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

as amended

made under section 10 of the

Therapeutic Goods Act 1989

**Compilation start date:** 1 October 2013

**Includes amendments up to:** Therapeutic Goods Order No. 80A *Amendments to Therapeutic Goods Order No. 80 Child-Resistant Packaging Requirements for Medicines*

**About this compilation**

**This compilation**

This is a compilation of the Therapeutic Goods Order No. 80 *Child-Resistant Packaging Requirements for Medicines* as in force on 1 October 2013. It includes any commenced amendment affecting the legislation to that date.

This compilation was prepared on 20 January 2014.

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of each amended provision.

**Uncommenced amendments**

The effect of uncommenced amendments is not reflected in the text of the compiled law but the text of the amendments is included in the endnotes.

**Application, saving and transitional provisions for provisions and amendments**

If the operation of a provision or amendment is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

**Modifications**

If a provision of the compiled law is affected by a modification that is in force, details are included in the endnotes.

**Provisions ceasing to have effect**

If a provision of the compiled law has expired or otherwise ceased to have effect in accordance with a provision of the law, details are included in the endnotes.

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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 apackage 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  Enalapril  Fosinopril  Lisinopril | Perindopril  Quinapril  Ramipril  Trandolapril |
| ANAESTHETICS, LOCAL | Amethocaine  Articaine  Benzocaine  Bupivacaine  Cinchocaine  Levobupivacaine | Lignocaine  Mepivacaine  Oxybuprocaine  Procaine  Ropivacaine |
| ANGIOTENSIN II ANTAGONISTS | Candesartan  Eprosartan  Irbesartan  Losartan | Olmesartan  Telmisartan  Valsartan |
| ANTIARRHYTHMICS | Amiodarone  Bretylium tosilate  Disopyramide  Dofetilide  Esmolol  Flecainide  Ibutilide | Lignocaine  Mexiletine  Procainamide  Quinidine  Sotalol  Verapamil |
| ANTICHOLINERGICS | Atropine  Benzhexol  Benztropine  Biperiden  Cyclopentolate  Glycopyrrolate  Homatropine | Orphenadrine  Oxybutamine  Pilocarpine  Procyclidine  Solifenacin  Tolterodine  Tropicamide |
| ANTI‑DEMENTIA DRUGS | Donepezil  Galantamine | Memantine  Rivastigmine |
| ANTIDEPRESSANTS | Amitriptyline  Citalopram  Clomipramine  Desipramine  Desvenlafaxine  Dothiepin  Doxepin  Duloxetine  Escitalopram  Fluoxetine  Fluvoxamine  Imipramine | Mianserin  Mirtazapine  Moclobemide  Nefazodone  Nortriptyline  Paroxetine  Protriptyline  Reboxetine  Sertraline  Trazodone  Trimipramine  Venlafaxine |
| ANTIEMETICS AND ANTINAUSEANTS | Aprepitant  Dimenhydrinate  Dolasetron  Domperidone  Granisetron | Hyoscine  Metoclopramide  Ondansetron  Tropisetron |
| ANTIEPILEPTICS | Carbamazepine  Clonazepam  Ethosuximide  Gabapentin  Lacosamide  Lamotrigine  Levetiracetam  Methylphenobarbitone  Oxcarbazepine  Phenobarbitone | Phenytoin  Pregabalin  Primidone  Sodium valproate  Sulthiame  Tiagabine  Topiramate  Valproic acid  Vigabatrin  Zonisamide |
| ANTIHISTAMINES | Antazoline  Astemizole  Azatadine  Azelastine  Brompheniramine  Cetirizine  Chlorpheniramine  Clemizole  Cyproheptadine  Desloratadine  Dexchlorpheniramine  Dimenhydrinate  Diphenhydramine  Doxylamine  Fexofenadine | Hydroxyzine  Ketotifen  Levocabastine  Levocetirazine  Loratadine  Meclozine  Mepyramine  Mequitazine  Methdilazine  Pheniramine  Promethazine  Terfenadine  Thiethylperazine  Trimeprazine  Triprolidine |
| ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON‑STEROIDS | Benzydamine  Bufexamac  Celecoxib  Diclofenac  Etoricoxib  Flurbiprofen  Ibuprofen  Indomethacin  Ketoprofen  Ketorolac  Lumiracoxib | Mefenamic acid  Meloxicam  Nabumetone  Naproxen  Parecoxib  Phenylbutazone  Piroxicam  Sulindac  Tiaprofenic acid  Valdecoxib |
| ANTIMALARIALS, except doxycycline. | Artemether  Atovaquone  Chloroquine  Hydroxychloroquine  Lumefantrine  Mefloquine | Primaquine  Proguanil  Pyrimethamine  Quinine  Sulfadoxine |
| ANTINEOPLASTIC AGENTS | Altretamine  Arsenic trioxide  Bevacizumab  Bleomycin  Busulfan  Capecitabine  Carboplatin  Carmustine  Cetuximab  Chlorambucil  Cisplatin  Cladribine  Cyclophosphamide  Cytarabine  Dacarbazine  Dactinomycin  Dasatinib  Daunorubicin  Docetaxel  Doxorubicin  Epirubicin  Erlotinib  Estramustine  Etoposide  Fludarabine  Fluorouracil  Fotemustine  Gefitinib  Gemcitabine  Hydroxyurea  Idarubicin  Ifosfamide | Imatinib  Irinotecan  Lapatinib  Levamisole  Lomustine  Melphalan  Mercaptopurine  Methotrexate  Methyl aminolevulinate  Mitomycin  Mitotane  Mitoxantrone  Nilotinib  Paclitaxel  Pemetrexed  Procarbazine  Raltitrexed  Rituximab  Sorafenib  Sunitinib  Tegafur  Temozolomide  Teniposide  Thioguanine  Thiotepa  Topotecan  Trastuzumab  Tretinoin  Verteporfin  Vinblastine  Vincristine  Vindesine  Vinorelbine |
| ANTI‑PARKINSON DRUGS | Amantadine  Apomorphine  Benzhexol  Benztropine  Biperiden  Bromocriptine  Cabergoline  Entacapone | Levodopa  Orphenadrine  Pergolide  Pramipexole  Procyclidine  Ropinirole  Rotigotine  Selegiline |
| ANTIPSYCHOTICS | Amisulpride  Aripiprazole  Chlorpromazine  Clozapine  Droperidol  Flupenthixol  Fluphenazine  Haloperidol  Lithium carbonate  Methyltrimeprazine  Olanzapine  Paliperidone  Pericyazine  Perphenazine | Pimozide  Prochlorperazine  Promazine  Promethazine  Quetiapine  Risperidone  Sulpiride  Tetrabenazine  Thioridazine  Trifluoperazine  Trimeprazine  Ziprasidone  Zuclopenthixol |
| ANTITHROMBOTIC AGENTS | Clopidogrel  Dabigatran  Dipyridamole  Phenindione | Prasugrel  Rivaroxaban  Ticlopidine  Warfarin |
| BENZODIAZEPINE DERIVATIVES and BENZODIAZEPINE RELATED DRUGS | Alprazolam  Bromazepam  Clobazam  Clonazepam  Diazepam  Flunitrazepam  Lorazepam  Lormetazepam  Midazolam | Nitrazepam  Oxazepam  Potassium clorazepate  Temazepam  Triazolam  Zaleplon  Zolpidem  Zopiclone |
| BETA BLOCKING AGENTS | Acebutolol  Atenolol  Betaxolol  Bisoprolol  Carvedilol  Celiprolol  Esmolol  Labetalol | Levobunolol  Metoprolol  Nadolol  Nebivolol  Oxprenolol  Pindolol  Propranolol  Sotalol  Timolol |
| CALCIUM CHANNEL BLOCKERS | Amlodipine  Diltiazem  Felodipine  Isradipine  Lercanidipine | Nifedipine  Nimodipine  Perhexiline  Verapamil |
| CARDIAC GLYCOSIDES | Digitalis lanata  Digitalis purpurea | Digoxin |
| CENTRALLY ACTING SYMPATHOMIMETICS | Atomoxetine  Dexamphetamine | Methylphenidate  Modafinil |
| DIURETICS | Amiloride  Bendrofluazide  Chlorothiazide  Chlorthalidone  Ethacrynic acid  Frusemide | Hydrochlorothiazide  Hydroflumethiazide  Indapamide  Spironolactone  Triamterene |
| ERGOT ALKALOIDS | Dihydroergotamine  Ergotamine | Methysergide |
| MONOAMINE OXIDASE INHIBITORS | Moclobemide  Phenelzine | Tranylcypromine |
| OPIOIDS | Alfentanil  Buprenorphine  Butorphanol  Codeine  Dextromoramide  Dextropropoxyphene  Dihydrocodeine  Diphenoxylate  Fentanyl  Hydromorphone | Loperamide  Methadone  Morphine  Opium  Oxycodone  Papaver somniferum  Pentazocine  Pethidine  Remifentanyl  Tramadol |
| ORAL BLOOD GLUCOSE LOWERING AGENTS | Acarbose  Chlorpropamide  Glibenclamide  Gliclazide  Glimepiride  Glipizide  Metformin | Miglitol  Nateglinide  Pioglitazone  Repaglinide  Rosiglitazone  Sitagliptin  Tolazamide  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.

ALISKIREN.

AMBRISENTAN.

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.

ASPIRIN.

*Azadirachta indica* (Neem), in a preparation for human dermal use containing more than 1 per cent of cold pressed neem seed oil.

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 this Part.

BOSENTAN.

BROMHEXINE.

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.

CAMPHORATED OIL.

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.

*Carapichea ipecacuanha* (ipecacuanha).

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

CHLORAL HYDRATE.

CILOSTAZOL.

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 this Part.

CLONIDINE.

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.

COLCHICINE.

Deferasirox.

Dextromethorphan.

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

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.

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

Guaiphenesin; GUAIFENESIN.

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.

Ivabradine.

Lanthanum.

Lenalidomide.

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.

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.

METHYL SALICYLATE, in a liquid preparation containing 5 per cent or more of methyl salicylate.

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

MOUTHWASH preparations — *see* ETHANOL.

NICOTINE.

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.

Oxymetazoline.

PARACETAMOL ‑ all solid dosage forms and liquid preparations.

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

Pentoxyverine.

PHENYLEPHRINE.

Pholcodine.

*POLYGALA SENEGA* (Senega).

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.

PSEUDOEPHEDRINE.

RILUZOLE.

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.

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.

THEOPHYLLINE.

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.

THYROXINE.

Varenicline.

WINTERGREEN OIL — *see* METHYL SALICYLATE.

XYLOMETAZOLINE.

## 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*).

Aliskiren.

Alprazolam (*Benzodiazepine Derivatives)*.

Altretamine (*Antineoplastic Agents*).

Amantadine (*Anti‑Parkinson Drugs*).

Ambrisentan.

Amethocaine (*Anaesthetics, Local)*

Amiloride (*Diuretics*).

Amiodarone (*Antiarrhythmics*).

Amisulpride (*Antipsychotics*).

Amitriptyline (*Antidepressants*).

Amlodipine (*Calcium Channel Blockers*).

ANAESTHETICS, LOCAL.

ANGIOTENSIN II ANTAGONISTS.

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*).

*Azadirachta indica* (Neem), in a preparation for human dermal use containing more than 1 per cent of cold pressed neem seed oil.

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.

BENZODIAZEPINE RELATED DRUGS.

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*).

Bosentan.

Bretylium tosilate (*Antiarrhythmics*).

Bromazepam (*Benzodiazepine Derivatives*).

Bromhexine.

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.

Candesartan (*Angiotensin II Antagonists*).

Capecitabine (*Antineoplastic Agents*).

Captopril (*ACE Inhibitors*).

*Carapichea ipecacuanha* (Ipecacuanha).

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*).

Chloral hydrate.

Chlorambucil (*Antineoplastic Agents*).

Chloroquine (*Antimalarials*).

Chlorothiazide (*Diuretics*).

Chlorpheniramine (*Antihistamines)*

Chlorpromazine (*Antipsychotics*).

Chlorpropamide (*Oral Blood Glucose Lowering Agents*).

Chlorthalidone (*Diuretics*).

Cilostazol.

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*).

Dabigatran (*Antithrombotic Agents*).

Dacarbazine (*Antineoplastic Agents*).

Dactinomycin (*Antineoplastic Agents*).

Dasatinib (*Antineoplastic Agents*).

Daunorubicin (*Antineoplastic Agents*).

Deferasirox.

Desipramine (*Antidepressants*).

Desloratadine (*Antihistamines*).

Desvenlafaxine (*Antidepressants).*

Dexamphetamine (*Centrally Acting Sympathomimetics*).

Dexchlorpheniramine (*Antihistamines*).

Dextromethorphan.

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*).

Duloxetine (*Antidepressants*)*.*

Enalapril (*ACE Inhibitors*).

Entacapone (*Anti‑Parkinson Drugs*).

Epirubicin (*Antineoplastic Agents*).

Eprosartan (*Angiotensin II Antagonists*).

ERGOT ALKALOIDS.

Ergotamine (*Ergot Alkaloids*).

Erlotinib (*Antineoplastic Agents*).

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*).

Guaiphenesin; Guaifenesin.

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*).

Irbesartan (*Angiotensin II Antagonists*).

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*).

Ivabradine.

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

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

Ketotifen (*Antihistamines*).

Labetalol (*Beta Blocking Agents*).

Lacosamide (*Antiepileptics).*

Lamotrigine (*Antiepileptics*).

Lanthanum.

Lapatinib (*Antineoplastic Agents*).

Lenalidomide.

Lercanidipine (*Calcium Channel Blockers*).

Levamisole (*Antineoplastic Agents*).

Levetiracetam (*Antiepileptics*).

Levobunolol (*Beta Blocking Agents*).

Levobupivacaine (*Anaesthetics, Local*).

Levocabastine (*Antihistamines*).

Levocetirazine (*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*).

Losartan (*Angiotensin II Antagonists*).

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 5 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*).

Nebivolol (*Beta Blocking Agents*).

Nefazodone (*Antidepressants*).

Nicotine.

Nifedipine (*Calcium Channel Blockers*).

Nilotinib (*Antineoplastic Agents*).

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*).

Olmesartan (*Angiotensin II Antagonists*).

Ondansetron (*Antiemetics and Antinauseants*).

OPIOIDS.

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*).

Oxymetazoline.

Paclitaxel (*Antineoplastic Agents*).

Paliperidone (*Antipsychotics*).

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*).

Pentoxyverine.

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*).

Pholcodine.

Pilocarpine (*Anticholinergics*).

Pimozide (*Antipsychotics*).

Pindolol (*Beta Blocking Agents*).

Pioglitazone (*Oral Blood Glucose Lowering Agents*).

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

*Polygala senega* (Senega).

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*).

Prasugrel (*Antithrombotic Agents).*

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*).

Rivaroxaban (*Antithrombotic Agents).*

Rivastigmine (*Anti‑Dementia Drugs*).

Ropinirole (*Anti‑Parkinson Drugs*).

Ropivacaine (*Anaesthetics, Local*).

Rosiglitazone (*Oral Blood Glucose Lowering Agents*).

Rotigotine (*Anti-Parkinson Drugs*).

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*).

Sitagliptin (*Oral Blood Glucose Lowering Agents*).

Sodium valproate (*Antiepileptics*).

Solifenacin (*Anticholinergics).*

Sorafenib (*Antineoplastic Agents*).

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*).

Sunitinib (*Antineoplastic Agents*).

Tea tree oil - see Melaleuca oil.

Tegafur (*Antineoplastic Agents*).

Telmisartan (*Angiotensin II Antagonists*).

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*).

Valsartan (*Angiotensin II Antagonists*).

Varenicline.

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.

Xylometazoline.

Zaleplon (*Benzodiazepine Derivatives and Benzodiazepine Related Drugs*).

Ziprasidone (*Antipsychotics*).

Zolpidem (*Benzodiazepine Derivatives and Benzodiazepine Related Drugs*).

Zonisamide (*Antiepileptics*).

Zopiclone (*Benzodiazepine Derivatives and Benzodiazepine Related Drugs*).

Zuclopenthixol (*Antipsychotics*).

Endnotes

Endnote 1—About the endnotes

The endnotes provide details of the history of this legislation and its provisions. The following endnotes are included in each compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

Endnote 5—Uncommenced amendments

Endnote 6—Modifications

Endnote 7—Misdescribed amendments

Endnote 8—Miscellaneous

If there is no information under a particular endnote, the word “none” will appear in square brackets after the endnote heading.

**Abbreviation key—Endnote 2**

The abbreviation key in this endnote sets out abbreviations that may be used in the endnotes.

**Legislation history and amendment history—Endnotes 3 and 4**

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended the compiled law. The information includes commencement information for amending laws and details of application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision level. It also includes information about any provisions that have expired or otherwise ceased to have effect in accordance with a provision of the compiled law.

**Uncommenced amendments—Endnote 5**

The effect of uncommenced amendments is not reflected in the text of the compiled law, but the text of the amendments is included in endnote 5.

**Modifications—Endnote 6**

If the compiled law is affected by a modification that is in force, details of the modification are included in endnote 6.

**Misdescribed amendments—Endnote 7**

An amendment is a misdescribed amendment if the effect of the amendment cannot be incorporated into the text of the compilation. Any misdescribed amendment is included in endnote 7.

**Miscellaneous—Endnote 8**

Endnote 8 includes any additional information that may be helpful for a reader of the compilation.

Endnote 2—Abbreviation key

|  |  |
| --- | --- |
| ad = added or inserted | pres = present |
| am = amended | prev = previous |
| c = clause(s) | (prev) = previously |
| Ch = Chapter(s) | Pt = Part(s) |
| def = definition(s) | r = regulation(s)/rule(s) |
| Dict = Dictionary | Reg = Regulation/Regulations |
| disallowed = disallowed by Parliament | reloc = relocated |
| Div = Division(s) | renum = renumbered |
| exp = expired or ceased to have effect | rep = repealed |
| hdg = heading(s) | rs = repealed and substituted |
| LI = legislative instrument | s = section(s) |
| LIA = *Legislative Instruments Act 2003* | Sch = Schedule(s) |
| mod = modified/modification | Sdiv = Subdivision(s) |
| No = Number(s) | SLI = Select Legislative Instrument |
| o = order(s) | SR = Statutory Rules |
| Ord = Ordinance | Sub-Ch = Sub-Chapter(s) |
| orig = original | SubPt = Subpart(s) |
| par = paragraph(s)/subparagraph(s) |  |
| /sub-subparagraph(s) |  |

Endnote 3—Legislation history

| Name | FRLI registration | Commencement | Application, saving and transitional provisions |
| --- | --- | --- | --- |
| Therapeutic Goods Order No. 80  Child-Resistant Packaging Requirements for Medicines | 5 Sept 2008 (*see* F2008L03428) | 6 Sept 2008 | \_ |
| Therapeutic Goods Order No. 80A Amendments to Therapeutic Goods Order No. 80  Child-Resistant Packaging Requirements for Medicines | 25 Sept 2012 (*see* F2012L01920) | 1 Oct 2013 | \_ |

Endnote 4—Amendment history

| Provision affected | How affected |
| --- | --- |
| Schedule 1, Part 1  Schedule 1, Part 2  Schedule 1, Part 3 | am. TGO 80A  am. TGO 80A  am. TGO 80A |
|  |  |
|  |  |

Endnote 5—Uncommenced amendments [none]

Endnote 6—Modifications [none]

Endnote 7—Misdescribed amendments [none]

Endnote 8—Miscellaneous [none]