

## Therapeutic Goods (Poisons Standard— June 2025) Instrument 2025

I, Sarah Syme, as delegate of the Secretary of the Department of Health, Disability and Ageing, make the following instrument.

Dated 22 May 2025

Sarah Syme Assistant Secretary Regulatory Engagement Branch Health Products Regulation Group Department of Health, Disability and Ageing

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## **Reader's guide**

## Introduction

This instrument is made under paragraph 52D(2)(b) of the *Therapeutic Goods Act 1989* (the *Act*), and is a compilation of decisions made under section 52D of the Act. This instrument should be read in conjunction with the *Scheduling Policy Framework* (the *SPF*) of the Australian Health Ministers' Advisory Council. Further information on the scheduling amendments and the SPF can be viewed on the Therapeutic Goods Administration's website (www.tga.gov.au). Refer to section 6 for definitions of specific terms used in this document including "medicine" and "poison" (noting that the definition of poison includes medicine).

This instrument serves 2 key purposes.

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

Secondly, this instrument includes provisions for labelling, containers, storage, disposal, record-keeping, supply and possession of poisons in general which are intended to be adopted for use in each jurisdiction of Australia. Other government agencies may also impose controls on certain products.

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

Poisons which are packed and sold solely for industrial, manufacturing, laboratory or dispensary use are exempt from all labelling requirements included in this instrument as they are covered by labelling requirements under applicable jurisdictional Work Health and Safety laws, as amended from time to time. Note, however that this exemption does not extend to controls on supply of these poisons.

This instrument is presented with a view to promoting uniform:

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

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

- the Act;
- the Agricultural and Veterinary Chemicals Code Act 1994;
- the Agricultural and Veterinary Chemicals Code Regulations 1995;

- the *Therapeutic Goods Order No. 91 Standard for labels of prescription and related medicines*;
- the Therapeutic Goods Order No. 92 Standard for labels of non-prescription medicines;
- the Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017;
- the *Therapeutic Goods Order No.* 95 *Child-resistant packaging requirements for medicines* 2017 (TGO 95);
- the Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021;
- the *Therapeutic Goods (Medicines Advisory Statements) Specification 2021* Schedule 1 Required Advisory Statements for Medicine Labels No. 6 (RASML).

## Classification

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

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

## **Principles of scheduling**

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

This instrument lists poisons in 10 Schedules according to the degree of control recommended to be exercised over their availability to the public.

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

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

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

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

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

## **Reading the schedules**

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

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

Secondly, Schedule entries have been expressed in either positive or negative terms and care must be taken to distinguish between the 2 different forms of expression. Thus, selenium is in Schedule 6 only when one of the clauses in this Schedule entry applies, while fluorides are in Schedule 6 unless one of the exempting clauses applies.

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

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

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

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

It is important to remember that a Schedule entry includes preparations containing the poison in any concentration and all salts and derivatives of the poison unless it specifically states otherwise (see section 7).

It is important to note that a substance is not classed as a derivative on the basis of a single, prescriptive set of criteria. Classification of a substance as a derivative of a scheduled poison relies on a balanced consideration of factors to decide if a substance has a similar nature (e.g. structurally, pharmacologically, and toxicologically) to a scheduled poison or is readily converted (either physically or chemically) to a scheduled poison. However, a substance is only considered a derivative of a scheduled poison if it is not individually listed elsewhere in the Schedules, or captured by a more restrictive group or class entry. Additionally, some entries specifically exclude derivatives. Once a substance is determined to be a derivative of a scheduled poison, the same scheduling requirements as the scheduled poison, including limits on access, supply and availability, will apply.

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

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

## Availability of poisons

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

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

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

- indicate that the poison is available; or
- indicate that it is has been approved or is efficacious for any use that may be specified in a Schedule; or
- negate any obligation for registration of therapeutic goods, or agricultural or veterinary chemical product containing that poison.

## Appendices

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

Appendix	Title	Purpose/controls imposed
Appendix A	General exemptions	List of preparations and products exempted from this instrument.
Appendix B	Substances considered not to require control by scheduling	List of poisons exempted from scheduling.
Appendix C	Appendix is intentionally left blank	See Schedule 10.
Appendix D	Additional controls on possession or supply of poisons included in Schedule 4 or 8	List of poisons included in Schedule 4 or 8 where additional specified controls apply on possession or supply.
Appendix E	First aid instructions for poisons	First aid instructions for poisons (other than agricultural and veterinary chemicals and chemicals packed and sold solely for industrial, dispensary, manufacturing or laboratory use).
Appendix F	Warning statements and general safety directions for poisons	Warning statements and general safety directions for poisons (other than human medicines, agricultural and veterinary chemicals and chemicals packed and sold solely for industrial, dispensary, manufacturing or laboratory use).
Appendix G	Dilute preparations	Concentration cut-offs for specified poisons, below which the requirements of this instrument do not apply
Appendix H	Schedule 3 medicines permitted to be advertised	List of medicines included in Schedule 3 that are permitted to be advertised to the public.
Appendix I	Appendix is intentionally left blank	-
Appendix J	Conditions for availability and use of Schedule 7 poisons	List of poisons included in Schedule 7 where additional specified conditions apply to their availability and use.
Appendix K	Human medicines required to be labelled with a sedation warning	List of poisons in medicines for human use required to be labelled with a warning regarding their sedation potential.
Appendix L	Requirements for dispensing labels for medicines	Requirements applying to labels attached to medicines at the time of dispensing.
Appendix M	Additional controls or supply requirements for poisons included in Schedule 3 to allow them to be provided by a pharmacist	
	Appendix is intentionally left blank and is reserved for future use.	

## **Appendix A (General exemptions)**

Appendix A lists preparations and products that are exempted from this instrument.

### Appendix B (Substances considered not to require control by scheduling)

Substances for which the available information suggests that inclusion in the Poisons Schedules is not necessary, or not the most appropriate means of controlling the risk to public health, have been considered at various times.

Inclusion in Appendix B indicates that a decision has been taken not to include substances anywhere in the Schedules, either for a specific purpose, or generally. It is an inclusive, but not an exhaustive, list (that is, there may be substances not included in the Schedules, and not included in Appendix B, which may be hazardous or non-hazardous, but have not been considered in relation to the need for scheduling).

Substances may be included in Appendix B because they have intrinsically low toxicity, or where other factors suggest that the potential public health risk would be minimal. Factors which are considered when determining an Appendix B entry include:

- the toxicology profile was adequately characterised and not consistent with inclusion in any of the Schedules;
- the use, purpose or product presentation minimised any hazard to the public such as to not require scheduling; or
- the public access was limited such that scheduling was inappropriate or unnecessary.

The list of substances included in Appendix B was developed from scheduling files and historical records. For transparency, where the reason for entry and/or purpose or use for the substance was apparent in the consideration, this has been included in the columns "Reason for Entry" and "Area of Use".

Inclusion in Appendix B will not prevent reconsideration of the scheduling of a substance where adverse information becomes available about the Appendix B entry for that substance.

Applications are considered for scheduling. Applications for inclusion in Appendix B will not be accepted.

## Appendix C (blank)

Appendix C is intentionally blank.

# Appendix D (Additional controls on possession or supply of poisons included in Schedule 4 or 8)

Appendix D lists poisons included in Schedule 4 or 8 where additional specified controls apply on possession or supply.

### **Appendix E (First aid instructions for poisons)**

Under poisons legislation, scheduled substances and their preparations are required to be labelled with appropriate directions for first aid attention in case of poisoning. It is the responsibility of the manufacturer, packer and supplier of a drug or poison to ensure that the first aid instructions included on the label of a poison are appropriate for a specific product. Standard statements have been prepared as a guide for health authorities and manufacturers in drafting suitable first aid directions for this purpose. Standard statements specified in Appendix E may be varied provided that the intent is not changed.

The directions listed for any particular substance may require modification to take into account combination of that substance with other substances, both toxic and non-toxic, in a formulation, as well as the physical form and presentation of the product. Any such modification should be concise and readily understood.

The First Aid Instructions include action to be taken in case of eye contamination from substances recognised as causing direct poisoning via the eye, causing severe eye damage or

requiring prolonged flushing to free the absorbed substance from the eye tissue. However, it is recognised that many other substances or preparations will require a statement of varying nature depending on the detailed formulation. While the necessity to flush the eyes in case of accident will be so self-evident as not to justify label space in many instances, a statement such as "If in eyes rinse well with water" may be appropriate.

# Appendix F (Warning statements and general safety directions for poisons)

It is the responsibility of the manufacturer, packer and supplier of a drug or poison to ensure that the purchaser or user of a product is given sufficient information to be able to use it correctly and safely.

Under poisons legislation, scheduled substances, which may be harmful to the user, must be labelled with appropriate warning statements and/or safety directions. The selection of warning statements and safety directions will depend on the formulation of the product, and the use for which it is sold or supplied. Warning statements and safety directions have been prepared as a guide for this purpose.

The wording of warning statements and safety directions specified in Appendix F may be varied provided that the intent is not changed. Additional statements also may be added to ensure that the user of a product is sufficiently advised of its harmful nature and how to avoid any deleterious effects.

## **Appendix G (Dilute preparations)**

Appendix G lists concentration cut-offs for specified substances, below which the requirements of this instrument do not apply.

## Appendix H (Schedule 3 medicines permitted to be advertised)

Appendix H lists medicines included in Schedule 3 that are permitted to be advertised to the public.

## Appendix I (blank)

Appendix I is intentionally blank.

# Appendix J (Conditions for availability and use of certain poisons included in Schedule 7)

All poisons included in Appendix J are not to be available except to authorised or licensed persons.

The use of a poison may be restricted for a particular purpose. Controls recommended for the Schedule 7 poisons included in Appendix J may be implemented through poisons controls or other State or Territory legislation.

# Appendix K (Human medicines required to be labelled with a sedation warning)

Medicines for human use that contain a poison included in Appendix K are required to be labelled with a warning regarding their sedation potential.

## Appendix L (Requirements for dispensing labels for medicines)

Appendix L sets out the requirements for labels attached to medicines at the time of dispensing.

## Appendix M (blank)

Appendix M is intentionally blank and is reserved for future use.

## Poisons Information Centre telephone numbers for first aid instructions, warning statements and general safety directions for poisons

Companies should use the Poisons Information Centre telephone number(s) (Australia 13 11 26; New Zealand 0800 764 766) appropriate to the country(ies) of sale for the product.

Companies wishing to use a poisons information centre telephone number other than the national telephone numbers for Australia and New Zealand must meet the following criteria:

1. the poisons information service whose number is used must be attended by adequately trained staff for 24 hour emergency poisons information; and

2. calls must be logged and submitted for incorporation into the official collection of poisoning data.

## Part 1—Preliminary and interpretation

#### 1 Name

- (1) This instrument is the *Therapeutic Goods (Poisons Standard—June 2025) Instrument 2025.*
- (2) This instrument may also be cited as the Standard for the Uniform Scheduling of Medicines and Poisons No. 47.
  - Note: This instrument is the *current Poisons Standard* for the purposes of the Act until a document is prepared in substitution for it (see sections 52A and 52D of the Act).

#### 2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1 Column 2 Colu		Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	1 June 2025.	1 June 2025

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

#### **3** Authority

This instrument is made under paragraph 52D(2)(b) of the *Therapeutic Goods* Act 1989.

#### 4 Repeal and transitional provisions

#### Repeal

(1) The *Therapeutic Goods (Poisons Standard—February 2025) Instrument 2025* is repealed.

Saving-things done under the repealed instrument

- (2) If:
  - (a) a thing was done for a particular purpose under the *Therapeutic Goods* (*Poisons Standard—February 2025*) Instrument 2025 as in force immediately before that instrument was repealed; and

(b) the thing could be done for that purpose under this instrument; the thing has effect for the purposes of this instrument as if it had been done for that purpose under this instrument.

(3) Without limiting subsection (2), a reference in that subsection to a thing being done includes a reference to an approval, authorisation, certificate, exemption, requirement or other instrument being given, made, granted or issued.

#### 5 Reader's guide and Index

- (1) The Reader's guide is not part of this instrument.
- (2) The Index is not part of this instrument.

#### **6** Definitions

Note 1: The following expressions used in this instrument are defined in the Act:

- (a) current Poisons Standard;
- (b) poison;
- (c) Register;
- (d) Secretary;
- (e) supply;
- (f) therapeutic goods.
- Note 2: The definition of *poison* in the Act is as follows:

*poison* means an ingredient, compound, material or preparation which, or the use of which, may cause death, illness or injury and includes any ingredient, compound, material or preparation referred to in a schedule to the current Poisons Standard.

#### In this instrument:

Act means the Therapeutic Goods Act 1989.

#### agricultural chemical means:

- (a) a substance that is represented, imported, manufactured, supplied or used as a means of directly or indirectly:
  - (i) destroying, stupefying, repelling, inhibiting the feeding of, or preventing infestation by or attacks of, any pest in relation to a plant, a place or a thing; or
  - (ii) destroying a plant; or
  - (iii) modifying the physiology of a plant or pest so as to alter its natural development, productivity, quality or reproductive capacity; or
  - (iv) modifying an effect of another agricultural chemical; or
  - (v) attracting a pest for the purpose of destroying it; or
- (b) an active ingredient included in a product declared by regulation under the *Agricultural and Veterinary Chemicals Code Act 1994* to be an agricultural chemical product;

but does not include a veterinary chemical.

*agricultural chemical product* has the same meaning as in the Agricultural and Veterinary Chemicals Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*.

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

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

#### appropriate authority: each of the following is an appropriate authority:

- (a) each person who is the head of the body (however described) in a State or Territory that is responsible for the administration of matters relating to health in that State or Territory;
- (b) the Deputy Secretary of the Department with responsibility for the part of the Department known as the Therapeutic Goods Administration, or their delegate;
- (c) the Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority, or their delegate.

#### approved name means:

- (a) for a poison that is for human therapeutic use—the name for the poison in the Australian Approved Names List within the meaning of the *Therapeutic Goods Regulations 1990*; or
- (b) for a poison that is for animal or agricultural use—the name approved for use by the Australian Pesticides and Veterinary Medicines Authority under the Agricultural and Veterinary Chemicals Code set out in the Schedule to the Agricultural and Veterinary Chemicals Code Act 1994; or
- (c) for any other poison—the name for the poison mentioned in the first-occurring of the following paragraphs that applies to the poison:
  - (i) the name used for the poison in this instrument;
  - (ii) the name recommended by Standards Australia as the common name for the poison;
  - (iii) the English name given to the poison by the International Organization for Standardization;
  - (iv) the name given to the poison by the British Standards Institution;
  - (v) the English name given to the poison by the European Committee for Standardization (CEN);
  - (vi) the international non-proprietary name recommended for the poison by the World Health Organization;
  - (vii) the International Nomenclature Cosmetic Ingredient name for the poison listed in the International Cosmetic Ingredient Dictionary & Handbook published by the Personal Care Products Council of America;
  - (viii) the accepted scientific name or the name descriptive of the true nature and origin of the poison.

*Australian Dangerous Goods Code* means the *Australian Code for the Transport of Dangerous Goods by Road & Rail*, published by the National Transport Commission, as existing from time to time.

Note: The Australian Dangerous Goods Code could in 2022 be viewed on the Commission's website (www.ntc.gov.au).

authorised prescriber means any of the following:

- (a) a dental practitioner;
- (b) a medical practitioner;
- (c) a veterinarian;
- (d) a person for whom an authorisation, given for the purposes of this paragraph by an appropriate authority, is in effect.

blood means whole blood extracted from human donors.

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

#### child-resistant closure means:

- (a) a closure that complies with the requirements for a child-resistant closure in Australian Standard AS 1928-2007, *Child-resistant packaging – Requirements and testing procedures for reclosable packages (ISO* 8317:2015, MOD); or
- (b) a closure that complies with the requirements for child-resistant closures specified in *Therapeutic Goods Order No. 95 Child-resistant packaging requirements for medicines 2017* (TGO 95); or
- (c) a closure that is taken to comply with the requirements mentioned in paragraph (b) under *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*; or
- (d) in the case of a can fitted with a press-on lid, a lid of the design known as "double tight" or "triple tight".
- Note: See also the definition of *non-access packaging*.

#### *child-resistant packaging* means packaging that:

- (a) complies with the requirements of Australian Standard AS 1928-2007, *Child resistant packaging – Requirements and testing procedures for reclosable packages (ISO 8317:2015, MOD)*; or
- (b) is reclosable and complies with the requirements of at least one of the following:
  - (i) the International Organization for Standardization Standard ISO 8317:2015, Child-resistant packaging—Requirements and testing procedures for reclosable packages;
  - (ii) the British Standards Institution Standard BS EN ISO 8317:2015, *Child-resistant packaging—Requirements and testing procedures for reclosable packages*;
  - (iii) the Canadian Standards Association Standard CSA Z76.1:21, Reclosable Child-Resistant Packages;
  - (iv) the United States Code of Federal Regulations, Title 16, Section 1700.15, *Poison prevention packaging standards* and Section 1700.20, *Testing procedure for special packaging*, as in force from time to time; or

- (c) a closure that complies with the requirements for child-resistant packaging specified in *Therapeutic Goods Order No. 95 Child-resistant packaging requirements for medicines 2017* (TGO 95); or
- (d) a closure that is taken to comply with the requirements mentioned in paragraph (c) under *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021*; or
- (e) is in the form of blister or strip packaging:
  - (i) in which a unit of use is individually protected until the time of release; and
  - (ii) that complies with section 3 (Requirements for non-reclosable packages) of Australian Standard AS1928-2007, *Child-resistant packages*.

Note: See also the definition of *non-access packaging*.

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

*cosmetic* means a substance or preparation intended for placement in contact with any external part of the human body, including:

- (a) the mucous membranes of the oral cavity; and
- (b) the teeth;

with a view to:

- (c) altering the odours of the body; or
- (d) changing its appearance; or
- (e) cleansing it; or
- (f) maintaining it in good condition; or
- (g) perfuming it; or
- (h) protecting it.

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

*dental practitioner* means a person who is registered, in a State or internal Territory, as a dental practitioner (other than a dental therapist, dental hygienist, dental prosthetist or oral health therapist).

dermal use means application to the skin primarily for localised effect.

designated solvent means the following:

- (a) acetone;
- (b) dimethylformamide;
- (c) *N*-(*N*-dodecyl)-2-pyrrolidone;
- (d) hydrocarbons, liquid;
- (e) methanol when included in Schedule 5;
- (f) methyl ethyl ketone;
- (g) methyl isoamyl ketone;
- (h) methyl isobutyl ketone;
- (i) N-methyl-2-pyrrolidone;

- (j) *N*-(*N*-octyl)-2-pyrrolidone;
- (k) phenyl methyl ketone;
- (l) styrene;
- (m) tetrachloroethylene;
- (n) 1,1,1-trichloroethane.

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

Note: See section 40 and Appendix L.

distributor means a person who imports or supplies a poison.

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

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

*drug* means a poison intended for human or animal therapeutic use.

#### essential oils means:

- (a) products obtained from natural raw materials by distillation with water or steam or from the epicarp of citrus fruits by a mechanical process, or by dry distillation; or
- (b) oils of equivalent composition to products mentioned in paragraph (a) that are derived through synthetic means; or
- (c) prepared mixtures of oils of equivalent composition to products mentioned in paragraph (a) that comprise a mixture of synthetic and natural components.

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

first group paint: see section 67.

*free formaldehyde* includes all hydrated and non-hydrated formaldehyde present in aqueous solution, including methylene glycol and formaldehyde released from formaldehyde donors.

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

hand sanitiser preparation means an antimicrobial skin care product that:

- (a) consists of, contains or generates one or more antimicrobial active substances; and
- (b) is represented in any way to be, or is likely to be taken to be (whether because of the way in which it is presented or for any other reason):
  - (i) for use on hands when soap and water are not available; and

- (ii) applied to the hands without rinsing off; and
- (iii) intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any microbes on the skin.

*hawking* means to supply (including peddle or distribute or cause to be distributed) in a public place.

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

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

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

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

internal use means administration:

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

#### label:

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

main label, for a container of poison, means:

- (a) the part of the label that is most likely to be displayed, presented, shown, or examined under ordinary or customary conditions of display; and
- (b) if there are 2 or more labels:
  - (i) the label or the part of the label where the product name is more or most conspicuously shown; or
  - (ii) if the product name is equally more or most conspicuously displayed on more than one of those labels—each of the labels on which the product name is equally more or most conspicuously displayed.

*manufacturer* of a poison means a person who manufactures, produces, or packs a poison.

*marker dyes or pigments* means any product that is added to a liquid used in agricultural or veterinary chemicals to identify or distinguish treated from

untreated objects, land or organisms by temporarily imparting colour on the relevant object, land or organism through, for example, spot- or boom-spraying.

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

*medical practitioner* means a person who is registered, in a State or internal Territory, as a medical practitioner.

*medicine* means any poison for therapeutic use.

*midwife* means a person who is registered, in a State or internal Territory, as a midwife.

*non-access packaging*, for a product that is not intended for human therapeutic use, means packaging that complies with the requirements of AS 4710-2001, *Packages for chemicals not intended for access or contact with their contents by humans*.

Note: See also the definitions of *child-resistant closure* and *child-resistant packaging*.

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

*nurse* means a person who is registered, in a State or internal Territory, as a nurse.

*oromucosal use* means administration to the oral mucosa, specifically the oral cavity and/or the pharynx.

*paint* includes any substance used or intended to be used for application as a colouring or protective coating to any surface but does not include graphic material or paints for therapeutic use.

*pesticide* means any substance or mixture of substances used or intended to be used:

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

*pharmacist* means a person who is registered, in a State or internal Territory, as a pharmacist.

*primary pack*, in relation to a poison, means the pack in which the poison and its immediate container or immediate wrapper or measure pack are presented for supply.

product sample means a packed poison supplied directly to a consumer:

- (a) free of charge or for a nominal charge; and
- (b) as a mechanism to promote the supply of the product; and
- (c) in the form of:
  - (i) a small pack produced specifically for the purposes of promotion; or
  - (ii) a normal commercial pack that in other circumstances could be purchased by the consumer.

*public place* means any place where members of the public are lawfully entitled, invited or permitted to be present in their capacity as members of the public.

Note: Examples of a public place include a street, road, footway, court, alley or thoroughfare that the public may use in any residential premises or to get from door to door, place to place or house to house.

*required advisory statements for medicine labels* means the *Therapeutic Goods* (Medicines Advisory Statements) Specification 2021.

#### restricted flow insert means a restriction:

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

second group paint: see section 68.

#### selected container means:

- (a) an injection vial having a nominal capacity of 10 ml or less; or
- (b) a single use syringe; or
- (c) any other container for substances for therapeutic use having a nominal capacity of 10 ml or less.

#### solid includes powder.

substance has the same meaning as in Part 6-3 of the Act.

Note 1: In general terms, that definition covers an ingredient, compound, material or preparation which, or the use of which, may cause death, illness or injury to persons or animals.

Note 2: See also section 7.

therapeutic use means use in or in connection with:

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

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

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

*toy* means an object or number of objects manufactured, designed, labelled or marketed as a plaything for a child or children up to the age of 14 years.

transdermal use means application to the skin primarily for systemic effect.

*veterinarian* means a person who is registered under the law of a State or Territory as a veterinarian, a veterinary practitioner or a veterinary surgeon.

#### veterinary chemical means:

- (a) a substance that is represented as being suitable for, or is manufactured, supplied or used for, administration or application to an animal by any means, or consumption by an animal, as a way of directly or indirectly:
  - (i) preventing, diagnosing, curing or alleviating a disease or condition in the animal or an infestation of the animal by a pest; or
  - (ii) curing or alleviating an injury suffered by the animal; or
  - (iii) modifying the physiology of the animal:
    - (A) so as to alter its natural development, productivity, quality or reproductive capacity; or
    - (B) so as to make it more manageable; or
  - (iv) modifying the effect of another veterinary chemical; or
- (b) any vitamin, mineral substance, or additive, if, and only if, the vitamin, substance or additive is used for a purpose mentioned in paragraph (a); or
- (c) any active ingredient included in a product declared by regulation under the *Agricultural and Veterinary Chemicals Code Act 1994* to be a veterinary chemical product;

but does not include an agricultural chemical.

*veterinary chemical product* has the same meaning as in the Agricultural and Veterinary Chemicals Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*.

#### 7 References to substances

In this instrument, unless the contrary intention appears, a reference to a substance includes the following:

- (a) that substance prepared from natural sources or artificially;
- (b) if the substance is a plant (other than a plant included in Schedule 8 or 9) that plant or any part of that plant when packed or prepared for therapeutic use;
- (c) every salt, active principle or derivative of the substance, including esters and ethers, and every salt of such an active principle or derivative;
- (d) every alkaloid of the substance and every salt of such an alkaloid;
- (e) every stereoisomer of the substance and every salt of such a stereoisomer;

- (f) every recombinant form of the substance;
- (g) a preparation or admixture containing any proportion of the substance.
- Note: Part 2 (controls on substances) does not apply in relation to certain substances (see section 11).

#### 8 References to concentration, strength or quantity of substances

In this instrument, for a reference to a concentration, strength or quantity of a substance:

- (a) if the substance is present as a salt, active principle or derivative (including an ester or ether), the concentration, strength or quantity is calculated as the equivalent amount of the substance; and
- (b) the expression "1%" means:
  - (i) in the case of a liquid preparation, 1 g of the substance per 100 mL of the preparation; or
  - (ii) in the case of a solid, semi-solid or pressurised spray aerosol preparation, 1 g of the substance per 100 g of the preparation; and
  - (iii) any expression of greater or lesser percentages shall have a corresponding meaning; and
- (c) in the case of codeine, such concentration, strength or quantity is calculated as anhydrous codeine.

#### 9 References to boiling or distillation temperatures

In this instrument, a reference to a boiling or distillation temperature means that temperature at an atmospheric pressure of 101.325 kPa (760 mm of mercury).

#### 10 References to standards

A reference in this instrument to an Australian standard, an international standard or a standard of a foreign country is a reference to that standard as it exists from time to time.

## Part 2—Controls on substances

### **Division 1—Preliminary**

#### 11 Application of Part 2

This Part applies to a substance or preparation included in a schedule to this instrument, other than the following:

- (a) a preparation or product included in the table in clause 1 of Appendix A;
- (b) a substance included in the table in clause 3 of Appendix B when used in an area, sub-area or sub-sub-area of use specified in the table in relation to that substance;
- (c) a substance included in the table in clause 1 of Appendix G at a concentration not exceeding the concentration specified in that table in relation to that substance;
- (d) any other substance included in Schedules 1 to 6, at a concentration not exceeding 10 mg per litre or 10 mg per kilogram, unless that substance is also included in Schedule 7 or 8;
- (e) any substance present as an impurity in a pesticide, at a concentration at or below the maximum content for that substance, specified for the pesticide in the Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022, published by the Australian Pesticides and Veterinary Medicines Authority, as existing from time to time.
- Note: For paragraph (e), the *Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022* is a legislative instrument that could in 2023 be accessed at www.legislation.gov.au.

#### 12 Preparations containing poisons included in different schedules

- (1) If a preparation contains 2 or more poisons, the provisions relating to each of the schedules in which those poisons are included apply to the preparation.
- (2) However, if it is not possible to comply both with a provision relating to one of those schedules and with a provision relating to another of those schedules, the provision relating to the more restrictive schedule applies, unless a contrary intention is indicated in the schedules or relevant State or Territory legislation.
- (3) The Schedules listed in order of greatest to least restrictiveness are 9, 10, 8, 4, 7, 3, 2, 6, 5.

Note: Schedule 1 is not currently in use.

## **Division 2—Labels**

## Subdivision A—General

#### **13** General requirements

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

#### 14 Immediate wrapper

If a poison is enclosed in an immediate wrapper:

- (a) the poison must be contained in a primary pack labelled in accordance with section 15; and
- (b) the immediate wrapper must be conspicuously labelled with:
  - (i) the name of the manufacturer or distributor or the brand name or trade name used exclusively by the manufacturer or distributor for that poison; and
  - (ii) the approved name of the poison; and
  - (iii) a statement of the quantity, proportion or strength of the poison in accordance with section 34.

### Subdivision B—Primary packs and immediate containers

#### 15 Primary packs and immediate containers

This Subdivision sets out how the primary pack and immediate container of a poison must be labelled.

#### 16 Signal words

- (1) The signal word or words for the poison, as shown in the following table, must be written:
  - (a) on the first line or lines of the main label; and
  - (b) in bold-face sans serif capital letters of uniform thickness; and
  - (c) subject to subsection (3), in letters at least half the height of the largest letter or numeral on the label; and
  - (d) with nothing else other than the following written on the same line or lines:
    - (i) if the poison is included in Schedule 5—a class label as specified in the Australian Dangerous Goods Code or a statement of the principal hazard of the poison;
    - (ii) if the poison is not included in Schedule 5—a class label as specified in the Australian Dangerous Goods Code.

Signal word or words for poisons			
Item	For a poison included in the following schedule	that is to be used for the following purpose 	the signal word or words are
1	Schedule 2	for any purpose	PHARMACY MEDICINE
2	Schedule 3	for any purpose	PHARMACIST ONLY MEDICINE
3	Schedule 4	for human use	PRESCRIPTION ONLY MEDICINE
4	Schedule 4	for animal use	PRESCRIPTION ANIMAL REMEDY
5	Schedule 5	for any purpose	CAUTION
6	Schedule 6	for any purpose	POISON
7	Schedule 7	for any purpose	DANGEROUS POISON
8	Schedule 8	for any purpose	CONTROLLED DRUG

(2) For the purposes of paragraph (1)(c), the largest letter or numeral does not include:

- (a) a single letter or numeral which is larger than other lettering on the label; or
- (b) an affix forming part of the trade name for the poison; or
- (c) in the case of a poison for therapeutic use—numerals used to distinguish the strength of a preparation from the strengths of other preparations of the same poison.
- (3) For the purposes of paragraph (1)(c), the letters need not be larger than:
  - (a) 6 mm on labels for packages having a nominal capacity of 2 L or less; or
  - (b) 15 mm on labels for packages having a nominal capacity of more than 2 L.

#### 17 Cautionary statement—possession without authority illegal

If the poison is included in Schedule 8, the cautionary statement:

#### POSSESSION WITHOUT AUTHORITY ILLEGAL

must be written:

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- (a) on a separate line or lines immediately below the signal words required by section 16; and
- (b) in **bold-face** sans serif capital letters of uniform thickness; and
- (c) in letters at least four-tenths the height of the letters used for the signal words; and
- (d) with no other statement written on the same line or lines.

#### 18 Cautionary statement—keep out of reach of children

The cautionary statement:

#### **KEEP OUT OF REACH OF CHILDREN**

must be written:

- (a) on a separate line or lines:
  - (i) immediately below the signal word or words required by section 16; or
  - (ii) if the cautionary statement "POSSESSION WITHOUT AUTHORITY ILLEGAL" is required by section 17—immediately below that statement; and
- (b) in bold-face sans serif capital letters of uniform thickness; and
- (c) in letters at least four-tenths the height of the letters used for the signal word or words; and
- (d) with nothing, other than a class label as specified in the Australian Dangerous Goods Code, written on the same line or lines.

#### 19 Cautionary statement—fire and explosion hazard

(1) If the poison is a dry chlorinating compound containing more than 10% of available chlorine, the cautionary statement:

#### FIRE AND EXPLOSION HAZARD

must be written:

- (a) on a separate line or lines immediately below the cautionary statement "KEEP OUT OF REACH OF CHILDREN" as required by section 18; and
- (b) in bold-face sans serif capital letters of uniform thickness; and
- (c) in letters at least four-tenths the height of the letters used for the signal word or words; and
- (d) with nothing, other than a class label as specified in the Australian Dangerous Goods Code, written on the same line or lines.
- (2) This section does not apply to a preparation certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5, Division 5.1: Oxidising substances, as specified in the Australian Dangerous Goods Code.

#### 20 Cautionary statement—burns skin and throat

If the poison is an alkaline salt in a dishwashing machine product, the cautionary statement:

#### **BURNS SKIN AND THROAT**

must be written:

- (a) on a separate line or lines immediately below the cautionary statement "KEEP OUT OF REACH OF CHILDREN" as required by section 18; and
- (b) in bold-face sans serif capital letters of uniform thickness; and
- (c) in letters at least four-tenths the height of the letters used for the signal word; and
- (d) with nothing, other than a class label as specified in the Australian Dangerous Goods Code, written on the same line or lines of the main label.

#### 21 Cautionary statements for aqueous solution of paraquat

If the poison is an aqueous solution of paraquat, the cautionary statements:

#### CAN KILL IF SWALLOWED

#### **DO NOT PUT IN DRINK BOTTLES**

#### **KEEP LOCKED UP**

must be written:

- (a) on separate lines immediately below the cautionary statement "KEEP OUT OF REACH OF CHILDREN" as required by section 18; and
- (b) in **bold-face** sans serif capital letters of uniform thickness; and
- (c) in letters at least four-tenths the height of the letters used for the signal words; and
- (d) with nothing, other than a class label as specified in the Australian Dangerous Goods Code, written on the same lines of the main label.

#### 22 Cautionary statement—read safety directions

(1) If safety directions are required on the label by section 29, the following cautionary statement:

#### **READ SAFETY DIRECTIONS BEFORE OPENING OR USING**

or the following cautionary statement:

#### **READ SAFETY DIRECTIONS**

must be written:

- (a) on a separate line or lines:
  - (i) immediately below the cautionary statement "KEEP OUT OF REACH OF CHILDREN" as required by section 18; or
  - (ii) if one or more other cautionary statements is required to be on the line immediately below "KEEP OUT OF REACH OF CHILDREN", immediately below that statement or those statements; and
- (b) in **bold-face** sans serif capital letters of uniform thickness; and
- (c) in letters at least four-tenths the height of the letters used for the signal word or words; and
- (d) with nothing, other than a class label as specified in the Australian Dangerous Goods Code, written on the same line or lines.
- (2) This section does not apply to a medicine for human use that is labelled in accordance with the required advisory statements for medicine labels.
## 23 Cautionary statement—flammable

If the poison meets the criteria for a "flammable liquid" in the Australian Dangerous Goods Code, the cautionary statement:

## FLAMMABLE

must be written on the main label in bold-face sans serif capital letters of uniform thickness, unless already present in accordance with the requirements of the Australian Dangerous Goods Code.

## 24 Cautionary statement—for animal treatment only

If the poison is only for the treatment of animals, the cautionary statement:

## FOR ANIMAL TREATMENT ONLY

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

## 25 Cautionary statement—do not swallow

If the poison is included in Schedule 5 and is intended for any purpose other than internal or pesticidal use, the cautionary statement:

## **DO NOT SWALLOW**

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

## 26 Approved name and quantity, proportion or strength

- (1) The approved name of the poison and a statement of the quantity, proportion or strength of the poison in accordance with section 34 must be:
  - (a) if the poison is for human therapeutic use—written on the main label in accordance with the standards for the goods specified in orders made under subsection 10(1) of the Act; or
  - (b) if the poison is not for human therapeutic use—written in bold-face sans serif capital letters on the main label, unless:
    - (i) a list of approved names is required; and
    - (ii) it is impractical to include the list on the main label; and
    - (iii) it is included on another part of the label in accordance with an authorisation given by an appropriate authority.
- (2) If the poison is included in Schedule 5 and is referred to in column 1 of an item of the following table, the appropriate name in column 2 of that item may be used as the approved name.

Appropriate names for poisons		
Item	Column 1 Poison	Column 2 Appropriate name
1	Alkaline salts	Alkaline salts

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Appropriate names for poisons			
Item	Column 1 Poison	Column 2 Appropriate name	
2	Amines for use as curing agents for epoxy resins (unless separately specified in the Schedules)	Aliphatic amines or aromatic amines	
3	Epoxy resins, liquid	Liquid epoxy resins	
4	Hydrocarbons, liquid	Liquid hydrocarbons	
5	Quaternary ammonium compounds	Quaternary ammonium compound(s)	

(3) If a poison contains a mixture of designated solvents in excess of 25% of the total volume of the poison but the proportion of one or more individual designated solvents in the mixture is equal to or less than 25%, the approved names of those solvents may be expressed as follows:

- (a) where the designated solvent is a liquid hydrocarbon—as "liquid hydrocarbons";
- (b) where the designated solvent is a ketone—as "ketones";
- (c) in any other case—as "solvents" or "other solvents".

## 27 Statement—an anticholinesterase compound

(1) If the poison is an organophosphorus compound or carbamate for pesticidal use or for the treatment of animals, the following expression:

## AN ANTICHOLINESTERASE COMPOUND

must be written immediately below the approved name or the list of declared contents on the label.

- (2) This section does not apply to:
  - (a) dazomet, mancozeb, metiram, propineb, thiram, tri-allate, zineb or ziram; or
  - (b) an organophosphorus compound or carbamate contained in impregnated plastic resin strips, medallions or granules; or
  - (c) an organophosphorus compound or carbamate contained in a pressurised spray pack for household use.

## 28 Directions for use

If the poison is prepared, packed or sold for a specific purpose, it must be labelled with clear and adequate directions for use, unless:

- (a) it is a medicine for human use that is labelled in accordance with:
  - (i) Therapeutic Goods Order No. 91 Standard for labels of prescription and related medicines; or
  - (ii) Therapeutic Goods Order No. 92 Standard for labels of non-prescription medicines; or
- (b) it is in an agricultural or veterinary chemical product labelled in compliance with the *Agricultural and Veterinary Chemicals Code Act* 1994; or
- (c) it is included in Schedule 4 or 8; or
- (d) all of the following apply:

- (i) it is impractical to include such directions on the label;
- (ii) the primary pack and the immediate container are labelled with the statement "DIRECTIONS FOR USE: See package insert";
- (iii) an appropriate authority has authorised the directions for use to be written on a package insert instead of the label;
- (iv) the insert is enclosed in the primary pack.

## **29** Safety directions

(1) If the poison is included in the table in clause 4 of Appendix F, it must be labelled with each safety direction required for the poison by that clause, grouped together as a distinct section of the label and prefaced by the words:

#### SAFETY DIRECTIONS

written in bold-face capital letters.

- (2) This section does not apply to the following:
  - (a) a poison that:
    - (i) is a medicine for human use; and
    - (ii) is labelled in accordance with the required advisory statements for medicine labels;
  - (b) a poison that:
    - (i) is an agricultural chemical or a veterinary chemical; and
    - (ii) is a registered chemical product within the meaning of the Agricultural and Veterinary Chemicals Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*.

## **30** Warning statements

- (1) If the poison is included in the table in clause 4 of Appendix F, it must be labelled with each warning statement required for the poison by that clause, grouped together:
  - (a) if safety directions are included on the label—immediately after the words "SAFETY DIRECTIONS"; or
  - (b) if there are no safety directions—immediately preceding the directions for use.
- (2) This section does not apply to the following:
  - (a) a poison that:
    - (i) is a medicine for human use; and
    - (ii) is labelled in accordance with the required advisory statements for medicine labels;
  - (b) a poison that:
    - (i) is an agricultural chemical or a veterinary chemical; and
    - (ii) is a registered chemical product within the meaning of the Agricultural and Veterinary Chemicals Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*.

## 31 First aid

- (1) If the poison is included in the table in clause 3 of Appendix E, it must be labelled with each statement required for the poison by clause 3 of Appendix E:
  - (a) grouped together and prefaced by the following words:

## FIRST AID

written in bold-face capital letters; or

- (b) if a primary pack contains 2 or more immediate containers of poisons each requiring different first aid instructions:
  - (i) written on each immediate container as specified in paragraph (a); and
  - (ii) replaced on the primary pack with the statement:

FIRST AID: See inner packs.

- (2) This section does not apply to the following:
  - (a) a poison that:
    - (i) is for human internal use; and
    - (ii) is included in Schedule 3, 4 or 8;
  - (b) a poison that:
    - (i) is a medicine for human use; and
    - (ii) is labelled in accordance with the required advisory statements for medicine labels;
  - (c) a poison that:
    - (i) is an agricultural chemical or a veterinary chemical; and
    - (ii) is a registered chemical product within the meaning of the Agricultural and Veterinary Chemicals Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*.

## 32 Name and address of manufacturer or distributor

- (1) The poison must be labelled with the name and address of its manufacturer or distributor. The address:
  - (a) must be a physical address in Australia; and
  - (b) must not be a post office, cable, telegraphic or code address.
- (2) However, if the manufacturer or distributor is a company incorporated under the law of a State or Territory, or a firm registered under a law of a State or Territory dealing with business names, the name and address may be:
  - (a) the registered name of the corporation or firm, or its branch or division; and
  - (b) the city or town in which a registered office of the company or firm is situated.

# 33 Warning statements and sedation warnings for certain medicines for human use

#### Warning statements for certain medicines

(1) A dispensed medicine for human use containing a poison included in column 1 of the table in clause 2 of Appendix L must be clearly labelled with each warning statement required for the poison by that clause.

#### Sedation warning for certain medicines

(2) A dispensed medicine for human use containing a poison included in Appendix K must be clearly labelled with a warning statement set out in item 39, 40 or 90 of the table in clause 1 of Appendix F.

## Subdivision C-Statements of quantity, proportion or strength

## 34 Statements of quantity, proportion or strength

- (1) The statement of the quantity, proportion or strength of a poison must be expressed in the most appropriate of the following forms:
  - (a) if the poison is for human therapeutic use—the manner required by the standards for the goods specified in orders made under subsection 10(1) of the Act;
  - (b) if the poison is for a purpose or purposes other than human therapeutic use—as follows:
    - (i) if the poison is in a pressurised spray aerosol preparation—as the mass of the poison per stated mass of the preparation;
    - (ii) if the poison is a liquid in a liquid preparation—as the mass or volume of the poison per stated volume of the preparation;
    - (iii) if the poison is a liquid in a solid or semi-solid preparation—as the mass or volume of the poison per stated mass of the preparation;
    - (iv) if the poison is a solid or semi-solid in a liquid preparation—as the mass of the poison per stated volume of the preparation;
    - (v) if the poison is a solid or semi-solid in a solid or semi-solid preparation—as the mass of the poison per stated mass of the preparation;
    - (vi) if the poison is a gas in a liquid preparation—as the mass of the poison per stated volume of the preparation;
    - (vii) if the poison is a gas in a solid or semi-solid preparation—as the mass of the poison per stated mass of the preparation;
    - (viii) if the poison is a gas in a gaseous preparation—as the mass of the poison per stated mass of the preparation;
  - (c) if the poison is a solution of a mineral acid, the proportion of the acid (un-neutralised by any bases present in the preparation) in a preparation may be expressed as the un-neutralised mass of the acid per stated mass of the preparation;
  - (d) if the poison is an inorganic pigment, the proportion may be expressed as a percentage of the metal present using one of the following expressions as appropriate:

- (i) "contains not more than 10 per cent of (insert name of the metal)";
- (ii) "contains not more than 30 per cent of (insert name of the metal)";
- (iii) "contains more than 30 per cent of (insert name of the metal)";
- (e) if the poison is included in a paint, other than a paint for therapeutic or cosmetic use, the proportion may be expressed as a range provided that the limits of the range do not differ by more than 5% of the product;
- (f) if the poison is a lead-based pigment included in automotive paint, the proportion may be expressed as the maximum content of the lead that may be present in the non-volatile content of the paint;
- (g) if a preparation contains more than one derivative of a poison, the quantity or proportion of the poison may be expressed as the equivalent quantity or proportion of one of the derivatives present which it would contain if all of the derivatives were that derivative.
- (2) In paragraph (1)(g):

derivative includes alkaloid.

Note: For requirements to state the quantity, proportion or strength of a poison, see subparagraph 14(b)(iii), section 26 and sub-subparagraphs 35(b)(ii)(B) and 36(1)(b)(ii)(A) and (2)(b)(iii)(B).

## Subdivision D—Exemptions from labelling requirements

## 35 Selected containers and measure packs

The requirements of Subdivision B do not apply to an immediate container of poison that is a measure pack or a selected container (other than an ampoule, a pre-filled syringe or an injection vial to which subsections 36(1) or (2) applies) if:

- (a) the poison is therapeutic goods and is labelled in accordance with the standards for the goods specified in orders made under subsection 10(1) of the Act; or
- (b) the immediate container is:
  - (i) packed in a primary pack labelled in accordance with Subdivision B; and
  - (ii) labelled with:
    - (A) the signal word or words for the poison as shown in the table in subsection 16(1); and
    - (B) the approved name of the poison and the quantity, proportion or strength of the poison in accordance with section 34; and
    - (C) the name of the manufacturer or distributor or the brand name or trade name used exclusively by the manufacturer or distributor for the poison; and
    - (D) if the poison is only for the treatment of animals—the cautionary statement:

FOR ANIMAL TREATMENT ONLY

written in sans serif capital letters.

## 36 Ampoules, pre-filled syringes and injection vials

- (1) The requirements of Subdivision B do not apply to a selected container of poison or an ampoule of poison (other than an ampoule to which subsection (2) applies) when:
  - (a) the poison is therapeutic goods and is labelled in accordance with the standards for the goods specified in orders made under subsection 10(1) of the Act; or
  - (b) the selected container or ampoule is:
    - (i) packed in a primary pack labelled in accordance with Subdivision B; and
    - (ii) labelled with:
      - (A) the approved name of the poison and the quantity, proportion or strength of the poison in accordance with section 34; and
      - (B) the name of the manufacturer or distributor or the brand name or trade name used exclusively by the manufacturer or distributor for the poison; and
      - (C) if the poison is only for the treatment of animals—the cautionary statement:

#### FOR ANIMAL TREATMENT ONLY

written in sans serif capital letters.

- (2) The requirements of Subdivision B do not apply to a selected container of poison that is a plastic ampoule that is continuous with a strip of the same material and opens as it is detached from the strip when:
  - (a) the poison is therapeutic goods and is labelled in accordance with the standards for the goods specified in orders made under subsection 10(1) of the Act; or
  - (b) the poison is not therapeutic goods and all of the following apply:
    - (i) the ampoule is packed in a primary pack labelled in accordance with Subdivision B;
    - (ii) the strip is labelled in accordance with this section;
    - (iii) the ampoule is labelled with:
      - (A) the approved name of the poison or the trade name of the poison; and
      - (B) the quantity, proportion or strength of the poison in accordance with section 34.

## 37 Transport containers and wrappings

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

## 38 Dispensary, industrial, laboratory and manufacturing poisons

The labelling requirements of this instrument do not apply to a poison that:

(a) is packed and sold solely for dispensary, industrial, laboratory or manufacturing purposes; and

(b) is labelled in accordance with requirements under applicable jurisdictional work health and safety laws, as in force from time to time.

#### **39** Exemptions from label requirements in certain circumstances

- (1) A requirement specified in Subdivision B or section 35 or 37 does not apply to a poison if an appropriate authority has granted a labelling exemption under this subsection in relation to that requirement for the poison.
- (2) A labelling exemption granted by an appropriate authority under subsection (1) remains in force:
  - (a) if the exemption relates to a product that is indicated for the treatment or prevention of the coronavirus known as COVID-19:
    - (i) for the period specified in the exemption; or
    - (ii) if no period is specified—until revoked by the appropriate authority; or
  - (b) in any other case:
    - (i) for the period, specified in the exemption, that is 12 months or less from the date of commencement of the exemption; or
    - (ii) if no period is specified—12 months from the date of commencement of the exemption.
- (3) For the avoidance of doubt, this section does not apply to an authorisation given under subparagraph 28(d)(iii).

## 40 Dispensed medicines

Unless otherwise specified in relevant State or Territory legislation and subject to section 33, the labelling requirements of this instrument do not apply to a medicine that:

- (a) is:
  - (i) supplied by an authorised prescriber; or
  - (ii) supplied on and in accordance with a prescription written by an authorised prescriber; or
  - (iii) prepared and supplied by a pharmacist for an individual patient; and
- (b) is labelled in accordance with the requirements of clause 1 of Appendix L.

#### 41 Gas cylinders

The requirements of paragraph 16(1)(d) and paragraphs 18(d) and 22(1)(d) do not apply to a cylinder containing a poison that is a compressed gas.

## 42 Paints

The requirements of Subdivision B do not apply to:

- (a) a paint (other than a paint for therapeutic or cosmetic use) that contains only poisons included in Schedule 5; or
- (b) a first group paint or second group paint that is labelled with:

- (i) the word "WARNING", written in bold-face sans serif capital letters, the height of which is not less than 5 mm, on the first line of the main label with no other words written on that line; and
- (ii) the expression "KEEP OUT OF REACH OF CHILDREN", written in bold-face sans serif capital letters, the height of which is not less than 2.5 mm, on a separate line immediately below the word "WARNING"; and
- (iii) the appropriate warnings required for the paint by clause 4 of Appendix F, written immediately below the expression "KEEP OUT OF REACH OF CHILDREN"; and
- (iv) the name and proportion of the first group or second group poisons it contains, provided that where the substance is a metal or metal salt the proportion is expressed as the metallic element present "calculated on the non-volatile content" or "in the dried film" of the paint; or
- (c) a tinter which contains only poisons included in Schedule 5; or
- (d) a tinter that contains a poison mentioned in a table in section 67 or 68, if:
  - (i) the tinter is labelled with the name and proportion of the poison; and
  - (ii) if the poison is a metal or metal salt—the proportion is expressed as the metallic element present as "calculated on the non-volatile content" or "in the dried film".

## 43 Camphor and naphthalene

The labelling requirements of paragraph 13(2)(d) and Subdivision B do not apply to a device that contains camphor or naphthalene in block, ball, disc, pellet or flake form if the device:

- (a) complies with section 52; and
- (b) is sold or supplied in a primary pack labelled in accordance with section 13 and Subdivision B.

# Subdivision E—Prohibitions

## 44 **Prohibitions**

- (1) A label used in connection with a poison must not include:
  - (a) any reference to this instrument, or any comment on, reference to, or explanation of any expression required by this instrument that directly or by implication contradicts, qualifies or modifies such expression; or
  - (b) any expression or device suggesting or implying that the poison is safe, harmless, non-toxic, non-poisonous, or is recommended or approved by a government or government authority unless required by legislation; or
  - (c) any expression or device which is false or misleading in any particular concerning the safety of the poison or any of its ingredients; or
  - (d) any trade name or description that:
    - (i) represents any single constituent of a compound preparation; or
    - (ii) misrepresents the composition or any property or quality of the poison; or
    - (iii) gives any false or misleading indication of origin or place of manufacture of the poison.

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(2) A label must not be attached to the immediate container or primary pack used in connection with any poison in such a manner as to obscure any of the ribs or any expression required by this instrument to be written or embossed on the container or pack.

# **Division 3—Containers**

## 45 General requirements

A poison must not be supplied unless the requirements of this Division for the immediate container for the poison are met.

## 46 Containers for poisons other than poisons included in Schedule 5

- (1) If a poison, other than a poison included in Schedule 5, is supplied in a container with a nominal capacity of 2 L or less, the container must comply with Australian Standard AS 2216-1997, *Packaging for poisonous substances*.
- (2) Despite subsection (1), a poison included in Schedule 6 that is an essential oil may be packed in an amber glass container which does not comply with the tactile identification requirements of Australian Standard AS 2216-1997, *Packaging for poisonous substances*, if:
  - (a) other safety factors are not diminished; and
  - (b) the container has a restricted flow insert and a child-resistant closure.
- (3) If a poison, other than a poison included in Schedule 5, is supplied in a container with a nominal capacity of more than 2 L:
  - (a) the container must comply with subsection 1.4 (General Requirements) of Australian Standard AS 2216-1997, *Packaging for poisonous substances*; and
  - (b) the word "POISON" must be embossed, or indelibly written in a colour in distinct contrast to the background colour, on the side or shoulder of the container, in sans serif capital letters the height of which is at least one thirty-second part of the length, height or width of the container, whichever is the greatest.

## 47 Containers for poisons included in Schedule 5

- (1) The container in which a poison included in Schedule 5 is supplied must:
  - (a) comply with the container requirements of subsection 46(1) or (3); or(b) comply with subsection (2).
  - (b) comply with subsection (2).
- (2) A container complies with this subsection if:
  - (a) it is readily distinguishable from a container in which food (including a condiment) or drink is sold; and
  - (b) it complies with subsection 1.4 (General Requirements) of Australian Standard AS 2216-1997, *Packaging for poisonous substances*, excluding paragraph 1.4.3; and
  - (c) it is securely closed and, except when containing a preparation for use on one occasion only, is capable of being re-closed to prevent spillage of its contents; and
  - (d) the expression "POISON", "NOT TO BE TAKEN" or "NOT TO BE USED AS A FOOD CONTAINER" is:
    - (i) embossed or indelibly written on the container; or

- (ii) printed on a label that complies with subsection (3) that is attached to the container.
- (3) For the purposes of subparagraph (2)(d)(ii), the label must be a permanent adhesive label designed to adhere to a substrate without lifting and which cannot be removed without damaging either the label or the substrate.
- (4) Despite subsection (1), the following poisons included in Schedule 5:
  - (a) methylated spirit(s);
  - (b) liquid hydrocarbons when packed as kerosene, lamp oil, mineral turpentine, thinners, reducers, white petroleum spirit or dry cleaning fluid;
  - (c) petrol;
  - (d) toluene;
  - (e) xylene;

must not be supplied in a bottle or jar having a nominal capacity of 2 L or less, unless the immediate container complies with the container requirements of subsection 46(1).

## 48 Approved containers

Despite subsections 46(1) and (3) and section 47, a poison may be packed in a container that does not comply with the tactile identification requirements of AS2216-1997 (*Packaging for poisonous substances*) or the requirements of paragraph 46(3)(b) or 47(2)(d) if:

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

#### 49 Child-resistant closures

- (1) If a poison specified in column 1 of an item of the following table is supplied in a container having a nominal capacity specified in column 2 of the item, it must be closed with a child-resistant closure that:
  - (a) is appropriate for the container and the poison; and
  - (b) will retain its child-resistant properties for the expected life of the poison.

Item	Column 1 Poison	Column 2 Nominal capacity of container
1	Alkaline salts included in Schedule 5, when packed and labelled as dishwashing machine tablets	All sizes
2	Alkaline salts included in Schedule 5, when packed and labelled as dishwashing machine liquids, solids or gels	5 L/kg or less
3	Alkaline salts included in Schedule 5, when packed and labelled as a food additive	2.5 L or less
4	Anise oil when included in Schedule 5	200 mL or less
5	Basil oil when included in Schedule 5	200 mL or less

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Item	Column 1 Poison	Column 2 Nominal capacity of container
6	Bay oil when included in Schedule 6	200 mL or less
7	Cajuput oil when included in Schedule 6	200 mL or less
8	Cassia oil when included in Schedule 5	200 mL or less
9	Cineole when included in Schedule 6	2 L or less
10	Cinnamon bark oil when included in Schedule 5	200 mL or less
11	Cinnamon leaf oil when included in Schedule 6	200 mL or less
12	Clove oil when included in Schedule 6	200 mL or less
13	CYCLOSILAZANES, DI-ME, ME HYDROGEN, POLYMERS WITH DI-ME, ME HYDROGEN SILAZANES, REACTION PRODUCTS WITH 3-(TRIETHOXYSILYL)-1-PROPANAMINE (CAS 475645-84-2) when included in Schedule 6, when presented in a wipe	All sizes
14	Essential oils when included in Schedule 6 because of their natural camphor component	200 mL or less
15	Ethylene glycol when included in Schedule 6	5 L or less
16	Ethylene glycol when included in Schedule 5 in preparations containing more than 50% of ethylene glycol	5 L or less
17	Eucalyptus oil when included in Schedule 6	2 L or less
18	Eugenol when included in Schedule 6	200 mL or less
19	Fennel oil when included in Schedule 5	200 mL or less
20	Hydrocarbons, liquid, when packed as kerosene, lamp oil, mineral turpentine, thinners, reducers, white petroleum spirit or dry cleaning fluid	5 L or less
21	Hydrochloric acid when included in Schedule 6	5 L or less
22	Leptospermum scoparium oil (manuka oil) when included in Schedule 6	200 mL or less
23	Marjoram oil when included in Schedule 5	200 mL or less
24	Melaleuca oil (tea-tree oil) when included in Schedule 6	200 mL or less
25	Methylated spirit excluding preparations or admixtures	5 L or less
26	Methyl salicylate and preparations containing more than 50% of methyl salicylate	200 mL or less
27	Nicotine in liquid preparations when included in Schedule 3 or 4.	All sizes
28	Nutmeg oil when included in Schedule 5	200 mL or less
29	Oil of turpentine	5 L or less
30	Paracetamol included in Schedule 4, when packed and labelled for the treatment of animals	All sizes
31	Pennyroyal oil when included in Schedule 6	200 mL or less
32	Potassium hydroxide as such	2.5 L or less

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Poisons that must be closed with a child-resistant closure		
Item	Column 1 Poison	Column 2 Nominal capacity of container
33	Potassium hydroxide in oven, hot plate or drain cleaners when included in Schedule 6 <b>except</b> when in pressurised spray packs	5 L or less
34	<b>D</b> -Pulegone when included in Schedule 6	200 mL or less
35	Sage oil (Dalmatian) when included in Schedule 6	200 mL or less
36	Sodium hydroxide as such	2.5 L or less
37	Sodium hydroxide in oven, hot plate or drain cleaners when included in Schedule 6 <b>except</b> when in pressurised spray packs	5 L or less
38	Thujone when included in Schedule 6	200 mL or less
39	Thyme oil when included in Schedule 5	200 mL or less

(2) This section does not apply to a poison included in therapeutic goods that are packaged in accordance with the standards for the goods specified in orders made under subsection 10(1) of the Act.

## 50 Poisons included in Schedule 8

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

## 51 Exemptions

- (1) Subsections 46(1) and (3) and section 47 do not apply to the immediate container of a poison prepared, packed and sold:
  - (a) for human internal or animal internal use; or
  - (b) as a solid or semi-solid preparation for human external or animal external use; or
  - (c) as a paint, other than a paint for therapeutic or cosmetic use; or
  - (d) in containers having a nominal capacity of 15 mL or less; or
  - (e) for use in automatic photographic or photocopy processing machines if the container is specifically designed to fit into the machines; or
  - (f) solely for dispensary, industrial, laboratory or manufacturing purposes.

- (2) Section 49 does not apply to a poison prepared, packed and sold solely for dispensary, industrial, laboratory or manufacturing purposes.
- (3) The tactile identification or embossing required by subsections 46(1) and (3) and section 47 or Australian Standard AS 2216-1997, *Packaging for poisonous substances*, do not apply to a container that is an aerosol container, a collapsible tube, or a measure pack which is a flexible sachet.

## 52 Camphor and naphthalene

- The container requirements of subsection 46(1) do not apply to a device that contains only camphor or naphthalene in block, ball, disc, pellet or flake form for domestic use, if the device:
  - (a) in normal use, prevents removal or ingestion of its contents; and
  - (b) is incapable of reacting with the poison; and
  - (c) is sufficiently strong to withstand the ordinary risks of handling, storage or transport; and
  - (d) has the word "POISON" and the approved name of the poison embossed or indelibly printed on it.
- (2) Camphor or naphthalene must not be supplied in ball, block, disc, pellet or flake form for domestic use unless the balls, blocks, discs, pellets or flakes are enclosed in a device which prevents removal or ingestion of its contents.

#### 53 Prohibitions—use of containers for poisons

- (1) A poison must not be supplied in a container that is embossed or indelibly marked with the name of another poison.
- (2) A container that complies with subsection 46(1) or (3) or section 47 must not be used to supply a poison for internal use.
- (3) A container that complies with subsection 46(1) or (3) or section 47 must not be used to supply food (including a condiment) or drink.
- (4) A poison must not be supplied in a container that is not readily distinguishable from a container in which food (including a condiment) or drink is sold.

Part 2 Controls on substances Division 4 Storage

Section 54

## **Division 4—Storage**

## 54 General storage requirements

Poisons included in Schedule 2

(1) A poison included in Schedule 2 that is stored at premises for supply to the public must be stored in such a way that public access to advice from a pharmacist is available if required.

Poisons included in Schedules 3 and 4

(2) A poison included in Schedule 3 or 4 that is stored at premises for supply to the public must be stored in a part of the premises to which the public does not have access.

Poisons included in Schedule 6

(3) A poison included in Schedule 6 that is stored at premises for supply by way of retail sale must be stored in such a way as to prevent access by children.

Poisons included in Schedule 7

- (4) A poison included in Schedule 7 that is stored at premises for supply by retail sale must be stored in an area of the premises, and in a manner, that allows physical access only by the following:
  - (a) the owner of the retail establishment;
  - (b) an employee of the owner;
  - (c) a person who is legally permitted to purchase the poison and is under the supervision of the owner or an employee of the owner.

# **Division 5—Disposal**

## 55 General disposal requirements

A poison included in Schedule 5, 6 or 7 must not be disposed of in any place or manner that constitutes or is likely to constitute a risk to public health or safety.

Note: Controls on the disposal of poisons included in Schedules 2, 3, 4 and 8 are dealt with in State and Territory legislation.

# **Division 6—Record keeping**

## 56 General record-keeping requirements

- (1) If a poison included in Schedule 7 is supplied, a record of the following must be kept:
  - (a) the name and address of the supplier and of the purchaser;
  - (b) the date of the order and supply;
  - (c) the approved name or trade name of the poison;
  - (d) the quantity supplied or sold;
  - (e) if an authorisation is required for purchase of the poison under the law of the jurisdiction in which the purchaser purchases the poison—proof that the purchaser has the required authorisation.
- (2) The records mentioned in subsection (1) must be kept for at least 5 years.
  - Note: Controls on record keeping for the supply of poisons included in Schedules 2, 3, 4 and 8 are dealt with in State and Territory legislation.

# **Division 7—Advertising**

## 57 General advertising requirements

Poisons included in Schedule 3, 4 and 8

- (1) A reference to a poison included in:
  - (a) Schedule 3, unless included in Appendix H; or
  - (b) Schedule 4; or
  - (c) Schedule 8;

must not be included in any advertisement except in genuine professional or trade journals or other publications intended for circulation only within the medical, nursing, veterinary, dental or pharmaceutical professions or the wholesale drug industry.

Poisons included in Schedules 9 and 10

(2) A reference to a poison included in Schedule 9 or Schedule 10 must not be included in any advertisement.

Note: Schedule 10 includes poisons previously listed in Appendix C.

# Division 8—Supply, prescribing, possession or use

## 58 Poisons included in Schedule 2

- (1) A poison included in Schedule 2 must not be supplied by a person other than:
  - (a) a person who:
    - (i) is a pharmacist (or an assistant under the direction of a pharmacist) or a medical practitioner, dental practitioner or veterinarian; and
    - (ii) is acting in the lawful practice of the person's profession; or
  - (b) a person who is licensed to supply the poison under the law of the jurisdiction from which the person will supply the poison.
- (2) A person is not eligible to be granted a licence to supply a poison included in Schedule 2 unless:
  - (a) the person is carrying on the business of supplying goods by retail sale; and
  - (b) the premises from which the poison will be supplied is more than 25 km by the shortest practicable route from the nearest pharmacy; and
  - (c) if required by the law of the jurisdiction from which the person will supply the poison—the person produces evidence that the person is a fit and proper person to be so licensed.
- (3) Subsection (1) does not apply to the supply of a poison included in Schedule 2 by way of wholesale dealing to:
  - (a) a pharmacist, medical practitioner, dental practitioner or veterinarian; or
  - (b) another person who is licensed or otherwise authorised, under the law of the jurisdiction from which the person supplies the poison, to possess or supply the poison.

## 59 Poisons included in Schedule 3

- (1) A poison included in Schedule 3 must not be supplied by a person other than a person who:
  - (a) is a pharmacist, medical practitioner, dental practitioner or veterinarian; and
  - (b) is acting in the lawful practice of the person's profession.
- (2) The following requirements apply if a poison included in Schedule 3 is supplied:
  - (a) adequate instructions for use, either written or verbal, must be provided at the time of supply;
  - (b) the container of the poison must be labelled with:
    - (i) the name of the supplier or the name of the pharmacy (as applicable); and
    - (ii) the address from which it was supplied;
  - (c) if required by the law of the jurisdiction from which the supplies the poison—a record of the transaction must be made in a prescription book or other approved recording system.
- (3) This section does not apply to the supply of a poison included in Schedule 3 by way of wholesale dealing to:
  - (a) a pharmacist, medical practitioner, dental practitioner or veterinarian; or

(b) another person who is licensed or otherwise authorised, under the law of the jurisdiction from which the person supplies the poison, to possess or supply the poison.

## 60 Poisons included in Schedule 4

- (1) A poison included in Schedule 4 must not be supplied by a person other than:
  - (a) a person who:
    - (i) is a medical practitioner, dental practitioner or veterinarian; and
    - (ii) is acting in the lawful practice of the person's profession; or
  - (b) a pharmacist dispensing a legal prescription for the poison; or
  - (c) a pharmacist supplying the poison without a prescription as permitted by subsection (2).
- (2) A poison included in Schedule 4 may be supplied to a person (the *patient*) by a pharmacist without a prescription if:
  - (a) the poison is not excepted from this provision by the law of the jurisdiction from which the pharmacist supplies the poison; and
  - (b) the patient is under medical treatment with the poison and continuation of medication is essential; and
  - (c) the quantity supplied does not exceed 3 days' medication; and
  - (d) the pharmacist is satisfied that an emergency exists.
- (3) Subsection (1) does not apply to the supply of a poison included in Schedule 4 by way of wholesale dealing to:
  - (a) a pharmacist, medical practitioner, dental practitioner or veterinarian; or
  - (b) another person who is licensed or otherwise authorised, under the law of the jurisdiction from which the person supplies the poison, to possess or supply the poison.

## 61 Poisons included in Schedules 5 and 6

- (1) A product sample containing a poison included in Schedule 5 or 6 must not be supplied in any manner unless the recipient has the opportunity to refuse at the time of supply.
- (2) A product sample containing a poison included in Schedule 5 or 6 must not be supplied in an unsolicited manner (for example by post or by attaching the sample to another product).
- (3) A product sample containing a poison included in Schedule 5 or 6 must not be supplied in a manner that does not promote disposal in accordance with Division 5.

## 62 Poisons included in Schedule 7

Possession or use for domestic or domestic garden purposes prohibited

(1) A poison included in Schedule 7 must not be possessed or used for domestic or domestic garden purposes.

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Supply for domestic or domestic garden purposes prohibited

(2) A poison included in Schedule 7 must not be supplied for domestic or domestic garden purposes.

Supply of liquid preparations containing paraquat

(3) A poison included in Schedule 7 that is a liquid preparation containing paraquat must not be supplied unless it is coloured blue or green and contains sufficient stenching agent to produce an offensive smell.

Supply if authorisation required by appropriate authority

(4) A poison included in Schedule 7 for which an authorisation to purchase, possess or use is required by the appropriate authority must not be supplied unless the purchaser produces the required authorisation.

Product samples prohibited

(5) A product sample containing a poison included in Schedule 7 must not be supplied.

Supply of poisons included in Appendix J

(6) A poison included in Schedule 7 that is included in the table in clause 1 of Appendix J may be supplied only in accordance with that clause.

## 63 Poisons included in Schedule 10

A poison included in Schedule 10 must not be possessed, supplied or used for a purpose indicated in relation to that poison in Schedule 10.

Note: Schedule 10 includes poisons previously listed in Appendix C.

## 64 Poisons included in Schedule 4 or 8 and Appendix D

(1) This section applies to a poison included in Schedule 4 or 8.

Supply or prescribing

- (2) A poison included in a table in clause 1, 2, 3, 4, 6 or 7 of Appendix D must not be supplied, other than by way of wholesale dealing, or prescribed, except in accordance with the clause that contains the table.
- (3) A poison referred to in clause 8 or 10 of Appendix D must not be supplied, other than by way of wholesale dealing, or prescribed, except in accordance with clause 8 or 10 (as applicable) of Appendix D.

Possession

(4) A poison included in the table in clause 5 of Appendix D must not be possessed by a person without authority under the law of the jurisdiction in which the possession occurs.

#### Storage

(5) A poison included in the table in clause 9 of Appendix D must be stored in a locked container to prevent unauthorised access.

# 65 Hawking

A poison included in Schedule 7 must not be supplied by way of hawking.

Note: Controls on supply by way of hawking of poisons included in Schedules 2, 3, 4 and 8 are dealt with in State and Territory legislation.

# **Division 9—Paints and tinters**

Note: Paints and tinters are poisons that were previously listed in Appendix I.

## 66 General requirements

- (1) A first group paint must not be manufactured, supplied or used for application to:
  - (a) a roof or any surface to be used for the collection or storage of potable water; or
  - (b) furniture; or
  - (c) any fence, wall, post, gate or building (interior or exterior) other than a building that is used exclusively for industrial purposes or mining or as an oil terminal; or
  - (d) any premises used for the manufacture, processing, preparation, packing or serving of products intended for human or animal consumption.
- (2) An anti-fouling paint containing more than 0.1% lead (the proportion of lead for the purposes of this section is calculated as a percentage of the element present in the non-volatile content of the paint) must not be manufactured, supplied or used.
- (3) A paint (other than an anti-fouling paint) or tinter containing more than 0.009% lead (calculated as a percentage of the element present in the non-volatile content of the paint) must not be manufactured, supplied or used.
- (4) A paint for application to toys must not be manufactured, supplied or used unless it complies with the specification for coating materials contained in Australian/New Zealand Standard AS/NZS ISO 8124.3:2012, Safety of toys Part 3: Migration of certain elements (ISO 8124-03:2010, MOD), published jointly by, or on behalf of, Standards Australia and Standards New Zealand.
- (5) A paint or tinter containing a pesticide other than a fungicide, algaecide, bactericide or antifouling agent must not be manufactured, supplied or used.

## 67 Definition of first group paint

A paint containing a substance mentioned in column 1 of an item in the following table in the proportion (calculated as a percentage of the element present in the non-volatile content of the paint) specified in column 2 of the item is a *first group paint*.

First g	First group paints		
Item	Column 1 Substance	Column 2 Proportion	
1	ANTIMONY or antimony compounds other than antimony titanate pigments	more than 5%	
2	BARIUM salts except barium sulfate or barium metaborate	more than 5%	
3	CADMIUM or cadmium compounds	more than 0.1%	
4	CHROMIUM as chromates of ammonia, barium, potassium sodium, strontium or zinc	more than 5%	
5	SELENIUM or selenium compounds	more than 0.1%	

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# 68 Definition of second group paint

A paint containing a substance mentioned in column 1 of an item in the following table in the proportion specified in column 2 of the item is a *second group paint*.

Second group paints		
Item	Column 1 Substance	Column 2 Proportion
1	DICHLOROMETHANE (methylene chloride)	more than 5% by weight
2	ETHYLENE GLYCOL MONOALKYL ETHERS and their acetates	more than 10% by volume
3	HEXYLOXYETHANOL	more than 10% by volume
4	TOLUENE	more than 50% by volume
5	XYLENE	more than 50% by volume

# Schedule 1—Blank

Note: Schedule 1 is intentionally blank.

# Schedule 2—Pharmacy medicines

- Note: See section 16, subsection 54(1) and section 58.
- ACETIC ACID (excluding its salts and derivatives) and preparations containing more than 80% of acetic acid (CH<sub>3</sub>COOH) for therapeutic use.
- ACETYLCYSTEINE in preparations for oral use **except** when labelled with a recommended daily dose of 1 g or less of acetylcysteine.

ACONITUM spp. for therapeutic use in adults:

- (a) in preparations for oral use in packs each containing 0.2 mg or less of total alkaloids **except** in packs containing 0.02 mg or less of total alkaloids; or
- (b) in preparations for dermal use containing 0.02% or less of total alkaloids, in packs each containing 0.2 mg or less of total alkaloids except in packs containing 0.02 mg or less of total alkaloids.
- ALIMEMAZINE when combined with one or more other therapeutically active substances in solid oral preparations when:
  - (a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
  - (b) in a day-night pack containing alimemazine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper;

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

#### ALOXIPRIN.

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

ANTAZOLINE in eye drops.

#### ASPIRIN except when:

- (a) included in Schedule 4, 5 or 6; or
- (b) in individually wrapped powders or sachets of granules each containing 650 mg or less of aspirin as the only therapeutically active constituent other than when combined with an effervescent agent, that are:
  - (i) enclosed in a primary pack that contains 12 or less individually wrapped powders or sachets of granules; and
  - (ii) compliant with the requirements of the required advisory statements for medicine labels; or
- (c) in tablets or capsules containing aspirin as the only therapeutically active constituent other than when combined with an effervescent agent, that are:
  - (i) either:
    - (A) packed in blister or strip packing; or

- (B) in a container with a child-resistant closure; and
- (ii) either:
  - (A) in a primary pack that contains not more than 25 tablets or capsules, each containing 325 mg or less of aspirin; or
  - (B) in a primary pack that contains not more than 16 tablets or capsules, each containing 500 mg or less of aspirin; or
  - (C) in a primary pack that contains not more than 100 tablets or capsules, each containing 100 mg or less of aspirin, and that is labelled for the prevention of cardiovascular disease or for the inhibition of platelet aggregation; and
- (iii) compliant with the requirements of the required advisory statements for medicine labels.

ASTODRIMER SODIUM when used in a nasal spray.

#### ATROPA BELLADONNA (belladonna):

- (a) for external use in preparations containing 0.03% or less of total solanaceous alkaloids; or
- (b) for oral use in adults and children 6 years of age and over:
  - (i) in undivided preparations containing 0.03% or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
  - (ii) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit, when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

ATROPINE (excluding atropine methonitrate) for oral use:

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

AZELAIC ACID in dermal preparations for human therapeutic use.

#### AZELASTINE:

- (a) in preparations for nasal use; or
- (b) in topical eye preparations containing 0.05% or less of azelastine.
- BECLOMETASONE in aqueous nasal sprays delivering 50 micrograms or less of beclometasone per actuation when the maximum recommended daily dose is no greater than 400 micrograms and when packed in a primary pack containing 200 actuations or

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less, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.

BENZOCAINE in preparations for topical use other than eye drops:

- (a) containing 10% or less of total local anaesthetic substances, **except** in dermal preparations containing 2% or less of total local anaesthetic substances; or
- (b) in divided preparations containing 200 mg or less of total local anaesthetic substances per dosage unit, except in lozenges containing 30 mg or less of total local anaesthetic substances per dosage unit.
- BENZOYL PEROXIDE in preparations for human external therapeutic use containing 10% or less of benzoyl peroxide **except** in preparations containing 5% or less of benzoyl peroxide.

BENZYDAMINE in preparations for topical use, except:

- (a) in preparations for dermal use; or
- (b) in divided topical oral preparations containing 3 mg or less of benzydamine; or
- (c) in undivided topical oral preparations containing 0.3% or less of benzydamine in a primary pack containing not more than 50 mL.
- BEPHENIUM SALTS.

BIFONAZOLE in preparations for dermal use except:

- (a) in preparations containing 1% or less of bifonazole for the treatment of the scalp; or
- (b) in preparations for the treatment of tinea pedis.
- BILASTINE in oral preparations when labelled with a recommended daily dose not exceeding 20 mg bilastine for the treatment of adults and children aged 12 years and over.

## BISACODYL in divided preparations for:

- (a) oral use **except** in a primary pack containing 20 dosage units or less containing 5 mg or less of bisacodyl per dosage unit; or
- (b) rectal use **except**:
  - (i) in a primary pack containing 12 dosage units or less of suppositories containing 10 mg or less of bisacodyl per dosage unit; or
  - (ii) in a primary pack containing 25 dosage units or less of enemas containing 10 mg or less of bisacodyl per dosage unit.
- BRIMONIDINE in ophthalmic preparations for adult use containing not more than 0.025% of brimonidine.

## BROMHEXINE.

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

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

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

- BUDESONIDE in aqueous nasal sprays delivering 64 micrograms or less of budesonide per actuation when the maximum recommended daily dose is no greater than 400 micrograms, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.
- CARBETAPENTANE except in preparations containing 0.5% or less of carbetapentane.

#### CARBOCISTEINE.

- CETIRIZINE in preparations for oral use **except** in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 6 years of age and over when:
  - (a) in a primary pack containing not more than 10 days' supply; and
  - (b) labelled with a recommended daily dose not exceeding 10 mg of cetirizine.

#### CHLOPHEDIANOL.

CHLORBUTANOL for human use in topical preparations containing 5% or less of chlorbutanol **except** in preparations containing 0.5% or less of chlorbutanol.

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

- (a) when included in Schedule 4; or
- (b) in preparations containing 0.5% or less of chloroform.
- CHLORPHENAMINE when combined with one or more other therapeutically active substances in oral preparations when:
  - (a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
  - (b) in a day-night pack containing chlorphenamine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper;

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

CHOLINE SALICYLATE in preparations for oromucosal use.

## CICLOPIROX:

- (a) in preparations for dermal use containing 2% or less of ciclopirox **except** in preparations for the treatment of tinea pedis; or
- (b) in preparations for application to the nails containing 8% or less of ciclopirox.
- CINCHOCAINE in preparations for topical use other than eye drops, containing 0.5% or less of total local anaesthetic substances.

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## CINNAMEDRINE.

- CLOTRIMAZOLE for human use in dermal preparations and for application to the nails **except** in preparations for the treatment of tinea pedis.
- CREOSOTE derived from wood other than beechwood for human therapeutic use, **except** in preparations containing 10% or less of creosote derived from wood other than beechwood.

DATURA spp. for oral use:

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

except when separately specified in these Schedules.

DATURA STRAMONIUM (stramonium) for oral use when:

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

**except** for smoking or burning.

- DATURA TATULA (stramonium) for oral use:
  - (a) in undivided preparations containing 0.03% or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
  - (b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids;

except for smoking or burning.

- DELPHINIUM STAPHISAGRIA except in preparations containing 0.2% or less of Delphinium staphisagria.
- DESLORATADINE in preparations for oral use **except** in divided preparations for the treatment of seasonal allergic rhinitis when:
  - (a) in a primary pack containing 10 dosage units or less when labelled for adults and children 6 years and over; and
  - (b) labelled with a recommended daily dose not exceeding 5 mg of desloratadine.

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

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

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

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

DIBROMOPROPAMIDINE for ophthalmic use.

DICLOFENAC when:

- (a) in divided preparations for oral use containing 12.5 mg or less of diclofenac per dosage unit in a pack containing 20 or less dosage units and labelled with a recommended daily dose of 75 mg or less of diclofenac; or
- (b) in preparations for dermal use containing 4% or less of diclofenac **except** in preparations for dermal use containing 2% or less of diclofenac or for the treatment of solar keratosis; or
- (c) in transdermal preparations for topical use containing 140 mg or less of diclofenac.
- DIMENHYDRINATE in primary packs of 10 doses or less for the prevention or treatment of motion sickness, **except** in preparations for the treatment of children under 2 years of age.
- DIPHENHYDRAMINE in oral preparations:
  - (a) in a primary pack containing 10 dosage units or less for the prevention or treatment of motion sickness; or
  - (b) when combined with one or more other therapeutically active substances when:
    - (i) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
    - (ii) in a day-night pack containing diphenhydramine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper;

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

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

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

## DUBOISIA LEICHHARDTII for oral use:

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

## DUBOISIA MYOPOROIDES for oral use:

- (a) in undivided preparations containing 0.03% or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
- (b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.
- ECONAZOLE for human use in dermal preparations **except** in preparations for the treatment of tinea pedis.
- ESOMEPRAZOLE in oral preparations containing 20 mg or less per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply.

## ETAFEDRINE.

ETHER for therapeutic use except:

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

ETOFENAMATE in preparations for external use.

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

FELBINAC in preparations for external use.

FEXOFENADINE in preparations for oral use **except** in divided preparations:

- (a) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:
  - (i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and
  - (ii) labelled with a recommended daily dose not exceeding 120 mg of fexofenadine; or
- (b) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

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- (i) in a primary pack containing 10 dosage units or less and not more than 10 days' supply; and
- (ii) labelled with a recommended daily dose not exceeding 180 mg of fexofenadine; or
- (c) for the treatment of seasonal allergic rhinitis and children 6 years of age and over when:
  - (i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and
  - (ii) labelled with a recommended daily dose not exceeding 60 mg of fexofenadine.

#### FLUORIDES for human use:

- (a) in preparations for ingestion containing 0.5 mg or less of fluoride ion per dosage unit; or
- (b) in liquid preparations for topical use containing 1000 mg/kg or less of fluoride ion, in a container with a child-resistant closure:
  - (i) for therapeutic use when compliant with the requirements of the required advisory statements for medicine labels **except** in preparations containing 220 mg/kg or less of fluoride ion, in packs containing not more than 120 mg total fluoride when fitted with a child-resistant closure and compliant with the requirements of required advisory statements for medicine labels; or
  - (ii) for non-therapeutic use when labelled with warnings to the following effect:
    - (A) Do not swallow; and
    - (B) Do not use [this product/insert name of product] in children 6 years of age or less;

**except** in preparations containing 220 mg/kg or less of fluoride ion, in packs containing not more than 120 mg total fluoride, when fitted with a child-resistant closure and labelled with warnings to the following effect:

- (C) Do not swallow; and
- (D) Do not use [this product/insert name of product] in children 6 years of age or less;

**except** in preparations containing 15 mg/kg or less of fluoride ion or preparations for supply to registered dental professionals or by approval of an appropriate authority.

FLURBIPROFEN in preparations for topical oral use when:

- (a) in divided preparations containing 10 mg or less of flurbiprofen per dosage unit **except** when:
  - (i) in a primary pack containing not more than 16 dosage units; and
  - (ii) labelled only for the treatment of adults and children over 12 years; or
- (b) in undivided preparations containing either:
  - (i) 0.25% or less of flurbiprofen per dose; or
  - (ii) 10 mg or less of flurbiprofen per dose;

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except when:

- (iii) in a primary pack containing not more than 15 mL; and
- (iv) labelled only for the treatment of adults 18 years and over.
- FLUTICASONE PROPIONATE (excluding derivatives) in aqueous nasal sprays delivering 50 micrograms or less of fluticasone per actuation when the maximum recommended daily dose is no greater than 400 micrograms, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.

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

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

FOLINIC ACID for human therapeutic use except:

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

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

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

#### GELSEMIUM SEMPERVIRENS.

GLUTARAL for human therapeutic use.

- GUAIFENESIN in a modified release dosage form of 1200 mg or less of guaifenesin with a recommended daily dose of 2400 mg or less when not labelled for the treatment of children under 12 years of age.
- HEXACHLOROPHENE in preparations for human use containing 3% or less of hexachlorophene **except**:
  - (a) in preparations for use on infants, as specified in Schedule 4; or
  - (b) in preparations for cosmetic use, as specified in Schedule 6; or
  - (c) in other preparations containing 0.75% or less of hexachlorophene.
- HYDROCORTISONE and HYDROCORTISONE ACETATE, but excluding other salts and derivatives, in preparations for human therapeutic use:
  - (a) for dermal use in preparations containing 0.5% or less of hydrocortisone, in packs containing 30 g or less of such preparations, containing no other therapeutically active constituent other than an antifungal substance; or
  - (b) for dermal use in preparations containing 1% or less of hydrocortisone, in packs containing 15 g or less of such preparations, containing an antifungal substance and no other therapeutically active constituent:

- (i) for the treatment of tinea (tinea pedis, tinea cruris, tinea corporis) and other fungal skin infections; and
- (ii) not labelled for the treatment of children under 12 years of age; or
- (c) for rectal use in preparations containing 0.5% or less of hydrocortisone, when combined with a local anaesthetic substance but no other therapeutically active constituent **except** unscheduled astringents:
  - (i) in undivided preparations in packs of 35 g or less; or
  - (ii) in packs containing 12 or less suppositories.
- HYDROQUINONE (excluding monobenzone and alkyl ethers of hydroquinone included in Schedule 4) in preparations for human external therapeutic or cosmetic use containing 2% or less of hydroquinone **except**:
  - (a) in hair preparations containing 0.3% or less of hydroquinone; or
  - (b) in cosmetic nail preparations containing 0.02% or less of hydroquinone.

## HYOSCINE:

- (a) for transdermal use in preparations containing 2 mg or less of total solanaceous alkaloids per dosage unit; or
- (b) for oral use:
  - (i) in undivided preparations containing 0.03% or less of total solanaceous alkaloids, when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
  - (ii) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.
- HYOSCINE BUTYLBROMIDE as the only therapeutically active substance, in divided preparations for oral use, containing 20 mg or less of hyoscine butylbromide per dosage unit in a pack containing 200 mg or less of hyoscine butylbromide.

## HYOSCYAMINE:

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

## HYOSCYAMUS NIGER for oral use:
- (a) in undivided preparations containing 0.03% or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
- (b) in divided preparations containing 0.3 mg of total solanaceous alkaloids or less per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids;

except in a pack containing 0.03 mg or less of total solanaceous alkaloids.

- IBUPROFEN in preparations for oral use that are labelled with a recommended daily dose of 1200 mg or less of ibuprofen, when:
  - (a) in liquid preparations that are sold in the manufacturer's original pack containing 8 g or less of ibuprofen; or
  - (b) in divided immediate release preparations:
    - (i) each containing 400 mg or less of ibuprofen in a primary pack containing not more than 12 dosage units; and
    - (ii) that are labelled not for the treatment of children under 12 years; or
  - (c) in divided preparations, each containing 200 mg or less of ibuprofen, in packs of not more than 100 dosage units **except** when:
    - (i) ibuprofen is the only therapeutically active constituent, other than phenylephrine or when combined with an effervescent agent; and
    - (ii) packed in blister or strip packaging or in a container with a child-resistant closure; and
    - (iii) in a primary pack containing not more than 25 dosage units; and
    - (iv) compliant with the requirements of the required advisory statements for medicine labels; and
    - (v) not labelled for the treatment of children 6 years or under; and
    - (vi) if combined with phenylephrine—not labelled for the treatment of children under 12 years.

# INDANAZOLINE.

INDOMETACIN in preparations for external use containing 1% or less of indometacin.

# IODINE:

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

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

IPRATROPIUM in preparations for nasal use.

- IRON COMPOUNDS (excluding iron oxides when present as an excipient, in divided preparations containing 10 mg or less of total iron oxides per dosage unit or in undivided preparations containing 1% or less of total iron oxides) for human internal use **except**:
  - (a) when included in Schedule 4; or
  - (b) when labelled with a recommended daily dose of 24 mg or less of iron:
    - (i) in undivided preparations supplied in packs each containing 750 mg or less of iron; or
    - (ii) in divided preparations:
      - (A) containing more than 5 mg of iron per dosage unit in packs each containing 750 mg or less of iron; or
      - (B) containing 5 mg or less of iron per dosage unit.

ISOCONAZOLE for human use in dermal preparations.

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

KETOCONAZOLE in preparations for dermal use except:

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

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

LANSOPRAZOLE in oral preparations 15 mg or less of lansoprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 7 days' supply.

LEVOCABASTINE in topical eye or nasal preparations.

- LEVOCETIRIZINE in preparations for oral use **except** in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:
  - (a) in a primary pack containing not more than 5 days' supply; and
  - (b) labelled with a recommended daily dose not exceeding 5 mg of levocetirizine.

LIDOCAINE in preparations for topical use other than eye drops:

- (a) containing 10% or less of total local anaesthetic substances, except:
  - (i) in dermal preparations containing 2% or less of total local anaesthetic substances; or
  - (ii) in aqueous sprays for oromucosal use containing 0.6% or less of total local anaesthetic substances; or
- (b) in divided preparations containing 200 mg or less of total local anaesthetic substances, except in lozenges containing 30 mg or less of total local anaesthetic substances per dosage unit.

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

LITHIUM in preparations for dermal use containing 1% or less of lithium except:

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

LOBELIA INFLATA except for smoking or burning.

LOBELINE except in preparations for smoking or burning.

LODOXAMIDE in preparations for ophthalmic use.

- LOPERAMIDE in divided preparations for oral use in packs of 20 dosage units or less **except** in preparations containing 2 mg or less of loperamide per dosage unit, in a primary pack containing 8 dosage units or less.
- LORATADINE in preparations for oral use **except** in divided preparations for the treatment of seasonal allergic rhinitis when:
  - (a) in a primary pack containing 10 dosage units or less when labelled for adults and children 6 years and over; and
  - (b) labelled with a recommended daily dose not exceeding 10 mg of loratadine.

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

MEBENDAZOLE for human therapeutic use.

- MECLOZINE in primary packs containing 12 or less tablets or capsules of meclozine for the prevention or treatment of motion sickness, **except** in preparations for the treatment of children under 2 years of age.
- MEFENAMIC ACID in divided preparations for oral use in packs of 30 or less dosage units for the treatment of dysmenorrhoea.
- MEPYRAMINE for dermal use.
- MERCUROCHROME in preparations for external use containing 2% or less of mercurochrome **except** when included in Schedule 6.
- MERCURY for external use in preparations containing 0.5% or less of mercury.
- METHOXAMINE in preparations for external use **except** in preparations containing 1% or less of methoxamine.

METHOXYPHENAMINE.

METHYLEPHEDRINE.

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

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

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

NAPHAZOLINE.

- NAPROXEN in divided preparations containing 250 mg or less of naproxen per dosage unit in packs of 30 or less dosage units.
- NICLOSAMIDE for human therapeutic use.
- NIZATIDINE when sold in the manufacturer's original pack containing not more than 14 days' supply.

NOSCAPINE.

NYSTATIN in dermal preparations.

- OLOPATADINE in preparations for nasal use delivering 600 micrograms or less of olopatadine per dose when the maximum recommended daily dose is no greater than 4,800 micrograms for the treatment of allergic rhinitis or rhinoconjunctivitis for up to 6 months in adults and children 12 years of age and over.
- OMEPRAZOLE in oral preparations containing 20 mg or less of omeprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 7 days' supply.
- OXETACAINE (oxethazaine) in preparations for internal use.
- OXICONAZOLE for dermal use except in preparations for the treatment of tinea pedis.

OXYMETAZOLINE.

- OXYQUINOLINE and its non-halogenated derivatives for human therapeutic use, **except** in preparations for external use containing 1% or less of such substances.
- PAPAVERINE **except** when included in Schedule 4.
- PANTOPRAZOLE in oral preparations containing 20 mg or less of pantoprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 7 days' supply.

PARACETAMOL for therapeutic use:

- (a) in liquid preparations for oral use containing a maximum of 10 g of paracetamol per container; or
- (b) when combined with ibuprofen in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen in divided doses in a primary pack containing no more than 12 dosage units per pack; or

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- (c) in tablets or capsules in blister or strip packaging enclosed in a primary pack containing not more than 50 tablets or capsules; or
- (d) in individually wrapped powders or sachets of granules enclosed in a primary pack containing not more than 25 wrapped powders or sachets of granules; or
- (e) in other preparations **except**:
  - (i) when included in Schedule 3 or 4; or
  - (ii) in individually wrapped powders or sachets of granules each containing 1000 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine, phenylephrine and/or guaifenesin or when combined with effervescent agents) when:
    - (A) enclosed in a primary pack that contains not more than 10 such powders or sachets of granules;
    - (B) compliant with the requirements of the required advisory statements for medicine labels;
    - (C) not labelled for the treatment of children 6 years of age or less; and
    - (D) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin; or
  - (iii) in tablets or capsules each containing 500 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine, phenylephrine and/or guaifenesin or when combined with effervescent agents) when:
    - (A) packed in blister or strip packaging;
    - (B) in a primary pack containing not more than 16 tablets or capsules;
    - (C) compliant with the requirements of the required advisory statements for medicine labels;
    - (D) not labelled for the treatment of children 6 years of age or less; and
    - (E) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin.

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

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

### PHEDRAZINE.

PHENAZONE for human external use.

# PHENIRAMINE:

- (a) in eye drops; or
- (b) when combined with one or more other therapeutically active substances in oral preparations when:
  - (i) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or

 (ii) in a day-night pack containing pheniramine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper;

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

- PHENOL, or any homologue boiling below 220°C, for human therapeutic use except:
  - (a) when included in Schedule 4; or
  - (b) in preparations for external use containing 1% or less of phenol and in preparations for external use containing 3% or less of cresols and xylenols and other homologues of phenol.

# PHENYLEPHRINE except:

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

# PHOLCODINE:

- (a) in liquid preparations containing 0.5% or less of pholcodine and with a recommended dose not exceeding 25 mg of pholcodine; or
- (b) when compounded with one or more other therapeutically active substances in divided preparations containing 10 mg or less of pholcodine per dosage unit and with a recommended dose not exceeding 25 mg of pholcodine.
- PIPERAZINE for human therapeutic use.
- PODOPHYLLOTOXIN in preparations containing 0.5% or less of podophyllotoxin for human use for the treatment of warts other than anogenital warts.
- PODOPHYLLUM EMODI (podophyllin) in preparations containing 10% or less of podophyllin for human use for the treatment of warts other than anogenital warts.
- PODOPHYLLUM PELTATUM (podophyllin) in preparations containing 10% or less of podophyllin for human use for the treatment of warts other than anogenital warts.
- POTASSIUM CHLORATE for therapeutic use **except** in preparations containing 10% or less of potassium chlorate.
- PRILOCAINE in preparations for dermal use containing 10% or less of total local anaesthetic substances.
- PROCYCLIDINE in preparations containing 5% or less of procyclidine for dermal use.

PROMETHAZINE in oral preparations:

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

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

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

PROPAMIDINE for ophthalmic use.

PYRANTEL for human therapeutic use.

- PYRETHRINS, naturally occurring, being pyrethrolone, cinerolone or jasmolone esters of chrysanthemic or pyrethric acids, for human therapeutic use in preparations containing more than 10% of such substances.
- PYRITHIONE ZINC for human therapeutic use, **except** in preparations for the treatment of the scalp containing 2% or less of pyrithione zinc when compliant with the requirements of the required advisory statements for medicine labels.
- RABEPRAZOLE in oral preparations containing 10 mg or less of rabeprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 7 days' supply.
- RANITIDINE in preparations supplied in the manufacturer's original pack containing not more than 14 days' supply **except**:
  - (a) in divided preparations for oral use containing 150 mg or less of ranitidine per dosage unit in the manufacturer's original pack containing not more than 14 dosage units; or
  - (b) in divided preparations for oral use containing 300 mg or less of ranitidine per dosage unit in the manufacturer's original pack containing not more than 7 dosage units.

SALICYLAMIDE except when included in Schedule 4.

SELENIUM in preparations for human therapeutic use except:

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

SILVER for therapeutic use **except**:

- (a) in solutions for human oral use containing 0.3% or less of silver when compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in other preparations containing 1% or less of silver.

SODIUM CROMOGLYCATE in preparations for nasal or ophthalmic use.

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

SQUILL except in preparations containing 1% or less of squill.

SULCONAZOLE in preparations for dermal use.

- TERBINAFINE for dermal use except in preparations for the treatment of tinea pedis.
- TETRACAINE in preparations for topical use other than eye drops, containing 10% or less of total local anaesthetic substances **except** in dermal preparations containing 2% or less of total local anaesthetic substances.

TETRACHLOROETHYLENE for human therapeutic use.

TETRYZOLINE.

THIABENDAZOLE for human therapeutic use.

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

### TRAMAZOLINE.

- TRIAMCINOLONE in aqueous nasal sprays delivering 55 micrograms or less of triamcinolone per actuation when the maximum recommended daily dose is no greater than 220 micrograms, for prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.
- TRIPROLIDINE when combined with one or more other therapeutically active substances in oral preparations when:
  - (a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
  - (b) in a day-night pack containing triprolidine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper;

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

TUAMINOHEPTANE.

# TYMAZOLINE.

# XYLOMETAZOLINE.

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

# Schedule 3—Pharmacist only medicines

- Note: See sections 16 and 31, subsections 54(2) and 57(1) and section 59.
- ADAPALENE in topical preparations containing 0.1% or less of adapalene for the treatment of acne vulgaris in adults and in children over 12 years of age.
- ADRENALINE in preparations containing 1% or less of adrenaline **except** in preparations that are not for injection containing 0.02% or less of adrenaline.
- ALCLOMETASONE as the only therapeutically active substance in preparations for dermal use containing 0.05% or less of alclometasone in packs containing 30 g or less of the preparation.

### ALIMEMAZINE:

- (a) in solid oral preparations except when included in Schedule 2; or
- (b) in liquid oral preparations containing 10 mg or less of alimemazine per 5 mL;

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

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

AMYL NITRITE when in preparations for human therapeutic use and packaged in containers with child-resistant closures.

# ASTODRIMER SODIUM except:

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

AZATADINE in oral preparations.

BILASTINE in oral preparations when labelled with a recommended daily dose not exceeding 10 mg of bilastine for the treatment of children 6-11 years of age **except** when included in Schedule 2.

# BROMPHENIRAMINE in oral preparations except:

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

### BUCLIZINE in oral preparations.

- BUTOCONAZOLE in preparations for vaginal use.
- CANNABIDIOL in oral, oromucosal and sublingual preparations included in the Register when:
  - (a) the cannabidiol is either plant derived or, when synthetic, only contains the (-)-CBD enantiomer; and

- (b) the cannabidiol comprises 98% or more of the total cannabinoid content of the preparation; and
- (c) any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the preparation and of which tetrahydrocannabinol (THC) can only comprise 1% of the total cannabinoid content; and
- (d) the maximum recommended daily dose is 150 mg or less of cannabidiol; and
- (e) packed in blister or strip packaging or in a container fitted with a child-resistant closure; and
- (f) in packs containing not more than 30 days' supply; and
- (g) for persons aged 18 years and over.
- CELECOXIB in tablets or capsules each containing 200 mg or less of celecoxib, in a primary pack containing not more than 10 dosage units for the short-term treatment of acute pain due to primary dysmenorrhea or musculoskeletal or soft tissue injuries in adults.
- CHLORAMPHENICOL for ophthalmic use only.

CHLORBUTANOL in preparations for human use except:

- (a) when included in Schedule 2; or
- (b) in preparations containing 0.5% or less of chlorbutanol.
- CHLORPHENAMINE in oral preparations except:
  - (a) when included in Schedule 2; or
  - (b) for the treatment of children under 2 years of age.

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

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

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

CLEMASTINE in preparations for oral use.

- CLOBETASONE (clobetasone-17-butyrate) as the only therapeutically active substance in preparations for dermal use containing 0.05% or less of clobetasone in packs containing 30 g or less of the preparation.
- CLOTRIMAZOLE in preparations for vaginal use.
- CYCLIZINE in divided preparations for oral use in primary packs containing 6 dosage units or less.

CYPROHEPTADINE in oral preparations.

CYTISINE in divided oral and oromucosal preparations with a recommended daily dose of 9 mg or less of cytisine as an aid in withdrawal from tobacco smoking in adults.

DEXCHLORPHENAMINE in oral preparations **except**:

- (a) when included in Schedule 2; or
- (b) for the treatment of children under 2 years of age.
- DICLOFENAC in divided preparations for oral use containing 25 mg or less of diclofenac per dosage unit in a pack containing 30 or less dosage units **except** when included in Schedule 2.
- DIHYDROCODEINE when indicated for cough suppression and compounded with one or more other therapeutically active substances:
  - (a) in divided preparations containing 10 mg or less of dihydrocodeine per dosage unit and with a recommended dose not exceeding 15 mg of dihydrocodeine; or
  - (b) in undivided preparations containing 0.25% or less of dihydrocodeine with a recommended dose not exceeding 15 mg of dihydrocodeine.

DIIODOHYDROXYQUINOLINE (iodoquinol) for vaginal use.

DIMENHYDRINATE in oral preparations except when included in Schedule 2.

DIMETHINDENE in oral preparations.

DIPHENHYDRAMINE in oral preparations except:

- (a) when included in Schedule 2; or
- (b) for the treatment of children under 2 years of age.
- DIPHENOXYLATE in packs of 8 or less dosage units, each dosage unit containing 2.5 mg or less of diphenoxylate and a quantity of atropine sulfate equivalent to at least 1% of the dose of diphenoxylate.

DITHRANOL for therapeutic use.

DOXYLAMINE in oral preparations except:

- (a) when included in Schedule 2; or
- (b) for the treatment of children under 2 years of age.
- ECONAZOLE in preparations for vaginal use.
- ELETRIPTAN for oral use in tablets containing 40 mg or less per tablet and when in a pack containing not more than 2 dosage units for the acute relief of migraine in patients who have a stable, well-established pattern of symptoms.

ERYTHRITYL TETRANITRATE for therapeutic use.

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

FLAVOXATE.

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

### FLUORIDES for human topical use:

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

### GLUCAGON.

#### **GLYCERYL TRINITRATE:**

- (a) in preparations for oral use; or
- (b) in preparations for rectal use.
- HYDROCORTISONE and HYDROCORTISONE ACETATE, but excluding other salts and derivatives, in preparations for human therapeutic use containing 1% or less of hydrocortisone:
  - (a) for dermal use, in packs containing 30 g or less of such preparations, containing no other therapeutically active constituent other than an antifungal substance; or
  - (b) for dermal use, in packs containing 2 g or less of such preparations, containing no other therapeutically active constituent other than aciclovir (5% w/w or less) in adults and adolescents (12 years of age and older); or
  - (c) for rectal use when combined with a local anaesthetic substance but no other therapeutically active constituent **except** unscheduled astringents:
    - (i) in undivided preparations, in packs of 35 g or less; or
    - (ii) in packs containing 12 or less suppositories;

except when included in Schedule 2.

HYOSCINE BUTYLBROMIDE in undivided preparations for oral use with a recommended single dose not exceeding 20 mg of hyoscine butylbromide in a pack containing 100 mg or less of hyoscine butylbromide when labelled for adults and children 6 years and over.

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### IBUPROFEN when:

- (a) either:
  - (i) in divided preparations, each containing 400 mg or less of ibuprofen, in a primary pack containing not more than 50 dosage units; or
  - (ii) in a modified release dosage form, each containing 600 mg of ibuprofen, in a primary pack containing not more than 32 dosage units; and
- (b) labelled:
  - (i) with a recommended daily dose of 1200 mg or less of ibuprofen; and
  - (ii) not for the treatment of children under 12 years;

### except when:

- (c) included in Schedule 2; or
- (d) in preparations for oral use that are labelled with a recommended daily dose of 1200 mg or less of ibuprofen in divided preparations, each containing 200 mg or less of ibuprofen, in a pack containing not more than 100 dosage units when:
  - (i) ibuprofen is the only therapeutically active constitutent, other than phenylephrine or when combined with an effervescent agent; and
  - (ii) packed in a blister or strip packaging or in a container with a child-resistant closure; and
  - (iii) in a primary pack containing not more than 25 dosage units; and
  - (iv) compliant with the requirements of the required advisory statements for medicine labels; and
  - (v) not labelled for the treatment of children 6 years or under; and
  - (vi) when combined with phenylephrine—not labelled for the treatment of children under 12 years.

INOSITOL NICOTINATE.

ISOCONAZOLE in preparations for vaginal use.

- ISOSORBIDE DINITRATE in oral preparations containing 10 mg or less of isosorbide dinitrate per dosage unit.
- KETOPROFEN in divided preparations for oral use containing 25 mg or less of ketoprofen per dosage unit in a pack containing 30 or less dosage units.
- LANSOPRAZOLE in oral preparations containing 15 mg or less of lansoprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply **except** when included in Schedule 2.

LEVONORGESTREL for emergency post-coital contraception.

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

- MAGNESIUM SULFATE for human therapeutic use in divided oral preparations **except** when containing 1.5 g or less of magnesium sulfate per recommended daily dose.
- MALATHION in preparations for human external use **except** in preparations containing 2% or less of malathion.

MANNITYL HEXANITRATE for therapeutic use.

MELATONIN in:

- (a) modified release tablets containing 2 mg or less of melatonin for monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep for adults aged 55 or over, in packs containing not more than 30 tablets; or
- (b) immediate release preparations containing 5 mg or less of melatonin for the treatment of jet lag in adults 18 years and over, in a primary pack containing no more than 10 dosage units.

MEPYRAMINE in oral preparations.

METHDILAZINE in oral preparations.

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

MICONAZOLE for human use in topical preparations:

- (a) for the treatment of oral candidiasis; or
- (b) for vaginal use.
- MOMETASONE as the only therapeutically active substance in preparations for dermal use containing 0.1% or less of mometasone in packs containing 15 g or less.

NALOXONE when used for the treatment of opioid overdose.

- NAPROXEN in a modified release dosage form of 600 mg or less of naproxen per dosage unit in packs of 16 or less dosage units when labelled not for the treatment of children under 12 years of age.
- NARATRIPTAN when in divided oral preparations containing 2.5 mg or less of naratriptan per dosage unit and when sold in a pack containing not more than 2 dosage units for the acute relief of migraine in patients who have a stable, well-established pattern of symptoms.
- NICOTINE in therapeutic vaping goods (within the meaning of the *Therapeutic Goods Regulations 1990*) in final dosage form for smoking cessation or the management of nicotine dependence when:
  - (a) for supply to persons aged 18 years and over; and
  - (b) the pharmacist requests and sights evidence of the patient's identity and age; and
  - (c) the pharmacist provides professional advice to the patient on alternative cessation supports and therapies, appropriate dose and frequency depending on age, weight

and severity of condition, length of treatment, suitable titration, and interactions with other medicines; and

- (d) the pharmacist provides contact details about smoking cessation support services to the patient; and
- (e) the quantity of the goods does not exceed the quantity that is reasonably required for a patient's therapeutic use for 1 month and that quantity is supplied to the patient only once in a month; and
- (f) the concentration of nicotine in the goods does not exceed 20 mg/mL; and

### except:

- (g) in preparations for oromucosal or transdermal administration for human therapeutic use when included in the Register as an aid in withdrawal either from tobacco smoking or nicotine vaping; or
- (h) in tobacco prepared and packed for smoking.
- NICOTINIC ACID for human therapeutic use in divided preparations containing 250 mg or less of nicotinic acid per dosage unit **except**:
  - (a) in preparations containing 100 mg or less of nicotinic acid per dosage unit; or
  - (b) nicotinamide.
- NICOTINYL ALCOHOL **except** in preparations containing 100 mg or less of nicotinyl alcohol per dosage unit.
- NYSTATIN in preparations for topical use except when included in Schedule 2.
- OMEPRAZOLE in oral preparations containing 20 mg or less of omeprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply **except** when included in Schedule 2.
- ORLISTAT in oral preparations for weight-control purposes containing 120 mg or less of orlistat per dosage unit.
- OXICONAZOLE in preparations for vaginal use.
- PANTOPRAZOLE in oral preparations containing 20 mg or less of pantoprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply **except** when included in Schedule 2.

PARACETAMOL:

- (a) when combined with ibuprofen in a primary pack containing 30 dosage units or less **except** when included in Schedule 2; or
- (b) in modified release tablets or capsules containing 665 mg or less paracetamol enclosed in a primary pack containing not more than 100 tablets or capsules; or
- (c) in modified release tablets or capsules containing 665 mg or less paracetamol enclosed in a primary pack containing more than 100 tablets or capsules intended

only as a bulk medicine and labelled "For dispensing only" and "This pack is not to be supplied to a patient"; or

- (d) in non-modified release tablets or capsules containing not more than 500 mg paracetamol and in a primary pack containing not more than 100 tablets or capsules **except** when included in or expressly excluded from Schedule 2; or
- (e) in tablets or capsules enclosed in a primary pack containing more than 100 tablets or capsules intended only as a bulk medicine pack and labelled "For dispensing only" and "This pack is not to be supplied to a patient"; or
- (f) in individually wrapped powders or sachets of granules enclosed in a primary pack containing not more than 50 wrapped powders or sachets of granules **except** when included in or expressly excluded from Schedule 2; or
- (g) in individually wrapped powders or sachets of granules enclosed in a primary pack containing more than 50 wrapped powders or sachets of granules intended only as a bulk medicine pack and labelled "For dispensing only" and "This pack is not to be supplied to a patient"; or
- (h) in liquid preparations for oral use **except** when in Schedule 2.

PHENIRAMINE in oral preparations except:

- (a) when included in Schedule 2; or
- (b) for the treatment of children under 2 years of age.
- PODOPHYLLOTOXIN in preparations containing 1% or less of podophyllotoxin for human use for the treatment of warts other than anogenital warts **except** when included in Schedule 2.
- PODOPHYLLUM EMODI (podophyllin) in preparations containing 20% or less of podophyllin for human use for the treatment of warts other than anogenital warts **except** when included in Schedule 2.
- PODOPHYLLUM PELTATUM (podophyllin) in preparations containing 20% or less of podophyllin for human use for the treatment of warts other than anogenital warts **except** when included in Schedule 2.
- PROCHLORPERAZINE in divided preparations for oral use in packs containing not more than 10 dosage units for the treatment of nausea associated with migraine.

PROMETHAZINE in oral preparations except:

- (a) when included in Schedule 2; or
- (b) in preparations for the treatment of children under 2 years of age.
- PSEUDOEPHEDRINE (other than preparations for stimulant, appetite suppression or weight-control purposes) when supplied in a primary pack:
  - (a) in liquid preparations containing 800 mg or less of pseudoephedrine hydrochloride (or its equivalent); or
  - (b) in other preparations containing 720 mg or less of pseudoephedrine hydrochloride (or its equivalent).

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- RABEPRAZOLE in oral preparations containing 10 mg or less of rabeprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply **except** when included in Schedule 2.
- RIZATRIPTAN when in divided oral preparations containing 5 mg or less per dosage unit and when sold in a pack containing not more than 2 dosage units for the acute relief of migraine in patients who have a stable, well-established pattern of migraine symptoms.
- SALBUTAMOL as the only therapeutically active substance:
  - (a) in metered aerosols delivering 100 micrograms or less of salbutamol per metered dose; or
  - (b) in dry powders for inhalation delivering 200 micrograms or less of salbutamol per dose.
- SALICYLIC ACID in preparations for dermal use **except** in preparations containing 40% or less of salicylic acid.

### SANTONIN.

- SODIUM PHOSPHATE in preparations for oral use for bowel cleansing prior to diagnostic medical and surgical procedures.
- SODIUM PICOSULFATE in preparations for oral use for bowel cleansing prior to diagnostic medical or surgical procedures.
- SULFACETAMIDE in preparations for ophthalmic use containing 10% or less of sulfacetamide.
- SUMATRIPTAN when in divided oral preparations containing 50 mg or less per dosage unit and when sold in a pack containing not more than 2 dosage units for the acute relief of migraine in patients who have a stable, well-established pattern of symptoms.

TERBUTALINE as the only therapeutically active substance:

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

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

TIOCONAZOLE in preparations for vaginal use.

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

TRIPROLIDINE in oral preparations except:

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

ULIPRISTAL for emergency post-coital contraception.

- VITAMIN D for human internal therapeutic use in preparations containing 175 micrograms or less of vitamin D per recommended single weekly dose **except** in preparations containing 25 micrograms or less of vitamin D per recommended daily dose.
- ZOLMITRIPTAN when in divided oral preparations containing 2.5 mg or less per dosage unit and when sold in a pack containing not more than 2 dosage units for the acute relief of migraine in patients who have a stable, well-established pattern of symptoms.

# Schedule 4—Prescription only medicines and prescription animal remedies

Note 1: See sections 16, 28, 31 and 49, subsections 54(2) and 57(1) and section 60.

Note 2: Substances marked # are listed in Appendix D.

ABACAVIR.

ABALOPARATIDE.

ABATACEPT.

ABIRATERONE ACETATE.

ABCIXIMAB.

ABEMACICLIB.

ABROCITINIB.

ACALABRUTINIB.

ACAMPROSATE CALCIUM.

ACARBOSE.

ACEBUTOLOL.

ACEPROMAZINE.

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

ACETARSOL.

ACETAZOLAMIDE.

ACETOHEXAMIDE.

ACETYL ISOVALERYLTYLOSIN.

ACETYLCARBROMAL.

ACETYLCHOLINE.

ACETYLCYSTEINE except:

(a) when included in Schedule 2; or

Substances marked # are listed in Appendix D

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

# ACETYLDIGITOXIN.

# ACETYLMETHYLDIMETHYLOXIMIDOPHENYLHYDRAZINE.

# ACETYLSTROPHANTHIDIN.

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

ACIPIMOX.

- # ACITRETIN.
- ACLIDINIUM BROMIDE.

ACOKANTHERA OUABAIO.

ACOKANTHERA SCHIMPERI.

ACONITUM spp. except:

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

### ACRIVASTINE.

ADALIMUMAB.

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

ADEFOVIR.

ADENOSINE for human therapeutic use in preparations for injection.

ADIPHENINE.

ADONIS VERNALIS.

ADRAFINIL.

ADRENALINE in:

(a) topical preparations for the treatment of wounds in humans; or

Substances marked # are listed in Appendix D

(b) all other preparations containing adrenaline **except** when included in or expressly excluded from Schedule 3.

ADRENOCORTICAL HORMONES except when separately specified in these Schedules.

AFAMELANOTIDE.

AFATINIB DIMALEATE.

AFLIBERCEPT.

AGALSIDASE.

AGLEPRISTONE.

AGOMELATINE.

ALANYLGLUTAMINE.

ALATROFLOXACIN MESILATE.

ALBENDAZOLE except:

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

ALCLOFENAC.

ALCLOMETASONE except when included in Schedule 3.

ALCURONIUM.

ALDESLEUKIN.

ALDOSTERONE.

ALECTINIB.

# ALEFACEPT.

ALEMTUZUMAB.

ALENDRONIC ACID.

ALFACALCIDOL.

ALFUZOSIN.

ALGLUCERASE.

Substances marked # are listed in Appendix D

ALGLUCOSIDASE.

ALIMEMAZINE except when included in Schedule 2 or 3.

ALIROCUMAB.

ALISKIREN.

ALKYL NITRITES except when separately specified in these Schedules.

ALLERGENS for therapeutic use.

ALLOPURINOL.

ALLYLESTRENOL.

ALOGLIPTIN.

ALOSETRON.

ALPELISIB.

ALPHA1-PROTEINASE INHIBITOR (HUMAN).

ALPHADOLONE.

ALPHAXALONE.

ALPRENOLOL.

ALPROSTADIL.

ALSEROXYLON.

ALTEPLASE.

ALTRENOGEST.

ALTRETAMINE (hexamethylmelamine).

AMANTADINE.

AMBENONIUM CHLORIDE.

# AMBRISENTAN.

AMBUCETAMIDE.

AMBUTONIUM BROMIDE.

Substances marked # are listed in Appendix D

AMCINONIDE.

AMIFAMPRIDINE.

AMIFOSTINE.

AMIKACIN.

AMILORIDE.

AMINOCAPROIC ACID.

AMINOGLUTETHIMIDE.

5-AMINOLEVULINIC ACID.

AMINOMETRADINE.

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

AMINOPHYLLINE except when included in Schedule 3.

AMINOPTERIN.

4-AMINOPYRIDINE for therapeutic use.

AMINOREX.

AMINOSALICYLIC ACID.

AMIODARONE.

AMIPHENAZOLE.

AMISOMETRADINE.

AMISULPRIDE.

AMITRIPTYLINE.

AMLODIPINE.

AMMI VISNAGA.

AMMONIUM BROMIDE for therapeutic use.

AMOBARBITAL when packed and labelled for injection.

AMODIAQUINE.

Substances marked # are listed in Appendix D

# AMOROLFINE except:

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

AMOXAPINE.

AMOXICILLIN.

AMPHOMYCIN.

AMPHOTERICIN B.

AMPICILLIN.

AMPRENAVIR.

AMRINONE.

AMSACRINE.

AMYL NITRITE except when included in Schedule 3.

AMYLOCAINE.

# ANABOLIC STEROIDAL AGENTS.

ANAGRELIDE.

ANAKINRA.

ANASTROZOLE.

ANCESTIM.

ANCROD and its immunoglobulin antidote.

ANDEXANET ALFA.

ANECORTAVE.

# ANDROGENIC STEROIDAL AGENTS.

# ANDROISOXAZOLE.

# ANDROSTANOLONE.

# ANDROSTENEDIOL.

# ANDROSTENEDIONE.

Substances marked # are listed in Appendix D

# ANGIOTENSIN AMIDE.

# ANIDULAFUNGIN.

# ANIMAL BLOOD PRODUCTS for veterinary use including:

- (a) whole blood;
- (b) blood components, including red cells, white cells, platelets, and plasma (including cryoprecipitate); and
- (c) the following plasma-derived therapeutic proteins, and their equivalent recombinant alternatives:
  - (i) albumin;
  - (ii) anticoagulation complex;
  - (iii) C1 esterase inhibitors;
  - (iv) clotting factors;
  - (v) fibrinogen;
  - (vi) protein C;
  - (vii) prothrombin complex concentrate (PCC);
  - (viii)thrombin;
  - (ix) haemoglobin.

# ANIRACETAM.

# ANISTREPLASE.

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

# ANTIBIOTIC SUBSTANCES except:

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

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

# ANTIHISTAMINES except:

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

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

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

# AOD-9604 (CAS No. 221231-10-3).

Substances marked # are listed in Appendix D

APALUTAMIDE.

APIXABAN.

APOCYNUM spp.

APOMORPHINE.

APRACLONIDINE.

APRAMYCIN.

APREMILAST.

APREPITANT.

APROTININ.

ARBUTIN (BETA) in oral preparations **except** herbal preparations containing 500 mg or less beta-arbutin per recommended daily dose.

ARECOLINE.

ARIPIPRAZOLE.

ARMODAFINIL.

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

ARTEMETHER.

ARTICAINE.

ASCIMINIB.

ASENAPINE.

ASFOTASE ALFA.

### ASPARAGINASE.

ASPIRIN when:

- (a) combined with caffeine, paracetamol or salicylamide; or
- (b) combined with any derivative of the substances mentioned in paragraph (a); or
- (c) for injection.

ASTEMIZOLE.

# ASUNAPREVIR.

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Substances marked # are listed in Appendix D

# ATAMESTANE.

ATAZANAVIR.

ATENOLOL.

ATEZOLIZUMAB.

ATIPAMEZOLE.

ATOMOXETINE.

ATORVASTATIN.

ATOSIBAN.

ATOVAQUONE.

ATRACURIUM BESILATE.

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

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

ATROPINE METHONITRATE.

AURANOFIN.

AUROTHIOMALATE SODIUM.

AVACOPAN.

AVATROMBOPAG.

AVELUMAB.

AVILAMYCIN except:

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

AVIPTADIL.

AXITINIB.

AVOPARCIN.

AZACITIDINE.

AZACYCLONOL.

Substances marked # are listed in Appendix D

AZAPERONE.

AZAPROPAZONE.

AZARIBINE.

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

AZATHIOPRINE.

AZELAIC ACID for therapeutic use **except** when included in Schedule 2.

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

AZITHROMYCIN.

AZLOCILLIN.

AZTREONAM.

BACAMPICILLIN.

BACITRACIN.

BACLOFEN.

BALOXAVIR MARBOXIL.

BALSALAZIDE.

BAMBERMYCIN (flavophospholipol) except:

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

BAMBUTEROL.

BAMETHAN.

BAMIPINE.

BARBITURATES except when separately specified in these Schedules.

BARICITINIB.

BASILIXIMAB.

BAZEDOXIFENE.

Substances marked # are listed in Appendix D

BECAPLERMIN.

BECLAMIDE.

BECLOMETASONE except when included in Schedule 2.

BELATACEPT.

BELIMUMAB.

BELUMOSUDIL.

BELZUTIFAN.

BEMEGRIDE.

BENACTYZINE.

BENAZEPRIL.

BENDAMUSTINE.

BENDROFLUAZIDE.

BENETHAMINE PENICILLIN.

BENORYLATE.

BENOXAPROFEN.

BENPERIDOL.

BENRALIZUMAB.

BENSERAZIDE.

BENZATHINE PENICILLIN.

BENZILONIUM.

# BENZOCAINE except:

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

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

Substances marked # are listed in Appendix D

BENZOYL PEROXIDE in preparations for human therapeutic use except:

- (a) when included in Schedule 2; or
- (b) in preparations for external use containing 5% or less of benzoyl peroxide.

BENZPHETAMINE.

BENZTHIAZIDE.

BENZATROPINE.

BENZYDAMINE except:

- (a) when included in Schedule 2; or
- (b) in preparations for dermal use; or
- (c) in divided topical oral preparations containing 3 mg or less of benzydamine; or
- (d) in undivided topical oral preparations containing 0.3% or less of benzydamine in a primary pack containing not more than 50 mL.

BENZYLPENICILLIN.

BEPRIDIL.

BERACTANT.

BESIFLOXACIN.

BETAHISTINE.

BETAMETHASONE.

BETAXOLOL.

BETHANECHOL CHLORIDE.

BETHANIDINE.

BEVACIZUMAB.

BEVANTOLOL.

# BEXAROTENE.

BEZAFIBRATE.

BEZLOTOXUMAB.

BICALUTAMIDE.

Substances marked # are listed in Appendix D

# BICTEGRAVIR.

# BIFONAZOLE except:

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

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

BIMATOPROST.

BINIMETINIB.

BIPERIDEN.

BISMUTH COMPOUNDS for cosmetic use, except:

- (a) bismuth citrate when incorporated in hair colourant preparations in concentrations of 0.5% or less; or
- (b) bismuth oxychloride.
- BISMUTH COMPOUNDS for human therapeutic use, **except** bismuth formic iodide or bismuth subiodide in dusting powders containing 3% or less of bismuth.

BISOPROLOL.

BIVALIRUDIN.

BLEOMYCIN.

BLINATUMOMAB.

BOCEPREVIR.

# BOLANDIOL.

**# BOLASTERONE.** 

# BOLAZINE.

# BOLDENONE (dehydrotestosterone).

# BOLENOL.

# BOLMANTALATE.

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

Substances marked # are listed in Appendix D

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

BORTEZOMIB.

# BOSENTAN.

BOSUTINIB.

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

# BPC-157.

BRENTUXIMAB VEDOTIN.

BRETYLIUM TOSILATE.

BREXPIPRAZOLE.

BRIGATINIB.

BRIMONIDINE except when included in Schedule 2.

BRINZOLAMIDE.

BRIVARACETAM.

# BROMAZEPAM.

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

BROMOCRIPTINE.

BROMOFORM for therapeutic use.

BROMPHENIRAMINE except when included in Schedule 2 or 3.

BROMVALETONE.

BRUGMANSIA spp.

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

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

Substances marked # are listed in Appendix D

BUFEXAMAC.

BULEVIRTIDE.

BUMETANIDE.

BUPHENINE.

BUPIVACAINE except when included in Schedule 5.

BUPROPION.

BUSERELIN.

BUSPIRONE.

BUSULPHAN.

BUTACAINE.

BUTAMBEN except in dermal preparations containing 2% or less of total local anaesthetic substances.

BUTOCONAZOLE except when included in Schedule 3.

BUTRACONAZOLE.

BUTYLCHLORAL HYDRATE.

BUTYL NITRITE.

CABAZITAXEL.

CABERGOLINE.

CABOTEGRAVIR.

CABOZANTINIB.

CADMIUM COMPOUNDS for human therapeutic use.

CAFFEINE for internal therapeutic use except:

- (a) in divided preparations when labelled with a maximum recommended daily dose of no greater than 600 mg of total caffeine; or
- (b) in undivided preparations with a concentration of less than 5% of caffeine and when labelled with a maximum recommended daily dose of no greater than 600 mg of total caffeine.

Substances marked # are listed in Appendix D

CALCIFEDIOL for human internal therapeutic use **except** in preparations containing 10 micrograms or less of calcifediol per recommended daily dose.

CALCIPOTRIOL.

CALCITONIN.

CALCITONIN SALMON.

CALCITRIOL.

CALCIUM CARBIMIDE for therapeutic use.

CALCIUM HYDROXYLAPATITE in preparations for injection or implantation:

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

CALCIUM POLYSTYRENE SULPHONATE.

CALOTROPIS GIGANTEA.

CALOTROPIS PROCERA.

# CALUSTERONE.

CAMPHORATED OIL for therapeutic use.

CAMPHOTAMIDE.

CANAGLIFLOZIN.

CANAKINUMAB.

CANDESARTAN CILEXETIL.

CANDICIDIN.

CANINE TICK ANTI-SERUM.

CANNABIDIOL in preparations for therapeutic use or analytical and scientific research where:

- (a) cannabidiol comprises 98% or more of the total cannabinoid content of the preparation; and
- (b) any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the preparation;

except when:

Substances marked # are listed in Appendix D

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- (c) included in Schedule 3; or
- (d) in hemp seed oil at a concentration of 75 mg/kg or less.

CANTHARIDIN.

CAPECITABINE.

CAPIVASERTIB.

CAPREOMYCIN.

# CAPROMORELIN.

CAPTODIAME.

CAPTOPRIL.

CAPURIDE.

CARAMIPHEN.

CARBACHOL.

CARBAMAZEPINE.

CARBARYL for human therapeutic use.

CARBAZOCHROME.

CARBENICILLIN.

CARBENOXOLONE for internal use.

CARBETOCIN.

CARBIDOPA.

CARBIMAZOLE.

CARBOCROMEN.

CARBOPLATIN.

CARBOPROST.

CARBROMAL.

CARBUTAMIDE.

CARBUTEROL.

Substances marked # are listed in Appendix D

CARFILZOMIB.

CARGLUMIC ACID (N-carbamoyl-L-glutamic acid).

CARINDACILLIN.

CARIPRAZINE.

CARISOPRODOL.

CARMUSTINE.

CARNIDAZOLE.

CARPROFEN.

CARVEDILOL.

CASIRIVIMAB.

CASPOFUNGIN.

CATHINE.

CATUMAXOMAB.

CEDAZURIDINE.

CEFACETRILE.

CEFACLOR.

CEFADROXIL.

CEFALEXIN.

CEFALORIDINE.

CEFALOTIN.

CEFAMANDOLE.

CEFAPIRIN.

CEFAZOLIN.

CEFEPIME.

CEFETAMET.

Substances marked # are listed in Appendix D
CEFIXIME.

CEFODIZIME.

CEFONICID.

CEFOPERAZONE.

CEFOTAXIME.

CEFOTETAN.

CEFOTIAM.

CEFOVECIN for veterinary use.

CEFOXITIN.

CEFPIROME.

CEFPODOXIME.

CEFQUINOME.

CEFTAROLINE FOSAMIL.

CEFSULODIN.

CEFTAZIDIME.

CEFTIBUTEN.

CEFTIOFUR.

CEFTRIAXONE.

CEFUROXIME.

CELECOXIB except when included in Schedule 3.

CELIPROLOL.

CENEGERMIN.

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

CEPHAELIS IPECACUANHA except in preparations containing 0.2% or less of emetine.

CEPHALONIUM.

Substances marked # are listed in Appendix D

CEPHRADINE.

CERITINIB.

CERIVASTATIN.

CERLIPONASE ALFA.

CERTOLIZUMAB PEGOL.

CERULETIDE.

# **CETIRIZINE** except

- (a) when included in Schedule 2; or
- (b) in divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and children 6 years of age and over when:
  - (i) in a primary pack containing not more than 10 days' supply; and
  - (ii) labelled with a recommended daily dose not exceeding 10 mg of cetirizine.

CETRORELIX.

CETUXIMAB.

CHENODEOXYCHOLIC ACID.

CHLORAL FORMAMIDE.

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

CHLORALOSE except when included in Schedule 6.

CHLORAMBUCIL.

CHLORAMPHENICOL except when included in Schedule 3.

# CHLORANDROSTENOLONE.

CHLORAZANIL.

CHLORCYCLIZINE.

# CHLORDIAZEPOXIDE.

CHLORMERODRIN.

CHLORMETHIAZOLE.

Substances marked # are listed in Appendix D

CHLORMEZANONE.

CHLOROFORM for use in anaesthesia.

# 4-CHLOROMETHANDIENONE.

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

CHLOROQUINE.

CHLOROTHIAZIDE.

CHLOROTRIANISENE.

# CHLOROXYDIENONE.

CHLORPHENAMINE except when included in Schedule 2 or 3.

CHLORPHENTERMINE.

CHLORPROMAZINE.

CHLORPROPAMIDE.

CHLORPROTHIXENE.

CHLORQUINALDOL for human topical use.

CHLORTALIDONE.

CHLORTETRACYCLINE except when included in Schedule 5.

CHLORZOXAZONE.

CHOLERA VACCINE.

CHOLIC ACID.

CHYMOPAPAIN for human therapeutic use.

CICLACILLIN.

CICLESONIDE.

CICLOPIROX except:

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

CICLOSPORIN.

Substances marked # are listed in Appendix D

CIDOFOVIR.

CILASTATIN.

CILAZAPRIL.

CILGAVIMAB.

CILOSTAZOL.

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

CIMICOXIB.

CINACALCET.

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

CINNARIZINE.

CINOXACIN.

CIPAGLUCOSIDASE ALFA.

CIPROFLOXACIN.

CISAPRIDE.

CISATRACURIUM BESILATE.

CISPLATIN.

CITALOPRAM.

# CJC-1295 (CAS No. 863288-34-0).

CLADRIBINE.

CLANOBUTIN.

CLARITHROMYCIN.

CLASCOTERONE.

CLAVULANIC ACID.

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

CLEMIZOLE.

Substances marked # are listed in Appendix D

CLENBUTEROL.

CLEVIDIPINE.

CLIDINIUM BROMIDE.

CLINDAMYCIN.

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

CLOBAZAM.

CLOBETASOL.

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

CLOCORTOLONE.

CLODRONIC ACID (includes sodium clodronate).

CLOFARABINE.

CLOFAZIMINE.

CLOFENAMIDE.

CLOFIBRATE.

# CLOMIFENE.

CLOMIPRAMINE.

CLOMOCYCLINE.

# CLONAZEPAM.

CLONIDINE.

CLOPAMIDE.

CLOPIDOGREL.

CLOPROSTENOL.

# CLORAZEPATE.

CLOREXOLONE.

CLORPRENALINE.

Substances marked # are listed in Appendix D

# CLOSTEBOL (4-chlorotestosterone).

#### CLOTRIMAZOLE except:

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

#### CLOXACILLIN.

# CLOZAPINE.

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

COBICISTAT.

#### COBIMETINIB.

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

- (a) in divided preparations containing 30 mg or less of codeine per dosage unit; or
- (b) in undivided preparations containing 1% or less of codeine.

## CO-DERGOCRINE.

COLCHICINE.

COLCHICUM AUTUMNALE.

COLESTIPOL.

COLESTYRAMINE for human therapeutic use.

COLFOSCERIL PALMITATE for human therapeutic use.

COLISTIN.

COLLAGEN in preparations for injection or implantation:

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

COLLAGENASE CLOSTRIDIUM HISTOLYTICUM.

COLURACETAM.

CONCIZUMAB.

CONVALLARIA KEISKI.

Substances marked # are listed in Appendix D

CONVALLARIA MAJALIS.

COPPER COMPOUNDS for human use except:

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

# CORIFOLLITROPIN ALFA.

CORONILLA spp.

CORTICOSTERONE.

CORTICOTROPHIN.

CORTISONE.

CO-TRIMOXAZOLE.

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

CRISABOROLE.

CRIZOTINIB.

CROFELEMER.

CUPRIMYXIN.

CURARE.

CYCLANDELATE.

CYCLIZINE except when included in Schedule 3.

CYCLOBENZAPRINE.

# CYCLOFENIL.

CYCLOHEXIMIDE.

CYCLOPENTHIAZIDE.

CYCLOPENTOLATE.

CYCLOPHOSPHAMIDE.

CYCLOPROPANE for therapeutic use.

Substances marked # are listed in Appendix D

CYCLOSERINE.

CYCLOTHIAZIDE.

CYCRIMINE.

CYMARIN.

CYPROHEPTADINE except when included in Schedule 3.

CYPROTERONE.

CYTARABINE.

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

DABRAFENIB MESILATE.

DABIGATRAN.

DACARBAZINE.

DACLATASVIR.

DACLIZUMAB.

DACTINOMYCIN.

DALFOPRISTIN.

DALTEPARIN (includes dalteparin sodium).

DANAPAROID (includes danaparoid sodium).

# DANAZOL.

DANICOPAN.

DANTHRON for human use.

DANTROLENE.

DAPAGLIFLOZIN.

DAPOXETINE.

DAPSONE.

DAPTOMYCIN.

Substances marked # are listed in Appendix D

DARATUMUMAB.

# DARBEPOETIN.

DARIFENACIN.

DAROLUTAMIDE.

DARUNAVIR.

DATOPOTAMAB DERUXTECAN.

DATURA spp. except:

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

# DASABUVIR.

DASATINIB.

DATURA STRAMONIUM (stramonium) except:

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

# DATURA TATULA (stramonium) except:

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

DAUNORUBICIN.

DEANOL for therapeutic use.

DEBRISOQUINE.

DECAMETHONIUM.

DECITABINE.

DEFERASIROX.

DEFERIPRONE.

DEFIBROTIDE.

DEFLAZACORT.

DEGARELIX.

Substances marked # are listed in Appendix D

# DEHYDROCHLOROMETHYLTESTOSTERONE.

DEHYDROCORTICOSTERONE.

DELAVIRDINE MESILATE.

DEMBREXINE except when included in Schedule 5.

DEMECARIUM.

DEMECLOCYCLINE.

DENGUE VACCINE.

DENOSUMAB.

DEOXYCHOLIC ACID.

DEOXYCORTONE.

DEOXYRIBONUCLEASE except:

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

DERACOXIB.

# DERMATOPHAGOIDES PTERONYSSINUS AND DERMATOPHAGOIDES FARINAE EXTRACT.

DESFERRIOXAMINE.

DESFLURANE.

DESIPRAMINE.

DESIRUDIN.

## DESLANOSIDE.

## **DESLORATADINE** except:

- (a) when included in Schedule 2; or
- (b) in divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and children 6 years of age and over, when:
  - (i) in a primary pack containing 10 dosage units or less; and
  - (ii) labelled with a recommended daily dose not exceeding 5 mg of desloratadine.

DESLORELIN.

Substances marked # are listed in Appendix D

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

DESOGESTREL.

DESONIDE.

DESOXYMETHASONE.

DESVENLAFAXINE.

DETOMIDINE.

DEUCRAVACITINIB.

DEUTETRABENAZINE.

DEXAMETHASONE.

DEXCHLORPHENAMINE except when included in Schedule 2 or 3.

DEXFENFLURAMINE.

DEXMEDETOMIDINE.

DEXRAZOXANE.

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

# # DEXTROPROPOXYPHENE:

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

DEXTRORPHAN (excluding its stereoisomers).

DIAMTHAZOLE.

DIAVERIDINE.

# DIAZEPAM.

DIAZOXIDE.

DIBENZEPIN.

DIBOTERMIN.

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

Substances marked # are listed in Appendix D

DICHLORALPHENAZONE.

DICHLOROPHEN for human therapeutic use.

DICHLORPHENAMIDE.

DICLOFENAC except:

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

DICLOXACILLIN.

DICYCLOMINE.

DIDANOSINE.

DIENESTROL.

DIENOGEST.

DIETHAZINE.

DIETHYLCARBAMAZINE for human therapeutic use.

DIETHYLPROPION.

DIFELIKEFALIN.

DIFENOXIN in preparations containing, per dosage unit, 0.5 mg or less of difenoxin and a quantity of atropine sulfate equivalent to at least 5% of the dose of difenoxin.

DIFLORASONE.

DIFLOXACIN.

DIFLUCORTOLONE.

DIFLUNISAL.

DIGITALIS LANATA.

DIGITALIS PURPUREA.

DIGITOXIN.

DIGOXIN.

Substances marked # are listed in Appendix D

# DIGOXIN-SPECIFIC ANTIBODY FRAGMENT F (Ab).

## DIHYDRALAZINE.

- DIHYDROCODEINE when compounded with one or more other therapeutically active substances:
  - (a) in divided preparations containing not more than 100 mg of dihydrocodeine per dosage unit; or
  - (b) in undivided preparations with a concentration of not more than 2.5% of dihydrocodeine;

except when included in Schedule 3.

#### DIHYDROERGOTOXINE.

# DIHYDROLONE.

DIHYDROSTREPTOMYCIN.

DIHYDROTACHYSTEROL.

DIIODOHYDROXYQUINOLINE (iodoquinol) except:

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

DIISOPROPYLAMINE DICHLOROACETATE.

DILTIAZEM.

DIMENHYDRINATE except when included in Schedule 2 or 3.

DIMERCAPROL.

# DIMETHANDROSTANOLONE.

# DIMETHAZINE.

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

DIMETHOTHIAZINE.

DIMETHOXANATE.

DIMETHYL FUMARATE.

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

(a) when included in Schedule 6; or

Substances marked # are listed in Appendix D

- (b) in *in vitro* test kits; or
- (c) when used as a flavour component in compliance with the current Therapeutic Goods (Permissible Ingredients) determination for listed medicines.

DIMETRIDAZOLE.

DIMIRACETAM.

2,4-DINITROCHLOROBENZENE for therapeutic use.

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

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

DINITROPHENOLS for therapeutic use.

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

# DINOPROST.

# DINOPROSTONE.

DIPERODON.

DIPHEMANIL except in preparations for dermal use.

DIPHENHYDRAMINE except when included in Schedule 2 or 3.

DIPHENIDOL.

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

DIPHENYLPYRALINE.

DIPHTHERIA TOXOID.

DIPIVEFRIN.

DIPYRIDAMOLE.

DIRITHROMYCIN.

DIRLOTAPIDE.

DIROXIMEL FUMARATE.

Substances marked # are listed in Appendix D

DISOPHENOL.

DISOPYRAMIDE.

DISTIGMINE.

DISULFIRAM for therapeutic use.

DISULPHAMIDE.

DITHIAZANINE except when included in Schedule 6.

DITIOCARB.

DOBUTAMINE.

DOCETAXEL.

DOFETILIDE.

DOLASETRON.

DOLUTEGRAVIR.

DOMPERIDONE.

DONEPEZIL.

DOPAMINE.

DOPEXAMINE.

DORAVIRINE.

DORIPENEM.

DORNASE.

DORZOLAMIDE.

DOSULEPIN.

DOXANTRAZOLE.

DOXAPRAM.

DOXAZOSIN.

DOXEPIN.

Substances marked # are listed in Appendix D

DOXORUBICIN.

DOXYCYCLINE.

DOXYLAMINE except when included in Schedule 2 or 3.

DRONEDARONE.

DROPERIDOL.

DROSPIRENONE.

# DROSTANOLONE.

DROTRECOGIN.

DUBOISIA LEICHHARDTII except when included in Schedule 2.

DUBOISIA MYOPOROIDES except when included in Schedule 2.

DULAGLUTIDE.

DULOXETINE.

DUPILUMAB.

DURVALUMAB.

DUTASTERIDE.

DYDROGESTERONE.

ECONAZOLE except:

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

ECOTHIOPATE (includes ecothiopate iodide).

ECTYLUREA.

ECULIZUMAB.

EDARAVONE.

- EDETIC ACID for human therapeutic use **except**:
  - (a) in preparations containing 0.25% or less of edetic acid; or
  - (b) as dicobalt edetate in preparations for the treatment of cyanide poisoning; or
  - (c) in contact lens preparations.

Substances marked # are listed in Appendix D

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EDOXUDINE.

EDROPHONIUM.

EFALIZUMAB.

EFAVIRENZ.

EFGARTIGIMOD ALFA.

EFLORNITHINE.

ELACESTRANT DIHYDROCHLORIDE.

ELAFIBRANOR.

ELBASVIR.

ELETRIPTAN except when included in Schedule 3.

ELEXACAFTOR.

ELOSULFASE ALFA.

ELOTUZUMAB.

ELRANATAMAB.

ELTENAC.

ELTROMBOPAG.

ELUXADOLINE.

ELVITEGRAVIR.

EMEPRONIUM.

EMETINE except in preparations containing 0.2% or less of emetine.

EMPAGLIFLOZIN.

EMTRICITABINE.

ENALAPRIL.

ENASIDENIB.

ENCORAFENIB.

Substances marked # are listed in Appendix D

# ENESTEBOL.

ENFLURANE for therapeutic use.

ENFORTUMAB VEDOTIN.

ENFUVIRTIDE.

# ENOBOSARM.

ENOXACIN.

ENOXAPARIN.

ENOXIMONE.

ENPROSTIL.

ENROFLOXACIN.

ENTACAPONE.

ENTECAVIR.

ENTRECTINIB.

ENZALUTAMIDE.

EPHEDRA spp. except in preparations containing 0.001% or less of ephedrine.

# EPHEDRINE.

EPICILLIN.

EPINASTINE.

EPIRUBICIN.

# EPITIOSTANOL.

EPLERENONE.

# EPOETINS.

EPOPROSTENOL.

EPROSARTAN.

EPTIFIBATIDE.

Substances marked # are listed in Appendix D

ERENUMAB.

ERGOMETRINE.

ERGOT.

ERGOTAMINE.

ERGOTOXINE.

ERIBULIN MESILATE.

ERLOTINIB.

ERTAPENEM.

ERTUGLIFLOZIN.

ERYSIMUM spp.

ERYTHROMYCIN.

# ERYTHROPOIETIN.

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

ESCITALOPRAM.

ESLICARBAZEPINE ACETATE.

ESMOLOL.

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

ESTETROL MONOHYDRATE.

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

ESTRIOL.

ESTRAMUSTINE.

ESTROGENS except when separately specified in these Schedules.

ESTRONE.

ESTROPIPATE (piperazine estrone sulfate).

ETACRYNIC ACID.

Substances marked # are listed in Appendix D

ETANERCEPT.

ETHAMBUTOL.

ETHAMIVAN.

ETHCHLORVYNOL.

ETHER for use in anaesthesia.

ETHINAMATE.

ETHINYLESTRADIOL.

ETHIONAMIDE.

# ETHISTERONE.

ETHOGLUCID.

ETHOHEPTAZINE.

ETHOPROPAZINE.

ETHOSUXIMIDE.

ETHOTOIN.

ETHOXZOLAMIDE.

ETHYL CHLORIDE for human therapeutic use.

# ETHYLDIENOLONE.

- ETHYLMORPHINE when compounded with one or more other therapeutically active substances:
  - (a) in divided preparations containing not more than 100 mg of ethylmorphine per dosage unit; or
  - (b) in undivided preparations with a concentration of not more than 2.5% of ethylmorphine.

#### # ETHYLESTRENOL.

# ETIDOCAINE.

ETIDRONIC ACID (includes etidronate disodium):

(a) for internal use; or

Substances marked # are listed in Appendix D

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

ETILEFRIN.

ETIPROSTON.

ETODOLAC.

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

ETONOGESTREL.

ETOPOSIDE.

ETORICOXIB.

ETRANACOGENE DEZAPARVOVEC.

ETRASIMOD.

ETRAVIRINE.

# ETRETINATE.

ETYNODIOL.

EVEROLIMUS.

EXEMESTANE.

EXENATIDE.

EZETIMIBE.

FAMCICLOVIR except when included in Schedule 3.

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

FARICIMAB.

FASORACETAM.

FEBUXOSTAT.

FEDRATINIB.

FELBINAC except when included in Schedule 2.

FELODIPINE.

Substances marked # are listed in Appendix D

FELYPRESSIN.

FENBUFEN.

FENCAMFAMIN.

FENCLOFENAC.

FENFLURAMINE.

FENOFIBRATE.

FENOLDOPAM.

FENOPROFEN.

FENOTEROL.

FENPIPRAMIDE.

FENPIPRANE.

FENPROPOREX.

FENPROSTALENE.

#### FERRIC DERISOMALTOSE.

## FEXOFENADINE except:

- (a) when included in Schedule 2; or
- (b) in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:
  - (i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and
  - (ii) labelled with a recommended daily dose not exceeding 120 mg of fexofenadine; or
- (c) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:
  - (i) in a primary pack containing 10 dosage units or less and not more than 10 days' supply; and
  - (ii) labelled with a recommended daily dose not exceeding 180 mg of fexofenadine; or
- (d) for the treatment of seasonal allergic rhinitis and children 6 years of age and over when:

Substances marked # are listed in Appendix D

- (i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and
- (ii) labelled with a recommended daily dose not exceeding 60 mg of fexofenadine.

FEZOLINETANT.

FIBRINOLYSIN except for external use.

# FIBROBLAST GROWTH FACTORS.

FIDAXOMICIN.

FILGOTINIB.

FILGRASTIM.

FINASTERIDE.

FINERENONE.

FINGOLIMOD.

FIROCOXIB.

FLECAINIDE.

FLEROXACIN.

FLOCTAFENINE.

FLORFENICOL.

FLUANISONE.

FLUCLOROLONE.

FLUCLOXACILLIN.

FLUCONAZOLE except when included in Schedule 3.

FLUCYTOSINE.

FLUDARABINE.

FLUDROCORTISONE.

FLUFENAMIC ACID.

FLUMAZENIL.

Substances marked # are listed in Appendix D

FLUMETASONE.

FLUMETHIAZIDE.

FLUNISOLIDE.

FLUNIXIN MEGLUMINE.

FLUOCINOLONE.

FLUOCINONIDE.

FLUOCORTIN.

FLUOCORTOLONE.

FLUORESCEIN in preparations for injection.

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

FLUOROMETHOLONE.

FLUOROURACIL.

FLUOXETINE.

# FLUOXYMESTERONE.

FLUPENTIXOL.

FLUPHENAZINE.

FLUPROSTENOL.

FLURALANER in injectable preparations for use in companion animals.

FLURANDRENOLONE.

# FLURAZEPAM.

FLURBIPROFEN except when:

- (a) included in Schedule 2; or
- (b) in divided preparations for topical oral use that contain 10 mg or less of flurbiprofen per dosage unit and that are:
  - (i) in a primary pack containing not more than 16 dosage units; and
  - (ii) labelled only for the treatment of adults and children over 12 years; or
- (c) in undivided preparations for topical oral use containing either:

Substances marked # are listed in Appendix D

- (i) 0.25% or less of flurbiprofen per dose; or
- (ii) 10 mg or less of flurbiprofen per dose; and

that are:

- (iii) in a primary pack containing not more than 15 Ml; and
- (iv) labelled only for the treatment of adults 18 years and over.

FLUROXENE for human therapeutic use.

FLUSPIRILENE.

FLUTAMIDE.

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

FLUVASTATIN.

FLUVOXAMINE.

FOLIC ACID in preparations for human use for injection.

FOLINIC ACID in preparations for human use for injection.

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

# FOLLISTATIN.

# FOLLITROPIN ALFA.

# FOLLITROPIN BETA.

# FOLLITROPIN DELTA.

FOMEPIZOLE.

FOMIVIRSEN.

FONDAPARINUX.

# FORMEBOLONE.

FORMESTANE.

FORMOTEROL

FOSAMPRENAVIR.

FOSAPREPITANT.

Substances marked # are listed in Appendix D

FOSCARNET.

FOSFESTROL (diethylstilbestrol diphosphate).

FOSFOMYCIN.

FOSINOPRIL.

FOSNETUPITANT.

FOSPHENYTOIN.

FOSTEMSAVIR.

FOTEMUSTINE.

FRAMYCETIN.

FRUQUINTINIB.

FULVESTRANT.

FURALTADONE.

# FURAZABOL.

FURAZOLIDONE.

FUROSEMIDE (frusemide).

FUSIDIC ACID.

FUTIBATINIB.

FUZAPLADIB SODIUM.

GABAPENTIN.

GALANTAMINE.

GALANTHUS spp.

GALCANEZUMAB.

GALLAMINE.

GALSULFASE.

GANCICLOVIR.

Substances marked # are listed in Appendix D

GANIRELIX.

GARADACIMAB.

GATIFLOXACIN.

GRAZOPREVIR.

GEFITINIB.

GEMCITABINE.

GEMEPROST.

GEMFIBROZIL.

GEMIFLOXACIN.

GEMTUZUMAB OZOGAMICIN.

GENTAMICIN.

GESTODENE.

GESTONORONE.

# GESTRINONE.

GHRH INJECTABLE PLASMID.

GILTERITINIB.

GITALIN.

GIVOSIRAN.

GLATIRAMER ACETATE.

GLECAPREVIR.

GLIBENCLAMIDE.

GLIBORNURIDE.

GLICLAZIDE.

GLIMEPIRIDE.

GLIPIZIDE.

Substances marked # are listed in Appendix D

GLIPTINS except when separately specified in these Schedules.

GLISOXEPIDE.

GLOFITAMAB.

GLUTATHIONE for parenteral use.

# GLUTETHIMIDE.

GLYCERYL TRINITRATE except when included in Schedule 3.

GLYCOPYRRONIUM.

GLYMIDINE.

GnRH VACCINE.

GOLIMUMAB.

GONADORELIN.

GONADOTROPHIC HORMONES except when separately specified in this Schedule.

GOSERELIN.

GRAMICIDIN.

GRANISETRON.

GRAPIPRANT.

GREPAFLOXACIN.

GRISEOFULVIN.

# GROWTH HORMONE RELEASING HORMONES\* (GHRHs).

# GROWTH HORMONE RELEASING PEPTIDES (GHRPs).

# GROWTH HORMONE RELEASING PEPTIDE-6 (GHRP-6).

# GROWTH HORMONE SECRETAGOGUES\* (GHSs).

GUAIFENESIN for human therapeutic use except:

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

Substances marked # are listed in Appendix D

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GUANABENZ.

GUANACLINE.

GUANETHIDINE.

GUANFACINE.

GUANIDINE for therapeutic use.

GUSELKUMAB.

HACHIMYCIN.

HAEMATIN.

HAEMOPHILUS INFLUENZAE VACCINE.

HALCINONIDE.

HALOFANTRINE.

HALOFENATE.

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

HALOPERIDOL.

HALOTHANE for therapeutic use.

HEMEROCALLIS (Hemerocallis flava).

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

HEPATITIS A VACCINE.

HEPATITIS B VACCINE.

HETACILLIN.

HEXACHLOROPHENE:

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

HEXAMETHONIUM.

Substances marked # are listed in Appendix D

# HEXARELIN.

HEXETIDINE for human internal use.

HEXOBENDINE.

HEXOCYCLIUM.

HEXOPRENALINE.

HEXYL AMINOLEVULINATE (AS HYDROCHLORIDE).

HISTAMINE for therapeutic use except in preparations containing 0.5% or less of histamine.

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

HOMATROPINE.

HUMAN CHORIONIC GONADOTROPHIN except in pregnancy test kits.

HUMAN PAPILLOMAVIRUS VACCINE.

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

HYDRALAZINE.

HYDRARGAPHEN.

HYDROCHLOROTHIAZIDE.

## HYDROCORTISONE:

- (a) for human use **except** when included in Schedule 2 or 3; or
- (b) for the treatment of animals.
- HYDROCYANIC ACID for therapeutic use **except** in preparations containing 10 mg/kg or less of hydrocyanic acid.

## HYDROFLUMETHIAZIDE.

- HYDROQUINONE (other than its alkyl ethers separately specified in this Schedule) in preparations for human therapeutic or cosmetic use **except**:
  - (a) when included in Schedule 2; or
  - (b) in hair preparations containing 0.3% or less of hydroquinone; or
  - (c) in cosmetic nail preparations containing 0.02% or less of hydroquinone.

HYDROXYCARBAMIDE.

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Substances marked # are listed in Appendix D

HYDROXYCHLOROQUINE.

HYDROXYEPHEDRINE.

HYDROXYPHENAMATE.

HYDROXYPROGESTERONE.

# HYDROXYSTENOZOL.

HYDROXYZINE.

HYGROMYCIN.

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

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

HYOSCINE BUTYLBROMIDE except when included in Schedule 2 or Schedule 3.

HYOSCYAMUS NIGER except:

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

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

HYPROMELLOSE in preparations for injection.

IBAFLOXACIN for veterinary use.

IBANDRONIC ACID.

IBOGAINE.

IBRITUMOMAB.

IBRUTINIB.

IBUFENAC.

IBUPROFEN except when:

- (a) included in Schedule 2 or 3; or
- (b) in preparations for dermal use; or
- (c) in preparations for oral use that are labelled with a recommended daily dose of 1200 mg or less of ibuprofen in divided preparations, each containing 200 mg or less of ibuprofen, in a pack containing not more than 100 dosage units when:

Substances marked # are listed in Appendix D

- (i) ibuprofen is the only therapeutically active constituent, other than phenylephrine or when combined with an effervescent agent; and
- (ii) packed in blister or strip packaging or in a container with a child-resistant closure; and
- (iii) in a primary pack containing not more than 25 dosage units; and
- (iv) compliant with the requirements of the required advisory statements for medicine labels; and
- (v) not labelled for the treatment of children 6 years and under; and
- (vi) if combined with phenylephrine—not labelled for the treatment of children under 12 years.

# IBUTAMOREN.

IBUTEROL.

IBUTILIDE.

ICATIBANT.

IDARUBICIN.

IDARUCIZUMAB.

IDEBENONE.

IDOXURIDINE except in preparations containing 0.5% or less of idoxuridine for dermal use.

IDURSULFASE.

IFOSFAMIDE.

ILOPROST.

ILUNOCITINIB.

IMATINIB.

IMDEVIMAB.

IMEPITOIN.

IMIDAPRIL.

IMIGLUCERASE.

IMIPENEM.

Substances marked # are listed in Appendix D

IMIPRAMINE.

IMIQUIMOD.

IMLIFIDASE.

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

INAVOLISIB.

INCLISIRAN.

INDACATEROL.

INDAPAMIDE.

INDINAVIR.

INDOMETACIN except when included in Schedule 2.

INDOPROFEN.

INDORAMIN.

INEBILIZUMAB.

INFIGRATINIB.

INFLIXIMAB.

INFLUENZA AND CORYZA VACCINES:

- (a) for parenteral use; or
- (b) for nasal administration.

INGENOL MEBUTATE.

INOTUZUMAB OZOGAMICIN.

INSULIN DEGLUDEC.

INSULIN GLARGINE.

# INSULIN-LIKE GROWTH FACTOR I.

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

INSULINS.

Substances marked # are listed in Appendix D

INTERFERONS.

INTERLEUKINS except when separately specified in these Schedules.

IODOTHIOURACIL.

# IPAMORELIN.

IPILIMUMAB.

IPRATROPIUM except when included in Schedule 2.

IPRIFLAVONE.

IPRINDOLE.

IPRONIAZID.

IPTACOPAN.

IRBESARTAN.

IRINOTECAN.

IRON COMPOUNDS in injectable preparations for human use.

ISAVUCONAZOLE.

ISOAMINILE.

ISOAMYL NITRITE.

ISOBUTYL NITRITE.

ISOCARBOXAZID.

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

ISOETARINE.

ISOFLURANE for therapeutic use.

ISOMETHEPTENE.

ISONIAZID.

ISOPRENALINE.

ISOPRINOSINE.

Substances marked # are listed in Appendix D

ISOPROPAMIDE except when included in Schedule 2.

ISOSORBIDE DINITRATE except when included in Schedule 3.

ISOSORBIDE MONONITRATE.

# ISOTRETINOIN.

ISOXICAM.

ISOXSUPRINE.

ISRADIPINE.

ITRACONAZOLE.

IVABRADINE.

IVACAFTOR.

**IVERMECTIN:** 

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

IVOSIDENIB.

IXABEPILONE.

IXAZOMIB.

IXEKIZUMAB.

JAPANESE ENCEPHALITIS VACCINE.

KANAMYCIN.

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

# KETAZOLAM.

## KETOCONAZOLE except:

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

Substances marked # are listed in Appendix D

## KETOPROFEN except:

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

KETOROLAC (includes ketorolac trometamol).

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

KHELLIN.

KITASAMYCIN except:

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

LABETALOL.

LACIDIPINE.

LACOSAMIDE.

LAMIVUDINE.

LAMOTRIGINE.

LANADELUMAB.

LANATOSIDES.

LANDIOLOL.

LANREOTIDE.

LANSOPRAZOLE except when included in Schedule 2 or 3.

LANTHANUM for therapeutic use.

LAPATINIB.

LARONIDASE.

LAROPIPRANT.

LAROTRECTINIB.

LATAMOXEF.

LATANOPROST.

Substances marked # are listed in Appendix D
# LAUDEXIUM.

LAUROMACROGOLS in preparations for injection except:

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

LAZERTINIB.

LEBRIKIZUMAB.

LECANEMAB.

LEDIPASVIR.

LEFETAMINE.

LEFLUNOMIDE.

LEMBOREXANT.

LENACAPAVIR.

# LENALIDOMIDE.

LENOGRASTIM.

LENVATINIB.

LEPIRUDIN.

LEPTAZOL.

LERCANIDIPINE.

LESINURAD.

LETERMOVIR.

LETROZOLE.

LEUPRORELIN.

LEVALLORPHAN.

LEVAMISOLE:

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

Substances marked # are listed in Appendix D

## LEVETIRACETAM.

### LEVOBUNOLOL.

## LEVOBUPIVACAINE.

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

### LEVOCETIRIZINE except:

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

## LEVODOPA.

LEVOMEPROMAZINE.

LEVOMILNACIPRAN.

LEVONORGESTREL except when included in Schedule 3.

LEVOSIMENDAN.

LIDOCAINE except:

- (a) when included in Schedules 2 or 5; or
- (b) in dermal preparations containing 2% or less of total local anaesthetic substances per dosage unit; or
- (c) in lozenges containing 30 mg or less of total anaesthetic substances per dosage unit.

LIDOFLAZINE.

LIFITEGRAST.

LINACLOTIDE.

LINAGLIPTIN.

LINCOMYCIN.

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

LINEZOLID.

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LIOTHYRONINE.

LIPEGFILGRASTIM.

LIRAGLUTIDE.

LISINOPRIL.

LISURIDE.

LITHIUM for therapeutic use except:

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

## LIXISENATIDE.

LODOXAMIDE except when included in Schedule 2.

LOFEXIDINE.

LOGIPARIN for internal use.

LOMEFLOXACIN.

LOMUSTINE.

LOPERAMIDE except:

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

LOPINAVIR.

### # LOPRAZOLAM.

### LORACARBEF.

### LORATADINE **except**:

- (a) when included in Schedule 2; or
- (b) in divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and children 6 years of age and over, when:
  - (i) in a primary pack containing 10 dosage units or less; and
  - (ii) labelled with a recommended daily dose not exceeding 10 mg of loratadine.

Substances marked # are listed in Appendix D

# LORAZEPAM.

LORLATINIB.

# LORMETAZEPAM.

LOSARTAN.

LOTEPREDNOL.

LOXAPINE.

LUMACAFTOR.

LUMASIRAN.

LUMEFANTRINE.

LUMIRACOXIB.

LURASIDONE.

LURBINECTEDIN.

LUSPATERCEPT.

# LUTEINISING HORMONE except in ovulation test kits.

LYMECYCLINE.

MACITENTAN for human use.

MAFENIDE except when included in Schedule 6.

MANDRAGORA OFFICINARUM.

MANNOMUSTINE.

MAPROTILINE.

MARAVIROC.

MARBOFLOXACIN.

MARIBAVIR.

MAROPITANT.

MARSTACIMAB.

Substances marked # are listed in Appendix D

MAVACAMTEN.

MAVACOXIB.

MAZINDOL.

MEASLES VACCINE.

MEBANAZINE.

MEBEVERINE.

MEBHYDROLIN.

# MEBOLAZINE.

MEBUTAMATE.

MECAMYLAMINE.

MECASERMIN.

MECILLINAM.

MECLOCYCLINE.

MECLOFENAMATE.

MECLOFENOXATE.

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

# MEDAZEPAM.

MEDETOMIDINE.

MEDIGOXIN (methyldigoxin).

MEDROXYPROGESTERONE.

MEDRYSONE.

MEFENAMIC ACID except when included in Schedule 2.

MEFENOREX.

MEFLOQUINE.

MEFRUSIDE.

Substances marked # are listed in Appendix D

MEGESTROL.

MELAGATRAN.

MELANOTAN II.

MELATONIN for human use **except** when included in Schedule 3.

MELENGESTROL except when included in Schedule 6.

MELOXICAM except when included in Schedule 6.

MELPHALAN.

MEMANTINE.

MENINGOCOCCAL VACCINE.

MENINGOCOCCAL GROUP B VACCINE.

MENOTROPHIN.

MEPACRINE.

MEPENZOLATE.

MEPHENESIN.

MEPHENTERMINE.

MEPINDOLOL.

# MEPITIOSTANE.

MEPIVACAINE.

MEPROBAMATE.

MEPTAZINOL.

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

MEQUITAZINE.

MERCAPTAMINE for human therapeutic use.

MERCAPTOMERIN.

MERCAPTOPURINE.

Substances marked # are listed in Appendix D

MERCUROCHROME except when included in Schedule 2 or 6.

MERCURY for cosmetic or therapeutic use except:

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

MEROPENEM.

MERSALYL.

# MESABOLONE.

MESALAZINE.

MESNA.

# MESTANOLONE (androstalone).

# MESTEROLONE.

MESTRANOL.

# METANDIENONE.

METARAMINOL.

# METENOLONE.

METERGOLINE.

METFORMIN.

METHACHOLINE.

METHACYCLINE.

METHALLENESTRIL.

# METHANDRIOL.

METHANTHELINIUM.

METHAZOLAMIDE.

METHDILAZINE except when included in Schedule 3.

# METHENOLONE.

METHICILLIN.

Substances marked # are listed in Appendix D

METHIMAZOLE.

METHISAZONE.

METHIXENE.

METHOCARBAMOL.

METHOHEXITONE.

METHOIN.

METHOTREXATE.

METHOXAMINE except:

- (a) when included in Schedule 2; or
- (b) in preparations for external use containing 1% or less of methoxamine.

METHOXSALEN.

METHOXYFLURANE.

METHSUXIMIDE.

METHYCLOTHIAZIDE.

METHYL AMINOLEVULINATE.

#METHYLANDROSTANOLONE.

# METHYLCLOSTEBOL.

METHYLDOPA.

METHYLENE BLUE in preparations for injection.

METHYLERGOMETRINE.

METHYLMERCURY for therapeutic use.

METHYLNALTREXONE.

METHYLPENTYNOL.

METHYLPHENOBARBITAL.

METHYLPHENYLPIRACETAM.

METHYLPREDNISOLONE.

Substances marked # are listed in Appendix D

METHYLROSANILINIUM CHLORIDE for human use **except** when used as a dermal marker.

METHYL SALICYLATE in preparations for internal therapeutic use.

# METHYLTESTOSTERONE.

METHYLTHIOURACIL.

# METHYLTRIENOLONE.

METHYPRYLONE.

METHYSERGIDE.

METOCLOPRAMIDE except when included in Schedule 3.

METOLAZONE.

METOPROLOL.

# METRIBOLONE.

METRIFONATE (trichlorfon) for human therapeutic use.

METRONIDAZOLE.

METYRAPONE.

MEXILETINE.

MEZLOCILLIN.

MIANSERIN.

MIBEFRADIL.

# MIBOLERONE.

MICAFUNGIN.

MICONAZOLE except:

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

# MIDAZOLAM.

MIDOSTAURIN.

Substances marked # are listed in Appendix D

MIDODRINE.

MIFEPRISTONE.

MIGALASTAT.

MIGLITOL.

MIGLUSTAT.

MILBEMYCIN OXIME except when included in Schedule 5.

MILNACIPRAN.

MILRINONE.

MINOCYCLINE.

MINOXIDIL except when included in Schedule 2.

MIRABEGRON.

MIRIKIZUMAB.

MIRTAZAPINE.

MISOPROSTOL.

MITOBRONITOL.

MITOMYCIN.

MITOTANE.

MITOXANTRONE.

MITRATAPIDE.

MIVACURIUM CHLORIDE.

MOBOCERTINIB.

MOCLOBEMIDE.

MODAFINIL.

MOLGRAMOSTIM.

# MOLIDUSTAT.

Substances marked # are listed in Appendix D

MOLINDONE.

MOLNUPIRAVIR.

#### MOMELOTINIB.

MOMETASONE except when included in Schedule 2 or Schedule 3.

#### MONENSIN except:

- (a) when included in Schedule 5 or 6; or
- (b) in animal feeds containing 360 mg/kg or less of antibiotic substances.
- MONOBENZONE and alkyl ethers of hydroquinone for human therapeutic use or cosmetic use **except** in cosmetic nail preparations containing 0.02% or less of monobenzone or alkyl ethers of hydroquinone.

MONOCLONAL ANTIBODIES for therapeutic use except:

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

MONOETHANOLAMINE in preparations for injection.

MONTELUKAST.

MOPERONE.

MORAZONE.

MORICIZINE.

MOTRAZEPAM.

MOTRETINIDE.

MOXIDECTIN in preparations for injection containing 10% or less of moxidectin **except** when included in Schedule 5 or 6.

MOXIFLOXACIN.

MOXONIDINE.

MUMPS VACCINE.

MUPIROCIN.

MURAGLITAZAR.

MUROMONAB.

Substances marked # are listed in Appendix D

MUSTINE (nitrogen mustard).

MYCOPHENOLIC ACID (includes mycophenolate mofetil).

NABUMETONE.

NADOLOL.

NADROPARIN.

NAFARELIN.

NAFTIDROFURYL.

NALBUPHINE.

NALIDIXIC ACID.

NALMEFENE.

NALORPHINE.

NALOXEGOL.

NALOXONE except when in Schedule 3.

NALTREXONE.

# NANDROLONE.

NAPROXEN except when included in Schedule 2 or 3.

NARASIN except:

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

NARATRIPTAN except when included in Schedule 3.

NATALIZUMAB.

NATAMYCIN except for use as a food additive.

NATEGLINIDE.

NEBACUMAB.

NEBIVOLOL.

NEBRACETAM.

Substances marked # are listed in Appendix D

NEDOCROMIL.

NEFAZODONE.

NEFIRACETAM.

NEFOPAM.

NELARABINE.

NELFINAVIR (includes nelfinavir mesilate).

NEOMYCIN.

NEOSTIGMINE.

NEPAFENAC.

NERATINIB.

NERIUM OLEANDER.

NESIRITIDE.

NETILMICIN.

NETUPITANT.

NEVIRAPINE.

NIALAMIDE.

NICARDIPINE.

NICERGOLINE.

NICOFURANOSE.

NICORANDIL.

# NICOTINE in preparations for human use except:

- (a) when included in Schedule 3; or
- (b) in preparations for oromucosal or transdermal administration for human therapeutic use when included in the Register as an aid in withdrawal either from tobacco smoking or nicotine vaping; or
- (c) in tobacco prepared and packed for smoking.

NICOTINIC ACID in preparations for:

Substances marked # are listed in Appendix D

## (a) human therapeutic use **except**:

- (i) when separately specified in these Schedules; or
- (ii) in preparations containing 100 mg or less of nicotinic acid per dosage unit; or
- (iii) nicotinamide; or
- (b) animal therapeutic use when packed and labelled for injection.

NICOUMALONE.

NIFEDIPINE.

NIFENAZONE.

NIKETHAMIDE.

NILOTINIB.

NILUTAMIDE.

NIMESULIDE.

NIMODIPINE.

NIMORAZOLE.

NINTEDANIB.

NIRAPARIB.

NIRIDAZOLE.

NIRMATRELVIR.

NIRSEVIMAB.

NISOLDIPINE.

NITISINONE.

# NITRAZEPAM.

NITRENDIPINE.

NITRIC OXIDE for human therapeutic use.

NITROFURANTOIN.

NITROFURAZONE.

Substances marked # are listed in Appendix D

NITROUS OXIDE for therapeutic use.

NITROXOLINE.

NIVOLUMAB.

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

NOMEGESTROL.

NOMIFENSINE.

NORADRENALINE.

# 19-NORANDROSTENEDIOL.

# 19-NORANDROSTENEDIONE.

# NORANDROSTENOLONE.

# NORBOLETHONE.

# NORCLOSTEBOL.

NORELGESTROMIN.

# NORETHANDROLONE.

NORETHISTERONE.

NORFLOXACIN.

NORGESTREL.

NORIBOGAINE.

NORMAL HUMAN IMMUNOGLOBULIN.

# NORMETHANDRONE.

NORTRIPTYLINE.

NOVOBIOCIN.

NOXIPTYLINE.

NUSINERSEN.

NYSTATIN except when included in Schedule 2 or 3.

Substances marked # are listed in Appendix D

OBETICHOLIC ACID.

OCLACITINIB.

OCRELIZUMAB.

OCRIPLASMIN.

OCTAMYLAMINE.

OCTATROPINE.

OCTREOTIDE.

OCTYL NITRITE.

ODEVIXIBAT.

OFATUMUMAB.

OFLOXACIN.

OLANZAPINE.

OLAPARIB.

OLARATUMAB.

OLEANDOMYCIN except:

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

OLEANDRIN.

OLIPUDASE ALFA.

OLMESARTAN.

OLODATEROL.

OLOPATADINE except when included in Schedule 2.

OLSALAZINE.

OMALIZUMAB.

OMBERACETAM.

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Substances marked # are listed in Appendix D

## OMBITASVIR.

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

OMEPRAZOLE except when included in Schedule 2 or 3.

ONASEMNOGENE ABEPARVOVEC.

ONDANSETRON.

OPICAPONE.

OPIPRAMOL.

ORBIFLOXACIN.

ORCIPRENALINE.

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

- (a) when separately specified in these Schedules; or
- (b) in preparations containing 2% or less of malathion for external use.

ORLISTAT except when included in Schedule 3.

ORNIDAZOLE.

ORNIPRESSIN.

ORPHENADRINE.

ORTHOPTERIN.

OSELTAMIVIR.

OSILODROSTAT.

OSIMERTINIB.

OUABAIN.

# OVANDROTONE.

# OXABOLONE.

OXACILLIN.

OXALIPLATIN.

Substances marked # are listed in Appendix D

# OXANDROLONE.

OXAPROZIN.

# OXAZEPAM.

OXCARBAZEPINE.

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

OXETACAINE (oxethazaine) except when included in Schedule 2.

OXICONAZOLE except:

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

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

OXIRACETAM.

OXITROPIUM.

OXOLAMINE.

OXOLINIC ACID.

OXPRENOLOL.

OXYBUPROCAINE.

OXYBUTYNIN.

# OXYMESTERONE.

# OXYMETHOLONE.

OXYPHENBUTAZONE.

OXYPHENCYCLIMINE.

OXYPHENONIUM.

OXYTETRACYCLINE except when included in Schedule 5.

OXYTOCIN.

OZANIMOD.

PACLITAXEL.

Substances marked # are listed in Appendix D

PALBOCICLIB.

PALIFERMIN.

PALIPERIDONE.

PALIVIZUMAB.

PALONOSETRON.

PALOPEGTERIPARATIDE.

PALOVAROTENE.

PAMAQUIN.

PAMIDRONIC ACID (includes pamidronate disodium).

## PANCREATIC ENZYMES except:

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

PANCURONIUM.

PANITUMUMAB.

PANOBINOSTAT.

PANTOPRAZOLE except when included in Schedule 2 or 3.

PAPAVERINE in preparations for injection.

PARACETAMOL:

- (a) when combined with aspirin or salicylamide or any derivative of these substances **except** when separately specified in these Schedules; or
- (b) when combined with ibuprofen in a primary pack containing more than 30 dosage units; or
- (c) in modified release tablets or capsules containing more than 665 mg paracetamol; or
- (d) in non-modified release tablets or capsules containing more than 500 mg paracetamol; or
- (e) in individually wrapped powders or sachets of granules each containing more than 1000 mg paracetamol; or
- (f) in tablets or capsules enclosed in a primary pack containing more than 100 tablets or capsules **except** in Schedule 3; or

Substances marked # are listed in Appendix D

- (g) in individually wrapped powders or sachets of granules enclosed in a primary pack containing more than 50 wrapped powders or sachets of granules **except** when included in Schedule 3; or
- (h) for injection; or
- (i) for the treatment of animals.

### PARALDEHYDE.

PARAMETHADIONE.

PARAMETHASONE.

PARECOXIB.

PARICALCITOL.

PARITAPREVIR.

PAROMOMYCIN.

PAROXETINE.

PASIREOTIDE.

PATIROMER SORBITEX CALCIUM.

PATISIRAN.

PAZOPANIB.

PECAZINE.

PEFLOXACIN.

PEGAPTANIB.

PEGASPARGASE.

PEGCETACOPLAN.

PEGFILGRASTIM.

PEGINTERFERON.

PEGUNIGALSIDASE ALFA.

PEGVALIASE.

PEGVISOMANT.

Substances marked # are listed in Appendix D

PEMBROLIZUMAB.

PEMETREXED.

PEMIGATINIB.

PEMOLINE.

PEMPIDINE.

PENBUTOLOL.

PENCICLOVIR **except** in preparations containing 1% or less of penciclovir for the treatment of *herpes labialis* in packs containing 10 g or less.

PENETHAMATE.

PENICILLAMINE.

PENTAERYTHRITYL TETRANITRATE.

PENTAGASTRIN.

PENTAMETHONIUM.

PENTAMIDINE (includes pentamidine isetionate).

PENTHIENATE.

# PENTOBARBITAL when packed and labelled for injection.

PENTOLINIUM.

PENTOSAN POLYSULFATE SODIUM.

PENTOXIFYLLINE.

PERAMIVIR.

# PERAMPANEL.

PERGOLIDE.

PERHEXILINE.

PERICIAZINE.

PERINDOPRIL.

Substances marked # are listed in Appendix D

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

PERPHENAZINE.

PERTUSSIS ANTIGEN.

PERTUZUMAB.

PHENACEMIDE.

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

PHENAGLYCODOL.

PHENAZONE except when included in Schedule 2 or 5.

PHENAZOPYRIDINE.

PHENELZINE.

PHENETICILLIN.

PHENFORMIN.

PHENGLUTARIMIDE.

PHENINDIONE.

PHENIRAMINE except when included in Schedule 2 or 3.

PHENISATIN.

PHENOBARBITAL.

PHENOL in preparations for injection.

PHENOLPHTHALEIN for human therapeutic use.

PHENOXYBENZAMINE.

PHENOXYMETHYLPENICILLIN.

PHENSUXIMIDE.

**# PHENTERMINE.** 

PHENTHIMENTONIUM.

PHENTOLAMINE.

Substances marked # are listed in Appendix D

#### PHENYLBUTAZONE.

#### PHENYLEPHRINE:

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

# PHENYLPIRACETAM.

#### PHENYLPROPANOLAMINE.

PHENYLTOLOXAMINE.

#### PHENYTOIN.

PHLEUM PRATENSE POLLEN EXTRACT (Timothy-grass pollen extract).

#### PHOLCODINE:

- (a) in divided preparations containing 100 mg or less of pholcodine per dosage unit; or
- (b) in undivided preparations containing 2.5% or less of pholcodine;

except when included in Schedule 2.

### PHOSPHODIESTERASE TYPE 5 INHIBITORS except:

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

### PHTHALYLSULFATHIAZOLE.

PHYSOSTIGMINE.

PIBRENTASVIR.

PICROTOXIN.

PILOCARPINE except in preparations containing 0.025% or less of pilocarpine.

PIMECROLIMUS.

PIMOBENDAN.

PIMOZIDE.

PINACIDIL.

PINAVERIUM BROMIDE.

Substances marked # are listed in Appendix D

PINDOLOL.

PIOGLITAZONE.

PIPECURONIUM.

PIPEMIDIC ACID.

PIPENZOLATE.

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

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

and, where containing more than 25 mg of kavalactones per dose, compliant with the requirements of the required advisory statements for medicine labels; or

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

PIPERACILLIN.

PIPERIDINE.

PIPERIDOLATE.

PIPOBROMAN.

PIPOTHIAZINE.

PIPRADROL.

PIRACETAM.

PIRBUTEROL.

PIRENOXINE (catalin).

PIRENZEPINE.

PIRETANIDE.

Substances marked # are listed in Appendix D

PIRFENIDONE.

PIROXICAM except in preparations for dermal use.

PIRPROFEN.

PITAVASTATIN.

PITUITARY HORMONES except when separately specified in these Schedules.

PIVAMPICILLIN.

PIZOTIFEN.

PLICAMYCIN.

PLITIDEPSIN.

PLERIXAFOR.

PNEUMOCOCCAL VACCINE.

PODOPHYLLOTOXIN for human use:

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

PODOPHYLLUM EMODI (podophyllin) for human use:

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

PODOPHYLLUM PELTATUM (podophyllin) for human use:

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

POLIDEXIDE.

### POLIOMYELITIS VACCINE.

### POLYACRYLAMIDE in preparations for injection or implantation:

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

Substances marked # are listed in Appendix D

(c) for veterinary use.

POLYCAPROLACTONE in preparations for injection or implantation:

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

POLYESTRADIOL.

POLYLACTIC ACID in preparations for injection or implantation:

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

POLYMYXIN.

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

POLYTHIAZIDE.

POMALIDOMIDE.

PONATINIB.

PONESIMOD.

PORACTANT.

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POSACONAZOLE.
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POTASSIUM BROMIDE for therapeutic use.

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

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

POTASSIUM PERCHLORATE for therapeutic use.

PRACTOLOL.

PRADOFLOXACIN.

PRALATREXATE.

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Substances marked # are listed in Appendix D

PRALIDOXIME.

PRAMIPEXOLE.

PRAMIRACETAM.

PRAMOCAINE.

# PRALMORELIN (GROWTH HORMONE RELEASING PEPTIDE-2 (GHRP-2)).

PRALSETINIB.

PRAMPINE.

# PRASTERONE (dehydroepiandrosterone, dehydroisoandrosterone).

PRASUGREL.

PRAVASTATIN.

# PRAZEPAM.

PRAZIQUANTEL for human therapeutic use.

PRAZOSIN.

PREDNISOLONE.

PREDNISONE.

PREGABALIN.

PREGNENOLONE.

PRENALTEROL.

PRENYLAMINE.

PRILOCAINE except when included in Schedule 2.

PRIMAQUINE.

PRIMIDONE.

PROBENECID.

PROBUCOL.

PROCAINAMIDE.

Substances marked # are listed in Appendix D

PROCAINE.

PROCAINE BENZYLPENICILLIN.

PROCARBAZINE.

PROCHLORPERAZINE except when included in Schedule 3.

PROCYCLIDINE except when included in Schedule 2.

PROGESTERONE except when included in Schedule 5.

PROGESTOGENS except when separately specified in these Schedules.

PROGLUMIDE.

PROGUANIL.

PROLINTANE.

PROMAZINE.

PROMETHAZINE except when included in Schedule 2 or 3.

PROMOXOLANE.

PROPAFENONE.

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

PROPANIDID.

PROPANTHELINE.

PROPENTOFYLLINE.

# PROPETANDROL.

PROPIONIBACTERIUM ACNES for therapeutic use.

PROPOFOL.

PROPRANOLOL.

PROPYLHEXEDRINE.

PROPYLTHIOURACIL.

PROPYPHENAZONE.

Substances marked # are listed in Appendix D

PROQUAZONE.

PROSCILLARIDIN.

PROSTAGLANDINS except when separately specified in this Schedule.

PROSTIANOL.

PROTAMINE.

PROTHIONAMIDE.

PROTHIPENDYL.

PROTIRELIN.

PROTOVERATRINES.

PROTRIPTYLINE.

PROXYMETACAINE.

PRUCALOPRIDE.

PSEUDOEPHEDRINE except when included in Schedule 3.

PYRAZINAMIDE.

PYRIDINOLCARBAMATE.

PYRIDOSTIGMINE.

PYRIDOXINE, PYRIDOXAL OR PYRIDOXAMINE for human therapeutic use except:

- (a) in oral preparations containing 200 mg or less but more than 50 mg of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose when compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in oral preparations containing 50 mg or less of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose.

PYRIMETHAMINE.

PYROVALERONE.

PYRVINIUM.

# QUAZEPAM.

QUETIAPINE.

Substances marked # are listed in Appendix D

QUINAGOLIDE.

QUINAPRIL.

# QUINBOLONE.

QUINETHAZONE.

QUINIDINE.

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

QUINISOCAINE (dimethisoquin).

QUINUPRISTIN.

RABEPRAZOLE except when included in Schedule 2 or 3.

RABIES VACCINE.

RACETAMS except when separately specified in these Schedules.

RACTOPAMINE except when included in Schedule 5.

RALOXIFENE.

RALTEGRAVIR.

RALTITREXED.

RAMIPRIL.

RAMUCIRUMAB.

RANIBIZUMAB.

RANITIDINE except:

- (a) when included in Schedule 2; or
- (b) in divided preparations for oral use containing 150mg or less of ranitidine per dosage unit when supplied in the manufacturer's original pack containing not more than 14 dosage units; or
- (c) in divided preparations for oral use containing 300mg or less of ranitidine per dosage unit in the manufacturer's original pack containing not more than 7 dosage units.

RANOLAZINE.

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Substances marked # are listed in Appendix D

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RAPACURONIUM.

RASAGILINE.

RASBURICASE.

RAUWOLFIA SERPENTINA.

RAUWOLFIA VOMITORIA.

RAZOXANE.

REBOXETINE.

RED YEAST RICE for human therapeutic use.

REMDESIVIR.

REGDANVIMAB.

REGORAFENIB.

RELUGOLIX.

REMOXIPRIDE.

REPAGLINIDE.

REPOTRECTINIB.

RESERPINE.

RESLIZUMAB.

RETAPAMULIN.

RETEPLASE.

RETIGABINE.

RIBAVIRIN.

RIBOCICLIB.

RIDAFOROLIMUS.

RIFABUTIN.

RIFAMPICIN.

Substances marked # are listed in Appendix D

RIFAMYCIN.

RIFAPENTINE.

RIFAXIMIN.

RILPIVIRINE.

RILUZOLE.

RIMEGEPANT.

RIMEXOLONE.

RIMITEROL.

RIMONABANT.

# RIOCIGUAT.

RIPRETINIB.

RISANKIZUMAB.

RISDIPLAM.

RISEDRONIC ACID.

RISPERIDONE.

RITLECITINIB.

RITODRINE.

RITONAVIR.

RITUXIMAB.

RIVAROXABAN.

RIVASTIGMINE.

RIZATRIPTAN except when included in Schedule 3.

ROBENACOXIB.

ROCURONIUM.

ROFECOXIB.

Substances marked # are listed in Appendix D

ROFLUMILAST.

ROLITETRACYCLINE.

ROLZIRACETAM.

ROMIDEPSIN.

ROMIFIDINE.

ROMIPLOSTIM.

ROMOSOZUMAB.

RONIDAZOLE.

ROPINIROLE.

ROPIVACAINE.

ROSIGLITAZONE.

ROSOXACIN.

ROSUVASTATIN.

ROTIGOTINE.

# ROXIBOLONE.

ROXITHROMYCIN.

ROZANOLIXIZUMAB.

RUBELLA VACCINE.

RUBOXISTAURIN.

RUFINAMIDE.

RUPATADINE.

RUXOLITINIB.

SACITUZUMAB GOVITECAN.

SACUBITRIL.

SAFINAMIDE.

Substances marked # are listed in Appendix D

SALBUTAMOL except when included in Schedule 3.

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

SALINOMYCIN except:

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

SALMETEROL.

SAPROPTERIN.

SAQUINAVIR.

SARILUMAB.

SARS-COV-2 (COVID-19) VACCINE.

SAXAGLIPTIN.

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

SCOPOLIA CARNIOLICA for therapeutic use.

SEBELIPASE ALFA.

SECUKINUMAB.

# SELECTIVE ANDROGEN RECEPTOR MODULATORS (SARM).

SELEGILINE.

SELENIUM:

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

Substances marked # are listed in Appendix D

SELETRACETAM.

SELEXIPAG.

SELINEXOR.

SELPERCATINIB.

SELUMETINIB.

SEMAGLUTIDE.

SEPIAPTERIN.

SERELAXIN.

SERMORELIN.

SERTINDOLE.

SERTRALINE.

SEVELAMER.

#### SEVOFLURANE.

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

SIBUTRAMINE.

# SILANDRONE.

SILDENAFIL.

SILICONES for intra-ocular use.

SILODOSIN.

SILTUXIMAB.

SILVER SULFADIAZINE.

SIMEPREVIR.

SIMVASTATIN.

SIPONIMOD.

SIROLIMUS.

Substances marked # are listed in Appendix D

SISOMICIN (sisomycin).

SITAGLIPTIN.

# SITAXENTAN.

SODIUM BROMIDE for therapeutic use.

SODIUM CELLULOSE PHOSPHATE for human internal use.

SODIUM CITRATE DIHYDRATE for therapeutic use in dialysis, diafiltration, or total plasma exchange.

SODIUM CROMOGLYCATE except when included in Schedule 2.

SODIUM GLYCEROPHOSPHATE HYDRATE.

SODIUM MORRHUATE in preparations for injection.

SODIUM NITROPRUSSIDE for human therapeutic use.

SODIUM PHENYLBUTYRATE.

SODIUM PHOSPHATE in preparations for oral laxative use.

SODIUM POLYSTYRENE SULPHONATE for human therapeutic use.

SODIUM SALICYLATE in preparations for internal use for the treatment of animals.

SODIUM TETRADECYLSULFATE in preparations for injection.

SODIUM ZIRCONIUM CYCLOSILICATE.

SOFOSBUVIR.

SOLASODINE.

SOLIFENACIN.

SOMAPACITAN.

SOMATOSTATIN.

SOMATOTROPIN EQUINE.

# SOMATROPIN (human growth hormone).

SONIDEGIB.

SONTOQUINE.

Substances marked # are listed in Appendix D
SORAFENIB.

SOTALOL.

SOTATERCEPT.

SOTORASIB.

SOTROVIMAB.

SPARFLOXACIN.

SPARTEINE.

SPECTINOMYCIN.

SPESOLIMAB.

SPIRAMYCIN.

SPIRAPRIL.

SPIRONOLACTONE.

# STANOLONE.

# STANOZOLOL.

STAVUDINE.

# STENABOLIC (SR9009) and other synthetic REV-ERB agonists.

# STENBOLONE.

STEROID HORMONES except when separately specified in these Schedules.

STILBESTROL (diethylstilbestrol).

STIRIPENTOL.

STREPTODORNASE.

STREPTOKINASE.

STREPTOMYCIN.

STRONTIUM RANELATE.

STROPHANTHINS.

Substances marked # are listed in Appendix D

STROPHANTHUS spp.

- STRYCHNINE in preparations containing 1.5% or less of strychnine for the treatment of animals.
- STRYCHNOS spp. **except** in preparations containing 1 mg or less per litre or per kilogram of strychnine.

STYRAMATE.

SUCCIMER.

SUCROFERRIC OXYHYDROXIDE.

SUGAMMADEX.

SULBACTAM.

SULCONAZOLE except when included in Schedule 2.

SULFACETAMIDE except when included in Schedule 3 or 5.

SULFADIAZINE except when included in Schedule 5.

SULFADIMETHOXINE.

SULFADIMIDINE except when included in Schedule 5.

SULFADOXINE.

SULFAFURAZOLE.

SULFAGUANIDINE.

SULFAMERAZINE except when included in Schedule 5.

SULFAMETHIZOLE.

SULFAMETHOXAZOLE.

SULFAMETHOXYDIAZINE.

SULFAMETHOXYPYRIDAZINE.

SULFAMETROLE.

SULFAMONOMETHOXINE.

SULFAMOXOLE.

Substances marked # are listed in Appendix D

SULFAPHENAZOLE.

SULFAPYRIDINE.

SULFAQUINOXALINE.

SULFASALAZINE.

SULFATHIAZOLE except when included in Schedule 5.

SULFATROXAZOLE.

SULFINPYRAZONE.

SULFOMYXIN.

SULFONAMIDE ANTIBIOTICS except when separately specified in these Schedules.

SULFONMETHANE (sulfonal) and alkyl sulfonals.

SULINDAC.

SULTAMICILLIN.

SULTHIAME.

SUMATRIPTAN except when included in Schedule 3.

SUNIFIRAM.

SUNITINIB.

SUPROFEN.

SUTILAINS.

SUXAMETHONIUM.

SUXETHONIUM.

SUVOREXANT.

TACRINE.

TACROLIMUS.

TADALAFIL.

TAFAMIDIS.

TAFASITAMAB.

Substances marked # are listed in Appendix D

TAFENOQUINE SUCCINATE.

TAFLUPROST.

TAGRAXOFUSP.

TALAZOPARIB.

TALIGLUCERASE ALFA.

TALIMOGENE LAHERPAREPVEC.

TAMOXIFEN.

TAMSULOSIN.

TANACETUM VULGARE except in preparations containing 0.8% or less of oil of tansy.

TASONERMIN.

TAZAROTENE.

TAZOBACTAM.

# TB-500.

T-CELL RECEPTOR ANTIBODY.

TEBENTAFUSP.

TECLISTAMAB.

TEDUGLUTIDE.

TEGAFUR.

TEGASEROD.

TELAPREVIR.

TELITHROMYCIN.

TEICOPLANIN.

TELBIVUDINE.

TELMISARTAN.

TELOTRISTAT ETHYL.

Substances marked # are listed in Appendix D

# TEMAZEPAM.

TEMOZOLOMIDE.

TEMSIROLIMUS.

TENECTEPLASE.

TENIPOSIDE.

TENOFOVIR.

TENOXICAM.

TEPOTINIB.

TEPOXALIN.

TEPROTUMUMAB.

TERAZOSIN.

TERBINAFINE **except**:

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

TERBUTALINE except when included in Schedule 3.

TERFENADINE.

TERIFLUNOMIDE.

# TERIPARATIDE.

TERLIPRESSIN.

TERODILINE.

TEROPTERIN.

# TESTOLACTONE.

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

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

TETANUS TOXOID for human use.

Substances marked # are listed in Appendix D

# TETRABENAZINE.

# TETRACAINE except:

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

TETRACOSACTIDE.

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

TETRAETHYLAMMONIUM.

TETROXOPRIM.

TEZACAFTOR.

TEZEPELUMAB.

# THALIDOMIDE.

THENYLDIAMINE.

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

THEVETIA PERUVIANA.

THEVETIN.

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

THIAMBUTOSINE.

THIAZOSULFONE.

THIETHYLPERAZINE.

THIOACETAZONE.

THIOCARLIDE.

# THIOMESTERONE (tiomesterone).

THIOPENTAL.

THIOPROPAZATE.

THIOPROPERAZINE.

THIORIDAZINE.

Substances marked # are listed in Appendix D

THIOSTREPTON.

THIOTEPA.

THIOTHIXENE.

THIOURACIL.

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

# THYMOSIN BETA 4 (THYMOSIN β4).

THYMOXAMINE (includes thymoxamine hydrochloride).

THYROID except when separately specified in this Schedule.

THYROTROPHIN.

THYROXINE (includes thyroxine sodium).

TIAGABINE.

TIAMULIN.

# TIANEPTINE.

TIAPROFENIC ACID.

TIARAMIDE.

TIBOLONE.

TICAGRELOR.

TICARCILLIN.

TICLOPIDINE.

TIEMONIUM.

TIENILIC ACID.

TIGECYCLINE.

TIGILANOL TIGLATE.

TIGLOIDINE.

TILDIPIROSIN.

Substances marked # are listed in Appendix D

TILETAMINE.

TILMANOCEPT.

TILMICOSIN.

TILUDRONIC ACID (includes disodium tiludronate).

TIMOLOL.

TINIDAZOLE.

TINZAPARIN (includes tinzaparin sodium).

TIOCONAZOLE except:

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

TIOGUANINE.

TIOTROPIUM.

TIPEPIDINE.

TIPIRACIL.

TIPRANAVIR.

TIRBANIBULIN.

TIRILAZAD.

TIROFIBAN.

TIRZEPATIDE.

TISLELIZUMAB.

TIXAGEVIMAB.

TOBRAMYCIN.

TOCAINIDE.

TOCERANIB.

TOCILIZUMAB.

TOFACITINIB.

Substances marked # are listed in Appendix D

TOLAZAMIDE.

TOLAZOLINE.

TOLBUTAMIDE.

TOLCAPONE.

TOLFENAMIC ACID.

TOLMETIN.

TOLONIUM.

TOLPROPAMINE.

TOLRESTAT.

TOLTERODINE.

TOLVAPTAN.

TOPIRAMATE.

TOPOTECAN.

TORASEMIDE.

TOREMIFENE.

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

TRABECTEDIN.

TRAMADOL.

TRANDOLAPRIL.

TRAMETINIB DIMETHYL SULFOXIDE.

TRANEXAMIC ACID **except** in preparations containing 3% or less of tranexamic acid for dermal cosmetic use.

TRANYLCYPROMINE.

TRASTUZUMAB.

TRASTUZUMAB DERUXTECAN.

TRASTUZUMAB EMTANSINE.

Substances marked # are listed in Appendix D

TRAVOPROST.

TRAZODONE.

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

TREOSULPHAN.

TREPROSTINIL.

# TRESTOLONE.

TRETAMINE.

# TRETINOIN **except** the ester hydroxypinacolone retinoate in preparations for dermal use containing 0.5% or less of hydroxypinacolone retinoate.

TRIACETYLOLEANDOMYCIN.

TRIAMCINOLONE except when included in Schedule 2 or 3.

TRIAMTERENE.

TRIAZIQUONE.

# TRIAZOLAM.

TRICHLORMETHIAZIDE.

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

TRICHLOROETHYLENE for therapeutic use.

TRICLOFOS.

TRICYCLAMOL.

TRIDIHEXETHYL.

TRIENTINE.

TRIFAROTENE.

TRIFLUOPERAZINE.

TRIFLUPERIDOL.

TRIFLUPROMAZINE.

Substances marked # are listed in Appendix D

TRIFLURIDINE.

TRIHEXYPHENIDYL.

TRILOSTANE.

TRIMETAPHAN.

TRIMETHOPRIM.

TRIMIPRAMINE.

TRIMUSTINE.

TRINITROPHENOL (excluding its derivatives) in preparations for human therapeutic use.

TRIOXYSALEN.

TRIPELENNAMINE.

TRIPROLIDINE except when included in Schedule 2 or 3.

TRIPTORELIN.

TROGLITAZONE.

TROLAMINE when in preparations for tattoo removal.

TROMETAMOL in preparations for injection **except** in preparations containing 3% or less of trometamol.

TROPICAMIDE.

TROPISETRON.

TROVAFLOXACIN.

TROXIDONE.

TRYPTOPHAN for human therapeutic use **except** in preparations labelled with a recommended daily dose of 100 mg or less of tryptophan.

TUBERCULIN.

TUBOCURARINE.

TUCATINIB.

TULATHROMYCIN.

Substances marked # are listed in Appendix D

TULOBUTEROL.

TYLOSIN.

TYPHOID VACCINE.

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

UMECLIDINIUM.

UNIFIRAM.

UNOPROSTONE.

UPADACITINIB.

URACIL.

URAPIDIL.

URETHANE (excluding its derivatives) for therapeutic use.

# UROFOLLITROPIN.

UROKINASE.

URSODEOXYCHOLIC ACID.

USTEKINUMAB.

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

VACCINES for veterinary live virus except:

- (a) poultry vaccines; or
- (b) pigeon pox vaccine; or
- (c) scabby mouth vaccine; or
- (d) bovine ephemeral fever vaccine; or
- (e) bovine herpesvirus-1 vaccine.
- VACCINES PLASMID DNA for animal use **except** when separately specified in these Schedules.

# VACCINIA VIRUS VACCINE.

# VADADUSTAT.

VALACICLOVIR.

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Substances marked # are listed in Appendix D

VALDECOXIB.

VALGANCICLOVIR.

VALNOCTAMIDE.

VALPROIC ACID.

VALSARTAN.

VANCOMYCIN.

VANDETANIB.

VARDENAFIL.

VARENICLINE.

VARICELLA VACCINE.

RECOMBINANT VARICELLA ZOSTER VIRUS GLYCOPROTEIN E ANTIGEN.

VASOPRESSIN.

VATINOXAN HYDROCHLORIDE.

VECURONIUM.

VEDAPROFEN.

VEDOLIZUMAB.

VELAGLIFLOZIN.

VELAGLUCERASE ALFA.

VELMANASE ALFA.

VELPATASVIR.

VEMURAFENIB.

VENETOCLAX.

VENLAFAXINE.

VERAPAMIL.

VERATRUM spp. except when separately specified in this Schedule.

Substances marked # are listed in Appendix D

VERICIGUAT.

VERNAKALANT.

VERTEPORFIN.

VIDARABINE.

VIGABATRIN.

VILANTEROL.

VILDAGLIPTIN.

VILOXAZINE.

VINBLASTINE.

VINCAMINE.

VINCRISTINE.

VINDESINE.

VINFLUNINE.

VINORELBINE.

VINYL ETHER for therapeutic use.

VIRGINIAMYCIN except when included in Schedule 5.

VISMODEGIB.

VISNADINE.

VITAMIN A for human therapeutic or cosmetic use except:

- (a) in preparations for topical use containing 1% or less of Vitamin A; or
- (b) in preparations for internal use containing 3000 micrograms retinol equivalents or less of Vitamin A per daily dose; or
- (c) in preparations for parenteral nutrition replacement.

VITAMIN D for human internal therapeutic use except:

- (a) in preparations containing 25 micrograms or less of vitamin D per recommended daily dose ; or
- (b) when included in Schedule 3.

#### VORAPAXAR.

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Substances marked # are listed in Appendix D

VORASIDENIB.

VORETIGENE NEPARVOVEC.

VORICONAZOLE.

VORINOSTAT.

VORTIOXETINE.

VOSORITIDE.

VOXILAPREVIR.

VUTRISIRAN.

WARFARIN for therapeutic use.

XAMOTEROL.

XANTHINOL NICOTINATE.

XIMELAGATRAN.

XIPAMIDE.

XYLAZINE.

YOHIMBINE.

ZAFIRLUKAST.

ZALCITABINE.

ZALEPLON.

ZANAMIVIR.

ZANUBRUTINIB.

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

ZIDOVUDINE.

ZILPATEROL.

ZILUCOPLAN.

ZIMELDINE.

Substances marked # are listed in Appendix D

ZINC COMPOUNDS for human internal use except:

- (a) in preparations with a recommended daily dose of 25 mg or less of zinc; or
- (b) in preparations with a recommended daily dose of more than 25 mg but not more than 50 mg of zinc when compliant with the requirements of the required advisory statements for medicine labels.

ZIPRASIDONE.

ZOLAZEPAM.

ZOLBETUXIMAB.

ZOLEDRONIC ACID.

ZOLMITRIPTAN except when included in Schedule 3.

ZOLPIDEM.

ZONISAMIDE.

ZOPICLONE.

ZOXAZOLAMINE.

ZUCLOPENTHIXOL.

Substances marked # are listed in Appendix D

# **Schedule 5—Caution**

Note: See paragraph (e) of the definition of *designated solvent* in section 6, paragraph 7(j), sections 16 and 25, subsection 26(2) and sections 42, 46, 47, 49, 55 and 61.

# ABAMECTIN

- (a) in preparations, for internal use for the treatment of animals, containing 1% or less of abamectin; or
- (b) in gel formulations containing 0.05% or less of abamectin in applicators containing 50 mg or less of abamectin.

#### ABSCISIC ACID.

#### ACEQUINOCYL.

- ACETIC ACID (excluding its salts and derivatives) in preparations containing more than 30% of acetic acid (CH<sub>3</sub>COOH) except:
  - (a) when included in Schedule 2 or 6; or
  - (b) for therapeutic use.
- ACETONE except in preparations containing 25% or less of designated solvents.
- ACRIFLAVINIUM CHLORIDE in preparations for veterinary use containing 2.5% or less of acriflavinium chloride.
- AFOXOLANER in oral divided preparations each containing 150 mg or less of afoxolaner per dosage unit
  - (a) for the treatment and prevention of flea infestations and control of ticks in dogs; or
  - (b) for the treatment and prevention of flea infestations, control of ticks, gastrointestinal nematodes and heartworm in dogs, when combined with milbemycin oxime.

#### AKLOMIDE.

- ALBENDAZOLE for the treatment of animals, in preparations containing 12.5% or less of albendazole **except** in intraruminal implants each containing 3.85 g or less of albendazole.
- ALKALINE SALTS, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination:
  - (a) in solid orthodontic device cleaning preparations, the pH of which as an "in-use" aqueous solution is more than 11.5; or
  - (b) in solid automatic dishwashing preparations, the pH of which in a 500 g/L aqueous solution or mixture is more than 11.5 but less than or equal to 12.5; or
  - (c) in other solid preparations, the pH of which in a 10 g/L aqueous solution is more than 11.5; or

- (d) in liquid or semi-solid preparations, the pH of which is more than 11.5, unless:
  - (i) in food additive preparations for domestic use; or
  - (ii) in automatic dish washing preparations for domestic use with a pH of more than 12.5;

except when separately specified in these Schedules.

- ALKOXYLATED FATTY ALKYLAMINE POLYMER in preparations containing 50% or less of alkoxylated fatty alkylamine polymer **except** in preparations containing 20% or less of alkoxylated fatty alkylamine polymer.
- ALLETHRIN in preparations containing 10% or less of allethrin except:
  - (a) in insecticidal mats; or
  - (b) in other preparations containing 1% or less of allethrin.

#### ALLOXYDIM.

#### ALPHA-CYPERMETHRIN:

- (a) in aqueous preparations containing 3% or less of alpha-cypermethrin; or
- (b) in other preparations containing 1.5% or less of alpha-cypermethrin.

#### AMETRYN.

- AMINES for use as curing agents for epoxy resins **except** when separately specified in these Schedules.
- AMINOACRIDINE in preparations for veterinary use containing 2.5% or less of aminoacridine.
- AMINOCYCLOPYRACHLOR **except** in preparations containing 25% or less of aminocyclopyrachlor.
- AMINOPYRALID in preparations containing 22% or less of aminopyralid.

# AMISULBROM.

# AMITROLE.

- AMMONIA (excluding its salts and derivatives other than ammonium hydroxide) in preparations containing 5% or less of ammonia **except**:
  - (a) in preparations for human internal therapeutic use; or
  - (b) in preparations for inhalation when absorbed in an inert solid material; or
  - (c) in preparations containing 0.5% or less of free ammonia.
- AMMONIUM THIOCYANATE **except** in preparations containing 10% or less of ammonium thiocyanate.

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

# ANISE OIL except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert, and labelled with the warning:

# KEEP OUT OF REACH OF CHILDREN; or

- (c) in preparations containing 50% or less of anise oil.
- ASPIRIN for the treatment of animals, that is in divided preparations, when:
  - (a) packed in blister or strip packaging; or
  - (b) in a container with a child-resistant closure.

# ATRAZINE.

- AZADIRACHTA INDICA EXTRACTS (neem extracts), extracted from neem seed kernels using water, methanol or ethanol, in preparations containing 5% or less of total limonoids, for agricultural use.
- AZELAIC ACID except when included in Schedule 2 or 4.

# AZOXYSTROBIN.

- BACILLUS THURINGIENSIS DELTA ENDOTOXIN encapsulated in killed Pseudomonas fluorescens.
- BARIUM SILICOFLUORIDE when coated on paper in an amount not exceeding 8 mg of barium silicofluoride per sq. cm.

# BASIL OIL except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert, and labelled with the warning:

KEEP OUT OF REACH OF CHILDREN; or

- (c) in preparations containing 5% or less of methyl chavicol.
- BEAUVERIA BASSIANA in preparations containing 1 x 10<sup>8</sup> Colony Forming Units (CFu)/mL or less of Beauveria bassiana.

BENALAXYL.

BENDIOCARB in preparations containing 2% or less of bendiocarb.

# BENTAZONE.

BENZALKONIUM CHLORIDE in preparations containing 10% or less of benzalkonium chloride **except** in preparations containing 5% or less of benzalkonium chloride.

#### BENZOFENAP.

BENZOIC ACID (excluding its salts and derivatives) in preparations for agricultural use **except** preparations containing 1% or less of benzoic acid.

#### BENZOYL PEROXIDE except:

- (a) when included in Schedule 2 or 4; or
- (b) in preparations containing 5% or less of benzoyl peroxide.

# BERGAMOT OIL except:

- (a) when steam distilled or rectified; or
- (b) in preparations for internal use; or
- (c) in preparations containing 0.4% or less of bergamot oil; or
- (d) in soaps or bath or shower gels that are washed off the skin; or
- (e) in medicines for human therapeutic use when compliant with the requirements of the required advisory statements for medicine labels; or
- (f) in other preparations when packed in containers labelled with the statement:

Application to the skin may increase sensitivity to sunlight.

#### BETACYFLUTHRIN:

- (a) in aqueous preparations containing 2.5% or less of betacyfluthrin; or
- (b) in solid preparations containing 8% or less of betacyfluthrin in a plastic matrix.

BICYCLOPYRONE in preparations containing 20% or less of bicyclopyrone.

- BIFLUORIDES (including ammonium, potassium and sodium salts), in preparations containing 0.3% or less of total bifluorides.
- BIOALLETHRIN in preparations containing 10% or less of bioallethrin **except** in preparations containing 1% or less of bioallethrin.

BIORESMETHRIN except in preparations containing 10% or less of bioresmethrin.

BISPYRIBAC except in preparations containing 10% or less of bispyribac.

# BIXAFEN.

# BORIC ACID except:

(a) when included in Schedule 4; or

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(b) in cosmetic hand cleaning preparations when labelled with a warning to the following effect:

NOT TO BE USED FOR CHILDREN UNDER 3 YEARS OF AGE; and

if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words:

NOT TO BE USED ON PEELING OR IRRITATED SKIN; or

(c) in cosmetic talc preparations containing 5% or less calculated as boric acid when labelled with a warning to the following effect:

NOT TO BE USED FOR CHILDREN UNDER 3 YEARS OF AGE; and

if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words:

NOT TO BE USED ON PEELING OR IRRITATED SKIN; or

(d) in cosmetic oral hygiene preparations containing 0.1% or less calculated as boric acid when labelled with a warning to the following effect:

NOT TO BE SWALLOWED. NOT TO BE USED FOR CHILDREN UNDER 3 YEARS OF AGE; or

(e) in other cosmetic preparations containing 3% or less calculated as boric acid when labelled with a warning to the following effect:

NOT TO BE USED FOR CHILDREN UNDER 3 YEARS OF AGE; and

if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words:

NOT TO BE USED ON PEELING OR IRRITATED SKIN; or

(f) in preparations, other than insect baits, containing 6% or less calculated as boric acid.

BORON TRIFLUORIDE in preparations containing 0.1% or less of boron trifluoride (BF<sub>3</sub>).

BROFLANILIDE in preparations containing 0.3% or less of broflanilide.

BROMUCONAZOLE in preparations containing 20% or less of bromuconazole.

BUPIVACAINE in aqueous gel preparations containing 0.5% or less of bupivacaine, for the dermal spray-on administration to the wounds of animals.

BUPROFEZIN except in preparations containing 40% or less of buprofezin.

BUTHIDAZOLE.

BUTOXYCARBOXIM in solid preparations containing 10% or less of butoxycarboxim.

BUTRALIN.

BUTROXYDIM.

*n*-BUTYL ALCOHOL in preparations containing 10% or less of n-butyl alcohol except:

- (a) in preparations containing 5% or less of n-butyl alcohol; or
- (b) in preparations for cosmetic or therapeutic use other than spray form.
- CAMPHOR as a natural component in essential oils containing 10% or less of camphor **except**:
  - (a) in medicines for human therapeutic use, in essential oils when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
  - (b) in preparations other than medicines for human therapeutic use, in essential oils when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert, and labelled with the warnings:
    - (i) KEEP OUT OF REACH OF CHILDREN; and
    - (ii) NOT TO BE TAKEN; or
  - (c) in rosemary oil, sage oil (Spanish), or lavandin oils; or
  - (d) in preparations containing 2.5% or less of camphor.

CARBAMIDE PEROXIDE in preparations containing 18% or less of carbamide peroxide **except** in preparations containing 9% or less of carbamide peroxide.

# CARBARYL:

- (a) in preparations containing 10% or less of carbaryl **except** when included in Schedule 4; or
- (b) when impregnated into plastic resin material containing 20% or less of carbaryl.

# CASSIA OIL except:

- (a) in food additives; or
- (b) in preparations for dermal use as a rubefacient containing 5% or less of cassia oil; or
- (c) in other preparations containing 2% or less of cassia oil.

# CHLORFENAC.

CHLORFENAPYR. in preparations containing 0.5% or less of chlorfenapyr.

# CHLORFENSON.

CHLORHEXIDINE in preparations containing 3% or less of chlorhexidine except:

- (a) in preparations containing 1% or less of chlorhexidine; or
- (b) when in solid preparations.

CHLORINATING COMPOUNDS containing 20% or less of available chlorine, except:

- (a) when separately specified in these Schedules; or
- (b) sodium hypochlorite preparations with a pH of less than 11.5; or

(c) liquid preparations containing not less than 2% but not more than 4% 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; or

- (d) liquid preparations containing less than 2% of available chlorine; or
- (e) other preparations containing 4% or less of available chlorine.

# CHLORNIDINE.

CHLOROCRESOL except in preparations containing 3% or less of chlorocresol.

# CHLORPROPHAM.

#### CHLORPYRIFOS:

- (a) in aqueous preparations containing 20% or less of microencapsulated chlorpyrifos; or
- (b) in controlled release granular preparations containing 10% or less of chlorpyrifos; or
- (c) in other preparations containing 5% or less of chlorpyrifos;

**except** in prepared potting or soil mixes containing 100 g or less of chlorpyrifos per cubic metre.

#### CHLORSULFURON.

#### CHLORTETRACYCLINE in preparations:

- (a) for topical application to animals for ocular use only; or
- (b) containing 40% or less of chlortetracycline, when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

# CHLORTHAL-DIMETHYL.

#### CINMETHYLIN.

#### CINNAMON BARK OIL except:

- (a) in food additives; or
- (b) in preparations containing 2% or less of cinnamon bark oil.
- CIS-JASMONE when prepared and packaged as an agricultural chemical **except** when present as a fragrance.

# CLETHODIM.

#### CLIMBAZOLE in preparations containing 40% or less of climbazole except:

(a) in leave-on hair, face and foot cosmetic preparations containing 0.5% or less of climbazole; or

(b) in other preparations (that are not leave-on cosmetic preparations) containing 2% or less of climbazole.

CLOFENTEZINE.

CLOPYRALID.

CLOQUINTOCET.

CLORSULON.

- CLOTHIANIDIN in preparations containing 20% or less of clothianidin **except** in gel preparations dispensed in sealed cartridges containing 1% or less of clothianidin.
- CLOVE OIL for topical use in the mouth in a pack containing 5 mL or less of clove oil **except** in preparations containing 25% or less of clove oil.
- COPPER ACETATE in preparations containing 20% or less of copper acetate **except** in preparations containing 5% or less of copper acetate.
- COPPER COMPOUNDS in animal feed additives containing 5% or less of copper **except** in preparations containing 1% or less of copper.
- COPPER HYDROXIDE in preparations containing 50% or less of copper hydroxide **except** in preparations containing 12.5% or less of copper hydroxide.

COPPER OXIDES in preparations containing 25% or less of copper oxides except:

- (a) in preparations for internal use; or
- (b) in marine paints; or
- (c) in other preparations containing 5% or less of copper oxides.
- COPPER OXYCHLORIDE in preparations containing 50% or less of copper oxychloride **except** in preparations containing 12.5% or less of copper oxychloride.

COPPER SULFATE in preparations containing 15% or less of copper sulfate except:

- (a) in preparations for internal use; or
- (b) in other preparations containing 5% or less of copper sulfate.

COUMATETRALYL in rodenticides containing 0.05% or less of coumatetralyl.

4-CPA.

CYANATRYN.

CYANOACRYLATE ESTERS in contact adhesives **except**:

(a) when labelled with the warning:

KEEP OUT OF REACH OF CHILDREN. Avoid contact with skin and eyes and avoid breathing vapour. Bonds on contact. Should fingers stick together apply a solvent such as acetone to contact areas then wash off with water. Do not use solvents near eyes or open wounds. In case of eye contact immediately flush with water; or

- (b) when packed in sealed measure packs each containing 0.5 g or less of cyanoacrylate esters:
  - (i) labelled with the approved name or trade name of the poison, the quantity and the warning:

Can cause eye injury. Instantly bonds skin; and

enclosed in a primary pack labelled with the warning:

KEEP OUT OF REACH OF CHILDREN. Avoid contact with skin and eyes and avoid breathing vapour. Bonds on contact. Should fingers stick together apply a solvent such as acetone to contact areas then wash off with water. Do not use solvents near eyes or open wounds. In case of eye contact immediately flush with water.

CYANTRANILIPROLE.

CYANURIC ACID (excluding its salts and derivatives).

CYAZOFAMID.

CYCLOHEXANONE PEROXIDE.

CYCLOPROTHRIN except in preparations containing 10% or less of cycloprothrin.

CYCLOXYDIM.

CYFLUFENAMID.

CYFLUMETOFEN.

CYFLUTHRIN:

- (a) in wettable powders containing 10% or less of cyfluthrin; or
- (b) in emulsifiable concentrates containing 2% or less of cyfluthrin; or
- (c) in emulsions containing 5% or less of cyfluthrin.

CYHALOFOP-BUTYL.

CYMIAZOLE.

CYPERMETHRIN in preparations containing 10% or less of cypermethrin.

CYPHENOTHRIN in preparations containing 10% or less of cyphenothrin.

CYPROCONAZOLE except in preparations containing 10% or less of cyproconazole.

CYPRODINIL.

CYTHIOATE for the treatment of animals:

- (a) in divided preparations containing 30 mg or less of cythioate per dosage unit when packed in blister or strip packaging or in a container with a child-resistant closure; or
- (b) in undivided preparations containing 5% or less of cythioate.

2,4-D in preparations containing 20% or less of 2,4-D.

# DAMINOZIDE.

2,4-DB.

# DECOQUINATE:

# DELTAMETHRIN:

- (a) when impregnated in plastic resin strip material containing 4% or less of deltamethrin; or
- (b) in aqueous preparations containing 5% or less of deltamethrin when no organic solvent other than a glycol is present; or
- (c) in wettable granular preparations containing 25% or less of deltamethrin when packed in child-resistant packaging each containing 3 g or less of the formulation; or
- (d) in water-dispersible tablets each containing 500 mg or less of deltamethrin in child-resistant packaging; or
- (e) in other preparations containing 0.5% or less of deltamethrin;

# except:

- (f) in factory prepared mosquito nets containing 1% or less deltamethrin; or
- (g) in preparations containing 0.1% or less of deltamethrin.

DEMBREXINE in oral preparations for the treatment of animals.

# 2,4-DES.

DIAFENTHIURON.

- *N*,*N*-DIALLYLDICHLOROACETAMIDE **except** in preparations containing 10% or less of *N*,*N*-diallyldichloroacetamide.
- DIAZINON in dust preparations containing 2% or less of diazinon.
- DICAMBA (including its salts and derivatives) in preparations containing 20% or less of dicamba.

DICHLONE.

*p*-DICHLOROBENZENE.

DICHLOROISOCYANURIC ACID containing 40% or less of available chlorine, except in:

(a) liquid preparations containing not less than 2% but not more than 4% 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; or

- (b) liquid preparations containing less than 2% of available chlorine; or
- (c) other preparations containing 4% or less of available chlorine.

# DICHLOROMETHANE (methylene chloride) except:

- (a) in preparations in pressurised spray packs labelled as degreasers, decarbonisers or paint strippers and containing 10% or less of dichloromethane; or
- (b) in other preparations in pressurised spray packs; or
- (c) in paints and tinters containing 5% or less of dichloromethane; or
- (d) in preparations for human therapeutic use.

DICHLOROPHEN for the treatment of animals.

#### **DICHLORVOS:**

- (a) when impregnated in plastic resin strip material containing 20% or less of dichlorvos; or
- (b) in sustained release resin pellets containing 20% or less of dichlorvos for the treatment of animals; or
- (c) in pressurised spray packs containing 10 g or less of dichlorvos.

# DICLOBUTRAZOL.

#### DICLORAN.

# DICOFOL.

- DIETHANOLAMINE (excluding its salts and derivatives) in preparations containing 20% or less of diethanolamine **except** in preparations containing 5% or less of diethanolamine.
- DIETHYLENE GLYCOL (excluding its salts and derivatives) in preparations containing not less than 10 mg/kg of denatonium benzoate as a bittering agent **except**:
  - (a) in paints or paint tinters; or
  - (b) in toothpastes or mouthwashes containing more than 0.25% of diethylene glycol; or
  - (c) in other preparations containing 2.5% or less of diethylene glycol.
- DIETHYLENE GLYCOL MONOBUTYL ETHER **except** in preparations containing 10% or less of diethylene glycol monobutyl ether.

# DIETHYLTOLUAMIDE (DEET) except:

- (a) in medicines for human therapeutic use containing 20% or less of diethyltoluamide, when compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in preparations for human use, other than medicines, containing 20% or less of diethyltoluamide, when labelled with the warning statement:

WARNING: May be dangerous, particularly to children, if you use large amounts on the skin, clothes or bedding or on large areas of the body, especially if you keep using it for a long time; or

(c) in preparations other than for human use containing 20% or less of diethyltoluamide.

DIFENOCONAZOLE.

DIFLUBENZURON.

DIMETHICODIETHYLBENZALMALONATE **except** when included in preparations containing 10% or less of dimethicodiethylbenzalmalonate.

DIMETHIRIMOL.

DIMETHOMORPH except in preparations containing 10% or less of dimethomorph.

- DIMETHYLACETAMIDE in preparations containing 40% or less of dimethylacetamide in single dose flow-limited tubes of 5 mL or less for dermal application to companion animals.
- DIMETHYLFORMAMIDE in preparations containing 10% or less of dimethylformamide **except** in silicone rubber mastic containing 2% or less of dimethylformamide.
- 1,4-DIMETHYLNAPHTHALENE for use as agricultural chemicals.
- 3,7-DIMETHYL-2,6-OCTADIENAL and its isomers in cosmetic and household cleaning preparations **except** in preparations containing 5% or less of 3,7-dimethyl-2,6,-octadienal isomers.

DIMPROPYRIDAZ in preparations containing 13% or less of dimpropyridaz.

DINICONAZOLE.

DINOTEFURAN except in preparations containing 1% or less of dinotefuran.

DI-n-PROPYL ISOCINCHOMERONATE except in preparations containing 25% or less of di-n-propyl isocinchomeronate.

DIPHENAMID.

DIRECT RED 254 in preparations containing 30% or less of Direct Red 254 calculated as free acid.

DITHIOPYR.

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- N-(N-DODECYL)-2-PYRROLIDONE in preparations containing 50% or less of N-(N-dodecyl)-2-pyrrolidone or preparations containing 50% or less of a mixture of any two or more of N-(N-dodecyl)-2-pyrrolidone, N-methyl-2-pyrrolidone or N-(N-octyl)-2-pyrrolidone except in preparations containing 25% or less of designated solvents.
- DORAMECTIN for internal use for the treatment of animals, in preparations containing 2% or less of doramectin.

EMAMECTIN in preparations containing 2% or less of emamectin.

**EMODEPSIDE** in preparations:

- (a) containing 2.5% or less of emodepside for the external treatment of animals; or
- (b) containing 30 mg or less of emodepside per dosage unit for the oral treatment of animals.

EPOXICONAZOLE.

EPOXY RESINS, LIQUID.

EPRINOMECTIN in preparations containing 0.5% or less of eprinomectin.

EPYRIFENACIL.

ESBIOTHRIN in preparations containing 10% or less of esbiothrin **except** in pressurised spray packs containing 1% or less of esbiothrin.

ESFENVALERATE in preparations containing 0.1% or less of esfenvalerate.

ESTRADIOL in implant preparations for growth promotion in animals.

- 1,2-ETHANEDIAMINE POLYMERWITH (CHLOROMETHYL) OXIRANE AND N-METHYLMETHANAMINE.
- ETHER in preparations containing more than 10% of ether for use in internal combustion engines.

ETHOFUMESATE.

ETHOXYQUIN except in preparations containing 10% or less of ethoxyquin.

ETHOXYSULFURON.

- ETHYLENE GLYCOL (excluding its salts and derivatives) in preparations containing not less than 10 mg/kg of denatonium benzoate as a bittering agent **except**:
  - (a) in paints or paint tinters; or
  - (b) in toothpastes or mouthwashes containing more than 0.25% of ethylene glycol; or
  - (c) in other preparations containing 2.5% or less of ethylene glycol.

ETHYL METHACRYLATE (excluding its derivatives) for cosmetic use **except** in preparations containing 1% or less of ethyl methacrylate as residual monomer in a polymer.

# ETRIDIAZOLE.

- EUGENOL for topical use in the mouth in a pack containing 5 mL or less of eugenol **except** in preparations containing 25% or less of eugenol.
- EXTRACT OF LEMON EUCALYPTUS, being acid modified oil of lemon eucalyptus (Corymbia citriodora), **except** in preparations containing 40% or less of extract of lemon eucalyptus.

FENARIMOL.

FENBENDAZOLE for the treatment of animals.

FENBUCONAZOLE.

FENCHLORAZOLE-ETHYL.

FENNEL OIL except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and compliant with the requirements of an instrument made under subsection 3(5A) of the Act relating to medicine advisory statements; or
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert, and labelled with the warning:

KEEP OUT OF REACH OF CHILDREN; or

(c) in preparations containing 5% or less of methyl chavicol.

FENOPROP.

FENOXAPROP-ETHYL.

FENOXAPROP-*p*-ETHYL.

FENPYRAZAMINE except in preparations containing 40% or less of fenpyrazamine.

FENSON.

FENTHION:

- (a) in preparations containing 25% or less of fenthion when packed in single-use containers having a capacity of 2 mL or less; or
- (b) in preparations containing 10% or less of fenthion.
- FIPRONIL in preparations containing 10% or less of fipronil **except** in preparations containing 0.05% or less of fipronil.

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FLAMPROP-METHYL.

FLAMPROP-*M*-METHYL.

FLAZASULFURON.

FLORASULAM.

FLUAZAINDOLIZINE in preparations containing 50% or less fluazaindolizine.

FLUAZURON.

FLUBENDAZOLE for the treatment of animals.

FLUBENDIAMIDE.

FLUCHLORALIN.

FLUDIOXONIL except in preparations containing 10% or less of fludioxonil.

FLUMETHRIN:

- (a) when impregnated in plastic resin strip material containing 3% or less of flumethrin; or
- (b) in oil based preparations containing 1% or less of flumethrin.

FLUMICLORAC PENTYL.

FLUOPYRAM except in preparations containing 50% or less of fluopyram.

FLUORIDES in preparations containing 3% or less of fluoride ion except:

- (a) in preparations for human use; or
- (b) in preparations containing 15 mg/kg or less of fluoride ion.

FLURALANER except when included in Schedule 4.

FLUVALINATE in aqueous preparations containing 25% or less of fluvalinate.

FLUXAPYROXAD.

FORAMSULFURON.

- FORMIC ACID (excluding its salts and derivatives) **except** in preparations containing 0.5% or less of formic acid.
- FOSPIRATE when impregnated in plastic resin strip material containing 20% or less of fospirate.

FURALAXYL.

FURATHIOCARB in microencapsulated suspensions containing 50% or less of furathiocarb.

GAMMA-CYHALOTHRIN in aqueous preparations containing 15% or less of microencapsulated gamma-cyhalothrin.

# GLUFOSINATE-AMMONIUM.

GLUTARAL in preparations containing 5% or less of glutaral except:

- (a) when included in Schedule 2; or
- (b) in preparations containing 0.5% or less of glutaral when labelled with the statements:
  - (A) IRRITANT; and
  - (B) Avoid contact with eyes.

GLYPHOSATE.

HALOSULFURON-METHYL.

HEXACONAZOLE except in preparations containing 5% or less of hexaconazole.

HEXAZINONE in preparations containing 25% or less of hexazinone.

HOMOBRASSINOLIDE.

- HYDRAMETHYLNON in solid baits containing 2% or less of hydramethylnon in welded plastic labyrinths.
- HYDROCARBONS, LIQUID, including kerosene, diesel (distillate), mineral turpentine, white petroleum spirit, toluene, xylene and light mineral and paraffin oils (but excluding their derivatives), **except**:
  - (a) toluene and xylene when included in Schedule 6; or
  - (b) benzene and liquid aromatic hydrocarbons when included in Schedule 7; or
  - (c) food grade and pharmaceutical grade white mineral oils; or
  - (d) in solid or semi-solid preparations; or
  - (e) in preparations containing 25% or less of designated solvents; or
  - (f) in preparations packed in pressurised spray packs; or
  - (g) in adhesives packed in containers each containing 50 g or less of adhesive; or
  - (h) in writing correction fluids and thinners for writing correction fluids packed in containers having a capacity of 20 mL or less; or
  - (i) in other preparations when packed in containers with a capacity of 2 mL or less.

# HYDROCHLORIC ACID (excluding its salts and derivatives) in preparations containing 10% or less of hydrochloric acid (HCl) **except**:

- (a) in preparations containing 0.5% or less of hydrochloric acid (HCl); or
- (b) for therapeutic use.

HYDROFLUORIC ACID (excluding its salts and derivatives) and admixtures that generate hydrofluoric acid, in preparations containing 0.1% or less of hydrogen fluoride.

HYDROGEN PEROXIDE (excluding its salts and derivatives):

- (a) in hair dye preparations containing 12% or less of hydrogen peroxide **except** in hair dyes containing 6% or less of hydrogen peroxide; or
- (b) in other preparations containing 6% (20 volume) or less of hydrogen peroxide **except** in preparations containing 3% (10 volume) or less of hydrogen peroxide.

HYDROSILICOFLUORIC ACID (excluding its salts and derivatives) in preparations containing 0.1% or less of hydrosilicofluoric acid (H<sub>2</sub>SiF<sub>6</sub>).

#### 2-HYDROXYETHYL METHACRYLATE except:

- (a) when included in dental restorative preparations for therapeutic use; or
- (b) in nail preparations when labelled "Avoid contact with skin"; or
- (c) in other preparations containing 0.1% or less of 2-hydroxyethyl methacrylate when labelled "Avoid contact with skin".
- 2-HYDROXYPROPYL METHACRYLATE in nail preparations **except** when labelled "Avoid contact with skin".

IMAZALIL.

IMAZAMOX except in preparations containing 25% or less of imazamox.

IMAZAPIC except in preparations containing 25% or less of imazapic.

- IMAZAPYR except in preparations containing 25% or less of imazapyr.
- IMAZETHAPYR except in preparations containing 25% or less of imazethapyr.
- IMIDACLOPRID in preparations containing 20% or less of imidacloprid **except** in preparations containing 5% or less of imidacloprid.
- IMIPROTHRIN in preparations containing 50% or less of imiprothrin **except** in preparations containing 10% or less of imiprothrin.
- INDOXACARB (includes the R and S enantiomers) in preparations containing 1% or less of indoxacarb.
- 3-IODO-2-PROPYNYL BUTYL CARBAMATE (Iodocarb) in preparations containing 10% or less of 3-iodo-2-propynyl butyl carbamate **except**:
  - (a) in aqueous preparations not for cosmetic use containing 10% or less
    3-iodo-2-propynyl butyl carbamate; or
  - (b) in cosmetic preparations (other than aerosolised preparations) containing 0.1% or less of 3-iodo-2-propynyl butyl carbamate.

IODOSULFURON-METHYL-SODIUM.

IPCONAZOLE in preparations containing 2% or less of ipconazole.

#### **IRON COMPOUNDS:**

- (a) for the treatment of animals (excluding up to 1% of iron oxides when present as an excipient):
  - (i) in preparations for injection containing 20% or less of iron **except** in preparations containing 0.1% or less of iron; or
  - (ii) in other preparations containing 4% or less of iron except:
    - (A) in liquid or gel preparations containing 0.1% or less of iron; or
    - (B) in animal feeds or feed premixes; or
- (b) for use as agricultural chemicals **except** in preparations containing 4% or less of iron.
- ISOEUGENOL in preparations not intended for skin contact containing 25% or less of isoeugenol **except** in preparations containing 10% or less of isoeugenol.

# ISOPHORONE.

ISOXABEN.

# ISOXAFLUTOLE.

IVERMECTIN for use in animals:

- (a) in preparations for the prophylaxis of heartworm in cats and dogs; or
- (b) in intraruminal implants containing 160 mg or less of ivermectin; or
- (c) in preparations containing 3.5% or less of ivermectin when packed in child-resistant packaging or in packaging approved by the relevant registration authority; or
- (d) in other preparations containing 2% or less of ivermectin.
- KITASAMYCIN in animal feed premixes for growth promotion containing 2% or less of antibiotic substances.

# LAMBDA-CYHALOTHRIN:

- (a) in aqueous preparations containing 1% or less of lambda- cyhalothrin; or
- (b) in aqueous preparations containing 10% or less of microencapsulated lambda-cyhalothrin.
- LASIODIPLODIA PSEUDOTHEOBROMAE except when used as a herbicide in capsule preparations at a concentration of 16 CFU or less per capsule.

# LEMON OIL except:

- (a) when steam distilled or rectified; or
- (b) in preparations for internal use; or
- (c) in preparations containing 0.05% or less of lemon oil; or

- (d) in soaps or bath or shower gels that are washed off the skin; or
- (e) in medicines for human therapeutic use, when compliant with the requirements of the required advisory statements for medicine labels; or
- (f) in other preparations when packed in containers labelled with the statement:

Application to the skin may increase sensitivity to sunlight.

- LEMONGRASS OIL in cosmetic and household cleaning preparations **except** in preparations containing 5% or less of 3,7-dimethyl-2,6-octadienal.
- LEVAMISOLE in preparations containing 15% or less of levamisole for the treatment of animals **except**:
  - (a) when included in Schedule 4; or
  - (b) in preparations for the treatment of ornamental birds or ornamental fish, in packs containing 10 mg or less of levamisole.

# LIDOCAINE:

- (a) in aqueous gel preparations containing 4.5% or less of lidocaine, for the dermal spray-on administration to the wounds of animals; or
- (b) in injectable preparations containing 2% or less of lidocaine when packaged in a container with a tamper resistant cartridge which can only be dispensed through a rubber ring applicator for tail docking and castration of lambs; or castration of calves.

# LIME OIL except:

- (a) when steam distilled or rectified; or
- (b) in preparations for internal use; or
- (c) in preparations containing 0.5% or less of lime oil; or
- (d) in soaps or bath or shower gels that are washed off the skin; or
- (e) in medicines for human therapeutic use, when compliant with the requirements of the required advisory statements for medicine labels; or
- (f) in other preparations when packed in containers labelled with the statement:

Application to the skin may increase sensitivity to sunlight.

LINDANE in preparations containing 10% or less of lindane **except** when included in Schedule 2 or 4.

# LOTILANER.

# LUFENURON except:

- (a) in divided preparations each containing 500 mg or less of lufenuron for the treatment of animals; or
- (b) in single use syringes each containing 500 mg or less of lufenuron for the treatment of animals.

- MACROPHOMINA PHASEOLINA **except** when used as a herbicide in capsule preparations at a concentration of 16 CFU or less per capsule.
- MADURAMICIN in animal feed premixes containing 1% or less of antibiotic substances.
- MAGNESIUM CHLORATE **except** in preparations containing 10% or less of magnesium chlorate.
- MALACHITE GREEN in preparations for veterinary use containing 10% or less of malachite green.

#### MALATHION in preparations containing 10% or less of malathion except:

- (a) for human therapeutic use; or
- (b) in dust preparations containing 2% or less of malathion.

#### MANCOZEB.

MANDESTROBIN except in preparations containing 25% or less of mandestrobin.

#### MANDIPROPAMID.

# MARJORAM OIL except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert, and labelled with the warning:

KEEP OUT OF REACH OF CHILDREN; or

(c) in preparations containing 50% or less of marjoram oil.

# MCPA:

- (a) in preparations containing 25% or less of MCPA (acid); or
- (b) in preparations containing 50% or less of the salts and esters of MCPA.

# MEBENDAZOLE for the treatment of animals:

- (a) in divided preparations each containing 300 mg or less of mebendazole per dosage unit; or
- (b) in undivided preparations containing 25% or less of mebendazole.

MECLOFENAMIC ACID for the treatment of animals.

MECOPROP in preparations containing 2% or less of mecoprop.

# MEFENPYR-DIETHYL.
MEFENTRIFLUCONAZOLE **except** in preparations containing 7.5% or less of mefentrifluconazole.

### MEPIQUAT.

- MERCAPTAMINE in cosmetic preparations containing 6% or less of mercaptamine **except** in preparations containing 1% or less of mercaptamine.
- MERCAPTOACETIC ACID and its salts, but excluding its derivatives, in cosmetic preparations containing 20% or less of mercaptoacetic acid or its salts (as mercapturic acid), **except** in preparations containing 5% or less of mercaptoacetic acid or its salts (as mercapturic acid)

MESOTRIONE.

METAFLUMIZONE.

METALAXYL in preparations containing 35% or less of metalaxyl.

METALDEHYDE in preparations containing 2% or less of metaldehyde.

METARYLPICOXAMID.

METAZACHLOR.

#### METHABENZTHIAZURON.

- METHANOL (excluding its derivatives) in preparations containing 10 % or less of methanol **except:** 
  - (a) when included in Schedule 10; or
  - (b) in preparations containing 2% or less of methanol; or
  - (c) when methanol is present only as a denaturant of ethanol.
- METHENAMINE in cosmetic preparations, **except** in preparations containing 0.15% or less of methenamine.

METHIOCARB in pelleted preparations containing 2% or less of methiocarb.

METHIOZOLIN.

#### METHOXYCHLOR.

- METHYLATED SPIRIT(S) (being ethanol denatured with denatonium benzoate, methyl isobutyl ketone and fluorescein) **except**:
  - (a) when included in preparations or admixtures; or
  - (b) when packed in containers having a capacity of more than 5 L.
- METHYLATED SPIRIT(S) when packed and labelled as a "biofuel" suitable for use in "spirit burners".

- METHYLENE BLUE in preparations for veterinary use containing 50% or less of methylene blue.
- METHYL ETHYL KETONE **except** in preparations containing 25% or less of designated solvents.
- METHYL ETHYL KETONE PEROXIDE.
- METHYL ISOAMYL KETONE **except** in preparations containing 25% or less of designated solvents.
- METHYL ISOBUTYL KETONE **except** in preparations containing 25% or less of designated solvents.

### *N*-METHYL-2-PYRROLIDONE:

- (a) when packed in single use containers having a capacity of 2 mL or less; or
- (b) in preparations containing 50% or less of *N*-methyl-2-pyrrolidone or preparations containing 50% or less of a mixture of any two or more of *N*-methyl-2-pyrrolidone, *N*-(*N*-octyl)-2-pyrrolidone or *N*-(*N*-dodecyl)-2-pyrrolidone except in preparations containing 25% or less of designated solvents.
- METHYL SALICYLATE in preparations containing 25% or less of methyl salicylate except:
  - (a) in preparations for therapeutic use; or
  - (b) in preparations containing 5% or less of methyl salicylate.
- 2-METHYLTHIO-4-(2-METHYLPROP-2-YL) AMINO-6-CYCLOPROPYLAMINO-5-TRIAZINE.

### METIRAM.

METOBROMURON except in preparations containing 50% or less of metobromuron.

### METOFLUTHRIN:

- (a) in impregnated fabric mosquito repellent preparations for use in a vaporiser containing 15 mg or less of metofluthrin per disk; or
- (b) when impregnated into a polyethylene slow release matrix containing 250 mg or less of metofluthrin.

### METOLACHLOR.

METRAFENONE in preparations containing 50% or less of metrafenone.

MILBEMECTIN in preparations containing 1% or less of milbemectin.

### MILBEMYCIN OXIME

(a) for the prophylaxis of heartworm in dogs and cats; or

(b) for the treatment and prevention of flea infestations, control of ticks, gastrointestinal nematodes and heartworm in dogs, when combined with afoxolaner, in oral divided preparations each containing 150 mg or less of afoxolaner per dosage unit.

MONENSIN in intraruminal implants for cattle, each containing 35 g or less of monensin.

### MONEPANTEL.

- MONOETHANOLAMINE (excluding its salts and derivatives) in preparations containing 20% or less of monoethanolamine **except**:
  - (a) when included in Schedule 4; or
  - (b) in preparations containing 5% or less of monoethanolamine.
- MORANTEL in preparations containing 25% or less of morantel **except** in preparations containing 10% or less of morantel.

MOXIDECTIN:

- (a) in preparations for external use for the treatment of animals other than cats and dogs, containing 0.5% or less of moxidectin; or
- (b) in preparations for external use for the treatment of cats and dogs, containing 25 mg or less of moxidectin packed in single dose tubes; or
- (c) for internal use for the treatment of animals:
  - (i) in divided preparations for dogs, containing 250 micrograms or less of moxidectin per dosage unit in a pack containing six or less dosage units; or
  - (ii) in other preparations containing 2% or less of moxidectin.

MYCLOBUTANIL.

NAA except in preparations containing 25% or less of NAA.

NALED when impregnated in plastic resin strip material containing 20% or less of naled.

NAPTALAM.

- NEOSCYTALIDIUM NOVAEHOLLANDIAE **except** when used as a herbicide in capsule preparations at a concentration of 16 CFU or less per capsule.
- NETOBIMIN for the treatment of animals, in preparations containing 12.5% or less of netobimin.
- NICLOSAMIDE in tablet or paste preparations for use in companion animals.
- NICOTINIC ACID when packed and labelled for use as an agricultural chemical.
- NITRIC ACID (excluding its salts and derivatives) in preparations containing 10% or less of nitric acid (HNO<sub>3</sub>) **except** in preparations containing 0.5% or less of nitric acid.

NITROSCANATE for the treatment of animals.

### NONANOIC ACID:

- (a) when used in a pesticide; or
- (b) in other preparations **except** in preparations containing 10% or less of nonanoic acid.

NONOXINOL 9 in preparations containing 25% or less of nonoxinol 9 except:

- (a) when labelled with the statements:
  - (i) IRRITANT; and
  - (ii) Avoid contact with eyes; or
- (b) in preparations containing 12.5% or less of nonoxinol 9; or
- (c) in preparations for human use.

### NORBORMIDE.

### NUTMEG OIL except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert, and labelled with the warning:

KEEP OUT OF REACH OF CHILDREN; or

- (c) in preparations containing 50% or less of nutmeg oil.
- *N*-OCTYL BICYCLOHEPTENE DICARBOXIMIDE **except** in preparations containing 10% or less of *N*-octyl bicycloheptene dicarboximide.

*N*-(*N*-OCTYL)-2-PYRROLIDONE in preparations containing 50% or less of:

- (a) *N*-(*N*-octyl)-2-pyrrolidone or preparations containing 50% or less of a mixture of any two or more of *N*-(*N*-octyl)-2-pyrrolidone, N-methyl-2-pyrrolidone; or
- (b) *N*-(*N*-dodecyl)-2-pyrrolidone **except** in preparations containing 25% or less of designated solvents.
- OLEANDOMYCIN in animal feed premixes for growth promotion.
- OMETHOATE in pressurised spray packs containing 0.2% or less of omethoate.

### ORANGE OIL (BITTER) except:

- (a) when steam distilled or rectified; or
- (b) in preparations for internal use; or
- (c) in preparations containing 1.4% or less of orange oil (bitter); or
- (d) in soaps or bath or shower gels that are washed off the skin; or

- (e) in medicines for human therapeutic use, when compliant with the requirements of the required advisory statements for medicine labels; or
- (f) in other preparations when packed in containers labelled with the statement:

Application to the skin may increase sensitivity to sunlight.

### OXADIARGYL.

OXADIXYL.

OXANTEL EMBONATE for the treatment of animals.

OXFENDAZOLE for the treatment of animals.

OXIBENDAZOLE for the treatment of animals.

### OXYCARBOXIN.

OXYTETRACYCLINE in preparations:

- (a) for topical application to animals for ocular use only; or
- (b) containing 40% or less of oxytetracycline per dose, when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

OXYTHIOQUINOX.

PACLOBUTRAZOL.

PENCONAZOLE.

PENDIMETHALIN.

PENFLUFEN.

PENTHIOPYRAD except in preparations containing 20% or less of penthiopyrad.

PERACETIC ACID in concentrations of 10% or less of peracetic acid.

PERMETHRIN (excluding preparations for human therapeutic use):

- (a) in preparations containing 25% or less of permethrin; or
- (b) in preparations for external use, for the treatment of dogs, containing 50% or less of permethrin when packed in single use containers having a capacity of 4 mL or less;

except in preparations containing 2% or less of permethrin.

PETROL except preparations containing 25% or less of petrol.

PHENAZONE for the external treatment of animals.

PHENISOPHAM.

- PHENOL, including cresols and xylenols and any other homologue of phenol boiling below 220°C, when in animal feed additives containing 15% or less of such substances, **except** in preparations containing 1% or less of phenol and in preparations containing 3% or less of cresols and xylenols and other homologues of phenol.
- PHENYL METHYL KETONE **except** in preparations containing 25% or less of designated solvents.
- o-PHENYLPHENOL except in preparations containing 5% or less of o-phenylphenol.
- PHOSPHONIC ACID (excluding its salts and derivatives) **except** in preparations containing 10% or less of phosphonic acid (H<sub>3</sub>PO<sub>3</sub>).
- PHOSPHORIC ACID (excluding its salts and derivatives) in preparations containing 35% or less of phosphoric acid (H<sub>3</sub>PO<sub>4</sub>) **except**:
  - (a) in preparations containing 15% or less of phosphoric acid  $(H_3PO_4)$ ; or
  - (b) in solid or semi-solid preparations; or
  - (c) in professional dental kits.
- o-PHTHALALDEHYDE in preparations containing 1% or less of o-phthalaldehyde.
- PICARIDIN except in preparations containing 20% or less of picaridin.
- PINE OILS in preparations containing 25% or less of pine oils when packed and labelled as a herbicide.
- PINOXADEN in preparations containing 10% or less of pinoxaden.
- PIPERAZINE for animal use.
- PIRIMICARB in preparations containing 0.5% or less of pirimicarb.
- POLIXETONIUM SALTS in preparations containing 60% or less of polixetonium salts **except** in preparations containing 1% or less of polixetonium salts.
- POLYETHANOXY (15) TALLOW AMINE.

### POLYOXIN D ZINC SALT.

POLY(OXY-1,2-ETHANEDIYL),  $\alpha$  -[2-[(2-HYDROXYETHYL)AMINO]-2-OXOETHYL]- $\alpha$  -HYDROXY-,MONO-C<sub>13-15</sub>-ALKYL ETHERS.

### POTASSIUM CHLORATE except:

- (a) when included in Schedule 2; or
- (b) in preparations containing 10% or less of potassium chlorate.
- POTASSIUM HYDROXIDE (excluding its salts and derivatives) in preparations containing 5% or less of potassium hydroxide being:

- (a) solid preparations, the pH of which in a 10 g/L aqueous solution is more than 11.5; or
- (b) liquid or semi-solid preparations, the pH of which is more than 11.5 **except** in food additive preparations for domestic use.
- POTASSIUM METABISULPHITE when packed for domestic use **except** in preparations containing 10% or less of potassium metabisulphite.

POTASSIUM NITRITE in preparations containing 1% or less of potassium nitrite except:

- (a) in preparations containing 0.5% or less of potassium nitrite;
- (b) when present as an excipient in preparations for therapeutic use; or
- (c) in aerosols.
- POTASSIUM PEROXOMONOSULFATE TRIPLE SALT in preparations containing 5% or less of potassium peroxomonosulfate triple salt being:
  - (a) solid preparations, the pH of which in a 10 g/L aqueous solution is less than 2.5; or
  - (b) liquid or semi-solid preparations, the pH of which is less than 2.5.
- POTASSIUM SULFIDE in preparations for metal treatment in containers each containing 50 g or less of potassium sulfide.
- PRALLETHRIN (cis:trans=20:80) in preparations containing 10% or less of prallethrin **except** in insecticidal mats containing 1% or less of prallethrin.

PROFOXYDIM except in preparations containing 20% or less of profoxydim.

**PROGESTERONE:** 

- (a) in implant preparations or controlled release pessaries for synchronisation of oestrus in cattle, sheep or goats; or
- (b) in implant preparations for growth promotion in cattle.

### PROHEXADIONE CALCIUM.

PROMETRYN.

PROPAMOCARB.

PROPANIL.

PROPAQUIZAFOP.

PROPICONAZOLE in preparations containing 20% or less of propiconazole.

- PROPIONIC ACID (excluding its salts and derivatives) in preparations containing 80% or less of propionic acid, **except**:
  - (a) in preparations containing 30% or less of propionic acid; or
  - (b) for therapeutic use.

### **PROPOXUR:**

- (a) when impregnated in plastic resin strip material containing 10% or less of propoxur; or
- (b) in dust preparations containing 3% or less of propoxur; or
- (c) in granular sugar-based fly baits containing 1% or less of propoxur, a dark colouring agent and a separate bittering agent; or
- (d) in pressurised spray packs containing 2% or less of propoxur; or
- (e) in printed paper sheets for pest control containing 0.5% or less of propoxur and in any case not more than 100 mg of propoxur per sheet.

*n*-PROPYL ALCOHOL in preparations containing 10% or less of *n*-propyl alcohol **except**:

- (a) in preparations containing 5% or less of *n*-propyl alcohol; or
- (b) in preparations for cosmetic or therapeutic use other than in spray form.

### PROPYZAMIDE.

- PROTHIOCONAZOLE-DESCHLORO except in preparations containing 0.5% or less of prothioconazole-deschloro.
- PROTHIOCONAZOLE-TRIAZOLIDINETHIONE **except** in preparations containing 0.5% or less of prothioconazole-triazolidinethione.

### PYMETROZINE.

### PYRACLOSTROBIN.

PYRAFLUFEN-ETHYL.

PYRASULFOTOLE.

- PYRETHRINS, naturally occurring, being pyrethrolone, cinerolone or jasmolone esters of chrysanthemic or pyrethric acids **except**:
  - (a) in preparations for human therapeutic use; or
  - (b) in preparations containing 10% or less of such substances.

PYRIDABEN in preparations containing 25% or less of pyridaben.

PYRIFENOX.

PYRITHIOBAC SODIUM.

PYRITHIONE ZINC in paints containing 0.5% or less of pyrithione zinc calculated on the non-volatile content of the paint **except** in paints containing 0.1% or less of pyrithione zinc calculated on the non-volatile content of the paint.

PYRIOFENONE in preparations containing 30% or less of pyriofenone.

QUATERNARY AMMONIUM COMPOUNDS in preparations containing 20% or less of quaternary ammonium compounds **except**:

- (a) when separately specified in these Schedules; or
- (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% or less of such quaternary ammonium compounds.

QUINCLORAC.

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

QUINTOZENE.

QUIZALOFOP-*p*-ETHYL in aqueous preparations containing 40% or less of quizalofop-*p*-ethyl.

RACTOPAMINE in animal feed premixes containing 10% or less of ractopamine.

RESMETHRIN in preparations containing 10% or less of resmethrin.

RIMSULFURON.

ROBENIDINE except in preparations containing 20% or less of robenidine.

ROSIN when packaged for use as a soldering flux or in flux-cored solder.

SAFLUFENACIL in water dispersible granules or a water-based suspension concentrate.

SALICYLANILIDE.

SAROLANER for veterinary use in divided preparations each containing 120 mg or less of sarolaner per dosage unit.

SEDAXANE.

SELAMECTIN except in preparations containing 12% or less of selamectin.

SETHOXYDIM.

SIDURON.

SILICOFLUORIDES in preparations containing 3% or less of fluoride ion except:

- (a) barium silicofluoride when separately specified in this Schedule; or
- (b) in preparations containing 15 mg/kg or less of fluoride ion.
- SINBIOALLETHRIN in preparations containing 10% or less of sinbioallethrin **except** in preparations containing 1% or less of sinbioallethrin.

SODIUM BROMIDE except when included in Schedule 4.

SODIUM CHLORATE except in preparations containing 10% or less of sodium chlorate.

- SODIUM DIACETATE except in preparations containing 60% or less of sodium diacetate.
- SODIUM DODECYLBENZENE SULFONATE **except** in preparations containing 30% or less of sodium dodecylbenzene sulfonate.
- SODIUM HYDROGEN SULFATE **except** in preparations containing 10% or less of sodium hydrogen sulfate.
- SODIUM HYDROSULFITE when packed for domestic use **except** in preparations containing 10% or less of sodium hydrosulfite.
- SODIUM HYDROXIDE (excluding its salts and derivatives) in preparations containing 5% or less of sodium hydroxide being:
  - (a) solid preparations, the pH of which in a 10 g/L aqueous solution is more than 11.5; or
  - (b) liquid or semi-solid preparations, the pH of which is more than 11.5 **except** in food additive preparations for domestic use.
- SODIUM LAURETH-6 CARBOXYLATE **except** in preparations containing 1% or less of sodium laureth-6 carboxylate.
- SODIUM METABISULPHITE when packed for domestic use **except** in preparations containing 10% or less of sodium metabisulphite.
- SODIUM NITRITE in preparations containing 1% or less of sodium nitrite except:
  - (a) in preparations containing 0.5% or less of sodium nitrite; or
  - (b) when present as an excipient in preparations for therapeutic use; or
  - (c) in aerosols.
- SODIUM PERCARBONATE (CAS No. 15630-89-4) in preparations containing 35% or less of sodium percarbonate **except** in preparations containing 15% or less of sodium percarbonate.
- SODIUM POLYSTYRENE SULPHONATE in preparations for cosmetic use **except** in preparations containing 10% or less of sodium polystyrene sulphonate.
- SODIUM STANNATE **except** in preparations for cosmetic use containing 1% or less of sodium stannate.
- SODIUM SULFIDE in preparations for metal treatment in containers each containing 50 g or less of sodium sulfide.

SPINETORAM.

SPINOSAD except in aqueous suspensions containing 25% or less of spinosad.

SPIROMESIFEN for agricultural use.

#### STAR ANISE OIL except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert, and labelled with the warning:

KEEP OUT OF REACH OF CHILDREN; or

(c) in preparations containing 50% or less of star anise oil.

STYRENE (excluding its derivatives).

- SULFACETAMIDE when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.
- SULFADIAZINE when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.
- SULFADIMIDINE when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.
- SULFAMERAZINE when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.
- SULFAMIC ACID (excluding its salts and derivatives) in preparations containing 10% or less of sulfamic acid (H<sub>3</sub>NO<sub>3</sub>S).
- SULFATHIAZOLE when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

SULFOMETURON-METHYL.

- SULFOXAFLOR in preparations containing 25% or less of sulfoxaflor.
- SYMPHYTUM spp. (Comfrey) for dermal therapeutic or dermal cosmetic use.

2,3,6-TBA.

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

TEBUCONAZOLE.

TEBUFENOZIDE.

TEFLUTHRIN in preparations containing 2% or less of tefluthrin.

**TEMEPHOS:** 

(a) in liquid preparations containing 10% or less of temephos; or

- (b) in powders containing 2% or less of temephos; or
- (c) in preparations containing 40% or less of temephos when packed in single use containers having a capacity of 2 mL or less.

### TEPRALOXYDIM.

### TERBUTRYN.

TETRACHLOROETHYLENE in preparations containing 5% or less of tetrachloroethylene **except**:

- (a) when included in Schedule 2; or
- (b) in preparations for the treatment of animals; or
- (c) when absorbed into an inert solid.
- TETRACHLORVINPHOS **except** in animal feeds containing 0.2% or less of tetrachlorvinphos.
- TETRACONAZOLE in preparations containing 20% or less of tetraconazole.

TETRACYCLINE in preparations:

- (a) for topical application to animals for ocular use only; or
- (b) containing 40% or less of tetracycline when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

TETRAMETHRIN [(R, cis): (R, trans) = 20:80] except in pressurised spray packs.

TETRANILIPROLE except in preparations containing 20% or less tetraniliprole.

THIABENDAZOLE:

- (a) for the treatment of animals; or
- (b) when packed and labelled for use as a fungicide **except** in preparations containing 50% or less of thiabendazole.

THIAMETHOXAM in preparations containing 60% or less of thiamethoxam.

### THIAZOPYR.

THIFENSULFURON.

THIOBENCARB.

THIODICARB in pelleted preparations containing 1.5% or less of thiodicarb.

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

THYME OIL except:

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- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert, and labelled with the warning:

KEEP OUT OF REACH OF CHILDREN; or

(c) in preparations containing 50% or less of thyme oil.

TIGOLANER in preparations containing 10% or less of tigolaner.

TIOCARBAZIL.

TOLCLOFOS-METHYL.

TOLTRAZURIL.

TOPRAMEZONE

TRALKOXYDIM.

TRENBOLONE in implant preparations for growth promotion in animals.

TRIADIMEFON in wettable powders containing 25% or less of triadimefon.

TRIADIMENOL.

TRI-ALLATE.

TRIBENURON-METHYL.

TRICHLOROACETIC ACID, alkali salts of.

1,1,1-TRICHLOROETHANE except:

- (a) in preparations packed in pressurised spray packs; or
- (b) in preparations containing 25% or less of designated solvents; or
- (c) in preparations, other than writing correction fluids or thinners for writing correction fluids in containers having a capacity of 50 mL or less; or
- (d) in writing correction fluids or thinners for writing correction fluids, in containers having a capacity of 50 mL or less labelled with:
  - (i) the word "Trichloroethane" written in letters not less than 1 mm in height and in distinct contrast to the background; and
  - (ii) the expression:

WARNING – DO NOT DELIBERATELY SNIFF THIS PRODUCT. SNIFFING MIGHT HARM OR KILL YOU;

written in bold face sans serif capital letters not less than 1 mm in height and in distinct contrast to the background.

TRIDIPHANE.

TRIETAZINE.

TRIFLOXYSTROBIN.

TRIFLUDIMOXAZIN except in preparations containing 12.5% or less.

TRIFLUMIZOLE.

TRIFLUMURON.

- TRIISOPROPANOLAMINE LAURYL ETHER SULFATE **except** in preparations containing 30% or less of triisopropanolamine lauryl ether sulfate when labelled with the statements:
  - (a) Avoid contact with eyes and skin; and
  - (b) Wash hands after handling.

TRINEXAPAC-ETHYL except:

- (a) when packed in a sealed water-soluble measure pack; or
- (b) in solid preparations containing 25% or less of trinexapac-ethyl in packs of 50 g or less.

3,6,9-TRIOXAUNDECANEDIOIC ACID **except** in preparations containing 5% or less of 3,6,9-trioxaundecanedioic acid, the pH of which is 3.5 or greater.

TRITICONAZOLE.

TROLAMINE (excluding its salts and derivatives) except:

- (a) when in Schedule 4; or
- (b) in preparations containing 5% or less of trolamine.

TURPENTINE OIL except in preparations containing 25% or less of turpentine oil.

VIRGINIAMYCIN in animal feed additives containing 1% or less of virginiamycin for the prevention of laminitis in horses when in a pack of 5 kg or less.

VERNOLATE.

WARFARIN in rodent baits containing 0.1% or less of warfarin.

ZINEB.

## Schedule 6—Poisons

Note: See section 16, subsection 46(2), section 49, subsection 54(3) and sections 55 and 61.

### ABAMECTIN:

- (a) in preparations for pesticidal use containing 4% or less of abamectin except when included in Schedule 5; or
- (b) in slow-release plastic matrix ear tags for livestock use containing 1 g or less of abamectin.

### ACEPHATE.

ACETAMIPRID except in preparations containing 1% or less of acetamiprid.

- ACETIC ACID (excluding its salts and derivatives) and preparations containing more than 80% of acetic acid (CH<sub>3</sub>COOH) **except** when included in Schedule 2.
- ACETIC ANHYDRIDE excluding its derivatives.

### ACIFLUORFEN.

ACINITRAZOLE except in preparations containing 20% or less of acinitrazole.

#### ACLONIFEN.

ALBENDAZOLE for the treatment of animals except:

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

### ALDRIN.

- ALKALINE SALTS, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination for non-domestic use:
  - (a) in solid automatic dishwashing preparations, the pH of which in a 500 g/L aqueous solution or mixture is more than 12.5; or
  - (b) in liquid or semi-solid automatic dishwashing preparations, the pH of which is more than 12.5.

### ALKOXYLATED FATTY ALKYLAMINE POLYMER except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 20% or less of alkoxylated fatty alkylamine polymer.

#### ALLETHRIN except:

- (a) when included in Schedule 5; or
- (b) in insecticidal mats containing 20% or less of allethrin; or
- (c) in other preparations containing 1% or less of allethrin.

ALLYL ESTERS (excluding derivatives) being:

- (a) ALLYL CYCLOHEXANEACETATE (CAS No. 4728-82-9); or
- (b) ALLYL CYCLOHEXANEPROPIONATE (CAS No. 2705-87-5); or
- (c) ALLYL HEPTANOATE/ALLYL HEPTYLATE (CAS No. 142-19-8); or
- (d) ALLYL HEXANOATE (CAS No. 123-68-2); or
- (e) ALLYL ISOVALERATE (CAS No. 2835-39-4); or
- (f) ALLYL NONANOATE (CAS No. 7493-72-3); or
- (g) ALLYL OCTANOATE (CAS No. 4230-97-1); or
- (h) ALLYL PHENYLACETATE (CAS No. 1797-74-6); or
- (i) ALLYL TRIMETHYLHEXANOATE (CAS No. 68132-80-9); or
- (j) ALLYL PHENOXYACETATE (CAS No. 7493-74-5); or
- (k) ALLYL (CYCLOHEXYLOXY)ACETATE (CAS No. 68901-15-5);

in preparations containing 0.1% or less of free allyl alcohol by weight of allyl ester **except** in preparations containing 5% or less of allyl esters with 0.1% or less of free allyl alcohol by weight of allyl esters.

### ALPHA-CYPERMETHRIN:

- (a) in aqueous preparations containing 30% or less of alpha-cypermethrin; or
- (b) in other preparations containing 10% or less of alpha-cypermethrin;

except when included in Schedule 5.

### AMICARBAZONE.

### AMIDITHION.

### AMIDOPROPYL BETAINES except:

 (a) in cosmetic wash-off preparations containing 30% or less of amidopropyl betaines and, if containing more than 5% of amidopropyl betaines when labelled with a warning to the following effect:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER; or

- (b) in cosmetic leave-on preparations containing 1.5% or less of amidopropyl betaines; or
- (c) in other preparations containing 30% or less of amidopropyl betaines and, if containing more than 5% of amidopropyl betaines, when labelled with warnings to the following effect:
  - (i) IF IN EYES WASH OUT IMMEDIATELY WITH WATER; and
  - (ii) IF SKIN OR HAIR CONTACT OCCURS, REMOVE CONTAMINATED CLOTHING AND FLUSH SKIN AND HAIR WITH RUNNING WATER.
- 2-AMINO-6-CHLORO-4-NITROPHENOL in hair dye and eyebrow/eyelash colouring preparations, **except**:

- (a) in preparations containing 2% or less of 2-amino-6-chloro-4-nitrophenol when applied directly to the hair, or containing 2% or less of 2-amino-6-chloro-4-nitrophenol after mixing and when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;
- (b) in eyelash and eyebrow tinting products containing 1.5% or less of 2-amino-6-chloro-4-nitrophenol after mixing for use when the immediate container and primary pack are labelled with the following statement:

WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals, and when used for eyelash or eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5mm in height.

4-AMINO-*m*-CRESOL in hair dyes and eyebrow/eyelash colouring preparations except:

- (a) in hair dye preparations containing 1.5% or less of 4-amino-m-cresol after mixing for use when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5mm in height; or

(b) in eyelash and eyebrow tinting products containing 1.5% or less of 4-amino-*m*-cresol after mixing for use when the immediate container and primary pack are labelled with the following statement:

WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals, and when used for eyelash or eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5mm in height.

- 2-AMINO-5-ETHYLPHENOL in hair dye preparations **except** in preparations containing 1% or less of 2-amino-5-ethylphenol when the immediate container and primary pack are labelled with the following statements:
  - (a) KEEP OUT OF REACH OF CHILDREN; and
  - (b) WARNING This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions

should be made before use. This product must not be used for dyeing eyelashes and eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height.

- 4-AMINO-2-HYDROXYTOLUENE in hair dyes and eyebrow/eyelash colouring products except:
  - (a) in hair dye preparations containing 1.5% or less of 4-amino-2-hydroxytoluene after mixing for use when the immediate container and primary pack are labelled with the following statements:
    - (i) KEEP OUT OF REACH OF CHILDREN; and
    - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5mm in height; or

(b) in eyelash and eyebrow tinting products containing 1.5% or less of 4-amino-2-hydroxytoluene after mixing for use when the immediate container and primary pack are labelled with the following statement:

WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals, and when used for eyelash or eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5mm in height.

AMINOCARB in preparations containing 25% or less of aminocarb.

AMINOETHOXYVINYLGLYCINE **except** in preparations containing 15% or less of aminoethoxyvinylglycine.

### 1-AMINOMETHANAMIDE DIHYDROGEN TETRAOXOSULFATE.

### 4-AMINO-3-NITROPHENOL except:

- (a) in non-oxidative hair dye preparations and eyebrow/eyelash colouring products containing 1% or less of 4-amino-3-nitrophenol when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5 mm in height; or

(b) in oxidative hair dye preparations and eyebrow/eyelash colouring products containing 1% or less of 4-amino-3-nitrophenol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements:

- (i) KEEP OUT OF REACH OF CHILDREN; and
- (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5 mm in height.

### 2,2'-[(4-AMINO-3-NITROPHENYL)IMINO]BISETHANOL (including its salts) except:

- (a) in non-oxidative hair dye preparations containing 2.5% or less of 2,2'-[(4-amino-3-nitrophenyl)imino]bisethanol after mixing when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5 mm in height; or

- (b) in oxidative hair dye preparations containing 1.25% or less of 2,2'-[(4-amino-3-nitrophenyl)imino]bisethanol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height.

- *m*-AMINOPHENOL **except** when used in hair dye and eyebrow/eyelash preparations at a concentration of 1.2% or less of *m*-aminophenol after mixing for use when the immediate container and primary pack are labelled with the following statements:
  - (a) KEEP OUT OF REACH OF CHILDREN; and
  - (b) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5 mm in height.

- *p* AMINOPHENOL **except** when used in hair dye and eyebrow/eyelash colouring products at a concentration of 1% or less of *p*-aminophenol after mixing for use when the immediate container and primary pack are labelled with the following statements:
  - (a) KEEP OUT OF REACH OF CHILDREN; and
  - (b) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5 mm in height.

AMINOPYRALID except when included in Schedule 5.

### AMITRAZ.

AMMONIA (excluding its salts and derivatives other than ammonium hydroxide) except:

- (a) when included in Schedule 5; or
- (b) in preparations for human internal therapeutic use; or
- (c) in preparations for inhalation when absorbed in an inert solid material; or
- (d) in preparations containing 0.5% or less of ammonia.
- AMMONIUM COCOYL ISETHIONATE, **except** in cosmetic rinse-off preparations containing 30% or less of ammonium cocoyl isethionate and, if containing more than 5% of ammonium cocoyl isethionate, when labelled with a warning to the following effect:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER.

#### AMMONIUM PERSULFATE in hair preparations.

ANILINE (excluding its salts and derivatives) **except** in preparations containing 1% or less of aniline.

### ANTIMONY COMPOUNDS except:

- (a) when included in Schedule 4; or
- (b) antimony chloride in polishes; or
- (c) antimony titanate pigments in paint; or
- (d) in paints or tinters containing 5% or less of antimony calculated on the non-volatile content of the paint or tinter.

#### ARBUTIN (ALPHA) except:

- (a) in preparations for application to the face containing 2% or less alpha-arbutin with hydroquinone levels of 10mg/kg or less; or
- (b) in preparations for application to the body containing 0.5% or less alpha-arbutin with hydroquinone levels of 10mg/kg or less.

### ARBUTIN (BETA) except:

- (a) when included in Schedule 4; or
- (b) oral herbal preparations containing 500 mg or less beta-arbutin per recommended daily dose; or
- (c) in preparations for application to the face containing 7% or less beta-arbutin with hydroquinone levels of 10mg/kg or less.

### ARBUTIN (DEOXY OR OTHER DERIVATIVES).

#### ARSENIC:

- (a) in ant poisons containing 0.4% or less of arsenic; or
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- (b) in animal feed premixes containing 4% or less of arsenic; or
- (c) in preparations for the treatment of animals **except** thiacetarsamide when included in Schedule 4,

except when separately specified in this Schedule.

ASPIRIN for the treatment of animals except when included in Schedule 4 or 5.

AZACONAZOLE except in preparations containing 1% or less of azaconazole.

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

- (a) when included in Schedule 5; or
- (b) in preparations for human internal use; or
- (c) debitterised neem seed oil; or
- (d) in preparations for human dermal therapeutic use containing cold pressed neem seed oil, when in a container fitted with a child-resistant closure and compliant with the requirements of the required advisory statements for medicine labels; or
- (e) in preparations for dermal use containing 1% or less of cold pressed neem seed oil.

### AZAMETHIPHOS.

### AZOBENZENE.

BAMBERMYCIN (flavophospholipol) in animal feed premixes for growth promotion containing 2% or less of antibiotic substances.

#### BARIUM SALTS except:

- (a) when included in Schedule 5; or
- (b) barium sulfate; or
- (c) in paints or tinters containing 5% or less of barium calculated on the non-volatile content of the paint or tinter.
- BASIC BLUE 26 (CAS No. 2580-56-5) **except** when used as a colourant in cosmetics not intended to be in contact with mucous membranes.

### BASIC ORANGE 31 (2-[(4-aminophenyl)azo]-1,3-dimethyl-1H-imidazolium chloride) except:

- (a) in preparations for skin colouration and dyeing of eyelashes or eyebrows; or
- (b) in hair dye preparations containing 1% or less of Basic Orange 31 when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN;
  - (ii) IF IN EYES WASH OUT IMMEDIATELY WITH WATER; and
  - (iii) WARNING This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not

be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height.

BASIC RED 76 (CAS No. 68391-30-0) in non-oxidative hair dye preparations and eyebrow/eyelash colouring products containing 2% or less of Basic Red 76 and 0.001% or less of free *o*-anisidine.

### BAY OIL except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the required advisory statements for medicine labels; or
- (c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (e) in preparations containing 25% or less of bay oil.

BEAUVERIA BASSIANA except when included in Schedule 5.

#### **BENDIOCARB:**

- (a) in wettable powders containing 80% or less of bendiocarb when packed in containers or primary packs containing not less than 100 g of bendiocarb; or
- (b) in wettable powders containing 20% or less of bendiocarb and not less than 0.002% of denatonium benzoate when packed in containers or primary packs containing not less than 48 g of bendiocarb and labelled for use as a fly control preparation; or
- (c) in insoluble granular preparations containing 5% or less of bendiocarb; or
- (d) when impregnated in plastic resin strip material containing 10% or less of bendiocarb;

except when included in Schedule 5.

#### BENQUINOX.

### BENSULIDE.

### BENZALKONIUM CHLORIDE except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 5% or less of benzalkonium chloride.

1,2-BENZENEDIOL.

BENZOVINDIFLUPYR.

6-BENZYLADENINE except in preparations containing 10% or less of 6-benzyladenine.

BERYLLIUM.

BETACYFLUTHRIN in preparations containing 12.5% or less of betacyfluthrin **except** when included in Schedule 5.

BETA-CYPERMETHRIN.

BHC (excluding lindane).

- BICYCLOPYRONE except when included in Schedule 5.
- BIFENTHRIN in preparations containing 25% or less of bifenthrin **except** in preparations containing 0.5% or less of bifenthrin.
- BIFLUORIDES (including ammonium, potassium and sodium salts) in preparations containing 3% or less of total bifluorides **except** when included in Schedule 5.

BIOALLETHRIN except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 1% or less of bioallethrin.
- 1,3-BIS(2,4-DIAMINOPHENOXY)PROPANE (including its salts) **except** when in hair dye preparations containing 1.2% or less of 1,3-bis(2,4-diaminophenoxy)propane after mixing when the immediate container and primary pack are labelled with the following statements:
  - (a) KEEP OUT OF REACH OF CHILDREN; and
  - (b) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height.

BIS-ISOBUTYL PEG/PPG-20/35/AMODIMETICONE COPOLYMER except in rinse-off cosmetic products containing 1% or less of bis-isobutyl PEG/PPG-20/35/amodimeticone copolymer when labelled with a warning to the following effect:

### IF IN EYES, WASH OUT IMMEDIATELY WITH WATER.

### *N*,*N*-BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE-2,5-DIMETHANAMINE

**except** in preparations containing 1% or less of *N*,*N*-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,5-dimethanamine, or a combination of

*N*,*N*-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,5-dimethanamine and N,N-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,6-dimethanamine, when labelled with statements to the effect of:

- (a) IRRITANT; and
- (b) REPEATED EXPOSURE MAY CAUSE SENSITISATION; and
- (c) Avoid contact with eyes; and
- (d) Avoid contact with skin; and
- (e) Wear protective gloves when mixing or using; and
- (f) Ensure adequate ventilation when using.

## *N*,*N*-BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE-2,6-DIMETHANAMINE except in preparations containing 1% or less of

N,N-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,6-dimethanamine, or a combination of N,N-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,5-dimethanamine and N,N-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,6-dimethanamine, when labelled with statements to the effect of:

- (a) IRRITANT; and
- (b) REPEATED EXPOSURE MAY CAUSE SENSITISATION; and
- (c) Avoid contact with eyes; and
- (d) Avoid contact with skin; and
- (e) Wear protective gloves when mixing or using; and
- (f) Ensure adequate ventilation when using.

BITHIONOL for the treatment of animals.

BORON TRIFLUORIDE in preparations containing 1% or less of boron trifluoride (BF<sub>3</sub>) except when included in Schedule 5.

BRODIFACOUM in preparations containing 0.25% or less of brodifacoum.

BROFLANILIDE except when included in Schedule 5.

BROMADIOLONE in preparations containing 0.25% or less of bromadiolone.

BROMETHALIN in rodent baits containing 0.01% or less of bromethalin.

BROMOFORM except when included in Schedule 4.

BROMOPHOS.

**BROMOPHOS-ETHYL**.

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BROMOXYNIL in preparations containing 1.5% or less of bromoxynil.

BROMUCONAZOLE except when included in Schedule 5.

BROTIANIDE.

BUNAMIDINE.

BUTACARB.

BUTOXYCARBOXIM except when included in Schedule 5.

### 2-BUTOXYETHANOL and its acetates **except**:

- (a) in plant growth regulator preparations containing 20% or less of such substances; or
- (b) in other preparations containing 10% or less of such substances.

### 2-BUTOXY-2'-THIOCYANODIETHYL ETHER.

### *n*-BUTYL ALCOHOL **except**:

- (a) when included in Schedule 5; or
- (b) in preparations containing 5% or less of n-butyl alcohol; or
- (c) in preparations for cosmetic or therapeutic use other than in spray form.

BUTYRIC ACID in preparations for use as insect lures.

### CACODYLIC ACID:

- (a) in animal feed premixes containing 4% or less of arsenic; or
- (b) in herbicide or defoliant preparations containing 10% or less of cacodylic acid.

### CADMIUM COMPOUNDS except:

- (a) when included in Schedule 4; or
- (b) in paints or tinters containing 0.1% or less of cadmium calculated on the non-volatile content of the paint or tinter.
- CADUSAFOS in aqueous preparations containing 20% or less of microencapsulated cadusafos.

### CAFFEINE except:

- (a) when included in Schedule 4; or
- (b) in divided preparations for internal human therapeutic use when labelled with a maximum recommended daily dose of no greater than 600 mg of total caffeine; or
- (c) in undivided preparations for internal human therapeutic use with a concentration of less than 5% of total caffeine and when labelled with a maximum recommended daily dose of no greater than 600 mg of total caffeine; or
- (d) in preparations for external use; or

(e) in other preparations with a concentration of less than 5% of caffeine.

### CAJUPUT OIL except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the required advisory statements for medicine labels; or
- (c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (e) in preparations containing 25% or less of cajuput oil; or
- (f) in oils containing 25% or less of cajuput oil.

CALCIFEROL in rodent baits containing 0.1% or less of calciferol.

### CAMBENDAZOLE.

### CAMPHOR except:

- (a) when included in Schedule 4 or 5; or
- (b) when enclosed in an inhaler device which prevents ingestion of its contents; or
- (c) in solid or semi-solid preparations containing 12.5% or less of camphor; or
- (d) in liquid preparations containing 2.5% or less of camphor; or
- (e) in essential oils when the camphor is present as a natural component of the oil:
  - (i) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
  - (ii) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the required advisory statements for medicine labels; or

- (iii) in essential oils other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:
  - (A) KEEP OUT OF REACH OF CHILDREN; and
  - (B) NOT TO BE TAKEN; or
- (iv) in essential oils other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:
  - (A) KEEP OUT OF REACH OF CHILDREN; and
  - (B) NOT TO BE TAKEN; or
- (f) in rosemary oil, sage oil (Spanish), or lavandin oil as such.

### CAPTAN.

CARBARYL except when included in Schedule 4 or 5.

### CARBON DISULFIDE.

### CARBAMIDE PEROXIDE except:

- (a) when included in Schedule 5; or
- (b) in other preparations containing 9% or less of carbamide peroxide.

### CARBETAMIDE.

- CASTOR OIL, MONOMALEATE (excluding its salts and derivatives) in preparations for cosmetic use **except** in wash-off preparations containing 1% or less of castor oil, monomaleate.
- CHLORALOSE (alpha-CHLORALOSE) when packed and labelled for use as a pesticide.

### CHLORDANE.

CHLORFENAPYR in preparations containing 36% or less of chlorfenapyr **except** when included in Schedule 5.

### CHLORFENETHOL.

CHLORHEXIDINE in preparations containing 7% or less of chlorhexidine except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 1% or less of chlorhexidine; or
- (c) when in solid preparations.

### CHLORINATING COMPOUNDS except:

- (a) when included in Schedule 5; or
- (b) when separately specified in these Schedules; or

- (c) sodium hypochlorite preparations with a pH of less than 11.5; or
- (d) in liquid preparations containing not less than 2% but not more than 4% 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; or

- (e) in liquid preparations containing less than 2% of available chlorine; or
- (f) in other preparations containing 4% or less of available chlorine.

#### CHLORMEQUAT.

#### CHLOROACETAMIDE

- (a) in preparations for cosmetic use; or
- (b) in preparations for topical therapeutic use; or
- (c) in other preparations containing more than 0.3% of chloroacetamide.

### 2-CHLORO-6-(ETHYLAMINO)-4-NITROPHENOL except:

- (a) in non-oxidative hair dye preparations containing 3% or less of
  2-chloro-6-(ethylamino)-4-nitrophenol after mixing for use when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5 mm in height; or

- (b) in oxidative hair dye preparations containing 1.5% or less of
  2-chloro-6-(ethylamino)-4-nitrophenol after mixing for use when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5 mm in height.

### CHLOROFORM except:

- (a) when included in Schedule 2 or 4; or
- (b) in preparations containing 10% or less of chloroform.

### ALPHA-CHLOROHYDRIN.

#### CHLOROPHACINONE.

(*E*)-(*S*)-1-(4-CHLOROPHENYL)-4,4-DIMETHYL-2-(1H-1,2,4-TRIAZOL-1-YL)PENT-1-E N-3-OL (uniconazole-p) **except** in preparations containing 5% or less of (*E*)-(*S*)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1*H*-1,2,4-triazol-1-yl)pent-1-en-3-ol.

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CHLOROPICRIN in preparations containing 5% or less of chloropicrin.

CHLOROTHALONIL except in water-based paint containing 0.5% or less of chlorothalonil.

2-CHLORO-6-(TRICHLOROMETHYL)-PYRIDINE.

### CHLORPYRIFOS except:

- (a) when included in Schedule 5; or
- (b) in prepared potting or soil mixes containing 100 g or less of chlorpyrifos per cubic metre.

### CHLORPYRIFOS-METHYL.

### CHLORTHIAMID.

- CHROMATES (including dichromates) **except** in paints or tinters containing 5% or less of chromium as the ammonium, barium, calcium, iron, potassium, sodium, strontium or zinc chromate calculated on the non-volatile content of the paint or tinter.
- CHROMIUM TRICHLORIDE HEXAHYDRATE **except** in preparations containing 0.5% or less chromium.
- CHROMIUM TRIOXIDE (excluding its salts and derivatives).

CHRYSOIDINE BASE except when in Schedule 10.

### CINEOLE except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the required advisory statements for medicine labels; or
- (c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (e) in preparations containing 25% or less of cineole; or
- (f) in oils containing 25% or less of cineole; or

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

### CINNAMON LEAF OIL except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the required advisory statements for medicine labels; or
- (c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (e) in preparations containing 25% or less of cinnamon leaf oil.

#### CLIMBAZOLE except:

- (a) when included in Schedule 5; or
- (b) in leave-on hair, face and foot cosmetic preparations containing 0.5% or less of climbazole; or
- (c) in other preparations (that are not leave-on cosmetic preparations) containing 2% or less of climbazole.

### CLODINAFOP-PROPARGYL.

#### CLOMAZONE.

#### CLOSANTEL.

#### CLOTHIANIDIN except

- (a) when included in Schedule 5; or
- (b) when in gel preparations dispensed in sealed cartridges containing 1% or less of clothianidin.

### CLOTRIMAZOLE for the external treatment of animals.

### CLOVE OIL except:

(a) when included in Schedule 5; or

- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
- (c) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the required advisory statements for medicine labels; or
- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN;
- (e) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (f) in preparations containing 25% or less of clove oil.

#### N-COCO-1,3-DIAMINOPROPANE.

#### COCOYL GLYCINATE in cosmetic preparations except:

- (a) in leave-on preparations containing 5% or less of cocoyl glycinate; or
- (b) in wash-off preparations containing 30% or less of cocoyl glycinate and, when containing more than 5% of cocoyl glycinate labelled with a warning to the following effect:

### IF IN EYES WASH OUT IMMEDIATELY WITH WATER.

#### COPPER ACETATE except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 5% or less of copper acetate.

### COPPER COMPOUNDS except:

- (a) when separately specified in these Schedules; or
- (b) in preparations for human internal use containing 5 mg or less of copper per recommended daily dose; or
- (c) pigments where the solubility of the copper compound(s) in water is 1 g per litre or less; or
- (d) in feed additives containing 1% or less of copper; or
- (e) in other preparations containing 5% or less of copper compounds.

### COPPER HYDROXIDE except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 12.5% or less of copper hydroxide.
- COPPER NITRATE in preparations containing copper chloride for the treatment of footrot in sheep.

#### COPPER OXIDES except:

- (a) when included in Schedule 5; or
- (b) in preparations for internal use; or
- (c) in marine paints; or
- (d) in other preparations containing 5% or less of copper oxides.

### COPPER OXYCHLORIDE except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 12.5% of less of copper oxychloride.

### COPPER SULFATE except:

- (a) when included in Schedule 5; or
- (b) in preparations for internal use; or
- (c) in other preparations containing 5% or less of copper sulfate.

#### **COUMAPHOS:**

- (a) in slow-release plastic matrix ear tags for livestock use containing 6 g or less of coumaphos; or
- (b) in other preparations containing 5% or less of coumaphos.
- COUMATETRALYL in rodenticides containing 1% or less of coumatetralyl **except** when included in Schedule 5.

### CREOSOTE derived from wood other than beechwood except:

- (a) when included in Schedule 2; or
- (b) in preparations for human therapeutic use containing 10% or less of creosote derived from wood other than beechwood; or
- (c) in other preparations containing 3% or less of phenols and homologues of phenol boiling below 220°C.

#### CROTOXYPHOS.

CRUFOMATE.

CYANAMIDE.

### CYANAZINE.

### CYCLANILIDE.

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### *N*-CYCLOHEXYLDIAZENIUMDIOXY-POTASSIUM.

### CYCLOSILAZANES, DI-ME, ME HYDROGEN, POLYMERS WITH DI-ME, ME HYDROGEN SILAZANES, REACTION PRODUCTS WITH 3-(TRIETHOXYSILYL)-1-PROPANAMINE (CAS 475645-84-2) when presented in a wipe and when packaged in a container with a child-resistant closure, with chemical resistant gloves and labelled with the following effect:

- (a) DO NOT USE WITHOUT PROTECTIVE GLOVES; and
- (b) KEEP OUT OF EYES.

### CYFLUTHRIN except:

- (a) when included in Schedule 5; or
- (b) in pressurised spray packs containing 1% or less of cyfluthrin.

### CYOMETRINIL.

CYPERMETHRIN except when included in Schedule 5.

CYPHENOTHRIN except when included in Schedule 5.

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

2,4-D except when included in Schedule 5.

### DAZOMET.

### DELTAMETHRIN:

- (a) in aqueous preparations containing 25% or less of deltamethrin, when no organic solvent, other than 10% or less of a glycol, is present; or
- (b) in wettable granular preparations containing 25% or less of deltamethrin; or
- (c) in water-dispersible tablets each containing 500 mg or less of deltamethrin; or
- (d) in emulsifiable concentrates containing 11% or less of deltamethrin in a solvent containing 40% or less of acetophenone and 45% or less of liquid hydrocarbons; or
- (e) in other preparations containing 3% or less of deltamethrin;

### except:

- (f) when included in Schedule 5; or
- (g) in factory prepared mosquito nets containing 1% or less of deltamethrin; or
- (h) in preparations containing 0.1% or less of deltamethrin.

### DERQUANTEL.

1-DEOXY-1-(METHYLAMINO)-D-GLUCITOL N-COCO ACYL DERIVATIVES except:

 (a) in cosmetic rinse-off preparations containing 8% or less of 1-deoxy-1-(methylamino)-d-glucitol N-coco acyl derivatives when labelled with the following statement:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER, or

(b) in household cleaning preparations, other than those intended to be sprayed, containing 10% or less of 1-deoxy-1-(methylamino)-d-glucitol N-coco acyl derivatives when labelled with the following statement:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER.

- 2,4-DIAMINOPHENOXYETHANOL **except** when used in hair dye and eyebrow/eyelash preparations at concentrations of 2% or less of 2,4-diaminophenoxyethanol after mixing for use when the immediate container and primary pack are labelled with the following statements:
  - (a) KEEP OUT OF REACH OF CHILDREN; and
  - (b) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5 mm in height.

DIAZINON except when included in Schedule 5.

DICAMBA (including its salts and derivatives) except when included in Schedule 5.

DICHLOBENIL.

DICHLOFENTHION.

DICHLOFLUANID.

o-DICHLOROBENZENE.

### DICHLOROETHYL ETHER.

#### DICHLOROISOCYANURIC ACID except:

- (a) when included in Schedule 5; or
- (b) in liquid preparations containing not less than 2% but not more than 4% 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; or

- (c) in liquid preparations containing less than 2% of available chlorine; or
- (d) in other preparations containing 4% or less of available chlorine.

### 4,5-DICHLORO-2-N-OCTYL-3(2H)-ISOTHIAZOLONE.

#### DICHLOROPHEN except:

(a) when included in Schedule 4 or 5; or

- (b) in fabrics other than when:
  - (i) for human therapeutic use; or
  - (ii) as part of a registered pesticidal product.

### 1,2-DICHLOROPROPANE.

- 2,4-DICHLORPROP (including the R and S enantiomers).
- DICHLORVOS in preparations containing 50% or less of dichlorvos **except** when included in Schedule 5.

DICLOFOP-METHYL.

DICYCLANIL except in preparations containing 6.5% or less of dicyclanil.

DIDECYLDIMETHYLAMMONIUM SALTS **except** in preparations containing 1% or less of didecyldimethylammonium salts labelled with the statement:

Avoid contact with eyes.

### DIELDRIN.

DIETHANOLAMINE (excluding its salts and derivatives) except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 5% or less of diethanolamine.

DIETHYLENE GLYCOL (excluding its salts and derivatives) except:

- (a) when included in Schedule 5; or
- (b) in paints or paint tinters; or
- (c) in toothpastes or mouthwashes containing more than 0.25% of diethylene glycol; or
- (d) in other preparations containing 2.5% or less of diethylene glycol.

DIETHYLENE GLYCOL MONOMETHYL ETHER.

DIFENACOUM in preparations containing 0.25% or less of difenacoum.

DIFENZOQUAT.

DIFETHIALONE in rodent baits containing 0.0025% or less of difethialone.

5,6-DIHYDROXYINDOLINE.

DIMETHENAMID-P.

DIMETHIPIN.

DIMETHOATE.

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### 2,6-DIMETHOXY-3,5-PYRIDINEDIAMINE **except** when used in hair dye and eyebrow/eyelash colouring products at a concentration of 0.25% or less of 2,6-dimethoxy-3,5-pyridinediamine after mixing for use when the immediate container and primary pack are labelled with the following statements:

- (a) KEEP OUT OF REACH OF CHILDREN; and
- (b) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5 mm in height.

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

### *N*,*N*-DIMETHYLDECANAMIDE.

#### DIMETHYLFORMAMIDE except:

- (a) when included in Schedule 5; or
- (b) in silicone rubber mastic containing 2% or less of dimethylformamide.

### 4,4-DIMETHYL-1-CYCLOHEXENE-1-PROPANAL except:

- (a) in leave-on cosmetic preparations containing 0.1% or less of 4,4-dimethyl-1-cyclohexene-1-propanal; or
- (b) in rinse-off cosmetic preparations containing 0.5% or less of 4,4-dimethyl-1-cyclohexene-1-propanal; or
- (c) in other preparations containing 1% or less of 4,4-dimethyl-1-cyclohexene-1-propanal.
- 3,7-DIMETHYL-2,6-OCTADIEN-1-OL and its isomers **except** in products containing 5% or less 3,7-dimethyl-2,6-octadien-1-ol and its isomers.

#### *N*,*N*-DIMETHYLOCTANAMIDE.

#### DIMETHYL SULFOXIDE (excluding dimethyl sulfone):

- (a) when not for therapeutic use; or
- (b) in cosmetic preparations; or
- (c) for the treatment of animals:
  - (i) when combined with no other therapeutic substance(s); or
  - (ii) in liquid preparations containing copper salicylate and 1% or less of methyl salicylate as the only other therapeutic substances; or
  - (iii) in clay poultices containing 2% or less of dimethyl sulfoxide; or
- (d) in other preparations except when containing 10% or less of dimethyl sulfoxide.

### DIMPROPYRIDAZ except when included in Schedule 5.

# DINITROCRESOLS and their homologues in preparations containing 5% or less of such compounds **except**:

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- (a) when included in Schedule 4; or
- (b) when separately specified in this Schedule.
- DINITROPHENOLS and their homologues in preparations containing 5% or less of such compounds **except**:
  - (a) when included in Schedule 4; or
  - (b) when separately specified in this Schedule.

# DIOXACARB.

DIOXANE except:

- (a) in preparations for cosmetic or human internal therapeutic use containing 0.001% or less of dioxane; or
- (b) in other preparations containing 0.01% or less of dioxane.

#### DIPHACINONE.

DIQUAT in preparations containing 20% or less of diquat.

DIRECT RED 254 except when included in Schedule 5.

DISPERSE YELLOW 3 except when in Schedule 10.

DISULFIRAM except when included in Schedule 4.

DISULFOTON in granular preparations containing 5% or less of disulfoton.

DITHIANON.

DITHIAZANINE in preparations containing 2% or less of dithiazanine for the treatment of animals.

DIUREDOSAN.

*N*-(*N*-DODECYL)-2-PYRROLIDONE except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 25% or less of designated solvents.

# DODINE.

DORAMECTIN for external use for the treatment of animals, in preparations containing 2% or less of doramectin.

DSMA in herbicide or defoliant preparations containing 10% or less of DSMA.

ECONAZOLE for the external treatment of animals.

EMAMECTIN in preparations containing 5% or less of emamectin **except** when included in Schedule 5.

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EMODEPSIDE for the treatment of animals except when included in Schedule 5.

- ENDOSULFAN in aqueous preparations containing 33% or less of microencapsulated endosulfan.
- ENDOTHAL in preparations containing 20% or less of endothal.
- EPRINOMECTIN for internal use in preparations containing 5% or less of eprinomectin **except** when included in Schedule 5.

EPTC.

ESBIOTHRIN except:

- (a) when included in Schedule 5; or
- (b) in pressurised spray packs containing 1% or less of esbiothrin.

ESFENVALERATE except when included in Schedule 5.

ETHEPHON (excluding its salts and derivatives).

#### ETHER except:

- (a) when included in Schedule 2, 4 or 5; or
- (b) in preparations containing 10% or less of ether.

# ETHIOFENCARB.

ETHOATE-METHYL.

ETHOPROPHOS in granular formulations containing 10% or less of ethoprophos and 2% of linseed oil.

ETHYL BROMIDE.

ETHYLENE CHLOROHYDRIN.

ETHYLENE DICHLORIDE.

ETHYLENE GLYCOL (excluding its salts and derivatives) except:

- (a) when included in Schedule 5; or
- (b) in paints or paint tinters; or
- (c) in toothpastes or mouthwashes containing more than 0.25% of ethylene glycol; or
- (d) in other preparations containing 2.5% or less of ethylene glycol.

ETHYLENE GLYCOL MONOALKYL ETHERS and their acetates, except:

(a) when separately specified in these Schedules; or

(b) in preparations containing 10% or less of such substances.

ETHYL FORMATE when packed and labelled for use as a fumigant.

ETHYLHEXANEDIOL except in preparations containing 5% or less of ethylhexanediol.

2-ETHYLHEXANOIC ACID and its alkyl esters **except** in preparations containing 5% or less calculated as 2-ethylhexanoic acid.

#### ETRIMFOS.

#### EUCALYPTUS OIL except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the required advisory statements for medicine labels; or
- (c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (e) in preparations containing 25% or less of eucalyptus oil.

#### EUGENOL except:

- (a) when included in Schedule 5; or
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
- (c) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the required advisory statements for medicine labels; or
- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and

# (ii) NOT TO BE TAKEN; or

- (e) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (f) in preparations containing 25% or less of eugenol.

FAMOXADONE.

FAMPHUR in preparations containing 20% or less of famphur.

FEBANTEL **except**:

- (a) in divided preparations containing 1000 mg or less of febantel per dosage unit; or
- (b) in undivided preparations containing 10% or less of febantel.

FENAMIPHOS in granular preparations containing 5% or less of fenamiphos.

FENAZAFLOR.

FENBUTATIN OXIDE.

FENCHLORPHOS.

FENITROTHION.

FENOXACRIM in preparations for the treatment of carpets during manufacture.

FENPROPIDIN.

FENPYROXIMATE.

FENTHION in preparations containing 60% or less of fenthion **except** when included in Schedule 5.

FENVALERATE.

# FIPRONIL except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 0.05% or less of fipronil.
- FLOCOUMAFEN in preparations containing 0.005% or less of flocoumafen.

FLONICAMID.

FLUAZAINDOLIZINE except when included in Schedule 5.

FLUAZIFOP-BUTYL.

FLUAZIFOP-p-BUTYL.

FLUAZINAM.

FLUCOFURON in preparations for the treatment of carpets during manufacture.

FLUENSULFONE.

FLUMETHRIN except when included in Schedule 5.

FLUMIOXAZIN when contained in water soluble bags individually packed in sealed sachets.

FLUORIDES except:

- (a) when included in Schedule 5; or
- (b) in preparations for human use; or
- (c) in preparations containing 15 mg/kg or less of fluoride ion.

FLUPROPANATE.

FLUPYRADIFURONE.

FLUQUINCONAZOLE.

FLUSILAZOL.

FLUTRIAFOL except in fertilisers containing 0.5% or less of flutriafol.

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

FOLPET.

FOMESAFEN SODIUM.

FORMALDEHYDE (excluding its derivatives) in preparations containing 0.05% or more of free formaldehyde **except**:

- (a) for human therapeutic use; or
- (b) in oral hygiene preparations; or
- (c) in nail hardener cosmetic preparations containing 5% or more of free formaldehyde; or
- (d) in nail hardener cosmetic preparations containing 0.2% or less of free formaldehyde when labelled with the statement:

PROTECT CUTICLES WITH GREASE OR OIL;

- (e) in all other cosmetic preparations; or
- (f) in other preparations containing 0.2% or less of free formaldehyde when labelled with the warning statement:

CONTAINS FORMALDEHYDE.

# FORMOTHION.

FOSPIRATE except when included in Schedule 5.

#### FUMAGILLIN.

FURFURAL except in preparations containing 0.1% or less of furfural.

#### GLUTARAL except:

- (a) when included in Schedule 2 or 5; or
- (b) in preparations containing 0.5% or less of glutaral when labelled with the statements:

IRRITANT; and

Avoid contact with eyes.

GLYCERYL THIOGLYCOLLATE in hair waving preparations **except** when labelled with directions for use that include the statement:

Wear protective gloves when using. Keep out of eyes.

- GLYCOLIC ACID (including its salts and esters) in cosmetic products or when packed and labelled for use as an agricultural chemical **except**:
  - (a) in cosmetic preparations for salon use only, when labelled in accordance with requirements under applicable jurisdictional Work Health and Safety laws, as amended from time to time; or
  - (b) in preparations containing 5% or less of glycolic acid; or
  - (c) in preparations containing 20% or less of glycolic acid with a pH of 3.5 or greater.

# GUANIDINE except:

- (a) when included in Schedule 4; or
- (b) in preparations containing 1% or less of guanidine.

# GUAZATINE.

# HALOXON.

# HALOXYFOP.

- HC VIOLET 1 except:
  - (a) in non-oxidative hair dye preparations containing 0.28% or less of HC Violet 1 after mixing when the immediate container and primary pack are labelled with the following statements:
    - (i) KEEP OUT OF REACH OF CHILDREN; and
    - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5 mm in height; or

- (b) in oxidative hair dye preparations containing 0.25% or less of HC Violet 1 after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height.

# HEPTACHLOR.

#### HEXACHLOROPHENE:

- (a) in preparations for the treatment of animals; or
- (b) for cosmetic use.

HEXAZINONE except when included in Schedule 5.

HEXYLOXYETHANOL except in preparations containing 10% or less of hexyloxyethanol.

HYDRAMETHYLNON except when included in Schedule 5.

#### HYDRAZINE.

HYDROCHLORIC ACID (excluding its salts and derivatives) except:

- (a) when included in Schedule 5; or
- (b) in preparations for therapeutic use; or
- (c) in preparations containing 0.5% or less of hydrochloric acid (HCl).
- HYDROFLUORIC ACID (excluding its salts and derivatives) and admixtures that generate hydrofluoric acid, in preparations containing 1% or less of hydrogen fluoride **except** when included in Schedule 5.

#### HYDROGEN PEROXIDE (excluding its salts and derivatives) except:

- (a) when included in Schedule 5; or
- (b) in hair dye preparations containing 6% (20 volume) or less of hydrogen peroxide; or
- (c) in other preparations containing 3% (10 volume) or less of hydrogen peroxide.

# HYDROQUINONE except:

- (a) when included in Schedule 2 or 4; or
- (b) in preparations containing 10% or less of hydroquinone.

- HYDROSILICOFLUORIC ACID (excluding its salts and derivatives) in preparations containing 1% or less of hydrosilicofluoric acid (H<sub>2</sub>SiF<sub>6</sub>) **except** when included in Schedule 5.
- HYDROXYETHYL-3,4-METHYLENEDIOXYANILINE (including its salts) **except** in oxidative hair dye preparations containing 1.5% or less of hydroxyethyl-3,4-methylenedioxyaniline after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements:
  - (a) KEEP OUT OF REACH OF CHILDREN; and
  - (b) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height.

# IMIDACLOPRID except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 5% or less of imidacloprid.

#### IMIDOCARB.

# IMINOCTADINE TRIALBESILATE.

#### IMIPROTHRIN except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 10% or less of imiprothrin.

# INDAZIFLAM.

INDOXACARB (includes the R and S enantiomers) except when included in Schedule 5.

# INPYRFLUXAM.

# IODINE (excluding its salts, derivatives and iodophors) except:

- (a) when included in Schedule 2; or
- (b) in solid or semi-solid preparations containing 2.5% or less of available iodine.

#### IODOPHORS except in preparations containing 1.5% or less of available iodine.

# 3-IODO-2-PROPYNYL BUTYL CARBAMATE (Iodocarb) except:

- (a) when included in Schedule 5; or
- (b) in aqueous preparations not for cosmetic use containing 10% or less of 3-iodo-2-propynyl butyl carbamate (Iodocarb); or
- (c) in cosmetic preparations (other than aerosolised preparations) containing 0.1% or less of 3-iodo-2-propynyl butyl carbamate.

# IOXYNIL.

IPCONAZOLE except when included in Schedule 5.

- IRON COMPOUNDS (excluding up to 1% of iron oxides when present as an excipient) for the treatment of animals **except**:
  - (a) when included in Schedule 5; or
  - (b) in liquid or gel preparations containing 0.1% or less of iron; or
  - (c) in animal feeds or feed premixes.

ISOCONAZOLE for the external treatment of animals.

ISOCYANATES, free organic, boiling below 300° C, except in:

- (a) viscous polyurethane adhesives; or
- (b) viscous polyurethane sealants;

containing not more than 0.7% of free organic isocyanates boiling below 300°C.

# ISOCYCLOSERAM.

# ISOEUGENOL except:

- (a) when included in Schedule 5; or
- (b) in preparations not intended for skin contact containing 10% or less of isoeugenol; or
- (c) in preparations intended for skin contact containing 0.02% or less of isoeugenol.

#### ISOPYRAZAM.

ISOTIANIL.

#### LAMBDA-CYHALOTHRIN:

- (a) in aqueous preparations containing 25% or less of microencapsulated lambda-cyhalothrin; or
- (b) in emulsifiable granule formulations containing 25% or less lambda-cyhalothrin; or
- (c) in other preparations containing 1.6% or less of lambda-cyhalothrin;

except when included in Schedule 5.

LASALOCID except in animal feeds containing 100 mg/kg or less of antibiotic substances.

LAURETH CARBOXYLIC ACIDS (excluding their salts and derivatives) except:

- (a) in leave-on preparations containing 1.5% or less of laureth carboxylic acids; or
- (b) in wash-off preparations containing 30% or less of laureth carboxylic acids and, if containing more than 5% of laureth carboxylic acids, when labelled with a warning to the following effect:

# IF IN EYES WASH OUT IMMEDIATELY WITH WATER; or

- (c) in other preparations containing 30% or less of laureth carboxylic acids and, if containing more than 5% of laureth carboxylic acids, when labelled with warnings to the following effect:
  - (i) IF IN EYES WASH OUT IMMEDIATELY WITH WATER; and
  - (ii) IF SKIN OR HAIR CONTACT OCCURS, REMOVE CONTAMINATED CLOTHING AND FLUSH SKIN AND HAIR WITH RUNNING WATER.

# LAURYL ISOQUINOLINIUM BROMIDE.

LAURYL SULFATE SALTS (excluding their derivatives) except:

 (a) in wash-off preparations containing 30% or less of lauryl sulfates and, if containing more than 5% of lauryl sulfates, when labelled with a warning to the following effect:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER; or

- (b) in leave-on preparations containing 1.5% or less of lauryl sulfates; or
- (c) in toothpaste and oral hygiene preparations containing 5% or less of lauryl sulfates; or
- (d) in other preparations for animal use containing 2% or less of lauryl sulfates; or
- (e) in other preparations containing 30% or less of lauryl sulfates and, if containing more than 5% of lauryl sulfates, when labelled with warnings to the following effect:
  - (i) IF IN EYES WASH OUT IMMEDIATELY WITH WATER; and
  - (ii) IF SKIN OR HAIR CONTACT OCCURS, REMOVE CONTAMINATED CLOTHING AND FLUSH SKIN AND HAIR WITH RUNNING WATER.

# LEAD COMPOUNDS except:

- (a) when included in, or expressly excluded from, Schedule 10; or
- (b) in preparations for cosmetic use containing 10 mg/kg or less of lead; or
- (c) in pencil cores, finger colours, showcard colours, pastels, crayons, poster paints/colours or coloured chalks containing 25 mg/kg or less of lead; or
- (d) in ceramic glazes when labelled with the warning statement:

CAUTION – Harmful if swallowed. Do not use on surfaces which contact food or drink;

written in letters not less than 1.5 mm in height.

#### LEPTOSPERMUM SCOPARIUM OIL (manuka oil) except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a

child-resistant closure and compliant with the requirements of the required advisory statements for medicine labels; or

- (c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings;
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (e) in preparations containing 25% or less of Leptospermum scoparium oil.

LEVAMISOLE for the treatment of animals except:

- (a) when included in Schedule 4 or 5; or
- (b) in preparations for the treatment of ornamental birds or ornamental fish, in packs containing 10 mg or less of levamisole.

LINDANE except when included in Schedule 2, 4 or 5.

MAFENIDE when packed and labelled for the treatment of ornamental fish only.

#### MALATHION except:

- (a) when included in Schedule 5; or
- (b) for human therapeutic use; or
- (c) in dust preparations containing 2% or less of malathion.

MCPA except when included in Schedule 5.

MCPB.

MEBENDAZOLE for the treatment of animals except when included in Schedule 5.

MECOPROP except when included in Schedule 5.

MECOPROP-P.

MEFLUIDIDE.

MELALEUCA OIL (tea tree oil) except:

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and compliant with the requirements of the required advisory statements for medicine labels; or

- (b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the required advisory statements for medicine labels; or
- (c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (e) in preparations containing 25% or less of melaleuca oil.

MELENGESTROL ACETATE when used as an animal feed additive.

#### MELOXICAM in:

- (a) oral transmucosal preparations containing 1% or less of meloxicam for pre-surgical treatment and pain management in livestock during routine husbandry procedures; or
- (b) injectable vaccines containing bacterial antigens and 1% or less of meloxicam for single use in lambs undergoing husbandry procedures at marking.

#### MENAZON.

MERCAPTAMINE for cosmetic use except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 1% or less of mercaptamine.
- MERCAPTOACETIC ACID and its salts, but excluding its derivatives, in cosmetic preparations **except**:
  - (a) when included in Schedule 5; or
  - (b) in preparations containing 5% or less of mercaptoacetic acid or its salts (as mercapturic acid).

2-MERCAPTOETHANOL in preparations for use as insect lures.

MERCURIC OXIDE for the treatment of animals, in preparations for ocular use.

MERCUROCHROME for the treatment of animals, in preparations for topical use.

METACRESOLSULPHONIC ACID AND FORMALDEHYDE CONDENSATION PRODUCT for the treatment of animals. METALAXYL except when included in Schedule 5.

METALDEHYDE except when included in Schedule 5.

METHACRIFOS in preparations containing 60% or less of methacrifos.

METHAM.

METAMITRON.

METHANOL (excluding its derivatives) except:

- (a) when included in Schedule 5; or
- (b) when included in Schedule 10; or
- (c) in preparations containing 2% or less of methanol.
- METHIOCARB in preparations containing 20% or less of methiocarb **except** when included in Schedule 5.
- METHOMYL in fly-baits containing 1% or less of methomyl and not less than 0.002% of denatonium benzoate as a bittering agent.
- 6-METHOXY-N2-METHYL-2,3-PYRIDINEDIAMINE **except** when used in oxidative or non- oxidative hair dyes at a concentration of 1% or less when the immediate container and primary pack are labelled with the following statements:
  - (a) KEEP OUT OF REACH OF CHILDREN; and
  - (b) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5 mm in height.

# 2-METHOXY-5-NITROPHENOL.

# METHYLCHLOROISOTHIAZOLINONE except:

- (a) in rinse-off cosmetic preparations or therapeutic goods intended for topical rinse-off application containing 0.0015% or less of methylchloroisothiazolinone and methylisothiazolinone in total; or
- (b) in other preparations that are not intended for direct application to the skin containing 0.1% or less of methylchloroisothiazolinone and methylisothiazolinone in total.
- METHYLCYCLOPENTADIENYL MANGANESE TRICARBONYL in preparations containing 10% or less of methylcyclopentadienyl manganese tricarbonyl when fitted with a child-resistant closure.

METHYLDIBROMO GLUTARONITRILE except when in Schedule 10.

- METHYLENE BISTHIOCYANATE **except** in preparations containing 1% or less of methylene bisthiocyanate.
- METHYLEUGENOL except in preparations containing 1% or less of methyleugenol.

METHYL ETHYL KETONE OXIME except:

- (a) in viscous silicone adhesives or viscous silicone sealants containing 2.5% or less of methyl ethyl ketone oxime; or
- (b) in other preparations containing 1% or less of methyl ethyl ketone oxime.
- *p*-METHYLAMINOPHENOL **except** when used in hair dye and eyebrow/eyelash colouring products at a concentration of 1% or less of *p*-methylaminophenol after mixing for use when the immediate container and primary pack are labelled with the following statements:
  - (a) KEEP OUT OF REACH OF CHILDREN; and
  - (b) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5 mm in height.

#### METHYL ISOTHIOCYANATE.

#### METHYL METHACRYLATE (excluding its derivatives) except:

- (a) for cosmetic use; or
- (b) in preparations containing 1% or less of methyl methacrylate as residual monomer in a polymer.
- METHYL NEODECANAMIDE **except** in liquid preparations containing 2% or less of methyl neodecanamide.

#### METHYLISOTHIAZOLINONE except:

- (a) in rinse-off cosmetic preparations or therapeutic goods intended for topical rinse-off application containing 0.0015% or less of methylisothiazolinone; or
- (b) in other preparations that are not intended for direct application to the skin containing 0.1% or less of methylisothiazolinone

#### METHYLNORBORNYLPYRIDINE.

#### *N*-METHYL-2-PYRROLIDONE except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 25% or less of designated solvents.

# 2-METHYLRESORCINOL except:

 (a) in non-oxidative hair dye preparations containing 1.8% or less of 2-methylresorcinol when the immediate container and primary pack are labelled with the following statements:

- (i) KEEP OUT OF REACH OF CHILDREN; and
- (ii) WARNING This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height; or

- (b) in oxidative hair dye preparations containing 1.8% or less of 2-methylresorcinol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letter not less than 1.5 mm in height.

- METHYLROSANILINIUM CHLORIDE (formerly known as crystal violet CAS No. 548-62-9) and the following TRIARYLMETHANE DYES:
  - (a) Acid Violet 49 (CAS No. 1694-09-3);
  - (b) Ethyl Violet (CAS No. 2390-59-2);
  - (c) Basic Blue 7 (CAS No. 2390-60-5);
  - (d) Methylium, 4-(dimethylamino)phenylbis4-(ethylamino)-3-methylphenyl-, acetate (CAS No. 72102-55-7);

except when included in Schedule 4 or Schedule 10.

#### METHYL SALICYLATE except:

- (a) when included in Schedule 5; or
- (b) in preparations for therapeutic use; or
- (c) in preparations containing 5% or less of methyl salicylate.

METOFLUTHRIN except when included in Schedule 5.

METOSULAM.

METRAFENONE except when included in Schedule 5.

METRIBUZIN.

MICONAZOLE for the external treatment of animals.

MILBEMECTIN except when included in Schedule 5.

MOMFLUOROTHRIN except in preparations containing 0.2% or less of momfluorothrin.

MONENSIN:

- (a) in animal feed premixes containing 12.5% or less of antibiotic substances; or
- (b) in stockfeed supplements, blocks or licks containing 0.75% or less of antibiotic substances.

MONOETHANOLAMINE (excluding its salts and derivatives) except:

- (a) when included in Schedule 4 or 5; or
- (b) in preparations containing 5% or less of monoethanolamine.

# MORANTEL except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 10% or less of morantel.

#### MOXIDECTIN:

- (a) in preparations for external use containing 2.5% or less of moxidectin when packed in single dose tubes for the treatment of cats and dogs; or
- (b) in preparations for external use containing 2% or less of moxidectin for the treatment of animals; or
- (c) in preparations for internal use containing 10% or less of moxidectin for the treatment of sheep or cattle;

except when included in Schedule 5.

MSMA in herbicide or defoliant preparations containing 10% or less of MSMA.

NALED except when included in Schedule 5.

NAPHTHALENE (excluding its derivatives) except in liquid hydrocarbons.

#### 1,5-NAPHTHALENEDIOL except:

- (a) in non-oxidative hair dye preparations containing 1% or less of 1,5-naphthalenediol when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height; or

- (b) in oxidative hair dye preparations containing 1% or less of 1,5-naphthalenediol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height.

#### 2,7-NAPHTHALENEDIOL except:

- (a) in non-oxidative hair dye preparations containing 1% or less of
   2,7-naphthalenediol when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height; or

- (b) in oxidative hair dye preparations containing 1% or less of 2,7-naphthalenediol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height.

- 1-NAPHTHOL **except** in hair dye preparations containing 1% or less of 1-naphthol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height.

NAPHTHALOPHOS in preparations containing 80% or less of naphthalophos.

NARASIN in animal feed premixes containing 12% or less of narasin.

NETOBIMIN for the treatment of animals **except** when included in Schedule 5.

NICKEL SULFATE.

NICLOSAMIDE except when included in Schedule 2 or Schedule 5.

NIMIDANE in preparations containing 25% or less of nimidane.

NITENPYRAM except in divided preparations containing 100 mg or less of nitenpyram.

NITRIC ACID (excluding its salts and derivatives) except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 0.5% or less of nitric acid (HNO<sub>3</sub>).

# NITROBENZENE except:

- (a) in solid or semi-solid polishes; or
- (b) in soaps containing 1% or less of nitrobenzene; or
- (c) in other preparations containing 0.1% or less of nitrobenzene.

#### 3-NITRO-p-HYDROXYETHYLAMINOPHENOL except

- (a) in non-oxidative hair dye preparations containing 1.85% or less of 3-nitro-*p*-hydroxyethylaminophenol after mixing when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height; or

- (b) in oxidative hair dye preparations containing 3% or less of 3-nitro-p-hydroxyethylaminophenol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height.

- NITROPHENOLS, ortho, meta and para, **except** when separately specified in these Schedules.
- NITROPRUSSIDES in preparations containing 2.5% or less of nitroprussides **except** when included in Schedule 4.

NITROUS OXIDE except when included in Schedule 4.

# NITROXYNIL.

#### NONOXINOL 9 except:

(a) when included in Schedule 5; or

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- (b) in preparations containing 25% or less of nonoxinol 9 when labelled with the statements:
  - (i) IRRITANT; and
  - (ii) Avoid contact with eyes; or
- (c) in preparations containing 12.5% or less of nonoxinol 9; or
- (d) in preparations for human use.
- 1-OCTEN-3-OL except in preparations containing 5% or less of 1-octen-3-ol.
- OCTHILINONE **except** in paints, jointing compounds and sealants containing 1% or less of octhilinone calculated on the non-volatile content.

# *N*-(*N*-OCTYL)-2-PYRROLIDONE except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 25% or less of designated solvents.
- OLAQUINDOX except in preparations containing 10% or less of olaquindox.

#### *N*-OLEYL-1,3-DIAMINOPROPANE.

OMETHOATE in preparations containing 30% or less of omethoate **except** when included in Schedule 5.

# OXADIAZON.

# OXALIC ACID except

- (a) in dental care preparations, including mouthwashes, containing 3% or less of soluble salts of oxalic acid; or
- (b) its insoluble salts.

# OXYCLOZANIDE.

# PAECILOMYCES LILACINUS STRAIN 251.

# PALMITOYLETHANOLAMIDE (excluding derivatives) except:

- (a) in preparations for therapeutic use; or
- (b) in preparations for dermal cosmetic use containing 1% or less of palmitoylethanolamide.
- PARAFORMALDEHYDE (excluding its derivatives) in preparations containing 0.05% or more of free formaldehyde **except**:
  - (a) for human therapeutic use; or
  - (b) in oral hygiene preparations; or
  - (c) in nail hardener cosmetic preparations containing 5% or more of free formaldehyde; or

(d) in nail hardener cosmetic preparations containing 0.2% or less of free formaldehyde when labelled with the statement:

PROTECT CUTICLES WITH GREASE OR OIL; or

- (e) in all other cosmetic preparations; or
- (f) in other preparations containing 0.2% or less of free formaldehyde when labelled with the warning statement:

CONTAINS FORMALDEHYDE.

PARATHION-METHYL in aqueous preparations containing 45% or less of microencapsulated parathion-methyl.

# PARBENDAZOLE.

# PEBULATE.

#### PENNYROYAL OIL except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (c) in preparations containing 4% or less of **D**-pulegone.

PENTACHLOROPHENOL in preparations containing 1.5% or less of pentachlorophenol.

PERACETIC ACID except when included in Schedule 5.

#### PERFLUIDONE.

PERMANGANATES **except** potassium permanganate in aqueous solutions containing 1% or less of potassium permanganate.

# PERMETHRIN except:

- (a) when included in Schedule 4 or 5; or
- (b) in preparations for human therapeutic use containing 5% or less of permethrin; or
- (c) in preparations containing 2% or less of permethrin.

# 2-PHENOXYETHANOL except:

- (a) in cosmetic preparations containing 1% or less of 2-phenoxyethanol; or
- (b) in other preparations containing 15% or less of 2-phenoxyethanol.

- PHENOL, including cresols and xylenols and any other homologue of phenol boiling below 220°C, except:
  - (a) when separately specified in these Schedules; or
  - (b) in preparations containing 1% or less of phenols, and in preparations containing 3% or less of cresols and xylenols and other homologues of phenol.
- PHENOTHIAZINE (excluding its derivatives) **except** in preparations containing 10% or less of phenothiazine.

#### PHENOXYMETHYL OXIRANE.

- PHENYLENEDIAMINES including alkylated, arylated, halogenated and nitro derivatives not elsewhere specified in these Schedules:
  - (a) in preparations packed and labelled for photographic purposes; or
  - (b) in preparations packed and labelled for testing water except tablets containing 10 mg or less of diethyl-para-phenylenediamine or dimethyl-para-phenylenediamine in opaque strip packaging provided the directions for use include the statement, "Do not discard testing solutions into the pool"; or
  - (c) in hair dye preparations **except** when the immediate container and primary pack are labelled with the following statements:
    - (i) KEEP OUT OF REACH OF CHILDREN; and
    - (ii) WARNING This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height; or

(d) in eyelash and eyebrow tinting products when the immediate container and primary pack are labelled with the following statement:

WARNING – This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5 mm in height.

- PHENYL METHYL PYRAZOLONE **except** when used in hair dye and eyebrow/eyelash preparations at a concentration of 0.25% or less after mixing for use when the immediate container and primary pack are labelled with warning statements to the following effect:
  - (a) KEEP OUT OF REACH OF CHILDREN; and
  - (b) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use.

written in letters not less than 1.5 mm in height.

#### PHOSALONE.

#### PHOSMET.

PHOSPHORIC ACID (excluding its salts and derivatives) except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 15% or less of phosphoric acid  $(H_3PO_4)$ ; or
- (c) in solid or semi-solid preparations; or
- (d) in professional dental kits.

#### PHOXIM.

o-PHTHALALDEHYDE except when included in Schedule 5.

- PICRAMIC ACID including its salts (excluding other derivatives) **except** when used in hair dye products at a concentration of 0.6% or less of picramic acid after mixing for use when the immediate container and primary pack are labelled with the following statements:
  - (a) KEEP OUT OF REACH OF CHILDREN; and
  - (b) WARNING This product contains ingredients which may cause skin allergy to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height.

#### PINDONE.

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

PINOXADEN except when included in Schedule 5.

PIPEROPHOS.

PIRIMICARB except when included in Schedule 5.

PIRIMIPHOS-ETHYL.

PIRIMIPHOS-METHYL.

#### POLIHEXANIDE except:

- (a) in cosmetic preparations containing 0.3% or less of polihexanide; or
- (b) when packed and labelled for therapeutic use; or
- (c) in other preparations containing 5% or less of polihexanide.

# POLIXETONIUM SALTS except:

(a) when included in Schedule 5; or

- (b) in preparations containing 1% or less of polixetonium salts.
- POTASSIUM AZELOYL DIGLYCINATE **except** in preparations for cosmetic use containing 1% or less of potassium azeloyl diglycinate.
- POTASSIUM BROMATE **except** in preparations containing 0.5% or less of potassium bromate.

# POTASSIUM CYANATE.

# POTASSIUM HYDROXIDE (excluding its salts and derivatives) except:

- (a) when included in Schedule 5 or Schedule 10; or
- (b) in preparations containing 5% or less of potassium hydroxide being:
  - (i) solid preparations, the pH of which in a 10 g/L aqueous solution is 11.5 or less; or
  - (ii) liquid or semi-solid preparations, the pH of which is 11.5 or less.

#### POTASSIUM NITRITE in preparations containing 40% or less of potassium nitrite except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 0.5% or less of potassium nitrite; or
- (c) when present as an excipient in preparations for therapeutic use; or
- (d) in aerosols containing 2% or less of potassium nitrite.

# POTASSIUM PEROXOMONOSULFATE TRIPLE SALT except:

- (a) when included in Schedule 5; or
- (b) in solid orthodontic device cleaning preparations, the pH of which as an "in-use" aqueous solution is 2.5 or more, but not more than 11.5; or
- (c) in preparations containing 5% or less of potassium peroxomonosulfate triple salt being:
  - (i) solid preparations, the pH of which in a 10 g/L aqueous solution is 2.5 or more; or
  - (ii) liquid or semi-solid preparations, the pH of which is 2.5 or more.

#### POTASSIUM PERSULFATE in hair preparations.

#### PRALLETHRIN (cis:trans=20:80) except:

- (a) when included in Schedule 5; or
- (b) in insecticidal mats containing 1% or less of prallethrin.

#### PROCHLORAZ.

# PROFENOFOS.

# PROMACYL.

PROPACHLOR.

PROPARGITE.

PROPETAMPHOS.

PROPICONAZOLE except when included in Schedule 5.

PROPINEB.

PROPIONIC ACID (excluding its salts and derivatives) except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 30% or less of propionic acid; or
- (c) for therapeutic use.

PROPOXUR except when included in Schedule 5.

# *n*-PROPYL ALCOHOL **except**:

- (a) when included in Schedule 5; or
- (b) in preparations containing 5% or less of *n*-propyl alcohol; or
- (c) in preparations for cosmetic or therapeutic use other than in spray form.

PROQUINAZID.

PROSULFOCARB.

PROSULFURON.

PROTHIOFOS.

**D**-PULEGONE **except** in preparations containing 4% or less of d-pulegone.

PYRACLOFOS.

PYRAZOPHOS.

PYRIDABEN except when included in Schedule 5.

PYRIDALYL.

PYRIDATE.

PYRIPROLE.

PYRITHIONE COPPER.

PYRITHIONE ZINC except:

(a) when included in Schedule 2 or 5; or

- (b) for human use in preparations for the treatment of the scalp containing 2% or less of pyrithione zinc when compliant with the requirements of the required advisory statements for medicine labels; or
- (c) in semi-solid hair preparations for animal use; or
- (d) in shampoos for animal use containing 2% or less of pyrithione zinc when labelled with the statements "Keep out of eyes" and "If in eyes rinse well with water"; or
- (e) when immobilised in solid preparations containing 0.5% or less of pyrithione zinc; or
- (f) in paints, jointing materials or sealants containing 0.1% or less of pyrithione zinc calculated on the non-volatile content.

PYRIOFENONE except when included in Schedule 5.

#### PYROXASULFONE.

#### PYROXSULAM.

QUATERNARY AMMONIUM COMPOUNDS except:

- (a) when separately specified in these Schedules; or
- (b) when included in Schedule 5; or
- (c) dialkyl or dialkoyl quaternary ammonium compounds where the alkyl or alkoyl groups are derived from tallow or hydrogenated tallow or similar chain length (C16/C18) sources; or
- (d) in preparations containing 5% or less of such quaternary ammonium compounds.
- QUININE in cosmetic preparations except:
  - (a) in rinse-off hair preparations containing 0.5% or less of quinine calculated as free base; or
  - (b) in leave-on hair preparations containing 0.2% or less of quinine calculated as free base.

QUINOLINE and its salts (excluding other derivatives).

#### QUIZALOFOP ETHYL.

QUIZALOFOP-*p*-ETHYL **except** when included in Schedule 5.

QUIZALOFOP-p-TEFURYL.

RESCALURE for agricultural use **except** when enclosed in a vapour releasing device which in normal use prevents access to its contents.

RESMETHRIN except when included in Schedule 5.

# RESORCINOL except:

(a) in preparations for human therapeutic use; or

- (b) in oxidative hair dye preparations containing 1.25% or less of resorcinol after mixing for use when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height; or

- (c) in oxidative eyelash and eyebrow dye preparations containing 1.25% or less of resorcinol after mixing for use when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5 mm in height; or

(d) in hair lotions/shampoo products containing 0.5% or less of resorcinol when the immediate container and primary pack are labelled with the following statement:

WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals;

written in letters not less than 1.5 mm in height.

ROTENONE except in solid or semi-solid preparations containing 2% or less of rotenone.

# SAFROLE except:

- (a) for internal use; or
- (b) in other preparations containing 1% or less of safrole.

SAGE OIL (Dalmatian) except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and a child-resistant closure and compliant with the requirements of the required advisory statements for medicine labels; or
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) NOT TO BE TAKEN; or
- (c) in preparations containing 4% or less of thujone.

SALINOMYCIN in animal feed premixes containing 12% or less of antibiotic substances.

SAROLANER except when included in Schedule 5.

# SASSAFRAS OIL except:

- (a) for internal use; or
- (b) in other preparations containing 1% or less of safrole.

#### **SELENIUM:**

- (a) in preparations containing 2.5% or less of selenium when packed and labelled:
  - (i) for the blueing of gun barrels; or
  - (ii) for photographic purposes; or
  - (iii) for the colouring of lead or lead alloys; or
- b) in coated granules containing 1% or less of selenium for application to pasture **except** in fertilisers containing 200 g/tonne or less of selenium; or
- (c) for the treatment of animals:
  - (i) in a drench, injection, paste, stocklick, vaccine or horse feed supplement containing 0.5% or less of selenium; or
  - (ii) in animal feed premixes containing 2% or less of selenium for the preparation of feeds containing 1 g/tonne or less of selenium; or
  - (iii) in controlled release bolus preparations containing 25 mg or less of selenium with a release rate not greater than 0.25 mg/day; or
  - (iv) as barium selenate in preparations for injection containing 5% or less of selenium.
- SEMDURAMICIN in animal feed premixes for coccidiosis prevention containing 5% or less of antibiotic substances.

#### SILICOFLUORIDES except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 15 mg/kg or less of fluoride ion.

#### SILVER NITRATE except:

- (a) when included in or expressly excluded from Schedule 2; or
- (b) in preparations containing 1% or less of silver.

# SINBIOALLETHRIN except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 1% or less of sinbioallethrin.

# SODIUM ALUMINATE (excluding its salts and derivatives) except:

- (a) in solid preparations, the pH of which in a 10 g/L aqueous solution is 11.5 or less; or
- (b) in liquid preparations, the pH of which is 11.5 or less.

SODIUM BROMATE except in preparations containing 0.5% or less of sodium bromate.

SODIUM HYDROXIDE (excluding its salts and derivatives) except:

- (a) when included in Schedule 5 or Schedule 10; or
- (b) in preparations containing 5% or less of sodium hydroxide being:
  - (i) solid preparations, the pH of which in a 10 g/L aqueous solution is 11.5 or less; or
  - (ii) liquid or semi-solid preparations, the pH of which is 11.5 or less.

# SODIUM NITRITE:

- (a) in preparations containing 15% or less of sodium nitrite **except**:
  - (i) when included in Schedule 2 or 5; or
  - (ii) in preparations containing 0.5% or less of sodium nitrite; or
  - (iii) when present as an excipient in preparations for therapeutic use; or
  - (iv) in aerosols containing 2% or less of sodium nitrite; or
- (b) for use in closed-loop water treatment systems (products).

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

- (a) when included in Schedule 5; or
- (b) in preparations containing 15% or less of sodium percarbonate.

# SODIUM PERSULFATE:

- (a) in hair preparations; or
- (b) in products for the treatment of water for swimming pools and spas.

SODIUM SULFIDE in preparations for use as insect lures.

SPIROPIDION.

SPIROTETRAMAT.

SPIROXAMINE.

SULCOFURON in preparations for the treatment of carpets during manufacture.

SULFAMIC ACID (excluding its salts and derivatives) except when included in Schedule 5.

SULFLURAMID.

SULFOXAFLOR except when included in Schedule 5.

SULFURIC ACID (excluding its salts and derivatives) except:

- (a) in fire extinguishers; or
- (b) in preparations containing 0.5% or less of sulfuric acid (H<sub>2</sub>SO<sub>4</sub>).

# SULFURYL FLUORIDE.

# SULPROFOS.

2,4,5-T.

# *N*-TALLOW ALKYL-1,3-PROPANEDIAMINE DIACETATE and TALLOW ALKYLAMINE ACETATES.

TAR ACIDS distilling within the range 230-290°C inclusive.

TCMTB (2-[thiocyanomethylthio]benzothiazole).

TDE (1,1-dichloro-2,2-bis[4-chlorophenyl]ethane) except when included in Schedule 5.

TEBUFENPYRAD.

TEBUTHIURON.

TEMEPHOS except when in Schedule 5.

TERBUTHYLAZINE except in preparations containing 5% or less of terbuthylazine.

TERPENES, CHLORINATED.

TESTOSTERONE in implant preparations for use in animals.

#### TETRACHLOROETHYLENE **except**:

- (a) when included in Schedule 2 or 5; or
- (b) in preparations containing 6% or less of tetrachloroethylene when absorbed into an inert solid; or
- (c) in preparations for the treatment of animals.

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

TETRADIFON.

TETRAHYDROFURFURYL ALCOHOL (excluding its derivatives).

2,2',6,6'-TETRAISOPROPYL-DIPHENYL-CARBODIIMIDE in amitraz formulations containing 2% or less of 2,2',6,6'-tetraisopropyl-diphenyl-carbodiimide.

TETRAMISOLE in preparations for the treatment of animals.

THIACLOPRID.

THIAMETHOXAM except when included in Schedule 5.

THIAZAFLURON.

THIODICARB except when included in Schedule 5.

THIOMETON.

THIOPHANATE-METHYL except when included in Schedule 5.

# THIOUREA AND ALKYL THIOUREAS except:

- (a) when separately specified in these Schedules; or
- (b) for therapeutic use.

THIRAM except in paint containing 0.5% or less of thiram.

THUJONE except in preparations containing 4% or less of thujone.

THYMOL when packed and labelled for use as a pesticide.

TIGOLANER except when in Schedule 5.

TOLUENE (excluding its derivatives) **except** in preparations containing 50% or less of toluene or toluene and xylene.

TOLUENEDIAMINES not elsewhere specified in these Schedules:

- (a) in hair dye preparations **except** when the immediate container and primary pack are labelled with the following statements:
  - (i) KEEP OUT OF REACH OF CHILDREN; and
  - (ii) WARNING This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye;

written in letters not less than 1.5 mm in height; or

(b) in eyelash and eyebrow tinting products when the immediate container and primary pack are labelled with the following statement:

WARNING – This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use;

written in letters not less than 1.5 mm in height; or

(c) in nail polish preparations containing 2,5-toluenediamine **except** when labelled "avoid contact with skin".

# TOLYLFLUANID.

# TRANSFLUTHRIN except:

- (a) in preparations containing 1% or less of transfluthrin; or
- (b) in a cartridge for vaporiser use containing 600 mg or less of transfluthrin per cartridge.

#### TRIADIMEFON except:

(a) when included in Schedule 5; or

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(b) in fertilisers containing 5 g/kg or less of triadimefon.

TRICHLORFON except metrifonate included in Schedule 4.

TRICHLOROACETIC ACID except:

- (a) when included in Schedule 4 or 5; or
- (b) in human dermal preparations containing 12.5% or less of trichloroacetic acid for the treatment of warts other than anogenital warts.

TRICHLOROETHYLENE except when included in Schedule 4.

TRICHLOROPHENOL.

TRICLABENDAZOLE except in preparations containing 20% or less of triclabendazole.

TRICLOPYR.

TRICLOSAN in cosmetic preparations for human use containing more than 0.3% of triclosan.

TRIDEMORPH.

TRIETHYL PHOSPHATE.

TRIFLUOROMETHANESULFONIC ACID.

TRINITROPHENOL (excluding its derivatives) except:

- (a) in preparations for human therapeutic use; or
- (b) in preparations containing 5% or less of trinitrophenol.
- TRISODIUM NITRILOTRIACETATE **except** in preparations containing 20% or less of trisodium nitrilotriacetate.

# VAMIDOTHION.

VINYL ACETATE MONOMER (excluding its derivatives) except:

- (a) in preparations for therapeutic use; or
- (b) in cosmetic preparations containing 0.01% or less of vinyl acetate as residual monomer in a polymer; or
- (c) in other preparations containing 1% or less of vinyl acetate.

WARFARIN except when included in Schedule 4 or 5.

XYLENE (excluding its derivatives) **except** in preparations containing 50% or less of xylene or xylene and toluene.

ZERANOL in ear implants for use as a growth promotant in steer cattle.

ZETA-CYPERMETHRIN in preparations containing 10% or less of zeta-cypermethrin.

ZINC BORATE (excluding its derivatives) for use as an agricultural chemical.

#### ZINC CHLORIDE except:

- (a) when included in Schedule 2; or
- (b) in preparations containing 5% or less of zinc chloride.
- ZINC para-PHENOLSULFONATE **except** in preparations containing 5% or less of zinc para-phenolsulfonate.
- ZINC LACTATE in toothpaste **except** in toothpaste preparations containing 2.5% or less of zinc lactate and labelled with the statement:

Not recommended for children under twelve years of age.

#### ZINC SULFATE except:

- (a) when included in or expressly excluded from Schedule 4; or
- (b) in other preparations containing 5% or less of zinc sulfate.

ZIRAM in granular preparations.

# Schedule 7—Dangerous poisons

Note: See section 16, subsection 54(4) and sections 55, 56, 62 and 65.

ABAMECTIN except when included in Schedule 5 or 6.

ACIBENZOLAR-S-METHYL.

ACRIFLAVINIUM CHLORIDE for veterinary use except when in Schedule 5.

ACROLEIN.

ACRYLONITRILE.

ALACHLOR.

ALDICARB.

ALDOXYCARB.

ALLYL ALCOHOL except:

- (a) in preparations containing 5% or less of allyl esters with 0.1% or less of free allyl alcohol by weight of allyl ester; or
- (b) when separately specified in these Schedules.

ALPHA-CYPERMETHRIN except when included in Schedule 5 or 6.

AMINOACRIDINE for veterinary use **except** when included in Schedule 5.

AMINOCARB except when included in Schedule 6.

2-AMINO-5-METHYLPHENOL except when included in Schedule 10.

4-AMINOPROPIOPHENONE.

4-AMINOPYRIDINE except when included in Schedule 4.

AMITON.

ARPRINOCID.

ARSENIC except:

- (a) when separately specified in this Schedule; or
- (b) when included in Schedule 4 or 6; or
- (c) as selenium arsenide in photocopier drums; or
- (d) as 10,10'-oxydiphenoxarsine in silicone rubber mastic containing 120 mg/kg or less of arsenic; or

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- (e) as 10,10'-oxydiphenoxarsine contained in polyvinyl chloride and polyurethane extruded and moulded articles containing 160 mg/kg or less of arsenic other than when included in articles:
  - (i) in contact with foodstuffs, animal feeds or potable water; or
  - (ii) of clothing and footwear in contact with the skin; or
  - (iii) used as infant wear; or
  - (iv) intended for use as packaging materials; or
- (f) in animal feeds containing 75 g/tonne or less of arsenic; or
- (g) in paints containing 0.1% or less of arsenic calculated on the non-volatile content of the paint.

AZAFENIDIN.

AZINPHOS-ETHYL.

AZINPHOS-METHYL.

AZOCYCLOTIN.

AZO DYES that are derivatives by diazotisation of any of the following substances:

- (a) *p*-aminoazobenzene (CAS No. 60-09-3);
- (b) o-aminoazotoluene (CAS No. 97-56-3);
- (c) *o*-anisidine (CAS No. 90-04-0);
- (d) p-chloroaniline (CAS No. 106-47-8);
- (e) 4-chloro-o-toluidine (CAS No. 95-69-2);
- (f) 2,4-diaminoanisole (CAS No. 615-05-4);
- (g) 6-methoxy-m-toluidine (p-cresidine) (CAS No. 120-71-8);
- (h) 4,4-methylenedianiline (CAS No. 101-77-9);
- (i) 2-naphthylamine (CAS No. 91-59-8);
- (j) 5-nitro-o-toluidine (CAS No. 99-55-8);
- (k) 2,4-toluenediamine (CAS No. 95-80-7);
- (l) *o*-toluidine (CAS No. 95-53-4);
- (m) 2,4,5-trimethylaniline (CAS No. 137-17-7);

except for BASIC RED 76 (CAS No. 68391-30-0) when included in Schedule 6.

BENDIOCARB except when included in Schedule 5 or 6.

BENOMYL except in paints containing 0.5% or less of benomyl.

BENZENE (excluding its derivatives) except:

(a) preparations containing 15 mL/L or less of benzene; or

(b) petrol containing 50 mL/L or less of benzene.

# BENZIDINE-BASED AZO DYES being:

- (a) 2,2'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[*N*-(4-chlorophenyl)-3-oxobutanamide] (CAS No. 94249-03-3); or
- (b) Acid Red 85 (Acid Fast Red A): 1,3-Naphthalenedisulfonic acid,
  7-hydroxy-8-[[4'-[[4-[[(4-methylphenyl)sulfonyl]oxy]phenyl]azo][1,1'-biphenyl]-4
  -yl]azo]-, disodium salt (CAS No. 3567-65-5); or
- (c) C.I Acid Black 29: (CAS No. 12217-14-0); or
- (d) C.I. Direct Orange 1: (CAS No. 54579-28-1); or
- (e) Direct Black 38: 2,7-Naphthalenedisulfonic acid,
   4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(p
   henylazo)-, disodium salt (CAS No. 1937-37-7); or
- (f) Direct Blue 2: 2,7-Naphthalenedisulfonic acid,
  5-amino-3-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4
  -yl]azo]-4-hydroxy-, trisodium salt (CAS No. 2429-73-4); or
- (g) Direct Blue 6: 2,7-Naphthalenedisulfonic acid,
   3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[5-amino-4-hydroxy-, tetrasodium salt (CAS No. 2602-46-2); or
- (h) Direct Brown 2: 5-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy- benzoic acid disodium salt (CAS No. 2429-82-5); or
- (i) Direct Brown 95: Cuprate(2-),
  [5-[[4'-[[2,6-dihydroxy-3-[(2-hydroxy-5-sulfophenyl)azo]phenyl]azo][1,1'-bipheny
  1]-4-yl]azo]-2-hydroxybenzoato(4-)]-, disodium salt (CAS No. 16071-86-6); or
- (j) Direct Green 1: 2,7-Naphthalenedisulfonic acid,
   4-amino-5-hydroxy-3-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-6-(phe nylazo)-, disodium salt (CAS No. 3626-28-6); or
- (k) Direct Green 6: 2,7-Naphthalenedisulfonic acid,
   4-amino-5-hydroxy-6-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-3-[(4-nitrophenyl)azo]-, disodium salt (CAS No. 4335-09-5); or
- Direct Red 28 (Congo Red): 1-Naphthalenesulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[4-amino-, disodium salt (CAS No. 573-58-0); or
- (m) Direct Red 37: 1,3-Naphthalenedisulfonic acid, 8-[[4'-[(4-ethoxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-7-hydroxy-, disodium salt (CAS No. 3530-19-6).

BENZIDINE-CONGENER (3,3'-disubstituted) AZO DYES.

BETACYFLUTHRIN except when included in Schedule 5 or 6.

# BIFENTHRIN except:

(a) when included in Schedule 6; or

(b) in preparations containing 0.5% or less of bifenthrin.

BIFLUORIDES (including ammonium, potassium and sodium salts) **except** when included in Schedule 5 or 6.

BORON TRIFLUORIDE except when included in Schedule 5 or 6.

BRODIFACOUM except when included in Schedule 6.

BROMADIOLONE except when included in Schedule 6.

BROMETHALIN except when included in Schedule 6.

BROMINE (excluding its salts and derivatives).

BROMOXYNIL except when included in Schedule 6.

BRUCINE except in alcohol containing 0.02% or less of brucine as a denaturant.

#### CACODYLIC ACID except:

- (a) when included in Schedule 6; or
- (b) in animal feeds containing 75 g/tonne or less of arsenic.

CADUSAFOS except when included in Schedule 6.

CALCIFEROL for use as a rodenticide except when included in Schedule 6.

CAPTAFOL.

CARBADOX.

CARBENDAZIM except in paints, jointing compounds and sealants containing 0.35% or less of carbendazim.

CARBOFURAN.

CARBON TETRACHLORIDE **except** in chlorinated rubber based paint containing 1% or less of carbon tetrachloride.

CARBONYL SULFIDE when packed and labelled for use as a fumigant.

CARBOPHENOTHION.

CARBOSULFAN.

CHLORDECONE.

CHLORDIMEFORM.

CHLORFENAPYR except when included in Schedule 5 or 6.
#### CHLORFENVINPHOS.

CHLORINE (excluding its salts and derivatives).

#### CHLORHEXIDINE except:

- (a) when included in Schedule 5 or 6; or
- (b) in preparations containing 1% or less of chlorhexidine; or
- (c) in solid preparations.

CHLOROMETHIURON.

5-CHLORO-3-METHYL-4-NITROPYRAZOLE.

4-CHLORO-*o*-TOLUIDINE.

CHLOROPICRIN except when included in Schedule 6.

CHLORTHIOPHOS.

COLECALCIFEROL for use as a rodenticide.

COUMAPHOS except when included in Schedule 6.

COUMATETRALYL except when included in Schedule 5 or 6.

CREOSOTE derived from coal.

CREOSOTE derived from beechwood.

CYANIDES, metallic except:

- (a) ferricyanides; or
- (b) ferrocyanides; or
- (c) when separately specified in these Schedules.

CYANOGEN.

CYCLOSILAZANES, DI-ME, ME HYDROGEN, POLYMERS WITH DI-ME, ME HYDROGEN SILAZANES, REACTION PRODUCTS WITH 3-(TRIETHOXYSILYL)-1-PROPANAMINE (CAS 475645-84-2) **except** when included in Schedule 6.

#### CYHALOTHRIn (aRS,1R,cis,Z):(aRS,1S,cis,Z) = 50:50.

#### CYHEXATIN.

#### **DELTAMETHRIN** except:

- (a) when included in Schedule 5 or 6; or
- (b) in factory prepared mosquito nets containing 1% or less of deltamethrin; or

(c) in preparations containing 0.1% or less of deltamethrin.

DEMETON.

DEMETON-O-METHYL.

DEMETON-S-METHYL.

DIALIFOS.

4,4-DIAMINODIPHENYLMETHANE (Methylene dianiline).

1,2-DIBROMO-3-CHLOROPROPANE.

1,3-DICHLOROPROPENE except in biocidal preparations containing 0.3% or less of 1,3-dichloropropene.

DICHLORVOS except when included in Schedule 5 or 6.

DICROTOPHOS.

DIFENACOUM except when included in Schedule 6.

DIFETHIALONE except when included in Schedule 6.

DIMEFOX.

4-DIMETHYLAMINOAZOBENZENE (*N*,*N*-dimethyl-4-[phenylazo]-benzenamine).

DIMETHYL SULFATE.

DIMETILAN.

DINITROCRESOLS except when included in Schedule 4 or 6.

DINITROPHENOLS except when included in Schedule 4, 6 or 10.

DINOCAP.

DINOSEB.

DIQUAT except when included in Schedule 6.

DISULFOTON except when included in Schedule 6.

DORAMECTIN **except** when included in Schedule 5 or 6.

DSMA except when included in Schedule 6.

EMAMECTIN **except** when included in Schedule 5 or 6.

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

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ENDOTHAL except when included in Schedule 6.

ENDRIN.

EPICHLOROHYDRIN.

EPIDERMAL GROWTH FACTOR except in preparations for human therapeutic use.

EPRINOMECTIN except when included in Schedule 5 or 6.

ETACONAZOLE.

ETHALFLURALIN.

ETHION.

ETHOPROPHOS except when included in Schedule 6.

2-ETHOXYETHANOL and its acetates **except** in preparations containing 0.5% or less of 2-ethoxyethanol.

ETHYLENE DIBROMIDE.

ETHYLENE OXIDE.

FAMPHUR except when included in Schedule 6.

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

FENOXACRIM except:

- (a) when included in Schedule 6; or
- (b) in treated carpets.

FENSULFOTHION.

FENTHION except when included in Schedule 5 or 6.

FENTHION-ETHYL.

FLOCOUMAFEN except when included in Schedule 6.

#### FLUCOFURON except:

- (a) when included in Schedule 6; or
- (b) in treated carpets.

FLUCYTHRINATE.

FLUMIOXAZIN except when included in Schedule 6.

FLUOROACETAMIDE.

FLUOROACETIC ACID.

FORMETANATE.

FOSTHIAZATE.

FURATHIOCARB except when included in Schedule 5.

GAMMA-CYHALOTHRIN except when included in Schedule 5.

HALOFUGINONE except when included in Schedule 4.

HALOGENATED DIBENZODIOXINS AND DIBENZOFURANS.

HCB.

HYDROCARBONS LIQUID AROMATIC (including aromatic extract oils), any fraction of which boils above 350°C except:

- (a) when in solid polymers; or
- (b) when containing 1% or less of total polycyclic aromatic compounds as measured by IP 346; or
- (c) when having a Mutagenicity Index of zero as measured by ASTM E1687-95.

#### HYDROCYANIC ACID except:

- (a) when included in Schedule 4; or
- (b) its salts and derivatives other than cyanides separately specified in this Schedule; or
- (c) in preparations containing 10 mg/kg or less of hydrocyanic acid.
- HYDROFLUORIC ACID (excluding its salts and derivatives) **except** when included in Schedule 5 or 6.

#### HYDROGEN SULFIDE.

HYDROSILICOFLUORIC ACID (excluding its salts and derivatives) **except** when included in Schedule 5 or 6.

IODOMETHANE.

ISOCARBOPHOS.

ISOFENPHOS.

ISOPROTURON.

IVERMECTIN except when included in Schedule 4 or 5.

LAMBDA-CYHALOTHRIN except when included in Schedule 5 or 6.

#### LEPTOPHOS.

LITHIUM PERFLUOROOCTANE SULFONATE except in sealed bait stations containing 1% or less of lithium perfluorooctane sulfonate.

#### MADURAMICIN except:

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

MALACHITE GREEN for veterinary use except when included in Schedule 5.

MAZIDOX.

MECARBAM.

- 2-METHOXYETHANOL and its acetates **except** in preparations containing 0.5% or less of 2-methoxyethanol.
- MERCURIC CHLORIDE when prepared for use for agricultural, industrial, pastoral or horticultural purposes.

#### MERCURY except:

- (a) when separately specified in this Schedule; or
- (b) when included in Schedule 2, 4 or 6; or
- (c) in preparations containing 0.01% or less of mercury in organic form as a preservative; or
- (d) mercury (metallic) in scientific instruments; or
- (e) dental amalgams; or
- (f) in a sealed device, for therapeutic use, which prevents access to the mercury.

METHACRIFOS except when included in Schedule 6.

METHAMIDOPHOS.

METHAPYRILENE.

METHAZOLE.

METHIDATHION.

METHIOCARB except when included in Schedule 5 or 6.

METHOMYL except when included in Schedule 6.

METHOXYETHYLMERCURIC ACETATE.

METHOXYETHYLMERCURIC CHLORIDE.

#### METHYL BROMIDE.

#### METHYLCYCLOPENTADIENYL MANGANESE TRICARBONYL except:

- (a) when included in Schedule 6; or
- (b) when used in laboratory analysis; or
- (c) when packed for industrial use in containers with a nominal capacity of 100 L or more.

4,4'-METHYLENEBIS[2-CHLOROANILINE] (MOCA).

METHYLENE BLUE for veterinary use except when included in Schedules 4 or 5.

MEVINPHOS.

MIPAFOX.

MIREX.

MOLINATE.

MONOCROTOPHOS.

MOXIDECTIN except when included in Schedule 4, 5 or 6.

MSMA except when included in Schedule 6.

NAPHTHALOPHOS except when included in Schedule 6.

NICOTINE except:

- (a) when included in Schedule 3 or 4; or
- (b) in preparations for oromucosal or transdermal administration for human therapeutic use when included in the Register as an aid in withdrawal either from tobacco smoking or nicotine vaping; or
- (c) in tobacco prepared and packed for smoking.

NIMIDANE except when included in Schedule 6.

#### NITROFEN.

NITROPRUSSIDES except when included in Schedule 4 or 6.

2-NITROTOLUENE.

OMETHOATE except when included in Schedule 5 or 6.

OXAMYL.

OXYDEMETON METHYL.

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#### PARAQUAT.

PARATHION.

PARATHION-METHYL except when included in Schedule 6.

PENTACHLOROPHENOL except when included in Schedule 6.

PHENYLMERCURIC ACETATE **except** in preparations containing 0.01% or less of mercury as a preservative.

PHORATE.

PHOSFOLAN.

PHOSPHIDES, METALLIC.

PHOSPHINE.

PHOSPHORUS, YELLOW (excluding its salts and derivatives).

#### POTASSIUM NITRITE except:

- (a) when included in Schedule 5 or 6; or
- (b) in preparations containing 0.5% or less of potassium nitrite; or
- (c) when present as an excipient in preparations for therapeutic use; or
- (d) in aerosols containing 2% or less of potassium nitrite.

#### PROCYMIDONE.

#### PROPYLENE OXIDE.

PYRINURON.

QUININE for veterinary use except when included in Schedule 5.

SAFLUFENACIL except when included in Schedule 5.

#### SCHRADAN.

#### SELENIUM except:

- (a) when included in Schedule 6; or
- (b) as selenium arsenide in photocopier drums; or
- (c) in preparations for therapeutic use other than:
  - (i) drench concentrates containing 2.5% or less of selenium; or
  - (ii) pour-on preparations containing 0.5% or less of selenium; or
- (d) in paints or tinters containing 0.1% or less of selenium calculated on the non-volatile content of the paint or tinter; or

(e) in fertilisers containing 200 g/tonne or less of selenium.

#### SEMDURAMICIN except:

- (a) when included in Schedule 6; or
- (b) in animal feeds containing 25 mg/kg or less of antibiotic substances.

#### SODIUM NITRITE except:

- (a) when included in Schedule 2, 5 or 6; or
- (b) in preparations containing 0.5% or less of sodium nitrite; or
- (c) when present as an excipient in preparations for therapeutic use; or
- (d) in aerosols containing 2% or less of sodium nitrite.

#### STRYCHNINE **except** when included in Schedule 4.

#### SULCOFURON except:

- (a) when included in Schedule 6; or
- (b) in treated carpets.

#### SULFENTRAZONE.

SULFOTEP.

TEFLUTHRIN except when included in Schedule 5.

TEPP.

TERBUFOS.

#### TETRACHLOROETHANE.

2,2',6,6'-TETRAISOPROPYL-DIPHENYL-CARBODIIMIDE except when included in Schedule 6.

THALLIUM.

#### THIOFANOX.

- TIN ORGANIC COMPOUNDS, being dialkyl, trialkyl and triphenyl tin compounds where the alkyl group is methyl, ethyl, propyl or butyl **except**:
  - (a) when separately specified in this Schedule; or
  - (b) in plastics; or
  - (c) in semi-solid sealants, adhesives or elastomers containing 1% or less of the dialkyl, trialkyl or triphenyl tin component; or
  - (d) in paint containing 1% or less of such compounds calculated as tin in the non-volatile content of the paint.

o-TOLIDINE except in solid-state diagnostic therapeutic reagents.

TRIAMIPHOS.

TRIAZBUTIL.

TRIBUFOS (S,S,S-tributylphosphorotrithioate).

VINCLOZOLIN.

VINYL CHLORIDE.

ZETA-CYPERMETHRIN except when included in Schedule 6.

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

## Schedule 8—Controlled drugs

Note 1: See paragraph 7(b), sections 16, 17, 28, 31, 50 and subsection 57(1).

Note 2: Substances marked # are listed in Appendix D.

ACETYLDIHYDROCODEINE.

ACETYLMETHADOL.

ACETYLMORPHINES.

ALFENTANIL.

ALPHACETYLMETHADOL.

ALPHAPRODINE.

# ALPRAZOLAM.

AMFETAMINE.

AMOBARBITAL except when included in Schedule 4.

ANILERIDINE.

BENZYLMORPHINE.

BEZITRAMIDE.

BUPRENORPHINE.

BUTOBARBITAL.

BUTORPHANOL.

# CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use, when:

- (a) cultivated or produced, or in products manufactured<sup>1</sup>, in accordance with the *Narcotic Drugs Act 1967*; and/or
- (b) for use in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or
- (c) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Act; and/or
- (d) in therapeutic goods supplied in accordance with the Act;

except:

<sup>&</sup>lt;sup>1</sup> "Cultivation", "production" and "manufacture" have the same meaning as in the Narcotic Drugs Act 1967

- (e) when it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic *Goods Regulations 1990* applies; or
- (f) when separately specified in the NABIXIMOLS entry in this Schedule; or
- (g) when captured by the CANNABIDIOL entry in Schedule 4 or Schedule 3; or
- (h) hemp seed oil containing 75 mg/kg or less of cannabidiol and 10 mg/kg or less of tetrahydrocannabinols.

CARFENTANYL.

COCAINE.

CODEINE except when included in Schedule 4.

CODEINE-*N*-OXIDE.

CONCENTRATE OF POPPY STRAW (the material arising when poppy straw has entered into a process for concentration of its alkaloids).

4-CYANO-1-METHYL-4-PHENYLPIPERIDINE (Pethidine intermediate A).

CYCLOBARBITAL.

DEXAMFETAMINE.

DEXTROMORAMIDE.

# DEXTROPROPOXYPHENE except when included in Schedule 4.

DIFENOXIN except when included in Schedule 4.

DIHYDROCODEINE except when included in Schedule 3 or 4.

DIHYDROMORPHINE.

# N,  $\alpha$  -DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE \*(MDMA) in preparations for human therapeutic use for the treatment of post-traumatic stress disorder.

DIPHENOXYLATE **except** when included in Schedule 3 or 4.

#### DIPIPANONE.

# DRONABINOL (delta-9-tetrahydrocannabinol) when prepared and packed for therapeutic use.

DROTEBANOL.

ESKETAMINE.

ETHYLAMFETAMINE.

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

FENTANYL.

# FLUNITRAZEPAM.

HYDROCODONE.

HYDROMORPHINOL.

HYDROMORPHONE.

KETAMINE.

LEVAMFETAMINE.

LEVOMETHAMFETAMINE.

LEVOMORAMIDE.

LEVORPHANOL (excluding its stereoisomers).

LISDEXAMFETAMINE.

METHADONE.

METAMFETAMINE.

METHYLDIHYDROMORPHINE.

METHYLPHENIDATE.

1-METHYL-4-PHENYLPIPERIDINE-4-CARBOXYLIC ACID (Pethidine intermediate C).

MORPHINE.

MORPHINE METHOBROMIDE.

MORPHINE-N-OXIDE.

NABILONE.

# NABIXIMOLS (botanical extract of *Cannabis sativa* which includes the following cannabinoids: tetrahydrocannabinols, cannabidiol, cannabinol, cannabigerol, cannabichromene, cannabidiolic acid, tetrahydrocannabinolic acids, tetrahydrocannabivarol, and cannabidivarol, where tetrahydrocannabinols and cannabidiol (in approximately equal proportions) comprise not less than 90% of the total cannabinoid content) in a buccal spray for human therapeutic use.

#### NORCODEINE.

#### NORMETHADONE.

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OPIUM **except** the alkaloids noscapine in Schedule 2 and papaverine when included in Schedule 2 or 4.

OXYCODONE.

OXYMORPHONE.

PENTAZOCINE.

# PENTOBARBITAL except when included in Schedule 4.

PETHIDINE.

PHENDIMETRAZINE.

PHENMETRAZINE.

PHENOPERIDINE.

4-PHENYLPIPERIDINE-4-CARBOXYLIC ACID ETHYL ESTER (Pethidine intermediate B).

PHOLCODINE except when included in Schedule 2 or 4.

PIRITRAMIDE.

PROPIRAM.

# PSILOCYBINE in preparations for human therapeutic use for the treatment of treatment-resistant depression.

RACEMORAMIDE.

REMIFENTANIL.

SECBUTOBARBITAL.

SECOBARBITAL.

# SODIUM OXYBATE for human therapeutic use.

SUFENTANIL.

TAPENTADOL.

- # TETRAHYDROCANNABINOLS when extracted from cannabis for human therapeutic use, when:
  - (a) included in products manufactured in accordance with the *Narcotic Drugs Act* 1967; and/or
  - (b) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Act; and/or

(c) in therapeutic goods supplied in accordance with the Act;

except when:

- (d) it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applies; or
- (e) separately specified in the NABIXIMOLS entry in this Schedule; or
- (f) captured by the CANNABIDIOL entry in Schedule 4 or Schedule 3; or
- (g) in hemp seed oil at a concentration of 10 mg/kg or less.

THEBACON.

THEBAINE.

THIAFENTANIL.

TILIDINE.

### Schedule 9—Prohibited substances

- Note 1: See paragraph 7(b) and subsection 57(2).
- Note 2: Trivial or unofficial names are marked \*.

#### ACETORPHINE.

- ACETYL-ALPHA-METHYLFENTANYL.
- ALKOXYAMFETAMINES and substituted alkoxyamfetamines **except** when separately specified in these Schedules.
- ALKOXYPHENYLETHYLAMINES and substituted alkoxyphenylethylamines **except** when separately specified in these Schedules.
- ALKYLTHIOAMFETAMINES and substituted alkylthioamfetamines **except** when separately specified in these Schedules.

ALLYLPRODINE.

ALPHAMEPRODINE.

ALPHA-METHYLFENTANYL.

ALPHA-METHYLTHIOFENTANYL.

ALPHAMETHADOL.

ALPHA-PYRROLIDINOVALEROPHENONE \*(ALPHA-PVP).

2-AMINO-1-(2,5-DIMETHOXY-4-METHYL)PHENYLPROPANE \*(STP or DOM).

5-(2-AMINOPROPYL)INDAN and substituted 5-(2-aminopropyl)indans **except** when separately specified in these Schedules.

BENZETHIDINE.

BENZOYLINDOLES except when separately specified in these Schedules.

BENZYLPIPERAZINE \*(BZP).

BETACETYLMETHADOL.

BETA-HYDROXYFENTANYL.

BETA-HYDROXY-3-METHYLFENTANYL.

BETAMEPRODINE.

BETAMETHADOL.

#### BETAPRODINE.

1-(8-BROMOBENZO[1,2-B;4,5-B]DIFURAN-4-YL)-2-AMINOPROPANE \*(Bromo-Dragonfly).

#### 4-BROMO-2,5-DIMETHOXYPHENETHYLAMINE \*(BDMPEA).

#### BUFOTENINE.

#### BUTONITAZENE.

- CANNABIS (including seeds, extracts, resins, and the plant and any part of the plant when packed or prepared), **except**:
  - (a) when separately specified in these Schedules; or
  - (b) processed hemp fibre containing 0.1% or less of tetrahydrocannabinols and hemp fibre products manufactured from such fibre; or
  - (c) hemp seed oil containing 75 mg/kg or less of cannabidiol and 10 mg/kg or less of tetrahydrocannabinols.

CATHINONES except when separately specified in these Schedules.

CLONAZOLAM.

CLONITAZENE.

COCA LEAF.

CODOXIME.

4-CYANO-2-DIMETHYLAMINO-4,4'-DIPHENYLBUTANE.

#### CYCLOHEXYLPHENOLS except:

- (a) when separately specified in these Schedules; or
- (b) in preparations containing 0.5% or less of cyclohexylphenols.

#### DESCHLOROETIZOLAM.

#### DESOMORPHINE.

- *N,N*-DIALKYLAMINOCYCLOHEXYL ALKYL BENZAMIDES **except** when separately specified in these Schedules.
- *N,N*-DIALKYLAMINOCYCLOHEXYLMETHYL ALKYL BENZAMIDES except when separately specified in these Schedules.

#### DIAMPROMIDE.

#### DIBENZOPYRANS except when separately specified in these Schedules.

- 3,4-DICHLORO-N-[(1R,2R)-2-(DIMETHYLAMINO)CYCLOHEXYL]-*N*-METHYLBENZ AMIDE (U-47700).
- 3,4-DICHLORO-N-{[1- (DIMETHYLAMINO)CYCLOHEXYL]METHYL}BENZAMIDE \*(AH-7921).

DICLAZEPAM.

- DIETHYLTHIAMBUTENE.
- *N,N*-DIETHYLTRYPTAMINE \*(DET).
- 2,5-DIHYDRO-2-(1-METHYL-1-PHENYLETHYL)-5-PENTYL-1H-PYRIDO[4,3-B]INDO L-1-ONE (SGT-151).
- DIMENOXADOL.
- DIMEPHEPTANOL.
- 2,5-DIMETHOXYAMFETAMINE \*(DMA).
- 2,5-DIMETHOXY-4-BROMOAMFETAMINE \*(DOB).
- 2,5-DIMETHOXY-4-ETHYL-*a*-AMFETAMINE \*(DOET).
- 2,5-DIMETHOXY-4-ETHYLTHIOPHENETHYLAMINE \*(2C-T-2).
- 2,5-DIMETHOXY-4-IODOPHENETHYLAMINE \*(2C-I).
- 2,5-DIMETHOXY-4-(*N*)-PROPYLTHIOPHENETHYLAMINE \*(2C-T-7).
- 3-(2-DIMETHYLAMINOETHYL)-4-HYDROXYINDOLE \*(PSILOCINE or PSILOTSIN).
- 3-(1,2-DIMETHYLHEPTYL)-1-HYDROXY-7,8,9,10-TETRAHYDRO-6,6,9-TRIMETHYL-6H-DIBENZO (b,d) PYRAN \*(DMHP).
- *N*, α -DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE \*(MDMA) except when included in Schedule 8.
- *N*,*N*-DIMETHYLAMFETAMINE (Dimetamfetamine).
- DIMETHYLTHIAMBUTENE.
- *N*,*N*-DIMETHYLTRYPTAMINE \*(DMT).
- DIOXAPHETYL BUTYRATE.

DIPHENIDINE.

ECGONINE.

EPHENIDINE.

*N*-ETHYL-α-METHYL-3,4-(METHYLENEDIOXY)PHENETHYLAMINE \*(*N*-ETHYL MDA).

ETHYLMETHYLTHIAMBUTENE.

ETICYCLIDINE \*(PCE).

ETODESNITAZENE.

ETONITAZENE.

ETONITAZEPIPNE.

ETONITAZEPYNE.

ETORPHINE.

ETOXERIDINE.

FENETYLLINE.

4-FLUORO-N-METHYLAMFETAMINE.

FLUBROMAZEPAM.

FLUBROMAZOLAM.

FLUNITAZENE.

1-(5-FLUOROPENTYL)-3-(2-IODOBENZOYL)INDOLE \*(AM-694).

FURETHIDINE.

HARMALA ALKALOIDS except in herbs, or preparations, for therapeutic use:

- (a) containing 0.1% or less of harmala alkaloids; or
- (b) in divided preparations containing 2 mg or less of harmala alkaloids per recommended daily dose.

HEROIN.

- 3-HEXYL-1-HYDROXY-7,8,9,10-TETRAHYDRO-6,6,9-TRIMETHYL-6H-DIBENZO (b,d) PYRAN \*(PARAHEXYL).
- 4-HYDROXYBUTANOIC ACID and its salts **except** for sodium oxybate when in Schedule 8. \*(GAMMA HYDROXYBUTYRATE (GHB)).
- 2-[(1*R*,3*S*)-3-HYDROXYCYCLOHEXYL]-5-(2-METHYLNONAN-2-YL)PHENOL \*(Cannabicyclohexanol or CP 47,497 C8 homologue).
- 2-[(1*R*,3*S*)-3-HYDROXYCYCLOHEXYL]-5-(2-METHYLOCTAN-2-YL)PHENOL \*(CP 47,497).

HYDROXYPETHIDINE.

IBOTENIC ACID.

ISOMETHADONE.

ISOPHENIDINE.

ISOTONITAZENE.

KETOBEMIDONE.

LEVOMETHORPHAN (excluding its stereoisomers).

LEVOPHENACYLMORPHAN.

LYSERGIC ACID.

LYSERGIDE.

MECLONAZEPAM.

MECLOQUALONE.

METAZOCINE.

METHAQUALONE.

METHCATHINONE.

METHOXPHENIDINE.

5-METHOXY- α –METHYLTRYPTAMINE \*(5-MeO-AMT).

5-METHOXY-3,4-METHYLENEDIOXYAMFETAMINE \*(MMDA).

4-METHOXY- α –METHYLPHENYLETHYLAMINE \*(PMA).

2-(2-METHOXYPHENYL)-1-(1-PENTYLINDOL-3-YL)ETHANONE \*(JWH-250).

METHYL (2*S*, 4a*R*, 6a*R*, 7*R*, 9*S*, 10a*S*, 10b*R*)-9-ACETOXY-6a,10b-DIMETHYL-4,10-DIOXO-DODECAHYDRO-2-(3-FUR YL)-2H-NAPHTHO[2,1-c]PYRAN-7-CARBOXYLATE \*(SALVINORIN A).

4-METHYLAMINOREX.

METHYLDESORPHINE.

3,4-METHYLENEDIOXYAMFETAMINE \*(MDA).

3,4-METHYLENEDIOXYPYROVALERONE \*(MDPV).

3-METHYLFENTANYL.

4-METHYLMETHCATHINONE \*(MEPHEDRONE).

*N*- α -[METHYL-3,4-(METHYLENEDIOXY)PHENETHYL]HYDROXYLAMINE \*(*N*-HYDROXY MDA).

*N*-METHYL-1-(3,4-METHYLENEDIOXYPHENYL)-2-BUTANAMINE \*(MBDB).

2-METHYL-3-MORPHOLINO-1, 1-DIPHENYLPROPANE CARBOXYLIC ACID (Moramide intermediate).

METHYLONE \*(MDMC).

1-METHYL-4-PHENYL-4-PIPERIDINOL PROPIONATE \*(MPPP).

4-METHYLTHIOAMFETAMINE.

3-METHYLTHIOFENTANYL.

METODESNITAZENE.

METONITAZENE.

METOPON.

MITRAGYNA SPECIOSA.

MITRAGYNINE.

MORPHERIDINE.

(1-(2-MORPHOLIN-4-YLETHYL)INDOL-3-YL)-NAPTHALEN-1-YLMETHANONE \*(JWH-200).

MUSCIMOL.

MYROPHINE.

NAPHTHOYLINDOLES except when separately specified in these Schedules.

NAPHTHYLMETHYLINDOLES except when separately specified in these Schedules.

NAPHTHOYLPYRROLES except when separately specified in these Schedules.

NAPHTHYLMETHYLINDENES except when separately specified in these Schedules.

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

NICOCODINE.

NICODICODINE.

NICOMORPHINE.

NIFOXIPAM.

NORACYMETHADOL.

NORLEVORPHANOL.

NORMORPHINE.

NORPIPANONE.

PARA-FLUOROFENTANYL.

1-PENTYL-3-(4-METHYL-1-NAPTHOYL)INDOLE. \*(JWH-122).

1-PENTYL-3-(1-NAPHTHOYL)INDOLE \*(JWH-018).

PHENADOXONE.

PHENAMPROMIDE.

PHENAZOCINE.

PHENCYCLIDINE \*(PCP).

PHENIBUT.

*N*-PHENETHYL-4-PIPERIDONE.

PHENOMORPHAN.

PHENYLACETYLINDOLES except when separately specified in these Schedules.

1-PHENYLETHYL-4-PHENYL-4-PIPERIDINOL ACETATE \*(PEPAP).

PIMINODINE.

PROHEPTAZINE.

PROPERIDINE.

PROPYLPHENIDINE.

PROTONITAZENE.

PSILOCYBINE except when included in Schedule 8.

PYRAZOLAM.

RACEMETHORPHAN.

RACEMORPHAN.

#### ROLICYCLIDINE \*(PHP or PCPY).

#### SALVIA DIVINORUM.

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

TENOCYCLIDINE \*(TCP).

TETRAHYDROCANNABINOLS and their alkyl homologues, except:

- (a) when included in Schedule 4 or Schedule 8; or
- (b) processed hemp fibre containing 0.1% or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre; or
- (c) in hemp seed oil at a concentration of 10 mg/kg or less.

#### THIOFENTANYL.

1-(3-TRIFLUOROMETHYLPHENYL)PIPERAZINE \*(TFMPP).

#### TRIMEPERIDINE.

#### 3,4,5-TRIMETHOXY- α – METHYLPHENYLETHYLAMINE \*(TMA).

- 3,4,5-TRIMETHOXYPHENETHYLAMINE (mescaline) and other substances structurally derived from methoxy-phenylethylamine **except**:
  - (a) methoxyphenamine; or
  - (b) when separately specified in this Schedule.
- 1-(3,4,5-TRIMETHOXYPHENYL)-2-AMINOBUTANE.

## Schedule 10—Substances of such danger to health as to warrant prohibition of supply and use

- Note 1: See subsection 57(2) and section 63.
- Note 2: Schedule 10 contains substances previously included in Appendix C.

ABRUS PRECATORIUS (Jequirity) seed or root for therapeutic use.

- ACORUS CALAMUS (calamus) for human therapeutic use.
- ALKALINE SALTS, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination for domestic use:
  - (a) in liquid or semi-solid food additive preparations, the pH of which is more than 11.5; or
  - (b) in solid automatic dishwashing preparations, the pH of which in a 500 g/L aqueous solution or mixture is more than 12.5; or
  - (c) in liquid or semi-solid automatic dishwashing preparations, the pH of which is more than 12.5.
- ALKYLAMINES WITH STIMULANT PROPERTIES **except** when separately specified in these schedules.
- 2-AMINO-5-METHYLPHENOL in preparations for cosmetic use.
- AMINOPHENAZONE (amidopyrine) and its derivatives for human therapeutic use.
- AMYGDALIN for therapeutic use **except** in preparations containing 10 mg/kg or less of amygdalin.
- ANCHUSA OFFICINALIS for therapeutic use.
- *o*-ANISIDINE (excluding derivatives) in preparations for skin colouration (including tattooing) and dyeing of hair, eyelashes or eyebrows **except** in preparations containing 0.001% or less of *o*-anisidine.
- APRONAL for therapeutic use.

ARISTOLOCHIA spp. for therapeutic use.

- ARISTOLOCHIC ACID(S) for human therapeutic use.
- ASARUM spp. containing aristolochic acid(s) for human therapeutic use.
- AZADIRACHTA INDICA (neem) including its extracts and derivatives, in preparations for human internal use **except** "debitterised neem seed oil".
- BASIC ORANGE 31 (2-[(4-aminophenyl)azo]-1,3-dimethyl-1H-imidazolium chloride) in preparations for skin colouration and dyeing of eyelashes or eyebrows.

- 1,2-BENZENEDIAMINE in preparations for cosmetic use and skin colouration (including tattooing).
- 1,3-BENZENEDIAMINE in preparations for cosmetic use and skin colouration (including tattooing).
- BITHIONOL for human therapeutic use.
- BORAGO OFFICINALIS (Borage) for therapeutic use **except** the fixed oil derived from the seeds of Borago officinalis.
- BRAGANTIA spp. containing aristolochic acid(s) for human therapeutic use.
- BUCLOSAMIDE for therapeutic use.
- BUNIODYL SODIUM for therapeutic use.
- 1,4-BUTANEDIOL (excluding its derivatives) in non-polymerised form in preparations for domestic use.
- BUTYL BENZYL PHTHALATE for cosmetic use.
- CACALIA spp. for therapeutic use.
- CARBAMIDE PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 18% of carbamide peroxide **except** in preparations manufactured for, and supplied solely by, registered dental practitioners as part of their dental practice.

CARDARINE.

CHRYSOIDINE BASE in preparations for use in hair dyes.

- CINCHOPHEN and its derivatives for therapeutic use.
- CLIOQUINOL and other halogenated derivatives of oxyquinoline for human internal use except or when being used solely for experimental purposes in humans and where such use:
  - (a) is in accordance with:
    - (i) an approval granted under paragraph 19(1)(b) of the Act, including any conditions specified in the notice of approval; and
    - (ii) any conditions specified in the *Therapeutic Goods Regulations 1990* for the purposes of subsection 19(1A) of the Act; and
    - (iii) any conditions specified in the *Therapeutic Goods Regulations 1990* for the purposes of subsection 19(4A) of the Act; or
  - (b) is in accordance with the requirements of item 3 of Schedule 5A to the *Therapeutic Goods* Regulations 1990.

COAL TAR for cosmetic use other than in therapeutic goods.

CONIUM MACULATUM (coniine) for therapeutic use.

COTARNINE for therapeutic use.

CROTALARIA spp. for therapeutic use.

CROTON TIGLIUM for therapeutic use.

CYNOGLOSSUM spp. for therapeutic use.

DIBUTYL PHTHALATE for cosmetic use.

DICOPHANE (DDT) for therapeutic use.

DIETHYLENE GLYCOL for use in toothpastes or mouthwashes **except** in preparations containing 0.25% or less of diethylene glycol.

DIETHYLENE GLYCOL MONOMETHYL ETHER for cosmetic use.

DIETHYLHEXYL PHTHALATE for cosmetic use.

- DIETHYLPHTHALATE in sunscreens, personal insect repellents or body lotion preparations for human use **except** in preparations containing 0.5% or less of diethylphthalate.
- 5,6-DIHYDROXYINDOLINE for cosmetic use in preparations containing more than 2% of 5,6-dihydroxyindoline.

DIIODOHYDROXYQUINOLINE (iodoquinol) for human internal use.

DIISOBUTYL PHTHALATE for cosmetic use.

1,3-DIMETHYLAMYLAMINE (DMAA).

- 1,3-DIMETHYLBUTYLAMINE (DMBA) **except** when separately specified in these schedules.
- 1-(1,1-DIMETHYLETHYL)-2-METHOXY-4-METHYL-3,5-DINITROBENZENE (musk ambrette).
- 1,5-DIMETHYLHEXYLAMINE (DMHA) **except** when separately specified in these schedules.

DI(METHYLOXYETHYL) PHTHALATE for cosmetic use.

1,4-DIMETHYLPENTYLAMINE (DMPA).

DIMETHYLPHTHALATE in sunscreens, personal insect repellents or body lotion preparations for human use **except** in preparations containing 0.5% or less of dimethylphthalate.

2,4-DINITROPHENOL for human use.

DISPERSE YELLOW 3 for use in hair dyes.

DULCIN for therapeutic use.

ETHYLENE GLYCOL for use in toothpastes or mouthwashes **except** in preparations containing 0.25% or less of ethylene glycol.

EUPATORIUM CANNABINUM (Hemp Agrimony) for therapeutic use.

FARFUGIUM JAPONICUM for therapeutic use.

FORMALDEHYDE (excluding its derivatives):

- (a) in oral hygiene preparations containing more than 0.1% of free formaldehyde; or
- (b) in aerosol sprays for cosmetic use containing 0.005% or more of free formaldehyde; or
- (c) in nail hardener cosmetic preparations containing 5% or more of free formaldehyde; or
- (d) in all other cosmetic preparations containing 0.05% or more of free formaldehyde except in preparations containing 0.2% or less of free formaldehyde when labelled with the warning statement:

CONTAINS FORMALDEHYDE.

GAMMA BUTYROLACTONE (excluding its derivatives) in non-polymerised form in preparations for domestic and cosmetic use.

HELIOTROPIUM spp. for therapeutic use.

HYDROGEN PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 6% (20 volume) of hydrogen peroxide **except** in preparations manufactured for, and supplied solely by, registered dental practitioners as part of their dental practice.

ISOPROPYL NITRITE.

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

#### KAMBO.

#### LEAD COMPOUNDS:

- (a) in anti-fouling paints **except** in preparations containing 0.1% or less of lead calculated on the non-volatile content of the paint; or
- (b) in paints (other than anti-fouling paints), tinters, inks or ink additives except in preparations containing 0.009% or less of lead calculated on the non-volatile content of the paint, tinter, ink or ink additive; or
- (c) for human therapeutic use except in preparations containing 10 mg/kg or less of lead.

LIGULARIA DENTATA for therapeutic use.

MELIA AZEDARACH including its extracts and derivatives.

- METHANOL in hand sanitiser preparations containing more than 5% methanol.
- METHYLDIBROMO GLUTARONITRILE in preparations intended to be in contact with the skin, including cosmetic use.
- METHYL METHACRYLATE for cosmetic use **except** in preparations containing 1% or less of methyl methacrylate as residual monomer in a polymer.

METHYLROSANILINIUM CHLORIDE (formerly known as crystal violet) and the following TRIARYLMETHANE DYES – for use in hair dyes:

- (a) Acid Violet 49; or
- (b) Ethyl Violet; or
- (c) Basic Blue 7; or
- (d) Basic Blue 26 (CI 44045).
- NAPHTHALENE (excluding derivatives) in preparations in block, ball, disc, pellet or flake form for domestic use **except** when enclosed in a device which, in normal use, prevents removal or ingestion of its contents.

OXYPHENISATIN for therapeutic use.

PARAFORMALDEHYDE (excluding its derivatives):

- (a) in oral hygiene preparations containing more than 0.1% of free formaldehyde; or
- (b) in aerosol sprays for cosmetic use containing 0.005% or more of free formaldehyde; or
- (c) in nail hardener cosmetic preparations containing 5% or more of free formaldehyde; or
- (d) in all other cosmetic preparations containing 0.05% or more of free formaldehyde **except** in preparations containing 0.2% or less of free formaldehyde when labelled with the warning statement:

CONTAINS FORMALDEHYDE.

PETASITES spp. for therapeutic use.

PHENPROMETHAMINE.

- PHENYLENEDIAMINES, including alkylated, arylated, halogenated and nitro derivatives, in preparations for skin colouration, tattooing and dyeing of eyelashes or eyebrows **except** when included in Schedule 6.
- POTASSIUM HYDROXIDE (excluding its salts and derivatives), in liquid or semi-solid food additive preparations, for domestic use, the pH of which is more than 11.5.

*n*-PROPYL NITRITE.

PTERIDIUM spp. for therapeutic use.

- PULMONARIA spp. for therapeutic use.
- SAFROLE for internal therapeutic use **except** in preparations containing 0.1% or less of safrole.
- SANGUINARIA CANADENSIS (bloodroot) in preparations for human use **except** in preparations containing 0.01% or less of SANGUINARINE.
- SENECIO spp. for therapeutic use.
- SILICONES for injection or implantation except when included in Schedule 4.
- SODIUM HYDROXIDE (excluding its salts and derivatives), in liquid or semi-solid food additive preparations, for domestic use, the pH of which is more than 11.5.
- SYMPHYTUM spp. (Comfrey) in preparations for human or animal use **except** when in Schedule 5.
- 2,4-TOLUENEDIAMINE in preparations for skin colouration (including tattooing) and dyeing of hair, eyelashes or eyebrows.
- TOLUENEDIAMINES in preparations for skin colouration (including tattooing) and dyeing of eyelashes or eyebrows **except** when included in Schedule 6.
- *o*-TOLUIDINE (excluding derivatives) in preparations for skin colouration (including tattooing) and dyeing of hair, eyelashes or eyebrows **except** in preparations containing 0.001% or less of *o*-toluidine.
- 1,1,1-TRICHLOROETHANE in pressurised spray packs for therapeutic use.
- TRICHODESMA AFRICANA for therapeutic use.
- TRIPARANOL for therapeutic use.
- TUSSILAGO FARFARA for therapeutic use.

WILD CHERRY BARK for therapeutic use except in preparations containing:

- (a) 10 mg/kg or less of amygdalin; and
- (b) 10 mg/kg or less of hydrocyanic acid.

## **Appendix A—General exemptions**

Note: See paragraph 11(a).

#### 1 Exempt preparations and products

The following table specifies preparations and products for the purposes of paragraph 11(a).

Exemp	t preparations and products
Item	Column 1 Preparation or product
1	ALGICIDES, BACTERIOCIDES OR SLIMICIDES for industrial use that are not agricultural chemical products or veterinary chemical products
2	BACTERIAL CULTURE MEDIA containing antibiotics
3	CERAMICS
4	CHEMISTRY SETS for toy and educational use, when complying with the requirements of Australian Standard AS 8124.4:2020, <i>Safety of toys</i> , Part 4: <i>Experimental sets for chemistry and related activities</i>
5	COPPER COMPOUNDS in paints
6	DEXTRANS, GELATIN - SUCCINYLATED & ETHERIFIED STARCHES used as plasma substitutes/blood volume expanders
7	ELECTRICAL ACCUMULATORS, BATTERIES, COMPONENTS or LAMPS
8	ELECTRONIC COMPONENTS
9	ENHANCING AGENTS for use in ultrasonic and magnetic resonance imaging
10	EXPLOSIVES
11	FOOD except:
	(a) food additives before incorporation into food; or
	(b) when used as a means of administering a poison for therapeutic use
12	FRITTED GLAZING OR ENAMELLING PREPARATIONS in which the poison is confined as a non-migratory component of glassy solid flakes or granules
13	GLASS (including CRYSTAL WARE)
14	GLAZED POTTERY
15	HUMAN BLOOD PRODUCTS including:
	(a) whole blood;
	(b) blood components including red cells, white cells, platelets and plasma (including cryoprecipitate); and
	<ul> <li>(c) the following plasma-derived therapeutic proteins; and their equivalent recombinant alternatives: <ul> <li>(i) albumin;</li> <li>(ii) anticoagulation complex;</li> <li>(iii) C1 esterase inhibitors;</li> <li>(iv) clotting factors;</li> <li>(v) fibrinogen;</li> <li>(vi) protein C;</li> <li>(vii) prothrombin complex concentrate (PCC);</li> </ul> </li> </ul>

Exemp	ot preparations and products
Item	Column 1
	Preparation or product
	(viii) thrombin
16	IN VITRO DIAGNOSTIC AND ANALYTICAL PREPARATIONS containing 0.001% or less of a poison included in Schedules 1 to 8
17	INTRAOCULAR VISCOELASTIC PRODUCTS
18	LUBRICANTS in preparations that provide a lubricating action between machinery parts, <b>except</b> soluble oils and solvent-deposited lubricating agents
19	MATCHES
20	MEDICAL AND VETERINARY ADHESIVES, GLUES AND CEMENTS
21	MEDICAL DEVICES classified as Class III by the classification rules set out in Schedule 2 to the <i>Therapeutic Goods (Medical Devices) Regulation 2002</i> , <b>except</b> the following: (a) injectable tissue reconstructive, augmentation and restoration materials, including
	collagen;
	(b) medical devices which include anticoagulants;
	(c) artificial tears;
	(d) urinary catheters;
	(e) intra-articular fluids
22	MOTOR, HEATING or FURNACE FUELS except the following:
	(a) when the contrary intention appears in any Schedule;
	(b) when containing methanol;
	(c) toy or hobby fuels; or
	(d) petrol or kerosene when packed in containers having a capacity of 20 L or less
23	NUTRITION REPLACEMENT PREPARATIONS FOR PARENTERAL ADMINISTRATION
24	PAPER except:
	(a) when prepared for pesticidal use; or
	(b) when containing a poison included in Schedule 8 or 9
25	PHOTOGRAPHIC PAPER or FILM
26	PIGMENTS when immobilised in a polymer
27	PORCELAIN
28	PRINTING INKS or INK ADDITIVES except:
	(a) when containing a pesticide; or
	(b) preparations containing more than 0.009% of lead calculated on the non-volatile content of the ink or ink additive
29	RADIOGRAPHIC CONTRAST MEDIA (radiopaques) for therapeutic use
30	RADIOISOTOPES for therapeutic use
31	SEEDS treated with seed protectants
32	SINGLE-USE TUBES for the estimation of alcohol content of breath
33	TERMITE BARRIERS consisting of an active ingredient, other than arsenic, approved by the relevant registration authority, and laminated between impervious sheeting
34	TIMBER or WALLBOARD
35	TREATMENT LAYERS OF COATED METAL ARTICLES <b>except</b> articles intended for use in the collection of drinking water when not compliant with the health and safety

Clause	1
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Exempt preparations and products				
Item	Column 1			
	Preparation or product			
	requirements of the Australian Standard AS 4020:2018, Testing of products for use in			
	contact with drinking water			
36	VITREOUS ENAMELS			
37	WRITING CORRECTION PENS which do not allow ingestion of the contents and which			
	contain no scheduled poison other than designated solvents included in Schedule 5			

# Appendix B—Substances considered not to require control by scheduling

Note: See paragraph 11(b).

#### 1 Reasons for including substances in the table in clause 3

For the purposes of the table in clause 3, the letter specified in column 1 of an item of the following table represents the reason specified in column 2 of the item.

Reason	Reasons for including substances in the table in clause 3					
Item	Column 1 Letter	Column 2 Reason				
1	а	Low Toxicity				
2	b	Use pattern restricts hazard				
3	с	Presentation/packaging restricts hazard				
4	d	Industrial use only				

#### 2 Areas of use in relation to substances included in the table in clause 3

For the purposes of the table in clause 3, the number specified in column 1 of an item of the following table represents the area, sub-area or sub-sub-area of use specified in column 2, 3 or 4 (as applicable) of the item.

Areas	Areas of use in relation to substances included in the table in clause 3					
Item	Column 1 Number	Column 2 Area	Column 3 Sub-area	Column 4 Sub-sub-area		
1	1	Agriculture				
2	1.1		Herbicide			
3	1.2		Insecticide			
4	1.2.1			Insecticide for codling moth		
5	1.2.2			Termiticide		
6	1.3		Fungicide			
7	1.3.1			On seed fungicide		
8	1.4		Bird Repellent			
9	1.5		Fertiliser			
10	1.6		Plant Growth Regulator			
11	1.7		Insect Pheromone			
12	1.8		Mushroom Bactericide			
13	1.9		Acaricide			
14	1.10		Biological control agent			
15	1.11		Adjuvant in agricultural products			

ltem	Column 1 Number	Column 2 Area	Column 3 Sub-area	Column 4 Sub-sub-area
16	2	Veterinary		
7	2.1		For animal use	
8	2.2		Treatment of mastitis in cows	
9	2.3		Coccidiostat	
20	2.4		Feed additive	
1	2.5		Antiseptic	
22	2.6		Scabicide	
3	2.7		Anthelmintic	
.4	2.8		Vitamin/Mineral	
5	2.9		Growth Promotant	
26	2.10		Ectoparasiticide	
27	3	Domestic		
8	3.1		Aromatherapy	
9	3.2		Food additive	
0	3.3		Cosmetic	
1	3.4		Human use	
2	3.5		Miticide	
3	4	Industrial		
4	4.1		Water treatment	
5	4.2		Biological control agent	
6	5	Environmental		
7	5.1		Mosquito control	
8	6	Human therapeutic use	•	
9	6.1	ł	Diagnostic agent	
0	6.2		Medical device	
1	6.3		Antiseptic	
2	6.4		Sunscreen	
3	6.5		External use	
4	6.6		Laxative	
5	6.7		Antiseborrheic	
6	6.8		Cytoprotective	
.7	6.9		Vitamin/Mineral	
8	6.10		Eye Drops	
9	7	General		
0	7.1		Any use	
1	7.2		Excipient	
2	7.3		Synergist	
3	7.4		Flux	
1	7.5		Pesticide	

Item	Column 1 Number	Column 2 Area	Column 3 Sub-area	Column 4 Sub-sub-area
55	7.6		Insect repellent	
56	7.7		Solvent	
57	7.8		Disinfectant	
58	7.9		Preservative	
59	7.10		Antioxidant	
60	7.11		Resin activator/accelerant	
51	7.12		Sweetener artificial	
52	7.13		Food additive	

#### 3 Substances exempt in certain uses

For the purposes of paragraph 11(b), the following table specifies:

- (a) substances; and
- (b) areas, sub-areas and sub-sub-areas of use in relation to those substances.
- Note: Columns 3 and 4 of the table are included for information only.

Subst	ances exempt in certain uses			
Item	Column 1 Substance	Column 2 Area, sub-area or sub-sub-area of use	Column 3 Reason for inclusion	Column 4 Date of inclusion
1	4-[4-(ACETYLOXY)PHENYL]-2-BUTANONE	1.7	b	Feb 2005
2	AFIDOPYROPEN	1.2	b	Jun 2018
3	ALCOHOL, DEHYDRATED	6	b	Aug 2000
4	ALUM	7.1	a	May 1997
5	ALUMINIUM AMMONIUM SULFATE	7.1	а	May 1997
6	ALUMINIUM POTASSIUM SULFATE	7.1	а	May 1997
7	ALUMINIUM SILICATE	7.1	а	Nov 1974
8	ALUMINIUM tris (ETHYLPHOSPHONATE)	1	а	Aug 1986
9	AMETOCTRADIN	1.3	а	May 2012
10	AMMONIUM PHOSPHATE	7.1	а	Nov 1974
11	AMMONIUM THIOSULPHATE	7.1	а	Nov 1974
12	AMPROLIUM	2.3	а	Jun 1969
13	AMYL ACETATE	7.1	а	Nov 1974
14	α -AMYLASE derived from <i>Aspergillus niger</i>	2.4	а	Feb 2005
15	AMYL CINNAMALDEHYDE	3.3	a, b	Feb 2017
16	ANDROSTENEDIONE ALBUMEN CONJUGATE WITH DEA DEXTRAN ADJUNCT	2.1	a	Jun 2004
17	ASPARTIC ACID	6	а	-

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Item	Column 1 Substance	Column 2 Area, sub-area or sub-sub-area of use	Column 3 Reason for inclusion	Column 4 Date of inclusion
18	ASULAM	1	а	May 1986
19	<i>AUREOBASIDIUM PULLULANS</i> (strains DSM14940 and DSM14941)	1.3	а	Oct 2017
20	AZIMSULFURON	1.1	a	Jun 2003
21	BACILLUS AMYLOLIQUEFACIENS	1.3	a	Jun 2018
22	BACILLUS SPHAERICUS, STRAIN 2362	5.1	a	Feb 2003
23	BACILLUS THURINGIENSIS	5.1	a	May 1992
24	BACILLUS THURINGIENSIS (excluding endotoxin)	2.10	а	Jun 2003
25	BACILLUS TOYOI	2.9	а	Aug 1980
26	BACULOVIRUS CYDIA POMONELLA	1.2	а	Jun 2006
27	BENFLURALIN	1.1	а	-
28	BENSULFURON-METHYL	1	а	Aug 1987
29	BENTONITE	7.1	а	Jun 2002
30	BENZYL BENZOATE	1.2	а	Aug 1989
31	BETAINE HYDROCHLORIDE	7.1	а	Nov 1974
32	BIFENAZATE	1.9	а	Oct 2002
33	BISMUTH SUBNITRATE	2.1	b, c	Nov 1999
34	BISTRIFLURON	1.2.2	а	Feb 2014
35	BIURET	2.4	а	Nov 1974
36	BIXLOZONE	1.1	а	Feb 2020
37	BLAD (banda de Lupinus albus doce)	1.3	а	Feb 2016
38	BOSCALID	1.3	а	June 2003
39	BOVINE SOMATOTROPHIN	2	а	May 1992
40	BROMACIL	1	а	Aug 1987
41	BROMOPROPYLATE	1	а	Nov 1994
42	BUPIRIMATE	1	а	Nov 1990
43	BUTAFENACIL	1	а	May 2000
44	BUTOXYPOLYPROPYLENE GLYCOL	7.7	а	Nov 1974
45	n-BUTYL BUTYRATE	7.1	а	-
46	n-BUTYL LACTATE	7.1	a	-
47	CARBOXIN	1	a	Aug 1987
48	CARFENTRAZONE-ETHYL	1	а	Aug 1998
49	CELLULASE derived from Aspergillus niger	2.4	a	Feb 2005
50	CETYL ALCOHOL	7.1	a	Nov 1974
51	CHAMOMILE OIL	3.1	a	Feb 2000
52	CHINA CLAY	1.2	а	Sep 2008

Clause J	Cl	ause	3
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Item	Column 1 Substance	Column 2 Area, sub-area or sub-sub-area	Column 3 Reason for inclusion	Column 4 Date of inclusion
		of use		a <b>a</b> aaa
53	CHLORANTRANILIPROLE	1.2	a	Sep 2008
54	CHLORFLUAZURON	1.2.2	a	Oct 2005
55	CHLORFLURENOL	1.6	a	Feb 1974
56	CHLORIDAZON	1	a	May 1988
57	CHLOROXYLENOLS	7.8	а	Feb 1975
58	CITRONELLA OIL	7.1	а	Feb 2000
59	CLARY SAGE OIL	7.1	a	Feb 2000
60	CLITORIA TERNATEA EXTRACT	1.2	a	Feb 2016
61	CLOPIDOL	2.3	<u>d</u>	Nov 1974
62	COBALT NAPHTHENATE	7.1	d	-
63	CROSPOVIDONE	2	а	Aug 1996
64	CULICINOMYCES CLAVOSPORUS	5.1	а	Nov 1982
65	CYCLAMIC ACID	7.1	а	Nov 1971
66	CYCLANILIPROLE	1.2	a	Oct 2016
67	CYCLOBUTRIFLURAM	1.3, 1.3.1	а	Oct 2022
68	CYCLOHEXANE	7.7	а	Nov 1974
69	CYCLOHEXANOL ACETATE	7.7	а	-
70	CYPRINID HERPESVIRUS-3	1.10	а	Oct 2018
71	CYROMAZINE	2	а	Nov 1980
72	DICLAZURIL	2.3	а	Nov 2001
73	DIETHYL CARBONATE	7.1	а	-
74	DIFLUFENICAN	1	а	Feb 1987
75	DIKEGULAC-SODIUM	1.6	а	Mar 1980
76	DIMETHYL ETHER	4	d	Nov 1988
77	DIMETICONE	7.1	а	-
78	DIPHENYLAMINE	1	а	Feb 1988
79	DIPROPYLENE GLYCOL MONOMETHYL ETHER	4	a	Nov 1987
80	DISODIUM MANGANESE EDTA	2.1	а	Feb 2022
81	DIURON	1	a	Nov 1987
82	DOCUSATE SODIUM (DIOCTYL SODIUM SULFOSUCCINATE)	7.1	a	Feb 1970
83	2,2-DPA	1	a	Nov 1989
84	DROMETRIZOLE TRISILOXANE	6.4	a	Oct 2003
85	<i>DUDDINGTONIA FLAGRANS</i> , STRAIN IAH 1297	2.7	a	Feb 2018
86	EPSIPRANTEL	2	а	Nov 1991
87	ETHAMETSULFURON-METHYL	1.1	a	Nov 2000
Substances exempt in certain uses         Column 2         Column 3         Column 4				
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Item	Substance	Area, sub-area or sub-sub-area	Reason for inclusion	Date of inclusion
		of use	inclusion	
88	ETHOPABATE	2.3	d	Jun 1969
89	ETHYL ACETATE	7.1	а	Nov 1974
90	ETHYL ALCOHOL	7.1	а	Nov 1974
91	ETHYLBUTYLACETYL AMINOPROPRIONATE	3.4	a	Aug 2000
92	ETHYL BUTYRATE	7.1	а	-
93	ETHYL LACTATE	7.1	а	-
94	ETOFENPROX	1.2	a	Jun 2018
95	ETOXAZOLE	1.2	а	Oct 2003
96	EUBACTERIUM sp. strain DSM11798	2.4	а	Sep 2013
97	FENFURAM	1.3.1	a	May 1977
98	FENHEXAMID	1	а	Feb 1999
99	FENOXYCARB	1	а	Feb 1988
100	FLORPYRAUXIFEN-BENZYL	1, 1.1	а	Feb 2018
101	FLORYLPICOXAMID	1.3	а	Feb 2021
102	FLUFENOXURON	1	а	Feb 1997
103	FLUMETSULAM	1	а	Feb 1992
104	FLUOMETURON	1	а	Aug 1989
105	FLUOPICOLIDE	1.3	а	Oct 2016
106	FLUOXAPIPROLIN	1.3	а	Feb 2022
107	FLUTOLANIL	1.3	а	Nov 2001
108	FLUROXYPYR	1	a, c	May 1986
109	FORCHLORFENURON	1.6	а	Feb 2005
110	FULLERS EARTH	7.1	а	Nov 1974
111	FUNGAL PROTEASE derived from <i>Aspergillus</i> niger	2.4	a	Feb 2005
112	GERANIUM OIL	7.1	а	Feb 2000
113	GIBBERELLIC ACID	1.6	а	Nov 1974
114	α-GLUCANASE derived from Aspergillus niger	2.4	а	Feb 2005
115	HALAUXIFEN METHYL	1, 1.1	а	Oct 2014
116	HELIONAL	7	а	Feb 2023
117	HEXAFLURON	1	а	Nov 1988
118	HEXYL ACETATE	7.7	а	-
119	HEXYL CINNAMALDEHYDE	3.3	a, b	Feb 2017
120	HEXYTHIAZOX	1	а	Feb 1988
121	HUMAN OSTEOGENIC PROTEIN-1 (OP-1)	6.2	b	Aug 2001
122	HYDROPRENE	1	а	Feb 1988

Cl	ause	3

Substances exempt in certain uses				
Item	Column 1 Substance	Column 2 Area, sub-area or sub-sub-area of use	Column 3 Reason for inclusion	Column 4 Date of inclusion
123	HYDROXYPROPYL CELLULOSE	7.1	а	Nov 1982
124	ICODEXTRIN	6	b	Nov 2000
125	INDOLE-3-ACETIC ACID	1.6	b	Feb 1985
126	IPFLUFENOQUIN	1.3, 1.3.1	а	Sep 2022
127	ISOPRENE ALCOHOL	7.1	a	-
128	IPRODIONE	1	а	Feb 1997
129	ISETHIONATE, as mixed ammonium and ethanolamine salts of 2-hydroxyethanesulfonic acid	1.11	a, b	Jun 2016
130	ISOFETAMID	1.3	а	Feb 2018
131	ISOSTEARYL ALCOHOL ETHOXYLATE	5.1	а	Nov 1999
132	KAOLIN	7.1	а	Nov 1974
133	KINETIN	1.6	а	Feb 2022
134	KRESOXIM-METHYL	1	а	Aug 1999
135	KUNZEA OIL	7.1	а	Feb 2000
136	LAURIC ACID	7.1	а	Oct 2005
137	LAURYL ALCOHOL (1-DODECANOL)	7.1	а	Nov 1974
138	LAVANDIN OIL	7.1	а	Feb 2000
139	LAVENDER OIL	7.1	а	Feb 2000
140	LEAD METALLIC	7.1	а	-
141	LEPIDOPTEROUS SEX PHEROMONES	1	а	Nov 1990
142	LIMONENE (DIPENTENE)	7.1	а	Jun 2002
143	LINOLEIC ACID	7.1	а	Oct 2005
144	LINSEED FATTY ACIDS	2.1	а	Aug 1990
145	LINURON	1	а	Feb 1990
146	LIQUORICE, DEGLYCYRRHISINISED	7.1	а	May 1999
147	MAGNESIUM HYDROXIDE	7.1	а	Jun 2021
148	MALEIC HYDRAZIDE	1	а	Nov 1992
149	MANGANESE DIOXIDE	1	b	May 1999
150	MEGASPHAERA ELSDENII strain 41125	2.4	а	Sep 2013
151	MESOSULFURON-METHYL	1.1	а	Feb 2002
152	METARHIZIUM ANISOPLIAE	4.2	b	Feb 2000
153	METARHIZIUM ANISOPLIAE	1.10	а	Jun 2003
154	METCAMIFEN	1.1	а	Feb 2020
155	METHOPRENE	1	а	Aug 1987
156	METHOXYFENOZIDE	1	а	Nov 2000
157	METHYL ACETATE	7.7	а	-
158	METHYL BENZOQUATE	2.3	d	Nov 1974

Item	ances exempt in certain uses Column 1 Substance	Column 2 Area, sub-area or sub-sub-area of use	Column 3 Reason for inclusion	Column 4 Date of inclusion
159	1-METHYLCYCLOPROPENE	1.6	а	Jun 2003
160	METHYL <i>p</i> -HYDROXYBENZOATE	7.9	a	Nov 1974
161	METSULFURONMETHYL	1.1	a	Nov 1985
162	MYRISTIC ACID	7.1	а	Oct 2005
163	NAPROPAMIDE	1	а	Aug 1987
164	NAPTHYL ACETAMIDE	1.6	а	Nov 1974
165	NEROLI OIL	7.1	а	Feb 2000
166	NICARBAZIN	2.3	d	Jun 1969
167	NISIN	3.2	a	Jun 2003
168	NORFLURAZON	1.1	а	Nov 1983
169	NOVALURON	1	а	Nov 2000
170	NUCLEAR POLYHEDROSIS VIRUS of Helicoverpa armigera occlusion bodies	1.2	а	Feb 2004
171	OCTYL ALCOHOLS	7.1	а	Nov 1974
172	OLEIC ACID	7.1	а	Oct 2005
173	ORANGE OIL, SWEET	7.1	a	Aug 2000
174	OXABETRINIL	1	а	Feb 1987
175	OXATHIAPIPROLIN	1.3	a	Jun 2016
176	OXYFLUORFEN	1	a	May 2001
177	PALMAROSA OIL	7.1	а	Feb 2000
178	PALMITIC ACID	7.1	a	Oct 2005
179	PATCHOULI OIL	7.1	а	Feb 2000
180	PECTINASE derived from Aspergillus niger	2.4	a	Feb 2005
181	PEGBOVIGRASTIM	2.1	а	Jun 2017
182	PENCYCURON	1	а	Aug 1994
183	PENTADECANOIC ACID	7.1	а	Oct 2005
184	PEPPERMINT OIL	7.1	а	Feb 2000
185	PHENMEDIPHAM	1.1	а	May 1989
186	D-PHENOTHRIN	7.5, 1.2	а	Feb 1982
187	PHYTASE	2.4	а	Feb 1996
188	PICLORAM	1	а	Aug 1987
189	PICOLINAFEN	1	а	May 2000
190	PIMELIC ACID	7.1	а	Oct 2005
191	PIPERONYL BUTOXIDE	7.5	а	Aug 1991
192	POLOXALENE	7.1	а	Nov 1974
193	POLY DIALLYL DIMETHYL AMMONIUM CHLORIDE (PolyDADMAC)	4.1	a	Nov 1997

Cl	ause	3

Substances exempt in certain uses				
Item	Column 1 Substance	Column 2 Area, sub-area or sub-sub-area of use	Column 3 Reason for inclusion	Column 4 Date of inclusion
194	POLYHEDROSIS VIRUS of <i>Helico zea</i> occlusion bodies	1	a	Nov 1996
195	POLY (GNRF) OVALBUMIN	2	а	Feb 1990
196	POLYSORBATE 20	1	а	May 2001
197	PORCINE SOMATOTROPHIN	2	c	Nov 1991
198	POTASSIUM SORBATE	1.3	а	Oct 2004
199	POTASSIUM BICARBONATE	1	a	Jun 2004
200	PROPYL ACETATES	7.1	а	-
201	PROPYLENE GLYCOL	7.1	а	Nov 1974
202	2-PROPYLENE GLYCOL 1-MONOMETHYL ETHER	4	а	Nov 1987
203	PROTHIOCONAZOLE	1.3.1	а	Jun 2005
204	PSEUDOMONAS FLUORESCENS	1.8	a	May 1985
205	PYDIFLUMETOFEN	1.3	а	Feb 2018
206	PYRIMETHANIL	1	а	Feb 1996
207	PYRIPROXYFEN	1	а	Aug 1994
208	QUASSIA	6, 2.1	d	Nov 1974
209	QUINOXYFEN	1.3	a	Nov 2001
210	RHIZOBIUM RHIZOGENES	1	b	Nov 1989
211	ROSEMARY OIL	7.1	а	Feb 2000
212	SAGE OIL (Spanish)	7.1	а	Feb 2000
213	SANDALWOOD OIL	7.1	a	Feb 2000
214	SEAWEED & UNFRACTIONED SEAWEED EXTRACTS	1.5	d	Feb 1985
215	SILVER OXIDE	7.14	b	Jun 2018
216	SIMAZINE	1.1	а	Nov 1987
217	SODIUM BICARBONATE	1	а	Jun 2004
218	SODIUM PROPIONATE	1.3	а	Oct 2004
219	STERIC ACID	7.1	а	Oct 2005
220	STREPTOMYCES LYDICUS WYEC 108	1.3	а	Oct 2016
221	SUCRALFATE	6.8	a	Aug 1982
222	SULESOMAB	6.1	b	Jun 2002
223	SULFOSULFURON	1	а	Feb 1998
224	SULPHATED POLYSACCHARIDES	7.1	a	
225	TANNIC ACID	7.1	a	Dec 1965
226	TANNIC ACID/BENZYL ALCOHOL PRODUCT	7.1	a	Nov 1993
227	TERBACIL	1	a	Aug 1987

Item	Column 1 Substance	Column 2 Area, sub-area or sub-sub-area of use	Column 3 Reason for inclusion	Column 4 Date of inclusion
228	THAUMATIN	3.2	а	Nov 1990
229	THIDIAZURON	1	а	Nov 1989
230	TIAFENACIL	1	а	June 2019
231	TRIASULFURON	1	а	Feb 1988
232	TRICHODERMA HARZIANUM	1	а	May 1996
233	(Z)-9-TRICOSENE	1	а	Aug 1991
234	TRIETHYLENE GLYCOL	7.1	а	Nov 1974
235	TRIFLOXYSULFURON	1.1	а	Feb 2002
236	TRIFLURALIN	1	а	Aug 1990
237	TRIFORINE	1	а	Aug 1987
238	ULOCLADIUM OUDEMANSII	1.10	а	Oct 2003
239	UREA	7.1	а	Nov 1974
240	<sup>13</sup> C-UREA	6.1	а	May 2001
241	VETIVER OIL	7.1	а	Feb 2000
242	VINYL ETHER	6	b	Nov 1987
243	VITAMIN K	6.9, 2.8	а	Jul 1963
244	XANTHOPHYLL (lutein)	7.1	а	Nov 1974
245	XYLANASE derived from Aspergillus niger	2.4	а	Feb 2005
246	YLANG YLANG OIL	7.1	а	Feb 2000
247	ZINC NAPHTHENATE	1.3	а	-

### Appendix C—Blank

- Note 1: Appendix C is intentionally blank.
- Note 2: Appendix C previously included poisons now included in Schedule 10.

### Appendix D—Additional controls on possession or supply of poisons included in Schedule 4 or 8

Note: See section 64.

#### 1 Poisons available for human use only from or on the prescription or order of an authorised medical practitioner

A poison specified in the following table may be supplied for human use only by, on the prescription or order of, an authorised medical practitioner.

Item	Poison
1	CANNABIS for human use
2	CLOMIFENE for human use
3	CLOZAPINE for human use
4	CORIFOLLITROPIN ALFA (recombinant follicle stimulant) for human use
5	CYCLOFENIL for human use
6	DINOPROST for human use
7	DINOPROSTONE for human use
8	FOLLITROPIN ALFA (recombinant human follicle-stimulating hormone) for human use
9	FOLLITROPIN BETA (recombinant human follicle-stimulating hormone) for human use
10	FOLLITROPIN DELTA (recombinant human follicle-stimulating hormone) for human use
11	LUTEINISING HORMONE for human use
12	NABIXIMOLS for human use
13	SODIUM OXYBATE for human use
14	TETRAHYDROCANNABINOLS for human use
15	TERIPARATIDE for human use
16	UROFOLLITROPIN (human follicle-stimulating hormone) for human use

# 2 Poisons available for human use only from or on the prescription or order of a specialist physician or a dermatologist

A poison specified in the following table may be supplied for human use:

- (a) only by, or on the prescription or order of, a specialist physician or a dermatologist; and
- (b) if the person to whom the poison is to be supplied is a woman of child-bearing age—only if the specialist physician or dermatologist has:
  - (i) ensured that the possibility of pregnancy has been excluded prior to commencement of treatment; and
  - (ii) if the poison is acitretin or etretinate—advised the patient to avoid becoming pregnant during or for a period of 36 months after completion of treatment; and
  - (iii) if the poison is bexarotene, isotretinoin or thalidomide—advised the patient to avoid becoming pregnant during or for a period of 1 month after completion of treatment.

Appendix D Additional controls on possession or supply of poisons included in Schedule 4 or 8

#### Clause 3

Item	Poison
1	ACITRETIN for human use
2	BEXAROTENE for human use
3	ETRETINATE for human use
4	ISOTRETINOIN for human oral use
5	THALIDOMIDE for human use

# **3** Poisons available only from or on the prescription or order of a medical practitioner approved or authorised under section 19 of the Act

A poison specified in the following table may be supplied only by, or on the prescription or order of, a medical practitioner for whom an approval or authority under section 19 of the Act that covers the poison is in force.

Item	Poison
1	DRONABINOL (delta-9-tetrahydrocannabinol)

#### 4 Poisons available only from or on the order of a specialist physician

A poison specified in the following table may be supplied:

- (a) only by, or on the prescription or order of, a specialist physician; and
- (b) if the person to whom the poison is to be supplied is a woman of child-bearing age—only if the specialist physician has:
  - (i) ensured that the possibility of pregnancy has been excluded prior to commencement of treatment; and
  - (ii) advised the patient to avoid becoming pregnant during or for a period of 1 month after completion of treatment.

Item	Poison
1	LENALIDOMIDE
2	POMALIDOMIDE
3	RIOCIGUAT for human use
4	TRETINOIN for human oral use

#### 5 Poisons for which possession without authority is illegal

The following table specifies poisons that must not be possessed by a person without authority (for example, possession other than in accordance with a legal prescription).

Item	Poison
1	ANABOLIC STEROIDAL AGENTS, including those separately specified in Schedule 4
2	ANDROGENIC STEROIDAL AGENTS, including those separately specified in Schedule 4
3	AOD-9604 (CAS No. 221231-10-3)
	10D 700 (end 10. 221251 10 5)

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Item	Poison
4	BENZODIAZEPINE DERIVATIVES, including those separately specified in Schedule 4 and Schedule 8
5	BPC-157
6	CAPROMORELIN
7	CJC-1295 (CAS No. 863288-34-0)
8	DARBEPOETIN
9	DEXTROPROPOXYPHENE
10	N, α -DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE *(MDMA)
11	EPHEDRINE
12	EPOETINS
13	ERYTHROPOIETIN
14	ERYTHROPOIETINS except when separately specified in this Appendix
15	FIBROBLAST GROWTH FACTORS
16	FOLLISTATIN
17	GLUTETHIMIDE
18	GROWTH HORMONE RELEASING HORMONES (GHRHs) including those separately specified in Schedule 4
19	GROWTH HORMONE RELEASING PEPTIDES (GHRPs) including those separately specified in Schedule 4
20	GROWTH HORMONE RELEASING PEPTIDE-6 (GHRP-6)
21	GROWTH HORMONE SECRETAGOGUES including those separately specified in Schedule 4
22	HEXARELIN
23	IBUTAMOREN
24	INSULIN-LIKE GROWTH FACTORS
25	IPAMORELIN
26	MOLIDUSTAT
27	NICOTINE
28	PERAMPANEL for human use
29	PHENTERMINE
30	PRALMORELIN ((GROWTH HORMONE RELEASING PEPTIDE-2) (GHRP-2))
31	PSILOCYBINE
32	SELECTIVE ANDROGEN RECEPTOR MODULATORS (SARM), including those separately specified in Schedule 4
33	SOMATROPIN (human growth hormone)
34	STENABOLIC (SR9009) and other synthetic REV-ERB agonists
35	TB-500
36	THYMOSIN BETA 4 (THYMOSIN β4)
37	TIANEPTINE
38	VADADUSTAT

Appendix D Additional controls on possession or supply of poisons included in Schedule 4 or 8

#### Clause 6

# 6 Poisons available for human use only from or on the prescription or order of a specialist physician

A poison specified in the following table may be supplied for human use:

- (a) only by, or on the prescription or order of, a specialist physician; and
- (b) if the person to whom the poison is to be supplied is a woman of child-bearing age—only if the specialist physician has:
  - (i) ensured that the possibility of pregnancy has been excluded prior to commencement of treatment; and
  - (ii) advised the patient to avoid becoming pregnant during and for a period of 3 months after completion of treatment.

Item	Poison
1	AMBRISENTAN for human use
2	BOSENTAN for human use
3	ENZALUTAMIDE for human use
4	MACITENTAN for human use
5	SITAXENTAN for human use

# 7 Poisons available for human use only from or on the prescription or order of a dermatologist

A poison specified in the following table may be supplied for human use only by, or on the prescription or order of, a dermatologist.

Item	Poison
1	ALEFACEPT for human use

## 8 Poisons which must be stored in a locked container to prevent unauthorised access

The following table specifies poisons that must be stored in a locked container to prevent unauthorised access.

Item	Poison
1	PENTOBARBITAL in injectable preparations

#### 9 Poisons available only when prescribed or authorised in certain circumstances

*N*,  $\alpha$  -DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE \*(MDMA) in preparations for human use may be supplied only for the treatment of post-traumatic stress disorder:

- (a) if MDMA is prescribed, or its supply is authorised, by a medical practitioner:
  - (i) registered under State or Territory legislation that forms part of the Health Practitioner Regulation National Law as a specialist psychiatrist; and

- (ii) for whom an authority under subsection 19(5) of the Act that covers MDMA is in force; or
- (b) for use in a clinical trial that is approved by, or notified to, the Secretary under the Act.

PSILOCYBINE in preparations for human use may be supplied only for the treatment of treatment-resistant depression:

- (a) if psilocybine is prescribed, or its supply is authorised, by a medical practitioner:
  - (i) registered under State or Territory legislation that forms part of the Health Practitioner Regulation National Law as a specialist psychiatrist; and
  - (ii) for whom an authority under subsection 19(5) of the Act that covers psilocybine is in force; or
- (b) for use in a clinical trial that is approved by, or notified to, the Secretary under the Act.

### **Appendix E—First aid instructions for poisons**

Note: See section 31.

#### 1 Standard statements for first aid instructions

For the purposes of the table in clause 3, the statement code specified in column 2 of an item of the following table represents:

- (a) the statement specified in column 3 of the item; or
- (b) a different statement that has the same intent as the statement specified in column 3 of the item.

Item	Column 1 Category	Column 2 Statement code	Column 3 Statement
1	Basic	А	For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once).
2	Basic	Z	First aid is not generally required. If in doubt, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.
3	General	G1	Urgent hospital treatment is likely to be needed.
			(Note - the words "at once" to be added to instruction A).
4	General	G2	If swallowed, give activated charcoal if instructed.
			(Note - the words "at once" to be added to instruction A).
5	General	G3	If swallowed, do NOT induce vomiting.
6	General	G4	Immediately give a glass of water.
7	General	G5	Avoid giving milk or oils.
8	General	G6	If sprayed in mouth, rinse mouth with water.
9	Eyes	E1	If in eyes wash out immediately with water.
10	Eyes	E2	If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor, or for at least 15 minutes.
11	Respiratory system	R1	If inhaled, remove from contaminated area. Apply artificial respiration if not breathing.
12	Respiratory system	R2	If swallowed or inhaled, remove from contaminated area. Apply artificial respiration if not breathing. Do not give direct mouth-to-mouth resuscitation. To protect rescuer, use air-viva, oxy-viva or one-way mask. Resuscitate in a well-ventilated area.
13	Skin	S1	If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.
14	Skin	S2	If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water. Continue flushing with water until advised to stop by a Poisons Information Centre (e.g.

Clause	2
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Stand	Standard statements for first aid instructions				
Item	Column 1 Category	Column 2 Statement code	Column 3 Statement		
			phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.		
15	Skin	S3	If on skin, remove any contaminated clothing, wash skin thoroughly with soap and water, then methylated spirit if available. Contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.		
16	Skin	S4	If on skin, immediately remove any contaminated clothing, wash skin with methylated spirit or PEG (polyethylene glycol) 300 or 400 if available, then flush under running water until advised to stop by a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.		
17	Skin	S5	If skin contact occurs, immediately remove contaminated clothing. Flush skin under running water for 15 minutes. Then apply calcium gluconate gel. Contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766).		
18	Special Purpose	SP1	If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.		

#### 2 Poisons information centre contact information in statements

A statement required for a poison that includes a reference to a Poisons Information Centre must include:

- (a) the telephone number that is appropriate to the country or countries in which the poison is to be supplied; and
- (b) immediately following the reference to a Poisons Information Centre:
  - (i) the national telephone number for the Poisons Information Centre in Australia (13 11 26); or
  - (ii) the telephone number for another poisons information centre:
    - (A) that is attended by adequately trained staff for 24 hour emergency poisons information; and
    - (B) calls to which are logged and submitted for incorporation into the official collection of poisoning data.
- Note: For subparagraph (b)(ii), in 2022 the Poisons Information Centre telephone number in New Zealand was 0800 764 766.

#### **3** First aid instructions for poisons

- (1) For the purposes of subsection 31(1), and subject to subclause (2), the statement represented by each statement code specified in column 2 of an item of the following table is required for the poison specified in column 1 of the item.
- (2) A statement required for a poison must:

- (a) be modified for its use in relation to that poison as appropriate for the poison (for example if the poison is combined with other substances (whether toxic or non-toxic) or is in a particular physical form or presentation); and
- (b) if the statement refers to a Poisons Information Centre—comply with clause 2.

Poison	s that must be labelled with first aid instructions	
Item	Column 1 Poison	Column 2 Statement code
1	ACETIC ACID	A, G3, E2, S1
2	ACETIC ANHYDRIDE	A, G3, E2, S1
3	ACETONE	A, G3
4	ACROLEIN	A, G1, G2, G3, E2, R2, S2
5	ALKALINE SALTS	A, G3, E2, S1
6	ALKYL NITRITES	А
7	AMIDOPROPYL BETAINES—in cosmetic wash-off preparations when included in Schedule 6	E1
8	AMIDOPROPYL BETAINES—in other preparations when included in Schedule 6	E1, S1
9	AMINES for use as curing agents	A, G3, E1, S1
10	2-AMINO-6-CHLORO-4-NITROPHENOL	A, E1
11	4-AMINO-m-CRESOL	A, E1
12	2-AMINO-5-ETHYLPHENOL	А
13	4-AMINO-2-HYDROXYTOLUENE	A, E1
14	4-AMINO-3-NITROPHENOL	А
15	2,2'-[(4-AMINO-3-NITROPHENYL)IMINO]BISETHANOL	E1
16	<i>m</i> -AMINOPHENOL	A, S1
17	p-AMINOPHENOL	A, S1
18	4-AMINOPYRIDINE	A, G1, G2, E1, S1
19	AMMONIA—5% or less	А
20	AMMONIA—above 5%	A, G3, E1, R1, S1
21	AMMONIUM COCOYL ISETHIONATE	E1
22	AMMONIUM PERSULFATE	A, G3, E2
23	AMMONIUM THIOCYANATE	А
24	AMYL NITRITE	А
25	ANHYDRIDES, organic acid, for use as curing agents for epoxy resins	A, G3, E1, S1
26	ANILINE	A, E2, R1, S1
27	ANISE OIL	A, G3
28	ANITMONY CHLORIDE	A, E2, S2
29	ANTIMONY COMPOUNDS, except antimony chloride	А
30	ARBUTIN when included in Schedule 6	A, G2, G3, E2, R2, S1

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Poison	s that must be labelled with first aid instructions	
Item	Column 1 Poison	Column 2 Statement code
31	AZADIRACHTA INDICA (neem) including its extracts and derivatives when included in Schedule 6	A, E1
32	AZELAIC ACID	A, E1
33	AZO DYES (derivatives by diazotisation)	А
34	BARIUM SALTS, except barium sulfate	А
35	BASIC RED 76	А
36	BASIL OIL	A, G3
37	BAY OIL	A, G3
38	BENZALKONIUM CHLORIDE—when included in Schedule 5	A, G3, E2
39	BENZALKONIUM CHLORIDE—when included in Schedule 6	A, G3, E2, S1
40	BENZENE	A, G3, E1, R1, S1
41	1,2-BENZENEDIOL (Catechol)	A, E1, S1
42	BENZOYL PEROXIDE—above 20%	A, E2, S1
43	BENZOYL PEROXIDE—above 10% up to 20%	A, E1
44	BENZOYL PEROXIDE—10% or less	А
45	BERGAMOT OIL	A, G3
46	BIFLUORIDES (including ammonium, potassium and sodium salts)—when included in Schedule 5	A
47	BIFLUORIDES (including ammonium, potassium and sodium salts)—when included in Schedule 6 or 7	A, G3, E2, S5
48	1,3-BIS(2,4-DIAMINOPHENOXY)PROPANE	E1, S1
49	BIS-ISOBUTYL PEG/PPG-20/35/AMODIMETICONE COPOLYMER	A, E1
50	BORAX	А
51	BORIC ACID	А
52	BORON TRIFLUORIDE—when included in Schedule 5	А
53	BORON TRIFLUORIDE—when included in Schedule 6 or 7	A, G3, E2, S5
54	BROMOFORM	A, G3, E2, R1, S2
55	BRUCINE	A, G1, G2, G3, R2
56	2-BUTOXYETHANOL and its acetates	A, E2, S1
57	n-BUTYL ALCOHOL	A, E1, S1
58	BUTYL NITRITE	A
59	CADMIUM COMPOUNDS	А
60	CAJUPUT OIL	A, G3
61	CAMPHOR	A, G1, G3, G5
62	CARBAMIDE PEROXIDE—more than 9% up to 60%	A, G3, E2, S1
63	CARBAMIDE PEROXIDE—more than 60%	A, G1, G3, G4, E2, S1
64	CARBON DISULFIDE	A, G3, E2, R1, S2
65	CARBON TETRACHLORIDE	A, G3, E1, R1, S1

T/	s that must be labelled with first aid instructions	<u> </u>
Item	Column 1 Poison	Column 2 Statement code
66	CASSIA OIL	A, G3
67	CHLORINATING COMPOUNDS, <b>except</b> when separately specified—containing above 4% and below 10% of available chlorine	A, G3, E1, S1
68	CHLORINATING COMPOUNDS, <b>except</b> when separately specified—containing 10% or more of available chlorine	A, G3, E2, S1
69	CHLORIDE (gas)	A, E1, R1
70	CHLOROACETAMIDE	А
71	CHLOROCRESOL	A, G3, E2, S2
72	2-CHLORO-6-(ETHYLAMINO)-4-NITROPHENOL	A, S1
73	CHLOROFORM	A, G3, E1, R1, S1
74	CHROMATES	A, G3, E2, S1
75	CHROMIUM TRIOXIDE	A, G3, E2, S1
76	CHRYSOIDINE BASE	A, S1, E1
77	CINEOLE	A, G1, G3
78	CINNAMON BARK OIL	A, G3
79	CINNAMON LEAF OIL	A, G3
80	CLIMBAZOLE	А
81	CLOVE OIL	A, G1, G3, E2
82	COCOYL GLYCINATE	E1
83	COPPER SULFATE	A, G3, E2, S1
84	CREOSOTE	A, G3, E2, S1
85	CRESOLS	A, G3, E2, S3
86	CRESOLS in pressurised spray packs	A, G6, E1, S1
87	CYANIDES	A, G1, E1, R2
88	CYANOACRYLIC ACID ESTERS	А
89	CYANURIC ACID	А
90	CYCLOHEXANONE PEROXIDE	A, G3, E2, S1
91	CYCLOSILAZANES, DI-ME, ME HYDROGEN, POLYMERS WITH DI-ME, ME HYDROGEN SILAZANES, REACTION PRODUCTS WITH 3-(TRIETHOXYSILYL)-1-PROPANAMINE (CAS 475645-84-2)	A, E2, S1
92	CYCTEAMINE	E1
93	1-DEOXY-1-(METHYLAMINO)-d-GLUCITOL N-COCO ACYL DERIVATIVES	E1
94	2,4-DIAMINOPHENOXYETHANOL	A, E2, S1
95	o-DICHLOROBENZENE	A, G3, E1, S1
96	para-DICHLOROBENZENE (PDB)	А
97	DICHLOROETHYL ETHER	A, G3, E1, R1, S1
98	DICHLOROISOCYANURATES	A, G3, E1, S1

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	s that must be labelled with first aid instructions	~
Item	Column 1 Poison	Column 2 Statement code
99	DICHLOROMETHANE (methylene chloride)	A, G3, G5, E1, R1, S1
100	DICHLOROMETHANE (methylene chloride)—in pressurised spray packs	A, G6, S1
101	DICHROMATES	A, G1, G3, E2, S1
101	DIDECYLDIMETHYLAMMONIUM SALTS	A, G1, G3, E2, S1
102	DIESEL (distillate)	A, G3
103	DIETHANOLAMINE—when included in Schedule 5	A, G3
104	DIETHANOLAMINE—when included in Schedule 6	A, G3, E2, S1
105	DIETHYLENE GLYCOL MONOBUTYL ETHER	A, C3, E2, S1 A, E1, S1
100	5,6-DIHYDROXYINDOLINE	E1
107	DIMETHYLFORMAMIDE—less than 75%	A
108	DIMETHYLFORMAMIDE—Icss trian 75% DIMETHYLFORMAMIDE—75% or more	A, E1, R1, S1
109	4,4-DIMETHYL-1-CYCLOHEXENE-1-PROPANAL	A, E1, K1, S1 A, E2
111	3,7-DIMETHYL-2,6-OCTADIEN-1-OL	A, E1, S1
112	DIMETHYL SULFOXIDE	A, G3, E1, S1
112	DINITROCRESOLS	A, G3, E1, S1
113	DINITROPHENOLS	A, G1, E1, S1
114	DIOXANE	A, G1, E1, S1 A, G3, E1, R1, S1
115	DISPERSE YELLOW 3	A, 65, E1, K1, 51 A, S1
117	DISTILLATE	A, G3
118	<i>N-(N-DODECYL)-2-PYRROLIDONE</i> —when included in Schedule 5	A, G3, E1
119	<i>N-(N-DODECYL)-2-PYRROLIDONE</i> —when included in Schedule 6	A, G3, E2, S1
120	EPOXY RESINS liquid	A, G3, E2, S1
121	Essential oils containing CAMPHOR as natural component unless otherwise specified	A, G3
122	ETHER	A, G3, E1, R1
123	ETHYL BROMIDE	A, E2, S1, R1
124	ETHYLENE GLYCOL	A
125	ETHYLENE GLYCOL MONOALKYL ETHERS and their acetates, <b>except</b> when separately specified	A, G3, E2, S1
126	ETHYLENE OXIDE	A, E2, R1
127	ETHYLHEXANEDIOL	A, E2
128	2-ETHYLHEXANOIC ACID	A
129	EUCALYPTUS OIL	A, G1, G3
130	EUGENOL	A, G1, G3, E2
131	FENNEL OIL	A, G3
132	FLUORIDES <b>except</b> when separately specified—when included in Schedule 5	A

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Poisons that must be labelled with first aid instructions			
Item	Column 1 Poison	Column 2 Statement code	
133	FLUORIDES <b>except</b> when separately specified—when included in Schedule 6	A, G1, G3, E2, S1	
134	FORMALDEHYDE (see also paraformaldehyde)	A, G3, E2, R1, S1	
135	FORMIC ACID	A, G3, E2, S1	
136	FURFURAL	A, E1, S1	
137	GLUTARAL—below 5%	A, G3, E1	
138	GLUTARAL—5% or more	A, G3, E2, S1	
139	GLYCOLIC ACID	A, G3, E2	
140	GUANIDINE when included in Schedule 6	A, G3, E2, S1	
141	HC VIOLET 1	E1	
142	HEXACHLOROPHENE when included in Schedule 6	А	
143	HEXYLOXYETHANOL	A, G3, E2, S1	
144	HYDRAZINE	A, G1, G3, E2, R1, S1	
145	HYDROCARBONS, liquid	A, G3	
146	HYDROCHLORIC ACID	A, G3, E2, S1	
147	HYDROCHLORIC ACID—when included in Schedule 5	A, G3	
148	HYDROFLUORIC ACID and admixtures that generate hydrofluoric acid—when included in Schedule 5	А	
149	HYDROFLUORIC ACID and admixtures that generate hydrofluoric acid—when included in Schedule 6 or 7	A, G3, E2, S5	
150	HYDROGEN PEROXIDE—more than 3% up to 20%	A, G3, E2, S1	
151	HYDROGEN PEROXIDE—more than 20%	A, G1, G3, G4, E2, S1	
152	HYDROQUINONE—when included in Schedule 2	А	
153	HYDROQUINONE—when included in Schedule 4 or 6	A, G2, G3, E2, R2, S1	
154	HYDROSILICOFLUORIC ACID—when included in Schedule 5	А	
155	HYDROSILICOFLUORIC ACID—when included in Schedule 6 or 7	A, G3, E2, S5	
156	2-HYDROXYETHYL METHACRYLATE	A, E1, S1	
157	HYDROXYETHYL-3,4-METHYLENEDIOXYANILINE	E1, S1	
158	IODINE (excluding salts, derivatives and iodophors)—2.5% or more for human external use	A, E2	
159	IODINE (excluding salts, derivatives and iodophors)—2.5% or more for other uses	A, E2, S1	
160	IODINE (excluding salts, derivatives and iodophors)—below 2.5%	А	
161	IODOPHORS	А	
162	ISOAMYL NITRITE	А	
163	ISOBUTYL NITRITE	А	
164	ISOCYANATES, free organic	A, E2, S1	
165	ISOEUGENOL	A, E1, S1	
166	ISOPHORONE	A, G3, E2, S1	

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Poison	s that must be labelled with first aid instructions	
Item	Column 1 Poison	Column 2 Statement code
167	KEROSENE	A, G3
168	LAURETH CARBOXYLIC ACIDS—leave-on or wash-off preparations above 5%	E1
169	LAURETH CARBOXYLIC ACIDS—other preparations above 5%	E1, S1
170	LAURYL ISOQUINOLINIUM BROMIDE	A, E1
171	LEAD COMPOUNDS—in hair cosmetics	А
172	LEAD COMPOUNDS—in other preparations	A, S1
173	LEMON OIL	A, G3
174	LEPTOSPERMUM SCOPARIUM OIL (manuka oil)	A, G1, G3
175	LIME OIL	A, G3
176	MAGNESIUM CHLORATE	А
177	MALATHION at 20% or less	A
178	MARJORAM OIL	A, G3
179	MELALEUCA OIL	A, G1, G3
180	MERCAPTOACETIC ACID	A, E1
181	MERCURIC CHLORIDE—for external therapeutic use	A
182	MERCURIC CHLORIDE—for other uses	A, G1, G3, E2, R2, S1
183	MERCURIC IODIDE	A, G1, G3, E2, R2, S1
184	MERCURIC NITRATE	A, G1, G3, E2, R2, S1
185	MERCURIC OXIDE	A, G1, G3
186	MERCURIC POTASSIUM IODIDE	A, G1, G3, E2, R2, S1
187	MERCURIC THIOCYANATE	A, G1, G3, E2, R2, S1
188	MERCUROCHROME	A
189	MERCUROUS CHLORIDE	А
190	MERCURY—metallic	А
191	MERCURY—organic compounds	A, S1
192	MERCURY—organic compounds in preparations for human external use	A
193	METALDEHYDE	A, E1, S1
194	METHANOL—above 10%	A, G3
195	METHANOL—10% or less	А
196	METHYLATED SPIRIT(S)	A, G3
197	METHYLATED SPIRIT(S)—when packed and labelled as a "biofuel" suitable for use in "spirit burners"	A, G3
198	METHYL ETHYL KETONE	A, G3
199	METHYL ETHYL KETONE OXIME	A, E1, S1
200	METHYL ETHYL KETONE PEROXIDE	A, G3, E2, S1
201	METHYLEUGENOL	A
202	METHYL ISOAMYL KETONE	A, G3

Poison	s that must be labelled with first aid instructions	
Item	Column 1 Poison	Column 2 Statement code
203	METHYL ISOBUTYL KETONE	A, G3
204	N-METHYL-2-PYRROLIDONE—when included in Schedule 5	A, G3, E1
205	N-METHYL-2-PYRROLIDONE—when included in Schedule 6	A, G3, E2
206	2-METHYLRESORCINOL	A, E1
207	METHYL SALICYLATE LIQUID when included in Schedule 5 or 6	A, G3, E1
208	MONOETHANOLAMINE—when included in Schedule 5	A, G3, E1
209	MONOETHANOLAMINE—when included in Schedule 6	A, G3, E2, S1
210	1,5-NAPHTHALENEDIOL	A, E1, S1
211	2,7-NAPHTHALENEDIOL	A, E1, S1
212	NAPHTHALENE	A, G1, G3
213	1-NAPHTHOL	A, E1, S1
214	NITRIC ACID	A, G3, E2, S1
215	NITROBENZENE	A, G3, E1, S1
216	3-NITRO-p-HYDROXYETHYLAMINOPHENOL	E1
217	NITROPHENOL	A, G3, E2, S1
218	NITROPRUSSIDES—in aerosols	A, G6, R1
219	NITROPRUSSIDES—in other preparations	A, G3
220	NITROUS OXIDE	А
221	NONOXINOL 9	A, E2
222	NUTMEG OIL	A, G3
223	OCTHILINONE	A, G3, E2, S1
224	OCTYL NITRITE	А
225	<i>N</i> -( <i>N</i> -OCTYL)-2-PYRROLIDONE—when included in Schedule 5	A, G3, E1
226	<i>N</i> -( <i>N</i> -OCTYL)-2-PYRROLIDONE—when included in Schedule 6	A, G3, E2
227	ORANGE OIL (bitter)	A, G3
228	OXALIC ACID	A, G3, E2, S1
229	PARAFORMALDEHYDE	A, G3, E2, R1, S1
230	PENNYROYAL OIL	A, G3
231	PERACETIC ACID—when included in Schedule 5	A, G3, E1, S1
232	PERACETIC ACID—when included in Schedule 6	A, G3, E2, S1
233	PETROL	A, G3, R1
234	2-PHENOXYETHANOL	A, E1
235	PHENOL when included in Schedule 6	A, E1
236	PHENOLS—25% and less	A, G3, E2, S3
237	PHENOLS—above 25%	A, G3, E2, S4
238	PHENOLS—in pressurised spray packs	A, E1
239	PHENOXYMETHYL OXIRANE	A, E1

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Item	Column 1 Poison	Column 2 Statement code
240	PHENYLENEDIAMINES including alkylated, arylated, halogenated and nitro derivatives—in hair dyes	A, E1
241	PHENYLENEDIAMINES including alkylated, arylated, halogenated and nitro derivatives—in preparations other than hair dyes	A, G1, G3, E1, S1
242	PHENYL METHYL KETONE as such, or in preparations of similar viscosity	A, G3, E1
243	PHENYL METHYL PYRAZOLONE	A, S1
244	<i>N,N</i> -BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE -2,5-DIMETHANAMINE	A, E2, S1
245	<i>N,N</i> -BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE -2,6-DIMETHANAMINE	A, E2, S1
246	o-PHENYLPHENOL	A, G3, E2, S1
247	o-PHENYLPHENOL—in pressurised spray packs	A, G6, E2, S1
248	PHOSPHONIC ACID	A, G3, E2, S1
249	PHOSPHONIC ACID—neutralised to pH 6 (approx)	A
250	PHOSPHONIC ACID—in spray packs	A, E2, S1
251	PHOSPHORIC ACID	A, G3, E2, S1
252	PHOSPHORUS, YELLOW	A, G1, G3, E2, R2, S
253	o-PHTHALALDEHYDE—when included in Schedule 5	A, E1
254	o-PHTHALALDEHYDE—when included in Schedule 6	A, G3, E2, S1
255	PICRAMIC ACID including its salts (excluding other derivatives)	A, E1
256	PICRIC ACID	A, G1, G3, E2, R1, S
257	POLIHEXANIDE	E1
258	POLYETHANOXY (15) TALLOW AMINE	A, E2, S1
259	POLY(OXY-1,2-ETHANEDIYL), A -[2-[(2-HYDROXYETHYL)AMINO]-2-OXOETHYL]- A -HYDROXY-,MONO-C13-15-ALKYL ETHERS	A, E1
260	POTASSIUM BROMATE	А
261	POTASSIUM CHLORATE	А
262	POTASSIUM CYANATE	A, E1, S1
263	POTASSIUM HYDROXIDE	A, G3, E2, S1
264	POTASSIUM METABISULPHITE	А
265	POTASSIUM NITRITE—when included in Schedule 7	A, G1, G3
266	POTASSIUM NITRITE—when included in Schedule 5 or 6	A, G3
267	POTASSIUM PEROXOMONOSULFATE TRIPLE SALT— when included in Schedule 5	A, G3, E1
268	POTASSIUM PEROXOMONOSULFATE TRIPLE SALT— when included in Schedule 6	A, G3, E2, S1
269	POTASSIUM PERSULFATE	A, G3, E2
270	POTASSIUM SULFIDE	A, G3, E2, S1

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Poison	s that must be labelled with first aid instructions	
Item	Column 1 Poison	Column 2 Statement code
271	PROPIONIC ACID	A, G3, E1, S1
272	n-PROPYL ALCOHOL	A, E1
273	D-PULEGONE	A, G3
274	PYRITHIONE ZINC	A, E1
275	QUATERNARY AMMONIUM COMPOUNDS except when separately specified—above 20%	A, G3, E2
276	QUATERNARY AMMONIUM COMPOUNDS except when separately specified—20% and below	A, E2
277	QUATERNARY AMMONIUM COMPOUNDS except when separately specified—in pressurised spray packs	A, E2, G6
278	QUINOLINE	A, E1, S1
279	RESORCINOL	A, E2, S1
280	SAFROLE	A, G1, G3
281	SAGE OIL (Dalmatian)	A, G3
282	SASSAFRAS OIL	A, G1, G3
283	SELENIUM COMPOUNDS	A, G1, E1, S1
284	SILICOFLUORIDES—when included in Schedule 5	А
285	SILICOFLUORIDES—when included in Schedule 6	A, G1, G3, E2, S1
286	SILVER SALTS	A, E2
287	SODIUM ALUMINATE	A, G3, E2, S1
288	SODIUM BROMATE	A, G1
289	SODIUM CHLORATE	А
290	SODIUM DIACETATE	A, G3, E2, S1
291	SODIUM DICHLOROISOCYANURATE	A, G3, E1, S1
292	SODIUM DODECYLBENZENE SULFONATE	A, G3, E2, S1
293	SODIUM HYDROGEN SULFATE	A, G3, E1, S1
294	SODIUMHYDROSULFITE	A, G3, E2, S1
295	SODIUM HYDROXIDE	A, G3, E2, S1
296	SODIUM LAURETH-6 CARBOXYLATE	А
297	LAURYL SULFATE SALTS—leave-on or wash-off preparations above 5%	E1
298	LAURYL SULFATE SALTS—other preparations above 5%	E1, S1
299	SODIUM METABISULPHITE	A, G3
300	SODIUM NITRITE—when included in Schedule 7	A, G1, G3
301	SODIUM NITRITE—when included in Schedule 5 or 6	A, G3
302	SODIUM PERCARBONATE—when included in Schedule 5	A, G3, S1
303	SODIUM PERCARBONATE—when included in Schedule 6	A, G3, E2, S1
304	SODIUM PERSULFATE	A, G3, E2
305	SODIUM STANNATE	A, E1
306	SODIUM SULFIDE	A, G3, E2, S1

Poison	s that must be labelled with first aid instructions	
Item	Column 1 Poison	Column 2 Statement code
307	SODIUM TRICHLOROACETATE	А
308	STRYCHNINE	A, G1, G2, G3, R2
309	STYRENE	A, G3, S1, E1
310	SULCOFURON	А
311	SULFAMIC ACID	A, G3, E2, S1
312	SULFURIC ACID	A, G3, E2, S1
313	TERPENES, chlorinated	A, G3
314	TETRACHLOROETHANE	A, G3, E1, R1, S1
315	TETRACHLOROETHYLENE	A, G3, E2, R1, S1
316	THIOUREA	А
317	THUJONE	A, G3
318	THYME OIL	A, G3
319	o-TOLIDINE	А
320	TOLUENE—above 75%	A, G3, E1, R1, S1
321	TOLUENE—75% and below	A, G3
322	TOLUENE—in pressurised spray packs	А
323	TOLUENEDIAMINES—in hair dyes	A, E1
324	TOLUENEDIAMINES—in other preparations	A, G1, G3, E1, S1
325	TRICHLOROACETIC ACID	A, G3, E2, S1
326	TRICHLOROACETIC ACID ALKALI SALTS	А
327	1,1,1-TRICHLOROETHANE	A, G3, E1, R1, S1
328	TRICHLOROETHYLENE	A, G3, E1, R1, S1
329	TRICHLOROISOCYANURIC ACID	A, G3, E1, S1
330	TRIETHYL PHOSPHATE	A, E1
331	TRIFLUOROMETHANESULFONIC ACID	A, G3, E2
332	TRIISOPROPANOLAMINE LAURYL ETHER SULFATE	A, E1, S1
333	TROLAMINE	A, G3, E1, S1
334	TURPENTINE (mineral)	A, G3
335	TURPENTINE OIL (vegetable)	A, G3, E2
336	VINYL ACETATE MONOMER	A, R1
337	WHITE SPIRIT	A, G3
338	XYLENE—above 75%	A, G3, E1, R1, S1
339	XYLENE—75% and below	A, G3
340	XYLENE—in pressurised spray packs	A, G6, E1, S1
341	XYLENOLS in pressurised spray packs	A, E1
342	ZINC CHLORIDE	A, G3, E2, S1
343	ZINC SULFATE	A, G3, E2, S1

# Appendix F—Warning statements and general safety directions for poisons

Note: See sections 29 and 30, subsection 33(2) and section 42.

#### **1** Warning statements

For the purposes of the table in clause 4 of this Appendix and the table in clause 2 of Appendix L, the item number of an item of the following table represents the warning statement specified in column 1 of the item.

Note: See section 30.

Item	
Itterin	Column 1
	Warning statement
1	Highly corrosive.
2	Corrosive.
3	Corrosive liquid.
4	Strongly alkaline.
5	Irritant.
6	May cause cancer.
7	WARNING – Causes birth defects.
8	WARNING – May be fatal to children.
9	Can be fatal to children if sucked or swallowed.
10	May produce severe burns.
11	WARNING – Vapour may be harmful.
12	Vapour is harmful to health on prolonged exposure.
13	May be fatal if inhaled, swallowed or absorbed through skin.
14	Dust will irritate and burn eyes, nose and skin.
15	Liquid will cause burns.
16	Forms dangerous gas near radiators or naked flames.
17	Contact with eyes even for short periods can cause blindness.
18	Product will irritate the eyes, nose, throat and skin.
19	WARNING – Skin contact may be dangerous. Take every precaution to avoid contact – wash off after spillage and after use.
20	May give off dangerous gas if mixed with other products.
21	WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.
22	Highly reactive oxidising chlorine compound.
23	May cause fire or explosion.
24	For external washing only. Rinse skin thoroughly after use.
25	Do not use on broken skin. Wash hands thoroughly after use.

Warni	ng statements	
Item	Column 1 Warning statement	
26	(Powder) (and) (concentrated solutions) are dangerous if swallowed.	
27	Not for therapeutic use.	
28	(Over) (Repeated) exposure may cause sensitisation.	
29	If congestion persists, consult your doctor or pharmacist.	
30	WARNING – Do not use on face or on anal or genital areas.	
31	WARNING – Do not use on face or on anal or genital areas except on doctor's advice.	
32	This preparation should be part of an overall treatment plan regularly assessed with your doctor.	
33	Do not take for periods longer than four weeks except on medical advice.	
34	WARNING – This medication may be dangerous when used in large amounts or for a long time (period).	
35	CAUTION – This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. Prolonged use without medical supervision could be harmful. or	
	CAUTION – This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. Prolonged or excessive use without medical supervision could be harmful.	
36	For use under medical supervision only.	
37	Consult a doctor before giving this medication to children or teenagers with chicken pox, influenza or fever.	
38	CAUTION – Do not use for children under 2 years unless a doctor has told you to.	
39	This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.	
40	This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.	
41	Do not give to children under 12 years of age. Do not use beyond 48 hours or in pregnancy or lactation except on doctor's advice.	
42	WARNING – Overuse may stain the skin or mouth.	
43	Use of this product is not necessary in areas supplied with fluoridated water.	
44	WARNING – May be dangerous, particularly to children, if you use large amounts on the skin, clothes or bedding or on large areas of the body, especially if you keep using it for a long time.	
45	<ul> <li>WARNING – If a pigmented spot or mole has recently become darker, changed colour, become enlarged or itchy, or bleeds, do not use this product, see your doctor immediately. Do not use on children. Do not use near the eyes. Mild irritation may occur; stop use if it becomes severe. If fading is not evident in three months, seek doctor's advice.</li> </ul>	
46	WARNING – Contains (name of substance) which causes birth defects in laboratory animals. Women of child bearing age should avoid contact with (name of substance).	
47	WARNING – This product contains (name of substance) which causes birth defects in certain laboratory animals. Women of child bearing age are advised not to mix, load or spray this product. They should keep out of crops being sprayed.	
48	WARNING – This product forms cyhexatin which causes birth defects in certain laboratory animals. Women of child bearing age are advised not to mix, load or spray this product. They should keep out of crops being sprayed.	

Appendix F Warning statements and general safety directions for poisons

Clause	1
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Warni	ng statements		
Item	Column 1 Warning statement		
49	WARNING – Do not mix with other medication except on veterinarian's advice.		
50	Unless adequately fired, utensils glazed with this preparation must not be used as containers for food or beverages; to do so may cause lead poisoning.		
51	Irritant to skin, eyes, mucous membranes and upper respiratory tract.		
52	Breathing vapour or spray mist is harmful and may cause an asthma-like reaction.		
53	CAUTION – (Name of substance) should not be used by pregnant women.		
54	Seek medical advice before first course of treatment.		
55	Keep from eyes, lips, mouth and sensitive areas of the neck. If excessive swelling, irritation, redness or peeling occurs, discontinue use. If these persist, consult a physician. Avoid excessive exposure to sunlight and other sources of ultra violet light.		
56	WARNING – Can cause elevated blood pressure and interact adversely with other medication.		
57	Not to be applied to infants under 12 months of age unless on doctor's advice.		
58	Highly reactive oxidising bromine and chlorine compound.		
59	May cause allergy.		
60	Do not mix with detergents or other chemicals.		
61	WARNING - Can react with other medicines. Ask your doctor or pharmacist before taking.		
62	Do not use if pregnant.		
63	See a doctor if you are pregnant or diabetic.		
64	See a doctor (or) (dentist) if no better after (Insert number of days as per approved Product Information) days.		
65	If getting better, keep using for (Insert number of days as per approved Product Information) days.		
66	See a doctor if problem returns.		
67	Do not use if pregnant or likely to become pregnant.		
68	If symptoms persist beyond 5 days consult a doctor (or) (dentist).		
69	If symptoms recur within two weeks of completing the course, consult a doctor.		
70	Use only under medical supervision if you are taking other medicines.		
71	Do not use during the last three months of pregnancy.		
72	Do not use in the eyes.		
73	Do not use for acne.		
74	Do not use under waterproof bandages unless a doctor has told you to.		
75	Do not use for more than 7 days unless a doctor has told you to.		
76	Do not become pregnant during use or within (Insert number of months as per approved Product Information) month(s) of stopping treatment.		
77	WARNING - May cause birth defects.		
78	Attacks skin and eyes.		
79	Will irritate eyes.		
80	WARNING: Do not attempt to refill burner while it is in use or still warm; it could lead to serious burn injury.		

Warni	ng statements
Item	Column 1
	Warning statement
81	(Intentionally blank)
82	(Intentionally blank)
83	This paint is dangerous to health, even when dry.
	For industrial use only.
	Do not use on toys or furniture.
	Do not use on, in or around the home.
84	Breathing the vapour is dangerous.
	Provide adequate ventilation during application.
	Do not use in the presence of a naked flame.
	Do not smoke.
85	This paint contains lead and is dangerous to health, even when dry.
	For industrial use only.
	Do not use on toys or furniture.
	Do not use for painting any building or fixed structure.
	Do not use where contact with food or drinking water is possible.
86	This tinter contains lead.
	Do not add to any paint which is for application to any toy, furniture, building (interior or
	exterior), fixed structure or to anything which may contact food or drinking water.
87	(Insert brand name) remains in the body for many months after treatment has stopped. Do not become pregnant or father a child before consulting your doctor.
88	This product is not recommended for dyeing eyelashes or eyebrows. To do so may be
	injurious to the eye.
89	Application to skin may increase sensitivity to sunlight.
90	This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.
91	CAUTION – Total iodine intake may exceed recommended level when taking this preparation.
92	WARNING - Contains iodine - do not take when pregnant except on physician's advice.
93	Causes severe burns, which are not likely to be immediately painful or visible.
94	WARNING – Contains nitrite. Substitution for table or cooking salt may be dangerous, particularly for young children.
95	CAUTION – Do not use for children under 12 years unless a doctor has told you to.
96	CAUTION – This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. If symptoms persist or recur within two weeks, consult a doctor.
97	Adults: Keep to the recommended dose. Don't take this medicine for longer than a few days at a time unless advised to by a doctor.
98	Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor.
99	If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26; New Zealand 0800 764 766) or go to a hospital straight away even if you feel well because of the risk of delayed, serious liver damage.

Appendix F Warning statements and general safety directions for poisons

Clause 2
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Warning statements		
Item	Column 1 Warning statement	
100	Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.	
101	Don't use [this product/name of the product]:	
	If you have a stomach ulcer.	
	In the last 3 months of pregnancy. [This statement may be omitted in preparations used exclusively for the treatment of dysmenorrhoea.]	
	If you are allergic to (name of substance) or anti-inflammatory medicines.	
102	Unless a doctor has told you to, don't use [this product/name of the product]:	
	For more than a few days at a time.	
	With other medicines containing aspirin or other anti-inflammatory medicines.	
	If you have asthma.	
	In children under 12 years of age.	
	In children 12-16 years of age with or recovering from chicken pox, influenza or fever.	
	If you are pregnant.	
103	See a doctor before taking [this product/name of the product] for thinning the blood or for your heart. [This statement may be omitted in products for inhibition of platelet aggregation or with additional active ingredients.]	
104	Unless a doctor has told you to, don't use [this product/name of the product]:	
	For more than a few days at a time.	
	With other medicines containing (name of substance) or other anti-inflammatory medicines.	
	If you have asthma.	
	If you are pregnant. [This statement may be omitted in preparations used exclusively for the treatment of dysmenorrhoea.]	
105	Do not use on the bedding or clothing of infants or in the bedrooms of children 3 years of age or less.	
106	Contains formaldehyde.	
107	Not recommended for children under twelve years of age.	
108	Breathing of solder fumes is harmful and may cause asthma or sensitisation.	
109	See your healthcare provider if you consider that you may be at risk of a Sexually Transmitted Infection (STI).	
110	See a doctor if you plan to become pregnant, or are breastfeeding or plan to breastfeed.	
111	Do not use if breastfeeding or planning to breastfeed.	
112	WARNING – May cause irreversible nerve damage if inhaled.	

#### 2 Safety directions—general

For the purposes of the table in clause 4, the item number of an item of the following table represents the safety direction specified in column 1 of the item. Note: See section 29.

<u>Salety</u> Item	Safety directions		
Item	Column 1 Safety direction		
1	Avoid contact with eyes.		
2	Attacks eyes - protect eyes when using.		
3	Wear eye protection when mixing or using.		
4	Avoid contact with skin.		
5	Wear protective gloves when mixing or using.		
6	Wash hands after use.		
7	Wash hands thoroughly after use.		
8	Avoid breathing dust (or) vapour (or) spray mist.		
9	Use only in well ventilated area.		
10	Ensure adequate ventilation when using.		
11	No smoking.		
12	Do not allow product to come into contact with other chemicals, especially acids.		
13	Do not allow product to come into contact with combustible materials such as paper, fabric, sawdust or kerosene.		
14	Do not allow to get damp.		
15	Store under cover in a dry, clean, cool, well ventilated place away from sunlight.		
16	Store and transport in an upright container.		
17	Do not mix with other chemicals.		
18	Do not mix with different types of chlorinating chemicals.		
19	Use clean containers for dispensing.		
20	Mix with water only.		
21	Do not add water to product - add product to water, but in case of fire drench with water		
22	In case of spillage flush with large quantities of water.		
23	Keep away from heat, sparks and naked flames.		
24	Avoid contact of the crystals or strong solutions with the eyes, mouth, nose and other mucous membranes.		
25	Avoid contact with food.		
26	Avoid contact with clothing.		
27	Wear a positive-pressure air-supplied full-face respirator whilst spraying and until spray mist has been effectively dispersed.		
28	Do not mix with hot water.		
29	Obtain a supply of calcium gluconate gel.		
30	(Intentionally blank)		
31	Do not use on broken skin.		
32	Do not use under occlusive dressing.		
33	Mix strictly according to instructions.		
34	May cause fire if it comes into contact with other chemicals, paper or other flammable materials.		
35	Wash gloves thoroughly, immediately after use.		
36	Protect cuticles with grease or oil.		

Appendix F Warning statements and general safety directions for poisons

Clause 3

Safety directions		
Item	Column 1 Safety direction	
37	Avoid breathing solder fumes.	
38	Do not intentionally inhale contents.	

#### **3** Poisons information centre contact information in statements

A statement required for a poison that includes a reference to a Poisons Information Centre must include:

- (a) the telephone number that is appropriate to the country or countries in which the poison is to be supplied; and
- (b) immediately following the reference to a Poisons Information Centre:
  - (i) the national telephone number for the Poisons Information Centre in Australia (13 11 26); or
  - (ii) the telephone number for another poisons information centre:
    - (A) that is attended by adequately trained staff for 24 hour emergency poisons information; and
    - (B) calls to which are logged and submitted for incorporation into the official collection of poisoning data.
- Note: For subparagraph (b)(ii), in 2022 the Poisons Information Centre telephone number in New Zealand was 0800 764 766.

#### 4 Poisons that must be labelled with warning statements and safety directions

- For the purposes of subsections 29(1) and 30(1), and subject to subclauses (2) and (3), the following are required for a poison specified in column 1 of an item of the following table:
  - (a) the warning statement represented by each item number specified in column 2 of the item;
  - (b) the safety direction represented by each item number specified in column 3 of the item.
- (2) A warning statement or safety direction required for a poison must:
  - (a) be completed or modified for its use in relation to that poison if the statement or direction indicates that such completion is required or such modification is appropriate; and
  - (b) if the statement includes a reference to a Poisons Information Centre comply with clause 3.
  - Note: For paragraph (a), for example:
    - (a) a statement or direction may require completion by including the name of the poison; and
    - (b) a statement or direction may indicate that modification is appropriate by including different options for the text, or by stating that certain text is not needed in certain circumstances.
- (3) If more than one statement or direction is required for a poison, the statements and directions may be combined to form simple sentences (if appropriate).

Item	Column 1 Poison	Column 2 Warning statement item number	Column 3 Safety direction item number
1	ACETIC ACID in concentrations of 80% or more <b>except</b> when included in Schedule 2	2	1, 4, 8
2	ACETIC ANHYDRIDE	2	1, 4, 8
3	ACETONE in concentrations greater than 75%		1, 4, 8
4	ACITRETIN—for oral use	7, 62, 76	
5	ACITRETIN—for topical use	62, 77	
6	ADAPALENE for topical use	62, 77	
7	ALCLOMETASONE when included in Schedule 3	38, 72, 73, 74, 75	
8	ALKALINE SALTS	4	1,4
9	AMBRISENTAN	7, 62, 76	
10	AMINES used as curing agents for epoxy resins		1, 3, 4, 5, 8
11	2-AMINO-6-CHLORO-4-NITROPHENOL	28	
12	4-AMINO-m-CRESOL	28	
13	2-AMINO-5-ETHYLPHENOL	21	
14	4-AMINO-2-HYDROXYTOLUENE	28	
15	4-AMINO-3-NITROPHENOL	28	
16	2,2'-[(4-AMINO-3-NITROPHENYL)IMINO] BISETHANOL	28	
17	<i>m</i> -AMINOPHENOL	28	4, 8
18	<i>p</i> -AMINOPHENOL	28	
19	AMMONIA/AMMONIUM HYDROXIDE in concentrations greater than 20% ammonia <b>except</b> in smelling salts	4	1, 4, 8
20	AMMONIUM PERSULFATE	5, 21, 25	1, 5, 23, 33, 34
21	ANHYDRIDES, organic acid, for use as curing agents for epoxy resins		1, 3, 4, 5, 8
22	ANILINE	13	1, 4, 8
23	ANTIHISTAMINES not separately specified in this Appendix <b>except</b> the following:	39 or 40	
	(a) dermal, ocular, parenteral and paediatric preparations;		
	(b) oral preparations of astemizole, azelastine, bilastine, cetirizine, desloratadine, fexofenadine, loratadine, or terfenadine;		
	(c) nasal preparations of azelastine or olopatadine;		
	(d) preparations for the treatment of animals		
24	ARBUTIN when included in Schedule 6	45	1, 4
25	AROMATIC EXTRACT OILS		1, 3, 4, 5, 6
26	ASPIRIN—for inhibition of platelet aggregation	36	

Clause 4
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Item	Column 1 Poison	Column 2 Warning statement item number	Column 3 Safety direction item number
27	ASPIRIN—in sustained release preparations containing 650 mg or more of aspirin	36	
28	ASPIRIN—in other preparations	101, 102, 103	
29	ASTEMIZOLE	61	
30	ASTODRIMER SODIUM—for the treatment and relief of bacterial vaginosis	63, 64, 69, 75, 109, 110	
31	ASTODRIMER SODIUM—for the prevention of recurrent bacterial vaginosis	63, 75, 109, 110	
32	AZADIRACHTA INDICA including its extracts and derivatives when included in Schedule 6	67	
33	AZELAIC ACID		1, 4
34	AZOCYCLOTIN	48	
35	AZO DYES (derivatives by diazotisation)	6	5
36	BASIC RED 76		5
37	BENOMYL	46	
38	BENZENE	12	1, 4, 9
39	1,2-BENZENEDIOL (Catechol)	51, 59	1, 4, 8
40	BENZOYL PEROXIDE—when included in Schedule 2	55	
41	BENZOYL PEROXIDE—when included in Schedule 5		1, 4, 8
42	BERGAMOT OIL	89	
43	BERYLLIUM		1, 4, 8
44	BEXAROTENE—for human use	7, 62, 76	
45	BEXAROTENE—for topical use	62, 77	
46	BIFLUORIDES (including ammonium, potassium and sodium salts)—when included in Schedule 5	1, 4	
47	BIFLUORIDES (including ammonium, potassium and sodium salts)—when included in Schedule 6 or 7	1, 17, 93	1, 3, 4, 5, 8, 29, 35
48	1,3-BIS(2,4-DIAMINOPHENOXY)PROPANE	28, 79	1
49	BIS-ISOBUTYL PEG/PPG-20/35/AMODIMETICONE COPOLYMER		1
50	BITHIONOL for the treatment of animals		1, 4, 8
51	BORIC ACID when used in Schedule 5	25, 26	
52	BORON TRIFLUORIDE (including mixtures that generate boron trifluoride)—when included in Schedule 5	2	1, 4
53	BORON TRIFLUORIDE (including mixtures that generate boron trifluoride)—when included in Schedule 6 or 7	1, 17, 93	1, 3, 4, 5, 8, 29, 35
54	BOSENTAN	7, 62, 76	
55	BROMOFORM	1, 4, 8	
56	2-BUTOXY-2'-THIOCYANODIETHYL ETHER		1, 4, 8

Poisons that must be labelled with warning statements and safety directions			
Item	Column 1 Poison	Column 2 Warning statement item number	Column 3 Safety direction iter number
57	2-BUTOXYETHANOL and its acetates		1, 4, 8
58	n-BUTYL ALCOHOL	5	2, 4, 8
59	CAMPHOR—in block, ball, disc, pellet or flake form, enclosed in a device which, in normal use, prevents removal or ingestion of its contents	9	
60	CAMPHOR—in other forms	9	1
61	CANNABIDIOL when included in Schedule 3	67, 111	
62	CARBAMIDE PEROXIDE—more than 9% up to 30%	5	1
63	CARBAMIDE PEROXIDE—more than 30% up to 60%	5	2
64	CARBAMIDE PEROXIDE—more than 60%	2	2,4
65	CARBON DISULFIDE	12	1, 4, 8, 9, 23
66	CARBON TETRACHLORIDE	12	1, 4, 8, 9
67	CASSIA OIL		4
68	CHLORINATING COMPOUNDS—in household cleaning or bleaching preparations	20	
69	CHLORINATING COMPOUNDS—in preparations containing less than 10% of available chlorine	11	1, 4, 10
70	CHLORINATING COMPOUNDS—in liquid preparations containing 10% or more of available chlorine	3, 18	1, 4, 6, 8, 10, 15, 16, 17, 18 19, 20, 22, 26
71	CHLORINATING COMPOUNDS—in dry preparations containing 10% or more of available chlorine	10, 18, 22, 23	1, 4, 8, 12, 13 14, 15, 16, 17 18, 19, 20, 21 22, 26
72	CHLORINATING COMPOUNDS—in dry preparations containing 10% or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5, Division 5.1: Oxidising substances, as specified in the Australian Dangerous Goods Code	10, 18, 22	1, 4, 8, 12, 13 14, 15, 16, 17 18, 19, 20, 21 22, 26
73	CHLORINATING COMPOUNDS—in compressed block or tablets containing 10% or more of available chlorine <b>except</b> in preparations for use in toilet cisterns only, containing 15 g or less of trichloroisocyanuric acid	10, 22, 23	12, 13, 14, 15 17, 18, 19, 21
74	CHLORINATING COMPOUNDS—in other compressed blocks or tablets containing 10% or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5, Division 5.1: Oxidising substances, as specified in the Australian Dangerous Goods Code <b>except</b> in preparations for use in toilet cisterns only, containing 15 g or less of trichloroisocyanuric acid	10, 22	12, 13, 14, 15 17, 18, 19, 21
75	CHLOROACETAMIDE	28	4

Item	Column 1 Poison	Column 2 Warning statement item number	Column 3 Safety direction item number
76	2-CHLORO-6-(ETHYLAMINO)-4-NITROPHENOL	28	4
77	CHLOROFORM when included in Schedule 6		1, 4, 8
78	alpha-CHLOROHYDRIN	13, 51	1, 4, 8, 9
79	CHROMATES (including dichromates) of alkali metals or ammonia		1, 4, 8
80	CHROMIUM TRIOXIDE	2, 14, 15, 23	1, 4, 8, 13
81	CIMETIDINE when included in Schedule 3	70, 96	
82	CINNAMON BARK OIL		4
83	CLOBETASONE when included in Schedule 3	72, 73, 74, 75, 95	
84	CLOTRIMAZOLE in vaginal preparations when included in Schedule 3	54, 63, 64, 66	
85	CLOVE OIL		1
86	CYANIDES when included in Schedule 7	13	4, 8
87	CYANURIC ACID		1, 4, 8
88	CYCLOHEXANONE PEROXIDE		1, 4, 8
89	CYCLOSILAZANES, DI-ME, ME HYDROGEN, POLYMERS WITH DI-ME, ME HYDROGEN SILAZANES, REACTION PRODUCTS WITH 3-(TRIETHOXYSILYL)-1-PROPANAMINE (CAS 475645-84-2)	2, 10, 78	1, 4, 5, 35
90	CYCTEAMINE		1
91	1-DEOXY-1-(METHYLAMINO)-D-GLUCITOL N-COCO ACYL DERIVATIVES	79	1
92	4,4-DIAMINODIPHENYLMETHANE (methylene dianiline)		1, 4, 8
93	2,4-DIAMINOPHENOXYETHANOL	28, 79	1,4
94	o-DICHLOROBENZENE		1, 4, 8
95	para-DICHLOROBENZENE		1,4
96	DICHLOROETHYLENE		1, 4, 8
97	DICHLOEOETHYL ETHER		1, 4, 8
98	DICHLOROISOCYANURATES—in household cleaning or bleaching preparations	20	
99	DICHLOROISOCYANURATES—in preparations containing less than 10% of available chlorine	11	1, 4, 10
100	DICHLOROISOCYANURATES—in liquid preparations containing 10% or more of available chlorine	3, 18	1, 4, 6, 8, 10, 15, 16, 17, 18, 19, 20, 22, 26
101	DICHLOROISOCYANURATES—in dry preparations containing 10% or more of available chlorine	10, 18, 22, 23	1, 4, 8, 12, 13, 14, 15, 16, 17,

Item	Column 1 Poison	Column 2 Warning statement item number	Column 3 Safety direction item number
			18, 19, 20, 21, 22, 26
102	DICHLOROISOCYANURATES—in dry preparations containing 10% or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5, Division 5.1: Oxidising substances, as specified in the Australian Dangerous Goods Code	10, 18, 22	1, 4, 8, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 26
103	DICHLOROISOCYANURATES—in anti-bacterial tablets containing 2.5 g or less of sodium dichloroisocyanurate	60	
104	DICHLOROISOCYANURATES—in other compressed blocks or tablets containing 10% or more of available chlorine <b>except</b> in preparations containing 21 g or less of sodium dichloroisocyanurate for use in toilet cisterns only	10, 22, 23	12, 13, 14, 15, 17, 18, 19, 21
105	DICHLOROISOCYANURATES—in other compressed blocks or tablets containing 10% or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5, Division 5.1: Oxidising substances, as specified in the Australian Dangerous Goods Code <b>except</b> in preparations containing 21 g less of sodium dichloroisocyanurate for use in toilet cisterns only	10, 22	12, 13, 14, 15, 17, 18, 19, 21
106	DICHLOROISOCYANURATES—in other compressed blocks or tablets containing 10% or more of available chlorine in preparations containing 5 g or less of sodium dichloroisocyanurate for use in toilet bowls only—during storage	10, 22, 23	12, 13, 14, 15 17, 18, 21
107	DICHLOROISOCYANURATES—in other compressed blocks or tablets containing 10% or more of available chlorine in preparations containing 5 g or less of sodium dichloroisocyanurate for use in toilet bowls only—during use	5	1, 4, 7, 12
108	DICHLOROISOCYANURATES—in other compressed blocks or tablets containing 10% or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5, Division 5.1: Oxidising substances, as specified in the Australian Dangerous Goods Code in preparations containing 5 g or less of sodium dichloroisocyanurate for use in toilet bowls only—during storage	10, 22	12, 13, 14, 15, 17, 18, 21
109	DICHLOROISOCYANURATES—in other compressed blocks or tablets containing 10% or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5, Division 5.1: Oxidising substances, as specified in the Australian Dangerous Goods Code in preparations containing 5 g or	5	1, 4, 7, 12

Item	Column 1 Poison	Column 2 Warning statement item number	Column 3 Safety direction item number
	less of sodium dichloroisocyanurate for use in toilet bowls only—during use		
110	DICHLOROMETHANE (methylene chloride)—in paint or lacquer removers	12, 16	1, 4, 8, 11
111	DICHLOROMETHANE (methylene chloride)—other than in paint or lacquer removers		1, 4, 8, 25
112	DICLOFENAC	101, 104	
113	DIENESTROL	67	
114	DIETHANOLAMINE—when included in Schedule 5	5	1,4
115	DIETHANOLAMINE—when included in Schedule 6	2, 11, 18	1, 4, 8
116	DIETHYLTOLUAMIDE for human use	44	
117	DIETHYLENE GLYCOL MONOBUTYL ETHER	5	1, 4, 8, 9
118	5,6-DIHYDROXYINDOLINE	21, 28	, , , , , ,
119	2,6-DIMETHOXY-3,5-PYRIDINEDIAMINE	28	
120	DIMETHYLFORMAMIDE		1, 4, 8
121	4,4-DIMETHYL-1-CYCLOHEXENE-1-PROPANAL	5, 28	1, 2
122	3,7-DIMETHYL-2,6-OCTADIEN-1-OL	5	1,4
123	DIMETHYL SULFATE	2	1, 4, 8
124	DIMETHYL SULFOXIDE—when not packed and labelled for therapeutic use	27	1, 4, 5, 8
125	DIMETHYL SULFOXIDE—when packed and labelled for the treatment of animals	49	1, 4, 5, 8
126	DINITROCRESOLS (and their homologues) <b>except</b> when for therapeutic use		1, 4, 8
127	DINITROPHENOLS (and their homologues) <b>except</b> when for therapeutic use		1, 4, 8
128	DINOCAP	47	
129	DIOXANE		1, 4, 8
130	DIPHENOXYLATE when included in Schedule 3	39 or 40, 41	_, , , , ,
131	DISPERSE YELLOW 3	28	4
132	ECONAZOLE in vaginal preparations when included in Schedule 3	54, 63, 64, 66	
133	ENZALUTAMIDE	7, 67, 87	
134	EPHEDRINE in nasal preparations for topical use	29	
135	EPICHLOROHYDRIN	2	1, 4, 8
136	EPOXY RESINS, liquid		1, 3, 4, 5, 8
137	ETHER when included in Schedule 5 or 6		1, 4, 8
138	2-ETHOXYETHANOL	77	1, 4, 8
139	ETHOXYETHYLMERCURIC CHLORIDE		1, 1, 0
140	ETHYL BROMIDE		1, 4, 8
			Clause 4
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Poisons that must be labelled with warning statements and safety directions			
Item	Column 1 Poison	Column 2 Warning statement item number	Column 3 Safety direction iten number
141	ETHYLENE CHLOROHYDRIN		1, 4, 8
142	ETHYLENE GLYCOL MONOALKYL ETHERS and		1, 4, 8
143	their acetates <b>except</b> when separately specified ETHYLENE OXIDE		1 / 9
145		79	1, 4, 8 1
144	ETHYLHEXANEDIOL 2-ETHYLHEXANOIC ACID	53	1
145 146		33	1 4
	ETHYLMERCURIC CHLORIDE	28	1,4
147	ETHYL METHACRYLATE		4, 9, 23
148 149	ETRETINATE EUGENOL	7, 62, 76	1
		07	1
150	FAMOTIDINE when included in Schedule 2	96	
151	FENTEROL in metered aerosols	32	
152	FLUCONAZOLE in oral preparations when included in Schedule 3	64	
153	FLUORIDES (including silicofluorides) when included in Schedule 5 or 6 <b>except</b> when separately specified		1, 4
154	FORMALDEHYDE—in nail hardener cosmetics	106	1, 4, 8, 36
155	FORMALDEHYDE—in other preparations	106	1, 4, 8
156	FORMIC ACID		1, 4, 8
157	FURFURAL	5	1, 4
158	Glazing preparations containing LEAD COMPOUNDS	50	
159	GLUTARAL <b>except</b> when included in Schedule 2—25% or less	5, 59	1, 4, 5
160	GLUTARAL <b>except</b> when included in Schedule 2—more than 25%	3, 59	1, 4, 5, 8
161	GLYCOLIC ACID	79	1, 5, 6, 31
162	HC VIOLET 1	28	, , ,
1623	HEXACHLOROPHENE in preparations for skin cleansing purposes containing 3% or less of hexachlorophene	24	
164	HEXYLOXYETHANOL	2	1, 4, 8
165	HYDRAZINE		1, 4, 8
166	HYDROCHLORIC ACID—30% or less of HCl		1,4
167	HYDROCHLORIC ACID—more than 30% of HCl		1, 4, 8
1687	HYDROCORTISONE—for dermal use when included in Schedule 2 or 3	38, 72, 73, 74, 75	, , *
169	HYDROCORTISONE—for topical rectal use when included in Schedule 2 or 3	38, 75	
170	HYDROCYANIC ACID when included in Schedule 7	13	4, 8
171	HYDROFLUORIC ACID (including mixtures that generate hydrofluoric acid)—when included in Schedule 5	2	1, 4

Item	Column 1 Poison	Column 2 Warning statement item number	Column 3 Safety direction item number
172	HYDROFLUORIC ACID (including mixtures that generate hydrofluoric acid)—when included in Schedule 6 or 7	1, 17, 93	1, 3, 4, 5, 8, 29, 35
173	HYDROGEN PEROXIDE—more than 3% up to 10%	5	1
174	HYDROGEN PEROXIDE—more than 10% up to 20%	5	2
175	HYDROGEN PEROXIDE—more than 20%	2	2,4
176	HYDROQUINONE—when included in Schedule 2	45	
177	HYDROQUINONE— <b>except</b> when included in Schedule 2 or 4		1, 4
178	HYDROSILICOFLUORIC ACID (including mixtures that generate hydrosilicofluoric acid)—when included in Schedule 5	2	1, 4
179	HYDROSILICOFLUORIC ACID (including mixtures that generate hydrosilicofluoric acid)—when included in Schedule 6 or 7	1, 17, 93	1, 3, 4, 5, 8, 29, 35
180	2-HYDROXYETHYL METHACRYLATE	28	4
181	HYDROXYETHYL-3,4-METHYLENEDIOXYANILINE	28	
182	IBUPROFEN	101, 104	
183	IODINE—more than 20%		1, 4, 8
184	IODINE—in preparations for human internal therapeutic use containing 300 micrograms or more of iodine per recommended daily dose	91, 92	
185	IPRATROPIUM BROMIDE in metered aerosols	32	
186	ISOCYANATES (free organic)—when in paint	28, 52	1, 5, 8, 10, 27
187	ISOCYANATES (free organic)—other than in paint	28, 52	1, 4, 8
188	ISOEUGENOL	19, 28, 79	1, 4
189	ISOPRENALINE in metered aerosols	32	
190	ISOTRETINOIN—for human oral use	7, 62, 76	
191	ISOTRETINOIN—for topical use	62, 77	
192	LEAD COMPOUNDS—in hair cosmetics	25	
193	LEAD COMPOUNDS—when included in Schedule 6 preparations that are not hair cosmetics		1, 4, 8
194	LEFLUNOMIDE	7, 62, 87	
195	LEMON OIL	89	
196	LENALIDOMIDE	7, 62, 76	
197	LEVOCABASTINE—in eye or nasal preparations containing 0.5 mg/mL or less of levocabastine	62	
198	LEVOCABASTINE—in other preparations	62 and either 39 or 40	
199	LIME OIL	89	

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Item	Column 1 Poison	Column 2 Warning statement item number	Column 3 Safety direction iten number
200	LOPERAMIDE when included in Schedule 2	41	
201	MAGNESIUM CHLORATE		1,4
202	MEFENAMIC ACID	101, 104	
203	MERCAPTOACETIC ACID	5, 28	1, 31
204	MERCURIC THIOCYANATE		1,4
205	METACRESOLSULPHONIC ACID and formaldehyde condensation product for the treatment of animals		1, 4
206	METHANOL except in methylated spirit		1, 4, 8
207	METHOXAMINE in nasal preparations for topical use	29	
208	2-METHOXYETHANOL	77	1, 4, 8
209	METHYLATED SPIRIT(S) when packed and labelled as a "biofuel" suitable for use in "spirit burners"	80	
210	p-METHYLAMINOPHENOL	28	
211	METHYL CHLORIDE		1, 4, 8
212	METHYL ETHYL KETONE	5	1, 4, 8
213	METHYL ETHYL KETONE OXIME	5, 28	1, 4
214	METHYL ETHYL KETONE PEROXIDE	2	2, 3, 4, 6
215	METHYL ISOAMYL KETONE		1, 4, 8
216	METHYL ISOBUTYL KETONE		1, 4, 8
217	METHYL ISOTHIOCYANATE	5, 12	1, 4, 8
218	METHYL METHACRYLATE	28	4, 9, 23
219	METHYLCHLOROISOTHIAZOLINONE	28	
220	METHYLDIBROMO GLUTARONITRILE	28	1, 4, 7
221	METHYLENE BISTHIOCYANATE		1,4
222	METHYLEUGENOL		1,6
223	METHYLISOTHIAZOLINONE	28	
224	METHYLNORBORNYLPYRIDINE	59	
225	2-METHYLRESORCINOL		1
226	1-(BETA-METHYL SULPHONAMIDOETHYL)- 2-AMINO-3-N,N-DIETHYLAMINOBENZENE		1, 4, 8
227	MICONAZOLE in vaginal preparations when included in Schedule 3	54, 63, 64, 66	
228	MISOPROSTOL	53	
229	MONOETHANOLAMINE when included in Schedule 5	5	1,4
230	MONOETHANOLAMINE when included in Schedule 6	2, 11, 18	1, 4, 8
231	NAPHAZOLINE in nasal preparations for topical use	29	
232	NAPHTHALENE—in block, ball, disc, pellet or flake form, enclosed in a device which, in normal use, prevents removal or ingestion of its contents	9, 105	

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Poison: Item	s that must be labelled with warning statements and safety Column 1 Poison	Column 2 Warning statement item number	Column 3 Safety direction item number
233	NAPHTHALENE—in other forms	9, 105	1
234	1,5-NAPHTHALENEDIOL	28	1
235	2,7-NAPHTHALENEDIOL	28	1, 3
236	1-NAPHTHOL	28	1
237	NAPROXEN	101, 104	
238	NICOTINE except when in tobacco		1,4
239	NITRIC ACID—75% or less HNO <sub>3</sub>	2	1,4
240	NITRIC ACID—more than 75% HNO <sub>3</sub>	2	1, 4, 8
241	NITROBENZENE		1, 4, 8
242	3-NITRO-p-HYDROXYETHYLAMINOPHENOL	28	
243	NITROPHENOLS		1,4
244	NITROPRUSSIDES in aerosols	84	8
245	NITROUS OXIDE	112	38
246	NIZATIDINE when included in Schedule 2	96	
247	NORADRENALINE in metered aerosols	32	
248	NYSTATIN in vaginal preparations when included in Schedule 3	54, 63, 64, 65, 66	
249	ORANGE OIL (bitter)	89	
250	ORCIPRENALINE in metered aerosols	32	
251	OXALATES, metallic		4, 8
252	OXALIC ACID	2	4, 8
253	OXYMETAZOLINE in nasal preparations for topical use	29	
254	OXYQUINOLINE (including salts and derivatives) when prepared for internal use	33	
255	PAINT—first group paints	83	
256	PAINT—second group paints	84	
257	PALOVAROTENE	7, 62, 76, 111	
258	PARACETAMOL	97 and/or 98, 99, 100	
259	PENTACHLOROPHENOL		1, 4, 8
260	PERACETIC ACID	2	1, 4, 8
261	PERMANGANATES	2	24
262	2-PHENOXYETHANOL	5	1
263	PHENOL and any other homologue of phenol		1,4
264	PHENOL when included in Schedule 6	3, 51	2, 4, 8
265	PHENOLS		5
266	PHENOXYMETHYL OXIRANE	12, 28, 51	1, 3, 4, 5, 7, 8, 9

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Item	s that must be labelled with warning statements and safety Column 1 Poison	Column 2 Warning statement item number	Column 3 Safety direction item number
267	PHENYLENEDIAMINES including alkylated, arylated, halogenated and nitro derivatives—in hair dyes	21	
268	PHENYLENEDIAMINES including alkylated, arylated, halogenated and nitro derivatives—in preparations other than hair dyes	28	1, 4, 8
269	PHENYL METHYL PYRAZOLONE	28	4
270	PHENYLEPHRINE in nasal preparations for topical use	29	
271	POMALIDOMIDE	7, 62, 76	
272	<i>N,N</i> -BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HE PTANE-2,5-DIMETHANAMINE	5, 28	1, 4, 5, 10
273	o-PHENYLPHENOL except when in antiseptics		1, 4
274	PHENYLPROPANOLAMINE	56	
275	PHENYTOIN in pastes for the treatment of horses	9	
276	PHOSPHONIC ACID		1, 4
277	PHOSPHORIC ACID		1, 4
278	PHOSPHORUS (yellow)	2	1, 4
279	<i>o</i> -PHTHALALDEHYDE—when included in Schedule 5	51, 52, 59	1, 4, 5, 8, 10
280	o-PHTHALALDEHYDE—when included in Schedule 6	51, 52, 59	2, 4, 5, 8, 10
281	PICRAMIC ACID including its salts (excluding other derivatives)	28	5
282	PICRIC ACID (more than 20%)		1, 4
283	PODOPHYLLIN—in preparations specifically for use on anal or genital area	36	
284	PODOPHYLLIN—in other liquid preparations when included in Schedule 2 or 3	31	
285	PODOPHYLLIN—in other solid or semi-solid preparations when included in Schedule 2	30	
286	PODOPHYLLOTOXIN—in preparations specifically for use on anal or genital area	36	
287	PODOPHYLLOTOXIN—in other liquid preparations when included in Schedule 2 or 3	31	
288	PODOPHYLLOTOXIN—in other solid or semi-solid preparations when included in Schedule 2	30	
289	POLIHEXANIDE	28	1, 4, 8
290	POLYETHANOXY (15) TALLOW AMINE		1, 4
291	POLY(OXY-1,2-ETHANEDIYL), <i>A</i> -[2-[(2-HYDROXYETHYL)AMINO] -2-OXOETHYL]- A -HYDROXY-,MONO-C <sub>13-15</sub> -ALKYL ETHERS	5, 88	1, 5
292	POTASSIUM HYDROXIDE—in preparations containing 0.5% or less of potassium hydroxide	5	1, 4, 6

# Clause 4

Poison	s that must be labelled with warning statements and safety	directions	
Item	Column 1 Poison	Column 2 Warning statement item number	Column 3 Safety direction item number
293	POTASSIUM HYDROXIDE—in solid preparations containing more than 0.5% of potassium hydroxide	2, 10, 78	3, 5, 28
294	POTASSIUM HYDROXIDE—in liquid preparations containing more than 0.5% of potassium hydroxide	2, 10, 78	3, 5
295	POTASSIUM PERSULFATE	5, 21, 25	1, 5, 23, 33, 34
296	POTASSIUM SULFIDE	2	1,4
297	PROPIONIC ACID when included in Schedule 6	2	1, 4
298	n-PROPYL ALCOHOL	5	1, 9
299	QUININE	28	
300	QUINOLINE	79	1, 4
301	RANITIDINE when included in Schedule 2	96	
302	RESORCINOL	19, 28, 79	1, 3, 4
303	ROSIN	108	37
304	SAFROLE—in preparations for therapeutic use		1
305	SAFROLE—other than for therapeutic use		1,4
306	SALBUTAMOL in metered aerosols or in dry powder formulations	32	
307	SALICYLAMIDE	34 or 35	
308	SASSAFRAS OIL—in preparations for therapeutic use		1
309	SASSAFRAS OIL-other than for therapeutic use		1,4
310	SELENIUM COMPOUNDS <b>except</b> when for therapeutic use (human or animal)		1, 4, 8
311	SILVER in smoking deterrents	42	
312	SITAXENTAN	7, 62, 76	
313	SODIUM ALUMINATE	2	1, 4
314	SODIUM CHLORATE		1, 4
315	SODIUM DODECYLBENZENE SULFONATE	79	1
316	SODIUM FLUORIDE in preparations for human ingestion when included in Schedule 2	43	
317	SODIUM HYDROGEN SULFATE		1, 4, 8
318	SODIUM HYDROSULFITE (more than 50%)	5, 26	1, 4, 8
319	SODIUM HYDROXIDE—in preparations containing 0.5% or less of sodium hydroxide	5	1, 4, 6
320	SODIUM HYDROXIDE—in solid preparations containing more than 0.5% of sodium hydroxide	2, 10, 78	3, 5, 28
321	SODIUM HYDROXIDE—in liquid preparations containing more than 0.5% of sodium hydroxide	2, 10, 78	3, 5
322	SODIUM LAURETH-6 CARBOXYLATE	79	1
323	SODIUM METABISULPHITE (more than 50%)	5,26	1,4
324	SODIUM NITRITE in pickling or curing salts	94	

Poison	s that must be labelled with warning statements and safety	directions	
Item	Column 1 Poison	Column 2 Warning statement item number	Column 3 Safety direction iten number
325	SODIUM PERSULFATE	5, 21, 25	1, 5, 23, 33, 34
326	SODIUM SULFIDE	2	1,4
327	STYRENE		1, 4, 8
328	SULFAMIC ACID	2	1,4
329	SULFURIC ACID	2	1,4
330	SYMPHYTUM SPP. (Comfrey) when included in Schedule 5		31, 32
331	TAZAROTENE for topical use	77, 62	
332	TEPROTUMUMAB	7, 62, 76, 110	
333	TERBUTALINE in metered aerosols or in dry powder formulations	32	
334	TERFENADINE		61
335	TERIFLUNOMIDE	7, 62, 87	
336	TERPENES, chlorinated		1, 4, 8
337	TETRACHLOROETHANE	12	8
338	TETRACHLOROETHYLENE when included in Schedule 5 or 6	12, 16	1, 4, 8, 11
339	TETRYZOLINE in nasal preparations for topical use	29	
340	THALIDOMIDE	7, 62, 76	
341	THIOUREA		1,4
342	TOLUENE		1, 4, 8
343	TOLUENEDIAMINES—in hair dyes	21	
344	TOLUENEDIAMINES—in preparations other than hair dyes		1, 4, 8
345	TRAMAZOLINE in nasal preparations for topical use	29	
346	TRETINOIN—for human oral use	7, 62, 76	
347	TRETINOIN—for topical use	62, 77	
348	TRIAMCINOLONE when in topical preparations for the treatment of mouth ulcers	64 or 68	
349	TRICHLOROACETIC ACID <b>except</b> when for therapeutic use	2	1, 4
350	1,1,1-TRICHLOROETHANE		8, 9
351	TRICHLOROETHYLENE <b>except</b> when for therapeutic use	12	1, 4, 5, 8, 9
352	TRICHLOROPHENOL		1, 4, 8
353	TRIETHYL PHOSPHATE		1, 4, 8
354	TRIFLUOROMETHANESULFONIC ACID—more than 10%	1, 17	1, 4, 8
355	TRIFLUOROMETHANESULFONIC ACID-10% or		1, 4, 8

Appendix F Warning statements and general safety directions for poisons

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Poisons that must be labelled with warning statements and safety directions			
Item	Column 1 Poison	Column 2 Warning statement item number	Column 3 Safety direction item number
356	TRIISOPROPANOLAMINE LAURYL ETHER SULFATE		1, 4, 6
357	3,6,9-TRIOXAUNDECANEDIOIC ACID	5	1
358	TROLAMINE	5	1,4
359	TYMAZOLINE in nasal preparations for topical use	29	
360	VINCLOZOLIN	46	
361	VINYL ACETATE MONOMER	11	8,9
362	XYLENE		1, 4, 8
363	XYLOMETAZOLINE in nasal preparations for topical use	29	
364	ZINC CHLORIDE		1,4
365	ZINC LACTATE	107	
366	ZINC SULFATE when included in Schedule 6		1,4

# **Appendix G—Dilute preparations**

Note: See paragraph 11(c).

#### 1 Substances exempt at or below certain concentrations

- For the purposes of paragraph 11(c), the following table specifies:
  - (a) substances; and
  - (b) concentrations in relation to those substances.

Substances and concentrations		
Item	Column 1 Substance	Column 2 Concentration (quantity per litre or kilogram)
1	ACETYLCHOLINE	1 mg
2	ALDOSTERONE	10 micrograms
3	ANTIMONY COMPOUNDS	1 mg
4	APOMORPHINE	1 mg
5	ARSENIC	1 mg
6	ATROPA BELLADONNA (belladonna)	300 micrograms
7	ATROPINE	300 micrograms
8	CANTHARIDIN	10 micrograms
9	CHLORINE	5 mg
10	CROTON TIGLIUM (croton oil)	1 mg
11	EPIDERMAL GROWTH FACTOR	2 mg
12	ERYSIMUM spp.	1 mg
13	ESTRADIOL	10 micrograms
14	ESTRONE	100 micrograms
15	FOLLICLE-STIMULATING HORMONE	100 micrograms
16	GELSEMIUM SEMPERVIRENS	1 mg
17	GLUCAGON	100 micrograms
18	GLYCERYL TRINITRATE	100 micrograms
19	GROWTH HORMONE	10 micrograms
20	HALOPERIDOL	1 mg
21	HYDROCYANIC ACID	1 microgram
22	HYOSCINE	300 micrograms
23	HYOSCYAMINE	300 micrograms
24	HYOSCYAMUS NIGER	300 micrograms
25	HYPOTHALAMIC RELEASING FACTORS	10 micrograms
26	INDOMETACIN	1 mg
27	MERCURY	1 mg
28	METHYLMERCURY	300 micrograms
29	NAPHTHALENE	1 mg

# Clause 1

Substa	Substances and concentrations		
Item	Column 1 Substance	Column 2 Concentration (quantity per litre or kilogram)	
30	NERIUM OLEANDER	1 mg	
31	OXYTOCIN	1 microgram	
32	PHOSPHORUS	1 mg	
33	PODOPHYLLUM RESIN (podophyllin)	1 mg	
34	PROGESTERONE	1 mg	
35	PROPRANOLOL	1 mg	
36	SELENIUM	100 micrograms	
37	STROPHANTHUS spp.	1 mg	
38	STRYCHNINE	1 mg	
39	TESTOSTERONE	1 mg	
40	THYROXINE	10 micrograms	

# Appendix H—Schedule 3 medicines permitted to be advertised

Note: See paragraph 57(1)(a).

# 1 Schedule 3 medicines permitted to be advertised

The following table specifies poisons for the purposes of paragraph 57(1)(a).

Schedule 3 medicines permitted to be advertised	
Item	Column 1 Poison
1	ADAPALENE
2	ADRENALINE
3	ASTODRIMER SODIUM—for the treatment and relief of bacterial vaginosis and for the prevention of recurrent bacterial vaginosis
4	BILASTINE
5	BUTOCONAZOLE
6	CELECOXIB
7	CICLOPIROX
8	CLOBETASONE
9	CLOTRIMAZOLE
10	CYTISINE
11	DICLOFENAC
12	DIMENHYDRINATE—for the prevention and relief of motion sickness
13	DIPHENOXYLATE
14	ECONAZOLE
15	ELETRIPTAN
16	ESOMEPRAZOLE
17	FAMCICLOVIR
18	FLUCONAZOLE
19	FLUORIDES
20	GLUCAGON
21	GLYCERYL TRINITRATE
22	HYDROCORTISONE
23	HYOSCINE BUTYLBROMIDE
24	IBUPROFEN
25	ISOCONAZOLE
26	KETOPROFEN
27	LANSOPRAZOLE
28	LEVONORGESTREL
29	MELATONIN
30	MICONAZOLE

Appendix H Schedule 3 medicines permitted to be advertised

Clause	1
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Sched	Schedule 3 medicines permitted to be advertised	
Item	Column 1 Poison	
30	NALOXONE	
31	NAPROXEN	
32	NARATRIPTAN	
33	NYSTATIN	
34	OMEPRAZOLE	
35	OXICONAZOLE	
36	PANTOPRAZOLE	
37	PARACETAMOL	
38	PODOPHYLLOTOXIN	
39	PODOPHYLLUM EMODI (podophyllin)	
40	PODOPHYLLUM PELTATUM (podophyllin)	
41	RABEPRAZOLE	
42	RIZATRIPTAN	
43	SALICYLIC ACID	
44	SUMATRIPTAN	
45	TIOCONAZOLE	
46	TRIAMCINOLONE	
47	ULIPRISTAL—for emergency post-coital contraception	
48	VITAMIN D	
49	ZOLMITRIPTAN	

# Appendix I—Blank

- Note 1: Appendix I is intentionally blank.
- Note 2: Appendix I previously included poisons now dealt with in Division 9 of Part 2.

#### Clause 1

# Appendix J—Conditions for availability and use of certain poisons included in Schedule 7

Note: See subsection 62(6).

#### 1 Conditions for supply of certain poisons included in Schedule 7

For the purposes of subsection 62(6), a poison included in Schedule 7 that is specified in column 1 of an item of the following table may be supplied:

- (a) only to a person who is appropriately authorised or licensed under the law of the jurisdiction where the person will receive the poison; and
- (b) if "a" appears in column 2 of the item—only for analytical or research purposes; and
- (c) if "p" appears in column 2 of the item—only to a person who is authorised or licensed, under the law of the jurisdiction where the person will receive the poison, to possess and use the poison.

Conditions for supply of certain poisons included in Schedule 7		
Item	Column 1 Poison	Column 2 Condition
1	ABAMECTIN	
2	ACIBENZOLAR-S-METHYL	
3	ACROLEIN	
4	ACRYLONITRILE	
5	ALACHLOR	а
6	ALLYL ALCOHOL	
7	4-AMINOPROPIOPHENONE	р
8	4-AMINOPYRIDINE	
9	ARPRINOCID	a
10	ARSENIC	р
11	AZOCYCLOTIN	а
12	BENZENE	
13	BIFLUORIDE	
14	BORON TRIFLUORIDE	
15	BRODIFACOUM	
16	BROMADIOLONE	
17	BROMINE	
18	BRUCINE	
19	CALCIFEROL	
20	CARBADOX	
21	CARBON TETRACHLORIDE	
22	CARBONYL SULFIDE	
23	CHLORDECONE	а

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Condi	tions for supply of certain poisons included in Schedule 7	
Item	Column 1 Poison	Column 2 Condition
24	CHLORDIMEFORM	а
25	CHLORINE	
26	CHLOROMETHIURON	а
27	CHLOROPICRIN	
28	4-CHLORO-o-TOLUIDINE	а
29	COLECALCIFEROL	
30	COUMATETRALYL	
31	CYANOGEN	
32	CYHEXATIN	a
33	4,4-DIAMINODIPHENYLMETHANE	
34	1,2-DIBROMO-3-CHLOROPROPANE	а
35	1,3-DICHLOROPROPENE	
36	DIFENACOUM	
37	4-DIMETHYLAMINOAZOBENZENE	а
38	DINITROCRESOLS	a
39	DINITROPHENOLS	а
40	DINOSEB	а
41	EPICHLOROHYDRIN	
42	EPIDERMAL GROWTH FACTOR	
43	ETACONAZOLE	а
44	ETHYLENE DIBROMIDE	а
45	ETHYLENE OXIDE	
46	FLUOROACETAMIDE	р
47	FLUOROACETIC ACID	р
48	HALOFUGINONE	
49	HALOGENATED DIBENZODIOXINS AND DIBENZOFURANS	а
50	НСВ	а
51	HYDROCYANIC ACID AND CYANIDES	р
52	HYDROFLUORIC ACID	
53	HYDROSILICOFLUORIC ACID	
54	IODOMETHANE	
55	MADURAMICIN	
56	MERCURY	
57	METHACRIFOS	
58	METHOXYETHYLMERCURIC ACETATE	а
59	METHOXYETHYLMERCURIC CHLORIDE	
60	METHYL BROMIDE	
51	4,4'-METHYLENEBIS[2-CHLOROANILINE]	
52	MIREX	a

Appendix J Conditions for availability and use of certain poisons included in Schedule 7

C	lause	1
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Condi	Conditions for supply of certain poisons included in Schedule 7		
Item	Column 1 Poison	Column 2 Condition	
64	MOLINATE		
65	NICOTINE except when in tobacco		
66	NITROFEN	а	
67	PHENYLMERCURIC ACETATE		
68	PHOSPHIDE, metallic		
69	PHOSPHINE		
70	PROPYLENE OXIDE		
71	PYRINURON	a	
72	STRYCHNINE	р	
73	SULCOFURON	а	
74	TETRACHLOROETHANE		
75	2,2',6,6'-TETRAISOPROPYL-DIPHENYL-CARBODIIMIDE		
76	THALLIUM	р	
77	<i>o</i> -TOLIDINE		
78	VINYL CHLORIDE		

Clause 1

# Appendix K—Human medicines required to be labelled with a sedation warning

Note: See subsection 33(2).

# 1 Human medicines required to be labelled with a sedation warning

The following table specifies poisons for the purposes of subsection 33(2).

Human medicines required to be labelled with a sedation warning	
Item	Column 1 Poison
1	ALIMEMAZINE
2	ALPRAZOLAM
3	AMISULPRIDE
4	AMITRIPTYLINE
5	AMOBARBITAL
6	ARIPIPRAZOLE
7	ASENAPINE
8	AZATADINE
9	BACLOFEN
10	BENZATROPINE
11	BREXPIPRAZOLE
12	BRIVARACETAM
13	BROMAZEPAM
14	BROMPHENIRAMINE
15	BUCLIZINE
16	BUPRENORPHINE
17	BUTOBARBITAL
18	CANNABIS except cannabidiol when included in Schedule 3 or 4
19	CETIRIZINE
20	CHLORAL HYDRATE
21	CHLORDIAZEPOXIDE
22	CHLORMETHIAZOLE
23	CHLORPHENAMINE
24	CHLORPROMAZINE
25	CLEMASTINE
26	CLOMIPRAMINE
27	CLONAZEPAM
28	CLONIDINE
29	CLORAZEPATE
30	CLOZAPINE

Appendix K Human medicines required to be labelled with a sedation warning

Claus	se 1

Item       Column 1         Poison       31         31       CODEINE.         32       CYCLIZINE         33       CYCLOBARBITAL         34       CYCLOSERINE         35       CYPROHEPTADINE         36       DANTOLENE         37       DESTRAMINE         38       DEUTETRABENAZINE.         39       DEXCHLORPHENAMINE         40       DEXTROPOPOXYPHENE         41       DEXTROPROPOXYPHENE         42       DIAZEPAM         43       DIFELIKEFALIN         44       DIFENOXIN         45       DIHYDROCODEINE         46       DIMETHINDENE         47       DIMETHINDENE         48       DIPHENYLPYRALINE         51       DOSULEPIN         52       DOXEPIN         53       DOXYLAMINE         54       PRONABINOL (deha-9-TETRAHYDROCANNABINOL)         55       DROPERIDOL         56       DULOXETINE         57       ESKETAMINE         58       ETHYLMORPHINE         59       FENFLURAMINE         60       FENTANYL         61       FLUPENTINOL	Human medicines required to be labelled with a sedation warning	
31       CODEINE.         32       CYCLOBARBITAL         33       CYCLOBARBITAL         34       CYCLOBARBITAL         35       CYPROHEPTADINE         36       DANTROLENE         37       DESIPRAMINE         38       DEUTETRABENAZINE.         39       DEXCHLORPHENAMINE         40       DEXTROWORAMIDE         41       DEXTROPOXYPHENE         42       DIAZEPAM         43       DIFELIKEFALIN         44       DIFENOXIN         45       DIMENHYDRINATE         46       DIMENHYDRINATE         47       DIMETHINDENE         48       DIPHENNYDRAMINE         49       DIPHENNYDRAMINE         49       DIPHENNYDRAMINE         50       DIPHENNYDRAMINE         51       DOSULEPIN         52       DOXPLAMINE         53       DOXYLAMINE         54       DRONABINOL (deta-9-TETRAHYDROCANNABINOL)         55       DROPERIDOL         56       DULOXETINE         57       ESKETAMINE         58       ETHYLMORPHINE         59       FENFLURAMINE         60       FENTANYL		Column 1
32       CYCLIZINE         33       CYCLOBARBITAL         34       CYCLOSERINE         35       CYPROHEPTADINE         36       DANTROLENE         37       DESUPRAMINE         38       DEUTETRABENAZINE.         39       DEXCHLORPHENAMINE         40       DEXTROMORAMIDE         41       DEXTROPROPOXYPHENE         42       DIAZEPAM         43       DIFELIKEFALIN         44       DIFENOXIN         45       DIHYDROCODEINE         46       DIMENHYDRNATE         47       DIMETHINDENE         48       DIPHENOXYLATE         50       DIPHENVLPYRALINE         51       DOSULEPIN         52       DOXYLAMINE         54       DRONABINOL (delta-9-TETRAHYDROCANNABINOL)         55       DROVERIDOL         56       DULOXETINE         57       ESKETAMINE         58       ETHYLMORPHINE         59       FENFLURAMINE         60       FENTANYL         61       FLUNNTRAZEPAM         62       FLUPHENAZINE         63       GABAPENTIN         64       FLURAZEPAM	31	
33       CYCLOBARBITAL         34       CYCLOSERINE         35       CYPROHEPTADINE         36       DANTROLENE         37       DESIPRAMINE         38       DEUTETRABENAZINE.         39       DEXCHLORPHENAMINE         40       DEXTROMORAMIDE         41       DEXTROPROPOXYPHENE         42       DIAZEPAM         43       DIFELIKEFALIN         44       DIFENOXIN         45       DIHYDROCODEINE         46       DIMENHYDRINATE         47       DIMETHINDENE         48       DIPHENOYLATE         50       DIPHENOYLATE         51       DOSULEPIN         52       DOXEPIN         53       DOXYLAMINE         54       DRONABINOL (delta-9-TETRAHYDROCANNABINOL)         55       DROPERIDOL         56       DULOXETINE         57       FESKETAMINE         58       ETHYLMORPHINE         59       FENFLURAMINE         60       FENTANYL         61       FLUNTRAZEPAM         62       FLUPHENAZINE         63       GABAPENTIN         64       FLURAZEPAM <td></td> <td></td>		
34       CYCLOSERINE         35       CYPROHEPTADINE         36       DANTROLENE         37       DESIPRAMINE         38       DEUTETRABENAZINE.         39       DEXCHLORPHENAMINE         40       DEXTROMORAMIDE         41       DEXTROPOPOXYPHENE         42       DIAZEPAM         43       DIFFLIKEFALIN         44       DIFENOXIN         45       DIHYDROCODEINE         46       DIMENHYDRINATE         47       DIMETHINDENE         48       DIPHENYDRAMINE         49       DIPHENYDRAMINE         49       DIPHENYLATE         50       DOSULEPIN         51       DOSULEPIN         52       DOXEPIN         53       DOXYLAMINE         54       DRONABINOL (delta-9-TETRAHYDROCANNABINOL)         55       DROPERIDOL         56       DULOXETINE         57       ESKETAMINE         60       FENTLURAMINE         61       FLUPHENZINE         62       FLUPHENTINOL         63       FLUPHENZINE         64       FLUPHENZINE         65       GABAPENTIN <td></td> <td></td>		
35       CYPROHEPTADINE         36       DANTROLENE         37       DESIPRAMINE         38       DEUTETRABENAZINE.         39       DEXCHLORPHENAMINE         40       DEXTROPROPOXYPHENE         41       DERTROPROPOXYPHENE         42       DIAZEPAM         43       DIFELIKEFALIN         44       DIFENOZIN         45       DIHYDROCODEINE         46       DIMENHYDRIATE         47       DIMETHINDENE         48       DIPHENYLPYRALINE         50       DIPHENYLPYRALINE         51       DOSULEPIN         52       DOXPLINNE         53       DOXYLAMINE         54       DRONABINOL (delta-9-TETRAHYDROCANNABINOL)         55       DROPERIDOL         56       DULOXETINE         59       FENTURAMINE         58       ETHYLMORPHINE         59       FENTURAMINE         60       FENTANYL         61       FLUPIENAZINE         62       FLUPENTIXOL         63       GABAPENTIN         64       FLUPRENZINE         65       GABAPENTIN         66       GEUNTEHIMIDE <td>-</td> <td></td>	-	
36       DANTROLENE         37       DESIPRAMINE         38       DEUTETRABENAZINE.         39       DEXCHLORPHENAMINE         40       DEXTROPOROYAPHENE         41       DEXTROPROPOYPHENE         42       DIAZEPAM         43       DIFELIKEFALIN         44       DIFENOXIN         45       DIHYDROCODEINE         46       DIMENHYDRINATE         47       DIMETHINDENE         48       DIPHENYDRAMINE         49       DIPHENYLPYRALINE         50       DIPHENYLPYRALINE         51       DOSULEPIN         52       DOXPLAMINE         54       DROPABINOL (delta-9-TETRAHYDROCANNABINOL)         55       DROPERIDOL         56       DULOXETINE         57       ESKETAMINE         58       ETHYLMORPHINE         59       FENFLURAMINE         60       FENTANYL         61       FLUPHENTIXOL         63       FLUPHENTIXOL         64       FLUPRAZINE         64       FLUPRAZINE         64       FLUPRAZINE         64       FLUPRAZINE         65       GABAPENTIN		
37       DESIPRAMINE         38       DEUTETRABENAZINE.         39       DEXCHLORPHENAMINE         40       DEXTROMORAMIDE         41       DEXTROPROPOXYPHENE         42       DIAZEPAM         43       DIFELIKEFALIN         44       DIFENOXIN         45       DIHYDROCODEINE         46       DIMENHYDRINATE         47       DIMETHINDENE         48       DIPHENYLPYRALINE         50       DIPHENYLPYRALINE         51       DOSULEPIN         52       DOXYLAMINE         54       DROPERIDOL         55       DROPERIDOL         56       DULOXETINE         57       ESKETAMINE         58       ETHYLMORPHINE         59       FENFLURAMINE         60       FENTANYL         61       FLUNITRAZEPAM         62       FLUPHENAZINE         63       FLUPHENZINE         64       FLUPAZINE         65       GABAPENTIN         66       GEMCITABINE         67       GLUTETHIMIDE         68       GUANFACINE		
38       DEUTETRABENAZINE.         39       DEXCHLORPHENAMINE         40       DEXTROMORAMIDE         41       DEXTROPROPOXYPHENE         42       DIAZEPAM         43       DIFELIKEFALIN         44       DIFENOXIN         45       DIHYDROCODEINE         46       DIMENHYDRINATE         47       DIMETHINDENE         48       DIPHENYLPYRALINE         50       DIPHENYLPYRALINE         51       DOSULEPIN         52       DOXYLAMINE         54       DRONABINOL (delta-9-TETRAHYDROCANNABINOL)         55       DROPERIDOL         56       DULOXETINE         57       ESKETAMINE         58       ETHYLMORPHINE         59       FENFLURAMINE         60       FENTANYL         61       FLUPHENAZINE         64       FLUPHAZINE         64       FLUPHAZINE         64       FLUPHENAZINE         67       GLUTETHIMIDE         68       GUANFACINE	-	
39       DEXCHLORPHENAMINE         40       DEXTROMORAMIDE         41       DEXTROPROPOXYPHENE         42       DIAZEPAM         43       DIFELIKEFALIN         44       DIFENOXIN         45       DIHYDROCODEINE         46       DIMENHYDRINATE         47       DIMETHINDENE         48       DIPHENYLATE         50       DIPHENYLPYRALINE         51       DOSULEPIN         52       DOXPLAMINE         54       DRONABINOL (delta-9-TETRAHYDROCANNABINOL)         55       DROPERIDOL         56       DULOXETINE         57       ESKETAMINE         58       ETHYLMORPHINE         59       FENFLURAMINE         60       FENTANYL         61       FLUPENTIXOL         63       FLUPENTIXOL         64       FLUPAM         65       GABAPENTIN         66       GEMCITABINE         67       GLUTETHIMIDE         68       GUANFACINE	-	
40       DEXTROMORAMIDE         41       DEXTROPROPOXYPHENE         42       DIAZEPAM         43       DIFELIKEFALIN         44       DIFENOXIN         45       DIHYDROCODEINE         46       DIMENHYDRINATE         47       DIMETHINDENE         48       DIPHENHYDRAMINE         49       DIPHENOXYLATE         50       DIPHENYLPYRALINE         51       DOSULEPIN         52       DOXPLAMINE         54       DRONABINOL (delta-9-TETRAHYDROCANNABINOL)         55       DROPERIDOL         56       DULOXETINE         57       ESKETAMINE         58       ETHYLMORPHINE         59       FENFLURAMINE         60       FENTANYL         61       FLUPENTIXOL         62       FLUPENTIXOL         63       FLUPENTIXOL         64       FLUPRAZINE         64       FLUPHENAZINE         65       GABAPENTIN         66       GEWCITABINE         67       GLUTETHIMIDE         68       GUANFACINE		
41       DEXTROPROPOXYPHENE         42       DIAZEPAM         43       DIFELIKEFALIN         44       DIFENOXIN         45       DIHYDROCODEINE         46       DIMENHYDRINATE         47       DIMETHINDENE         48       DIPHENHYDRAMINE         49       DIPHENYLPYRALINE         50       DIPHENYLPYRALINE         51       DOSULEPIN         52       DOXPIN         53       DOXYLAMINE         54       DRONABINOL (delta-9-TETRAHYDROCANNABINOL)         55       DROPERIDOL         56       DULOXETINE         57       ESKETAMINE         58       ETHYLMORPHINE         59       FENFLURAMINE         60       FENTANYL         61       FLUPENTIXOL         63       FLUPHENAZINE         64       FLURAZEPAM         65       GABAPENTIN         66       GEMCITABINE         67       GLUTETHIMIDE         68       GUANFACINE		
42       DIAZEPAM         43       DIFELIKEFALIN         44       DIFENOXIN         45       DIHYDROCODEINE         46       DIMENHYDRINATE         47       DIMETHINDENE         48       DIPHENHYDRAMINE         49       DIPHENOXYLATE         50       DIPHENYLPYRALINE         51       DOSULEPIN         52       DOXPLAMINE         54       DRONABINOL (delta-9-TETRAHYDROCANNABINOL)         55       DROPERIDOL         56       DULOXETINE         57       ESKETAMINE         58       ETHYLMORPHINE         59       FENFLURAMINE         60       FENTANYL         61       FLUPENTIXOL         63       FLUPHENAZINE         64       FLURAZEPAM         65       GABAPENTIN         66       GEMCITABINE         67       GLUTETHIMIDE         68       GUANFACINE		
43DIFELIKEFALIN44DIFENOXIN45DIHYDROCODEINE46DIMENHYDRINATE47DIMETHINDENE48DIPHENHYDRAMINE49DIPHENOXYLATE50DIPHENYLPYRALINE51DOSULEPIN52DOXEPIN53DOXYLAMINE54DRONABINOL (delta-9-TETRAHYDROCANNABINOL)55DROPERIDOL56DULOXETINE57ESKETAMINE58ETHYLMORPHINE59FENFLURAMINE60FENTANYL61FLUPENTIXOL63FLUPENTIXOL64FLURAZEPAM65GABAPENTIN66GEMCITABINE68GUANFACINE		
45DIHYDROCODEINE46DIMENHYDRINATE47DIMETHINDENE48DIPHENHYDRAMINE49DIPHENOXYLATE50DIPHENYLPYRALINE51DOSULEPIN52DOXYLAMINE53DOXYLAMINE54DRONABINOL (delta-9-TETRAHYDROCANNABINOL)55DROPERIDOL56DULOXETINE57ESKETAMINE58ETHYLMORPHINE59FENFLURAMINE60FENTANYL61FLUPENTIXOL63FLUPENTIXOL64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE		
45DIHYDROCODEINE46DIMENHYDRINATE47DIMETHINDENE48DIPHENHYDRAMINE49DIPHENOXYLATE50DIPHENYLPYRALINE51DOSULEPIN52DOXYLAMINE53DOXYLAMINE54DRONABINOL (delta-9-TETRAHYDROCANNABINOL)55DROPERIDOL56DULOXETINE57ESKETAMINE58ETHYLMORPHINE59FENFLURAMINE60FENTANYL61FLUPENTIXOL63FLUPENTIXOL64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	-	
46DIMENHYDRINATE47DIMETHINDENE48DIPHENOXYLATE50DIPHENOXYLATE51DOSULEPIN52DOXEPIN53DOXYLAMINE54DRONABINOL (delta-9-TETRAHYDROCANNABINOL)55DROPERIDOL56DULOXETINE57ESKETAMINE58ETHYLMORPHINE59FENFLURAMINE60FENTANYL61FLUPENTIXOL63FLUPENTIXOL64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	45	
48DIPHENHYDRAMINE49DIPHENOXYLATE50DIPHENYLPYRALINE51DOSULEPIN52DOXEPIN53DOXYLAMINE54DRONABINOL (delta-9-TETRAHYDROCANNABINOL)55DROPERIDOL56DULOXETINE57ESKETAMINE58ETHYLMORPHINE59FENFLURAMINE60FENTANYL61FLUNITRAZEPAM62FLUPENTIXOL63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE		
49DIPHENOXYLATE50DIPHENYLPYRALINE51DOSULEPIN52DOXEPIN53DOXYLAMINE54DRONABINOL (delta-9-TETRAHYDROCANNABINOL)55DROPERIDOL56DULOXETINE57ESKETAMINE58ETHYLMORPHINE59FENFLURAMINE60FENTANYL61FLUNITRAZEPAM62FLUPENTIXOL63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	47	DIMETHINDENE
50DIPHENYLPYRALINE51DOSULEPIN52DOXEPIN53DOXYLAMINE54DRONABINOL (delta-9-TETRAHYDROCANNABINOL)55DROPERIDOL56DULOXETINE57ESKETAMINE58ETHYLMORPHINE59FENFLURAMINE60FENTANYL61FLUPIENTIXOL63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	48	DIPHENHYDRAMINE
51DOSULEPIN52DOXEPIN53DOXYLAMINE54DRONABINOL (delta-9-TETRAHYDROCANNABINOL)55DROPERIDOL56DULOXETINE57ESKETAMINE58ETHYLMORPHINE59FENFLURAMINE60FENTANYL61FLUNITRAZEPAM62FLUPENTIXOL63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	49	DIPHENOXYLATE
52DOXEPIN53DOXYLAMINE54DRONABINOL (delta-9-TETRAHYDROCANNABINOL)55DROPERIDOL56DULOXETINE57ESKETAMINE58ETHYLMORPHINE59FENFLURAMINE60FENTANYL61FLUNITRAZEPAM62FLUPENTIXOL63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	50	DIPHENYLPYRALINE
53DOXYLAMINE54DRONABINOL (delta-9-TETRAHYDROCANNABINOL)55DROPERIDOL56DULOXETINE57ESKETAMINE58ETHYLMORPHINE59FENFLURAMINE60FENTANYL61FLUNITRAZEPAM62FLUPENTIXOL63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	51	DOSULEPIN
54DRONABINOL (delta-9-TETRAHYDROCANNABINOL)55DROPERIDOL56DULOXETINE57ESKETAMINE58ETHYLMORPHINE59FENFLURAMINE60FENTANYL61FLUNITRAZEPAM62FLUPENTIXOL63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	52	DOXEPIN
55DROPERIDOL56DULOXETINE57ESKETAMINE58ETHYLMORPHINE59FENFLURAMINE60FENTANYL61FLUNITRAZEPAM62FLUPENTIXOL63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	53	DOXYLAMINE
56DULOXETINE57ESKETAMINE58ETHYLMORPHINE59FENFLURAMINE60FENTANYL61FLUNITRAZEPAM62FLUPENTIXOL63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	54	DRONABINOL (delta-9-TETRAHYDROCANNABINOL)
57ESKETAMINE58ETHYLMORPHINE59FENFLURAMINE60FENTANYL61FLUNITRAZEPAM62FLUPENTIXOL63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	55	DROPERIDOL
58ETHYLMORPHINE59FENFLURAMINE60FENTANYL61FLUNITRAZEPAM62FLUPENTIXOL63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	56	DULOXETINE
59FENFLURAMINE60FENTANYL61FLUNITRAZEPAM62FLUPENTIXOL63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	57	ESKETAMINE
60FENTANYL61FLUNITRAZEPAM62FLUPENTIXOL63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	58	ETHYLMORPHINE
61FLUNITRAZEPAM62FLUPENTIXOL63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	59	FENFLURAMINE
62FLUPENTIXOL63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	60	FENTANYL
63FLUPHENAZINE64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	61	FLUNITRAZEPAM
64FLURAZEPAM65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	62	FLUPENTIXOL
65GABAPENTIN66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	63	FLUPHENAZINE
66GEMCITABINE67GLUTETHIMIDE68GUANFACINE	64	FLURAZEPAM
67GLUTETHIMIDE68GUANFACINE	65	GABAPENTIN
68 GUANFACINE	66	GEMCITABINE
	67	GLUTETHIMIDE
69 HALOPERIDOL	68	GUANFACINE
	69	HALOPERIDOL

Huma	n medicines required to be labelled with a sedation warning
Item	Column 1
	Poison
70	HYDROCODONE
71	HYDROMORPHONE
72	HYDROXYZINE
73	IMIPRAMINE
74	LAMOTRIGINE
75	LEMBOREXANT.
76	LEVETIRACETAM
77	LEVOCABASTINE
78	LEVOCETIRIZINE
79	LORAZEPAM
80	LURASIDONE.
81	MAZINDOL
82	MEBHYDROLIN
83	MECLOZINE
84	MEDAZEPAM
85	MEPROBAMATE
86	MEPYRAMINE
87	MERCAPTAMINE
88	METHADONE
89	METHDILAZINE
90	METHOCARBAMOL
91	METHYLPHENOBARBITAL
92	MIANSERIN
93	MIDAZOLAM
94	MIRTAZAPINE
95	MORPHINE
96	NABIXIMOLS.
97	NALBUPHINE
98	NITRAZEPAM
99	NORMETHADONE
100	NORTRIPTYLINE
101	OLANZAPINE
102	OPIUM in any form except the alkaloids noscapine and papaverine
103	OXAZEPAM
104	OXYCODONE
105	PALIPERIDONE
106	PAPAVERETUM
107	PENTAZOCINE
108	PENTOBARBITAL

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Clause	1

Item	Column 1
	Poison
109	PERAMPANEL
110	PERICIAZINE
111	PERPHENAZINE
112	PETHIDINE
113	PHENELZINE
114	PHENIRAMINE
115	PHENOBARBITAL
116	PHENOPERIDINE
117	PHENYLTOLOXAMINE
118	PHOLCODINE
119	PIMOZIDE
120	PIZOTIFEN
121	PRAZEPAM
122	PREGABALIN
123	PROCHLORPERAZINE
124	PROMAZINE
125	PROMETHAZINE
126	PROTRIPTYLINE
127	QUETIAPINE
128	RETIGABINE
129	RISPERIDONE
130	ROTIGOTINE
131	RUFINAMIDE
132	RUPATADINE
133	SAFINAMIDE
134	SECBUTOBARBITAL
135	SECOBARBITAL
136	SELETRACETAM
137	SODIUM OXYBATE
138	STIRIPENTOL
139	SUVOREXANT
140	TAPENTADOL
141	TEMAZEPAM
142	TETRAHYDROCANNABINOLS except cannabidiol when included in Schedule 3 or 4
143	THENYLDIAMINE
144	THIETHYLPERAZINE
145	THIOPROPAZATE
146	THIORIDAZINE
147	THIOTHIXENE

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Clause 1

Huma	n medicines required to be labelled with a sedation warning
Item	Column 1 Poison
148	TRABECTEDIN
149	TRAMADOL
150	TRANYLCYPROMINE
151	TRIFLUOPERAZINE
152	TRIMIPRAMINE
153	TRIPROLIDINE
154	ZIPRASIDONE
155	ZOLPIDEM
156	ZONISAMIDE
157	ZOPICLONE

#### Clause 1

# Appendix L—Requirements for dispensing labels for medicines

Note: See subsection 33(1) and paragraph 40(b).

#### 1 General

- (1) This clause sets out requirements for the purposes of paragraph 40(b).
- (2) All details, words and other required information on a label on a container of a substance for therapeutic use must be in the English language in letters at least 1.5 mm in height.
- (3) All symbols, numbers and words on a label must be in durable characters.
- (4) The label on a container of a substance for therapeutic use must contain the following details:
  - (a) the name, address and telephone number of the dispenser supplying the substance;
  - (b) the approved name of the substance and/or its proprietary name (unless it is a preparation compounded in accordance with the dispenser's own formula);
  - (c) adequate directions for use;
  - (d) the strength and form of the substance;
  - (e) the total quantity of the goods in the container;
  - (f) the words "KEEP OUT OF REACH OF CHILDREN" in red on a white background;
  - (g) if the substance is intended for external use only, the word "POISON", or the words "FOR EXTERNAL USE ONLY", in red on a white background;
  - (h) if the substance is a medicine for human use, the name of the person for whom it was dispensed; and
  - (i) if the substance is a veterinary chemical, the species of animal, the name of the animal's owner and the words "FOR ANIMAL TREATMENT ONLY".
- (5) The label on a container of a medicine for human use, or a veterinary chemical, that is supplied on prescription must also include:
  - (a) the prescription reference number; and
  - (b) the date on which the prescription was supplied (unless that date is clear from the prescription reference number); and
  - (c) the directions for use set out in the prescription.

#### 2 Additional warning statements for certain human medicines

- (1) For the purposes of subsection 33(1), and subject to subclause (2), the warning statement represented by each item number specified in column 2 of an item of the following table is required for the poison specified in column 1 of the item.
  - Note: For the warning statements represented by the item numbers, see clause 1 of Appendix F.

(2) If more than one statement or direction is required for a poison, the statements and directions may be combined to form simple sentences (if appropriate).

Additional warning statements for certain human medicines Item Column 1 Column 2		
Item	Poison	Warning statement item number
1	ACITRETIN—for oral use	7, 62, 76
2	ACITRETIN—for topical use	62, 77
3	ADAPALENE—for oral use	7, 62, 76
4	ADAPALENE—for topical use	62, 77
5	AMBRISENTAN	7, 62, 76
6	BELUMOSUDIL	62, 77
7	BEXAROTENE—for oral use	7, 62, 76
8	BEXAROTENE—for topical use	62, 77
9	BOSENTAN	7, 62, 76
10	DIENESTROL	67
11	ETRETINATE—for oral use	7, 62, 76
12	ETRETINATE—for topical use	62, 77
13	ENZALUTAMIDE	7, 67, 87
14	FARICIMAB	76
15	FINERENONE	67, 111
16	FINGOLIMOD	76
17	ISAVUCONAZOLE	53
18	ISOTRETINOIN—for oral use	7, 62, 76
19	ISOTRETINOIN—for topical use	62, 77
20	LEFLUNOMIDE	7, 62, 87
21	LENALIDOMIDE—for oral use	7, 62, 76
22	LENALIDOMIDE—for topical use	62, 77
23	LEVOCABASTINE	62
24	MACITENTAN	7, 62, 76
25	MISOPROSTOL	53
26	PALOVAROTENE	7, 62, 76, 111
27	PLITIDEPSIN	7, 62, 63, 76, 87
28	POMALIDOMIDE	7, 62, 76
29	PONESIMOD	76
30	RIOCIGUAT	7, 62, 76
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32	SAFINAMIDE	62, 76, 77
33	SELINEXOR	62, 77
34	SELUMETINIB.	76
35	SITAXENTAN	7, 62, 76
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37	TERIFLUOMIDE	7, 62, 87

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Item	Column 1 Poison	Column 2 Warning statement item number
38	THALIDOMIDE—for oral use	7, 62, 76
39	THALIDOMIDE—for topical use	62, 77
40	TIRZEPATIDE	67
41	TRASTUZUMAB DERUXTECAN	62, 77
42	TRETINOIN—for oral use	7, 62, 76
43	TRETINOIN—for topical use	62, 77

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Note: Appendix M is intentionally blank. It is reserved for future use.

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