE	51
MANNOMUSTINE	95
MAPROTILINE	95
MARAVIROC	95
MARBOFLOXACIN	95
MARJORAM OIL	146, 246
MAROPITANT	95
MATCHES	223
MAVACOXIB	95
MAZIDOX	202
MAZINDOL	95, 283
MCPA	146, 180
MCPB	146
MEASLES VACCINE	95
MEBANAZINE	95
MEBENDAZOLE	43, 146, 181
MEBEVERINE	95
MEBHYDROLIN	95, 283
MEBOLAZINE	95
MEBUTAMATE	95
MECAMYLAMINE	95
MECARBAM	202
MECASERMIN	96
MECILLINAM	96
MECLOCYCLINE	96
MECLOFENAMATE	96
MECLOFENAMIC ACID	146
MECLOFENOXATE	96
MECLOQUALONE	212
MECLOZINE	43, 96, 283
MECOPROP	146, 181
MECOPROP-P	181
MEDAZEPAM	96, 283
MEDETOMIDINE	96
MEDICAL AND VETERINARY ADHESIVES, GLUES AND CEMENTS	223
MEDICAL DEVICES	223
MEDIGOXIN	96
MEDROXYPROGESTERONE	96
MEDRYSONE	96
MEFENAMIC ACID	43, 96, 268
MEFENOREX	96
MEFENPYR-DIETHYL	146
MEFLOQUINE	96
MEFLUIDIDE	181
MEFRUSIDE	96
<i>MEGASPHAERA ELSDENII</i> strain 41125	231
MEGESTROL	96
MELAGATRAN	96
MELALEUCA OIL	181, 246
MELATONIN	96
MELENGESTROL	96
MELENGESTROL ACETATE	181
MELIA AZEDARACH	219
MELOXICAM	96
MELPHALAN	96
MEMANTINE	96
MENAZON	181
MENINGOCOCCAL VACCINE	96
MENOTROPHIN	96
MEPACRINE	96
MEPENZOLATE	96
MEPHENESIN	96
MEPHENTERMINE	96
MEPINDOLOL	96
MEPIQUAT	146
MEPITIOSTANE	96

MEPIVACAINE	97
MEPROBAMATE	283
MEPROBAMATE	97
MEPTAZINOL	97
MEPYRAMINE	283
MEPYRAMINE	43, 51, 97
MEQUITAZINE	97
MERCAPTOMERIN	97
MERCAPTOPURINE	97
MERCURIC CHLORIDE	202
MERCURIC IODIDE	246
MERCURIC NIRATE	246
MERCURIC OXIDE	181, 246
MERCURIC POTASSIUM IODIDE	246
MERCURIC THIOCYANATE	246, 268
MERCUROCHROME	43, 97, 181, 246
MERCUROUS CHLORIDE	246
MERCURY	43, 97, 202, 276, 281
MERCURY metallic	246
MERCURY, organic compounds	246
MEROPENEM	97
MERSALYL	97
MERURIC CHLORIDE	246
MESABOLONE	97
MESALAZINE	97
MESNA	97
MESOLSULFURON-METHYL	231
MESOTRIONE	146
MESTANOLONE	97
MESTEROLONE	97
MESTRANOL	97
METACRESOLSULPHONIC ACID	181, 268
METAFLUMIZONE	146
METALAXYL	146, 181
METALDEHYDE	146, 181, 246
METANDIENONE	97
METARAMINOL	97
<i>METARHIZIUM ANISOPLIAE</i>	231
METAZOCINE	212
METENOLONE	97
METERGOLINE	97
METFORMIN	97
METHABENZTHIAZURON	146
METHACHOLINE	97
METHACRIFOS	181, 203, 281
METHACYCLINE	97
METHADONE	208, 283
METHALLENOESTRIL	97
METHAM	181
METHAMIDOPHOS	203
METHANDRIOL	97
METHANOL	146, 181, 246, 269
METHANTHELINIUM	97
METHAPYRILENE	203
METHAQUALONE	212
METHAZOLAMIDE	97
METHAZOLE	203
METHCATHINONE	212
METHDILAZINE	51, 98, 283
METHENOLONE	98
METHICILLIN	98
METHIDATHION	203
METHIMAZOLE	98
METHIOCARB	146, 182, 203
METHISAZONE	98
METHIXENE	98
METHOCARBAMOL	98, 283

METHOFLUTHRIN	147
METHOHEXITONE	98
METHOIN	98
METHOMYL	182, 203
METHOPRENE	231
METHOTREXATE	98
METHOXAMINE	43, 98, 269
METHOXSALEN	98
METHOXYCHLOR	147
METHOXYETHYLMERCURIC ACETATE	203, 281
METHOXYETHYLMERCURIC CHLORIDE	203
METHOXYFENOZIDE	231
METHOXYFLURANE	98
METHOXYPHENAMINE	43
METHSUXIMIDE	98
METHYCLOTHIAZIDE	98
METHYL (2 <i>S</i> , 4 <i>aR</i> , 6 <i>aR</i> , 7 <i>R</i> , 9 <i>S</i> , 10 <i>aS</i> , 10 <i>bR</i>)-9-ACETOXY-6 <i>a</i> ,10 <i>b</i> -DIMETHYL-4,10-DIOXO-DODECAHYDRO-2-(3-FURYL)-2 <i>H</i> -NAPHTHO[2,1- <i>c</i>]PYRAN-7-CARBOXYLATE	213
METHYL ACETATE	231
METHYL AMINOLEVULINATE	98
METHYL BENZOQUATE	231
METHYL BROMIDE	203, 281
METHYL CHLORIDE	269
METHYL ETHYL KETONE	147, 246, 269
METHYL ETHYL KETONE OXIME	182, 246, 269
METHYL ETHYL KETONE PEROXIDE	147, 246, 269
METHYL ISOAMYL KETONE	147, 246
METHYL ISOBUTYL KETONE	147, 246
METHYL ISOTHIOCYANATE	182
METHYL MERCURY	98
METHYL METHACRYLATE	269
METHYL METHACRYLATE	182, 219
METHYL NEODECANAMIDE	182
METHYL <i>p</i> -HYDROXYBENZOATE	231
METHYL SALICYLATE	98, 147, 182
METHYL SALICYLATE LIQUID	247
METHYLAMPHETAMINE	208
METHYLANDROSTANOLONE	98
METHYLATED SPIRIT	246
METHYLATED SPIRIT(S)	147
METHYLCLOSTEBOL	98
METHYLCYCLOPENTADIENYL MANGANESE TRICARBONYL	182, 203
METHYLDESORPHINE	213
METHYLDIBROMO GLUTARONITRILE	182, 219, 269
METHYLDIHYDROMORPHINE	208
METHYLDOPA	98
METHYLENE BISTHIOCYANATE	182, 269
METHYLENE BLUE	98, 147, 203
METHYLEPHEDRINE	43
METHYLERGOMETRINE	98
METHYLEUGENOL	182, 246, 269
METHYLMERCURY	276
METHYLNALTREXONE	98
METHYLNORBORNANYLPYRIDINE	182
METHYLPENTYNOL	98
METHYLPHENIDATE	208
METHYLPHENOBARBITONE	98
METHYLPREDNISOLONE	98
METHYLTESTOSTERONE	98
METHYLTHIOURACIL	99
METHYLTRIENOLONE	99
METHYPRYLONE	99
METHYSERGIDE	99
METIRAM	147
METOCLOPRAMIDE	51, 99
METOFLUTHRIN	182
METOLACHLOR	147

METOLAZONE	99
METOPON	213
METOPROLOL	99
METOSULAM	182
METRAFENONE	147, 182
METRIBOLONE	99
METRIBUZIN	183
METRIFONATE	99
METRONIDAZOLE	99
METSULFURONMETHYL	231
METYRAPONE	99
MEVINPHOS	203
MEXILETINE	99
MEZLOCILLIN	99
MIANSERIN	99, 283
MIBEFRADIL	99
MIBOLERONE	99
MICAFUNGIN	99
MICONAZOLE	43, 51, 99, 183, 269, 277
MIDAZOLAM	99
MIDODRINE	99
MIFEPRISTONE	99
MIGLITOL	99
MIGLUSTAT	99
MILBEMECTIN	147, 183
MILBEMYCIN OXIME	99, 147
MILRINONE	99
MINOCYCLINE	99
MINOXIDIL	43, 99
MIPAFIX	203
MIRABEGRON	99
MIREX	203, 281
MIRTAZAPINE	100, 283
MISOPROSTOL	100, 269, 286
MITOBRONITOL	100
MITOMYCIN	100
MITOTANE	100
MITOXANTRONE	100
MITRAGYNA SPECIOSA	213
MITRAGYNINE	213
MITRATAPIDE	100
MIVACURIUM CHLORIDE	100
MOCLOBEMIDE	100
MODAFINIL	100
MOLGRAMOSTIM	100
MOLINATE	203, 281
MOLINDONE	100
MOMETASONE	43, 100
MONENSIN	100, 147, 183
MONEPANTEL	147
MONOBENZONE	100
MONOCLONAL ANTIBODIES	100
MONOCROTOPHOS	203
MONTELUKAST	100
MOPERONE	100
MORANTEL	147, 183
MORAZONE	100
MORICIZINE	100
MORPHERIDINE	213
MORPHINE	208, 283
MORPHINE METHOBROMIDE	208
MORPHINE-N-OXIDE	208
MOTOR, HEATING or FURNACE FUELS	223
MOTRAZEPAM	100
MOTRETINIDE	100
MOXIDECTIN	100, 147, 183, 203
MOXIFLOXACIN	100

MOXONIDINE.....	100
MSMA	183, 203
MUMPS VACCINE.....	101
MUPIROCIN	101
MURAGLITAZAR.....	101
MUROMONAB.....	101
MUSCIMOL	213
MUSTINE.....	101
MYCLOBUTANIL.....	148
MYCOPHENOLIC ACID	101
MYRISTIC ACID	231
MYROPHINE.....	213

N

N- α -[METHYL-3,4-(METHYLENEDIOXY)PHENETHYL]HYDROXYLAMINE	213
N-(N-DODECYL)-2-PYRROLIDONE	140, 172, 243
N-(N-OCTYL)-2-PYRROLIDONE.....	148, 184, 247
N, α -DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE	211
N,N-BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE-2,5-DIMETHANAMINE	162, 248, 271
N,N-BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE-2,6-DIMETHANAMINE	162, 248, 271
N,N-DIALLYLDICHLOROACETAMIDE.....	138
N,N-DIETHYLTRYPTAMINE.....	211
N,N-DIMETHYLAMPHETAMINE.....	211
N,N-DIMETHYLTRYPTAMINE	211
NAA.....	148
NABILONE	208
NABIXIMOLS.....	208, 235, 283
NABUMETONE.....	101
NADOLOL	101
NADROPARIN.....	101
NAFARELIN	101
NAFTIDROFURYL.....	101
NALBUPHINE	101, 283
NALED	148, 183
NALIDIXIC ACID	101
NALMEFENE.....	101
NALORPHINE	101
NALOXONE	101
NALTREXONE.....	101
NANDROLONE	101
NAPHAZOLINE.....	43, 269
NAPHTHALENE	183, 247, 269, 276
NAPHTHALOPHOS	183, 203
NAPHTHOYLINDOLES	213
NAPHTHOYLPYRROLES	213
NAPHTHYLMETHYLINDENES.....	213
NAPHTHYLMETHYLINDOLES.....	213
NAPROPAMIDE.....	231
NAPROXEN	43, 51, 101, 269
NAPTALAM	148
NAPHTALEN-1-YL-(1-BUTYLINDOL-3-YL)METHANONE	214
NAPTHYL ACETAMIDE.....	231
NARASIN	101, 183
NARATRIPTAN.....	101
NATALIZUMAB	101
NATAMYCIN	101
NATEGLINIDE.....	101
n-BUTYL BUTYRATE	229
n-BUTYL LACTATE	229
N-COCO-1,3-DIAMINOPROPANE.....	168
N-CYCLOHEXYLDIAZENIUMDIOXY-POTASSIUM.....	169
NEBACUMAB	101
NEBIVOLOL.....	101
NEDOCROMIL.....	101
NEFAZODONE.....	101
NEFOPAM.....	102

NELFINAVIR.....	102
NEOMYCIN.....	102
NEOSTIGMINE.....	102
NEPAFENAC.....	102
NERIUM OLEANDER.....	102, 276
NEROLI OIL.....	231
NESIRITIDE.....	102
N-ETHYL- α -METHYL-3,4-(METHYLENEDIOXY)PHENETHYLAMINE.....	212
NETILMICIN.....	102
NETOBIMIN.....	148, 183
NEVIRAPINE.....	102
NIALAMIDE.....	102
NICARBAZIN.....	231
NICARDIPINE.....	102
NICERGOLINE.....	102
NICKEL SULFATE.....	183
NICLOSAMIDE.....	43
NICOCODINE.....	214
NICODICODINE.....	214
NICOFURANOSE.....	102
NICOMORPHINE.....	214
NICORANDIL.....	102
NICOTINE.....	102, 183, 203, 269, 281
NICOTINIC ACID.....	51, 102
NICOTINYL ALCOHOL.....	52
NICOUMALONE.....	102
NIFEDIPINE.....	102
NIFENAZONE.....	102
NIKETHAMIDE.....	102
NILOTINIB.....	102
NILUTAMIDE.....	102
NIMESULIDE.....	102
NIMIDANE.....	183, 203
NIMODIPINE.....	102
NIMORAZOLE.....	102
NIRIDAZOLE.....	102
NISIN.....	231
NISOLDIPINE.....	103
NITENPYRAM.....	183
NITISINONE.....	103
NITRAZEPAM.....	103, 283
NITRENDIPINE.....	103
NITRIC ACID.....	148, 183, 247, 269
NITRIC OXIDE.....	103
NITROBENZENE.....	183, 247, 270
NITROFEN.....	203, 281
NITROFURANTOIN.....	103
NITROFURAZONE.....	103
NITROPHENOLS.....	184, 247, 270
NITROPRUSSIDES.....	184, 204, 247, 270
NITROSCANATE.....	148
NITROUS OXIDE.....	103
NITROXOLINE.....	103
NITROXYNIL.....	184
NIZATIDINE.....	43, 103, 270
N-METHYL-1-(3,4-METHYLENEDIOXYPHENYL)-2-BUTANAMINE.....	213
N-METHYL-2-PYRROLIDONE.....	147, 182, 246
N-OCTYL BICYCLOHEPTENE DICARBOXIMIDE.....	148
N-OLEYL-1,3-DIAMINOPROPANE.....	184
NOMEGESTROL.....	103
NOMIFENSINE.....	103
NONOXINOL 9.....	148, 184, 247
NORACYMETHADOL.....	214
NORADRENALINE.....	103, 270
NORANDROSTENOLONE.....	103
NORBOLETHONE.....	103
NORBORMIDE.....	148

NORCLOSTEBOL	103
NORCODEINE	208
NORELGESTROMIN	103
NORETHANDROLONE	103
NORETHISTERONE	103
NORFLOXACIN	103
NORFLURAZON	231
NORGESTREL	103
NORIBOGAINE	103
NORLEVORPHANOL	214
NORMAL HUMAN IMMUNOGLOBULIN	103
NORMETHADONE	209, 283
NORMETHANDRONE	103
NORMORPHINE	214
NORPIPANONE	214
NORTRIPTYLINE	103, 283
NOSCAPINE	44
NOVALURON	231
NOVOBIOCIN	103
NOXIPTYLINE	103
N-PHENETHYL-4-PIPERIDONE	214
N-TALLOW ALKYL-1,3-PROPANEDIAMINE DIACETATE	192
NUTMEG OIL	148
NUTRITION REPLACEMENT PREPARATIONS FOR PARENTERAL ADMINISTRATION	223
NYSTATIN	44, 52, 103, 270, 277

O

OCLACITNIB	104
OCRIPLASMIN	104
OCTAMYLAMINE	104
OCTATROPINE	104
OCTHILINONE	184
OCTREOTIDE	104
OCTYL ALCOHOLS	231
OCTYL NITRITE	104
OESTRADIOL	104, 149, 276
OESTRIOL	104
OESTROGENS	104
OESTRONE	104, 276
OFATUMUMAB	104
OFLOXACIN	104
OLANZAPINE	283
OLANZAPINE	104
OLAQUINDOX	184
OLEANDOMYCIN	104, 149
OLEANDRIN	104
OLEIC ACID	231
OLMESARTAN	104
OLODATEROL	104
OLOPATADINE	104
OLSALAZINE	104
OMALIZUMAB	104
OMEGA-3-ACID ETHYL ESTERS	104
OMEPRAZOLE	52, 104
OMETHOATE	149, 184, 204
ONDANSETRON	104
OPIPRAMOL	104
OPIUM	283
OPIUM	209
ORANGE OIL	247
ORANGE OIL (BITTER)	149
ORANGE OIL, SWEET	231
ORBIFLOXACIN	104
ORCIPRENALINE	104, 270
ORGANOPHOSPHORUS COMPOUNDS	104
ORLISTAT	52, 105

ORNIDAZOLE	105
ORNIPRESSIN	105
ORPHENADRINE	105
ortho-DICHLOROBENZENE	263
ortho-PHENYLPHENOL	248, 271
ortho-PHTHALALDEHYDE	271
ortho-PHTHALALDEHYDE	248
ORTHOPTERIN	105
ORTHO-TOLIDINE	281
OSELTAMIVIR	105
OUABAIN	105
OVANDROTONE	105
OXABETRINIL	231
OXABOLONE	105
OXACILLIN	105
OXADIARGYL	149
OXADIAZON	184
OXADIXYL	149
OXALATES	270
OXALIC ACID	184, 247, 270
OXALIPLATIN	105
OXAMYL	204
OXANDROLONE	105
OXANTEL EMBONATE	149
OXAPROZIN	105
OXAZEPAM	105, 283
OXCARBAZEPINE	105
OXEDRINE	105
OXETACAINE	44, 105
OXFENDAZOLE	149
OXIBENDAZOLE	149
OXICONAZOLE	44, 52, 105
OXITROPIUM	105
OXOLAMINE	105
OXOLINIC ACID	105
XPENTIFYLLINE	105
XPRENOLOL	105
OXYBUPROCAINE	105
OXYBUTYNIN	105
OXYCARBOXIN	149
OXYCLOZANIDE	184
OXYCODONE	283
OXYCODONE	209
OXYDEMETON METHYL	204
OXYFLUORFEN	231
OXYMESTERONE	105
OXYMETAZOLINE	44, 270
OXYMETHOLONE	106
OXYMORPHONE	209
OXYPHENBUTAZONE	106
OXYPHENCYCLIMINE	106
OXYPHENISATIN	219
OXYPHENONIUM	106
OXYTETRACYCLINE	106, 149
OXYTHIOQUINOX	149
OXYTOCIN	106, 276

P

PACLITAXEL	106
PACLOBUTRAZOL	149
PAECILOMYCES LILACINUS STRAIN 251	184
PAINT	270
PALIFERMIN	106
PALIPERIDONE	106, 283
PALIVIZUMAB	106
PALMAROSA OIL	231

PALMITIC ACID	231
PALONOSETRON	106
PAMAQUIN	106
PAMIDRONIC ACID.....	106
PANCREATIC ENZYMES	106
PANCURONIUM	106
PANITUMUMAB.....	106
PANTOPRAZOLE	52, 106
PAPAVERETUM	283
PAPAVERINE.....	44, 106
PAPER	223
PARACETAMOL	44, 52, 106, 270
para-DICHLOROBENZENE	263
PARA-FLUOROFENTANYL	214
PARAFORMALDEHYDE	44, 184, 219, 247
PARALDEHYDE	106
PARAMETHADIONE.....	106
PARAMETHASONE.....	107
PARAQUAT	204
PARATHION.....	204
PARATHION-METHYL.....	185, 204
PARBENDAZOLE	185
PARECOXIB.....	107
PARICALCITOL	107
PAROMOMYCIN	107
PAROXETINE.....	107
PASIREOTIDE	107
PATCHOULI OIL	231
PAZOPANIB	107
PEBULATE	185
PECAZINE	107
PECTINASE derived from <i>Aspergillus niger</i>	231
PEFLOXACIN.....	107
PEGAPTANIB.....	107
PEGFILGRASTIM	107
PEGINTERFERON	107
PEGVISOMANT	107
PEHNOLS.....	247
PEMETREXED	107
PEMOLINE	107
PEMPIDINE	107
PENBUTOLOL.....	107
PENCICLOVIR	44, 107
PENCONAZOLE	149
PENCYCURON.....	231
PENDIMETHALIN	149
PENETHAMATE	107
PENFLUFEN.....	149
PENICILLAMINE.....	107
PENNYROYAL OIL	185, 247
PENTACHLOROPEHNOL	270
PENTACHLOROPHENOL	185, 204
PENTADECANOIC ACID.....	231
PENTAERYTHRITYL TETRANITRATE	107
PENTAGASTRIN.....	107
PENTAMETHONIUM	107
PENTAMIDINE	107
PENTAZOCINE	209, 283
PENTHIENATE	107
PENTHIOPYRAD	149
PENTOBARBITONE	107, 209, 283
PENTOLINIUM	107
PENTOSAN POLYSULFATE SODIUM.....	107
PEPPERMINT OIL.....	231
PERACETIC ACID	149, 185, 247, 270
PERAMPANEL	107, 236, 283
PERFLUIDONE	185

PERGOLIDE	107
PERHEXILINE	108
PERICYAZINE	108, 283
PERINDOPRIL	108
PERMANGANATES	185, 270
PERMETHRIN	108, 149, 185
PERPHENAZINE	108, 283
PERTUSSIS ANTIGEN	108
PERTUZUMAB	108
PETASITES spp	219
PETHIDINE	209, 283
PETROL	150, 247
PHEDRAZINE	44
PHENACEMIDE	108
PHENACETIN	108
PHENADOXONE	214
PHENAGLYCODOL	108
PHENAMPROMIDE	214
PHENAZOCINE	214
PHENAZONE	44, 108, 150
PHENAZOPYRIDINE	108
PHENCYCLIDINE	214
PHENDIMETRAZINE	209
PHENELZINE	108, 283
PHENETICILLIN	108
PHENFORMIN	108
PHENGLUTARIMIDE	108
PHENINDIONE	108
PHENIRAMINE	44, 52, 108, 283
PHENISATIN	108
PHENISOPHAM	150
PHENMEDIPHAM	231
PHENMETRAZINE	209
PHENOBARBITONE	108, 283
PHENOL	45, 108, 150, 185, 270
PHENOLPHTHALEIN	108
PHENOLS	247, 270
PHENOMORPHAN	214
PHENOPERIDINE	209, 283
PHENOTHIAZINE	186
PHENOXYBENZAMINE	108
PHENOXYMETHYLPENICILLIN	108
PHENSUXIMIDE	108
PHENTERMINE	108, 236
PHENTHIMENTONIUM	108
PHENTOLAMINE	108
PHENYL METHYL KETONE	150, 248
PHENYLACETYLINDOLES	214
PHENYLBUTAZONE	108
PHENYLENEDIAMINES	186, 219, 248, 270
PHENYLEPHRINE	45, 108, 270
PHENYLMERCURIC ACETATE	204, 281
PHENYLPHENOL	150
PHENYLPROPANOLAMINE	109
PHENYLTOLOXAMINE	109, 283
PHENYTOIN	109, 271
PHOLCODINE	45, 109, 209, 283
PHORATE	204
PHOSALONE	186
PHOSFOLAN	204
PHOSMET	186
PHOSPHIDE	281
PHOSPHIDES, METALLIC	204
PHOSPHINE	204, 281
PHOSPHODIESTERASE TYPE 5 INHIBITORS	109
PHOSPHONIC	150
PHOSPHONIC ACID	248, 271

PHOSPHORIC ACID	150, 186, 248, 271
PHOSPHORUS	271, 276
PHOSPHORUS,	248
PHOSPHORUS, YELLOW	204
PHOTOGRAPHIC PAPER or FILM	223
PHOXIM	186
PHTHALALDEHYDE	150, 186
PHTHALYLSULFATHIAZOLE	109
PHYSOSTIGMINE	109
PHYTASE	232
PICARIDIN	150
PICLORAM	232
PICOLINAFEN	232
PICRIC ACID	248, 271
PICROTOXIN	109
PIGMENTS	223
PILOCARPINE	109
PIMECROLIMUS	109
PIMELIC ACID	232
PIMINODINE	214
PIMOBENDAN	109
PIMOZIDE	109, 283
PINACIDIL	109
PINDOLOL	109
PINDONE	186
PINE OILS	150, 186
PINOXADEN	150, 187
PIOGLITAZONE	109
PIPECURONIUM	109
PIPEMIDIC ACID	109
PIPENZOLATE	109
PIPER METHYSTICUM	109
PIPERACILLIN	110
PIPERAZINE	45, 150
PIPERIDINE	110
PIPERIDOLATE	110
PIPERONYL BUTOXIDE	232
PIPEROPHOS	187
PIPOBROMAN	110
PIPOTHIAZINE	110
PIPRADROL	110
PIRACETAM	110
PIRBUTEROL	110
PIRENOXINE	110
PIRENZEPINE	110
PIRETANIDE	110
PIRIMICARB	150, 187
PIRIMIPHOS-ETHYL	187
PIRIMIPHOS-METHYL	187
PIRITRAMIDE	209
PIROXICAM	110
PIRPROFEN	110
PITAVASTATIN	110
PITUITARY HORMONES	110
PIVAMPICILLIN	110
PIZOTIFEN	110, 283
PLERIXAFOR	110
PLICAMYCIN	110
PNEUMOCOCCAL VACCINE	110
PODOPHYLLIN	271
PODOPHYLLOTOXIN	45, 52, 110, 271
PODOPHYLLUM EMODI	45, 52, 110
PODOPHYLLUM PELTATUM	45, 52, 111
PODOPHYLLUM RESIN	276
POLIDEXIDE	111
POLIHEXANIDE	150, 271
POLIOMYELITIS VACCINE	111

POLIXETONIUM SALTS.....	150, 187
POLOXALENE	232
POLY (GNRF) OVALBUMIN	232
POLY DIALLYL DIMETHYL AMMONIUM	232
POLY(OXY-1,2-ETHANEDIYL), α -[2-[(2-HYDROXYETHYL)AMINO]-2-OXOETHYL]- α -HYDROXY-, MONO-C ₁₃ - 15-ALKYL ETHERS	150, 248
POLYACRYLAMIDE	111
POLYCAPROLACTONE	111
POLYESTRADIOL	111
POLYETHANOXY (15) TALLOW AMINE	150, 248
POLYHEDROSIS VIRUS of	232
POLYLACTIC ACID	111
POLYMYXIN	111
POLYSORBATE 20	232
POLYSULFATED GLYCOSAMINOGLYCANS	111
POLYTHIAZIDE	111
PORACTANT	111
PORCELAIN	223
PORCINE SOMATOTROPHIN	232
POSACONAZOLE	111
POTASIU M BROMATE	248
POTASIU M CHLORATE	248
POTASSIU M AZELOYL DIGLYCINATE	187
POTASSIU M BICARBONATE	232
POTASSIU M BROMATE	187
POTASSIU M BROMIDE	111
POTASSIU M CHLORATE	45, 150
POTASSIU M CHLORIDE	111
POTASSIU M CYANATE	187, 248
POTASSIU M HYDROXIDE	150, 187, 219, 248, 272
POTASSIU M METABISULPHITE	151, 272
POTASSIU M NITRITE	151, 187, 204, 248, 272
POTASSIU M PERCHLORATE	112
POTASSIU M PEROXOMONOSULFATE TRIPLE SALT	151, 187
POTASSIU M PERSULFATE	188, 249, 272
POTASSIU M SORBATE	232
POTASSIU M SULFIDE	151, 249, 272
PRACTOLOL	112
PRADOFLOXACIN	112
PRALATREXATE	112
PRALIDOXIME	112
PRALLETHRIN	151, 188
PRAMIPEXOLE	112
PRAMOCAINE	112
PRAMPINE	112
PRASTERONE	112
PRASUGREL	112
PRAVASTATIN	112
PRAZEPAM	112, 283
PRAZIQUANTEL	112
PRAZOSIN	112
PREDNISOLONE	112
PREDNISON E	112
PREGABALIN	112, 283
PREGNENOLONE	112
PRENALTEROL	112
PRENYLAMINE	112
PRILOCAINE	45, 112
PRIMAQUINE	112
PRIMIDONE	112
PRINTING INKS or INK ADDITIVES	223
PROBENECID	112
PROBUCOL	112
PROCAINAMIDE	112
PROCAINE	112
PROCAINE PENICILLIN	112
PROCARBAZINE	112

PROCHLORAZ	188
PROCHLORPERAZINE	283
PROCHLORPERAZINE	52, 112
PROCYCLIDINE	45, 113
PROCYMIDONE	204
PROFENOFOS	188
PROFOXYDIM	151
PROGESTERONE	113, 151, 276
PROGESTOGENS	113
PROGLUMIDE	113
PROGUANIL	113
PROHEPTAZINE	214
PROHEXADIONE CALCIUM	151
PROLINTANE	113
PROMACYL	188
PROMAZINE	113, 283
PROMETHAZINE	45, 52, 113, 283
PROMETRYN	151
PROMOXOLANE	113
PROPACHLOR	188
PROPAFENONE	113
PROPAMIDINE	46, 113
PROPAMOCARB	151
PROPANIDID	113
PROPANIL	151
PROPANTHELINE	113
PROPAQUIZAFOP	151
PROPARGITE	188
PROPENTOFYLLINE	113
PROPERIDINE	214
PROPETAMPHOS	188
PROPETANDROL	113
PROPICONAZOLE	151, 188
PROPINEB	188
PROPIONIBACTERIUM ACNES	113
PROPIONIC ACID	151, 188, 249, 272
PROPIRAM	209
PROPOFOL	113
PROPOXUR	151, 188
PROPRANOLOL	113, 276
PROPYL ACETATES	232
PROPYLENE	204
PROPYLENE GLYCOL	232
PROPYLENE OXIDE	281
PROPYLHEXEDRINE	113
PROPYLTHIOURACIL	113
PROPYPHENAZONE	113
PROPYZAMIDE	152
PROQUAZONE	113
PROQUINAZID	188
PROSCILLARIDIN	113
PROSTAGLANDINS	113
PROSTIANOL	113
PROSULFOCARB	188
PROSULFURON	188
PROTAMINE	113
PROTHIOCONAZOLE	232
PROTHIOCONAZOLE-DESCHLORO	152
PROTHIOCONAZOLE-TRIAZOLIDINETHIONE	152
PROTHIOFOS	188
PROTHIONAMIDE	113
PROTHIPENDYL	113
PROTIRELIN	113
PROTOVERATRINES	113
PROTRIPTYLINE	283
PROTRIPTYLINE	114
PROXYMETACAINE	114

PRUCALOPRIDE.....	114
PSEUDOEPHEDRINE.....	52, 114
<i>PSEUDOMONAS FLUORESCENS</i>	232
PSILOCYBINE.....	214
PTERIDIUM spp.....	219
PULMONARIA spp.....	219
PYMETROZINE.....	152
PYRACLOFOS.....	188
PYRACLOSTROBIN.....	152
PYRAFLUFEN-ETHYL.....	152
PYRANTEL.....	46
PYRASULFOTOLE.....	152
PYRAZINAMIDE.....	114
PYRAZOPHOS.....	188
PYRETHRINS.....	46, 152
PYRIDABEN.....	152, 188
PYRIDALYL.....	188
PYRIDATE.....	188
PYRIDINOLCARBAMATE.....	114
PYRIDOSTIGMINE.....	114
PYRIDOXAL.....	114
PYRIDOXAMINE.....	114
PYRIDOXINE.....	114
PYRIFENOX.....	152
PYRIMETHAMINE.....	114
PYRIMETHANIL.....	232
PYRINURON.....	204, 281
PYRIOFENONE.....	189
PYRIPROLE.....	188
PYRIPROXYFEN.....	232
PYRITHIOBAC SODIUM.....	152
PYRITHIONE COPPER.....	188
PYRITHIONE ZINC.....	46, 152, 188, 249
PYROVALERONE.....	114
PYROXASULFONE.....	189
PYROXSULAM.....	189
PYRVINIUM.....	114

Q

QUASSIA.....	232
QUATERNARY AMMONIUM COMPOUNDS.....	152, 189
QUAZEPAM.....	114
QUETIAPINE.....	114, 284
QUINAGOLIDE.....	114
QUINALBARBITONE.....	209, 284
QUINAPRIL.....	114
QUINBOLONE.....	114
QUINCLORAC.....	152
QUINETHAZONE.....	114
QUINIDINE.....	114
QUININE.....	114, 152, 204
QUINISOCAINE.....	114
QUINOXYFEN.....	232
QUINTOZENE.....	152
QUINUPRISTIN.....	114
QUIZALOFOP ETHYL.....	189
QUIZALOFOP-P-ETHYL.....	153, 189
QUIZALOFOP-P-TEFURYL.....	189

R

RABEPRAZOLE.....	52, 114
RABIES VACCINE.....	114
RACEMETHORPHAN.....	214
RACEMORAMIDE.....	209
RACEMORPHAN.....	214

RACTOPAMINE.....	114, 153
RADIOGRAPHIC CONTRAST MEDIA.....	224
RADIOISOTOPES.....	224
RALOXIFENE.....	114
RALTEGRAVIR.....	114
RALTITREXED.....	115
RAMIPRIL.....	115
RANIBIZUMAB.....	115
RANITIDINE.....	46, 115, 272
RAPACURONIUM.....	115
RASAGILINE.....	115
RASBURICASE.....	115
RAUWOLFIA SERPENTINA.....	115
RAUWOLFIA VOMITORIA.....	115
RAZOXANE.....	115
REBOXETINE.....	115
RED YEAST RICE.....	115
REGORAFENIB.....	115
REMIFENTANIL.....	209
REMOXIPRIDE.....	115
REPAGLINIDE.....	115
RESERPINE.....	115
RESMETHRIN.....	153, 189
RETAPAMULIN.....	115
RETEPLASE.....	115
RETIGABINE.....	115, 284
RIBAVIRIN.....	115
RIDAFOROLIMUS.....	115
RIFABUTIN.....	115
RIFAMPICIN.....	115
RIFAMYCIN.....	115
RIFAPENTINE.....	115
RIFAXIMIN.....	115
RILPIVIRINE.....	115
RILUZOLE.....	116
RIMEXOLONE.....	116
RIMITEROL.....	116
RIMONABANT.....	116
RIMSULFURON.....	153
RIOCIGUAT.....	116, 235, 286
RISEDRONIC ACID.....	116
RISPERIDONE.....	116, 284
RITODRINE.....	116
RITONAVIR.....	116
RITUXIMAB.....	116
RIVAROXABAN.....	116
RIVASTIGMINE.....	116
RIZATRIPTAN.....	116
ROBENACOXIB.....	116
ROBENIDINE.....	153
ROFECOXIB.....	116
ROFLUMILAST.....	116
ROLICYCLIDINE.....	214
ROLITETRACYCLINE.....	116
ROMIDEPSIN.....	116
ROMIFIDINE.....	116
ROMIPLOSTIM.....	116
RONIDAZOLE.....	116
ROPINIROLE.....	116
ROPIVACAINE.....	116
ROSEMARY OIL.....	232
ROSIGLITAZONE.....	116
ROSOXACIN.....	116
ROSUVASTATIN.....	116
ROTENONE.....	189
ROTIGOTINE.....	116, 284
ROXIBOLONE.....	116

ROXITHROMYCIN	116
RUBELLA VACCINE	117
RUBOXISTAURIN	117
RUPATADINE	117, 284
RUXOLITINIB	117

S

SAFLUFENACIL	153, 204
SAFROLE	189, 219, 272
SAGE OIL	189, 249
SAGE OIL (Spanish)	232
SALBUTAMOL	52, 117, 272
SALCATONIN	117
SALFROLE	249
SALICYLAMIDE	46, 117, 272
SALICYLANILIDE	153
SALICYLIC ACID	53
SALINOMYCIN	117, 190
SALMETEROL	117
SALVIA DIVINORUM	214
SANDALWOOD OIL	232
SANTONIN	53
SAPROPTERIN	117
SAQUINAVIR	117
SASSAFRAS OIL	190, 249, 272
SAXAGLIPTIN	117
SCHOENOCaulon OFFICINALE	117
SCHRADAN	204
SCOPOLIA CARNIOLICA	117
SEAWEED & UNFRACTIONED	232
SECBUTOBARBITONE	209, 284
SEDAXANE	153
SEEDS	224
SELAMECTIN	153
SELECTIVE ANDROGEN RECEPTOR MODULATORS (SARM)	117, 236
SELEGILINE	117
SELENIUM	46, 117, 190, 204, 276
SELENIUM COMPOUNDS	249, 272
SEMDURAMICIN	190, 205
SENECIO spp.	220
SERELAXIN	117
SERMORELIN	117
SERTINDOLE	117
SERTRALINE	118
SETHOXYDIM	153
SEVELAMER	118
SEVOFLURANE	118
SEX HORMONES	118
SIBUTRAMINE	118
SIDURON	153
SILANDRONE	118
SILDENAFIL	118
SILICOFLUORIDES	153, 190
SILICONES	118, 220, 272
SILVER	46
SILVER NITRATE	190
SILVER SALTS	249
SILVER SULFADIAZINE	118
SIMAZINE	232
SIMEPREVIR	118
SIMVASTATIN	118
SINBIOALLETHRIN	153, 190
SINGLE-USE TUBES	224
SIROLIMUS	118
SISOMICIN	118
SITAGLIPTIN	118

SITAXENTAN	118, 236, 272, 286
SLIMICIDES	222
SODIUM ALUMINATE	191, 249, 272
SODIUM BICARBONATE	232
SODIUM BROMATE	191, 249
SODIUM BROMIDE	118
SODIUM CELLULOSE PHOSPHATE	118
SODIUM CHLORATE	153, 249, 272
SODIUM CROMOGLYCATE	46, 118
SODIUM DIACETATE	153, 249
SODIUM DICHLOROISOCYANURATE	249
SODIUM DODECYLBENZENE SULFONATE	273
SODIUM DODECYLBENZENE SULFONATE	153, 249
SODIUM FLUORIDE	273
SODIUM HYDROGEN SULFATE	153, 250, 273
SODIUM HYDROSULFITE	153, 273
SODIUM HYDROXIDE	153, 191, 220, 250, 273
SODIUM LAURETH-6 CARBOXYLATE	153, 250, 273
SODIUM LAURYL SULFATE	250
SODIUM METABISULPHITE	153, 250, 273
SODIUM MORRHUATE	118
SODIUM NITRITE	46, 153, 191, 205, 250, 273
SODIUM NITROPRUSSIDE	118
SODIUM OXYBATE	209, 235
SODIUM PERCARBONATE	154, 191
SODIUM PERSULFATE	192, 250, 273
SODIUM PHOSPHATE	53, 118
SODIUM PICOSULFATE	53
SODIUM POLYSTYRENE SULPHONATE	118, 154
SODIUM PRECARBONATE	250
SODIUM PROPIONATE	232
SODIUM SALICYLATE	118
SODIUM STANNATE	154, 250
SODIUM SULFIDE	154, 192, 250, 273
SODIUM TETRADECYLSULFATE	118
SODIUM TRICHLOROACETATE	250
SODIUMHYDROSULFITE	250
SOFOBUVIR	118
SOLASODINE	118
SOLIFENACIN	118
SOMATOSTATIN	118
SOMATOTROPIN EQUINE	118
SOMATROPIN	119, 236
SONTOQUINE	119
SORAFENIB	119
SOTALOL	119
SPARFLOXACIN	119
SPARTEINE	119
SPECTINOMYCIN	119
SPINETORAM	154
SPINOSAD	154
SPIRAMYCIN	119
SPIRAPRIL	119
SPIRONOLACTONE	119
SPIROTETRAMAT	192
SPIROXAMINE	192
SQUILL	46
STANOLONE	119
STANOZOLOL	119
STAR ANISE OIL	154
STAVUDINE	119
STENBOLONE	119
STERIC ACID	232
STEROID HORMONES	119
STILBOESTROL	119
STRCHNINE	250
STREPTODORNASE	119

STREPTOKINASE.....	119
STREPTOMYCIN.....	119
STRONTIUM RANELATE.....	119
STROPHANTHINS.....	119
STROPHANTHUS spp.....	119, 276
STRYCHNINE.....	119, 205, 276, 281
STRYCHNOS spp.....	119
STYRAMATE.....	119
STYRENE.....	154, 250, 273
SUCCIMER.....	119
SUCRALFATE.....	232
SUFENTANIL.....	209
SUGAMMADEX.....	119
SULBACTAM.....	119
SULCOFURON.....	192, 205, 250, 281
SULCONAZOLE.....	46, 119
SULESOMAB.....	232
SULFACETAMIDE.....	53, 119, 154
SULFADIAZINE.....	120, 154
SULFADIMETHOXINE.....	120
SULFADIMIDINE.....	120, 154
SULFADOXINE.....	120
SULFAFURAZOLE.....	120
SULFAGUANIDINE.....	120
SULFAMERAZINE.....	120, 154
SULFAMETHIZOLE.....	120
SULFAMETHOXAZOLE.....	120
SULFAMETHOXYDIAZINE.....	120
SULFAMETHOXPYRIDAZINE.....	120
SULFAMETROLE.....	120
SULFAMIC ACID.....	154, 192, 250, 273
SULFAMONOMETHOXINE.....	120
SULFAMOXOLE.....	120
SULFAPHENAZOLE.....	120
SULFAPYRIDINE.....	120
SULFAQUINOXALINE.....	120
SULFASALAZINE.....	120
SULFATHIAZOLE.....	120, 154
SULFATROXAZOLE.....	120
SULFENTRAZONE.....	205
SULFINPYRAZONE.....	120
SULFLURAMID.....	192
SULFOMETURON-METHYL.....	154
SULFOMYXIN.....	120
SULFONAMIDES.....	120
SULFONMETHANE.....	120
SULFOSULFURON.....	232
SULFOTEP.....	205
SULFOXAFLOL.....	154, 192
SULFURIC ACID.....	192, 250, 273
SULFURYL FLUORIDE.....	192
SULINDAC.....	120
SULPHATED POLYSACCHARIDES.....	232
SULPROFOS.....	192
SULTAMICILLIN.....	120
SULTHIAME.....	120
SUMATRIPTAN.....	121
SUNITINIB.....	121
SUPROFEN.....	121
SUTILAINS.....	121
SUVOREXANT.....	284
SUVOREXANT.....	121
SUXAMETHONIUM.....	121
SUXETHONIUM.....	121
SYMPHYTUM spp.....	154, 220, 273
SYNTHETIC CANNABINOMIMETICS.....	214

T

TACRINE	121
TACROLIMUS	121
TADALAFIL	121
TAFLUPROST	121
TALIGLUCERASE ALFA	121
TALLOW ALKYLAMINE ACETATES	192
TAMOXIFEN	121
TAMSULOSIN	121
TANACETUM VULGARE	121
TANNIC ACID	232
TANNIC ACID/BENZYL ALCOHOL	232
TAPENTADOL	209, 284
TAR ACIDS	192
TASONERMIN	121
TAZAROTENE	121, 273
TAZOBACTAM	121
T-CELL RECEPTOR ANTIBODY	121
TCMTB	192
TDE	192
TDE (1,1-dichloro-2,2-bis[4-chlorophenyl]ethane)	154
TEBUCONAZOLE	155
TEBUFENOZIDE	155
TEBUFENPYRAD	192
TEBUTHIURON	192
TEFLUTHRIN	155, 205
TEGAFUR	121
TEGASEROD	121
TEICOPLANIN	121
TELAPREVIR	121
TELBIVUDINE	121
TELITHROMYCIN	121
TELMISARTAN	121
TEMAZEPAM	121, 284
TEMEPHOS	155, 192
TEMOZOLOMIDE	121
TEMSIROLIMUS	121
TENECTEPLASE	121
TENIPOSIDE	122
TENOCYCLIDINE	214
TENOFOVIR	122
TENOXICAM	122
TEPOXALIN	122
TEPP	205
TEPRALOXIDIM	155
TERAZOSIN	122
TERBACIL	232
TERBINAFINE	46, 122
TERBUFOS	205
TERBUTALINE	53, 122, 273
TERBUTHYLAZINE	192
TERBUTRYN	155
TERFENADINE	122, 273
TERIFLUNOMIDE	122, 273
TERIFLUOMIDE	287
TERIPARATIDE	122, 235
TERLIPRESSIN	122
TERMITE BARRIERS	224
TERODILINE	122
TEROPTERIN	122
TERPENES	250, 273
TERPENES, CHLORINATED	192
TESTOLACTONE	122
TESTOSTERONE	122, 192, 276
TETANUS ANTITOXIN	122
TETANUS TOXOID	122

TETRABENAZINE.....	122
TETRACHLOROETHANE.....	205, 250, 273, 281
TETRACHLOROETHYLENE.....	46, 155, 192, 250, 273
TETRACHLORVINPHOS.....	155
TETRACONAZOLE.....	155, 193
TETRACOSACTRIN.....	122
TETRACYCLINE.....	122, 155
TETRADIFON.....	193
TETRAETHYLAMMONIUM.....	122
TETRAHYDROCANNABINOLS.....	214
TETRAHYDROZOLINE.....	46, 273
TETRAMETHRIN.....	155
TETRAMISOLE.....	193
TETROXOPRIM.....	122
THALIDOMIDE.....	122, 235, 274, 287
THALLIUM.....	205, 281
THAUMATIN.....	232
THEBACON.....	209
THEBAINE.....	209
THENYLDIAMINE.....	122, 284
THEOPHYLLINE.....	53, 122
THEVETIA PERUVIANA.....	122
THEVETIN.....	122
THIABENDAZOLE.....	46, 155
THIACETARSAMIDE.....	122
THIACLOPRID.....	193
THIAMBUTOSINE.....	123
THIAMETHOXAM.....	155, 193
THIAZAFURON.....	193
THIAZOPYR.....	155
THIAZOSULFONE.....	123
THIDIAZURON.....	232
THIETHYLPERAZINE.....	123, 284
THIFENSULFURON.....	155
THIOACETAZONE.....	123
THIOBENCARB.....	155
THIOCARLIDE.....	123
THIODICARB.....	155, 193
THIOFANOX.....	205
THIOFENTANYL.....	215
THIOGUANINE.....	123
THIOMESTERONE.....	123
THIOMETON.....	193
THIOPENTONE.....	123
THIOPHANATE-METHYL.....	155, 193
THIOPROPAZATE.....	123, 284
THIOPROPERAZINE.....	123
THIORIDAZINE.....	123, 284
THIOSTREPTON.....	123
THIOTEPA.....	123
THIOTHIXENE.....	123, 284
THIOURACIL.....	123
THIOUREA.....	123, 250, 274
THIOUREA AND ALKYL THIOUREAS.....	193
THIRAM.....	193
THUJONE.....	193, 250
THYME OIL.....	156, 250
THYMOL.....	193
THYMOXAMINE.....	123
THYROID.....	123
THYROTROPHIN.....	123
THYROXINE.....	123, 276
TIAGABINE.....	123
TIAMULIN.....	123
TIAPROFENIC ACID.....	123
TIARAMIDE.....	123
TIBOLONE.....	123

TICAGRELOR	123
TICARCILLIN	123
TICLOPIDINE	123
TIEMONIUM	123
TIENILIC ACID	123
TIGECYCLINE	124
TIGLOIDINE	124
TILDIPIROSIN	124
TILETAMINE	124
TILIDINE	209
TILMICOSIN	124
TILUDRONIC ACID	124
TIMBER or WALLBOARD	224
TIMOLOL	124
TIN ORGANIC COMPOUNDS	205
TINIDAZOLE	124
TINZAPARIN	124
TIOCARBAZIL	156
TIOCONAZOLE	46, 53, 124
TIOTROPIUM	124
TIPEPIDINE	124
TIPRANAVIR	124
TIRILAZAD	124
TIROFIBAN	124
TOBRAMYCIN	124
TOCAINIDE	124
TOCERANIB	124
TOCILIZUMAB	124
TOLAZAMIDE	124
TOLAZOLINE	124
TOLBUTAMIDE	124
TOLCAPONE	124
TOLCLOFOS-METHYL	156
TOLFENAMIC ACID	124
TOLIDINE	206, 251
TOLMETIN	124
TOLONIUM	124
TOLPROPAMINE	124
TOLRESTAT	124
TOLTERODINE	125
TOLTRAZURIL	156
TOLUENE	193, 251, 274
TOLUENEDIAMINE	193, 220, 251, 274
TOLVAPTAN	125
TOLYLFLUANID	194
TOPIRAMATE	125
TOPOTECAN	125
TORASEMIDE	125
TOREMIFENE	125
TOXOIDS	125
TRALKOXYDIM	156
TRAMADOL	125, 284
TRAMAZOLINE	46, 274
TRAMETINIB DIMETHYL SULFOXIDE	125
TRANDOLAPRIL	125
TRANEXAMIC ACID	125
TRANSFLUTHRIN	194
TRANLYCYPROMINE	125, 284
TRASTUZUMAB	125
TRASTUZUMAB EMTANSINE	125
TRAVOPROST	125
TRAZODONE	125
TRENBOLONE	125, 156
TREOSULPHAN	125
TREPROSTINIL	125
TRESTOLONE	125
TRETAMINE	125

TRETINOIN	125, 236, 274, 287
TRIACETYLOLEANDOMYCIN	125
TRIADIMEFON	156, 194
TRIADIMENOL	156
TRI-ALLATE	156
TRIAMCINOLONE	47, 53, 125, 274
TRIAMIPHOS	206
TRIAMTERENE	125
TRIASULFURON	233
TRIAZBUTIL	206
TRIAZQUONE	125
TRIAZOLAM	125
TRIBENURON-METHYL	156
TRIBUFOS	206
TRICHLORFON	194
TRICHLORMETHIAZIDE	125
TRICHLOROACETIC ACID	125, 156, 194, 251, 274
TRICHLOROACETIC ACID ALKALI SALTS	251
TRICHLOROETHYLENE	126, 194, 251, 274
TRICHLOROISOCYANURIC ACID	251, 281
TRICHLOROPHENOL	194, 274
TRICHODERMA HARZIANUM	233
TRICHODESMA AFRICANA	220
TRICLABENDAZOLE	194
TRICLOFOS	126
TRICLOPYR	194
TRICLOSAN	194
TRICYCLAMOL	126
TRIDEMORPH	194
TRIDIHEXETHYL	126
TRIDIPHANE	156
TRIETAZINE	157
TRIETHANOLAMINE	126, 157, 251, 274
TRIETHYL PHOSPHATE	194, 251
TRIETHYLENE GLYCOL	233
TRIFLOXYSTROBIN	157
TRIFLOXYSULFURON	233
TRIFLUMIZOLE	157
TRIFLUMURON	157
TRIFLUOPERAZINE	126, 284
TRIFLUOROMETHANESULFONIC ACID	194, 251, 274
TRIFLUPERIDOL	126
TRIFLUPROMAZINE	126
TRIFLURALIN	233
TRIFORINE	233
TRIISOPROPANOLAMINE LAURYL ETHER SULFATE	157, 251, 274
TRIOSTANE	126
TRIMEPRAZINE	284
TRIMEPRAZINE	47, 53, 126, 284
TRIMETAPHAN	126
TRIMETHOPRIM	126
TRIMIPRAMINE	126, 284
TRIMUSTINE	126
TRINEXAPAC-ETHYL	157
TRINITROPHENOL	126, 194
TRIOXYSALEN	126
TRIPARANOL	220
TRIPLENNAMINE	126
TRIPLE ANTIGEN VACCINE	126
TRIPROLIDINE	47, 53, 126, 284
TRIPTORELIN	126
TRISODIUM NITRILOTRIACETATE	194
TRITICONAZOLE	157
TROGLITAZONE	126
TROMETAMOL	126
TROPICAMIDE	126
TROPISETRON	126

TROVAFLOXACIN.....	126
TROXIDONE.....	126
TRYPTOPHAN.....	126
TUAMINOHEPTANE.....	47
TUBERCULIN.....	126
TUBOCURARINE.....	126
TULATHROMYCIN.....	126
TULOBUTEROL.....	127
TURPENTINE.....	251
TURPENTINE OIL.....	157, 251
TUSSILAGO FARFARA.....	220
TYLOSIN.....	127
TYMAZOLINE.....	47, 274
TYPHOID VACCINE.....	127

U

ULOCLADIUM OUDEMANSII.....	233
UMECLIDINIUM.....	127
UNOPROSTONE.....	127
URACIL.....	127
URAPIDIL.....	127
UREA.....	233
URETHANE.....	127
UROFOLLITROPIN.....	127, 235
UROKINASE.....	127
URSODEOXYCHOLIC ACID.....	127
USTEKINUMAB.....	127

V

VACCINES.....	127
VACCINIA VIRUS VACCINE.....	127
VALACICLOVIR.....	127
VALDECOXIB.....	127
VALGANCICLOVIR.....	127
VALNOCTAMIDE.....	127
VALPROIC ACID.....	127
VALSARTAN.....	127
VAMIDOTHION.....	194
VANCOMYCIN.....	127
VANDETANIB.....	127
VARDENAFIL.....	127
VARENICLINE.....	127
VARICELLA VACCINE.....	127
VASOPRESSIN.....	127
VECURONIUM.....	128
VEDAPROFEN.....	128
VEDOLIZUMAB.....	128
VELAGLUCERASE ALFA.....	128
VEMURAFENIB.....	128
VENLAFAXINE.....	128
VERAPAMIL.....	128
VERATRUM.....	128
VERNAKALANT.....	128
VERNOLATE.....	157
VERTEPORFIN.....	128
VETIVER OIL.....	233
VIDARABINE.....	128
VIGABATRIN.....	128
VILANTEROL.....	128
VILDAGLIPTIN.....	128
VILOXAZINE.....	128
VINBLASTINE.....	128
VINCAMINE.....	128
VINCLOZOLIN.....	206, 274
VINCRISTINE.....	128

VINDESINE	128
VINFLUNINE.....	128
VINORELBINE.....	128
VINYL CHLORIDE	206, 281
VINYL ETHER	128, 233
VIRGINIAMYCIN	128, 157
VISMODEGIB.....	128
VISNADINE.....	128
VITAMIN A	128
VITAMIN D	53, 129
VITAMIN K	233
VITREOUS ENAMELS	224
VORICONAZOLE.....	129
VORINOSTAT	129
VORTIOXETINE	129

W

WARFARIN	129, 157, 194
WHITE SPIRIT	251
WRITING CORRECTION PENS	224

X

XAMOTEROL.....	129
XANTHINOL NICOTINATE	129
XANTHOPHYLL	233
XIMELAGATRAN.....	129
XIPAMIDE	129
XYLANASE derived from <i>Aspergillus niger</i>	233
XYLAZINE	129
XYLENE.....	194, 251, 274
XYLENOLS.....	251
XYLOMETAZOLINE.....	47, 274

Y

YLANG YLANG OIL	233
YOHIMBINE.....	129

Z

ZAFIRLUKAST	129
ZALCITABINE	129
ZALEPLON	129
ZANAMIVIR.....	129
ZERANOL	129, 195
ZETA-CYPERMETHRIN	195, 206
ZIDOVUDINE.....	129
ZILPATEROL.....	129
ZIMELDINE	129
ZINC BORATE	195
ZINC CHLORIDE	47, 251
ZINC COMPOUNDS	129
ZINC NAPHTHENATE	233
ZINC para-PHENOLSULFONATE	195
ZINC SULFATE	195, 251, 275
ZINEB.....	157
ZIPRASIDONE.....	129, 284
ZIRAM.....	195, 206
ZOLAZEPAM.....	129
ZOLEDRONIC ACID.....	129
ZOLMITRIPTAN	129
ZOLPIDEM	129, 284
ZONISAMIDE	284
ZONISAMIDE.....	130

ZOPICLONE	130, 284
ZOXAZOLAMINE.....	130
ZUCLOPENTHIXOL	130

Cross Reference Index
for page numbers please see Index

1

1,1,1-TRICHLOROETHANE
See also DESIGNATED SOLVENT
1,1-DICHLORO-2,2-BIS[4-CHLOROPHENYL]ETHANE
See TDE
1-DODECANOL
See LAURYL ALCOHOL

2

2-[(4-AMINOPHENYL)AZO]-1,3-DIMETHYL-1H-IMIDAZOLIUM CHLORIDE
See BASIC ORANGE 31
2-[THIOCYANOMETHYLTHIO]BENZOTHAZOLE
See TCMTB
2C-I
See 2,5-DIMETHOXY-4-IODOPHENETHYLAMINE
2C-T-2
See 2,5-DIMETHOXY-4-ETHYLTHIOPHENETHYLAMINE
2C-T-7
See 2,5-DIMETHOXY-4-(N)-PROPYLTHIOPHENETHYLAMINE
2-(DIMETHYLAMINO)ETHANOL
See DMEA, DIMETHYL MEA, DEANOL
2-FURANCARBOXALDEHYDE
See FURFURAL

3

3,4-METHYLENEDIOXY-N- α -DIMETHYLPHENYLETHYLAMINE
See N,A-DIMETHYL-3,4-(METHYLENEDIOXYL)PHENYLETHYLAMINE

4

4-CHLOROTESTOSTERONE
See CLOSTEBOL
4-FLUORO-N-METHAMPHETAMINE
See 4-FLUORO-N-METHYLAMPHETAMINE
4-METHYLHEXANE-2-AMINE
See 1,3-DIMETHYLAMYLAMINE

5

5-MeO-AMT
See 5-METHOXY- α -METHYLTRYPTAMINE

8

8-HYDROXYQUINOLINE
See also CLIOQUINOL

A

Acetone
See also DESIGNATED SOLVENT
ALBUMIN
See HUMAN BLOOD PRODUCTS
ALKYL ACETANILIDES
See ACETANILIDE
ALKYL SULFONALS
See SULFONMETHANE
ALKYL THIOUREAS
See THIOUREA AND ALKYL THIOUREAS
ALKYLATED PHENYLENEDIAMINES
See PHENYLENEDIAMINES
ALUMINIUM PHOSPHIDE
See PHOSPHIDES, METALLIC
ALPHA-CHLORALOSE

Cross Reference Index
for page numbers please see Index

See CHLORALOSE
AM-694
See 1-(5-FLUOROPENTYL)-3-(2-IODOBENZOYL)INDOLE
AMFEBUTAMONE
See BUPROPION
AMIDOPYRINE
See AMINOPHENAZONE
2-[(4-AMINOPHENYL)AZO]-1,3-DIMETHYL-1H-IMIDAZOLIUM CHLORIDE
See BASIC ORANGE 31
Ammonia
See also CHROMATES
AMMONIUM BIFLUORIDE
See BIFLUORIDES
AMMONIUM CHROMATE
See CHROMATES
See CHROMIUM
AMMONIUM hydroxide
See AMMONIA
See AMMONIA/AMMONIUM HYDROXIDE
AMMONIUM SALTS
See BIFLUORIDES
ANALYTICAL PREPARATIONS
See IN VITRO DIAGNOSTIC AND ANALYTICAL PREPARATIONS
ANDROSTALONE
See MESTANOLONE
ANDROSTERONE
See ANABOLIC STEROIDAL AGENTS
ANTIBIOTIC SUBSTANCES
See also BACTERIAL CULTURE MEDIA
ANTICOAGULANT MEDICAL DEVICES
See MEDICAL DEVICES
ANTICOAGULATION COMPLEX
See HUMAN BLOOD PRODUCTS
ANTIMONY
See also ANTIMONY COMPOUNDS
ANTIMONY CHLORIDE
See also ANTIMONY COMPOUNDS
ANTIMONY COMPOUNDS
See also ANTIMONY
ANTIMONY TITANATE
See ANTIMONY COMPOUNDS
See ANTIMONY
ARBUTIN
See HYDROQUINONE
ARISTOLOCHIC ACID
See also bragantia
See also ASARUM spp
AROMATIC EXTRACT OILS
See also HYDROCARBONS LIQUID AROMATIC
ARSENIC
See also CACODYLIC ACID
See also TERMITE BARRIERS
ARSENIC TRIOXIDE
See ARSENIC
ARTIFICIAL TEARS
See MEDICAL DEVICES
ASPERGILLUS NIGER
See □-AMYLASE
See CELLULASE
See FUNGAL PROTEASE
See □-GLUCANASE
See PECTINASE
See XYLANASE
ASPIDOSPERMA QUEBRACHO
See YOHIMBINE
ASPIRIN
See also DIHYDROCODEINE (+ aspirin)

Cross Reference Index
for page numbers please see Index

See also PARACETAMOL (+ aspirin)
See also SALICYLAMIDE (+ aspirin)
ASTEMIZOLE
See also Antihistamines
ATROPINE METHONITRATE
See also ATROPINE
ATROPINE SULFATE
See DIFENOXIN (+ atropine sulfate)
See DIPHENOXYLATE (+ atropine sulfate)
AZELASTINE
See also ANTIHISTAMINES

B

BARIUM
See BARIUM SALTS
BARIUM CHROMATE
See CHROMATES
See CHROMIUM
BARIUM metaborate
See BARIUM SALTS
BARIUM SALTS
BARIUM SELENATE
See SELENIUM
BARIUM SILICOFLUORIDE
See also SILICOFLUORIDES
BARIUM SULFATE
See BARIUM SALTS
BATTERIES
See ELECTRICAL ACCUMULATORS, BATTERIES, COMPONENTS OR LAMPS
BDMPEA
See 4-BROMO-2,5-DIMETHOXYPHENETHYLAMINE
BEECHWOOD
See CREOSOTE
BELLADONNA
See ATROPA BELLADONNA
BENZALKONIUM CHLORIDE
See also QUATERNARY AMMONIUM COMPOUNDS
BENZATHINE PENICILLIN
BENZATROPINE
See BENZTROPINE
Benzene
See also HYDROCARBONS, LIQUID
BENZOYL METRONIDAZOLE
See METRONIDAZOLE
BISMUTH CITRATE
See BISMUTH COMPOUNDS
BISMUTH FORMIC IODIDE
See BISMUTH COMPOUNDS
BISMUTH OXYCHLORIDE
See BISMUTH COMPOUNDS
BISMUTH SUBIODIDE
See BISMUTH COMPOUNDS
BIS(TROBUTYLTINOXIDE)
See TRIBUTYL TIN OXIDE
BLEACHES
See CHLORINATING AGENTS
BLOOD
See also BLOOD COMPONENTS
See also DEXTRANS, GELATIN – SUCCINYLATED & ETHERIFIED STARCHES
See also HUMAN BLOOD PRODUCTS
Borage
See BORAGO OFFICINALIS
BORATES
See BORON
BORAX
See also BORON
BORIC ACID

Cross Reference Index
for page numbers please see Index

See also BORON
BORON
 See also BORIC ACID
BORON COMPOUNDS
 See BORON
BORON TRIFLUORIDE
 See also BORON
BROMO-DRAGONFLY
 See 1-(8-BROMOBENZO[1,2-B;4,5-B]DIFURAN-4-YL)-2-AMINOPROPANE
BROMOCHLORODIMETHYLHYDANTOIN
 See CHLORINATING COMPOUNDS
BUTYPHENONES
 See HALOPERIDOL
BZP
 See BENZYLPIPERAZINE

C

C1 ESTERASE INHIBITORS
 See HUMAN BLOOD PRODUCTS
CADMIUM
 See also CADMIUM COMPOUNDS
CADMIUM ACETATE
 See CADMIUM COMPOUNDS
CADMIUM CHLORIDE
 See CADMIUM COMPOUNDS
CADMIUM COMPOUNDS
 See also CADMIUM
CADMIUM NITRATE
 See CADMIUM COMPOUNDS
CAFFEINE
 See ASPIRIN (+ caffeine)
 See SALICYLAMIDE (+ caffeine)
calamus
 See ACORUS CALAMUS
CALCIUM FOLINATE
 See FOLINIC ACID
CALCIUM HYPOCHLORITE
 See CHLORINATING COMPOUNDS
CALOMEL
 See MERCURIC CHLORIDE
CAMPHOR
 See also ESSENTIAL OILS
CAMPHOR OIL (white)
 See CINEOLE
CANNABICHROMENE
 See NABIXIMOLS
CANNABICYCLOHEXANOL
 See 2-[(1R,3S)-3-HYDROXYCYCLOHEXYL]-5-(2-METHYLNONAN-2-YL)PHENOL
CANNABIDIOL
 See NABIXIMOLS
CANNABIDIOLIC ACID
 See NABIXIMOLS
CANNABIDIVAROL
 See NABIXIMOLS
CANNABIGEROL
 See NABIXIMOLS
CANNABINOL
 See NABIXIMOLS
CANNABINOL
 See NABIXIMOLS
CANNABIS SATIVA
 See HEMP SEED OIL
 See NABIXIMOLS
CARDIAC GLYCOSIDES
 See UNDER INDIVIDUAL ENTRIES
CATALIN
 See PIRENOXINE

Cross Reference Index
for page numbers please see Index

CATECHOL
See 1,2-BENZENEDIOL

CEPHACETRILE
See CEFACETRILE

CEPHALORIDINE
See CEFALORIDINE

CEPHAMANDOLE
See CEFAMANDOLE

CEPHAPIRIN
See CEFAPIRIN

CEPHAZOLIN
See CEFAZOLIN

CETYL TRANEXAMATE
See TRANEXAMIC ACID

CHILD-RESISTANT CLOSURE
See also NON-ACCESS PACKAGING

CHILD-RESISTANT PACKAGING
See also NON-ACCESS PACKAGING

CHLORINATED TERPENES
See TERPENES, CHLORINATED

chlorine
See also CHLORINATING COMPOUNDS
See also DICHLOROISOCYANURATES
See also DICHLOROISOCYANURIC ACID

CHLOROMESTERONE
See DEHYDROCHLOROMETHYLTESTOSTERONE

4-CHLOROTESTOSTERONE
See CLOSTEBOL

CHLORQUINALDOL
See also CLIOQUINOL

CHOLECALCIFEROL
See COLECALCIFEROL

CHOLINE SALICYLATE
See SALICYLIC ACID

Chromates
See also CHROMIUM

CHROMIC ACID
See CHROMIUM TRIOXIDE

CHROMIUM
See also CHROMATES

CHRYSANTHEMIC ACID ESTERS
See PYRETHRINS

2C-I
See 2,5-DIMETHOXY-4-IODOPHENETHYLAMINE

CINEROLONE
See PYRETHRINS

CLOTTING FACTORS
See HUMAN BLOOD PRODUCTS

COLECALCIFEROL
See also VITAMIN D

COLESTYRAMINE
See CHOLESTYRAMINE

COLLAGEN
See also MEDICAL DEVICES

COLTSFOOT
See TUSSILAGO

COMFREY
See SYMPHYTUM spp.

coniine
See CONIUM MACULATUM

CONTAINERS
See also IMMEDIATE CONTAINER
See also SELECTED CONTAINER

CONTRAST MEDIA, RADIOGRAPHIC (RADIOPAQUES)
See RADIOGRAPHIC CONTRAST MEDIA

COPPER CHLORIDE
See COPPER NITRATE

Cross Reference Index
for page numbers please see Index

COPPER-CHROME-ARSENIC
 See CHROMATES, AND ARSENIC
COPPER SALICYLATE
 See DIMETHYL SULFOXIDE
COPPER
 See COPPER COMPOUNDS
CORROSIVE SUBLIMATE
 See MERCUROUS CHLORIDE
CORYMBIA CITRIODORA
 See EXTRACT OF LEMON EUCALYPTUS
CP 47,497 C8 HOMOLOGUE
 See 2-[(1R,3S)-3-HYDROXYCYCLOHEXYL]-5-(2-METHYLNONAN-2-YL)PHENOL
CP 47,497
 See 2-[(1R,3S)-3-HYDROXYCYCLOHEXYL]-5-(2-METHYLOCTAN-2-YL)PHENOL
CREOSOTE
 See also PHENOL
CROTON OIL
 See CROTON TIGLIUM
CRYOPRECIPITATE
 See HUMAN BLOOD PRODUCTS
CRYSTAL WARE
 See GLASS
2C-T-2
 See 2,5-DIMETHOXY-4-ETHYLTHIOPHENETHYLAMINE
2C-T-7
 See 2,5-DIMETHOXY-4-(N)-PROPYLTHIOPHENETHYLAMINE
CUBE
 See ROTENONE
CURING AGENTS FOR EPOXY RESINS
 See AMINES FOR USE AS CURING AGENTS FOR EPOXY RESIN
 See ANHYDRIDES, ORGANIC ACID FOR USE AS CURING AGENTS FOR EPOXY RESINS
 See EPOXY RESINS
Cyanides
 See also HYDROCYANIC ACID AND CYANIDES
CYPERMETHRIN
 See also ZETA-CYPERMETHRIN, ALPHA-CYPERMETHRIN AND BETA-CYPERMETHRIN

D

DALMATIAN
 See SAGE OIL
D.D.A.V.P.
 See DESMOPRESSIN
DDT
 See DICOPHANE
DEANOL
 See 2-(DIMETHYLAMINO)ETHANOL, DMEA, DIMETHYL MEA
DEET
 See DIETHYLTOLUAMIDE
DEHYDROEPIANDROSTERONE
 See PRASTERONE
DEHYDROISOANDROSTERONE
 See PRASTERONE
DEHYDROTESTOSTERONE
 See BOLDENONE
DELAVIRDINE MESYLATE
 See DELAVIRDINE
DELTA-9-TETRAHYDROCANNABINOL
 See DRONABINOL
DENATONIUM BENZOATE
 See BENDIOCARB
 See DIETHYLENE GLYCOL
 See ETHYLENE GLYCOL
 See METHOMYL
 See METHYLATED SPIRIT(S)
DESLORATADINE
 See also ANTIHISTAMINES
DET

Cross Reference Index
for page numbers please see Index

See N,N-DIETHYLTRYPTAMINE
DIALKYL and DIALKOYL QUATERNARY AMMONIUM COMPOUNDS
See QUATERNARY AMMONIUM COMPOUNDS
DIALKYL TIN COMPOUNDS
See TIN ORGANIC COMPOUNDS
DIBENZODIOXINS, HALOGENATED
See HALOGENATED DIBENZODIOXINS
DIBENZOFURANS, HALOGENATED
See HALOGENATED DIBENZODIOXINS AND DIBENZOFURANS
DIBUTYL TIN COMPOUNDS
See TIN ORGANIC COMPOUNDS
1,1-DICHLORO-2,2-BIS[4-CHLOROPHENYL]ETHANE
See TDE
4,5-DICHLORO-2-N-OCTYL-3(2H)-ISOTHIAZOLONE
DICHLOROETHYL ETHER
See also CHLORINATING COMPOUNDS
DICHROMATES
See also CHROMATES
DICOBALT EDETATE
See COBALT
See EDETIC ACID
DIESEL (DISTILLATE)
See also HYDROCARBONS, LIQUID
DIETHYL TIN COMPOUNDS
See TIN ORGANIC COMPOUNDS
DIETHYL-PARA-PHENYLENEDIAMINE
See PHENYLENEDIAMINES
DIETHYLSTILBOESTROL
See STILBOESTROL
DIETHYLSTILBOESTROL DIPHOSPHATE
See FOSFESTROL
DI-iodohydroxyquinoline (iodoquinol)
DIMETAMFETAMINE
See N,N-DIMETHYLAMPHETAMINE
DIMETHISOQUIN
See QUINISOCAINE
DIMETHYL MEA
See 2-(DIMETHYLAMINO)ETHANOL, DEANOL, DMEA
DIMETHYL SULFONE
See METHYLSULFONYLMETHANE
DIMETHYL TIN DICHLORIDE
See TIN ORGANIC COMPOUNDS
DIMETHYL TIN COMPOUNDS
See TIN ORGANIC COMPOUNDS
DIMETHYLFORMAMIDE
See also DESIGNATED SOLVENT
DIMETHYL-PARA-PHENYLENEDIAMINE
See PHENYLENEDIAMINES
DI-N-PROPYL ISOCINCHOMERONATE
DIOCTYL SODIUM SULFOSUCCINATE
See DOCUSATE SODIUM
DIOXINS
See HALOGENATED DIBENZODIOXINS
DIPENTENE
See LIMONENE
DIPROPYL TIN COMPOUNDS
See TIN ORGANIC COMPOUNDS
DISODIUM ETIDRONATE
See ETIDRONIC ACID
DISODIUM PAMIDRONATE
See PAMIDRONIC ACID
DISODIUM TILUDRONATE
See TILUDRONIC ACID
DISTILLATE (DIESEL)
See Diesel
See also HYDROCARBONS, LIQUID
DITHIOCARBAMATES

Cross Reference Index
for page numbers please see Index

See UNDER INDIVIDUAL ENTRIES
DMA
See 2,5-DIMETHOXYAMPHETAMINE
DMAA
See 1,3-DIMETHYLAMYLAMINE
DMEA
See 2-(DIMETHYLAMINO)ETHANOL, DEANOL, DIMETHYL MEA
DMHP
See 3-(1,2-DIMETHYLHEPTYL)-1-HYDROXY-7,8,9,10-TETRAHYDRO-6,6,9- TRIMETHYL-6H-DIBENZO (b,d)
PYRAN
DMT
See N,N-DIMETHYLTRYPTAMINE
DOB
See 2,5-DIMETHOXY-4-BROMOAMPHETAMINE
1-DODECANOL
See LAURYL ALCOHOL
DOET
See 2,5-DIMETHOXY-4-ETHYL-a-AMPHETAMINE
DOM
See 2-AMINO-1-(2,5-DIMETHOXY-4-METHYL)PHENYLPROPANE
DRONABINOL (delta-9-TETRAHYDROCANNABINOL)
See also NABIXIMOLS
DRY CLEANING FLUID
See LIQUID HYDROCARBONS
See HYDROCARBONS, LIQUID

E

ECOTHIOPATE IODIDE
See ECOTHIOPATE
EMETINE
See also CEPHAELIS ACUMINATA
ENAMELLING PREPARATIONS
See FRITTED GLAZING OR ENAMELLING PREPARATIONS
ENDOTOXIN
See BACILLUS THURINGIENSIS
ENILCONAZOLE
See IMAZALIL
EPHEDRINE
See also EPHEDRA
EQUINE ANTI-HUMAN THYMOCYTE IMMUNOGLOBULIN
See IMMUNOGLOBULINS
ERGOCACIFEROL
See VITAMIN D
ESSENTIAL OILS
See also CAMPHOR
ETHANEDINITRILE
See CYANOGEN
ETHANOL
See METHYLATED SPIRIT(S)
See also ETHYL ALCOHOL
ETHOXYETHYLMERCURIC CHLORIDE
See also MERCURY
ETHOXYQUIN
See also MERCURY
ETHYL ALCOHOL
See also ETHANOL

F

FAMPRIDINE
See 4-AMINOPYRIDINE
FENBUTATIN OXIDE
See also TIN ORGANIC COMPOUNDS
FERRICYANIDES
See CYANIDES
FERROCYANIDES
See CYANIDES

Cross Reference Index
for page numbers please see Index

FEXOFENADINE
See also Antihistamines

FIBRINOGEN
See HUMAN BLOOD PRODUCTS

FILM OR PAPER, PHOTOGRAPHIC
See PHOTOGRAPHIC PAPER or FILM

FLAVOPHOSPHOLIPOL
See BAMBERMYCIN

FLUORESCCEIN
See also METHYLATED SPIRIT(S)

FLUORIDES
See also SILICOFLUORIDES

4-FLUORO-N-METHAMPHETAMINE
See 4-FLUORO-N-METHYLAMPHETAMINE

FLUOROSILICATES
See SILICOFLUORIDES

FLUOROSILICIC ACID
See HYDROSILICOFLUORIC ACID

FOLLICLE STIMULANT, RECOMBINANT
See CORIFOLLITROPIN ALFA

FOLLICLE-STIMULATING HORMONE, HUMAN
See UROFOLLITROPIN

FOLLICLE-STIMULATING HORMONE, RECOMBINANT HUMAN
See FOLLITROPIN ALPHA
See FOLLITROPIN BETA

FORMALDEHYDE
See also METACRESOLSULPHONIC ACID AND FORMALDEHYDE CONDENSATION PRODUCT
See also FREE FORMALDEHYDE

FORMOTEROL
See EFORMOTEROL

FREE FORMALDEHYDE
See also FORMALDEHYDE
See also PARAFORMALDEHYDE

FRUSEMIDE
See FUROSEMIDE

FUELS
See MOTOR, HEATING or FURNACE FUELS

FUELS, HOBBY
See MOTOR, HEATING or FURNACE FUELS

FUELS, TOY
See MOTOR, HEATING or FURNACE FUELS

G

GAMMA HYDROXYBUTYRATE (GHB)
See 4-HYDROXYBUTANOIC ACID

GENTIAN VIOLET
See CRYSTAL VIOLET

GHB (GAMMA HYDROXYBUTYRATE)
See 4-HYDROXYBUTANOIC ACID

GLYCOSYLATED HYDROQUINONE
See HYDROQUINONE

GUAIPHENESIN
See also PARACETAMOL (+ guaiphenesin)

H

H5N1 INFLUENZA VIRUS HAEMAGGLUTININ
See INFLUENZA AND CORYZA VACCINES

HALQUINOL
See CLIOQUINOL

HELICO ZEA OCCLUSION BODIES
See POLYHEDROSIS VIRUS

HELICOVERPA ARMIGERA
See NUCLEAR POLYHEDROSIS VIRUS

HEMP AGRIMONY
See EUPATORIUM CANNABINUM

HEMP

Cross Reference Index
for page numbers please see Index

See CANNABIS
HEMP SEED OIL
See also TETRAHYDROCANNABINOLS
HEXACHLOROPHANE
See also HCB
HEXAFLUOROSILICATES
See SILICOFLUORIDES
HEXAFLUOROSILIC ACID
See HYDROSILICOFLUORIC ACID
HEXAMETHYLMELAMINE
See ALTRETAMINE
HOBBY FUELS
See MOTOR, HEATING or FURNACE FUELS
HORMONE, FOLLICLE-STIMULATING
See also FOLLICLE-STIMULATING HORMONE
HORMONE, GROWTH
See GROWTH HORMONE
HORMONE, HUMAN FOLLICLE-STIMULATING
See UROFOLLITROPIN
HORMONE, HUMAN GROWTH
See SOMATROPIN
HORMONE, RECOMBINANT HUMAN FOLLICLE-STIMULATING
See FOLLITROPIN ALPHA
See FOLLITROPIN BETA
HUMAN BLOOD PRODUCTS
See also BLOOD
HUMAN FOLLICLE-STIMULATING HORMONE
See UROFOLLITROPIN
human growth hormone
See SOMATROPIN
HYDROCARBONS, LIQUID
See also DESIGNATED SOLVENT
See also NAPHTHALENE
See also LIQUID HYDROCARBONS
HYDROCHLORIC ACID
HYDROCARBONS LIQUID AROMATIC
See also HYDROCARBONS, LIQUID
HYDROFLUOSILICIC ACID
See HYDROSILICOFLUORIC ACID
HYDROGEN FLUORIDE
See HYDROFLUORIC ACID
HYDROQUINONE
See also MONOBENZONE
8-HYDROXYQUINOLINE
See also CLIOQUINOL
HYOSCINE BUTYLBROMIDE
See also HYOSCINE

I

IBUPROFEN
See also PARACETAMOL (+ ibuprofen)
IMMUNOSERA
See ANTISERA
INJECTABLE TISSUE RECONSTRUCTIVE, AUGMENTATION AND RESTORATION MATERIALS
See MEDICAL DEVICES
INK ADDITIVES
See PRINTING INKS OR INK ADDITIVES
INTRA-ARTICULAR FLUIDS
See MEDICAL DEVICES
Iodine
See also IODOPHORS
3-iodo-2-propynyl butyl carbamate (iodocarb)
Iodocarb
See 3-iodo-2-propynyl butyl carbamate
IODOPHORS
See also IODINE
iodoquinol

Cross Reference Index
for page numbers please see Index

See DI-iodohydroxyquinoline
IPECACUANHA
See CEPHAELIS IPECACUANHA
See CEPHAELIS ACUMINATA
IRON OXIDES
See IRON COMPOUNDS

J

JASMOLONE
See PYRETHRINS
JEQUIRITY
See ABRUS PRECATORIUS
JWH-018
See 1-PENTYL-3-(1-NAPHTHOYL)INDOLE
JWH-073
See NAPHTHALEN-1-YL-(1-BUTYLINDOL-3-YL)METHANONE
JWH-122
See 1-PENTYL-3-(4-METHYL-1-NAPHTHOYL)INDOLE
JWH-200
See 1-(2-MORPHOLIN-4-YLETHYL)INDOL-3-YL)-NAPHTHALEN-1-YLMETHANONE
JWH-250
See 2-(2-METHOXYPHENYL)-1-(1-PENTYLINDOL-3-YL)ETHANONE

K

KAVA
See PIPER METHYSTICUM
KAVALACTONES
See PIPER METHYSTICUM
KEROSENE
See also LIQUID HYDROCARBONS
See also HYDROCARBONS, LIQUID
See also MOTOR, HEATING or FURNACE FUELS
K-HDO
See N-CYCLOHEXYLDIAZENIUMDIOXY-POTASSIUM

L

LABELS
See also DISPENSING LABEL
See also MAIN LABEL
LAMP OIL
See LIQUID HYDROCARBONS
See HYDROCARBONS, LIQUID
LAMPS
See ELECTRICAL ACCUMULATORS, BATTERIES, COMPONENTS OR LAMPS
LAURETH-9
See LAUROMACROGOL
LAVANDIN OIL
See also CAMPHOR
LEAD & LEAD COMPOUNDS
See also PRINTING INKS or INK ADDITIVES
See also SELENIUM
See also GLAZING PREPARATIONS
LEMON EUCALYPTUS OIL
See EXTRACT OF LEMON EUCALYPTUS
LEVOCETIRIZINE
See CETIRIZINE
LIDOCAINE
See LIGNOCAINE
LIGHT MINERAL OILS
See HYDROCARBONS, LIQUID
LINDANE
See also BHC
LINSEED OIL
See ETHOPROPHOS
LIPASE

Cross Reference Index
for page numbers please see Index

See PANCREATIC ENZYMES
LIQUID AROMATIC HYDROCARBONS
See HYDROCARBONS, LIQUID
LIQUID Hydrocarbons
See also HYDROCARBONS, LIQUID
See also NAPHTHALENE
LORATADINE
See also ANTIHISTAMINES
LUTEIN
See XANTHOPHYLL
LYE WATER
See ALKALINE SALTS, SODIUM HYDROXIDE OR POTASSIUM HYDROXIDE

M

MAGNESIUM FLUOSILICATE
See FLUORIDES
MAGNESIUM PHOSPHIDE
See PHOSPHIDES, METALLIC
MAGNETIC RESONANCE IMAGING ENHANCING AGENTS
See ENHANCING AGENTS
Malathion
See also ORGANOPHOSPHORUS COMPOUNDS
MALDISON
See MALATHION
MANCOZEB
See also DITHIOCARBAMATES
MANUKA OIL
See LEPTOSPERMUM SCOPARIUM OIL
MBDB
See N-METHYL-1-(3,4-METHYLENEDIOXYPHENYL)-2-BUTANAMINE
MDA
See 3,4-METHYLENEDIOXYAMPHETAMINE
MDMA
See N,□-DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE
MDPV
See 3,4-METHYLENEDIOXYPYROVALERONE
MELANOCYTE STIMULATING HORMONE
See AFAMELANOTIDE
5-MeO-AMT
See 5-METHOXY-□-METHYLTRYPTAMINE
MEPHEDRONE
See 4-METHYLMETHCATHINONE
MERCURY
See also PHENYLMERCURIC ACETATE
MESCALINE
See 3,4,5-TRIMETHOXYPHENETHYLAMINE
METHADONE INTERMEDIATE
See 4-CYANO-2-DIMETHYLAMINO-4,4-DIPHENYLBUTANE
METHAM SODIUM
See METHAM
METHAMPHETAMINE
See METHYLAMPHETAMINE
METHANOL
See also MOTOR, HEATING or FURNACE FUELS
METHOTRIMEPRAZINE
See LEVOMEPRMAZINE
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA
See EPOETINS
METHOXYPHENAMINE
See also 3,4,5-TRIMETHOXYPHENETHYLAMINE (MESCALINE)
METHOXY-PHENYLETHYLAMINE
See 3,4,5-TRIMETHOXYPHENETHYLAMINE
METHYL CHAVICOL
See BASIL OIL
METHYL ETHYL KETONE
See also DESIGNATED SOLVENT
METHYL ISOAMYL KETONE

Cross Reference Index
for page numbers please see Index

See also DESIGNATED SOLVENT
METHYL ISOBUTYL KETONE
See also DESIGNATED SOLVENT
See also METHYLATED SPIRIT(S)
METHYL SALICYLATE
See also DIMETHYL SULFOXIDE
METHYLDIGOXIN
See MEDIGOXIN
METHYLENE CHLORIDE
See DICHLOROMETHANE
METHYLENE DIANILINE
See 4,4-DIAMINODIPHENYLMETHANE
METHYLENE GLYCOL
See FREE FORMALDEHYDE
See FORMALEDHYDE
3,4-METHYLENEDIOXY-N- α -DIMETHYLPHENYLETHYLAMINE
See N,A-DIMETHYL-3,4-(METHYLENEDIOXYL)PHENYLETHYLAMINE
4-METHYLHEXANE-2-AMINE
See 1,3-DIMETHYLAMYLAMINE
METHYLPHENOBARBITONE
See also BARBITURATE METHYLPREDNISOLONE
METHYLSULFONYLMETHANE
See DIMETHYL SULFONE
METRIFONATE (trichlorfon)
See also TRICHLORFON
MINERAL OILS
See HYDROCARBONS, LIQUID
MINERAL OILS, LIGHT
See HYDROCARBONS, LIQUID
MINERAL TURPENTINE
See LIQUID HYDROCARBONS
See HYDROCARBONS, LIQUID
MMDA
See 5-METHOXY-3,4-METHYLENEDIOXYAMPHETAMINE
MOCA
See 4-DIMETHYLAMINOAZOBENZENE
MONOBENZONE
See also HYDROQUINONE
MORAMIDE
See DEXTROMORAMIDE
MORAMIDE INTERMEDIATE
See 2-METHYL-3-MORPHOLINO-1, 1-DIPHENYLPROPANE CARBOXYLIC ACIDMPPP
See 1-METHYL-4-PHENYL-4-PIPERIDINOL PROPIONATE
MYCOPHENOLATE MOFETIL
See MYCOPHENOLIC ACID

N

N-(N-DODECYL)-2-PYRROLIDONE
See also DESIGNATED SOLVENT
See also N-(N-OCTYL)-2-PYRROLIDONE
See also N-METHYL-2-PYRROLIDONE
N-(N-octyl)-2- PYRROLIDONE
See also DESIGNATED SOLVENT
See also N-(N-DODECYL)-2-PYRROLIDONE
See also N-METHYL-2-PYRROLIDONE
N,N-BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE-2,5-DIMETHANAMINE
See also N,N-BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE-2,6-DIMETHANAMINE
N,N-bis(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE-2,6-DIMETHANAMINE
See also N,N-BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE-2,5-DIMETHANAMINE
N,N-DIMETHYL-4-[PHENYLAZO]-BENZENAMINE
See 4-DIMETHYLAMINOAZOBENZENE
NAPHTHALENEACETIC ACID
See NAA
NEEM
See DEBITTERISED NEEM SEED OIL
See Azadirachta indica
NEFAZODONE

Cross Reference Index
for page numbers please see Index

N-ETHYL MDA
See N-ETHYL- \square -METHYL-3,4-(METHYLENEDIOXY)PHENETHYLAMINE

N-HYDROXY MDA
See N- \square -[METHYL-3,4-(METHYLENEDIOXY)PHENETHYL]HYDROXYLAMINE

NICOTINAMIDE
See NICOTINIC ACID

NISIN
See also ANTIBIOTIC SUBSTANCES

nitrogen mustard
See MUSTINE

N-METHYL-2-PYRROLIDONE
See also DESIGNATED SOLVENT
See also N-(N-DODECYL)-2-PYRROLIDONE
See also N-(N-OCTYL)-2-PYRROLIDONE

N-METHYLMETHANAMINE
See 1,2-ETHANEDIAMINE POLYMER WITH (CHLOROMETHYL)OXIRANE and N-METHYLMETHANAMINE

NON-ACCESS PACKAGING
See also CHILD-RESISTANT CLOSURE
See also CHILD-RESISTANT PACKAGING

NOSCAPINE
See also OPIUM

NUX VOMICA
See STRYCHNINE

O

OCITHILINONE
See 2-OCTYL-4-ISOTHIAZOLIN-3-ONE

OIL OF LEMON EUCALYPTUS (*Corymbia citriodora*)
See EXTRACT OF LEMON EUCALYPTUS

OIL OF TANSY
See TANACETUM VULGARE

ORGANO TIN-COMPOUNDS
See TIN ORGANIC COMPOUNDS

OXALONITRILE
See CYANOGEN

OXETHAZAINE
See OXETACAINE

P

PACKAGING
See LABELS & CONTAINERS
See also PRIMARY PACK
See also MEASURE PACK

PAPAVERINE
See also OPIUM

PAPER
See also PHOTOGRAPHIC PAPER or FILM

Paracetamol
See also ASPIRIN (+ paracetamol)
See also METOCLOPRAMIDE (+ paracetamol)
See also SALICYLAMIDE (+ paracetamol)

PARAFFIN OILS
See HYDROCARBONS, LIQUIDPARAHEXYL
See 3-HEXYL-1-HYDROXY-7,8,9,10-TETRAHYDRO-6,6,9-TRIMETHYL-6H-DIBENZO (b,d) PYRAN

PCBS
See POLYCHLORINATED BIPHENYLS

PCE
See ETICYCLIDINE

PCP
See PHENCYCLIDINE

PCPY
See ROLICYCLIDINE

PDB
See PARA-Dichlorobenzene

PENTACHLORONITROBENZENE
See QUINTOZENE

Cross Reference Index
for page numbers please see Index

PENTOXIFYLLINE
See OXPENTIFYLLINE

PEPAP
See 1-PHENYLETHYL-4-PHENYL-4-PIPERIDINOL ACETATE

PETHIDINE INTERMEDIATE A
See 4-CYANO-1-METHYL-4-PHENYLPYPERIDINE

PETHIDINE INTERMEDIATE B
See 4-PHENYLPYPERIDINE-4-CARBOXYLIC ACID ETHYL ESTER

PETHIDINE INTERMEDIATE C
See 1-METHYL-4-PHENYLPYPERIDINE-4-CARBOXYLIC ACID

Petrol
See also BENZENE
See also MOTOR, HEATING or FURNACE FUELS

PETROLEUM OILS
See HYDROCARBONS, LIQUID

PHENOLS
See also CREOSOTE

PHENYL MERCURIC CHLORIDE
See MERCURY

PHENYL METHYL KETONE
See also DESIGNATED SOLVENT

Phenylephrine
See also CODEINE (+ phenylephrine)
See also PARACETAMOL (+ phenylephrine)
See also IBUPROFEN (+ phenylephrine)

PHOSPHOROUS ACID
See PHOSPHONIC ACID

PHP
See ROLICYCLIDINE

PHYTOMENADIONE
See VITAMIN K

PIMARCIN
See NATAMYCIN

PIPERAZINE OESTRONE SULFATE
See ESTROPIPATE

PLASMA
See BLOOD COMPONENTS
See HUMAN BLOOD PRODUCTS

PLASMA SUBSTITUTES
See DEXTRANS, GELATIN – SUCCINYLATED & ETHERIFIED STARCHES

PLASMA-DERIVED THERAPEUTIC PROTEINS
See HUMAN BLOOD PRODUCTS

PLATELETS
See BLOOD COMPONENTS
See HUMAN BLOOD PRODUCTS

PMA
See 4-METHOXY- α -METHYLPHENYLETHYLAMINE

PODOPHYLLIN
See also PODOPHYLLUM EMODI
See also PODOPHYLLUM PELTATUM
See also PODOPHYLLUM RESIN

POLYDADMAC
See POLY DIALLYL DIMETHYL AMMONIUM CHLORIDE

POLYSILICONE-15
See DIMETHICODIETHYLBENZALMALONATE

POTASSIUM CARBONATE
See ALKALINE SALTS

POTASSIUM CHROMATE
See CHROMATES
See CHROMIUM

POTASSIUM PERMANGANATE
see PERMANGANATES

POTASSIUM PHOSPHATE
See ALKALINE SALTS

POTASSIUM SALTS
See ALKALINE SALTS
See BIFLUORIDES

Cross Reference Index
for page numbers please see Index

POTASSIUM SILICATE
 See ALKALINE SALTS
propineb
 See also DITHIOCARBAMATES
PROTEIN C
 See HUMAN BLOOD PRODUCTS
PROTHROMBIN COMPLEX CONCENTRATE (PCC)
 See HUMAN BLOOD PRODUCTS
PSILOCINE
 See 3-(2-DIMETHYLAMINOETHYL)-4-HYDROXYINDOLE
PSILOTSIN
 See 3-(2-DIMETHYLAMINOETHYL)-4-HYDROXYINDOLE
PYRETHRIC ACIDS
 See PYRETHRINS
PYRETHROLONE
 See PYRETHRINS

Q

QUIZALOFOP ETHYL (D + ISOMER)
 See QUIZALOFOP ETHYL

R

RADIOPAQUES
 See RADIOGRAPHIC CONTRAST MEDIA
RASML
 See REQUIRED ADVISORY STATEMENTS FOR MEDICINE LABELS
RECOMBINANT FOLLICLE STIMULANT
 See CORIFOLLITROPIN ALFA
RECOMBINANT HUMAN FOLLICLE-STIMULATING HORMONE
 See FOLLITROPIN ALPHA
 See FOLLITROPIN BETA
RED CELLS
 See BLOOD COMPONENTS
 See HUMAN BLOOD PRODUCTS
REDUCERS
 See HYDROCARBONS, LIQUID
 See LIQUID HYDROCARBONS
ROSEMARY OIL
 See also CAMPHOR
 See also CINEOLE

S

s,s,s-TRIBUTYLPHOSPHOROTRITHIOATE
 See TRIBUFOS
SABADILLA
 See SCHOENOCAULON OFFICINALE
Safrole
 See also SASSAFRAS OIL
SAGE OIL (Spanish)
 See also CAMPHOR
Salicylamide
 See also ASPIRIN (+ salicylamide)
 See also PARACETAMOL (+ salicylamide)
SALVINORIN A
 See METHYL (2S, 4aR, 6aR, 7R, 9S, 10aS, 10bR)-9-ACETOXY-6a,10b-DIMETHYL-4,10-DIOXO-DODECAHYDRO-
 2-(3-FURYL)-2H-NAPHTHO[2,1-c]PYRAN-7-CARBOXYLATE
SARM
 See SELECTIVE ANDROGEN RECEPTOR MODULATORS
SAVIN(E)
 See JUNIPERUS SABINE
SECOBARBITAL
 See QUINALBARBITONE
SELENIUM ARSENIDE
 See ARSENIC
 See SELENIUM

Cross Reference Index
for page numbers please see Index

SELENIUM SULFIDE
See SELENIUM

SHUI OIL
See CAMPHOR

SILICOFLUORIC ACID
See HYDROSILICOFLUORIC ACID

SILICOFLUORIDES
See also FLUORIDES

SILVER SALTS
See also SILVER NITRATE

SODIUM CARBONATE
See ALKALINE SALTS

SODIUM CHROMATE
See CHROMATES
See CHROMIUM

SODIUM CLODRONATE
See CLODRONIC ACID

SODIUM DICHLOROISOCYANURATE
See also DICHLOROISOCYANURATES

SODIUM 2,2-DICHLOROPROPIONATE
See 2,2-DPA

SODIUM HYPOCHLORITE
See CHLORINATING COMPOUNDS

SODIUM OXYBATE
See 4-HYDROXYBUTANOIC ACID

SODIUM SALTS
See ALKALINE SALTS
See BIFLUORIDES

SODIUM SILICATE(S)
See ALKALINE SALTS

STABAXOL
See 2,2',6'6'-TETRAISOPROPYL-DIPHENYL-CARBODIIMIDE

STAPHISAGRIA
See DELPHINIUM STAPHISAGRIA

STATINS
See HMG-CoA REDUCTASE INHIBITORS

STEM CELLS
See BLOOD COMPONENTS
See also HUMAN BLOOD PRODUCTS

STEROIDAL AGENTS
See ANABOLIC STEROIDAL AGENTS
See ANDROGENIC STEROIDAL AGENTS

STP
See 2-AMINO-1-(2,5-DIMETHOXY-4-METHYL)PHENYLPROPANE

STRAMONIUM
See DATURA STRAMONIUM
See DATURA TATULA

STRONTIUM CHROMATE
See CHROMATES
See CHROMIUM

Styrene
See also DESIGNATED SOLVENT

SULFACETAMIDE
See also SULFONAMIDES

SULFONAL
See SULFONMETHANE

SULPHANILAMIDE
See SULFONAMIDES

SYNEPHRINE
See OXEDRINE

T

TANSY OIL
See TANACETUM VULGARE

TAPENTADOL

TAR
See PHENOL

Cross Reference Index
for page numbers please see Index

TBTO
See TRI-ALKYL TIN COMPOUNDS/SALTS

TCP
See TENOCYCLIDINE

TDE (1,1-dichloro-2,2-bis[4-chlorophenyl]ethane)

TEA TREE OIL
See MELALEUCA OIL

TERBUCONAZOLE
See TEBUCONAZOLE

TERFENADINE
See also ANTIHISTAMINES

TETRACAINE
See AMETHOCAINE

Tetrachloroethylene
See also DESIGNATED SOLVENT

TETRAHYDROCANNABINOLIC ACID
See NABIXIMOLS

TETRAHYDROCANNABINOLS
See also NABIXIMOLS

TETRAHYDROCANNABIVAROL
See NABIXIMOLS

TETRAPION
See FLUPROPANATE

TFMPP
See 1-(3-TRIFLUOROMETHYLPHENYL)PIPERAZINE

Thallium

THALLIUM SULFATE
See THALLIUM

THIACETARSAMIDE
See also ARSENIC

THIAMAZOLE
See METHIMAZOLE

THINNERS
See HYDROCARBONS, LIQUID
See LIQUID HYDROCARBONS

2-[THIOCYANOMETHYLTHIO]BENZOTHAZOLE
See TCMTB

thiram
See also DITHIOCARBAMATES

THROMBIN
See HUMAN BLOOD PRODUCTS

Thujone
See also SAGE OIL

TIOMESTERONE
See THIOMESTERONE

TISSUE RECONSTRUCTIVE, AUGMENTATION AND RESTORATION MATERIALS – INJECTABLE
See MEDICAL DEVICES

TMA
See 3,4,5-TRIMETHOXY- α -METHYLPHENYLETHYLAMINE

TOLUENE
See also HYDROCARBONS, LIQUID
See also XYLENE

TOY

TOY FUELS
See MOTOR, HEATING or FURNACE FUELS

TRIALKYL TIN COMPOUNDS
See TIN ORGANIC COMPOUNDS

TRIBUTYL TIN COMPOUNDS
See TIN ORGANIC COMPOUNDS

TRICHLORFON
See also METRIFONATE

1,1,1-TRICHLOROETHANE
See also DESIGNATED SOLVENT

TRICHLOROETHENE
See TRICHLOROETHYLENE

TRICHLOROISOCYANURIC ACID
See also CHLORINATING COMPOUNDS

Cross Reference Index
for page numbers please see Index

TRICOSENE
 See (Z)-9-TRICOSENE
TRIENBOLONE
 See TRENBOLONE
TRIENOLONE
 See TRENBOLONE
TRIETHYL TIN COMPOUNDS
 See TIN ORGANIC COMPOUNDS
TRIETHYLENE THIOPHOSPHORAMIDE
 See THIOTEPA
TRIIODOTHYRONINE
 See LIOTHYRONINE SODIUM
TRIMETHYL TIN COMPOUNDS
 See TIN ORGANIC COMPOUNDS
TRIPHENYL TIN COMPOUNDS
 See TIN ORGANIC COMPOUNDS
TRIPROPYL TIN COMPOUNDS
 See TIN ORGANIC COMPOUNDS
TSH
 See THYROTROPHIN
TURPENTINE OIL
 See also OIL OF TURPENTINE

U

ULTRASONIC AND MAGNETIC RESONANCE IMAGING ENHANCING AGENTS
 See ENHANCING AGENTS
UNICONAZOLE-P
 See (E)-(S)-1-(4-CHLOROPHENYL)-4,4-DIMETHYL-2-(1H-1,2,4-TRIAZOL-1-YL)PENT-1-EN-3-OL
URINARY CATHETERS
 See MEDICAL DEVICES

V

VINCA ALKALOIDS
 See UNDER INDIVIDUAL ENTRIES
VIPRYNIUM
 See PYRVINIUM

W

WALLBOARD
 See TIMBER
WHITE CELLS
 See BLOOD COMPONENTS
 See HUMAN BLOOD PRODUCTS
WHITE LEAD
 See BASIC LEAD CARBONATE
WHITE MINERAL OILS
 See HYDROCARBONS, LIQUID
WHITE PETROLEUM SPIRIT
 See LIQUID HYDROCARBONS
 See HYDROCARBONS, LIQUID
WHITE SPIRIT
 See also HYDROCARBONS, LIQUID
WHOLE BLOOD
 See HUMAN BLOOD PRODUCTS
WOOD
 See CREOSOTE

X

Xylene
 See also HYDROCARBONS, LIQUID
 See also TOLUENE
XYLENOLS
 See also PHENOL

Cross Reference Index
for page numbers please see Index

Y

YELLOW PHOSPHORUS
See PHOSPHORUS, YELLOW

Z

ZINC CHROMATE
See CHROMATES
See CHROMIUM
ZINC PHOSPHIDE
See PHOSPHIDES METALLIC
zineb
See also DITHIOCARBAMATES