Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

THERAPEUTIC GOODS ORDER NO. 80

Child-Resistant Packaging Requirements for Medicines

I, Rohan Hammett, delegate of the Minister for Health and Ageing for the purposes of the exercise of the Minister's powers under section 10 of the *Therapeutic Goods Act 1989* and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of that Act, HEREBY:

(1) REVOKE, on and from 1 September 2010, Therapeutic Goods Order No. 65 *Child-Resistant Packaging for Therapeutic Goods* made on 5th August 2004; and

(2) DETERMINE that the matters specified in this Order, other than section 4, Introduction, and Part 3 of Schedule 1, constitute a standard for medicines.

Dated this 27th day of August 2008

Rohan Hammett
Delegate of the Minister for Health and Ageing

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1 Name of Order

This Order is Therapeutic Goods Order No. 80 *Child-Resistant Packaging Requirements for Medicines.*

2 Commencement

This Order commences on the day after the day it is registered on the Federal Register of Legislative Instruments.

3 Transition

(a) Up to and including 31 August 2010, each medicine to which this Order applies must comply with either this Order or Therapeutic Goods Order No. 65 *Child-Resistant Packaging for Therapeutic Goods*.

(b) On and from 1 September 2010, each medicine to which this Order applies must comply with this Order.

4 Introduction

(1) The objective of this Order is to set particular requirements for the packaging of medicines that may present a significant risk of toxicity to children if accidentally ingested. These requirements relate to child-resistant packaging — that is, packaging that is designed to be resistant to opening by young children.

(2) Child-resistant packaging is not child-proof. While it has an important role in reducing the incidence and public health burden of accidental poisoning in children and the associated morbidity and mortality, it provides only one safeguard in that it delays the time taken by a child to open a package and access multiple units, thereby increasing the probability of adult intervention before the contents are fully accessible and can be ingested.

(3) Compliance of packaging with the national or international Standards for child-resistance referred to in this Order only establishes a packaging system as child-resistant, not child-proof.

(4) The criteria used by the committee advising on requirements for child-resistant packaging are:

(a) the toxicity of the substance contained in the medicine, and risk of harm if it is accidentally ingested by a young child; and

(b) the extent and patterns of availability in the community of medicines containing the substance; and

(c) the number and type of incidents reported to Poisons Information Centres and other relevant organisations involving accidental ingestion of medicines containing the substance; and

(d) the consequences of these incidents (hospital admission or other treatment, serious injury, or death), including the difficulty or complexity of treatment; and

(e) any special needs of patients who regularly need access to medicines containing the substances, such as older persons or people with a disability; and

(f) the technical feasibility and practicality of child-resistant packaging for medicines containing the substance, taking into account the usual dosage form and presentation; and

(g) other such matters as the committee thinks fit.

(5) A substance will, in general, be considered to be sufficiently toxic to warrant child-resistant packaging if the amount contained in a maximum prescription quantity (for example under the Pharmaceutical Benefits Scheme) or the largest retail pack quantity, is likely to produce significant harm (i.e. a requirement for hospital treatment, or death) in a child of 11 kg (i.e. a typical weight of an 18 month old child, representative of the age group in which accidental poisoning is most common).

(6) While the criteria set out in subsection 4(4) and the guideline set out in subsection 4(5) relate to toxicity only from ingestion, if a medicine presents a hazard in terms of potential to cause serious harm to young children through inadvertent contact with the eyes, the skin or mucous membranes, then these medicines will also be considered for child-resistant packaging.

(7) None of the criteria set out in subsection 4(4) are intended to be considered in isolation and recommendations for child-resistant packaging are made on balance. Consideration of all of the criteria permits the objective assessment of the risk/benefit balance although emphasis will be given to public health and safety.

(8) The criteria do recognise that child-resistant packaging can present difficulties for older persons and those with a disability. This also is recognised in each of the Standards for child-resistance referred to in this Order, which include protocols for testing not only with young children but also with adults who are between 50 and 70 years of age.

(9) The forms of packaging permitted by this Order may be either reclosable or non-reclosable. Requirements for reclosable child-resistant packages are performance-based and rely on compliance with at least one of a range of specified national or international Standards, together with a small number of other requirements.

(10) At this time, requirements of this Order for non-reclosable packages such as blister or foil strips do not involve performance testing, but instead are based on design and specified materials of construction. These requirements reflect the general requirements of Australian Standard AS 1928-2001 *Child-resistant packages*.

(11) While non-reclosable packaging has been accepted to date as providing a child-barrier, it is intended that a best practice guideline on this form of packaging will be developed in order to help sponsors improve the robustness and effectiveness of blister or foil strip packaging in order to further reduce the potential for accidental childhood poisoning from medicines packaged in this way.

5 Interpretation

(1) In this Order:

Act means the *Therapeutic Goods Act 1989*, as amended from time to time;

blister means a package in which:

(a) one or more dosage units are enclosed in pockets between a pre-formed tray with individual pockets and a lidding material which may be flat or shaped; and

(b) the dosage units can only be extracted from one pocket at a time; and

(c) the material of the tray is usually different from that of the lid; and

(d) the material of the tray or lid must be cut, torn or peeled open in order to access the contents of individual pockets.

bulk medicine pack means a pack intended to be broken down and repackaged by a pharmacist to allow individual courses of treatment to be dispensed to a patient.

child-resistant packaging means packaging that is designed or constructed to be difficult for young children to open, or gain access to the contents, within a reasonable time but is not unduly difficult for adults to use properly.

Note Child-resistant packaging does not mean packaging that is impossible for young children to open, or obtain the contents of, within a reasonable time. Child-resistant is not synonymous with child-proof.

closure means the part of a reclosable package that keeps the package closed.

Note A closure may be separately identifiable or an integral component of a package.

container has meaning given in subsection 3(1) of the Act.

export only medicine has the meaning given in subsection 3(1) of the Act.

homoeopathic preparation has the meaning given in regulation 2 of the regulations.

indications has the meaning given in subsection 3(1) of the Act.

label means a display of printed information on, or securely affixed to, the container, any intermediate packaging and any primary pack containing the medicine.

listed medicine means a medicine that is included in the Part of the Register for goods known as listed goods.

medicine has the meaning given in subsection 3(1) of the Act.

non-reclosable package means a package that, having been opened, is not capable of being reclosed to its original state.

packaging means the components that together immediately contain and protect the dosage form of a medicine.

Note The components that immediately contain and protect the dosage form include containers, closures and closure systems, and closure liners. Packaging may be either reclosable or non-reclosable.

primary pack has the meaning given in subsection 3(1) of the Act.

reclosable package means a package that, once opened, can be reclosed to its original state.

Register has the meaning given in subsection 3(1) of the Act.

registered medicine means a medicine that is included in the part of the Register for goods known as registered goods.

regulations means the *Therapeutic Goods Regulations 1990.*

restricted flow insert means a restriction that:

(a) is fitted or moulded into the neck of a container; and

(b) cannot readily be removed from the container by manual force; and

(c) limits the delivery of the contents to drops each of which is not more than 200 microlitres.

Secretary has the meaning given in subsection 3(1) of the Act.

sponsor has the meaning given in subsection 3(1) of the Act.

Standard means any of the national or international Standards referred to in section 9.

strip means packaging in which:

(a) one or more dosage units are enclosed individually in a continuous strip made by bonding two layers of material together so that the dosage units are separated and protected; and

(b) the dosage units can only be extracted from one pocket at a time; and

(c) each layer of material may be similar or different; and

(d) the material must be cut or torn in order to access the contents.

young children means children within the age groups specified in the protocols given in the Standards referred to in section 9 for the testing of child-resistance.

Note The age range specified in the protocols given in the Standards referred to in section 9 for the testing of child-resistance is 42 to 51 months inclusive.

6 Application

(1) This Order applies to each medicine for human use that is supplied by a sponsor and that is:

(a) a registered medicine that contains a substance, or a salt, ester or other derivative of a substance, that belongs to a class of substance specified in Part 1 of Schedule 1; or

(b) a listed or registered medicine that contains a substance, or a salt, ester or other derivative of a substance, specified in Part 2 of Schedule 1 in the strength or pack size specified in Part 2 to Schedule 1; or

(c) any other medicine that is labelled or packaged in a way that states or implies to a consumer or purchaser that the product, as presented, is child-resistant.

(2) However, this Order does not apply to a medicine that is exempted under section 7 or in relation to which an exemption from compliance with this Order has been granted by the Secretary in accordance with section 14 and 14A of the Act.

7 Exemptions

This Order does not apply to a medicine that is:

(a) in a container intended only as a bulk medicine pack and that is clearly labelled 'For dispensing only' and 'This pack not to be supplied to a patient' or words to that effect; or

(b) intended to be administered by injection; or

(c) a solid or semi-solid (excluding solid dosage forms) preparation intended for application to the skin or mucous membrane, including transdermal patches; or

(d) a liquid or semi-solid preparation intended for application to the eye, ear or mucous membrane, and supplied in a container that:

(i) has a nominal capacity of not more than 20 millilitres; or

(ii) is fitted with a restricted flow insert; or

(e) an individually wrapped powder; or

(f) a medicine containing only homoeopathic preparations; or

(g) a liquid preparation in spray presentation if:

(i) the delivery device is engaged into the container in such a way that prevents it from being readily removed; and

(ii) direct suction through the delivery device results in delivery of no more than one dosage unit; and

(iii) actuation of the spray device is ergonomically difficult for young children to accomplish; or

(h) a paste, powder or gel for the cleaning of teeth; or

(i) a starting material used in the manufacture of medicines except when pre-packaged for supply for other therapeutic purposes or formulated as a dosage form; or

(j) not at its final stage of manufacture; or

(k) to be used by, or administered to, a patient for treatment in a public hospital, private hospital, nursing home, dental hospital or dental surgery; or

(l) an export-only medicine.

8 General requirements

(1) The requirements of this Order apply in addition to any other packaging requirements that may be applied to medicines under the Act or regulations.

(2) The packaging for a medicine to which this Order applies must:

(a) remain fit for its purpose until the expiry date of the medicine; and

(b) retain its child-resistant properties for the expected number of openings and closings necessary to fully use the contents.

(3) Performance of the child-resistant feature must not be adversely affected by the contents of the package.

(4) Sight, unusual strength or unusual dexterity must not be required to access the contents of the package or, in the case of a reclosable package, to re-engage the child-resistant feature.

9 Reclosable packages

(1) If a medicine to which this Order applies is in a reclosable package, the package must comply with at least one of the following Standards:

(a) The International Standards Organisation Standard ISO 8317:2003 entitled *Child-resistant packaging — Requirements and testing procedures for reclosable packages* (as amended by Technical corrigendum issued January 2005: ISO 8317:2003/Cor 1:2005 : *Child-resistant packaging — Requirements and testing procedures for reclosable packages* — Technical Corrigendum 1);

(b) The British Standards Institution Standard BS EN ISO 8317:2004 entitled *Child-resistant packaging. Requirements and testing procedures for reclosable packages*;

(c) The Canadian Standards Association Standard CSA Z76.1-99 entitled *Reclosable Child-Resistant Packages*;]

(d) The United States Code of Federal Regulations, Title 16, Part 1700 Section [1700.]15, entitled *Poison prevention packaging standards* and Title 16, Part 1700, Section [1700.]20, entitled *Testing procedure for special packaging*, as in effect at the date of this Order;

(e) The Australian Standard AS 1928-2007 entitled *Child-resistant packaging- Requirements and testing procedures for reclosable packages* (ISO 8317:2003, MOD).

(2) If a medicine to which this Order applies is in a reclosable package that complies with a Standard mentioned in subsection 9(1), the sponsor of the medicine must hold evidence of the compliance. The evidence may consist of:

(a) a certificate (or an appropriately authorised copy of a certificate) from a test agency, attesting that the package complies with a relevant Standard, expressed in a way that makes it beyond doubt that the certification in fact refers to the package specified by the sponsor, together with a statement of the protocol used to demonstrate child-resistance and, if requested, evidence of the test agency's standing; or

(b) if the package is not certified as mentioned in paragraph (a), information proving compliance with a relevant Standard, expressed in a way that makes it beyond doubt that the information in fact refers to the package specified by the sponsor, together with a statement of the protocol used to demonstrate child-resistance; or

(c) information demonstrating that the package as specified by the sponsor has been established previously as complying with a relevant Standard.

(3) In addition to the requirements mentioned in subsections 9(1) and 9(2), if a medicine to which this Order applies is in a reclosable package, the sponsor must hold evidence demonstrating that the requirements of subsections 8(2) and 8(3) are met.

(4) If a change in specifications for a reclosable package occurs, the sponsor must hold additional evidence demonstrating that the child-resistant properties of the package and operation of the closure have not been adversely affected.

(5) In addition to the requirements mentioned in subsections 9(1), 9(2), 9(3), and 9(4), if a medicine to which this Order applies is in a reclosable package, the sponsor must hold information on:

(a) the types and sizes of container of immediate relevance to the sponsor's range of medicines to which a specified closure may be applied; and

(b) the suitability of the package for the type of medicine; and

(c) the correct application of the closure to the container after filling and engagement of the child-resistant mechanism, as appropriate to the particular packaging system; and

(d) the quality control tests applied to demonstrate that production lots of the package components are of consistent and satisfactory quality and appropriate for use.

(6) If a medicine to which this Order applies is in a reclosable package, adequate directions for opening and effectively reclosing the package must be:

(a) conspicuously marked or written on the package or on a label securely affixed or attached to the package; and

(b) written in English or clearly demonstrated in graphics.

(7) If a medicine to which this Order applies is packaged together with a separate dropper or applicator that is reasonably expected to replace the original closure on the medicine once the product is in use, then that configuration also must comply with the requirements of this Order.

10 Non-reclosable packages

(1) Subject to subsection 10(2), if a medicine to which this Order applies is in a non-reclosable package, the package must be in the form of a blister or other sealed unit formed from paper, film, plastic material, metal foil or other sheet or strip material, or a combination of these materials in which a single dosage unit is enclosed, whether as part of a continuous series comprising a strip or sheet of the same material or not.

(2) A non-reclosable package referred to in subsection 10(1) must not be formed from cellulose film or unlaminated paper.

Schedule 1 Medicines to which this Order applies

(section 6)

Part 1 Classes of substance

Note 1 Column 1 lists the classes of substance that, when included in a registered medicine, result in the requirements of this Order applying to the medicine irrespective of indications, unless the medicine is exempted under section 7 or an exemption from compliance with this Order has been granted under section 14 and 14A of the Act.

Note 2 Class names reflect the Anatomical Therapeutic Chemical (ATC) classification system of the World Health Organization *Collaborating Centre for Drug Statistics Methodology* (http://www.whocc.no/atcddd/). Classes shown include any substance included under the given ATC classification, unless the substance is specifically exempted from this Order.

Note 3 Columns 2 and 3 provide examples of substances classified as falling within each of the named classes. These lists are not exhaustive. When a new substance that is covered by a class set out below is used in medicine, the Schedule will apply to that substance.

Class	Examples of substances included in class	
ACE INHIBITORS	Captopril	Perindopril
	Enalapril	Quinapril
	Fosinopril	Ramipril
	Lisinopril	Trandolapril
ANAESTHETICS, LOCAL	Amethocaine	Lignocaine
	Articaine	Mepivacaine
	Benzocaine	Oxybuprocaine
	Bupivacaine	Procaine
	Cinchocaine	Ropivacaine
	Levobupivacaine	
ANTIARRHYTHMICS	Amiodarone	Lignocaine
	Bretylium tosilate	Mexiletine
	Disopyramide	Procainamide
	Dofetilide	Quinidine
	Esmolol	Sotalol
	Flecainide	Verapamil
	Ibutilide	

Class	Examples of substances included in class	
ANTICHOLINERGICS	Atropine	Orphenadrine
	Benzhexol	Oxybutamine
	Benztropine	Pilocarpine
	Biperiden	Procyclidine
	Cyclopentolate	Tolterodine
	Glycopyrrolate	Tropicamide
	Homatropine	
ANTI-DEMENTIA DRUGS	Donepezil	Memantine
	Galantamine	Rivastigmine
ANTIDEPRESSANTS	Amitriptyline	Mirtazapine
	Citalopram	Moclobemide
	Clomipramine	Nefazodone
	Desipramine	Nortriptyline
	Dothiepin	Paroxetine
	Doxepin	Protriptyline
	Escitalopram	Reboxetine
	Fluoxetine	Sertraline
	Fluvoxamine	Trazodone
	Imipramine	Trimipramine
	Mianserin	Venlafaxine
ANTIEMETICS AND ANTINAUSEANTS	Aprepitant	Hyoscine
	Dimenhydrinate	Metoclopramide
	Dolasetron	Ondansetron
	Domperidone	Tropisetron
	Granisetron	
ANTIEPILEPTICS	Carbamazepine	Phenytoin
	Clonazepam	Pregabalin
	Ethosuximide	Primidone
	Gabapentin	Sodium valproate
	Lamotrigine	Sulthiame
	Levetiracetam	Tiagabine
	Methylphenobarbitone	Topiramate
	Oxcarbazepine	Valproic acid
	Phenobarbitone	Vigabatrin

Class	Examples of substances included in class	
ANTIHISTAMINES	Antazoline	Hydroxyzine
	Astemizole	Ketotifen
	Azatadine	Levocabastine
	Azelastine	Loratadine
	Brompheniramine	Meclozine
	Cetirizine	Mepyramine
	Chlorpheniramine	Mequitazine
	Clemizole	Methdilazine
	Cyproheptadine	Pheniramine
	Desloratadine	Promethazine
	Dexchlorpheniramine	Terfenadine
	Dimenhydrinate	Thiethylperazine
	Diphenhydramine	Trimeprazine
	Doxylamine	Triprolidine
	Fexofenadine	
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS	Benzydamine	Mefenamic acid
	Bufexamac	Meloxicam
	Celecoxib	Nabumetone
	Diclofenac	Naproxen
	Etoricoxib	Parecoxib
	Flurbiprofen	Phenylbutazone
	Ibuprofen	Piroxicam
	Indomethacin	Sulindac
	Ketoprofen	Tiaprofenic acid
	Ketorolac	Valdecoxib
	Lumiracoxib	
ANTIMALARIALS, except doxycycline.	Artemether	Primaquine
	Atovaquone	Proguanil
	Chloroquine	Pyrimethamine
	Hydroxychloroquine	Quinine
	Lumefantrine	Sulfadoxine
	Mefloquine	

Class	Examples of substances included in class	
ANTINEOPLASTIC AGENTS	Altretamine	Imatinib
	Arsenic trioxide	Irinotecan
	Bevacizumab	Levamisole
	Bleomycin	Lomustine
	Busulfan	Melphalan
	Capecitabine	Mercaptopurine
	Carboplatin	Methotrexate
	Carmustine	Methyl aminolevulinate
	Cetuximab	Mitomycin
	Chlorambucil	Mitotane
	Cisplatin	Mitoxantrone
	Cladribine	Paclitaxel
	Cyclophosphamide	Pemetrexed
	Cytarabine	Procarbazine
	Dacarbazine	Raltitrexed
	Dactinomycin	Rituximab
	Daunorubicin	Tegafur
	Docetaxel	Temozolomide
	Doxorubicin	Teniposide
	Epirubicin	Thioguanine
	Estramustine	Thiotepa
	Etoposide	Topotecan
	Fludarabine	Trastuzumab
	Fluorouracil	Tretinoin
	Fotemustine	Verteporfin
	Gefitinib	Vinblastine
	Gemcitabine	Vincristine
	Hydroxyurea	Vindesine
	Idarubicin	Vinorelbine
	Ifosfamide	

Class	Examples of substances included in class	
ANTI-PARKINSON DRUGS	Amantadine	Levodopa
	Apomorphine	Orphenadrine
	Benzhexol	Pergolide
	Benztropine	Pramipexole
	Biperiden	Procyclidine
	Bromocriptine	Ropinirole
	Cabergoline	Selegiline
	Entacapone	
ANTIPSYCHOTICS	Amisulpride	Pimozide
	Aripiprazole	Prochlorperazine
	Chlorpromazine	Promazine
	Clozapine	Promethazine
	Droperidol	Quetiapine
	Flupenthixol	Risperidone
	Fluphenazine	Sulpiride
	Haloperidol	Tetrabenazine
	Lithium carbonate	Thioridazine
	Methyltrimeprazine	Trifluoperazine
	Olanzapine	Trimeprazine
	Pericyazine	Ziprasidone
	Perphenazine	Zuclopenthixol
ANTITHROMBOTIC AGENTS	Clopidogrel	Ticlopidine
	Dipyridamole	Warfarin
	Phenindione	
BENZODIAZEPINE DERIVATIVES	Alprazolam	Lormetazepam
	Bromazepam	Midazolam
	Clobazam	Nitrazepam
	Clonazepam	Oxazepam
	Diazepam	Potassium clorazepate
	Flunitrazepam	Temazepam
	Lorazepam	Triazolam

Class	Examples of substances included in class	
BETA BLOCKING AGENTS	Acebutolol	Levobunolol
	Atenolol	Metoprolol
	Betaxolol	Nadolol
	Bisoprolol	Oxprenolol
	Carvedilol	Pindolol
	Celiprolol	Propranolol
	Esmolol	Sotalol
	Labetalol	Timolol
CALCIUM CHANNEL BLOCKERS	Amlodipine	Nifedipine
	Diltiazem	Nimodipine
	Felodipine	Perhexiline
	Isradipine	Verapamil
	Lercanidipine	
CARDIAC GLYCOSIDES	Digitalis lanata	Digoxin
	Digitalis purpurea	
CENTRALLY ACTING SYMPATHOMIMETICS	Atomoxetine	Methylphenidate
	Dexamphetamine	Modafinil
DIURETICS	Amiloride	Hydrochlorothiazide
	Bendrofluazide	Hydroflumethiazide
	Chlorothiazide	Indapamide
	Chlorthalidone	Spironolactone
	Ethacrynic acid	Triamterene
	Frusemide	
ERGOT ALKALOIDS	Dihydroergotamine	Methysergide
	Ergotamine	
MONOAMINE OXIDASE INHIBITORS	Moclobemide	Tranylcypromine
	Phenelzine	

Class	Examples of substances included in class	
OPIOIDS, except pholcodine.	Alfentanil	Loperamide
	Buprenorphine	Methadone
	Butorphanol	Morphine
	Codeine	Opium
	Dextromoramide	Oxycodone
	Dextropropoxyphene	Papaver somniferum
	Dihydrocodeine	Pentazocine
	Diphenoxylate	Pethidine
	Fentanyl	Remifentanyl
	Hydromorphone	Tramadol
ORAL BLOOD GLUCOSE LOWERING AGENTS	Acarbose	Miglitol
	Chlorpropamide	Nateglinide
	Glibenclamide	Pioglitazone
	Gliclazide	Repaglinide
	Glimepiride	Rosiglitazone
	Glipizide	Tolazamide
	Metformin	Tolbutamide

Part 2 Individual substances

Note The substances listed in this Part, when contained in a listed or registered medicine in the strength or pack size specified in this Part, result in the requirements of this Order applying to the medicine unless the medicine is exempted under section 7 or an exemption from compliance with this Order has been granted under section 14 and section 14A of the Act. Where a substance is shown but no strength or pack size is specified, the requirements of this Order apply to all strengths and pack sizes of medicines containing that substance.

1 ANISE OIL, except:

(a) when packed in a container having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 50 per cent or less of anise oil, or a combination of anise oil and any other essential oil named in this Part.

2 ASPIRIN.

3 BASIL OIL, except:

(a) when packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation or oil containing 5 per cent or less of methyl chavicol.

4 BAY OIL, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of bay oil, or a combination of bay oil and any other essential oil named in this Part.

5 CAJUPUT OIL, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of cajuput oil, or a combination of cajuput oil and any other essential oil named in this Part.

6 CAMPHORATED OIL.

7 CAMPHOR, except:

(a) in a liquid preparation containing 2.5 per cent or less of camphor;

(b) in an essential oil containing 10 per cent or less of camphor, packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert;

(c) in an essential oil packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(d) in rosemary oil, sage oil (Spanish), or lavandin oil as such.

8 CASSIA OIL, except in a preparation containing 2 per cent or less of cassia oil.

9 CINEOLE, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert;

(b) in a preparation or oil containing 25 per cent or less of cineole; or

(c) in rosemary oil or camphor oil (white).

10 CINNAMON BARK OIL, except in a preparation containing 2 per cent or less of cinnamon bark oil.

11 CINNAMON LEAF OIL, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of cinnamon leaf oil, or a combination of cinnamon leaf oil and any other essential oil named in this Part.

12 CLONIDINE.

13 CLOVE OIL, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of clove oil, or a combination of clove oil and any other essential oil named in this Part.

14 COLCHICINE.

15 ETHANOL, in a mouthwash preparation containing more than 3 grams of ethanol in a single pack.

16 EUCALYPTUS OIL, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of eucalyptus oil, or a combination of eucalyptus oil and any other essential oil named in this Part.

17 FLUORIDE SALTS, in a pack containing the equivalent of more than 100 milligrams of elemental fluorine.

18 IRON COMPOUNDS, in a pack containing a total of more than 250 milligrams of elemental iron, except for divided preparations in which:

(a) the iron is compounded with one or more other active ingredients; and

(b) the amount of elemental iron per dosage unit is 5 milligrams or less.

However iron oxides that are present as an excipient, in either a divided preparation containing 10 milligrams or less of total iron oxides per dosage unit or an undivided preparation containing 1 per cent or less of total iron oxides, may be excluded from the calculation of elemental iron content.

19 MARJORAM OIL, except:

(a) when packed in a container having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert, or

(b) in a preparation containing 50 per cent or less of marjoram oil, or a combination of marjoram oil and any other essential oil named in this Part.

20 MELALEUCA OIL, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of melaleuca oil, or a combination of melaleuca oil and any other essential oil named in this Part.

21 METHYL SALICYLATE, in a liquid preparation containing 25 per cent or more of methyl salicylate.

22 MINOXIDIL, in a liquid preparation or a preparation for oral administration.

23 MOUTHWASH preparations — *see* ETHANOL.

24 NICOTINE.

25 NUTMEG OIL, except:

(a) when packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 50 per cent or less of nutmeg oil, or a combination of nutmeg oil and any other essential oil named in this Part.

26 PARACETAMOL - all solid dosage forms and liquid preparations.

27 PENNYROYAL OIL, except in a preparation containing 4 per cent or less of d-pulegone.

28 PHENYLEPHRINE.

29 POTASSIUM SALTS, in a pack containing a total of more than 4000 milligrams of elemental potassium, except:

(a) in a divided preparation in which the amount of elemental potassium per dosage unit is 40 milligrams to less; or

(b) when the potassium is present in the form of glucosamine sulfate potassium chloride complex.

30 PSEUDOEPHEDRINE.

31 RILUZOLE.

32 SAGE OIL DALMATIAN, except in a preparation containing 4 per cent or less of thujone.

33 SALBUTAMOL.

34 SASSAFRAS OIL, except in a preparation containing 1 per cent or less of safrole.

35 STAR ANISE OIL, except:

(a) when packed in a container having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 50 per cent or less of star anise oil, or a combination of star anise oil and any other essential oil named in this Part.

36 THEOPHYLLINE.

37 THYME OIL, except:

(a) when packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 50 per cent or less of thyme oil, or a combination of thyme oil and any other essential oil named in this Part.

38 THYROXINE.

39 WINTERGREEN OIL — *see* METHYL SALICYLATE.

Part 3 — Alphabetical listing of entries

Note This Part is included for information only.

Acarbose (*Oral Blood Glucose Lowering Agents*).

ACE INHIBITORS.

Acebutolol (*Beta Blocking Agents*).

Alfentanil (*Opioids*).

Alprazolam (*Benzodiazepine Derivatives)*.

Altretamine (*Antineoplastic Agents*).

Amantadine (*Anti-Parkinson Drugs*).

Amethocaine (*Anaesthetics, Local)*

Amiloride (*Diuretics*).

Amiodarone (*Antiarrhythmics*).

Amisulpride (*Antipsychotics*).

Amitriptyline (*Antidepressants*).

Amlodipine (*Calcium Channel Blockers*).

ANAESTHETICS, LOCAL.

Anise oil, except:

(a) when packed in a container having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 50 per cent or less of anise oil, or a combination of anise oil and any other essential oil named in Part 2.

Antazoline (*Antihistamines*).

ANTIARRHYTHMICS.

ANTICHOLINERGICS.

ANTI-DEMENTIA DRUGS.

ANTIDEPRESSANTS.

ANTIEMETICS AND ANTINAUSEANTS.

ANTIEPILEPTICS.

ANTIHISTAMINES.

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS.

ANTIMALARIALS, except doxycycline.

ANTINEOPLASTIC AGENTS.

ANTI-PARKINSON DRUGS.

ANTIPSYCHOTICS.

ANTITHROMBOTIC AGENTS.

Apomorphine (*Anti-Parkinson Drugs*).

Aprepitant (*Antiemetics and Antinauseants*).

Aripiprazole (*Antipsychotics*).

Arsenic trioxide (*Antineoplastic Agents*).

Artemether (*Antimalarials*).

Articaine (*Anaesthetics, Local*).

Aspirin.

Astemizole (*Antihistamines*).

Atenolol (*Beta Blocking Agents*).

Atomoxetine (*Centrally Acting Sympathomimetics*).

Atovaquone (*Antimalarials*).

Atropine (*Anticholinergics*).

Azatadine (*Antihistamines*).

Azelastine (*Antihistamines*).

Basil oil, except:

(a) when packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation or oil containing 5 per cent or less of methyl chavicol.

Bay oil, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of bay oil, or a combination of bay oil and any other essential oil named in Part 2.

Bendrofluazide (*Diuretics*).

Benzhexol (*Anticholinergics;* also *Anti-Parkinson Drugs*).

Benztropine (*Anticholinergics;* also *Anti-Parkinson Drugs*).

Benzocaine (*Anaesthetics, Local*).

BENZODIAZEPINE DERIVATIVES.

Benzydamine (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

BETA BLOCKING AGENTS.

Betaxolol (*Beta Blocking Agents*).

Bevacizumab (*Antineoplastic Agents*).

Biperiden (*Anticholinergics;* also *Anti-Parkinson Drugs*).

Bisoprolol (*Beta Blocking Agents*).

Bleomycin (*Antineoplastic Agents*).

Bretylium tosilate (*Antiarrhythmics*).

Bromazepam (*Benzodiazepine Derivatives*).

Bromocriptine (*Anti-Parkinson Drugs*).

Brompheniramine (*Antihistamines*).

Bufexamac (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Bupivacaine (*Anaesthetics, Local*).

Buprenorphine (*Opioids*).

Busulfan (*Antineoplastic Agents*).

Butorphanol (*Opioids*).

Cabergoline (*Anti-Parkinson Drugs*).

Cajuput oil, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of cajuput oil, or a combination of cajuput oil and any other essential oil named in Part 2.

CALCIUM CHANNEL BLOCKERS.

Camphorated oil.

Camphor, except:

(a) in a liquid preparations containing 2.5 per cent or less of camphor;

(b) in an essential oil containing 10 per cent or less of camphor, packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert;

(c) in an essential oil packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(d) in rosemary oil, sage oil (Spanish), or lavandin oil as such.

Capecitabine (*Antineoplastic Agents*).

Captopril (*ACE Inhibitors*).

Carbamazepine (*Antiepileptics*).

Carboplatin (*Antineoplastic Agents*).

CARDIAC GLYCOSIDES.

Carmustine (*Antineoplastic Agents*).

Carvedilol (*Beta Blocking Agents*).

Cassia oil, except in a preparation containing 2 per cent or less of cassia oil.

Celecoxib (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Celiprolol (*Beta Blocking Agents*).

CENTRALLY ACTING SYMPATHOMIMETICS.

Cetirizine (*Antihistamines*).

Cetuximab (*Antineoplastic Agents*).

Chlorambucil (*Antineoplastic Agents*).

Chloroquine (*Antimalarials*).

Chlorothiazide (*Diuretics*).

Chlorpheniramine (*Antihistamines)*

Chlorpromazine (*Antipsychotics*).

Chlorpropamide (*Oral Blood Glucose Lowering Agents*).

Chlorthalidone (*Diuretics*).

Cinchocaine (*Anaesthetics, Local*).

Cineole, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert;
(b) in a preparation or oil containing 25 per cent or less of cineole; or
(c) in rosemary oil or camphor oil (white).

Cinnamon bark oil, except in a preparation containing 2 per cent or less of cinnamon bark oil.

Cinnamon leaf oil, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
(b) in a preparation containing 25 per cent or less of cinnamon leaf oil, or a combination of cinnamon leaf oil and any other essential oil named in Part 2.

Cisplatin (*Antineoplastic Agents*).

Citalopram (*Antidepressants*).

Cladribine (*Antineoplastic Agents*).

Clemizole (*Antihistamines*).

Clobazam (*Benzodiazepine Derivatives*).

Clomipramine (*Antidepressants*).

Clonazepam (*Antiepileptics;* also *Benzodiazepine Derivatives*).

Clonidine.

Clopidogrel (*Antithrombotic Agents*).

Clove oil, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert;

(b) in a preparation containing 25 per cent or less of clove oil, or a combination of clove oil and any other essential oil named in Part 2.

Clozapine (*Antipsychotics*).

Codeine (*Opioids*).

Colchicine.

Cyclopentolate (*Anticholinergics*).

Cyclophosphamide (*Antineoplastic Agents*).

Cyproheptadine (*Antihistamines*).

Cytarabine (*Antineoplastic Agents*).

Dacarbazine (*Antineoplastic Agents*).

Dactinomycin (*Antineoplastic Agents*).

Daunorubicin (*Antineoplastic Agents*).

Desipramine (*Antidepressants*).

Desloratadine (*Antihistamines*).

Dexamphetamine (*Centrally Acting Sympathomimetics*).

Dexchlorpheniramine (*Antihistamines*).

Dextromoramide (*Opioids*).

Dextropropoxyphene (*Opioids*).

Diazepam (*Benzodiazepine Derivatives*).

Diclofenac (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Digitalis lanata (*Cardiac Glycosides*).

Digitalis purpurea (*Cardiac Glycosides*).

Digoxin (*Cardiac Glycosides*).

Dihydrocodeine (*Opioids*).

Dihydroergotamine (*Ergot Alkaloids*).

Diltiazem (*Calcium Channel Blockers*).

Dimenhydrinate (*Antiemetics and Antinauseants;* also *Antihistamines*).

Diphenhydramine (*Antihistamines*).

Diphenoxylate (*Opioids*).

Dipyridamole (*Antithrombotic Agents*).

Disopyramide (*Antiarrhythmics*).

DIURETICS.

Docetaxel (*Antineoplastic Agents*).

Dofetilide (*Antiarrhythmics*).

Dolasetron (*Antiemetics and Antinauseants*).

Domperidone (*Antiemetics and Antinauseants*).

Donepezil (*Anti-Dementia Drugs*).

Dothiepin (*Antidepressants*)

Doxepin (*Antidepressants*).

Doxorubicin (*Antineoplastic Agents*).

Doxylamine (*Antihistamines*).

Droperidol (*Antipsychotics*).

Enalapril (*ACE Inhibitors*).

Entacapone (*Anti-Parkinson Drugs*).

Epirubicin (*Antineoplastic Agents*).

ERGOT ALKALOIDS.

Ergotamine (*Ergot Alkaloids*).

Escitalopram (*Antidepressants*).

Esmolol (*Antiarrhythmics;* also *Beta Blocking Agents*).

Estramustine (*Antineoplastic Agents*).

Ethacrynic acid (*Diuretics*).

Ethanol, in mouthwash preparations containing more than 3 grams of ethanol in a single pack.

Ethosuximide (*Antiepileptics*).

Etoposide (*Antineoplastic Agents*).

Etoricoxib (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Eucalyptus oil, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of eucalyptus oil, or a combination of eucalyptus oil and any other essential oil named in Part 2.

Felodipine (*Calcium Channel Blockers*).

Fentanyl (*Opioids*).

Fexofenadine (*Antihistamines*).

Flecainide (*Antiarrhythmics*).

Fludarabine (*Antineoplastic Agents*).

Flunitrazepam (*Benzodiazepine Derivatives*).

Fluoride salts, in a pack containing the equivalent of more than 100 milligrams of elemental fluorine.

Fluorouracil (*Antineoplastic Agents*).

Fluoxetine (*Antidepressants*).

Flupenthixol (*Antipsychotics*).

Fluphenazine (*Antipsychotics*).

Flurbiprofen (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Fluvoxamine (*Antidepressants*).

Fosinopril (*ACE Inhibitors*).

Fotemustine (*Antineoplastic Agents*).

Frusemide (*Diuretics*).

Gabapentin (*Antiepileptics*).

Galantamine (*Anti-Dementia Drugs*).

Gefitinib (*Antineoplastic Agents*).

Gemcitabine (*Antineoplastic Agents*).

Glibenclamide (*Oral Blood Glucose Lowering Agents*).

Gliclazide (*Oral Blood Glucose Lowering Agents*).

Glimepiride (*Oral Blood Glucose Lowering Agents*).

Glipizide (*Oral Blood Glucose Lowering Agents*).

Glycopyrrolate (*Anticholinergics*).

Granisetron (*Antiemetics and Antinauseants*).

Haloperidol (*Antipsychotics*).

Homatropine (*Anticholinergics*).

Hydrochlorothiazide (*Diuretics*).

Hydroflumethiazide (*Diuretics*).

Hydromorphone (*Opioids*).

Hydroxychloroquine (*Antimalarials*).

Hydroxyurea (*Antineoplastic Agents*).

Hydroxyzine (*Antihistamines*).

Hyoscine (*Antiemetics and Antinauseants*).

Ibuprofen (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Ibutilide (*Antiarrhythmics*).

Idarubicin (*Antineoplastic Agents*).

Ifosfamide (*Antineoplastic Agents*).

Imatinib (*Antineoplastic Agents*).

Imipramine (*Antidepressants*).

Indapamide (*Diuretics*).

Indomethacin (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Irinotecan (*Antineoplastic Agents*).

Iron compounds, in a pack containing a total of more than 250 milligrams of elemental iron, except for divided preparations in which:

(a) the iron is compounded with one or more other active ingredients; and

(b) the amount of elemental iron per dosage unit is 5 milligrams or less.

However iron oxides that are present as an excipient, in either a divided preparation containing 10 milligrams or less of total iron oxides per dosage unit or an undivided preparation containing 1 per cent or less of total iron oxides, may be excluded from the calculation of elemental iron content.

Isradipine (*Calcium Channel Blockers*).

Ketoprofen (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Ketorolac (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Ketotifen (*Antihistamines*).

Labetalol (*Beta Blocking Agents*).

Lamotrigine (*Antiepileptics*).

Lercanidipine (*Calcium Channel Blockers*).

Levamisole (*Antineoplastic Agents*).

Levetiracetam (*Antiepileptics*).

Levobunolol (*Beta Blocking Agents*).

Levobupivacaine (*Anaesthetics, Local*).

Levocabastine (*Antihistamines*).

Levodopa (*Anti-Parkinson Drugs*).

Lignocaine (*Antiarrhythmics;* also *Anaesthetics, Local*).

Lisinopril (*ACE Inhibitors*).

Lithium carbonate (*Antipsychotics*).

Lomustine (*Antineoplastic Agents*).

Loperamide (*Opioids*).

Loratadine (*Antihistamines*).

Lorazepam (*Benzodiazepine Derivatives*).

Lormetazepam (*Benzodiazepine Derivatives*).

Lumefantrine (*Antimalarials*).

Lumiracoxib (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Marjoram oil, except:

(a) when packed in a container having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 50 per cent or less of marjoram oil, or a combination of marjoram oil and any other essential oil named in Part 2.

Meclozine (*Antihistamines*).

Mefenamic Acid (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Mefloquine (*Antimalarials*).

Melaleuca oil, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of melaleuca oil, or a combination of melaleuca oil and any other essential oil named in Part 2.

Meloxicam (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Melphalan (*Antineoplastic Agents*).

Memantine (A*nti-Dementia Drugs*).

Mepivacaine (*Anaesthetics, Local*).

Mepyramine (*Antihistamines*).

Mequitazine (*Antihistamines*).

Mercaptopurine (*Antineoplastic Agents*).

Metformin (*Oral Blood Glucose Lowering Agents*).

Methadone (*Opioids*).

Methdilazine (*Antihistamines*).

Methotrexate (*Antineoplastic Agents*).

Methyl aminolevulinate (*Antineoplastic Agents*).

Methyl salicylate, in a liquid preparation containing 25 per cent or more of methyl salicylate.

Methylphenidate (*Centrally Acting Sympathomimetics*).

Methylphenobarbitone (*Antiepileptics*).

Methyltrimeprazine (*Antipsychotics*).

Methysergide (*Ergot Alkaloids*).

Metoclopramide (*Antiemetics and Antinauseants*).

Metoprolol (*Beta Blocking Agents*).

Mexiletine (*Antiarrhythmics*).

Mianserin (*Antidepressants*).

Midazolam (*Benzodiazepine Derivatives*).

Miglitol (*Oral Blood Glucose Lowering Agents*).

Minoxidil, in a liquid preparation or a preparation for oral administration.

Mirtazapine (*Antidepressants*).

Mitomycin (*Antineoplastic Agents*).

Mitotane (*Antineoplastic Agents*).

Mitoxantrone (*Antineoplastic Agents*).

Moclobemide (*Antidepressants*; also *Monoamine Oxidase Inhibitors*).

Modafinil (*Centrally Acting Sympathomimetics*).

MONOAMINE OXIDASE INHIBITORS.

Morphine (*Opioids*).

Mouthwash preparations — see Ethanol.

Nabumetone (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Nadolol (*Beta Blocking Agents*).

Naproxen (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Nateglinide (*Oral Blood Glucose Lowering Agents*).

Nefazodone (*Antidepressants*).

Nicotine.

Nifedipine (*Calcium Channel Blockers*).

Nimodipine (*Calcium Channel Blockers*).

Nitrazepam (*Benzodiazepine Derivatives*).

Nortriptyline (*Antidepressants*).

Nutmeg oil, except:

(a) when packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 50 per cent or less of nutmeg oil, or a combination of nutmeg oil and any other essential oil named in Part 2.

Olanzapine (*Antipsychotics*).

Ondansetron (*Antiemetics and Antinauseants*).

OPIOIDS, except pholcodine.

Opium (*Opioids*).

ORAL BLOOD GLUCOSE LOWERING AGENTS.

Orphenadrine (*Anticholinergics;* also *Anti-Parkinson Drugs*).

Oxazepam (*Benzodiazepine Derivatives*).

Oxcarbazepine (*Antiepileptics*).

Oxprenolol (*Beta Blocking Agents*).

Oxybuprocaine (*Anaesthetics, Local*).

Oxybutamine (*Anticholinergics*).

Oxycodone (*Opioids*).

Paclitaxel (*Antineoplastic Agents*).

Papaver somniferum (*Opioids*).

Paracetamol - all solid dosage forms and liquid preparations.

Parecoxib (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Paroxetine (*Antidepressants*).

Pemetrexed (*Antineoplastic Agents*).

Pennyroyal oil, except in a preparation containing 4 per cent or less of d-pulegone.

Pentazocine (*Opioids*).

Pergolide (*Anti-Parkinson Drugs*).

Perhexiline (*Calcium Channel Blockers*).

Pericyazine (*Antipsychotics*).

Perindopril (*ACE Inhibitors*).

Perphenazine (*Antipsychotics*).

Pethidine (*Opioids*).

Phenelzine (*Monoamine Oxidase Inhibitors*).

Phenindione (*Antithrombotic Agents*).

Pheniramine (*Antihistamines*).

Phenobarbitone (*Antiepileptics*).

Phenylbutazone (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Phenylephrine.

Phenytoin (*Antiepileptics*).

Pilocarpine (*Anticholinergics*).

Pimozide (*Antipsychotics*).

Pindolol (*Beta Blocking Agents*).

Pioglitazone (*Oral Blood Glucose Lowering Agents*).

Piroxicam (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Potassium clorazepate (*Benzodiazepine Derivatives*).

Potassium salts, in a pack containing a total of more than 4000 milligrams of elemental potassium, except:

(a) in a divided preparation in which the amount of elemental potassium per dosage unit is 40 milligrams to less; or

(b) when the potassium is present in the form of glucosamine sulfate potassium chloride complex.

Pramipexole (*Anti-Parkinson Drugs*).

Pregabalin (*Antiepileptics*).

Primaquine (*Antimalarials*).

Primidone (*Antiepileptics*).

Procainamide (*Antiarrhythmics*).

Procaine (*Anaesthetics, Local*).

Procarbazine (*Antineoplastic Agents*).

Prochlorperazine (*Antipsychotics*).

Procyclidine (*Anticholinergics;* also *Anti-Parkinson Drugs*).

Proguanil (*Antimalarials*).

Promazine (*Antipsychotics*).

Promethazine (*Antihistamines;* also *Antipsychotics*).

Propranolol (*Beta Blocking Agents*).

Protriptyline (*Antidepressants*).

Pseudoephedrine.

Pyrimethamine (*Antimalarials*).

Quetiapine (*Antipsychotics*).

Quinapril (*ACE Inhibitors*).

Quinidine (*Antiarrhythmics*).

Quinine (*Antimalarials*).

Raltitrexed (*Antineoplastic Agents*).

Ramipril (*ACE Inhibitors*).

Reboxetine (*Antidepressants*).

Remifentanyl (*Opioids*).

Repaglinide (*Oral Blood Glucose Lowering Agents*).

Riluzole.

Risperidone (*Antipsychotics*).

Rituximab (*Antineoplastic Agents*).

Rivastigmine (*Anti-Dementia Drugs*).

Ropinirole (*Anti-Parkinson Drugs*).

Ropivacaine (*Anaesthetics, Local*).

Rosiglitazone (*Oral Blood Glucose Lowering Agents*).

Sage oil Dalmatian, except in a preparation containing 4 per cent or less of thujone.

Salbutamol.

Sassafras oil, except in a preparation containing 1 per cent or less of safrole.

Selegiline (*Anti-Parkinson Drugs*).

Sertraline (*Antidepressants*).

Sodium valproate (*Antiepileptics*).

Sotalol (*Antiarrhythmics;* also *Beta Blocking Agents*).

Spironolactone (*Diuretics*).

Star anise oil, except:

(a) when packed in a container having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 50 per cent or less of star anise oil, or a combination of star anise oil and any other essential oil named in Part 2.

Sulfadoxine (*Antimalarials*).

Sulindac (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Sulpiride (*Antipsychotics*).

Sulthiame (*Antiepileptics*).

Tea tree oil - see Melaleuca oil.

Tegafur (*Antineoplastic Agents*).

Temazepam (*Benzodiazepine Derivatives*).

Temozolomide (*Antineoplastic Agents*).

Teniposide (*Antineoplastic Agents*).

Terfenadine (*Antihistamines*).

Tetrabenazine (*Antipsychotics*).

Theophylline.

Thiethylperazine (*Antihistamines*).

Thioguanine (*Antineoplastic Agents*).

Thioridazine (*Antipsychotics*).

Thiotepa (*Antineoplastic Agents*).

Thyme oil, except:

(a) when packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 50 per cent or less of thyme oil, or a combination of thyme oil and any other essential oil named in Part 2.

Thyroxine.

Tiagabine (*Antiepileptics*).

Tiaprofenic acid (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Ticlopidine (*Antithrombotic Agents*).

Timolol (*Beta Blocking Agents*).

Tolazamide (*Oral Blood Glucose Lowering Agents*).

Tolbutamide (*Oral Blood Glucose Lowering Agents*).

Tolterodine (*Anticholinergics*).

Topiramate (*Antiepileptics*).

Topotecan (*Antineoplastic Agents*).

Tramadol (*Opioids*).

Trandolapril (*ACE Inhibitors*).

Tranylcypromine (*Monoamine Oxidase Inhibitors*).

Trastuzumab (*Antineoplastic Agents*).

Trazodone (*Antidepressants*).

Tretinoin (*Antineoplastic Agents*).

Triamterene (*Diuretics*).

Triazolam (*Benzodiazepine Derivatives*).

Trifluoperazine (*Antipsychotics*).

Trimeprazine (*Antihistamines;* also *Antipsychotics*).

Trimipramine (*Antidepressants*).

Triprolidine (*Antihistamines*).

Tropicamide (*Anticholinergics*).

Tropisetron (*Antiemetics and Antinauseants*).

Valdecoxib (*Antiinflammatory and Antirheumatic Products, Non-Steroids*).

Valproic acid (*Antiepileptics*).

Venlafaxine (*Antidepressants*).

Verapamil (*Antiarrhythmics;* also *Calcium Channel Blockers*).

Verteporfin (*Antineoplastic Agents*).

Vigabatrin (*Antiepileptics*).

Vinblastine (*Antineoplastic Agents*).

Vincristine (*Antineoplastic Agents*).

Vindesine (*Antineoplastic Agents*).

Vinorelbine (*Antineoplastic Agents*).

Warfarin (*Antithrombotic Agents*).

Wintergreen oil — *see* Methyl salicylate.

Ziprasidone (*Antipsychotics*).

Zuclopenthixol (*Antipsychotics*).