POISONS STANDARD AMENDMENT NO.3 OF 2008

The National Drugs and Poisons Schedule Committee, acting in accordance with its power under paragraph 52D(2)(a) of the *Therapeutic Goods Act 1989* (the Act), amends the Poisons Standard 2008 in the manner set out in Schedule 1.

The amendments to the Poisons Standard 2008 as set out in Schedule 1 commence on 1 January 2009.

Signed
DR RUTH LOPERT
CHAIR
NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

Dated this 4th day of December 2008

Schedule 1- Amendments to the Poisons Standard 2008

Schedule 1

STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS

No. 23

AMENDMENT No. 2

Effective Date – 1 January 2009

Australian Government

Department of Health and Ageing

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The amendments listed in this document were finalised at the June and October 2008 meetings of the National Drugs and Poisons Schedule Committee (NDPSC) except where separately specified. The basis of these amendments can be found in the 'Record of the Reasons', which can be accessed from the NDPSC website:

www.tga.gov.au/ndpsc

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Schedule 1

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.23 and recommends that these amendments be adopted by the States and Territories with effect from 1 January 2009 unless otherwise stated. The amendments arise from decisions made by the Committee at its June 2008 meeting and confirmed at the October 2008 meeting except where separately specified.

PART 2, LABELS AND CONTAINERS - AMENDMENT

(The following amended entry for paragraph 8.(2) arose from a decision made by the June 2007 meeting with a delayed implementation date of 1 January 2009)

Paragraph 8.(2) – Amend entry to read:

(2) if the poison is for a purpose or purposes other than human therapeutic use and:

(a) if the poison is in a pressurised spray aerosol preparation, as the mass of the poison per stated mass of the preparation;

(b) if the poison is a liquid in a liquid preparation, as the mass or volume of the poison per stated volume of the preparation;

(c) 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;

(d) 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;

(e) 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;

(f) if the poison is a gas in a liquid preparation, as the mass of the poison per stated volume of the preparation;

(g) 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;

(h) if the poison is a gas in a gaseous preparation, as the mass of the poison per stated mass of the preparation;

PART 4 – THE SCHEDULES

SCHEDULE 2 – AMENDMENTS

(The following entry for fluorides incorporates an editorial change identified at the October 2008 meeting under item 21.1.5)

FLUORIDES – Amend entry to read:

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 (September 2008)* **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 the *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/name of product] in children six 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:

(A) Do not swallow; and

(B) Do not use [this product/name of product] in children six 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.

GLYCERYL TRINITRATE **–** Delete entry.

SCHEDULE 3 – AMENDMENTS

(The following entry for fluorides also incorporates an editorial change identified at the October 2008 meeting under item 21.1.5)

FLUORIDES – Amend entry to read:

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*;

(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.

GLYCERYL TRINITRATE – Amend entry to read:

GLYCERYL TRINITRATE:

(a) in preparations for oral use; or

(b) in preparations for rectal use.

SCHEDULE 4 – NEW ENTRIES

ALGLUCOSIDASE.

DAPTOMYCIN.

IDURSULFASE.

IXABEPILONE.

LAROPIPRANT.

LENALIDOMIDE.

MARAVIROC.

MAROPITANT.

NITRIC OXIDE for human therapeutic use.

RALTEGRAVIR.

ROTIGOTINE.

TEMSIROLIMUS.

SCHEDULE 4 – AMENDMENTS

BORON – Amend entry to read:

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

(a) in preparations for internal use containing 6 mg or less of boron per recommended daily dose;

(b) in preparations for dermal use containing 0.35 per cent or less of boron, which are not for paediatric or antifungal use; or

(c) when present as an excipient.

GLYCERYL TRINITRATE – Amend entry to read:

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

SCHEDULE 5 – AMENDMENTS

(The following entry for 2,4-D arose from a decision made by the February 2008 meeting with an effective date of 1 January 2009)

2,4-D – Amend entry to read:

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

DELTAMETHRIN – Amend entry to read:

DELTAMETHRIN:

(a) in aqueous preparations containing 5 per cent or less of deltamethrin when no organic solvent other than a glycol is present;

(b) in wettable granular preparations containing 25 per cent or less of deltamethrin when packed in child-resistant packaging each containing 3 g or less of the formulation;

(c) in water-dispersible tablets each containing 500 mg or less of deltamethrin in child-resistant packaging; or

(d) in other preparations containing 0.5 per cent or less of deltamethrin.

SCHEDULE 6 – NEW ENTRIES

(The following entry for 2,4-D arose from a decision made by the February 2008 meeting with an effective date of 1 January 2009)

2,4-D **except** when included in Schedule 5.

SPIROTETRAMAT.

SCHEDULE 6 – AMENDMENTS

ABAMECTIN – Amend entry to read:

ABAMECTIN:

(a) in preparations for pesticidal use containing 2 per cent 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.

CARBENDAZIM – Amend entry to read:

CARBENDAZIM **except** in paints, jointing compounds and sealants containing 0.5 per cent or less of carbendazim.

COUMAPHOS – Amend entry to read:

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 per cent or less of coumaphos.

METHYLNORBORNYLPYRIDINE – Amend entry to read:

METHYLNORBORNYLPYRIDINE.

OCTHILINONE – Amend entry to read:

OCTHILINONE **except** in paints, jointing compounds and sealants containing 1 per cent or less of octhilinone calculated on the non-volatile content.

SCHEDULE 7 – NEW ENTRY

CYANOGEN.

PART 5 – APPENDICES

APPENDIX C – NEW ENTRIES

1,4-BUTANEDIOL (excluding its derivatives) in non-polymerised form in preparations for domestic use.

DIETHYLENE GLYCOL for use in toothpastes or mouthwashes **except** in preparations containing 0.25 per cent or less of diethylene glycol.

APPENDIX D – AMENDMENT

Paragraph 4 – Amend entry to read:

4. Poisons available only from or on the order of a specialist physician and for which the prescriber must, where the patient is a woman of child bearing age:

(a) ensure that the possibility of pregnancy has been excluded prior to commencement of treatment; and

(b) advise the patient to avoid becoming pregnant during or for a period of 1 month after completion of treatment.

TRETINOIN for human oral use.
LENALIDOMIDE.

APPENDIX J, PART 2 – NEW ENTRY

POISON	**CONDITION**
Cyanogen	1

APPENDIX K – NEW ENTRY

Rotigotine

EDITORIAL AMENDMENTS AND ERRATA

PART 1, INTERPRETATION – NEW ENTRY

"Australian Code for the Transport of Dangerous Goods by Road and Rail" means the sixth edition of the document of that name.

PART 1, INTERPRETATION – AMENDMENTS

"Appropriate authority" – Amend entry to read:

"Appropriate authority" means:

(a) in the Australian Capital Territory, ACT Health;

(b) in New South Wales, the Director-General of New South Wales Health;

(c) in the Northern Territory, the Chief Health Officer of the Department of Health & Families;

(d) in Queensland, the Chief Executive of Queensland Health;

(e) in South Australia, the Chief Executive of the Department of Health;

(f) in Tasmania, the Secretary of the Department of Health and Human Services;

(g) in Victoria, the Secretary to the Department of Human Services;

(h) in Western Australia, the Chief Executive Officer of the Department of Health.

"Child-resistant closure" – Amend entry to read:

"Child-resistant closure" means:

(a) a closure that complies with the requirements for a child-resistant closure in the Australian Standard AS 1928-2007 entitled *Child-resistant packaging – Requirements and testing procedures for reclosable packages* (ISO 8317:2003, MOD);

(b) a closure approved by an order made under section 10(3) of the Commonwealth *Therapeutic Goods Act 1989;* or

(c) in the case of a can fitted with a press-on lid, a lid of the design known as "double tight" or "triple tight".

"Child-resistant packaging" – Amend entry to read:

"Child-resistant packaging" means packaging that:

(a) complies with the requirements of the Australian Standard AS 1928-2007 entitled *Child-resistant packaging – Requirements and testing procedures for reclosable packages* (ISO 8317:2003, MOD);

(b) is reclosable and complies with the requirements of at least one of the following Standards:

(i) the International Organization for Standardization Standard ISO 8317:2003 entitled *Child-resistant packaging – Requirements and testing procedures for reclosable packages*;

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

(iii) the Canadian Standards Association Standard CSA Z76.1-06 entitled *Reclosable Child-Resistant Packages;*

(iv) the United States Code of Federal Regulations, Title 16, Section 1700.15, entitled *Poison prevention packaging standards* and Section 1700.20, entitled *Testing procedure for special packaging*;

(c) is approved as child-resistant by any order made under section 10(3) of the Commonwealth *Therapeutic Goods Act 1989*; or

(d) is in the form of blister or strip packaging in which a unit of use is individually protected until the time of release and that complies with Section 3 (Requirements for non-reclosable packages) of Australian Standard AS 1928-2001 entitled *Child-resistant packages.*

"Non-volatile content" – Amend entry to read:

"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 entitled *Paints and related materials – Methods of test – Non-volatile content by mass*.

"Required Advisory Statements for Medicine Labels" – Amend entry to read:

"Required Advisory Statements for Medicine Labels" means the document of that name, as published by the Therapeutic Goods Administration in September 2008.

Subparagraph (2)(k) – Amend entry to read:

(k) 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 *Standards for Active Constituents*, as published by the Australian Pesticides and Veterinary Medicines Authority.

PART 2, LABELS AND CONTAINERS – AMENDMENTS

Subparagraph 7(1)(d) – Amend entry to read:

(d) if the poison is a dry chlorinating compound containing more than 10 per cent of available chlorine, **except** for preparations certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5.1 (oxidising substances) as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail*, with the cautionary statement –

FIRE AND EXPLOSION HAZARD

written:

(i) on a separate line or lines immediately below the cautionary statement "KEEP OUT OF REACH OF CHILDREN" as required by sub-paragraph 7(1)(c); and

(ii) in bold-face sanserif capital letters of uniform thickness; and

(iii) in letters at least four tenths the height of the letters used for the signal word or words; and

(iv) with nothing, other than a Class label as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail*, written on the same line;

Subparagraph 7(1)(h) – Amend entry to read:

(h) if the poison meets the criteria for a 'flammable liquid' in the *Australian Code for the Transport of Dangerous Goods by Road and Rail*, with the cautionary statement –

FLAMMABLE

written on the main label in bold-face sanserif capital letters of uniform thickness, unless already present in accordance with the requirements of the *Australian Code for the Transport of Dangerous Goods by Road and Rail Rail;*

Subparagraph 13(2) – Amend entry to read:

(2) is labelled in accordance with the *National Occupational Health and Safety Commission's National Code of Practice for the Labelling of Workplace Substances* [NOHSC: 2012 (1994)].

Subparagraph 16(1)(b)(vi) – Amend entry to read:

(iv) the name and proportion of the First Schedule, Second Schedule or Third Schedule 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.

Paragraphs 21 and 21a **–** Amend entries to read:

21. If a poison, other than a Schedule 5 poison, is sold or supplied in a container with a nominal capacity of 2 litres or less, the container must comply with Australian Standard AS 2216-1997, entitled *Packaging for poisonous substances*.

21a. Notwithstanding subparagraph 21, a poison which is in Schedule 6 and 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, entitled *Packaging for poisonous substances*, if:

(1) the other safety factors are not diminished; and

(2) the container has a restricted flow insert and a child-resistant closure.

Subparagraph 22(1) – Amend entry to read:

(1) comply with sub-section 1.4 (General Requirements) of Australian Standard AS 2216-1997 entitled *Packaging for poisonous substances*; and

Subparagraph 23(1)(b)(i) – Amend entry to read:

(i) comply with sub-section 1.4 (General Requirements) of Australian Standard AS 2216-1997 entitled *Packaging for poisonous substances*, excluding paragraph 1.4.3;

Paragraph 24 – Amend entry to read:

24. Notwithstanding sub-paragraphs 21, 22 and 23 a poison may be packed in a container that does not comply with the tactile identification requirements of Australian Standard AS 2216-1997 entitled *Packaging for poisonous substances* or the requirements of paragraphs 22(2) or 23(1)(iii) if:

(1) the other safety factors are not diminished;

(2) the container is for a specific purpose; and

(3) an appropriate authority has approved the use of the container for that purpose.

Paragraph 27 – Amend entry to read:

27. The tactile identification or embossing required by paragraphs 21, 22 or 23 of this Standard or Australian Standard AS 2216-1997 entitled *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.

PART 3, MISCELLANEOUS REGULATIONS – AMENDMENT

Subparagraph 45(3) – Amend entry to read:

45. (3) acitretin, adapalene, bexarotene, etretinate, isotretinoin, lenalidomide, thalidomide or tretinoin:

(i) for oral use unless it is clearly labelled with warning statements 7, 62 and 76 in Appendix F, Part 1;

(ii) for topical use unless it is clearly labelled with warning statements 62 and 77 in Appendix F, Part 1; or

SCHEDULE 3 – AMENDMENT

DOXYLAMINE – Amend entry to read:

DOXYLAMINE in oral preparations **except**:

(a) when included in Schedule 2; or

(b) for the treatment of children under 2 years of age.

SCHEDULE 4 – AMENDMENTS

BIFONAZOLE – Amend entry to read:

BIFONAZOLE **except**:

(a) when included in Schedule 2;

(b) in preparations for dermal use containing 1 per cent or less of bifonazole for the treatment of the scalp; or

(c) in preparations for dermal use for the treatment of tinea pedis.

PIPER METHYSTICUM (kava) – Amend entry to read:

PIPER METHYSTICUM (kava) in preparations for human use **except** when included on the Australian Register of Therapeutic Goods 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 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*;

(b) in topical preparations for use on the rectum, vagina or throat containing dried whole or peeled rhizome or containing aqueous dispersions or aqueous extracts of whole or peeled rhizome; or

(c) in dermal preparations.

SCHEDULE 5 – AMENDMENT

TETRACHLORVINPHOS – Amend entry to read:

TETRACHLORVINPHOS **except** in animal feeds containing 0.2 per cent or less of tetrachlorvinphos.

SCHEDULE 6 – AMENDMENTS

GLYCOLIC ACID – Amend entry to read:

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 which are labelled in accordance with the *National Occupational Health and Safety Commission's National Code of Practice for the Labelling of Workplace Substances* [NOHSC:2012 (1994)];

(b) in preparations containing 5 per cent or less of glycolic acid; or

(c) in preparations containing 20 per cent or less of glycolic acid with a pH of 3.5 or greater.

METHOMYL – Amend entry to read:

METHOMYL in fly-baits containing 1 per cent or less of methomyl and not less than 0.002 per cent of denatonium benzoate as a bittering agent.

MORANTEL – Amend entry to read:

MORANTEL **except**:

(a) when included in Schedule 5; or

(b) in preparations containing 10 per cent or less of morantel.

PICRIC ACID – Delete entry.

APPENDIX E, PART 1 – AMENDMENTS

Standard Statement A – Amend entry to read:

A For advice, contact a Poisons Information Centre (e.g. phone Australia 131 126; New Zealand 0800 764 766) or a doctor (at once).

Standard Statement Z – Amend entry to read:

Z First aid is not generally required. If in doubt, contact a Poisons Information Centre (e.g. phone Australia 131 126; New Zealand 0800 764 766) or a doctor.

Standard Statement E2 – Amend entry to read:

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 131 126; New Zealand 0800 764 766) or a doctor, or for at least 15 minutes.

Standard Statement S2 – Amend entry to read:

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. phone Australia 131 126; New Zealand 0800 764 766) or a doctor.

Standard Statement S3 – Amend entry to read:

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 131 126; New Zealand 0800 764 766) or a doctor.

Standard Statement S4 – Amend entry to read:

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 131 126; New Zealand 0800 764 766) or a doctor.

Standard Statement S5 – Amend entry to read:

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 131 126; New Zealand 0800 764 766).

Standard Statement SP1 – Amend entry to read:

SP1 If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (e.g. phone Australia 131 126; 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.

APPENDIX E, PART 2 – AMENDMENT

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

	STANDARD STATEMENTS
Octhilinone	A,G3,E2,S1

APPENDIX F, PART 3 – AMENDMENTS

POISON	**WARNING STATEMENTS**	**SAFETY DIRECTIONS**
Chlorinating compounds – subparagraph (g) – Amend entry to read**:**		
(g) in other compressed blocks or tablets containing 10 per cent or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5.1 (oxidising substances), as specified in *the Australian Code for the Transport of Dangerous Goods by Road and Rail* **except** 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
Dichloroisocyanurates - subparagraphs (e), (h), (j) – Amend entries to read:		
(e) in dry preparations containing 10 per cent or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5.1 (oxidising substances), as specified in *the Australian Code for the Transport of Dangerous Goods by Road and Rail.*	10,18,22	1,4,8,12,13,14, 15,16,17,18,19, 20,21,22,26
(h) in other compressed blocks or tablets containing 10 per cent or more of available chlorine certified by a relevant State or Territory authority as not being a Dangerous Good of Class 5.1 (oxidising substances), as specified in *the Australian Code for the Transport of Dangerous Goods by Road and Rail* **except** in preparations containing 21 g or less of sodium dichloroisocyanurate for use in toilet cisterns only.	10,22	12,13,14,15,17, 18,19,21
(j) in other compressed blocks or tablets containing 10 per cent or more of available chlorine certified by a relevant State or Territory authority as not being a		

Dangerous Good of Class 5.1 (oxidising substances) as specified in *the Australian Code for the Transport of Dangerous Goods by Road and Rail* in preparations containing 5 g or less of sodium dichloroisocyanurate for use in toilet bowls only.			
(i)	during storage	10,22	12,13,14,15,17, 18,21
(ii)	during use	5	1,4,7,12