



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

POISONS STANDARD 2012

I, ANTHONY GILL, a delegate of the Secretary to the Department of Health and Ageing 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 and Ageing

Dated this 12th day of June 2012

1. Citation

This instrument is the *Poisons Standard 2012*.

2. The New Poisons Standard

The Poisons Standard 2012 consists of the Standard for the Uniform Scheduling of Medicines and Poisons No. 3 (the SUSMP 3) as set out in Schedule 1.

3. Commencement

The Poisons Standard 2012 commences on the day after registration.

Schedule 1-Standard for the Uniform Scheduling of Medicines and Poisons No. 3

**STANDARD FOR THE UNIFORM SCHEDULING OF
MEDICINES AND POISONS
No. 3**

June 2012

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<http://www.tga.gov.au/industry/scheduling-decisions-final.htm>

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INTRODUCTION

The *Standard for the Uniform Scheduling of Medicines and Poisons* (the Standard), or SUSMP, is established under section 52D 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 National Coordinating Committee on Therapeutic Goods. 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 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. Appropriate labelling and container requirements for products, other than therapeutic goods and agricultural and veterinary chemicals, are imposed through adoption of Parts 1, 2 and 3 of the SUSMP into State or Territory legislation. 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 and instruments 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.

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.

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).

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. It is recommended that the provisions of this Appendix be put into effect through inclusion of the substances in appropriate State and Territory legislation.

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, B and C and the 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, 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	Substances, other than those included in Schedule 9, of such danger to health as to warrant prohibition of sale, supply and use	List of poisons prohibited from sale, supply or use because of their known potential for harm to human and/or animal health.
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	Uniform Paint Standard	Requirements applying to poisons included in paints or tinters.
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 paragraphs 2 to 12 of this Standard

PART 1, INTERPRETATION - continued

by the Therapeutic Goods Administration, the National Manager or their delegate;

- (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.

PART 1, INTERPRETATION - continued

“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
- (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.

“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

PART 1, INTERPRETATION - continued

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 Schedule to Appendix I of this Standard.

“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 chinks, 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.

“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.

PART 1, INTERPRETATION - continued

“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 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".

PART 1, INTERPRETATION - continued

“Non-volatile content” in relation to a paint or tinter means that portion of a paint or tinter 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 Schedule to Appendix I 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*.

“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;

PART 1, INTERPRETATION - continued

- (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.

“Third Schedule Paint” means a paint containing the specified proportion of any substance in the Third Schedule to Appendix I of this Standard.

“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.

- (2) Unless the contrary intention appears a reference to a substance in a Schedule or an Appendix to this Standard includes:

PART 1, INTERPRETATION - continued

- (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

LABELS AND CONTAINERS

LABELS

2. A person must not sell or supply a poison unless it is labelled in accordance with paragraphs 3 to 19 of this Standard.

General requirements

3. Any word, expression or statement required by this Standard to be written on a label or container must be written:
- (1) on the outside face of the label or container; and
 - (2) in the English language; and
 - (3) in durable characters; and
 - (4) in a colour or colours to provide a distinct contrast to the background colour; and
 - (5) in letters at least 1.5 millimetres in height.
4. Subparagraph 3(5) 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:
- (1) an appropriate authority approves the use of smaller letters; and
 - (2) the letters are at least 1 millimetre in height.
5. The label must be printed on, or securely attached to:
- (1) the outside of the immediate container; and
 - (2) if the immediate container is enclosed in a primary pack, the outside of that primary pack.

Immediate wrapper

6. (1) A poison enclosed in an immediate wrapper must be contained in a primary pack labelled in accordance with paragraph 7 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 paragraph 8.

Primary packs and immediate containers

7. (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

PART 2, LABELS AND CONTAINERS – continued

for which it is to be used, as shown in the following table:

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 subparagraph 7(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;

PART 2, LABELS AND CONTAINERS – continued

- (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 subparagraph 7(1)(a); or
 - (B) where the cautionary statement “POSSESSION WITHOUT AUTHORITY ILLEGAL” is required by subparagraph 7(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 subparagraph 7(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 subparagraph 7(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;

PART 2, LABELS AND CONTAINERS – continued

- (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**

written:

- (i) on separate lines immediately below the cautionary statement “KEEP OUT OF REACH OF CHILDREN” as required by subparagraph 7(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 subparagraph 7(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 subparagraph 7(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*;

PART 2, LABELS AND CONTAINERS – continued

- (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

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 paragraph 8:
- (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”;

PART 2, LABELS AND CONTAINERS – continued

- (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 subparagraph 7(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
 - (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):

PART 2, LABELS AND CONTAINERS – continued

- (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 subparagraph 7(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.

- (2) For the purposes of subparagraph 7(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.

Statements of quantity, proportion or strength

- 8. The statement of the quantity, proportion or strength of a poison must be expressed in the most appropriate of the following forms:

- (1) 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*;

- (2) if the poison is for a purpose or purposes other than human therapeutic use and:

- (a) if the poison is in a pressurised spray aerosol preparation, as the mass of the poison per stated mass of the preparation;

- (b) if the poison is a liquid in a liquid preparation, as the mass or volume of the poison per stated volume of the preparation;

- (c) 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;

- (d) 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;

- (e) 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;

- (f) if the poison is a gas in a liquid preparation, as the mass of the poison per stated volume of the preparation;

- (g) 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;

- (h) if the poison is a gas in a gaseous preparation, as the mass of the poison per stated mass of the preparation;

PART 2, LABELS AND CONTAINERS – continued

- (3) 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;
- (4) 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*);
- (5) 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;
- (6) if the poison is a lead-based pigment included in automotive paint, the proportion may be expressed as the maximum content of the lead that may be present in the non-volatile content of the paint;
- (7) 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.
- (8) For the purposes of subparagraph 8(7) “derivative” includes alkaloid.

Exemptions

Selected containers and measure packs

- 9. The requirements of paragraph 7 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 paragraph 10 or 11 apply) when:
 - (1) 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
 - (2) the immediate container is:
 - (a) packed in a primary pack labelled in accordance with paragraph 7; and
 - (b) labelled with:
 - (i) 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 subparagraph 7(1)(a); and
 - (ii) the approved name of the poison and the quantity, proportion or strength of the poison in accordance with paragraph 8; and
 - (iii) 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
 - (iv) if the poison is for the treatment of animals, with the cautionary statement –

FOR ANIMAL TREATMENT ONLY

written in sans serif capital letters.

PART 2, LABELS AND CONTAINERS – continued

Ampoules, pre-filled syringes and injection vials

10. The requirements of paragraph 7 do not apply to a selected container, or an ampoule (other than an ampoule to which paragraph 11 applies) when:
- (1) 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
 - (2) the selected container or ampoule is:
 - (a) packed in a primary pack labelled in accordance with paragraph 7; and
 - (b) labelled with:
 - (i) the approved name of the poison and the quantity, proportion or strength of the poison in accordance with paragraph 8; and
 - (ii) 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
 - (iii) if the poison is for the treatment of animals, with the cautionary statement –

FOR ANIMAL TREATMENT ONLY

written in sans serif capital letters.

11. The requirements of paragraph 7 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:
- (1) 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
 - (2) 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:
 - (a) packed in a primary pack labelled in accordance with paragraph 7; and
 - (b) the strip is labelled in accordance with paragraph 10; and
 - (c) the ampoule is labelled with:
 - (i) the approved name of the poison or the trade name of the product; and
 - (ii) the quantity, proportion or strength of the poison in accordance with paragraph 8.

Transport containers and wrappings

12. 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.

Dispensary, industrial, laboratory and manufacturing poisons

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

PART 2, LABELS AND CONTAINERS – continued

Exemptions from label requirements in certain circumstances

- 13A.** (1) The labelling requirements of paragraphs 7 to 12 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 subparagraph (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 subparagraph 7(1)(m)(ii)(B) of this Standard.

Dispensed medicines

- 14.** Unless otherwise specified by regulation:

- (1) The labelling requirements of this Standard do not apply to a medicine that:
- (a) 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
 - (b) is supplied on and in accordance with a prescription written by an authorised prescriber and is labelled in accordance with the requirements of Appendix L Part 1 of this Standard; or
 - (c) 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.
- (2) A person must not supply a dispensed medicine for human use containing:
- (a) 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
 - (b) 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).

Gas cylinders

- 15.** The requirements of subparagraphs 7(1)(a)(iv), 7(1)(c)(iv), and 7(1)(g)(iv) do not apply to a cylinder containing a poison that is a compressed gas.

Paints

- 16.** The requirements of paragraph 7 do not apply to:

- (1) paint (other than a paint for therapeutic or cosmetic use) which:
- (a) contains only Schedule 5 poisons; or
 - (b) is a First Schedule or Second Schedule paint that is labelled with:
 - (i) 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
 - (ii) 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
 - (iii) the appropriate warnings specified for the paint in Appendix F, written immediately below the expression “KEEP OUT OF REACH OF CHILDREN”; and

PART 2, LABELS AND CONTAINERS – continued

- (iv) the name and proportion of the First Schedule or Second Schedule 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
- (2) a tinter which contains:
 - (a) only Schedule 5 poisons; or
 - (b) a poison included in the First Schedule or Second Schedule to Appendix I, 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”.

Camphor and naphthalene

- 17.** The labelling requirements of subparagraph 3(4) and paragraph 7 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 paragraph 28; and
- (2) is sold or supplied in a primary pack labelled in accordance with paragraphs 3 and 7.

Prohibitions

- 18.** A label used in connection with any poison must not include:

- (1) 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
- (2) 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
- (3) any expression or device which is false or misleading in any particular concerning the safety of the poison or any of its ingredients; or
- (4) any trade name or description that:
 - (a) represents any single constituent of a compound preparation; or
 - (b) misrepresents the composition or any property or quality of the poison; or
 - (c) gives any false or misleading indication of origin or place of manufacture of the poison.

- 19.** 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:

- (1) any expression required by this Standard to be written or embossed on the container or pack; or
- (2) any of the ribs or embossed or printed words required by paragraph 21, 22 or 23 as appropriate.

CONTAINERS

- 20.** A person must not sell or supply a poison unless the immediate container complies with the requirements of paragraphs 21 to 28 of this Standard.

PART 2, LABELS AND CONTAINERS – continued

Containers for poisons other than Schedule 5 poisons

21. 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*.
- 21a. Notwithstanding subparagraph 21, 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:
- (1) the other safety factors are not diminished; and
 - (2) the container has a restricted flow insert and a child-resistant closure.
22. 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:
- (1) comply with subsection 1.4 (General Requirements) of Australian Standard AS 2216-1997 entitled *Packaging for poisonous substances*; and
 - (2) have the word “POISON”:
 - (a) 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:
 - (i) embossed; or
 - (ii) indelibly written in a colour in distinct contrast to the background colour;
 - (b) on the side or shoulder of the container.

Containers for Schedule 5 poisons

23. (1) The container in which any Schedule 5 poison is sold or supplied must:
- (a) comply with the container requirements of paragraph 21 or paragraph 22; 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 subparagraph 23(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;

PART 2, LABELS AND CONTAINERS – continued

(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 paragraph 21.

Approved containers

24. 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 subparagraphs 22(2) or 23(1)(iii) if:

- (1) the other safety factors are not diminished;
- (2) the container is for a specific purpose; and
- (3) an appropriate authority has approved the use of the container for that purpose.

Child-resistant closures

25. (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.

TABLE

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

PART 2, LABELS AND CONTAINERS – continued

Column 1 Name of the poison	Column 2 Nominal capacity
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
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,	5 litres or less

PART 2, LABELS AND CONTAINERS – continued

Column 1 Name of the poison	Column 2 Nominal capacity
hot plate or drain cleaners when included in Schedule 6 except when in pressurised spray packs.	
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.

Schedule 8 poisons

- 25A.** (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
 - (d) nurse or midwife on the direction in writing of an authorised prescriber.

Exemptions

- 26.** (1) Paragraphs 21, 22 and 23 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

PART 2, LABELS AND CONTAINERS – continued

designed to fit into the machines; or

(f) solely for dispensary, industrial, laboratory or manufacturing purposes.

(2) Paragraph 25 does not apply to a poison prepared, packed and sold solely for dispensary, industrial, laboratory or manufacturing purposes.

27. The tactile identification or embossing required by paragraphs 21, 22 or 23 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.

Camphor and naphthalene

28. The container requirements of paragraph 21 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:

- (1) in normal use, prevents removal or ingestion of its contents; and
- (2) is incapable of reacting with the poison; and
- (3) is sufficiently strong to withstand the ordinary risks of handling, storage or transport; and
- (4) has the word “POISON” and the approved name of the poison embossed or indelibly printed on it.

Prohibitions

29. 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.

30. A person must not sell or supply a poison in a container which has the name of another poison embossed or indelibly marked thereon.

31. A person must not sell any poison which is for internal use or any food, drink or condiment in a container prescribed by paragraph 21, 22 or 23 of this Standard.

31A. A person must not sell any poison in a container used expressly for any food, drink or condiment.

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.)

ADVERTISING

- 32.** 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.
- 33.** A person must not include any reference to a poison included in Schedule 9 or Appendix C of this Standard in any advertisement.

SALE OR SUPPLY

Schedule 2 poisons

- 34.** 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.
- 35.** A person is not eligible to be granted a licence to sell a Schedule 2 poison by way of retail sale unless:
- (1) he or she is carrying on the business of selling goods by retail; and
 - (2) the premises from which the poison will be sold is more than 25 kilometres by the shortest practical route from the nearest pharmacy; and
 - (3) he or she produces such evidence, as may be required, that he or she is a fit and proper person to be so licensed.

Schedule 3 poisons

- 36.** 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.
- 37.** The person who sells or supplies a Schedule 3 poison must:
- (1) provide adequate instructions for use, either written or verbal, at the time of supply or sale; and
 - (2) 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
 - (3) if required by regulation, make a record of the transaction in a prescription book or other approved recording system.

PART 3, MISCELLANEOUS REGULATIONS –continued

Schedule 4 poisons

38. 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.
39. Paragraph 38 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:
- (1) the patient is under medical treatment with the poison and continuation of medication is essential; and
 - (2) the quantity sold or supplied does not exceed 3 days' medication; and
 - (3) the pharmacist is satisfied that an emergency exists.
40. Paragraphs 34, 36, 37 and 38 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.

Schedule 7 poisons

41. (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 possess or use is required by subparagraph (3) unless the purchaser produces his or her authorisation.
- (3) A person must not possess or use any of the following Schedule 7 poisons unless he or she is authorised to do so by the appropriate authority:
- Arsenic
 - Cyanides
 - Fluoroacetic acid
 - Fluoroacetamide
 - Hydrocyanic acid
 - Strychnine
 - Thallium.
- (4) The appropriate authority may exempt a person or a class of persons from the requirement to hold an authorisation under subparagraph (3) and may vary or revoke the exemption by notice in writing.

Prohibitions on sale, prescribing and possession

42. A person must not:
- (1) knowingly have in his or her possession or sell, supply or use a poison listed in Appendix C of this Standard for the purpose or purposes indicated in relation to that poison in Appendix C; or
 - (2) 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
 - (3) knowingly have in his or her possession a poison listed in Appendix D paragraph 5 without authority.

PART 3, MISCELLANEOUS REGULATIONS –continued

STORAGE

- 43.** 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.
- 44.** A person who sells or supplies Schedule 3, Schedule 4 or Schedule 7 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 (CH_3COOH) 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

SCHEDULE 2 – continued

closure;

- (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.

SCHEDULE 2 – continued

BEPHENIUM SALTS.

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.

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 in preparations for dermal use and for application to the nails containing 2 per cent or less of ciclopirox **except** in preparations for the treatment of tinea pedis.

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

SCHEDULE 2 – continued

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,

except for smoking or burning.

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

SCHEDULE 2 – continued

DESLOMATADINE 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; or
- (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.

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,

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

SCHEDULE 2 – continued

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 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 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.

SCHEDULE 2 – continued

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*.
 - (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.

SCHEDULE 2 – continued

† FORMALDEHYDE (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.

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 other 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** in hair preparations containing 0.3 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 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) not labelled for the treatment of children 6 years of age or less; and
 - (v) compliant with the requirements of the *Required Advisory Statements for Medicine Labels*.

INDANAZOLINE.

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

IODINE:

- (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),

SCHEDULE 2 – continued

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.

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

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

LODOXAMIDE in preparations for ophthalmic use.

SCHEDULE 2 – continued

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.

MEBENDAZOLE for human therapeutic use.

MECLOZINE in primary packs containing 12 or less tablets or capsules of meclozine 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.

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.

SCHEDULE 2 – continued

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 12 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 25 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
- (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,

SCHEDULE 2 – continued

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:
 - (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.

SCHEDULE 2 – continued

PROPAMIDINE for ophthalmic use.

PYRANTEL for human therapeutic use.

PYRETHRINS, naturally occurring, being pyrethrolone, cinerolone or jasmolone esters of chrysanthemic or pyrethric 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.

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.

SCHEDULE 2 – continued

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.

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:

SCHEDULE 3 – continued

- (i) in divided preparations containing 12 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 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.

SCHEDULE 3 – continued

ERYTHRITYL TETRANITRATE for therapeutic use.

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,

except when included in Schedule 2.

SCHEDULE 3 – continued

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.

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.

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.

SCHEDULE 3 – continued

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:

- (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.

SCHEDULE 3 – continued

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.

TRIMEPAZINE:

- (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.

SCHEDULE 4

(Substances marked † are listed in Appendix C)

(Substances marked # are listed in Appendix D)

ABACAVIR.

ABATACEPT.

ABCIXIMAB.

ACAMPROSATE CALCIUM.

ACARBOSE.

ACEBUTOLOL.

ACEPROMAZINE.

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

ACETARSOL.

ACETAZOLAMIDE.

ACETOHEXAMIDE.

ACETYL ISOVALERYLTYSIN.

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.

ACOKANTHERA OUABAIO.

ACOKANTHERA SCHIMPERI.

SCHEDULE 4 – continued

ACONITUM spp. **except:**

- (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.

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

AFAMELANOTIDE.

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

ALDOSTERONE.

ALEFACEPT.

ALEMTUZUMAB.

ALENDRONIC ACID.

ALFACALCIDOL.

ALFUZOSIN.

ALGLUCERASE.

ALGLUCOSIDASE.

ALISKIREN.

ALLERGENS.

ALLOPURINOL.

ALLYLOESTRENOL.

ALOSETRON.

ALPHA1-PROTEINASE INHIBITOR (HUMAN).

ALPHADOLONE.

ALPHAXALONE.

ALPRAZOLAM.

ALPRENOLOL.

ALPROSTADIL.

ALSEROXYLON.

ALTEPLASE.

ALTRENOGEST.

ALTRETAMINE (hexamethylmelamine).

AMANTADINE.

AMBENONIUM CHLORIDE.

AMBRISENTAN.

AMBUCETAMIDE.

AMBUTONIUM BROMIDE.

AMCINONIDE.

SCHEDULE 4 – continued

AMETHOCAINE **except:**

- (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.

SCHEDULE 4 – continued

AMPHOMYCIN.

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.

SCHEDULE 4 – continued

ANTI-HISTAMINES **except**:

- (a) when included in Schedule 2 or 3; or
- (b) when separately specified in this Schedule.

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

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

APIXABAN.

APOCYNUM spp.

APOMORPHINE.

APRACLOnidine.

APRAMYCIN.

APREPITANT.

APRONAL.

APROTININ.

ARECOLINE.

ARIPRAZOLE.

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.

SCHEDULE 4 – continued

ATOVAQUONE.

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.

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.

SCHEDULE 4 – continued

BALSALAZIDE.

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.

BENAZEPRIL.

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

- (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.

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

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.

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.

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

BRETYLIUM TOSYLATE.

BRIMONIDINE.

BRINZOLAMIDE.

BROMAZEPAM.

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

BROMOCRIPTINE.

SCHEDULE 4 – continued

BROMOFORM for therapeutic use.

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

BROMVALETONE.

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.

BUPROPION.

BUSERELIN.

BUSPIRONE.

BUSULPHAN.

BUTACAINE.

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

BUTRACONAZOLE.

BUTYL AMINO BENZOATE **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.

CALCITRIOL.

CALCIUM CARBIMIDE for therapeutic use.

SCHEDULE 4 – continued

CALCIUM POLYSTYRENE SULPHONATE.

CALOTROPIS GIGANTEA.

CALOTROPIS PROCERA.

CALUSTERONE.

CAMPHORATED OIL for therapeutic use.

CAMPHOTAMIDE.

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.

CARBIDOPA.

CARBIMAZOLE.

CARBOCROMEN.

CARBOPLATIN.

CARBOPROST.

CARBROMAL.

SCHEDULE 4 – continued

CARBUTAMIDE.

CARBUTEROL.

CARINDACILLIN.

CARISOPRODOL.

CARMUSTINE.

CARNIDAZOLE.

CARPROFEN.

CARVEDILOL.

CASPOFUNGIN.

CATHINE.

CATUMAXOMAB.

CEFACETRILE.

CEFACLOR.

CEFADROXIL.

CEFALORIDINE.

CEFAMANDOLE.

CEFAPIRIN.

CEFAZOLIN.

CEFEPIME.

CEFETAMET.

CEFIXIME.

CEFODIZIME.

CEFONICID.

CEFOPERAZONE.

CEFOTAXIME.

CEFOTETAN.

CEFOTIAM.

CEFOVECIN for veterinary use.

CEFOXITIN.

SCHEDULE 4 – continued

CEFPIROME.

CEFPODOXIME.

CEFQUINOME.

CEFTAROLINE FOSAMIL.

CEFSULODIN.

CEFTAZIDIME.

CEFTIBUTEN.

CEFTIOFUR.

CEFTRIAZONE.

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** when included in Schedule 2.

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.

SCHEDULE 4 – continued

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.

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** when included in Schedule 2 or 3.

SCHEDULE 4 – continued

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.

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).

SCHEDULE 4 – continued

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.

CLOXACILLIN.

CLOZAPINE.

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

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.

SCHEDULE 4 – continued

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.

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.

CORTISONE.

CO-TRIMOXAZOLE.

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

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.

SCHEDULE 4 – continued

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.

DABIGATRAN.

DACARBAZINE.

DACLIZUMAB.

DACTINOMYCIN.

DALFOPRISTIN.

DALTEPARIN (includes dalteparin sodium).

DANAPAROID (includes danaparoid sodium).

DANAOL.

DANTHRON for human use.

DANTROLENE.

DAPAGLIFLOZIN.

DAPOXETINE.

DAPSONE.

DAPTOMYCIN.

DARBEPOETIN.

DARIFENACIN.

DARUNAVIR.

SCHEDULE 4 – continued

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.

DEBRISOQUINE.

DECAMETHONIUM.

DEFERASIROX.

DEFERIPRONE.

DEFLAZACORT.

DEGARELIX.

DEHYDROCHLOROMETHYLTESTOSTERONE.

DEHYDROCORTICOSTERONE.

DELAVIRDINE (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.

SCHEDULE 4 – continued

DEFERRIOXAMINE.

DESFLURANE.

DESIPRAMINE.

DESIRUDIN.

DESLANOSIDE.

DESLOMATADINE **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.

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.

DEXTORPHAN (excluding its stereoisomers).

DIAMTHAZOLE.

DIAVERIDINE.

DIAZEPAM.

DIAZOXIDE.

DIBENZEPIN.

DIBOTERMIN.

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

SCHEDULE 4 – continued

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 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

SCHEDULE 4 – continued

- (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.

DIMETHOXANATE.

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.

SCHEDULE 4 – continued

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.

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

DITIOCARB.

DOBUTAMINE.

DOCETAXEL.

DOFETILIDE.

DOLASETRON.

DOMPERIDONE.

DONEPEZIL.

DOPAMINE.

DOPEXAMINE.

DORIPENEM.

DORNASE.

DORZOLAMIDE.

SCHEDULE 4 – continued

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.

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.

SCHEDULE 4 – continued

EFALIZUMAB.

EFAVIRENZ.

EFLORNITHINE.

ELETRIPTAN.

ELTENAC.

ELTROMBOPAG.

EMEPRONIUM.

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

EMTRICITABINE.

ENALAPRIL.

ENESTEBOL.

ENFLURANE for therapeutic use.

ENFUVIRTIDE.

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.

SCHEDULE 4 – continued

EPROSARTAN.

EPTIFIBATIDE.

ERGOMETRINE.

ERGOT.

ERGOTAMINE.

ERGOTOXINE.

ERIBULIN MESYLATE.

ERLOTINIB.

ERTAPENEM.

ERYSIMUM spp.

ERYTHROMYCIN.

ERYTHROPOIETIN.

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

ESCITALOPRAM.

ESMOLOL.

ESOMEPRAZOLE.

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.

SCHEDULE 4 – continued

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.

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.

SCHEDULE 4 – continued

EXENATIDE.

EZETIMIBE.

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

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

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

FELODIPINE.

FELYPRESSIN.

FENBUFEN.

FENCAMFAMIN.

FENCLOFENAC.

FENFLURAMINE.

FENOFIBRATE.

FENOLDOPAM.

FENOPROFEN.

FENOTEROL.

FENPIPRAMIDE.

FENPIPRANE.

FENPROPOREX.

FENPROSTALENE.

FEXOFENADINE **except**:

- (a) when included in Schedule 2; or
- (b) in preparations 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.

FILGRASTIM.

FINASTERIDE.

FINGOLIMOD.

FIROCOXIB.

SCHEDULE 4 – continued

FLECAINIDE.

FLEROXACIN.

FLOCTAFENINE.

FLORFENICOL.

FLUANISONE.

FLUCLOROLONE.

FLUCLOXACILLIN.

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

FLUCYTOSINE.

FLUDARABINE.

FLUDROCORTISONE.

FLUFENAMIC ACID.

FLUMAZENIL.

FLUMETHASONE.

FLUMETHIAZIDE.

FLUNISOLIDE.

FLUNIXIN MEGLUMINE.

FLUOCINOLONE.

FLUOCINONIDE.

FLUOCORTIN.

FLUOCORTOLONE.

FLUORESC EIN 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.

SCHEDULE 4 – continued

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.

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

FOLLISTATIN.

FOLLITROPIN ALPHA.

FOLLITROPIN BETA.

FOMIVIRSEN.

FONDAPARINUX.

FORMEBOLONE.

FORMESTANE.

FORMOTEROL.

FOSAMPRENAVIR.

FOSAPREPITANT.

FOSCARNET.

FOSFESTROL (diethylstilboestrol diphosphate).

FOSINOPRIL.

FOSPHENYTOIN.

FOTEMUSTINE.

FRAMYCETIN.

FULVESTRANT.

SCHEDULE 4 – continued

FURALTADONE.

FURAZABOL.

FURAZOLIDONE.

FUROSEMIDE (frusemide).

FUSIDIC ACID.

GABAPENTIN.

GALANTAMINE.

GALANTHUS spp.

GALLAMINE.

GALSULFASE.

GANCICLOVIR.

GANIRELIX.

GATIFLOXACIN.

GEFITINIB.

GEMCITABINE.

GEMEPROST.

GEMFIBROZIL.

GEMIFLOXACIN.

GEMTUZUMAB OZOGAMICIN.

GENTAMICIN.

GESTODENE.

GESTONORONE.

GESTRINONE.

GHRH INJECTABLE PLASMID.

GITALIN.

GLATIRAMER ACETATE.

GLIBENCLAMIDE.

GLIBORNURIDE.

GLICLAZIDE.

GLIMEPIRIDE.

SCHEDULE 4 – continued

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.

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.

SCHEDULE 4 – continued

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.

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.

SCHEDULE 4 – continued

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.

HYDROXYCHLOROQUINE.

HYDROXYEPHEDRINE.

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.

SCHEDULE 4 – continued

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.

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.

SCHEDULE 4 – continued

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.

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.

SCHEDULE 4 – continued

ISOXICAM.

ISOXSUPRINE.

ISRADIPINE.

ITRACONAZOLE.

IVABRADINE.

IVERMECTIN:

- (a) for human use; or
- (b) for the treatment of mange in dogs.

IXABEPILONE.

JAPANESE ENCEPHALITIS VACCINE.

KANAMYCIN.

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.

SCHEDULE 4 – continued

LAMIVUDINE.

LAMOTRIGINE.

LANATOSIDES.

LANREOTIDE.

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

LANTHANUM for therapeutic use.

LAPATINIB.

LARONIDASE.

LAROPIPRANT.

LATAMOXEF.

LATANOPROST.

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.

SCHEDULE 4 – continued

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 Schedule 2;
- (b) in dermal preparations containing 2 per cent or less of total local anaesthetic substances; or
- (c) in lozenges containing 30 mg or less of total local anaesthetic substances per dosage unit.

LINAGLIPTIN.

LINCOMYCIN.

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

LINEZOLID.

LIOETHYRONINE.

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.

SCHEDULE 4 – continued

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** when included in Schedule 2.

LORAZEPAM.

LORMETAZEPAM.

LOSARTAN.

LOXAPINE.

LUMEFANTRINE.

LUMIRACOXIB.

LUTEINISING HORMONE **except** in ovulation test kits.

LYMECYCLINE.

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

MANDRAGORA OFFICINARUM.

MANNOMUSTINE.

MAPROTILINE.

MARAVIROC.

MARBOFLOXACIN.

MAROPITANT.

MAVACOXIB.

MAZINDOL.

MEASLES VACCINE.

MEBANAZINE.

MEBEVERINE.

SCHEDULE 4 – continued

MEBHYDROLIN.

MEBOLAZINE.

MEBUTAMATE.

MECAMYLAMINE.

MECASERMIN.

MECILLINAM.

MECLOCYCLINE.

MECLOFENAMATE.

MECLOFENOXATE.

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

MEDAZEPAM.

MEDETOMIDINE.

MEDIGOXIN (methyldigoxin).

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.

SCHEDULE 4 – continued

MEPHENESIN.

MEPHENTERMINE.

MEPINDOLOL.

MEPITIOSTANE.

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.

SCHEDULE 4 – continued

METHACYCLINE.

METHALLENOESTRIL.

METHANDRIOL.

METHANTHELINIUM.

METHAZOLAMIDE.

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.

SCHEDULE 4 – continued

METHYLPENTYNOL.

METHYLPHENOBARBITONE.

METHYLPREDNISOLONE.

METHYL SALICYLATE in preparations for internal therapeutic use.

METHYLTESTOSTERONE.

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.

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.

SCHEDULE 4 – continued

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

MILRINONE.

MINOCYCLINE.

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

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 other alkyl ethers of hydroquinone for human therapeutic use or cosmetic use.

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.

SCHEDULE 4 – continued

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

MOXIFLOXACIN.

MOXONIDINE.

MUMPS VACCINE.

MUPIROCIN.

MURAGLITAZAR.

MUROMONAB.

MUSTINE (nitrogen mustard).

MYCOPHENOLIC ACID (includes mycophenolate mofetil).

NABUMETONE.

NADOLOL.

NADROPARIN.

NAFARELIN.

NAFTIDROFURYL.

NALBUPHINE.

NALIDIXIC ACID.

NALORPHINE.

NALOXONE.

NALTREXONE.

NANDROLONE.

NAPROXEN **except** when included 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.

SCHEDULE 4 – continued

NEBIVOLOL.

NEDOCROMIL.

NEFAZODONE.

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.

SCHEDULE 4 – continued

NIMODIPINE.

NIMORAZOLE.

NIRIDAZOLE.

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.

NORMETHANDRONE.

NORTRIPTYLINE.

SCHEDULE 4 – continued

NOVOBIOCIN.

NOXIPTYLINE.

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

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.

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.

SCHEDULE 4 – continued

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

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

SCHEDULE 4 – continued

OXYBUTYNIN.

OXYMESTERONE.

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.

SCHEDULE 4 – continued

PARALDEHYDE.

PARAMETHADIONE.

PARAMETHASONE.

PARECOXIB.

PARICALCITOL.

PAROMOMYCIN.

PAROXETINE.

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.

SCHEDULE 4 – continued

PERGOLIDE.

PERHEXILINE.

PERICYAZINE.

PERINDOPRIL.

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

PERPHENAZINE.

PERTUSSIS ANTIGEN.

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.

SCHEDULE 4 – continued

PHENYLEPHRINE:

- (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.

PTHALYLSULFATHIAZOLE.

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

SCHEDULE 4 – continued

or capsule; or

- (ii) the amount of dried whole or peeled rhizome in the teabag does not exceed 3 g;

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.

SCHEDULE 4 – continued

PODOPHYLLUM EMODI (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.

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.

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.

POTASSIUM PERCHLORATE for therapeutic use.

SCHEDULE 4 – continued

PRACTOLOL.

PRALIDOXIME.

PRAMIPEXOLE.

PRAMOCAINE.

PRAMPINE.

PRASTERONE (dehydroepiandrosterone, dehydroisoandrosterone).

PRASUGREL.

PRAVASTATIN.

PRAZEPAM.

PRAZQUANTEL for human therapeutic use.

PRAZOSIN.

PREDNISOLONE.

PREDNISONE.

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.

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

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

SCHEDULE 4 – continued

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.

PROTRIPTYLINE.

PROXYMETACAINE.

SCHEDULE 4 – continued

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.

RALTITREXED.

RAMIPRIL.

SCHEDULE 4 – continued

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.

REMOXIPRIDE.

REPAGLINIDE.

RESERPINE.

RETEPLASE.

RIBAVIRIN.

RIFABUTIN.

RIFAMPICIN.

RIFAMYCIN.

RIFAPENTINE.

RIFAXIMIN.

RILPIVIRINE.

RILUZOLE.

RIMEXOLONE.

RIMITEROL.

RIMONABANT.

RISEDRONIC ACID.

RISPERIDONE.

SCHEDULE 4 – continued

RITODRINE.

RITONAVIR.

RITUXIMAB.

RIVAROXABAN.

RIVASTIGMINE.

RIZATRIPTAN.

ROBENACOXIB.

ROCURONIUM.

ROFECOXIB.

ROFLUMILAST.

ROLITETRACYCLINE.

ROMIFIDINE.

ROMIPLOSTIM.

RONIDAZOLE.

ROPINIROLE.

ROPIVACAINE.

ROSIGLITAZONE.

ROSOXACIN.

ROSUVASTATIN.

ROTIGOTINE.

ROXIBOLONE.

ROXITHROMYCIN.

RUBELLA VACCINE.

RUBOXISTAURIN.

RUPATADINE.

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

SCHEDULE 4 – continued

- (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.

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.

SERMORELIN.

SERTINDOLE.

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.

SCHEDULE 4 – continued

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.

SOLASODINE.

SOLIFENACIN.

SOMATOSTATIN.

SOMATOTROPIN EQUINE.

SOMATROPIN (human growth hormone).

SONTOQUINE.

SORAFENIB.

SOTALOL.

SPARFLOXACIN.

SPARTEINE.

SPECTINOMYCIN.

SPIRAMYCIN.

SPIRAPRIL.

SPIRONOLACTONE.

STANOLONE.

STANOZOLOL.

SCHEDULE 4 – continued

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.

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.

SCHEDULE 4 – continued

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.

SUMATRIPTAN.

SUNITINIB.

SUPROFEN.

SUTILAINS.

SUXAMETHONIUM.

SUXETHONIUM.

TACRINE.

TACROLIMUS.

TADALAFIL.

TAFLUPROST.

TALIGLUCERASE ALFA.

SCHEDULE 4 – continued

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.

TELITHROMYCIN.

TEICOPLANIN.

TELBIVUDINE.

TELMISARTAN.

TEMAZEPAM.

TEMOZOLOMIDE.

TEMSIROLIMUS.

TENECTEPLASE.

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.

TERIPARATIDE.

TERLIPRESSIN.

SCHEDULE 4 – continued

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.

THIAMBUTOSINE.

THIAZOSULFONE.

THIETHYLPERAZINE.

THIOACETAZONE.

THIOCARLIDE.

THIOGUANINE.

THIOMESTERONE (tiomesterone).

THIOPENTONE.

THIOPROPAZATE.

THIOPROPERAZINE.

THIORIDAZINE.

THIOSTREPTON.

THIOTEPA.

SCHEDULE 4 – continued

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.

TIGECYCLINE.

TIGLOIDINE.

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.

SCHEDULE 4 – continued

TIPEPIDINE.

TIPRANAVIR.

TIRILAZAD.

TIROFIBAN.

TOBRAMYCIN.

TOCAINIDE.

TOCERANIB.

TOCILIZUMAB.

TOLAZAMIDE.

TOLAZOLINE.

TOLBUTAMIDE.

TOLCAPONE.

TOLFENAMIC ACID.

TOLMETIN.

TOLONIUM.

TOLPROPAMINE.

TOLRESTAT.

TOLTERODINE.

TOLVAPTAN.

TOPIRAMATE.

TOPOTECAN.

TORASEMIDE.

TOREMIFENE.

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

TRAMADOL.

TRANDOLAPRIL.

TRANEXAMIC ACID.

TRANYLCYPROMINE.

TRASTUZUMAB.

TRAVOPROST.

SCHEDULE 4 – continued

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.

TRICHLOROETHYLENE for therapeutic use.

TRICLOFOS.

TRICYCLAMOL.

TRIDIHEXETHYL.

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.

SCHEDULE 4 – continued

TRIPLENNAMINE.

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.

TULOBUTEROL.

TYLOSIN **except**:

- (a) when included in Schedule 5;
- (b) in animal feeds containing 50 mg/kg or less of antibiotic substances:
 - (i) for growth promotion;
 - (ii) for the prevention of liver abscesses in cattle; or
 - (iii) for the prevention of ileitis in pigs; or
- (c) in milk replacers for calves, or starter rations for pigs, containing 100 mg/kg or less of antibiotic substances.

TYPHOID VACCINE.

UNOPROSTONE.

URACIL.

URAPIDIL.

URETHANE (excluding its derivatives) for therapeutic use.

UROFOLLITROPIN.

SCHEDULE 4 – continued

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.

VARDENAFIL.

VARENICLINE.

VARICELLA VACCINE.

VASOPRESSIN.

VECURONIUM.

VEDAPROFEN.

VELAGLUCERASE ALFA.

VEMURAFENIB.

VENLAFAXINE.

VERAPAMIL.

VERATRUM spp. **except** when separately specified in this Schedule.

VERNAKALANT.

VERTEPORFIN.

VIDARABINE.

SCHEDULE 4 – continued

VIGABATRIN.

VILDAGLIPTIN.

VILOXAZINE.

VINBLASTINE.

VINCAMINE.

VINCRISTINE.

VINDESINE.

VINFLUNINE.

VINORELBINE.

VINYL ETHER for therapeutic use.

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

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.

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

VORICONAZOLE.

VORINOSTAT.

WARFARIN for therapeutic use.

XAMOTEROL.

XANTHINOL NICOTINATE.

XIMELAGATRAN.

XIPAMIDE.

XYLAZINE.

YOHIMBINE.

ZAFIRLUKAST.

ZALCITABINE.

SCHEDULE 4 – continued

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.

ZONISAMIDE.

ZOPICLONE.

ZOXAZOLAMINE.

ZUCLOPENTHIXOL.

SCHEDULE 5

(Substances marked † are listed in Appendix C)

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 (CH_3COOH) **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.

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 alkoxyalted fatty alkylamine polymer **except** in preparations containing 20 per cent or less of alkoxyalted 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.

SCHEDULE 5— continued

ALPHA-CYPERMETHRIN:

- (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.

AMITROLE.

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.

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.

SCHEDULE 5– continued

CASSIA OIL **except**:

- (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.

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.

SCHEDULE 5— continued

CHLORTHAL-DIMETHYL.

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.

SCHEDULE 5– continued

CYANOACRYLATE ESTERS in contact adhesives **except**:

- (a) when 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; 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).

CYCLOHEXANONE PEROXIDE.

CYCLOPROTHRIN **except** in preparations containing 10 per cent or less of cycloprothrin.

CYCLOXYDIM.

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.

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 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**:

- (a) in preparations in pressurised spray packs labelled as degreasers, decarbonisers or paint strippers and containing 10 per cent or less of dichloromethane;

SCHEDULE 5— continued

- (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.

DIMETHOMORPH **except** in preparations containing 10 per cent or less of dimethomorph.

SCHEDULE 5— continued

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.

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 (H_2SiF_6).

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** in aqueous preparations containing 10 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.

† LEAD COMPOUNDS in preparations for use as hair cosmetics.

SCHEDULE 5— continued

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.

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.

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 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 N-(N-dodecyl)-2-pyrrolidone **except** in preparations containing 25 per cent or less of designated solvents.

SCHEDULE 5— continued

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.

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 xlenols 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 (H_3PO_3).

PHOSPHORIC ACID (excluding its salts and derivatives) in preparations containing 35 per cent or less of phosphoric acid (H_3PO_4) **except**:

- (a) in preparations containing 15 per cent or less of phosphoric acid (H_3PO_4);
- (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 percent 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]- ω -HYDROXY-, MONO- C_{13-15} -ALKYL ETHERS.

POTASSIUM CHLORATE **except**:

- (a) when included in Schedule 2; or
- (b) in preparations containing 10 per cent or less of potassium chlorate.

SCHEDULE 5— continued

† POTASSIUM HYDROXIDE (excluding its salts and derivatives) in preparations containing 5 per cent or less of 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

SCHEDULE 5– continued

- (b) for therapeutic use.

PROPOXUR:

- (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 10 g 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.

SCHEDULE 5— continued

QUINCLORAC.

QUININE in preparations for veterinary use containing 1 per cent or less of quinine.

QUINTOZENE.

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.

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.

SCHEDULE 5— continued

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**:

- (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 ($\text{H}_3\text{NO}_3\text{S}$).

SULFATHIAZOLE when packed and labelled for treatment of ornamental caged birds or ornamental fish only.

SULFOMETURON-METHYL.

† SYMPHYTUM spp. (Comfrey) for dermal use.

2,3,6-TBA.

SCHEDULE 5— continued

TDE (1,1-dichloro-2,2-bis[4-chlorophenyl]ethane) in preparations containing 10 per cent or less of TDE.

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.

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.

SCHEDULE 5– continued

THIOPHANATE-METHYL in preparations containing 25 per cent or less of thiophanate-methyl.

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.

SCHEDULE 5— continued

TRIDIPHANE.

TRIETAZINE.

TRIETHANOLAMINE (excluding its salts and derivatives) **except** in preparations containing 5 per cent or less of triethanolamine.

TRIFLOXYSTROBIN.

TRIFLUMIZOLE.

TRIFLUMURON.

TRISOPROPANOLAMINE 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.

TYLOSIN in animal feed premixes containing 5 per cent or less of antibiotic substances:

- (a) for growth promotion;
- (b) for the prevention of liver abscesses in cattle; or
- (c) for the prevention of ileitis in pigs.

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

(Substances marked † are listed in Appendix C)

ABAMECTIN:

- (a) in preparations for pesticidal use containing 2 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 (CH_3COOH) **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 alkoxylated 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.

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 tints containing 5 per cent or less of antimony calculated on the non-volatile content of the paint or tint.

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

SCHEDULE 6 continued

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 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.

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.

BRODIFACOU 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.

BROMOPHOS-ETHYL.

BROMOXYNIL.

SCHEDULE 6 continued

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

NOT TO BE TAKEN;

- (e) in preparations containing 25 per cent or less of cajuput oil; or

SCHEDULE 6 continued

- (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.

CAMPHOR **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
- (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.

SCHEDULE 6 continued

CHLORALOSE (alpha-CHLORALOSE) when packed and labelled for use as a pesticide.

CHLORDANE.

CHLORFENAPYR in preparations containing 36 per cent or less of chlorfenapyr.

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.

CHLOROTHALONIL **except** in water-based paint containing 0.5 per cent or less of chlorothalonil.

CHLORPYRIFOS **except**:

- (a) when included in Schedule 5; or

SCHEDULE 6 continued

- (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, 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 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;

SCHEDULE 6 continued

- (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.

CLOTTRIMAZOLE 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 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.

SCHEDULE 6 continued

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:**

- (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.

SCHEDULE 6 continued

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.

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

CYSTEAMINE for cosmetic use **except**:

- (a) when included in Schedule 5; or
- (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,

SCHEDULE 6 continued

except when included in Schedule 5 or 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.

DICHOLOBENIL.

DICHOLOFENTHION.

DICHOLOFLUANID.

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
- (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.

SCHEDULE 6 continued

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.

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.

SCHEDULE 6 continued

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
- (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.

SCHEDULE 6 continued

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 CHLOROHYDRIN.

ETHYLENE DICHLORIDE.

† ETHYLENE 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 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:

SCHEDULE 6 continued

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 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.

FENAZAFLOL.

FENBUTATIN OXIDE.

FENCHLORPHOS.

SCHEDULE 6 continued

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.

FLUAZIFOP-BUTYL.

FLUAZIFOP-P-BUTYL.

FLUAZINAM.

FLUCOFURON in preparations for the treatment of carpets during manufacture.

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

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.

FORMOTHION.

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

FUMAGILLIN.

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:
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.

SCHEDULE 6 continued

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;
- (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.

SCHEDULE 6 continued

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; or
- (b) in aqueous preparations containing 10 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;
- (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 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:

SCHEDULE 6 continued

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.

LAURYLISOQUINOLINIUM BROMIDE.

† LEAD COMPOUNDS **except:**

- (a) when included in Schedule 4 or 5;
- (b) in paints, tinters, inks or ink additives;
- (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.

SCHEDULE 6 continued

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.

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.

SCHEDULE 6 continued

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**:

- (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 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.

METHYLNORBORNANYLPYRIDINE.

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.

SCHEDULE 6 continued

METOFLUTHRIN.

METOSULAM.

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

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

SCHEDULE 6 continued

- (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
- (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 octhilinone 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.

SCHEDULE 6 continued

† 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 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

SCHEDULE 6 continued

- (c) in preparations containing 2 per cent or less of permethrin.

PHENOL, including cresols and xlenols and any other homologue of phenol boiling below 220°C, **except**:

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

SCHEDULE 6 continued

PINDONE.

PINE OILs when packed and labelled as a herbicide **except** when included in Schedule 5.

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:

SCHEDULE 6 continued

- (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.

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.

SCHEDULE 6 continued

PYRITHIONE COPPER.

PYRITHIONE ZINC **except:**

- (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.

PYROXASULFONE in water dispersible granule preparations when for pre-emergence herbicide use.

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 safrole.

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

SCHEDULE 6 continued

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 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 safrole.

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.

SCHEDULE 6 continued

SINBIOALLETHRIN except:

- (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.

SCHEDULE 6 continued

SODIUM PERCARBONATE (CAS No. 15630-89-4) **except**:

- (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.

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 (H_2SO_4).

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.

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:

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

SCHEDULE 6 continued

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 and toluene.

SCHEDULE 6 continued

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 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.

AZAFENIDIN.

SCHEDULE 7 – continued

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.

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.

SCHEDULE 7 – continued

CARBOPHENOTHION.

CARBOSULFAN.

CHLORDECONE.

CHLORDIMEFORM.

CHLORFENAPYR **except** when included in Schedule 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.

SCHEDULE 7 – continued

DELTAMETHRIN **except**

- (a) when included in Schedule 5 or 6; or
- (b) when in preparations containing 0.1 per cent or less of deltamethrin.

DEMETON.

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.

DIFENACOU **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.

SCHEDULE 7 – continued

EPICHLOROHYDRIN.

EPIDERMAL GROWTH FACTOR **except** in preparations for human therapeutic use.

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

ETACONAZOLE.

ETHION.

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.

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

GAMMA-CYHALOTHRIN **except** when included in Schedule 5.

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

SCHEDULE 7 – continued

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; 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 PERFLUOROOCTANE 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.

SCHEDULE 7 – continued

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.

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.

SCHEDULE 7 – continued

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.

NITROPRUSSIDES **except** when included in Schedule 4 or 6.

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.

SCHEDULE 7 – continued

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

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:
 - (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.

SCHEDULE 7 – continued

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
- (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 subject to additional controls - see Appendix D)

ACETYLDIHYDROCODEINE.

ACETYLMETHADOL.

ACETYLMORPHINES.

ALFENTANIL.

ALPHACETYLMETHADOL.

ALPHAPRODINE.

AMPHETAMINE.

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

ANILERIDINE.

BENZYLMORPHINE.

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

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).

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.

NORMETHADONE.

SCHEDULE 8 – continued

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.

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.

SCHEDULE 9 – continued

CANNABIS **except**:

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

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).

SCHEDULE 9 – continued

DIOXAPHETYL BUTYRATE.

ECGONINE.

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-HYDROXYBUTANOIC ACID and its salts. *(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.

SCHEDULE 9 – continued

METAZOCINE.

METHAQUALONE.

METHCATHINONE.

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.

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

SCHEDULE 9 – continued

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

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

NAPTHALEN-1-YL-(1-BUTYLINDOL-3-YL)METHANONE *(JWH-073).

NICOCODINE.

NICODICODINE.

NICOMORPHINE.

NORACYMETHADOL.

NORLEVORPHANOL.

NORMORPHINE.

NORPIPANONE.

PARA-FLUOROFENTANYL.

1-PENTYL-3-(4-METHYL-1-NAPTHOYL)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.

SCHEDULE 9 – continued

TENOCYCLIDINE *(TCP).

SYNTHETIC CANNABINOMIMETICS **except** when separately specified in these Schedules.

TETRAHYDROCANNABINOLS and their alkyl homologues **except**:

- (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 methoxyphenylethylamine **except**:

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

1-(3,4,5-TRIMETHOXYPHENYL)-2-AMINOBTANE.

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PART 5 - 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;

APPENDIX A – continued

- (iv) clotting factors;
- (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.

APPENDIX A – continued

PRINTING INKS or INK ADDITIVES except:

- (a) when containing a pesticide; or
- (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

APPENDIX B, PART 2 – continued

- 4.2 Biological control agent
- 5. Environmental
 - 5.1 Mosquito control
- 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>	May 1992	a	5.1
(excluding endotoxin)	Jun 2003	a	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
BIURET	Nov 1974	a	2.4
BOSCALID	June 2003	a	1.3

APPENDIX B, PART 3 – continued

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
BOVINE SOMATOTROPHIN	May 1992	a	2
BROMACIL	Aug 1987	a	1
BROMOPROPYLATE	Nov 1994	a	1
BUPIRIMATE	Nov 1990	a	1
BUTAFENACIL	May 2000	a	1
BUTOXPOLYPROPYLENE GLYCOL	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

APPENDIX B, PART 3 – continued

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
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
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
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
β-GLUCANASE derived from <i>Aspergillus niger</i>		Feb 2005	a 2.4
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

APPENDIX B, PART 3 – continued

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
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
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
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
NAPTHYL 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

APPENDIX B, PART 3 – continued

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
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
d-PHENOTHYRIN	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

APPENDIX B, PART 3 – continued

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
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
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

SUBSTANCES, OTHER THAN THOSE INCLUDED IN SCHEDULE 9, 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
- (b) in liquid or semi-solid automatic dishwashing preparations, the pH of which is more than 12.5.

ALLYLISOPROPYLACETYLUREA for therapeutic use.

AMINOPHENAZONE (amidopyrine) and its derivatives for human therapeutic use.

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** 'de-bitterised neem seed oil'.

BASIC ORANGE 31 (2-[(4-aminophenyl)azo]-1,3-dimethyl-1H-imidazolium chloride) in preparations for skin colouration and dyeing of eyelashes or eyebrows.

BITHIONOL for human therapeutic use.

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.

CINCHOPHEN and its derivatives for therapeutic use.

CLIOQUINOL and other halogenated derivatives of 8-hydroxyquinoline for human internal use **except** when being

APPENDIX C – continued

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** in preparations containing 0.25 per cent or less of diethylene glycol.

DIETHYLHEXYL PHTHALATE for cosmetic use.

DIETHYLPHTHALATE in sunscreens or personal insect repellents 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.

DIMETHYLPHTHALATE in sunscreens or personal insect repellents 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** in preparations containing 0.25 per cent or less of ethylene glycol.

ETHYLHEXANEDIOL for human use.

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

APPENDIX C – continued

- (d) in all other cosmetic preparations containing 0.05 per cent or more of free formaldehyde **except** in preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement:

CONTAINS FORMALDEHYDE.

HELIOTROPIUM spp. for therapeutic use.

JUNIPERUS SABINE [savin(e)] for therapeutic use.

LEAD COMPOUNDS in paints, tinters, inks or ink additives **except** 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.

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.

METHYL METHACRYLATE for cosmetic use **except** in preparations containing 1 per cent or less of methyl methacrylate as residual monomer in a polymer.

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** in preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement:

CONTAINS FORMALDEHYDE.

PETASITES spp. for therapeutic use.

PHENYLENEDIAMINES 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.

PTERIDIUM spp. for therapeutic use.

PULMONARIA spp. for therapeutic use.

SAFROLE for internal therapeutic use **except** in preparations containing 0.1 per cent or less of safrole.

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.

SYMPHYTUM spp. (Comfrey) for therapeutic or cosmetic use **except** when included in Schedule 5.

APPENDIX C – continued

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.

TRICHODESMA AFRICANA for therapeutic use.

TRIPARANOL for therapeutic use.

TUSSILAGO FARFARA for therapeutic use.

APPENDIX D

ADDITIONAL CONTROLS ON POSSESSION OR SUPPLY OF POISONS INCLUDED IN SCHEDULE 4 OR 8

(Note: 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.
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).
NABIXIMOLS.

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.

TRETINOIN for human oral use.
LENALIDOMIDE.

APPENDIX D –continued

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.
DARBEPOETIN.
DEXTROPROPOXYPHENE.
EPHEDRINE.
EPOETINS.
ERYTHROPOIETIN.
ERYTHROPOIETINS **except** when separately specified in this Appendix.
FOLLISTATIN.
GLUTETHIMIDE.
INSULIN-LIKE GROWTH FACTORS.
PHENTERMINE.
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.

AMBRISANTAN for human use.
BOSENTAN 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

APPENDIX E, PART 1 – continued

methyated spirit if available. Contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.

- S4 If on skin, immediately remove any contaminated clothing, wash skin with methyated 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

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
Bay oil	A,G3
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
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

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
Carbon disulfide	A,G3,E2,R1,S2
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
Chlorine (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
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
Cysteamine	E1
ortho-Dichlorobenzene	A,G3,E1,S1
para-Dichlorobenzene (PDB)	A

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
Dichloroethyl ether	A,G3,E1,R1,S1
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

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
Ether	A,G3,E1,R1
Ethyl bromide	A,E2,S1,R1
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
Fluorides 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
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
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

APPENDIX E, PART 2 – continued

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

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
Malathion at 20 per cent or less	A
Marjoram oil	A,G3
Melaleuca oil	A,G1,G3
Mercuric chloride	
• for external therapeutic use	A
• for other uses	A,G1,G3,E2,R2,S1
Mercuric iodide	A,G1,G3,E2,R2,S1
Mercuric nitrate	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 peroxide	A,G3,E2,S1
Methyleugenol	A
Methyl isoamyl ketone	A,G3
Methyl isobutyl ketone	A,G3

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
N-Methyl-2-pyrrolidone	
• when included in Schedule 5	A,G3,E1
• 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

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
Phenols	
• 25 per cent and less	A,G3,E2,S3
• above 25 per cent	A,G3,E2,S4
Phenols in pressurised spray packs	A,E1
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), α -[2-[(2-hydroxyethyl)amino]-2-oxoethyl]- ω -hydroxy-, mono-C ₁₃₋₁₅ -alkyl ethers	A,E1

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
Potassium bromate	A
Potassium chlorate	A
Potassium cyanate	A,E1,S1
Potassium hydroxide	A,G3,E2,S1
Potassium metabisulphite	A
Potassium nitrite	
• 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
Pyrrhione zinc	A,E1
Quaternary ammonium compounds 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
Safrole	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

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
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
Sodium hydrogen sulfate	A,G3,E1,S1
Sodium hydrosulfite	A,G3,E2,S1
Sodium hydroxide	A,G3,E2,S1
Sodium laureth-6 carboxylate	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 percarbonate	
• 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
Strychnine	A,G1,G2,G3,R2
Styrene	A,G3,S1,E1
Sulcofuron	A
Sulfamic acid	A,G3,E2,S1

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
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
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
Triisopropanolamine lauryl ethersulfate	A,E1,S1
Turpentine (mineral)	A,G3
Turpentine oil (vegetable)	A,G3,E2
White spirit	A,G3

APPENDIX E, PART 2 – continued

POISON	STANDARD STATEMENTS
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.

APPENDIX F, PART 1 – continued

25. Do not use on broken skin. Wash hands thoroughly after use.
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

APPENDIX F, PART 1 – continued

animals. Women of child bearing age are advised not to mix, load or spray this product. They should keep out of crops being sprayed.

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.

APPENDIX F, PART 1 – continued

- 73. Do not use for acne.
- 74. Do not use under waterproof bandages unless a doctor has told you to.
- 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

APPENDIX F, PART 1 – continued

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.
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 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.

APPENDIX F, PART 2 – continued

25. Avoid contact with food.
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.	77,62	
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
Antihistamines not separately specified in this Appendix except :	39 or 40	
(a) dermal, ocular, parenteral and paediatric preparations;		
(b) oral preparations of astemizole, desloratadine, fexofenadine,		

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
loratadine or terfenadine;		
(c) nasal preparations of azelastine; or		
(d) preparations for the treatment of animals.		
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 (neem) including its extracts and derivatives when included in Schedule 6.	67	
Azocyclotin	48	
Benomyl	46	
Benzene	12	1,4,9
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

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
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	
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
Carbamide 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 disulphide	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	10,18,22	1,4,8,12,13,

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
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> .		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 trichloroisocyanuric acid.	10,22,23	12,13,14,15, 17,18,19,21
(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
Cysteamine		1
4,4-Diaminodiphenylmethane (methylene dianiline)		1,4,8

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
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 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 <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

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
(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 18,21	12,13,14,15,17,
(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 <i>the Australian Code for the Transport of Dangerous Goods by Road and Rail</i> in preparations containing 5 g or less of sodium dichloroisocyanurate for use in toilet bowls only.		
(i) during storage	10,22 18,21	12,13,14,15,17,
(ii) during use	5	1,4,7,12
Dichloromethane (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

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
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
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 chlorohydrin		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	

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
Fenoterol 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
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
Hexachlorophane in preparations for skin cleansing purposes containing 3 per cent or less of hexachlorophane.	24	
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

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
(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	
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	

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
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 condensation product for the treatment of animals.		1,4
Methanol except in methylated spirit.		1,4,8
Methoxamine in nasal preparations for topical use.	29	
Methyl chloride		1,4,8
Methylene bithiocyanate		1,4
Methyldibromo glutaronitrile	28	1,4,7
Methyl ethyl ketone	5	1,4,8
Methyl ethyl ketone peroxide	2	2,3,4,6
Methyleugenol		1,6
Methyl iso-amyl ketone		1,4,8
Methyl iso-butyl ketone		1,4,8
Methyl iso-thiocyanate	5,12	1,4,8
Methyl methacrylate	28	4,9,23
Methylnorbornylpyridine	59	

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
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		
(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	

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
Paint		
(a) First Schedule paints.	83	
(b) Second Schedule paints.	84	
Paracetamol	97 and/or 98,99,100	
Pentachlorophenol		1,4,8
Peracetic acid	2	1,4,8
Permanganates	2	24
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 for topical use.	29	
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

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
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), α-[2-[(2-hydroxyethyl)amino]-2-oxoethyl]-ω-hydroxy-, mono-C_{13-15}-alkyl ethers	5,88	1,5
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	

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
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
Silver in smoking deterrents.	42	
Sitaxentan	7, 62, 76	
Sodium aluminate	2	1,4
Sodium chlorate		1,4
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

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
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
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	
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

APPENDIX F, PART 3 – continued

POISON	WARNING STATEMENTS	SAFETY DIRECTION
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
Triisopropanolamine 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	
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

UNIFORM PAINT STANDARD

This Appendix provides regulations for adoption by the States and Territories.

1. A person must not manufacture, sell, supply or use a First Schedule Paint for application to:
 - (1) a roof or any surface to be used for the collection or storage of potable water; or
 - (2) furniture; or
 - (3) 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
 - (4) 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 Third Schedule 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 containing a pesticide except a fungicide, algicide, bactericide or antifouling agent.

The First Schedule

The proportion of a substance for the purposes of this Schedule 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 Schedule

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

The Third Schedule

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

Substance	Proportion
LEAD or lead compounds	more than 0.1 per cent

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
Arprinocid	1
Arsenic	1
Azocyclotin	1
Benzene	1
Bifluorides (including ammonium, potassium and sodium salts)	1
Boron trifluoride	1
Brodifacoum	1
Bromadiolone	1
Bromine	1
Brucine	1
Calciferol	1
Captafol	1
Carbadox	1
Carbon tetrachloride	1
Chlordecone	1
Chlordimeform	1
Chlorine	1
Chloromethiuron	1
Chloropicrin	1
4-Chloro-o-toluidine	1
Colecalciferol	1
Coumatetralyl	1
Cyanogen	1
Cyhexatin	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
Etaconazole	1
Ethylene dibromide	1
Ethylene oxide	1
Fluoracetamide	3

APPENDIX J, Part 2—continued

POISONS

CONDITIONS

Fluoroacetic acid	3
Folpet	1
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
Phosphides, metallic	1
Phosphine	1
Propylene oxide	1
Pyrinuron	1
Strychnine	1
Sulcofuron	1
Tetrachloroethane	1
2,2',6,6'-Tetraisopropyl-diphenyl-carbodiimide	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, Labels and Containers, subparagraph 14(2))

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

APPENDIX K – continued

ETHYLMORPHINE
FENFLURAMINE
FLUNITRAZEPAM
FLUPENTHIXOL
FLUPHENAZINE
FLURAZEPAM
GABAPENTIN
GEMCITABINE
GLUTETHIMIDE
HALOPERIDOL
HYDROCODONE
HYDROMORPHONE
HYDROXYZINE
IMIPRAMINE
LAMOTRIGINE
LEVETIRACETAM
LEVOCABASTINE
LORAZEPAM
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
PERICYAZINE
PERPHENAZINE
PETHIDINE
PHENELZINE
PHENIRAMINE
PHENOBARBITONE
PHENOPERIDINE
PHENYLTOLOXAMINE
PHOLCODINE
PIMOZIDE
PIZOTIFEN
PRAZEPAM
PREGABALIN
PROCHLORPERAZINE
PROMAZINE

APPENDIX K – continued

PROMETHAZINE
PROTRIPTYLINE
QUETIAPINE
QUINALBARBITONE
RISPERIDONE
ROTIGOTINE
RUPATADINE
SECBUTOBARBITONE
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. (ii) for topical use.	77, 62 and 76 62 and 77
Adapalene: (i) for oral use. (ii) for topical use.	77, 62 and 76 62 and 77
Ambrisentan:	77, 62 and 76
Bexarotene: (i) for oral use. (ii) for topical use.	77, 62 and 76 62 and 77
Bosentan..	77, 62 and 76
Dienestrol.	67
Etretinate: (i) for oral use. (ii) for topical use.	77, 62 and 76 62 and 77
Isotretinoin: (i) for oral use. (ii) for topical use.	77, 62 and 76 62 and 77
Leflunomide.	77, 62 and 87
Lenalidomide: (i) for oral use. (ii) for topical use.	77, 62 and 76 62 and 77
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Sitaxentan	77, 62 and 76

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Column 1 Substance	Column 2 Warning statement
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Tretinoin: (i) for oral use. (ii) for topical use.	77, 62 and 76 62 and 77

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