



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**



**DRAFT AUSTRALIA NEW ZEALAND THERAPEUTIC  
PRODUCTS AUTHORITY ORDER (MEDICINE  
STANDARDS) NO. X OF 2007 - PACKAGING  
REQUIREMENTS FOR SPECIFIED THERAPEUTIC  
PRODUCTS**

**May 2007**

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# AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AUTHORITY ORDER (MEDICINE STANDARDS) NO. X OF 2007 - PACKAGING REQUIREMENTS FOR SPECIFIED THERAPEUTIC PRODUCTS

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The Australia New Zealand Therapeutic Products Authority, having consulted with the Joint Interim Expert Advisory Committee on Standards and acting under section 2.02 of the *Australia New Zealand Therapeutic Products Regulatory Scheme (Medicines) Rule 2006*, determines that the matters specified in this Order constitute a standard for medicines of the kind identified in this Order,

Dated 2007

**[DRAFT ONLY – NOT FOR SIGNATURE]**

Managing Director of the Australia New Zealand Therapeutic Products Authority

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## **1 Name of Order**

This Order is the Australia New Zealand Therapeutic Products Order (Medicine Standards) No. X of 2007 – *Packaging Requirements for Specified Therapeutic Products*.

## **2 Commencement**

This Order commences on the day it is published on the Authority website.

## **3 Introduction**

*Note* This Section is included for information only.

- (1) The objective of this Order is to specify packaging requirements that may apply to certain types of therapeutic products.
- (2) For Australia, this Order reflects to the extent possible the transfer of control of poisons packaging requirements for therapeutic products<sup>1</sup>, as previously specified in the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP), from the States and Territories to the regulatory authority responsible for licensing therapeutic products, as recommended in the National Competition Policy Review of *Drugs, Poisons and Controlled Substances Legislation* (the Galbally Review) undertaken in 2001 and subsequently accepted by the Australian Health Ministers Advisory Council and Council of Australian Governments.
- (3) For New Zealand, this Order reflects to the extent possible requirements contained in the New Zealand Medicines Regulations 1984 relating to the use of poisons bottles for the packaging of medicines with poisonous properties.
- (4) In particular, this Order specifies packaging requirements that are intended to ensure that therapeutic products containing poisonous substances are packaged in containers that will not leak, are appropriately marked, and will maintain their integrity for the life of the product, thereby reducing the hazard presented to those handling, using, storing or otherwise coming into contact with such products.

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<sup>1</sup> Note to assist consultation – SUSDP poisons packaging requirements are relevant in Australia to both medicines as well as certain other therapeutic products such as some disinfectants, sterilants and dental products. Although this Order will be made under the Medicines Rule, it is intended that its requirements also will be adopted as a mandatory packaging standard for these other product types. For simplicity, the First Schedule does not differentiate between ingredients of medicines and ingredients in other types of therapeutic products.

- (5) This Order also imposes a requirement for medicines classified as Controlled Drugs by the Scheduling Standard<sup>2</sup> to be packaged in such a way that a sealed pack is readily distinguishable from a pack which has been unsealed. This requirement is intended to assist in reducing the potential for diversion of these medicines to illicit use or abuse.
- (6) It should be noted that the requirements of this Order are additional to, and complement, requirements for child-resistant packaging which apply to medicines that may present a significant risk of toxicity to children if accidentally ingested. For any particular product, requirements for child-resistant packaging may apply in addition to the requirements of this Order.
- (7) Sponsors should also note the existence of other legislative requirements, such as occupational health and safety requirements, and road, rail and air transport requirements, that may be pertinent to the packaging of therapeutic products, irrespective of whether or not those products are subject to the requirements of this Order.

#### 4 Interpretation

In this Order:

**‘Act’** has the same meaning as in the Australia New Zealand Therapeutic Products Regulatory Scheme (Administration and Interpretation) Rule 2007 (the Administration and Interpretation Rule).

**‘Administration and Interpretation Rule’** means the *Australia New Zealand Therapeutic Products Regulatory Scheme (Administration and Interpretation) Rule 2007*.

**‘Agreement’** has the same meaning as in the Administration and Interpretation Rule.

**‘Authority’** has the same meaning as in the Administration and Interpretation Rule.

**‘Authority Gazette’** has the same meaning as in the Administration and Interpretation Rule.

**‘Authority website’** has the same meaning as in the Administration and Interpretation Rule.

**‘child-resistant packaging’** means packaging that is designed or constructed to be significantly difficult for young children to open, or gain access to the contents of,

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<sup>2</sup> Note to assist consultation - In this Order, the term ‘Controlled Drug’ is used in a limited sense to refer to those medicines that are classified as such (Schedule 8 medicines) in the *Standard for the Uniform Scheduling of Medicines and Poisons*. The term does not encompass all drugs classified as Controlled Drugs under the New Zealand *Misuse of Drugs Act 1975* and Regulations, which include additional packaging requirements that apply in New Zealand to the various classes of Controlled Drugs listed in that legislation.

within a reasonable time but not unduly difficult for adults to use properly, but does not mean packaging which all young children cannot open, or obtain the contents of, within a reasonable time. Child-resistant is not synonymous with child-proof;

**‘Controlled Drug’** means a medicine for human use that is classified in the Scheduling Standard as a ‘Controlled Drug’;

**‘designated solvent’** means the following: acetone, dimethylformamide, N-(N-dodecyl)-2-pyrrolidone, hydrocarbons liquid, methanol, methyl ethyl ketone, methyl isoamyl ketone, methyl isobutyl ketone, N-methyl-2-pyrrolidone, N-(N-octyl)-2-pyrrolidone, phenyl methyl ketone, styrene, tetrachloroethylene, 1,1,1-trichloroethane.

**‘essential oils’** means products obtained from natural raw materials either by distillation with water or steam or from the epicarp of citrus fruits by a mechanical process, or by dry distillation. For the purposes of this Order, it also means:

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

**‘external use’**, in relation to the use of a medicine means application in the ears, eyes or nose or to a body surface other than in the mouth, rectum, vagina, urethra or other body orifice.

**‘immediate packaging’** has the same meaning as in the Administration and Interpretation Rule.

**‘internal use’** means administration:

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

**‘medicine’** has the meaning given by section 1.04 of the Medicines Rule.

**‘Medicines Rule’** means the *Australia New Zealand Therapeutic Products Regulatory Scheme (Medicines) Rule 2006*.

**‘nominal capacity’** means the quantity of product which the immediate packaging is deemed to contain, as stated on the label.

**‘outer packaging’** has the same meaning as in the Administration and Interpretation Rule.

**‘poisons packaging’** means packaging that appropriately identifies poisonous, or hazardous, substances or preparations, and is designed to meet specified performance and safety criteria intended to ensure that the immediate packaging will maintain its integrity for the life of the product and the contents will not leak during normal transport and handling. Poisons packaging differs from child-resistant packaging.

**‘product’** means a therapeutic product;

**‘packaging’** means packaging, including any closure system, being the sum of components that together immediately contain and protect the dosage form. It includes containers, closures and closure liners. Packaging may be either reclosable or non-reclosable;

**‘restricted flow insert’** means a restriction fitted, or moulded, in the neck of a container which:

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

**‘scheduled’**, in relation to a medicine, means a medicine classified by the Scheduling Standard as a ‘Pharmacy Medicine’, a ‘Pharmacist Only Medicine’, a ‘Prescription Only Medicine’ or a ‘Controlled Drug’.

**‘Scheduling Standard’** has the meaning given by section 10.02 of the Administration and Interpretation Rule.

**‘substance’** has the same meaning as in the Administration and Interpretation Rule.

**‘therapeutic product’** has the same meaning as in Article 1 of the Agreement Between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products dated 9 Sep 2003.

## **5 Application**

- (1) The requirements set out in this Order apply to those therapeutic products that come within the operation of the Medicines Rule, and:
  - (a) contain a substance included in the Scheduling Standard in such form, concentration and/or presentation that the product is classified by the Scheduling Standard as a ‘Pharmacy Medicine’, a ‘Pharmacist Only Medicine’, a ‘Prescription Only Medicine’ or a ‘Controlled Drug’; or
  - (b) contain a substance, or a salt, ester or other derivative of a substance, that is specified in the First Schedule to this Order.
- (2) However, the requirements set out in this Order do not apply to therapeutic products that are exempted under clause 6 or in relation to which an exemption from compliance with this Order has been granted by the Australia New Zealand Therapeutic Products Authority in accordance with section 5.02 of the Medicines Rule.

## **6 Exemptions**

- (1) The requirements of clause 8 (Poisons packaging requirements for therapeutic products containing scheduled substances) and clause 9 (Poisons packaging requirements for therapeutic products containing other specified substances) of this Order do not apply to therapeutic products that are:
  - (a) for human internal use;
  - (b) a solid or semi-solid preparation for human external use;
  - (c) in immediate packaging having a nominal capacity of 15 millilitres or less;
  - (d) solely for dispensary, industrial, laboratory or manufacturing purposes;
  - (e) a medical or dental adhesive, glue or cement; or
  - (f) an export-only product.
- (2) In addition, the requirements of clause 9 (Poisons packaging requirements for therapeutic products containing other specified substances) of this Order do not apply to therapeutic products that contain a substance specified in the First Schedule at a concentration not exceeding 10 mg per litre or 10 mg per kilogram.
- (3) The tactile identification or embossing requirements of subclause 8(2), 8(3) and 9(3) do not apply to immediate packaging that is an aerosol can, a collapsible tube, or a flexible sachet.

## **7 General requirements**

- (1) The requirements of this Order apply in addition to any other packaging requirements that are required to be applied to therapeutic products as set out in the Australian Act, the New Zealand Act, the Medicines Rule or another Order.
- (2) Where an exemption from poisons packaging is conditional, either wholly or in part, upon the product being packaged with a child-resistant closure, then that child-resistant closure must form part of packaging that meets the performance requirements specified in the Australia New Zealand Therapeutic Products Order (Medicine Standards) No. X 2007 - *Child-Resistant Packaging Requirements for Medicines*.
- (3) A medicine which is intended for internal use must not be packaged in the type of immediate packaging prescribed by subclause 8(2), 8(3) or 9(3) of this Order.

## 8 Poisons packaging requirements for therapeutic products containing scheduled substances<sup>3</sup>

- (1) This clause applies to the immediate packaging of therapeutic products classified by the Scheduling Standard as a 'Pharmacy Medicine', a 'Pharmacist Only Medicine', a 'Prescription Only Medicine' or a 'Controlled Drug'.
- (2) Where the immediate packaging of a therapeutic product to which this clause applies has a nominal capacity of 2 litres or less, the container must comply with Australian Standard AS 2216 – 1997, *Packaging for Poisonous Substances*, as published by Standards Australia, except that essential oils may be packaged in amber glass containers which do not comply with the tactile identification requirements of Australian Standard AS 2216 – 1997, *Packaging for Poisonous Substances*, if:
  - (a) the other safety factors are not diminished; and
  - (b) the packaging is child-resistant and includes a restricted flow insert.
- (3) Where the immediate packaging of a therapeutic product to which this clause applies has a nominal capacity of more than 2 litres, the container must:
  - (a) comply with sub-section 1.4 (General Requirements) of Australian Standard AS 2216 – 1997 *Packaging for Poisonous Substances*, as published by Standards Australia; and
  - (b) have the word "POISON" on the side or shoulder of the container, in sanserif capital letters the height of which is at least one thirty second part of the length, height or width of the container, whichever is the greatest:
    - (i) embossed; or
    - (ii) indelibly written in a colour in distinct contrast to the background colour.
- (4) However, a therapeutic product to which this clause applies may be packaged in immediate packaging that does not comply with the tactile identification requirements of Australian Standard AS 2216 – 1997 *Packaging for Poisonous Substances* or the requirements of paragraph 8(3)(b) if:
  - (a) the other safety factors are not diminished;
  - (b) the container is for a specific purpose; and
  - (c) the use of the container for this purpose has been justified and authorised.

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<sup>3</sup> Note to assist consultation - This Clause describes the poisons packaging requirements for therapeutic products that will remain in Schedules 2, 3, and/or 4 of the Scheduling Standard or are classified by the Scheduling Standard as a 'Controlled Drug'.

## 9 Poisons packaging requirements for therapeutic products containing specified substances<sup>4</sup>

- (1) This clause applies to the immediate packaging of therapeutic products that contain any substance included in the First Schedule<sup>5</sup> to this Order, unless the substance is present in a concentration below any specified concentration limit.
- (2) The requirements of this clause apply equally to therapeutic products in which the substance is present as an active ingredient or as an excipient, or is a natural component of any ingredient present.
- (3) Where a therapeutic product contains a substance included in the First Schedule to this Order, the immediate packaging must:
  - (a) comply with requirements of either subclause 8(2) or 8(3) as relevant; or
  - (b) be readily distinguishable from a container in which food, wine or other beverage is sold; and
    - (i) comply with sub-section 1.4 (General Requirements) of Australian Standard AS 2216 – 1997 excluding paragraph 1.4.3;
    - (ii) be securely closed and, except when containing a preparation for use on one occasion only, be capable of being re-closed to prevent spillage of its contents; and
    - (iii) have the expression “POISON”, “NOT TO BE TAKEN” or “NOT TO BE USED AS A FOOD CONTAINER” embossed or indelibly written thereon, or printed on a permanent adhesive label designed to adhere to the container without lifting and which cannot be removed without damaging either the label or the container,except that:
  - (c) essential oils may be packaged in amber glass containers which do not comply with the tactile identification requirements of Australian Standard AS 2216 – 1997 *Packaging for Poisonous Substances* if:
    - (i) the other safety factors are not diminished; and
    - (ii) the packaging is child-resistant and includes a restricted flow insert.
- (4) However a therapeutic product that contains any of the following substances, in a concentration specified in the First Schedule, must not be packaged in immediate packaging having a nominal capacity of 2 litres or less unless the container complies with the requirements of Australian Standard AS 2216 – 1997, *Packaging for Poisonous Substances*:

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<sup>4</sup> Note to assist consultation - This Clause provides poisons packaging requirements for those therapeutic products to which Schedules 5 and/or 6 of the SUSDP currently applies in Australia. As Schedules 5 and 6 of the Scheduling Standard will not be relevant to therapeutic products under ANZTPA, the substances affected have been listed in the First Schedule to the Order. Some of the substances listed may be relevant to products to be regulated as therapeutic products in Australia only.

<sup>5</sup> The First Schedule has been limited to those Schedule 5 or 6 substances which are currently present in, or are likely to be present in, therapeutic products for human use, in a form to which this Order is relevant. The substances listed may have use in medicines or therapeutic products of other types, or both.

- (a) methylated spirit(s);
  - (b) liquid hydrocarbons when packed as kerosene, lamp oil, mineral turpentine, thinners, reducers, or white petroleum spirit;
  - (c) toluene; or
  - (d) xylene.
- (5) A therapeutic product to which this clause applies may be packaged in immediate packaging that does not comply with the tactile identification requirements of Australian Standard AS 2216 – 1997 *Packaging for Poisonous Substances* or the requirements of subclause 9(3)(a) or 9(3)(b)(iii) if:
- (a) the other safety factors are not diminished;
  - (b) the container is for a specific purpose; and
  - (c) the use of the container for this purposes has been justified and authorised.

**10 Special packaging requirements for medicines classified as Controlled Drugs in the Scheduling Standard**

- (1) This clause applies to the outer packaging of medicines which are classified as Controlled Drugs in the Scheduling Standard.
- (2) The requirements of this clause do not apply to the supply of such medicines by a:
- (a) medical practitioner, dentist or veterinary surgeon in the practice of his or her profession;
  - (b) pharmacist on the prescription of a medical practitioner, dentist or veterinary surgeon;
  - (c) pharmacist employed at a hospital, on the written requisition of a medical practitioner, a dentist or the nurse in charge of the ward in which the Schedule 8 poison is to be used or stored; or
  - (d) nurse on the direction in writing of a medical practitioner or dentist.
- (3) The outer packaging of medicines classified as Controlled Drugs by the Scheduling Standard must be sealed in such a way that when the seal is broken, the open pack is readily distinguishable from a pack with sealed outer packaging.

## First Schedule

ACETONE **except** in preparations containing 25 per cent or less of designated solvents.

ALKALINE SALTS, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination in liquid preparations the pH of which is more than 11.5.

AMINES for use as curing agents for epoxy resins **except** if separately specified.

AMMONIA (excluding its salts and derivatives other than ammonium hydroxide) **except** in preparations containing 0.5 per cent or less of free ammonia.

AMMONIUM LAURETH SULFATE – *see Quaternary Ammonium Compounds*

AMMONIUM LAURYL SULFATE – *see Quaternary Ammonium Compounds*

AMMONIUM LAURYL SULFOSUCCINATE – *see Quaternary Ammonium Compounds*

AMMONIUM NONOXYNOL-4 SULFATE – *see Quaternary Ammonium Compounds*

ANHYDRIDES, ORGANIC ACID, for use as curing agents for epoxy resins **except** when separately specified in this Schedule.

ANISE OIL **except**:

- (a) when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert; or
- (b) in preparations containing 50 per cent or less of anise oil.

AZADIRACHTA INDICA (Neem) including its extracts and derivatives **except**:

- (a) debitterised neem seed oil;
- (b) in preparations for human dermal therapeutic use containing cold pressed neem seed oil, when in a container fitted with a child-resistant closure; or
- (c) in preparations for dermal use containing 1 per cent or less of cold pressed neem seed oil.

BASIL OIL **except**:

- (a) when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert; or
- (b) in preparations containing 5 per cent or less of methyl chavicol.

BAY OIL **except**:

- (a) when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert;
- (b) when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure; or
- (c) in preparations containing 25 per cent or less of bay oil.

BENZALKONIUM CHLORIDE **except** in preparations containing 5 per cent or less of benzalkonium chloride.

BENZETHONIUM CHLORIDE – *see Quaternary Ammonium Compounds*

BORIC ACID (excluding its salts) and BORAX (excluding when present as an excipient) **except** when included in Schedule 4 of the Scheduling Standard.

BROMOCHLORODIMETHYL HYDANTOIN – *see Chlorinating Compounds*

**CAJUPUT OIL except:**

- (a) when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert;
- (b) when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure; or
- (c) in preparations or oils containing 25 per cent or less of cajuput oil.

CALCIUM HYPOCHLORITE – *see Chlorinating Compounds,*

**CAMPHOR except:**

- (a) in preparations containing 2.5 per cent or less of camphor;
- (b) in essential oils when the camphor is present as a natural component of the oil:
  - (i) in oils containing 10 per cent or less of camphor, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert;
  - (ii) when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert;
  - (iii) when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure;
- (c) in rosemary oil, sage oil (Spanish), or lavandin oil as such.

CARBAMIDE PEROXIDE **except** in preparations containing 9 per cent or less of carbamide peroxide.

**CASSIA OIL except:**

- (a) in preparations for dermal use as a rubefacient containing 5 per cent or less of cassia oil; or
- (b) in other preparations containing 2 per cent or less of cassia oil.

CETALKONIUM CHLORIDE – *see Quaternary Ammonium Compounds*

CETRIMONIUM BROMIDE – *see Quaternary Ammonium Compounds*

CETYLPYRIDINIUM CHLORIDE – *see Quaternary Ammonium Compounds*

CETYL TRIMETHYLAMMONIUM BROMIDE – *see Quaternary Ammonium Compounds*

CHLORHEXIDINE **except** in preparations containing 1 per cent or less of chlorhexidine.

**CHLORINATING COMPOUNDS except:**

- (a) when separately specified in this Schedule;
- (b) sodium hypochlorite preparations with a pH of less than 11.5;
- (c) preparations containing less than 2 per cent of available chlorine; or
- (d) preparations containing not less than 2 per cent but not more than 4 per cent of available chlorine when labelled with the statements:

**WARNING** – Ensure adequate ventilation when using. Vapour may be harmful. May give off dangerous gas if mixed with other products;

CHLOROCRESOL **except** in preparations containing 3 per cent or less of chlorocresol.

CHLOROXYLENOL – *see Phenol*

**CINEOLE except:**

- (a) when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert;
- (b) when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure;
- (c) in oils or preparations containing 25 per cent or less of cineole; or
- (d) in rosemary oil or camphor oil (white).

**CINNAMON BARK OIL except** in preparations containing 2 per cent or less of cinnamon bark oil.

**CINNAMON LEAF OIL except:**

- (a) when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert;
- (b) when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure; or
- (c) in preparations containing 25 per cent or less of cinnamon leaf oil.

**CHLORINE DIOXIDE AND SIMILAR OXIDISING COMPOUNDS CAPABLE OF RELEASING CHLORINE** – *see Chlorinating Compounds*

**CLOVE OIL except:**

- (a) when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert;
- (b) when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure; or
- (c) in preparations containing 25 per cent or less of clove oil.

**COCAMIDOPROPYL BETAINE** – *see Quaternary Ammonium Compounds*

**CRESOL** – *see Phenol*

**DENATONIUM BENZOATE** – *see Quaternary Ammonium Compounds*

**DIAMMONIUM LAURYL SULFOSUCCINATE** – *see Quaternary Ammonium Compounds*

**DICHLOROISOCYANURATES** – *see Chlorinating Compounds*

**DICHLOROXYLENOL** – *see Phenol*

**DIDECYLDIMETHYLAMMONIUM CHLORIDE except** in preparations containing 1 per cent or less of didecyldimethylammonium chloride labelled with the statement “Avoid contact with eyes”.

**DODECYL DIMETHYLBENZYLAMMONIUM CHLORIDE** – *see Quaternary Ammonium Compounds*

**EPOXY RESINS, LIQUID.**

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

**ETHYLBENZALKONIUM CHLORIDE** – *see Quaternary Ammonium Compounds*

**ETHYLENE GLYCOL** (excluding its salts and derivatives) **except** in preparations containing 2.5 per cent or less of ethylene glycol.

**EUCALYPTUS OIL except:**

- (a) when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert;
- (b) when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure; or
- (c) in preparations containing 25 per cent or less of eucalyptus oil.

**EUGENOL except:**

- (a) when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert;
- (b) when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure; or
- (c) in preparations containing 25 per cent or less of eugenol.

**EXTRACT OF LEMON EUCALYPTUS**, being acid modified oil of lemon eucalyptus (*Corymbia citriodora*), **except** in preparations containing 40 per cent or less of extract of lemon eucalyptus.

**FORMIC ACID** (excluding its salts and derivatives) **except** in preparations containing 0.5 per cent or less of formic acid.

**GLYCIDYL TRIMETHYL AMMONIUM CHLORIDE** – *see Quaternary Ammonium Compounds*

**HYDROCARBONS LIQUID**, including kerosene, mineral turpentine, white petroleum spirit, toluene, xylene and light mineral and paraffin oils (but excluding their derivatives), **except** pharmaceutical grade white mineral oil, or preparations containing 25 per cent or less of designated solvents.

**HYDROFLUORIC ACID** (excluding its salts and derivatives) and admixtures that generate hydrofluoric acid.

**HYDROGEN PEROXIDE** (excluding its salts and derivatives) **except** in preparations containing 3 per cent (10 volume) or less of hydrogen peroxide.

**MARJORAM OIL except:**

- (a) when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert; or
- (b) in preparations containing 50 per cent or less of marjoram oil.

**MELALEUCA OIL** (tea tree oil) **except:**

- (a) when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert;
- (b) when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure; or
- (c) in preparations containing 25 per cent or less of melaleuca oil.

**META-CRESOL** – *see Phenol*

**METHANOL** (excluding its derivatives) **except** in preparations containing 2 per cent or less of methanol.

**METHYLATED SPIRIT(S)** (being ethanol denatured with denatonium benzoate, methyl isobutyl ketone and fluorescein) **except:**

- (a) when included in preparations or admixtures; or
- (b) when packed in containers having a capacity of more than 5 litres.

METHYL SALICYLATE **except** in preparations containing less than 25 per cent of methyl salicylate.

NITRIC ACID (excluding its salts and derivatives) **except** in preparations containing 0.5 per cent or less of nitric acid.

NUTMEG OIL **except**:

- (a) when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert; or
- (b) in preparations containing 50 per cent or less of nutmeg oil.

OLEYLTRIMETHYLAMMONIUM CHLORIDE – *see Quaternary Ammonium Compounds*

ORTHO-CRESOL – *see Phenol*

PARACHLOROPHENOL – *see Phenol*

PARA-CRESOL – *see Phenol*

PENNYROYAL OIL **except**:

- (a) when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and a child-resistant closure; or
- (b) in preparations containing 4 per cent or less of d-pulegone.

PERACETIC ACID.

PERMETHRIN **except** in preparations containing 2 per cent or less of permethrin.

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

- (a) when separately specified in this Schedule; or
- (b) in preparations containing 3 per cent or less of such substances.

ortho-PHENYLPHENOL **except** in preparations containing 5 per cent or less of o-phenylphenol.

POTASSIUM HYDROXIDE (excluding its salts and derivatives) **except** preparations containing 5 per cent or less of potassium hydroxide, the pH of which is 11.5 or less.

ortho-PHTHALALDEHYDE.

POTASSIUM CARBONATE – *see Alkaline Salts*

POTASSIUM PHOSPHATE – *see Alkaline Salts*

POTASSIUM SILICATE – *see Alkaline Salts*

d-PULEGONE **except** in oils or preparations containing 4 per cent or less of d-pulegone.

QUATERNARY AMMONIUM COMPOUNDS **except**:

- (a) when separately specified in these Schedules;
- (b) dialkyl or dialkoyl quaternary ammonium compounds where the alkyl or alkoyl groups are derived from tallow or hydrogenated tallow or similar chain length (C16/C18) sources; or
- (c) in preparations containing 5 per cent or less of such quaternary ammonium compounds.

SAFROLE **except** in preparations containing 1 per cent or less of safrole.

SAGE OIL (Dalmatian) **except:**

- (a) when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and a child-resistant closure; or
- (b) in preparations containing 4 per cent or less of thujone.

SASSAFRAS OIL **except** in preparations containing 1 per cent or less of safrole.

SODIUM CARBONATE – *see Alkaline Salts*

SODIUM PHOSPHATE – *see Alkaline Salts*

SODIUM SILICATE – *see Alkaline Salts*

SODIUM HYDROXIDE (excluding its salts and derivatives) **except** in preparations containing 5 per cent or less of sodium hydroxide, the pH of which is 11.5 or less.

SODIUM HYPOCHLORITE – *see Chlorinating Compounds*

SODIUM DICHLOROISOCYANURATE – *see Chlorinating Compounds*

STAR ANISE OIL **except:**

- (a) when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert; or
- (b) in preparations containing 50 per cent or less of star anise oil.

STEARALKONIUM CHLORIDE – *see Quaternary Ammonium Compounds*

SULFAMIC ACID (excluding its salts and derivatives).

SULFURIC ACID (excluding its salts and derivatives) **except** in preparations containing 0.5 per cent or less of sulfuric acid.

SYMPHYTUM spp. (Comfrey) for dermal use.

THUJONE **except** in oils or preparations containing 4 per cent or less of thujone.

THYME OIL **except:**

- (a) when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert; or
- (b) in preparations containing 50 per cent or less of thyme oil.

TRICHLOROISOCYANURIC ACID (symclosene) – *see Chlorinating Compounds*

TRICHLOROPHENOL.

TURPENTINE OIL **except** in preparations containing 25 per cent or less of turpentine oil.