

## **NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE**

**MEETING 30 (20-22 February 2001)**

### **RECORD OF REASONS FOR AMENDMENT TO THE STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS and ADVICE OF OTHER OUTCOMES**

**PART A** – contains the Record of Reasons for amendments to the Standard for the Uniform Scheduling of Drugs and Poisons notified in Commonwealth of Australia Gazette of 4 April 2001 as decisions arising from the 30<sup>th</sup> NDPSC Meeting held on 20-22 February 2001.

These amendments were made in respect of substances mentioned in the Gazette of 10 January 2001 as substances to be considered for scheduling at the February 2001 Meeting.

These amendments are **subject to the receipt of further public submissions**.

Persons who made a public submission in relation to the substances listed in this Part A are invited to make a further submission to the Secretary NDPSC. Submissions must be made by 25 April 2001 and address a matter mentioned in section 52E of the Act and be relevant to the reasons for the making of the decision.

If a submission is made to the Committee in respect of a substance set out below, the Committee must consider the submission and: confirm the amendment; or vary the amendment; or set aside the amendment, replace it with a new scheduling decision and publish notice of the decisions under section 52D of the Act. (If a new scheduling decision is made and notice of it published under section 52D, the public consultation process commences again). Subject to the matters set out above, the amendments in Part A come into effect on 1 September 2001, unless otherwise indicated.

**PART B** – advises of other outcomes from the 30<sup>th</sup> Meeting in relation to substances notified in the Gazette of 10 January 2001 as substances to be considered for scheduling at the February 2001 Meeting, and other general matters considered by the Committee.

These outcomes include proposals not supported, decisions to exempt substances from scheduling, deferral of matters to future meetings, and requests for further information.

**PART C** – List of substances for which amendments will be included in Amendment 4 to SUSDP 15 (the amendments arise from decisions made by the Committee at its August 2000 and November 2000 meetings and confirmed at the February 2001 ) and related matters.

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## PART A – RECORD OF REASONS

### 1. RESCHEDULING SUBMISSIONS

(a) **Salbutamol and Terbutaline** – Consideration of the scheduling of dry powder formulations to achieve consistency in scheduling with metered dose inhalers;

#### **SALBUTAMOL**

**Outcome** - The Committee agreed to align the scheduling of powdered formulations of salbutamol on the view that consistency in availability of powdered formulations, and increased practitioner and patient choice was appropriate.

#### **Schedule 3 - Amendment**

SALBUTAMOL - amend entry to read:

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.

#### **TERBUTALINE**

**Outcome** - The Committee agreed to align powdered formulations of terbutaline at 500 ug per dose on the view that powdered formulations should be have the same level of availability as metered dose inhalers, and it was appropriate that there be increased practitioner and patient choice.

#### **Schedule 3 - Amendment**

TERBUTALINE - amend entry to read:

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.
- (b) **Somatropin (human growth hormone)** – Consideration of inclusion in Appendix D, paragraph 5 – Poisons for which possession without authority is illegal;

**Outcome** - The Committee agreed to include somatropin (human growth hormone) in Appendix D, based on the potential for abuse and the need for a national approach for the control of possession of somatropin (human growth hormone).

### **Appendix D – Amendment**

Appendix D, Paragraph 5 – amend by adding to the list of poisons:

SOMATROPIN (human growth hormone)

- (c) **Mannityl Hexanitrate and Erythrityl Tetranitrate** – Consideration of scheduling;

**Outcome** - The Committee agreed to include mannityl hexanitrate and erythrityl tetranitrate in Schedule 3 of the SUSDP on the following grounds:

Consistent with the scheduling of isosorbide dinitrate and glyceryl trinitrate for the acute treatment of angina.

Allows supply without prescription but with the benefit of professional advice to assist management of the condition.

### **Schedule 3 – New entry**

MANNITYL HEXANITRATE for therapeutic use.

### **Schedule 3 – New entry**

ERYTHRITYL TETRANITRATE for therapeutic use.

### **Schedule 2 – Amendment**

ERYTHRITYL TETRANITRATE – delete entry.

- (d) **Folic Acid** – Consideration of inclusion in Appendix H - Schedule 3 Poisons Permitted to be Advertised.

**Outcome** - The NDPSC agreed to include folic acid in Appendix H based on the following grounds:

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Inclusion of folic acid in Appendix H does not constitute a significant risk to public health. Raising public awareness of the protective effect of folic acid supplementation during pregnancy in reducing neural tube defects would be beneficial to public health.

#### **Appendix H – New entry**

Folic Acid.

#### **2. MATTERS REFERRED BY THE AUSTRALIAN DRUG EVALUATION COMMITTEE**

No items.

#### **3. MATTERS REFERRED BY THE NATIONAL REGISTRATION AUTHORITY FOR AGRICULTURAL AND VETERINARY CHEMICALS**

##### **(a) Tepoxalin – new chemical – consideration of poisons scheduling;**

**Outcome** - The Committee considered the inclusion of tepoxalin in Schedule 4 of the SUSDP appropriate on the grounds that:

tepxalin was a new drug;  
the condition being treated required veterinary diagnosis and management; and  
side effects may be severe and would require professional intervention and management.

#### **Schedule 4 – New entry**

TEPOXALIN.

##### **(b) Phenols – consideration of poisons scheduling cut-offs associated with animal use;**

**Outcome** - The Committee agreed to amend the entry for phenol in Schedule 6 of the SUSDP and create a new entry for phenol in Schedule 5, to include any other homologue of phenol as well as incorporate the use of such substances as animal feed additives.

#### **Schedule 6 – Amendment**

PHENOL - amend to read:

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

- (a) when separately specified in these Schedules;
- (b) when included in Schedule 5; or
- (c) in preparations containing three per cent or less of such substances.

#### **Schedule 5 – New entry**

PHENOL, including cresols and xylenols and any other homologue of phenol boiling below 220°C, when in animal feed additives containing 15 per cent or less of such substances, **except** in preparations containing 3 per cent or less of such substances.

#### **Appendix F, Part 3 – Amendment**

Phenol - amend to read:

Phenol and any other homologue of phenol

Safety Directions.....1,4

- (c) **Sulfacetamide** – consideration of poisons scheduling for sulfacetamide when packed and labelled for the treatment of ornamental caged birds or ornamental fish;

**Outcome** - The Committee agreed to include sulfacetamide in Schedule 4 of the SUSDP based on the following grounds:

Scheduling consistency with other sulfonamides with a similar toxicity profile and use pattern.  
Safety of the use pattern and presentation.

Appropriate scheduling of a veterinary preparation for internal use in ornamental fish and birds.

#### **Schedule 4 – Amendment**

SULFACETAMIDE - amend to read:

SULFACETAMIDE **except** when included in Schedule 3 or 5.

#### **Schedule 5 – New entry**

SULFACETAMIDE when packed and labelled for the treatment of ornamental caged birds or

ornamental fish only.

**(d) Barium Selenate** – consideration of poisons scheduling;

**Outcome** - The decision below was based on the rationale that the product's presentation and intended use pattern did not present a significant risk to public health and that barium selenate had an anticipated low acute oral and parenteral toxicity following from its low solubility.

**Schedule 6 – Amendment**

SELENIUM - amend entry to read:

**SELENIUM**

- (a) in preparations containing 2.5 per cent or less of selenium when packed and labelled:
  - (i) for the blueing of gun barrels;
  - (ii) for photographic purposes; or
  - (ii) for the colouring of lead or lead alloys;
- (b) in coated granules containing 1 per cent or less of selenium for application to pasture **except** in fertilisers containing 200 g/tonne or less of selenium;
- (c) for the treatment of animals:
  - (i) in a drench, injection, paste, stocklick or vaccine containing 0.5 per cent or less of selenium for the treatment of animals;
  - (ii) in animal feed premixes containing 2 per cent or less of selenium for the preparation of feeds containing 1 g/tonne or less of selenium; or
  - (iii) as barium selenate in preparations for injection containing 5 per cent or less of selenium.

**(e) Cupric Acetate** – consideration of poisons scheduling;

**Outcome** - The Committee agreed that a Schedule 6 entry was appropriate and consistent with cupric acetate's extrapolated acute toxicity and the skin and eye irritation potential.

**Schedule 6 – New entry**

**COPPER ACETATE except:**

- (a) when included in Schedule 5; or
- (b) when in preparations containing 5 per cent or less of copper acetate.

**Schedule 5 – New entry**

COPPER ACETATE in preparations containing 20 per cent or less of copper acetate **except** when in preparations containing 5 per cent or less of copper acetate.

- (f) **Sulfluramid** – new chemical – consideration of poisons scheduling;

**Outcome** - The Committee agreed that a Schedule 6 entry was appropriate and consistent with the toxicity profile of sulfluramid.

**Schedule 6 – New entry**

SULFLURAMID.

- (g) **Copper proteinate** – new chemical – consideration of poisons scheduling;

**Outcome** – The Committee agreed on a Schedule 6 inclusion based on the following:

Predicted toxicity profile consistent with Schedule 6.

Delivery of an appropriate signal to the consumer for a product that may be attractive to children.

Consistency with the existing entry for copper sulphate.

**Schedule 6 – New entry**

COPPER COMPOUNDS in animal feed additives **except**:

- (a) when included in Schedule 5; or
- (b) in preparations containing 1 per cent or less of copper.

**Schedule 5 – New entry**

COPPER COMPOUNDS in animal feed additives containing 5% or less of copper **except** in preparations containing 1 per cent or less of copper.

(h) **Aglepristone** – new chemical – consideration of poisons scheduling.

**Outcome** - The Committee supported the inclusion of aglepristone in Schedule 4 of the SUSDP on the following grounds:

indicated use required professional management by a veterinarian; and any adverse reaction to use may require professional intervention and management by a veterinarian.

#### **Schedule 4 – New entry**

AGLEPRISTONE.

#### **4. OTHER MATTERS FOR CONSIDERATION**

(a) **Trans-4-[(3,5-dibromo-2-hydroxybenzyl) amino]cyclohexanol hydrochloride monohydrate (Sputolysin)** – Review of nomenclature used in entry.

**Outcome** - The Committee agreed to adopt the International Non-Proprietary Name on the following grounds:

- Consistent with the naming hierarchy specified in the SUSDP.
- Better placed to harmonise in the future.

#### **Schedule 4 - Amendment**

TRANS-4-[(3,5-DIBROMO-2-HYDROXYBENZYL)-AMINO]CYCLOHEXANOL HYDROCHLORIDE MONOHYDRATE – amend to read:

DEMBREXINE **except** when in Schedule 5.

#### **Schedule 5 – Amendment**

TRANS-4-[(3,5-DIBROMO-2-HYDROXYBENZYL)-AMINO]CYCLOHEXANOL HYDROCHLORIDE MONOHYDRATE – amend to read:

DEMBREXINE in oral preparations for the treatment of animals.

#### **6. PROPOSALS ARISING FROM TRANS-TASMAN WORKING PARTY ON THE HARMONISATION OF THE SCHEDULING OF DRUGS AND POISONS.**

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(a) **Substances for which scheduling recommendations have been made by the sixth meeting of the Working Party.** An extract of the draft scheduling recommendations and those matters referred to in 6(b) – *Extracted Draft Recommendations from the Sixth Meeting of the NDPSC Trans-Tasman Harmonisation Working Party* has been placed on the NDPSC website at <http://www.health.gov.au/tga/docs/html/ndpsc/ndpsc.htm>

***Harmonisation of Nomenclature - Herbals***

Aristolochic acid and Aristostolochia spp.  
Acokanthera schimperi and Acokanthera ouabaio  
Aconitum spp.  
Adonis vernalis  
Apocynum spp.  
Belladonna and Atropa belladonna  
Calotropis procera and Calotropis gigantea  
Clove oil  
Conium maculatum (coniine)  
Convallaria majalis and Convallaria keiski  
Coronilla spp.  
Croton tiglium  
Datura stramonium  
Digitalis purpurea and Digitalis lanata  
Delphinium staphisagria  
Erysimum spp.  
Galantamine  
Galanthus spp.  
Gelsemium sempervirens  
Hyoscyamus niger  
Juniperus sabina  
Strychnos ignatii  
Nerium oleander  
Podophyllum hexandrum, and Podophyllum peltatum  
Aspidosperma quebracho  
Rauwolfia serpentina and Rauwolfia vomitoria  
Strophanthus spp.  
Tanacetum vulgare  
Thevetia peruviana  
Veratrum spp. and Sabadilla

***Other Drugs – scheduling recommendations***

Anabolic and androgenic steroidal agents	Atropine
Atropine methonitrate	Atropine sulfate
Azapetine	Belladonna

Brucine	Carbenoxolone
Chlorbutol	Ciclopirox
Colestipol	Datura spp.
Dextromethorphan	Digoxin antibody
Duboisia leichardtii	Duboisia myoporoides
Estropipate	Ethoheptazine citrate
Fenclofenac	Fluorides
Follitrophin alpha and follitrophin beta	Homatropine
Hyaluronic acid	Hylan polymer
Hyoscine	Hyoscyamine
Hyoscyamus	Ion Exchange resins
Hyromellose phthalate	Mitotane
Local anaesthetics (amethocaine, benzamine, Mitotane, benzocaine, butyl aminobenzoate, cinchocaine, dimethisoquin, pramoxine, lignocaine, and prilocaine)	Noradrenaline
Nicoumalone	Orbifloxacin
Octatropine	Phenindione
Pertussis antigen	Podophyllum and podophyllotoxin
Phenylenediamines and alkylated phenylenediamines	Propentofylline
Pseudoephedrine	Salicylic acid
Sodium phosphate	Stramonium
Suxethonium bromide	Tetanus toxoid
Tolonium chloride	Vitamin D including ergocalciferol, dihydrotachysterol

**Outcome 1** – The Committee supported the following new inclusions and amendments to the SUSDP on the basis of harmonisation and adoption of common nomenclature for herbal substances.

## Schedule 2 – New entries

DATURA INNOXIA for therapeutic use, in preparations containing 0.25 per cent or less of the alkaloids of datura.

DATURA TATULA (stramonium) in preparations containing 0.25 per cent or less of the alkaloids of stramonium **except** in preparations for smoking or burning.

PODOPHYLLUM PELTATUM (podophyllin) in preparations for human external therapeutic use containing 10 per cent or less of podophyllin.

## **Schedule 2 – Amendments**

BELLADONNA – amend entry to read:

ATROPA BELLADONNA (belladonna) in preparations containing 0.25 per cent or less of the alkaloids of belladonna.

DATURA – amend entry to read:

DATURA METEL for therapeutic use, in preparations containing 0.25 per cent or less of the alkaloids of datura.

GELSEMIUM – amend entry to read:

GELSEMIUM SEMPERVIRENS.

HYOSYCAMUS – amend entry to read:

HYOSCYAMUS NIGER in preparations containing 0.25 per cent or less of the alkaloids of hyoscyamus.

LOBELIA – amend entry to read:

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

PODOPHYLLUM RESIN – amend entry to read:

PODOPHYLLUM HEXANDRUM (podophyllin) in preparations for human external therapeutic use containing 10 per cent or less of podophyllin.

STRAMONIUM – amend entry to read:

DATURA STRAMONIUM (stramonium) in preparations containing 0.25 per cent or less of the alkaloids of stramonium **except** in preparations for smoking or burning.

STAPHISAGRIA - amend entry to read:

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

## **Schedule 3 – New entry**

PODOPHYLLUM PELTATUM (podophyllin) in preparations for human external

therapeutic use containing 20 per cent or less of podophyllin **except** when included in Schedule 2.

### **Schedule 3 – Amendments**

PODOPHYLLUM RESIN – amend entry to read:

PODOPHYLLUM HEXANDRUM (podophyllin) in preparations for human external therapeutic use containing 20 per cent or less of podophyllin **except** when included in Schedule 2.

### **Schedule 4 – New entries**

ACOKANTHERA OUABAIO for therapeutic use.

CALOTROPIS GIGANTEA for therapeutic use.

CONVALLARIA KEISKI for therapeutic use.

DATURA INNOXIA for therapeutic use, **except**:

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

DATURA TATULA (stramonium) **except**:

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

DIGITALIS LANATA for therapeutic use.

PODOPHYLLUM PELTATUM (podophyllin) for human therapeutic use **except** when included in Schedule 2 or 3.

RAUWOLFIA VOMITORIA for therapeutic use.

### **Schedule 4 – Amendments**

ACONITE – amend entry to read:

ACONITUM spp. for therapeutic use.

ADONIS - amend entry to read:

ADONIS VERNALIS for therapeutic use.

APOCYNUM – amend entry to read:

APOCYNUM spp. for therapeutic use.

BELLADONNA – amend entry to read:

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

BRUCINE – delete entry

CALOTROPIS – amend entry to read:

CALOTROPIS PROCERA for therapeutic use.

CONVALLARIA – amend entry to read:

CONVALLARIA MAJALIS for therapeutic use.

CORONILLA – amend entry to read:

CORONILLA spp. for therapeutic use.

DATURA – amend entry to read:

DATURA METEL for therapeutic use, **except**:

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

DIGITALIS – amend entry to read:

DIGITALIS PURPUREA for therapeutic use.

ERYSIMUM – amend entry to read:

ERYSIMUM spp for therapeutic use.

GALANTHAMINE – amend entry to read:

GALANTAMINE.

GALANTHUS – amend entry to read:

GALANTHUS spp. for therapeutic use.

HYOSYCAMUS – amend entry to read:

HYOSCYAMUS NIGER **except** when included in Schedule 2.

OLEANDER – amend entry to read:

NERIUM OLEANDER for therapeutic use.

PODOPHYLLUM RESIN – amend entry to read:

PODOPHYLLUM HEXANDRUM (podophyllin) for human therapeutic use **except** when included in Schedule 2 or 3.

QUEBRACHO – amend entry to read:

ASPIDOSPERMA QUEBRACHO.

RAUWOLFIA – amend entry to read:

RAUWOLFIA SERPENTINA for therapeutic use.

SABADILLA – amend entry to read:

SCHOENOCAULON OFFICINALE (sabadilla).

STRAMONIUM – amend entry to read:

DATURA STRAMONIUM (stramonium) **except**:

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

STROPHANTHUS – amend entry to read:

STROPHANTHUS spp. for therapeutic use.

STRYCHNOS – amend entry to read:

STRYCHNOS spp.

THEVETIA – amend entry to read:

THEVETIA PERUVIANA for therapeutic use.

VERATRUM – amend entry to read:

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

### **Schedule 7 – Amendment**

BRUCINE – amend entry to read:

BRUCINE **except** in preparations containing 0.02 per cent or less of brucine for the denaturation of alcohol.

### **Appendix C – New entry**

ARISTOLOCHIC ACID.

### **Appendix C – Amendment**

ARISTOLOCHIA – amend entry to read:

ARISTOLOCHIACEAE; plants of this family containing aristolochic acid for therapeutic use.

CONIINE – amend entry to read:

CONIUM MACULATUM (coniine) for therapeutic use.

### **Appendix G – Amendments**

GELSEMIUM – amend entry to read:

GELSEMIUM SEMPERVIRENS

IGNATIA AMARA – amend entry to read:

## STRYCHNOS IGNATII

NUX VOMICA – amend entry to read:

STRYCHNOS NUX VOMICA.

**Outcome 2** - The Committee supported the following decisions on the grounds that there was a need to establish concentration and dose limit cut-off consistency across the schedule entries for solanaceous alkaloids.

## Schedule 2 – Amendments

ATROPINE – amend entry to read:

ATROPINE (excluding atropine methonitrate):

- a) for oral use:
  - (i) in undivided preparations containing 0.025 per cent or less of atropine, when labelled with a dose of 0.025 mg or less of atropine and a recommended daily dose of 0.5 mg or less of atropine; or
  - (ii) in divided preparations containing 0.025 mg or less of atropine per dosage unit and labelled with a recommended daily dose of 0.5 mg or less of atropine.
- b) in preparations containing atropine sulfate when packed and labelled for the treatment of organophosphorus poisoning:
  - (i) in tablets each containing 0.6 mg or less of atropine sulfate in packs of 20 tablets; or
  - (ii) in preparations for injection each containing 0.6 mg per ml or less of atropine sulfate in packs of 5.

BELLADONNA – amend entry to read:

BELLADONNA:

- a) for external use in preparations containing 0.025 per cent or less of the alkaloids of belladonna; or

b) for oral use:

- (i) in undivided preparations containing 0.025 per cent or less of the alkaloid of belladonna and 0.025 mg or less of the alkaloids of belladonna per dose, and labelled with a recommended daily dose of 0.5 mg or less of the alkaloids of belladonna; or
- (ii) in divided preparations containing 0.025 mg or less of the alkaloids of belladonna per dosage unit, and labelled with a recommended daily dose of 0.5 mg or less of the alkaloids of belladonna.

DATURA – amend entry to read:

DATURA spp. for oral use:

- a) in undivided preparations containing 0.025 per cent or less of the alkaloids of datura and 0.3 mg of the alkaloids of datura per dose, and labelled with a recommended daily dose of 1 mg or less of the alkaloids of datura; or
- b) in divided preparations containing 0.3 mg of the alkaloids of datura per dosage unit and labelled with a recommended daily dose of 1 mg or less of the alkaloids of datura.

DATURA STRAMONIUM (STRAMONIUM) **except** for smoking or burning for oral use when:

- a) in undivided preparations containing 0.025 per cent or less of the alkaloids of stramonium calculated as hyoscyamine and 0.025 mg or less of the alkaloids of stramonium calculated as hyoscyamine per dose, and labelled with a recommended daily dose of 0.5 mg or less of the alkaloids of stramonium calculated as hyoscyamine;
- b) in divided preparations containing 0.025 mg or less of the alkaloids of stramonium calculated as hyoscyamine per dosage unit and labelled with a recommended daily dose of 0.5 mg or less of the alkaloids of stramonium calculated as hyoscyamine.

DATURA TATULA (STRAMONIUM) **except** for smoking and burning when:

- a) in undivided preparations containing 0.025 per cent or less of the alkaloids of stramonium calculated as hyoscyamine and 0.025 mg or less of the alkaloids of stramonium calculated as hyoscyamine per dose, and labelled with a recommended daily dose of 0.5 mg or less of the alkaloids of stramonium calculated as hyoscyamine;

- b) in divided preparations containing 0.025 mg or less of the alkaloids of stramonium calculated as hyoscyamine per dosage unit and labelled with a recommended daily dose of 0.5 mg or less of the alkaloids of stramonium calculated as hyoscyamine.

DUBOISIA LEICHARDTII – amend entry to read:

DUBOISIA LEICHARDTII for oral use:

- a) in undivided preparations containing 0.025 per cent or less of the alkaloids of duboisia calculated as hyoscyamine and 0.025 mg or less of the alkaloids of duboisia calculated as hyoscyamine per dose and labelled with a recommended daily dose of 0.5 mg or less of the alkaloids of duboisia calculated as hyoscyamine; or
- b) in divided preparations containing 0.025 mg or less of the alkaloids of duboisia calculated as hyoscyamine per dosage unit and labelled with a recommended daily dose of 0.5 mg or less of the alkaloids of duboisia calculated as hyoscyamine.

DUBOISIA MYOPOROIDES – amend entry to read:

DUBOISIA MYOPOROIDES for oral use:

- a) in undivided preparations containing 0.025 per cent or less of the alkaloids of duboisia calculated as hyoscyamine and 0.025 mg or less of the alkaloids of duboisia calculated as hyoscyamine per dose and labelled with a recommended daily dose of 0.5 mg or less of the alkaloids of duboisia calculated as hyoscyamine;
- b) in divided preparations containing 0.025 mg or less of the alkaloids of duboisia calculated as hyoscyamine per dosage unit and labelled with a recommended daily dose of 0.5 mg or less of the alkaloids of duboisia calculated as hyoscyamine.

HYOSCYAMINE – amend entry to read:

HYOSCYAMINE:

- a) for external use in preparations containing 0.025 per cent or less of hyoscyamine; or
- b) for oral use:
  - (i) in undivided preparations containing 0.025 per cent or less of hyoscyamine, with a dose of 0.025 mg or less of hyoscamine and labelled with a recommended daily dose of 0.5 milligrams or less of hyoscamine; or

- (ii) in divided preparations containing 0.025 mg or less of hyoscyamine per dosage unit and labelled with a recommended daily dose of 0.5 mg or less hyoscamine.

HYOSCINE – amend entry to read:

HYOSCINE (excluding hyoscine butylbromide):

- a) for transdermal use in preparations containing 2 mg or less of hyoscine; or
- b) for oral use:
  - (i) in undivided preparations containing 0.025 per cent or less of hyoscine, with a dose of 0.3 mg or less of hyoscine and labelled with a recommended daily dose of 1 mg or less of hyoscine.
  - (ii) in divided preparations containing 0.3 mg or less of hyoscine per dosage unit and labelled with a recommended daily dose of 1 mg or less of hyoscine.

HYOSCYAMUS – amend entry to read:

HYOSCYAMUS for oral use:

- a) in undivided preparations containing 0.025 per cent or less of the alkaloids of hyoscyamus and 0.025 mg of the alkaloids of hyoscyamus per dose and labelled with a recommended daily dose of 0.5 mg or less of the alkaloids of hyoscyamus; or
- b) in divided preparations containing 0.025 mg of the alkaloids of hyoscyamus or less per dosage unit and labelled with a recommended daily dose of 0.5 mg or less of the alkaloids of hyoscyamus.

#### **Schedule 4 – Amendments**

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.

DUBOISIA LEICHARDTII – amend entry to read:

DUBOISIA LEICHARDTII **except** when included in Schedule 2.

DUBOISIA MYOPOROIDES – amend entry to read:

DUBOISIA MYOPOROIDES **except** when included in Schedule 2.

**Outcome 3** – The Committee supported the decisions below on the following considerations:  
harmonisation;  
use of appropriate nomenclature;  
safety considerations;  
for clarity; and  
relevance of entry.

### **Schedule 2 – New entries**

AMETHOCAINE in preparations for topical use other than eye drops, containing 10 per cent or less of total local anaesthetic substances, **except** in dermal preparations containing 2 per cent or less of total local anaesthetic substances.

CICLOPIROX in preparations for dermal use containing 1 per cent or less of ciclopirox.

### **Schedule 2 – Amendments**

BENZAMINE – delete entry.

BENZOCAINE – amend entry to read:

BENZOCAINE in preparations for topical use other than eye drops:

- a) containing 10 per cent or less of total local anaesthetic substances, except in dermal preparations containing 2 per cent or less of total local anaesthetic substances; or
- b) in divided preparations containing 200 mg or less of total local anaesthetic substances per dosage unit, except in lozenges containing 30 mg or less of total local anaesthetic substances per dosage unit.

BUTYLAMINOBENZOATE – delete entry.

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CARBENOXOLONE – delete entry.

CINCHOCAINE – amend entry to read:

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

CHLORBUTOL – amend entry to read:

CHLORBUTOL for human use in topical preparations containing 5 per cent or less of chlorbutol, **except** in preparations containing 0.5 per cent or less of chlorbutol.

DIMETHISOQUIN – delete entry.

ETHOHEPTAZINE – delete entry.

FLUORIDES - amend entry to read:

FLUORIDES for human therapeutic use (**except** in preparations containing 15 mg / kg or 15 mg / L or less of fluoride ion):

- a) as sodium fluoride, in preparations for ingestion containing 2.2 mg or less of sodium fluoride per dosage unit;
- b) in preparations for topical use containing 2.5 per cent or less of fluoride ion **except**:
  - (i) dentrifrices included in schedule 3;
  - (ii) dentrifrices containing 1000 mg / kg or less of fluoride ion; or
  - (iii) other dental hygiene products containing 100 mg / kg or 100 mg / L or less of fluoride ion.

HOMATROPIN – delete entry.

LIGNOCAINE – amend entry to read:

LIGNOCAINE in preparations for topical use other than eye drops:

- a) containing 10 per cent or less of total local anaesthetic substances, **except** in dermal preparations containing 2 per cent or less of total local anaesthetic substances; or

- b) in divided preparations containing 200 mg or less of total local anaesthetic substances per dosage unit, **except** in lozenges containing 30 mg or less of total local anaesthetic substances per dosage unit.

**OXETHAZAINE** – amend entry to read:

**OXETACAIN** (OXETHAZAINE) in preparations for internal use.

**PHENYLENEDIAMINES** – delete entry.

**PODOPHYLLIN RESIN** – amend entry to read:

**PODOPHYLLIN RESIN** (PODOPHYLLIN) in preparations for human external use containing 10 per cent or less of podophyllin resin when packed and labelled for the treatment of common warts.

**PRAMOXINE** – delete entry.

**PRILOCAINE** - amend entry to read:

**PRILOCAINE** in preparations for topical use other than eye drops, containing 10 per cent or less of total local anaesthetic substances.

### **Schedule 3 – New entries**

**CICLOPIROX** in preparations for dermal use **except** when included in Schedule 2.

**SALICYLIC ACID** in preparations for dermal use containing more than 40 per cent of salicylic acid.

### **Schedule 3 – Amendments**

**CHLORBUTOL** – amend entry to read:

**CHLORBUTOL** in preparations for human use **except**:

- a) when included in Schedule 2; or
- b) in preparations containing 0.5 per cent or less of chlorbutol.

**PODOPHYLLIN RESIN** – amend entry to read:

PODOPHYLLIN RESIN (PODOPHYLLIN) in preparations for human external use containing 20 per cent or less of podophyllin resin when packed and labelled for the treatment of common warts, **except** when included in Schedule 2.

SODIUM PHOSPHATE in oral preparations for bowel cleansing prior to diagnostic, medical or surgical procedures.

**Schedule 4 – New entries**

ANABOLIC STEROIDAL AGENTS.

ANDROGENIC STEROIDAL AGENTS.

ATROPINE METHONITRATE.

BAMBUTEROL HYDROCHLORIDE.

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

ESTROPIPATE (PIPERAZINE OESTRONE SULFATE).

FENCLOFENAC.

PERTUSSIS ANTIGEN.

PODOPHYLLUM EMOIDI **except** when separately specified in these schedules.

PODOPHYLLUM PELTATUM **except** when separately specified in these schedules.

PRAMOCAIN.

QUINISOCAIN (DIMETHISOQUIN).

SODIUM PHOSPHATE in preparations for oral laxative use.

SUXETHONIUM BROMIDE.

TETANUS TOXOID.

TOLONIUM CHLORIDE.

**Schedule 4 – Amendments**

*NDPSC 30 – Record of Reasons for amendment to the Standard for the Uniform Scheduling of Drugs and Poisons and advice of other outcomes.*

AMETHOCAINE – amend entry to read:

AMETHOCAINE **except:**

- a) when included in schedule 2; or
- b) in dermal preparations containing 2 per cent or less of total local anaesthetic substances.

ANABOLIC AND ANDROGENIC STEROIDAL AGENTS – delete entry.

AZAPETINE – delete entry.

BENZAMINE – amend entry to read:

BENZAMINE.

BENZOCAINE – amend entry to read:

BENZOCAINE **except:**

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

BRUCINE – delete entry.

BUTYLAMINOBENZOATE – amend entry to read:

BUTYL AMINOBENZOATE.

CARBENOXOLONE – amend entry to read:

CARBENOXOLONE for internal use.

CINCHOCAINE – amend entry to read:

CINCHOCAINE **except** when included in Schedule 2

COLESTIPOL – amend entry to read:

COLESTIPOL for human therapeutic use.

DIGOXIN ANTIBODY – amend entry to read:

DIGOXIN-SPECIFIC ANTIBODY FRAGMENT F (Ab).

DIMETHISOQUIN – delete entry.

ION-EXCHANGE RESINS – delete entry.

ISOETHARINE – amend entry to read:

ISOETARINE.

ETHOHEPTAZINE – amend entry to read:

ETHOHEPTAZINE CITRATE.

FLUORIDES - amend entry to read:

FLUORIDES in preparations for human therapeutic use **except**:

- a) when included in schedule 2 or 3;
- b) dentifrices containing 1000 mg / kg or less of fluoride ion;
- c) other dental hygiene products containing 100 mg / kg or 100 mg / L or less of fluoride ion; or
- d) in other substances containing 15 mg / kg or 15 mg / L or less of fluoride ion.

FOLLITROPIN ALPHA – amend entry to read:

FOLLITROPIN ALPHA.

FOLLITROPIN BETA – amend entry to read:

FOLLITROPIN BETA.

HOMATROPINE – amend entry to read:

HOMATROPINE.

LIGNOCAINE – amend entry to read:

LIGNOCAINE **except**:

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

NICOUMALONE – amend entry to read:

NICOUMALONE.

NORADRENALINE – amend entry to read:

NORADRENALINE.

OCTATROPINE – amend entry to read:

OCTATROPINE METHYLBROMIDE.

OXETHAZAINE – amend entry to read:

OXETACAIN (OXETHAZAINE) **except** when included in Schedule 2.

PHENINDIONE – amend entry to read:

PHENINDIONE.

PRAMOXINE – delete entry.

PRILOCAINE - amend entry to read:

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

UROFOLLITROPHIN – amend entry to read:

UROFOLLITROPHIN

## **Schedule 6 – Amendment**

PHENYLENEDIAMINES – amend entry to read:

PHENYLENEDIAMINES and alkylated phenylenediamines **except** when separately specified in this Schedule:

- a) when used in hair dyes;
- b) in preparations packed and labelled for photographic purposes; or
- c) in preparations packed and labelled for testing water except in 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.”

## **Schedule 7 – New entry**

BRUCINE **except** when used in concentrations of 0.02 per cent or less of brucine for the denaturation of alcohol.

## **Appendix D – New entries**

ANABOLIC STEROIDAL AGENTS, including those separately specified in Schedule 4.

ANDROGENIC STEROIDAL AGENTS, including those separately specified in Schedule 4.

## **Appendix D – Amendment**

ANABOLIC AND ANDROGENIC STEROIDAL AGENTS – delete entry.

### **(b) Recommendations to amend Part 1 to Part 3 the SUSDP**

1. Revise the definition of ‘approved name’ so that the ‘International Non-Proprietary Name’ is second on the decision tree;

**Outcome** – The Committee agreed to the proposal on the basis of harmonisation.

## **PART 1 – INTERPRETATION – Amendment**

Amend “approved name” under sub-paragraph 1(1) to read:

**“Approved name”** means:

- (a) in relation to a poison that is for therapeutic use -
  - (i) the Australian Approved Name for the poison, not including synonyms, as listed in the publication entitled “Therapeutic Goods Administration Approved Terminology for Medicines”, July 1999, or its successor, published by the Therapeutic Goods Administration, Canberra; or, if the poison is not listed in that publication,
  - (ii) the international non-proprietary name recommended for the poison by the World Health Organisation; or, if no such name is recommended,
  - (iii) the English name, not including synonyms, by which the poison is described in the British Pharmacopoeia, the British Pharmaceutical Codex, the Australian Pharmaceutical Formulary and Handbook or the British Pharmacopoeia (Veterinary); or, if the poison is not described in any of those publications,
  - (iv) the approved name given to the poison by the Medicines Commission of Great Britain; or, if no such name is given,
  - (v) the accepted scientific name or the name descriptive of the true nature and origin of the poison;
2. Adoption of a definition for ‘compounded’ based on the UN Single Convention on Narcotic Drugs and the NZ Misuse of Drugs Act;

**Outcome** – The Committee did not adopt the recommended definition from the trans-Tasman Harmonisation Working Party on the grounds that the issue needed to be further considered so a definition appropriate to both countries can be developed.

**(c) Recommendations arising from Seventh Meeting**

1. Consideration of specific Schedule 4 and Appendix G entries for ephedra associated with public health and safety concerns.

**Outcome** - The decision below was based on the following grounds:

- a separate entry would provide clarity to the scheduling of ephedra;
- consistent with the scheduling of ephedrine; and
- was not expected to significantly impact on current regulatory controls already in place for ephedra in States and Territories.

## **Schedule 4 – New entry**

EPHEDRA spp **except** in preparations containing 0.001 per cent or less of ephedrine.

### **7. MATTERS ARISING FROM THE ESSENTIAL OILS WORKING PARTY AND SUBSEQUENT DELIBERATIONS**

**(a) Revised Introduction to Appendix E incorporating details of new first aid instructions and transitional period.** The following incorporates changes to the draft Appendix E gazetted prior to the November 2000 meeting. The existing statements will be retained for a transitional period of two years from completion of the review of the substances by the NDPSC.

#### **APPENDIX E – INTRODUCTION - Amend to read:**

##### **Directions for First Aid Attention**

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

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

These First Aid Instructions include action to be taken in case of eye contamination from substances recognised as causing direct poisoning via the eye, causing severe eye damage or requiring prolonged flushing to free the absorbed substance from the eye tissue. However, it is recognised that many other substances or preparations will require a statement of varying nature depending on the detailed formulation. While the necessity to flush the eyes in case of accident will be so self-evident as not to justify label space in many instances, a statement such as “If in eyes rinse well with water” may be appropriate.

##### **Standard Statements – NEW and OLD**

Based on a review of the Standard First Aid Instruction Statements undertaken by a Working

Party of the National Drugs and Poisons Schedule Committee, a revised set of Standard Statements is to be phased in over the transitional period of *{insert start date}* to *{insert end date – to be 2 years from completion of the review of substances by the NDPSC}*. These revised Standard Statements are shown in Part 1 of this Appendix as “NEW” Standard Statements. The Standard Statements in force at commencement of the transitional period are shown in Part 1 of this Appendix as “OLD” Standard Statements.

Manufacturers, packers and suppliers are encouraged to switch to use of the NEW Standard Statements as early as possible in the transitional period particularly if the existing first aid instructions include reference to induction of vomiting. However poisons labelled with OLD Standard Statements may continue to be sold or supplied until the end of the transitional period.

Because of the transitional period during which poisons may be labelled with either NEW or OLD Standard Statements, Part 2 of this Appendix, which gives the Standard Statements for specific poisons, has been revised to show both NEW and OLD Standard Statements. A mix of NEW and OLD Standard Statements should not be used on labels.

New substances added to this Appendix after the beginning of the transitional period will not have entries made under the OLD Standard Statements. In such cases there is no transitional period and the specified first aid instructions should be applied by the effective date of the first document in which they are notified.

T-Values have been retained in Part 2 of this Appendix for use in conjunction with the OLD Standard Statements only.

### **Conflict between Instructions for Poison and Solvent**

This provision does NOT apply to the NEW statements.

Where a preparation contains a scheduled poison dissolved or suspended in a scheduled solvent, the First Aid Instructions for the poison and the solvent may conflict.

Thus, under the OLD Standard Statements, the poison may call for Instructions “b” or “h”, which prescribe the induction of vomiting, while the solvent may call for Instruction “c”, which specifies not to induce vomiting, due to the risks of aspiration of the solvent into the lungs when vomiting occurs. In such cases the risks of leaving the poison in the digestive system must be balanced against the risks of aspiration.

As a guide in deciding which Instruction should be adopted, the following rule may be used:-

“Where the First Aid Instruction for a poison and its solvent are in conflict, the Instruction for the poison is to prevail if its concentration, expressed in grams per litre or grams per kilogram of preparation, is greater than the T-value listed beside the poison in Appendix E. If the

concentration is equal to or less than T, then the instruction for the solvent is to prevail, provided that in the case of Instruction 'h', the statements on skin absorption are to be retained.

Where two or more poisons are present at concentrations less than their T-value and their First Aid Instructions are in conflict with the solvent calculate, for each poison, the proportion of its T-value which its actual concentration C represents (i.e., the C/T fraction) and add these fractions. If the total exceeds 1, the first aid for the poisons is to prevail."

It may be noted that where the solvent concentration is low enough to result in exemption of the solvent from scheduling, for example at 25 per cent for liquid hydrocarbons, then no conflict arises and the first aid for the poison automatically prevails.

On the other hand, for certain substances of very low toxicity, the first aid for the solvent will always prevail. In these cases the symbol 'SVT' is shown instead of a numerical T-value.

### **Modified First Aid Instruction on Primary Pack**

Where a primary pack contains two or more immediate containers of poisons each requiring different first aid instructions:

- (a) each immediate container must be labelled with first aid instructions appropriate for its contents; and
- (b) the primary pack must be labelled with the statement:  
FIRST AID: See inner packs.

### **Modified First Aid Instruction for Dilute Preparations**

Under the OLD system of Standard Statements, where the concentration of any poison, expressed in grams per litre or grams per kilogram, is less than one tenth of the T-value listed beside the poison in Appendix E, then only standard statement "a" need be shown.

This provision does not apply to the NEW Standard Statements.

### **Exempt Preparations**

This Appendix applies only to scheduled poisons. The directions are for substances and their preparations at the concentrations at which the schedules apply. If it is thought desirable to show first aid instructions for a substance exempted from the schedules, it is the responsibility of the manufacturer to ensure they are appropriate.

## **Poisons Information Centre Telephone Numbers**

Companies wishing to use a poisons information centre telephone number other than the national telephone numbers for Australia and New Zealand in either NEW statement A or OLD statement (a) in Part 1 of this Appendix must meet the following criteria:

1. The poisons information service whose number is used must be attended by adequately trained staff for 24 hour emergency poisons information; and
2. Calls must be logged and submitted for incorporation into the official collection of poisoning data.

## **APPENDIX E – PART 1 – amend to read:**

Insert the following heading and preamble preceding the existing statements:

### **OLD Standard Statements**

**These Standard Statements are to be phased-out over the period of {insert start date} to {insert end date} and replaced by the New Standard Statements given above, with specific requirements given in Part 2 of this Appendix.**

## **APPENDIX E – PART 1 – amend to read:**

Insert the following heading, preamble and statements after the words “...Sub-paragraph 7(p) of this Standard.”:

### **NEW Standard Statements**

**Manufacturers, packers and suppliers are encouraged to replace existing first aid instructions with these New Standard Statements as soon as practical, but no later than {insert end date for transition}.**

#### *Basic*

- A For advice, contact a Poisons Information Centre (Phone *eg Australia 131 126; New Zealand 03 4747 000*) or a doctor (at once).
- Z First aid is not generally required. If in doubt, contact a Poisons Information Centre (Phone 131 126) or a doctor.

### *General*

- G1    Urgent hospital treatment is likely to be needed. (Note - the words 'at once' to be added to instruction A).
- G2    If swallowed, give activated charcoal if instructed. (Note - the words 'at once' to be added to instruction A).
- G3    If swallowed, do NOT induce vomiting.
- G4    Immediately give a glass of water.
- G5    Avoid giving milk or oils.
- G6    If sprayed in mouth, rinse mouth with water

### *Eyes*

- E1    If in eyes wash out immediately with water.
- E2    If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.

### *Respiratory system*

- R1    If inhaled, remove from contaminated area. Apply artificial respiration if not breathing.
- R2    If inhaled, remove from contaminated area. Apply artificial respiration if not breathing. Do not give direct mouth-to-mouth resuscitation. To protect rescuer, use air-viva, oxy-viva or one-way mask. Resuscitate in a well-ventilated area.

### *Skin*

- S1    If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.
- S2    If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water. Continue flushing with water until advised to stop by the Poisons

Information Centre or a doctor.

- S3 If on skin, remove any contaminated clothing, wash skin thoroughly with soap and water, then methylated spirit if available. Contact the Poisons Information Centre or a doctor.
- 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 the Poisons Information Centre or a doctor.
- S5 If skin contact occurs, immediately remove contaminated clothing. Flush skin under running water for 15 minutes. Then apply calcium gluconate gel. Contact the Poisons Information Centre.

#### ***Special Purpose***

- SP1 If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone *eg Australia 131 126; New Zealand 03 4747 000*) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

***Outcome*** – The Committee supported the amendments below based on the following:

- Implementation of currently accepted clinical best practice in relation to first aid particularly in removing recommendations to induce vomiting.
- Providing an acceptable transition period for all affected stakeholders.
- Providing transitional arrangements for first aid instructions.

#### **APPENDIX E – INTRODUCTION, Amend to Read:**

##### **Directions for First Aid Attention**

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

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

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

### **Standard Statements – NEW and OLD**

Based on a review of the Standard First Aid Instruction Statements undertaken by a Working Party of the National Drugs and Poisons Schedule Committee, a revised set of Standard Statements is to be phased in over the transitional period of 1 September 2001 to 31 August 2003 where OLD statements b, h, r, and v are to be phased out; and to 31 August 2004 for all other OLD statements. These revised Standard Statements are shown in Part 1 of this Appendix as "NEW" Standard Statements. The Standard Statements in force at the commencement of the transitional period are shown in Part 1 of this Appendix as "OLD" Standard Statements.

Manufacturers, packers and suppliers are encouraged to switch to use of the NEW Standard Statements as early as possible in the transitional period particularly if the existing first aid instructions include reference to induction of vomiting. However poisons labelled with OLD Standard Statements may continue to be sold or supplied until 31 August 2004 unless they are labelled with the OLD standard statements b, h, r, or v in which case they may not be sold or supplied after 31 August 2003. Poisons labelled with the NEW standard statement G3 must also be phased in by 31 August 2003.

Because of the transitional period during which poisons may be labelled with either NEW or OLD Standard Statements, Part 2 of this Appendix, which gives the Standard Statements for specific poisons, has been revised to show both NEW and OLD Standard Statements. A mix of NEW and OLD Standard Statements must not be used on labels.

New substances added to this Appendix after the beginning of the transitional period will not have entries made under the OLD Standard Statements. In such cases there is no transitional period and the specified first aid instructions should be applied by the effective date of the first document in which they are notified.

T-Values have been retained in Part 2 of this Appendix for use in conjunction with the OLD Standard Statements only.

## **Conflict between Instructions for Poison and Solvent**

This provision does NOT apply to the NEW statements.

Where a preparation contains a scheduled poison dissolved or suspended in a scheduled solvent, the First Aid Instructions for the poison and the solvent may conflict.

Thus, under the OLD Standard Statements, the poison may call for Instructions “b” or “h”, which prescribe the induction of vomiting, while the solvent may call for Instruction “c”, which specifies not to induce vomiting, due to the risks of aspiration of the solvent into the lungs when vomiting occurs. In such cases the risks of leaving the poison in the digestive system must be balanced against the risks of aspiration.

As a guide in deciding which Instruction should be adopted, the following rule may be used:-

“Where the First Aid Instruction for a poison and its solvent are in conflict, the Instruction for the poison is to prevail if its concentration, expressed in grams per litre or grams per kilogram of preparation, is greater than the T-value listed beside the poison in Appendix E. If the concentration is equal to or less than T, then the instruction for the solvent is to prevail, provided that in the case of Instruction ‘h’, the statements on skin absorption are to be retained.

Where two or more poisons are present at concentrations less than their T-value and their First Aid Instructions are in conflict with the solvent calculate, for each poison, the proportion of its T-value which its actual concentration C represents (i.e., the C/T fraction) and add these fractions. If the total exceeds 1, the first aid for the poisons is to prevail.”

It may be noted that where the solvent concentration is low enough to result in exemption of the solvent from scheduling, for example at 25 per cent for liquid hydrocarbons, then no conflict arises and the first aid for the poison automatically prevails.

On the other hand, for certain substances of very low toxicity, the first aid for the solvent will always prevail. In these cases the symbol ‘SVT’ is shown instead of a numerical T-value.

## **Modified First Aid Instruction on Primary Pack**

Where a primary pack contains two or more immediate containers of poisons each requiring different first aid instructions:

- (a) each immediate container must be labelled with first aid instructions appropriate for its

contents; and

(b) the primary pack must be labelled with the statement:  
FIRST AID: See inner packs.

### **Modified First Aid Instruction for Dilute Preparations**

Under the OLD system of Standard Statements, where the concentration of any poison, expressed in grams per litre or grams per kilogram, is less than one tenth of the T-value listed beside the poison in Appendix E, then only standard statement "a" need be shown.

This provision does not apply to the NEW Standard Statements.

### **Exempt Preparations**

This Appendix applies only to scheduled poisons. The directions are for substances and their preparations at the concentrations at which the schedules apply. If it is thought desirable to show first aid instructions for a substance exempted from the schedules, it is the responsibility of the manufacturer to ensure they are appropriate.

### **Poisons Information Centre Telephone Numbers**

Companies wishing to use a poisons information centre telephone number other than the national telephone numbers for Australia and New Zealand in either NEW statement A or OLD statement (a) in Part 1 of this Appendix must meet the following criteria:

1. The poisons information service whose number is used must be attended by adequately trained staff for 24 hour emergency poisons information; and
2. Calls must be logged and submitted for incorporation into the official collection of poisoning data.

### **APPENDIX E – PART 1**

**Insert the following** heading, preamble and statements after the words "...Sub-paragraph 7(p) of this Standard).":

### **NEW Standard Statements**

**Manufacturers, packers and suppliers are encouraged to replace existing first aid instructions with these New Standard Statements as soon as practical, but no later than 31 August 2003 for those substances requiring statement G3 and no later than 31 August 2004 for all other statements.**

*Basic*

- A For advice, contact a Poisons Information Centre (Phone *eg Australia 131 126; New Zealand 03 4747 000*) or a doctor (at once).
- Z First aid is not generally required. If in doubt, contact a Poisons Information Centre (Phone 131 126) or a doctor.

*General*

- G1 Urgent hospital treatment is likely to be needed. (Note - the words 'at once' to be added to instruction A).
- G2 If swallowed, give activated charcoal if instructed. (Note - the words 'at once' to be added to instruction A).
- G3 If swallowed, do NOT induce vomiting.
- G4 Immediately give a glass of water.
- G5 Avoid giving milk or oils.
- G6 If sprayed in mouth, rinse mouth with water

*Eyes*

- E1 If in eyes wash out immediately with water.
- E2 If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.

*Respiratory system*

- R1 If inhaled, remove from contaminated area. Apply artificial respiration if not breathing.
- R2 If swallowed or inhaled, remove from contaminated area. Apply artificial respiration if

not breathing. Do not give direct mouth-to-mouth resuscitation. To protect rescuer, use air-viva, oxy-viva or one-way mask. Resuscitate in a well-ventilated area.

### *Skin*

- S1 If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.
- S2 If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water. Continue flushing with water until advised to stop by the Poisons Information Centre or a doctor.
- S3 If on skin, remove any contaminated clothing, wash skin thoroughly with soap and water, then methylated spirit if available. Contact the Poisons Information Centre or a doctor.
- 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 the Poisons Information Centre or a doctor.
- S5 If skin contact occurs, immediately remove contaminated clothing. Flush skin under running water for 15 minutes. Then apply calcium gluconate gel. Contact the Poisons Information Centre.

### *Special Purpose*

- SP1 If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone *eg Australia 131 126; New Zealand 03 4747 000*) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

### **OLD Standard Statements**

**These Standard Statements are to be phased-out over the period 1 September 2001 to 31 August 2003 for statements b, h, r, and v, and to 31 August 2004 for all other statements, and replaced by the New Standard Statements given above, with specific requirements given in Part 2 of this Appendix.**

- (b) **Review of first aid instructions** – The NDPSC is seeking comment on the following

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proposals for the allocation of the new standard statements.

**Outcome** – The Committee supported the decisions below based on the following considerations:

- Implementation of currently accepted clinical best practice in relation to first aid, particularly in removing recommendations to induce vomiting.
- Removal of entries outside the scope of Appendix E.

***Entries marked with an asterisk have been altered from those notified in the pre-meeting Gazette. This column (containing asterisks) should be omitted for the purposes of the amendment. Entries followed by the statement “Delete entry” should be omitted in their entirety.***

**Appendix F, Part 2 – Amend Part 2 to read:**

**PART 2**

**FIRST AID INSTRUCTIONS**

Standard statements in this Appendix apply to poisons other than agricultural and veterinary chemicals (including pesticides) registered by the National Registration Authority for Agricultural and Veterinary Chemicals. Labelling is not required at concentrations below scheduled levels (see the INTRODUCTION to this Appendix).

POISON	NEW STANDARD STATEMENTS	OLD STANDARD STATEMENTS AND ASSOCIATED T-VALUES	
		OLD STANDARD STATEMENTS	T-VALUE
Acetic acid	A, G3, E2, S1	a,c,f,s	
Acetic anhydride	A, G3, E2, S1	a,c,f,s	
Acetone	A, G3	a,c	
Acrolein	A,G1,G2,G3,E2, S2, R2	a,b,f,g,s	2
*	Alkaline salts	A, G3, E2, S2	a,c,s

	POISON	NEW STANDARD STATEMENTS	OLD STANDARD STATEMENTS AND ASSOCIATED T-VALUES	
			OLD STANDARD STATEMENTS	T-VALUE
	Amines for use as curing agents for epoxy resins	A, G3, E1, S1	a,c,f	
	4-Aminopyridine	A,G1,G2,E1,S1	a,b,f	4
	Ammonia 5 per cent or less above 5 per cent	A A, G3,E1,S1,R1	a a,c,f,g	
	Ammonium bifluoride when included in Schedule 5 when included in Schedule 6	A A,G3,E2,S5	a f,s,c,a,t	
	Ammonium persulfate	A,G3,E2	a,c,s	
	Ammonium thiocyanate	A	a,b	33
	Anhydrides, organic acid, for use as curing agents for epoxy resins	A,G3,E1,S1	a,c,f	
	Aniline	A, S1, E2, R1	a,b,f,g	40
	Anise oil	A,G3		
	Antimony chloride	A, S2, E2	a,b,s	
	Antimony compounds, except Antimony chloride	A	a,b	
	Barium salts, except Barium sulfate	A	a,b	
	Basil oil	A,G3		
	Bay oil	A,G3		
*	Benzalkonium chloride when included in Schedule 5 when included in Schedule 6	A,G3,E2 A,G3,E2,S1	a,c a,c,f,s	20
*	in pressurised spray packs	Delete entry	o	
	Benzene	A,G3,E1,S1,R1	a,c,f,g	160
	Benzoyl peroxide			10

	<b>POISON</b>	<b>NEW STANDARD STATEMENTS</b>	<b>OLD STANDARD STATEMENTS AND ASSOCIATED T-VALUES</b>	
			<b>OLD STANDARD STATEMENTS</b>	<b>T-VALUE</b>
	above 20 per cent	A, S1, E2	a,b,f,s	
	above 10 per cent up to 20 per cent	A, E1	a,b,f	
	10 per cent or less	A	a	
	Bergamot oil	A,G3		
	Borax	A	a,b	100
	Boric Acid	A	a,b	100
	Boron trifluoride	A,G3,E2,S1	a,c,f,s	
	Bromoform	A,G3,E2,R1,S2	a,b,f,g,s	
	Brucine	A,G1,G2,G3,R2	a,l	0.1
	2-Butoxyethanol and its acetates	A,E2,S1	a,f,s	
	Cadmium compounds	A	a,b	
	Cajuput oil	A,G3		
	Calcium hypochlorite in preparations containing above 4 per cent and below 10 per cent of available chlorine	A,G3,E1,S1	a,c,f	
	in preparations containing 10 per cent or more of available chlorine	A,G3,E2,S1	a,c,f,s	
	Camphor	A,G1,G3,G5	i,c,d	0.5
	Carbon disulphide	A,G3,E2,R1,S2	a,b,e,f,g,s	
	Carbon tetrachloride	A,G3,E1,R1,S1	a,b,d,e,f,g,s	0.7
	Cassia oil	A,G3		
*	Chlorinated lime in preparations containing above 4 per cent and below 10 per cent of available chlorine	A,G3,E1,S1	a,c,f	

	POISON	NEW STANDARD STATEMENTS	OLD STANDARD STATEMENTS AND ASSOCIATED T-VALUES	
			OLD STANDARD STATEMENTS	T-VALUE
*	in preparations containing 10 per cent or more of available chlorine	A,G3,E2,S1	a,c,f,s	
*	Chlorinating compounds, <b>except</b> when separately specified, containing above 4 per cent and below 10 per cent of available chlorine	A,G3,E1,S1	a,c,f	
*	10 per cent or more of available chlorine	A,G3,E2,S1	a,c,f,s	
*	Chlorine (gas)	A,R1,E1	a,g,s	
	Chlorocresol	A,G3,E2,S2	a,b,f,s	
	Chloroform	A,G3,E1,R1,S1	a,b,f,g,s	80
	Chromates	A,G3,E2,S1	a,b,f,s	
	Chromium trioxide	A,G3,E2,S1	a,c,f,s	
	Cineole	A,G1,G3	i,c	
	Cinnamon bark oil	A,G3		
	Cinnamon leaf oil	A,G3		
	Climbazole	A	a,b	20
	Clove oil	A,G1,G3,E2	i,c,s	
	Copper sulfate	A,G3,E2,S1	a,b,f,s	
	Creosote	A,G3,E2,S1	a,f,s	70
	Cresols	A,G3,E2,S3	a,c,j,s	
	Cresols in pressurised spray packs	A,E1,S1,G6	o	
*	Croton oil	(Delete entry)	s	
	Cyanides	A,G1,E1,R2	a,k	
	Cyanoacrylic acid esters	A	a	
	Cyanuric acid	A	z	
*	Cyclohexanone peroxide	A,E2,G3,S1	a,f,s	
*	o-Dichlorobenzene	A,G3,E1,S1	a,c,e,f,s	
	Dichloroethyl ether	A,G3,E1,S1,R1	a,f,g,s	7

	<b>POISON</b>	<b>NEW STANDARD STATEMENTS</b>	<b>OLD STANDARD STATEMENTS AND ASSOCIATED T-VALUES</b>	
			<b>OLD STANDARD STATEMENTS</b>	<b>T-VALUE</b>
	Dichloroisocyanurates	A,G3,E1,S1	a,c,f	
*	Dichloromethane (methylene chloride) in pressurised spray packs	A,G3,G5,E1,S1,R1 A,S1,G6	a,c,d,e,f,g,s o	
	Dichromates	A,G1,G3,E2,S1	a,b,f,s	
	Didecyldimethyl-ammonium chloride	A,G3,E2,S1	a,f,p,s	20
	Diesel (distillate)	A,G3	a,c	
	Diethanolamine when included in Schedule 5 when included in Schedule 6	A,G3 A,G3,E2,S1	a,c a,c,f,s	
	Dimethylformamide less than 75 per cent	A	a,b	
	75 per cent or more	A,E1,R1,S1	a,b,f,g,s	
	Dimethyl sulfoxide	A,G3,E1,S1	a,f	2000
	Dinitrocresols	A,G1,E1,S1	a,b,f,s	
	Dinitrophenols	A,G1,E1,S1	a,b,f,s	
	Dioxane	A,G3,E1,S1,R1	a,f,g	710
	Distillate	A,G3	a,c	
	N-(N-dodecyl)-2-pyrrolidone when included in Schedule 5 when included in Schedule 6	A,G3,E1 A,G3,E2,S1	a,c,n a,c,s	
	Epoxy resins liquid	A,G3,E2,S1	a,c,f,s	
	Essential oils containing camphor as natural component unless otherwise specified.	A,G3		
	Ethanolamine			

	POISON	NEW STANDARD STATEMENTS	OLD STANDARD STATEMENTS AND ASSOCIATED T-VALUES	
			OLD STANDARD STATEMENTS	T-VALUE
	when included in Schedule 5 when included in Schedule 6	A,G3,E1 A,G3,E2,S1	a,c a,c,f,s	
	Ether	A,G3,E1,R1	a,b,g	170
	Ethyl bromide	A,E2,S1,R1	a,g	
	Ethylene glycol	A	a,b	30
*	Ethylene glycol monoalkyl ethers and their acetates, except when separately specified	A,G3,E2,S1	a,f,s	
	Ethylene oxide	A,E2,R1	a,g,s	
	Eucalyptus oil	A,G1,G3	i,c	
	Eugenol	A,G1,G3,E2	i,c,s	
	Flucofuron	Delete entry	a	
	Fluorides except when separately specified when included in Schedule 5 when included in Schedule 6	A A,G1,G3,E2,S1	a a,b,s	
*	Fluoroacetic acid	Delete Entry	a,b,s	1
*	Formaldehyde (see also paraformaldehyde)	A,G3,E2,S1,R1		
*	10 per cent and above	Delete entry	a,p,f,g,s	
*	below 10 per cent	Delete entry	a,p	
	Formic acid	A,G3,E2,S1	a,c,f,s	
	Glutaraldehyde below 5 per cent 5 per cent or more	A,G3,E1 A,G3,E2,S1	a,p a,p,s	
	Glycolic acid	A,G3,E2	a,c,s	
	Hexachlorophane when included in Schedule 6	A	a	
	Hydrazine	A,G1,G3,E2,R1,S1	a,b,f,g,s	70
	Hydrocarbons, liquid	A,G3	a,c	

	<b>POISON</b>	<b>NEW STANDARD STATEMENTS</b>	<b>OLD STANDARD STATEMENTS AND ASSOCIATED T-VALUES</b>	
			<b>OLD STANDARD STATEMENTS</b>	<b>T-VALUE</b>
	Hydrochloric acid when included in Schedule 5	A,G3,E2,S1 A,G3	a,c,f,s a,c	
	Hydrofluoric acid when included in Schedule 5 when included in Schedule 6 or 7	A A,G3,E2,S5	a f,s,c,a,t	
	Hydrogen peroxide more than 3 per cent up to 20 per cent more than 20 per cent	A,G3,E2,S1 A,G1,G3,G4,E2,S1	a,c,s i,w,f,s	
	Hydroquinone	A,G2,G3,S1,E2,R2	a,b,s	30
	Hydrosilicofluoric acid when included in Schedule 5 when included in Schedule 6 or 7	A A,G3,E2,S5	a f,s,c,a,t	
	Iodine (excluding salts, derivatives and iodophors) 2.5 per cent or more for human external use 2.5 per cent or more for other uses below 2.5 per cent	A,E2 A,S1,E2 A	a,b,s a,b,f,s a	10
	Iodophors	A		
	Isocyanates, free organic	A,E2,S1	a,f	
	Isophorone	A,G3,E2,S1	a,c,f,s	
	Kerosene	A,G3	a,c	
	Lauryl isoquinolinium bromide	A,E1	a,b	
	Lead compounds in hair cosmetics	A	a,b	

	POISON	NEW STANDARD STATEMENTS	OLD STANDARD STATEMENTS AND ASSOCIATED T-VALUES	
			OLD STANDARD STATEMENTS	T-VALUE
	in other preparations	A,S1	a,b,f	
	Lemon oil	A,G3		
	Lime oil	A,G3		
*	Lindane greater than 2 per cent	Delete entry	i,c,d,f,s	8
*	2 per cent or less	Delete entry	i,c,d,s	
	Magnesium chlorate	A	a	
	Maldison at 20 per cent or less	A	a	
	Marjoram oil	A,G3		
	Melaleuca Oil	A,G1,G3	i,c	
	Mercuric chloride for external therapeutic use for other uses	A A,G1,G3,E2,R2,S1	a,r a,f,r	0.1
	Mercuric iodide	A,G1,G3,E2,R2,S1	a,r	4
	Mercuric nitrate	A,G1,G3,E2,R2,S1	a,r	
	Mercuric oxide	A,G1,G3	a,r	
	Mercuric potassium iodide	A,G1,G3,E2,R2,S1	a,r	
	Mercuric thiocyanate	A,G1,G3,E2,R2,S1	a,r	
	Mercurochrome	A	a,b	
	Mercurous chloride	A	a,b	
	Mercury metallic	A	a	
	Mercury, organic compounds in preparations for human external use	A,S1 A	a,b,f a,b	
*	Metaldehyde in pressurised sprays	A,E1,S1 Delete entry	a,b a,o	60
	Methanol			650
	above 10%	A,G3		
	10% or less	A		
	Methylated spirit	A,G3	a,b	
	Methyl ethyl ketone	A,G3		

POISON	NEW STANDARD STATEMENTS	OLD STANDARD STATEMENTS AND ASSOCIATED T-VALUES		
		OLD STANDARD STATEMENTS	T-VALUE	
Methyl ethyl ketone peroxide	A,G3,E2,S1	a,c,f,s	40	
Methyl iso-amyl ketone	A,G3			
Methyl iso-butyl ketone	A,G3			
N-methyl-2-pyrrolidone when included in Schedule 5 when included in Schedule 6	A,G3,E1 A,G3,E2	a,c,n a,c,s		
Methyl salicylate liquid when included in Schedule 5 or 6	A,G3,E1	a,b		
Naphthalene	A,G1,G3	i,b,d	220	
*	Nicotine	Delete entry	a,b,s	5
*	Except when in tobacco or Schedule 3 or schedule 2	Delete entry		
*	Schedule 2 or Schedule 3	Delete entry		
Nitric acid	A,G3,E2,S1	a,c,f,s		
Nitrobenzene	A,G3,E1,S1	a,b,f		
Nitrophenol	A,G3,E2,S1	a,b,f	90	
Nonoxinol 9	A,E2	a,s	180	
Nutmeg oil	A,G3			
2-Octyl-4-isothiazolin-3-one (Octhilinone)	A,G3,E2,S1	a,c,f,s		
N-(N-octyl)-2-pyrrolidone when included in Schedule 5 when included in Schedule 6	A,G3,E1 A,G3,E2	a,c,n a,c,s		
Orange oil (bitter)	A,G3			
Oxalic acid	A,G3,E2,S1	a,c,f	50	
Paraformaldehyde	A,G3,E2,R1,S1	a,b		

	POISON	NEW STANDARD STATEMENTS	OLD STANDARD STATEMENTS AND ASSOCIATED T-VALUES	
			OLD STANDARD STATEMENTS	T-VALUE
	PDB (paradichlorobenzene)	A	a,b,d	50
	Pennyroyal oil	A,G3		
	Peracetic acid when included in Schedule 5 when included in Schedule 6	A,G3,E1,S1 A,G3,E2,S1	a,c,f a,c,f,s	
	Permanganates	A,G3,E2,S1	a,c,f,s	
	Petrol	A,G3,R1	a,c,g	
	Phenols	A,G3,E2,S3	a,c,j,s	
	Phenols in pressurised spray packs	A,E1	o	
	Phenylenediamines and alkylated phenylenediamines in hair dyes in other preparations	A,E1 A,G1,G3,E1,S1	a,b a,b,f	
	Phenyl methyl ketone			
	As such, or in preparations of similar viscosity	A,G3,E1		
	N,N- bis(phenylmethylene)- bicyclo-(2.2.1)heptane- 2,5-dimethanamine	A,E2,S1	a,f,s	
	N,N- bis(phenylmethylene)- bicyclo-(2.2.1)heptane- 2,6-dimethanamine	A,E2,S1	a,f,s	
	ortho-Phenylphenol in pressurised spray packs	A,G3,E2,S1 A,G6,E2,S1	a,b,f o	240
	Phosphonic acid neutralised to pH 6 (approx)	A,G3,E2,S1 A	a,c,f a	

	<b>POISON</b>	<b>NEW STANDARD STATEMENTS</b>	<b>OLD STANDARD STATEMENTS AND ASSOCIATED T-VALUES</b>	
			<b>OLD STANDARD STATEMENTS</b>	<b>T-VALUE</b>
	in spray packs	A,E2,S1	a,o,s	
	Phosphoric acid	A,G3,E2,S1	a,c,f,s	150
	Phosphorus, yellow	A,G1,G3,E2,R2,S2	a,b,f	0.01
	ortho-Phthalaldehyde when included in Schedule 5 when included in Schedule 6	A,E1 A,G3,E2,S1	a,s a,c,f,s	
	Picric acid	A,G1,G3,E2,R1,S1	a,b,f,g	0.3
	Polyethanoxy alkylamine 2-methyl-1-propanol	A	a	
	Polyethanoxy (15) tallow amine	A,E2,S1	a,f,s	120
	Poly(Oxy-1,2-ethanediyl), $\alpha$ -[2-[(2-hydroxyethyl)amino]-2-oxoethyl]-? -hydroxy- mono-C <sub>13-15</sub> -alkyl ethers	A,E1	a,n	
	Potassium bromate	A	a,b	
	Potassium chlorate	A	a,b	
	Potassium cyanate	A,E1,S1	a,b	
	Potassium hydroxide	A,G3,E2,S1	a,c,f,s	
	Potassium metabisulphite	A	a,c	
	Potassium peroxomonosulfate triple salt when included in Schedule 5 when included in Schedule 6	A,G3,E1 A,G3,E2,S1	a,c,n a,c,f,s	120
	Potassium persulfate	A,G3,E2	a,c,s	
	Potassium sulfide	A,G3,E2,S1	a,c,f,s	
	Propionic acid	A,G3,E1,S1	a,b,s	260

	POISON	NEW STANDARD STATEMENTS	OLD STANDARD STATEMENTS AND ASSOCIATED T-VALUES	
			OLD STANDARD STATEMENTS	T-VALUE
	d-Pulegone	A,G3		
	Pyrithione zinc	A,E1	a,b	30
*	Quaternary ammonium compounds except when separately specified above 20 per cent	A,G3,E2	a,p	
*	20 per cent and below	A, E2	a	
*	in pressurised spray packs	A, E2, G6	o	
	Safrole	A,G1,G3	i,c	
	Sage oil (Dalmatian)	A,G3		
	Sassafras oil	A,G1,G3	i,c	
*	Selenium compounds in preparations for external therapeutic use (human or animal)	A,G1,E1,S1	a,b	
*	in other preparations	Delete entry		
*	Silicofluorides when included in Schedule 5	A	a	
	when included in Schedule 6	A,G1,G3,E2,S1	a,b,s	
	Silver salts	A,E2	a,s	
	Sodium aluminate	A,G3,E2,S1	a,c,f,s	
	Sodium blifluoride when included in Schedule 5	A	a	
	when included in Schedule 6	A,G3,E2,S5	f,s,c,a,t	
	Sodium bromate	A,G1	a,b	
	Sodium chlorate	A	a,b	
	Sodium diacetate	A,G3,E2,S1	a,c,f,s	
	Sodium dichloroisocyanurate	A,G3,E1,S1	a,c,f	140

	<b>POISON</b>	<b>NEW STANDARD STATEMENTS</b>	<b>OLD STANDARD STATEMENTS AND ASSOCIATED T-VALUES</b>	
			<b>OLD STANDARD STATEMENTS</b>	<b>T-VALUE</b>
	Sodium dodecylbenzene sulfonate	A,G3,E2,S1	a,c,f,s	40
	Sodium hydrogen sulfate	A,G3,E1,S1	a,c,f	
	Sodium hydrosulfite	A,G3,E2,S1	a,c,s	
	Sodium hydroxide	A,G3,E2,S1	a,c,f,s	
	Sodium hypochlorite in preparations containing above 4 per cent and below 10 per cent of available chlorine in preparations containing 10 per cent or more of available chlorine	A,G3,E1,S1 A,G3,E2,S1	a,c,f a,c,f,s	
	Sodium laureth-6 carboxylate	A	a	
*	Sodium metabisulphite	A, G3	a,c	
	Sodium nitrite	A,G3	a,b	10
	Sodium percarbonate when included in Schedule 5 when included in Schedule 6	A,G3,S1 A,G3,E2,S1	a,c,n a,c,f,s	240
	Sodium persulfate	A,G3,E2	a,c,s	
	Sodium stannate	A,E1	a	340
	Sodium sulfide	A,G3,E2,S1	a,c,f,s	
	Sodium trichloroacetate	A	a,b	320
	Sodium trichloroisocyanurate	A,G3,E1,S1	a,c,f	70
	Strychnine	A,G1,G2,G3,R2	a,l	0.5
	Styrene	A,G3,S1,E1	a,c,f	500
	Sulcofuron	A	a	
	Sulfamic acid	A,G3,E2,S1	a,c,f,s	310

	POISON	NEW STANDARD STATEMENTS	OLD STANDARD STATEMENTS AND ASSOCIATED T-VALUES	
			OLD STANDARD STATEMENTS	T-VALUE
	Sulfuric acid	A,G3,E2,S1	a,c,f,s	10
	Terpenes, chlorinated	A,G3	a,b	
	Tetrachloroethane	A,G3,E1,R1,S1	a,b,d,e,f,g,s	
	Tetrachloroethylene	A,G3,E2,S1,R1	a,c,d,e,f,g,s	
	Thiourea	A	a,b	0.1
	Thujone	A,G3		
	Thyme oil	A,G3		
	ortho-Tolidine	A	a,b	40
	Toluene above 75 per cent 75 per cent and below in pressurised spray packs	A,G3,E1,S1,R1 A,G3 A	a,c,f,g,s a,c o	
	Toluenediamine in hair dyes	A,E1	a,b	
	in other preparations	A,G1,G3,E1,S1	a,b,f	
	Trichloroacetic acid	A,G3,E2,S1	a,c,f,s	40
	Trichloroacetic acid alkali salts	A	a,b	320
	1,1,1-Trichloroethane	A,G3,E1,S1,R1	a,c,d,e,f,g,s	
	Trichloroethylene	A,G3,E1,S1,R1	a,c,d,e,f,g,s	715
	Trichloroisocyanuric acid	A,G3,E1,S1	a,c,f	70
	Triethanolamine	A,G3,E1,S1	a,c,f,n	
	Triethyl phosphate	A,E1	a,b	
	Trifluoromethane- sulphonic acid	A,G3,E2	a,p,s	
	Triisopropanolamine lauryl ether sulfate	A,E1,S1	a,f,n	
	Turpentine (mineral)	A,G3	a,c	
	Turpentine oil (vegetable)	A,G3,E2	i,c,s	
	White spirit	A,G3	a,c	
	Xylene above 75 per cent	A,G3,E1,S1,R1	a,c,f,g,s	

	<b>POISON</b>	<b>NEW STANDARD STATEMENTS</b>	<b>OLD STANDARD STATEMENTS AND ASSOCIATED T-VALUES</b>	
			<b>OLD STANDARD STATEMENTS</b>	<b>T-VALUE</b>
*	75 per cent and below in pressurised spray packs	A,G3 A,G6,E1,S1	a,c o	
	Xylenols in pressurised spray packs	A,G3,E2,S3 A,E1	a,c,j,s o	
	Zinc chloride	A,G3,E2,S1	a,c,s	30
	Zinc sulfate	A,G3,E2,S1	a,s	

## **8. MATTERS ARISING FROM THE ESSENTIAL OILS WORKING PARTY AND SUBSEQUENT DELIBERATIONS.**

**(a) Citrus oils (bergamot, lemon, lime and sweet orange)** – Consideration of cut-offs for exemption based on their photosensitising potential.

**Outcome** - The Committee confirmed the decision to include appropriate exempt concentration cut-offs.

### **Schedule 5 – New entry:**

#### **ORANGE OIL (BITTER) except:**

- (a) when steam distilled;
- (b) in preparations containing 1.4 per cent or less of orange oil (bitter) expressed; or
- (c) when packed in containers labelled with the statement:

Application to skin may increase sensitivity to sunlight.

#### **BERGAMOT OIL except:**

- (a) when steam distilled;

- (b) in preparations containing 0.4 per cent or less of bergamot oil expressed; or
- (c) when packed in containers labelled with the statement:  
Application to skin may increase sensitivity to sunlight.

**LEMON OIL except:**

- (a) when steam distilled;
- (b) in preparations containing 2 per cent or less of lemon oil expressed; or
- (c) when packed in containers labelled with the statement:  
Application to skin may increase sensitivity to sunlight.

**LIME OIL except:**

- (a) when steam distilled;
- (b) in preparations containing 0.7 per cent or less of lime oil expressed; or
- (c) when packed in containers labelled with the statement:  
Application to skin may increase sensitivity to sunlight.

**APPENDIX F, Part 1 – New entry**

Amend by adding the following:

89. Application to skin may increase sensitivity to sunlight.

**APPENDIX F, Part 3 – New entries**

Bergamot oil

Warning statement 89

Lemon oil

Warning statement	89
Lime oil	
Warning statement	89
Orange oil (bitter)	
Warning statement	89

## **PART B – OTHER OUTCOMES**

Outcome of: (i) proposals in relation to other substances mentioned in the Gazette of 10 January 2001 as being considered for scheduling at the February 2001 meeting; and (ii) other general matters considered by the Committee.

**(i) Proposals in relation to other substances mentioned in the Gazette of 10 January 2001 as being considered for scheduling at the February 2001 meeting.**

**(a) Paracetamol** – Consideration of variation to the dose limit for exempt preparations;

*Outcome* - Consideration deferred to a future meeting.

**(b) Adapalene** – Consideration of the need to retain the requirement for Appendix F Warning Statements 77 and 62; and

**Outcome** – Consideration deferred to a future meeting.

**(c) Ranitidine** – consideration of poisons scheduling for animal use;

*Outcome* – The Committee agreed that the Schedule 4 entry of ranitidine in the SUSDP remained appropriate.

**(d) Hydrofluoric acid** – consideration of labelling and packaging requirements including child-resistant closures

*Outcome* – The Committee agreed that the review of the labelling and packaging of domestic products containing corrosive fluorides, should be broadened to include a review of scheduling. The pre-meeting Gazette notice for this item (hydrofluoric acid) be broadened to include a review of scheduling, labelling and packaging requirements for products containing hydrofluoric acid and other corrosive fluorides.

- (ii) **Matters referred by the New Zealand Medicines Classification Committee.**
  - (a) **Iron Compounds** – Consideration of a proposal to harmonise with New Zealand in regard to the scheduling of iron containing medicines.  
*Outcome* – Consideration deferred to a future meeting.
  - (b) **Boron, Boric acid and Sodium perborate** – Consideration of a proposal to harmonise with New Zealand in regard to the scheduling of boron (to exempt from scheduling), boric acid and sodium perborate.  
*Outcome* – Consideration deferred to a future meeting.

## **PART C**

The public consultation process in respect of the substances set out in the Part C has been concluded. The amendments relating to substances set out in Part C are therefore final amendments and, as notified in the Gazette of 10 January 2001, come into effect on 1 June 2001. The amendments will be published in Amendment 4 to SUSDP 15.

### **Amendments to the Standard for the Uniform Scheduling of Drugs and Poisons**

The National Drugs and Poisons Schedule Committee directs that the amendments below be applied to the Standard for the Uniform Scheduling of Drugs and Poisons No.15 and recommends that these amendments be adopted by the States and Territories with effect from 1 June 2001. The amendments arise from decisions made by the Committee at its August 2000 and November 2000 meetings and confirmed at the February 2001 meeting.

### **PART 1 – INTERPRETATION – Amendment**

Amend paragraph 1 (1) to include:

**“Essential oils”** means products obtained from natural raw materials either by distillation with water or steam or from the epicarp of citrus fruits by a mechanical process, or by dry distillation. For scheduling purposes it also means:

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

### **PART 4 - THE SCHEDULES**

#### **Schedule 2 – New entries**

ACETYLCYSTEINE in preparations for oral use.

FAMOTIDINE for the relief of symptoms of gastro-oesophageal reflux, in packs containing not more than 14 days supply.

RANITIDINE for the relief of symptoms of gastro-oesophageal reflux, in packs containing not more than 14 days supply.

#### **Schedule 2 – Amendments**

GLYCERYL TRINITRATE – amend entry to read:

GLYCERYL TRINITRATE **except** when included in Schedule 3 or 4.

ISOSORBIDE DINITRATE – delete entry

LITHIUM – amend entry to read:

LITHIUM for dermal use in preparations containing 1 per cent or less of lithium **except in** preparations containing 0.01 per cent or less of lithium.

**Schedule 3 – New entries**

FLUTICASONE in aqueous nasal sprays delivering 50 micrograms or less of fluticasone per actuation when the maximum recommended daily dose is no greater than 200 micrograms and when packed in a primary pack containing 200 actuations or less, for the short-term prophylaxis or treatment of seasonal allergic rhinitis in adults and children 12 years and over.

GLYCERYL TRINITRATE in oral preparations.

ISOSORBIDE DINITRATE in oral preparations containing 10 mg or less of isosorbide dinitrate per dosage unit.

**Schedule 3 – Amendments**

ACEPIFYLLINE – delete entry

AMINOPHYLLINE – amend entry to read:

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

FAMOTIDINE – delete entry

RANITIDINE – delete entry

THEOPHYLLINE – amend entry to read:

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

**Schedule 4 - New entries**

ALOSETRON.

AMISULPRIDE.

AMPRENAVIR.

# ANDROSTANOLONE.

# ANDROSTENEDIOL.

# ANDROSTENEDIONE.

ARTEMETHER.

AVIPTADIL.

BALSALAZIDE.

BAMBUTEROL.

BIVALIRUDIN.

BRINZOLAMIDE.

BUPROPION.

CETRORELIX.

DEXMEDETOMIDINE.

ELETRIPTAN.

ESOMEPRAZOLE.

EXEMESTANE.

FLORFENICOL.

GANIRELIX.

GATIFLOXACIN.

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

LERCANIDIPINE.

LEVOBUPIVACAIN.

LINEZOLID.

LUMEFANTRINE.

# METENOLONE.

MOXIFLOXACIN.

NATEGLINIDE.

# 19-NORANDROSTENEDIOL.

# 19-NORANDROSTENEDIONE.

OSELTAMIVIR.

OXALIPLATIN.

OXCARBAZEPINE.

PIOGLITAZONE.

RABEPRAZOLE.

RAPACURONIUM BROMIDE.

SALCATONIN.

SERTINDOLE.

SIALOEPOETIN.

SIROLIMUS.

TASONERMIN.

TEGAFUR.

TEGASEROD.

TENECTEPLASE.

TRASTUZUMAB.

TROMETAMOL in preparations for injection.

UNOPROSTONE.

URACIL.

VERTEPORFIN.

ZALEPLON.

ZIPRASIDONE.

**Schedule 4 – Amendments**

ACEPIFYLLINE – delete entry

ACETYLCYSTEINE – amend entry to read:

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

CHLOROXYMESTERONE – amend entry to read:

# DEHYDROCHLOROMETHYLTESTOSTERONE.

FAMOTIDINE – amend entry to read:

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

FLUTICASONE – amend entry to read:

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

ISOETHARINE – amend entry to read:

ISOETARINE.

ISOSORBIDE DINITRATE – amend entry to read:

ISOSORBIDE DINITRATE **except** when included in Schedule 3.

LITHIUM – amend entry to read:

LITHIUM for therapeutic use, **except**:

- (a) when included in Schedule 2; or
- (b) in preparations containing 0.01 per cent or less of lithium.

METHANDIENONE – amend entry to read:

# METHANDIENONE (metandienone).

METHOXYFLURANE – amend entry to read:

METHOXYFLURANE.

RANITIDINE – amend entry to read:

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

TETANUS ANTITOXIN – amend entry to read:

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

VITAMIN A – amend entry to read:

VITAMIN A for human therapeutic or cosmetic use, **except**:

- (a) in preparations for topical use containing 1 per cent or less of vitamin A;
- (b) in preparations for internal use, containing 100 IU or less of vitamin A per dosage unit of a divided preparation, or 100 IU or less of vitamin A per gram of an undivided preparation; or
- (c) in other preparations for internal use labelled:
  - (i) with a recommended daily amount of 5 000 IU or less of vitamin A; and
  - (ii) where the preparation is labelled for adult use, in bold face letters not less than 1.5 mm high:

(A) with a statement to the following effect:

The recommended adult daily amount of vitamin A from all sources is 2 500 IU.

(B) and, at the beginning of the directions for use, with a warning statement to the following effect:

**WARNING** – When taken in excess of 8 000 IU vitamin A can cause birth defects. If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

or

**WARNING** – Taking more than 2 500IU a day during pregnancy may cause birth defects.  
(*until 1 June 2002*)

### Schedule 5 – New entries

BERGAMOT OIL except:

- (a) when steam distilled;
- (b) in preparations containing 0.4 per cent or less of bergamot oil;
- (c) in soaps or bath and shower gels that are washed off the skin; or
- (d) when packed in containers labelled with the statement:

Application to skin may increase sensitivity to sunlight.

LEMON OIL except:

- (a) when steam distilled;
- (b) in preparations containing 0.05 per cent or less of lemon oil;
- (c) in soaps or bath and shower gels that are washed off the skin; or
- (d) when packed in containers labelled with the statement:

Application to skin may increase sensitivity to sunlight.

LIME OIL except:

- (a) when steam distilled;
- (b) in preparations containing 0.5 per cent or less of lime oil; or
- (c) in soaps or bath and shower gels that are washed off the skin; or
- (d) when packed in containers labelled with the statement:

Application to skin may increase sensitivity to sunlight.

ORANGE OIL (bitter) except:

- (a) when steam distilled;
- (b) in preparations containing 1.4 per cent or less of orange oil (bitter); or
- (c) in soaps or bath and shower gels that are washed off the skin; or

(d) when packed in containers labelled with the statement:

Application to skin may increase sensitivity to sunlight.

### **Schedule 5 – Amendments**

2-[1-(ETHOXYIMINO)PROPYL]-3-HYDROXY-5-(3-BUTYRYL MESITYL)-CYCLOHEX-2-ENONE (Butroxydim) – amend entry to read:

BUTROXYDIM.

2-METHYLTHIO-4-(2-METHYLPROP-2-YL) AMINO-6-CYCLOPROPYLAMINO-5-TRIAZINE (Irgarol) – amend entry to read:

2-METHYLTHIO-4-(2-METHYLPROP-2-YL) AMINO-6-CYCLOPROPYLAMINO-5-TRIAZINE.

POLY (HEXAMETHYLENE BIGUANIDE) – amend entry to read:

POLIHEXANIDE **except** in preparations containing 5 percent or less of polihexanide.

QUATERNARY AMMONIUM COMPOUNDS – amend entry to read:

QUATERNARY AMMONIUM COMPOUNDS in preparations containing 20 per cent or less of quaternary ammonium compounds **except**:

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

2-TERT-BUTYL-5-(4-TERT-BUTYL BENZYLTHIO)-4-CHLOROPYRIDAZIN-3(2H)-ONE (Pyridaben) – amend entry to read:

PYRIDABEN in preparations containing 25 per cent or less of pyridaben.

### **Schedule 6 - New entry**

MECOPROP-P.

## Schedule 6 – Amendments

ALPHA-CYPERMETHRIN – amend entry to read:

ALPHA-CYPERMETHRIN

- (a) in aqueous preparations containing 25 per cent or less of alpha-cypermethrin **except** when included in Schedule 5; or
- (b) in other preparations containing 10 per cent or less of alpha-cypermethrin **except** when included in Schedule 5.

5-BENZYLFUR-3-YLMETHYL (1'R,3'S.E)-2',2'-DIMETHYL-3'-(2-OXO-2,3,4,5-TETRAHYDRO-3-THIENYLIDENEMETHYL)-CYCLOPROPANE CARBOXYLATE – delete entry

BIFENTHRIN – amend entry to read:

BIFENTHRIN in preparations containing 10 per cent or less of bifenthrin **except** in preparations containing 0.5 per cent or less of bifenthrin.

N-[5-CHLORO-4-[(4-CHLOROPHENYL)-CYANOMETHYL]-2METHYLPHENYL] -2-HYDROXY-3,5-DIODOBENZAMIDE (Closantel) – amend to read:

CLOSANTEL.

N-(2,6-DICHLORO-3-METHYLPHENYL)-5,7-DIMETHOXY-[1,2,4]-TRIAZOLO-[1,5a]PYRIMIDINE-2-SULFONAMIDE (Metosulam) – amend entry to read:

METOSULAM.

DIMETHYL SULFOXIDE – amend entry to read:

DIMETHYL SULFOXIDE

- (a) when not for therapeutic use; or
- (b) for the treatment of animals:
  - (i) when combined with no other therapeutic substance(s);

- (ii) in liquid preparations containing copper salicylate and 1 per cent or less of methyl salicylate as the only other therapeutic substances; or
- (iii) in clay poultices containing 2 per cent or less of dimethyl sulfoxide.

**(RS)-2-METHYL-4-OXO-3-PROP-2-YNYLCYCLOPENT-2-ENYL-(1RS,3RS;1RS,3S R)-2,2-DIMETHYL-3-(2-METHYLPROP-1-ENYL)- CYLOPROPANE CARBOXYLATE**  
(Prallethrin) (cis:trans=20:80) – amend entry to read:

**PRALLETHRIN** (cis:trans=20:80).

**2-OCTYL-4-ISOTHIAZOLIN-3-ONE** (octhilinone) – amend entry to read:

**OCTHILINONE except** in paints containing 1 per cent or less of octhilinone calculated on the non-volatile content of the paint.

**QUATERNARY AMMONIUM COMPOUNDS** – amend entry to read:

**QUATERNARY AMMONIUM COMPOUNDS except:**

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

**PYRITHIONE ZINC** – amend entry to read:

**PYRITHIONE ZINC except:**

- (a) when included in Schedule 2;
- (b) in semi-solid hair preparations; or
- (c) in shampoos containing 2 per cent or less of pyrithione zinc when labelled with the statement, “Keep out of eyes” or “If in eyes, rinse well with water”.

**2-TERT-BUTYL-5-(4-TERT-BUTYL BENZYLTHIO)-4-CHLOROPYRIDAZIN-3(2H)-ONE** (Pyridaben) – amend entry to read:

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

## **Schedule 7 – Amendment**

BIFENTHRIN – amend entry to read:

**BIFENTHRIN except:**

- (a) when included in Schedule 6; or
- (b) in preparations containing 0.5 per cent or less of bifenthrin.

## **PART 5 – APPENDICES**

### **Appendix E, Part 2 – Amendment**

2-Octyl-4-isothiazolin-3-one (Octhilinone) - amend entry to read:

Octhilinone..... a, c, f, s

### **Appendix F, Part 3 – New entries**

Bergamot oil

Warning statement 89

Lemon oil

Warning statement 89

Lime oil

Warning statement 89

Orange oil (bitter)

Warning statement 89

### **Appendix F, Part 3 – Amendments**

Famotidine – amend entry to read:

Famotidine when included in Schedule 2

Warning statements 35,68,69,70

Poly (hexamethylene biguanide) hydrochloride - amend entry to read:

Polihexanide

Safety directions 1,4,8

Ranitidine – amend entry to read:

Ranitidine when included in Schedule 2

Warning statements 35,68,69,70

### **Appendix H – New entry**

Fluticasone

### **Appendix H – Amendments**

Famotidine – delete entry

Ranitidine – delete entry