

NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

OUTCOME OF CONSIDERATIONS BY THE NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE AT ITS JUNE 2008 MEETING OF PROPOSALS FOR AMENDMENT TO THE STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS

Notice under subsection 52D(4) *Therapeutic Goods Act 1989* (the Act)

The National Drugs and Poisons Schedule Committee (NDPSC) hereby gives notice, pursuant to subsection 52D(4) of the Act, that an amendment has been made to the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP).

The notice is divided into four parts:

- Part A – Amendments to the SUSDP, Part 4 in respect of substances mentioned in the pre-meeting Gazette Notice;
- Part B – Other amendments to the SUSDP (Parts 1-3 and Part 5);
- Part C – Amendments to the SUSDP subject to further post-meeting public submissions; and
- Part D – Errata.

Please note that the basis for amendments to the SUSDP can be found in the Record of Reasons. The Record of Reasons, which also contains other outcomes arising from the NDPSC meeting, can be accessed through: <http://www.tga.gov.au/ndpsc>. Hard copies of the document can be obtained from the NDPSC Secretariat, tel 02 6160 3200.

The amendments arising from this notice will be incorporated into SUSDP 23 Amendment 2 effective 1 January 2009 (unless otherwise indicated), which should be available for purchase from National Mailing and Marketing Pty Ltd in December 2008, telephone (02) 6269 1035 (or using the subscription order form available at the following webpage <http://www.tga.gov.au/ndpsc/susdp.htm>).

Please note that SUSDP 23, Amendment 1 will soon be available from National Mailing and Marketing Pty Ltd.

Invitation to make a post-meeting submission

The amendments set out in Part A and B were made in respect of substances or issues mentioned in the Commonwealth of Australia Gazette No.16, 23 April 2008 as substances to be considered for scheduling at the June 2008 meeting. These amendments are subject to the receipt of further public submissions from persons who made a pre-meeting public submission in relation to substances listed in Part A or B.

Accordingly, these persons are invited to make a further submission to:

The Secretary
National Drugs and Poisons Schedule Committee
GPO Box 9848
CANBERRA ACT 2601
e-mail NDPSC@health.gov.au or Facsimile 02 6160 3299.

The NDPSC has moved to an E-agenda and is increasingly using electronic documents at its meetings. Persons making submissions to the Committee are encouraged to lodge submissions in electronic format via the NDPSC email address (word or unsecured PDF is preferred). Correspondence from the Committee will similarly be via email where possible.

Submissions must be made by **20 August 2008**, address a matter mentioned in section 52E of the Act and be relevant to the reasons for the making of the decision.

If a further submission is made to the Committee by an eligible person in respect of a substance set out below, the Committee must consider the submission and then: confirm the amendment; 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.

PART A – AMENDMENTS TO PART 4 – THE SCHEDULES OF THE SUSDP

Subject to the matters set out above, the amendments in Part A come into effect on **1 January 2009**, unless otherwise indicated.

Schedule 2 – Amendments

GLYCERYL TRINITRATE – delete entry.

Schedule 3 – Amendments

GLYCERYL TRINITRATE – Amend entry to read:

GLYCERYL TRINITRATE:

- (a) in preparations for oral use; or
- (b) in preparations for rectal use.

Schedule 4 – New Entry

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

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 grams 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 Entry

† METHYLDIBROMO GLUTARONITRILE **except** in preparations intended to be in contact with the skin, including cosmetic use.

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 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 paint, jointing materials and sealants containing 1 per cent or less of octhilinone calculated on the non-volatile content.

Schedule 7 – New Entry

CYANOGEN.

PART B – OTHER AMENDMENTS TO THE SUSDP (PARTS 1-3 AND PART 5)

Subject to the matters set out above, the amendments in Part B come into effect on **1 January 2009**, unless otherwise indicated.

PART 5 – APPENDICES

Appendix C – New Entry

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.

METHYLDIBROMO GLUTARONITRILE in preparations intended to be in contact with the skin, including cosmetic use.

Appendix D – Amendment

Appendix D, 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 F – Part 3 – New Entry

POISON	WARNING STATEMENTS	SAFETY DIRECTIONS
Methyldibromo glutaronitrile	28	1,4,7

Appendix J – Part 2 – New Entry

POISON	CONDITION
Cyanogen	1

Appendix K – New Entry

Rotigotine

PART C – AMENDMENTS TO THE SUSDP THAT WERE SUBJECT TO FURTHER PUBLIC SUBMISSIONS

The amendments set out in Part C have been made in response to post-meeting public submissions. The public consultation process in respect of these amendments has now concluded. The amendments in Part C will be published in SUSDP 23 Amendment 1 which will come into effect on **1 September 2008** unless otherwise indicated.

Schedule 2 – Amendments

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* **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 supplied to registered dental professionals or by approval of an appropriate authority.

Schedule 3 – Amendments

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 supplied to registered dental professionals or by approval of an appropriate authority.

Schedule 6 – Amendments

PYRITHIONE ZINC – Amend entry to read:

PYRITHIONE ZINC **except**:

- (a) when included in Schedule 2 or 5;
- (b) for human use in preparations for the treatment of the scalp containing 2 per cent or less of pyrithione zinc when compliant with the requirements of the Required Advisory Statements for Medicine Labels;
- (c) in semi-solid hair preparations for animal use;
- (d) in shampoos for animal use containing 2 per cent or less of pyrithione zinc when labelled with the statement “Keep out of eyes” and “If in eyes rinse well with water”; or
- (e) when immobilised in solid preparations containing 0.5 per cent or less of pyrithione zinc.

PART D – ERRATA

The Committee agreed to minor editorial amendments to the wording of these schedule entries to clarify the intent or implementation of the original decision or to adopt contemporary nomenclature. These corrections will be incorporated into SUSDP 23 Amendment 1, and come into effect on **1 September 2008** unless otherwise specified.

Schedule 2 – Amendment

DEXTROMETHORPHAN – Amend entry to read:

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

METHOXAMINE – Amend entry to read:

METHOXAMINE in preparations for external use **except** containing 1 per cent or less of methoxamine.

Schedule 3 – Amendment

The following editorial changes to the entries for brompheniramine, chlorpheniramine, dexchlorpheniramine, diphenhydramine, doxylamine, pheniramine and triprolidine relate to the decisions from the February 2008 NDPSC meeting (Resolution 2008/52 – 20).

BROMPHENIRAMINE – Amend entries to read:

BROMPHENIRAMINE in oral preparations **except**:

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

CHLORPHENIRAMINE – Amend entries to read:

CHLORPHENIRAMINE in oral preparations **except**:

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

DEXCHLORPHENIRAMINE – Amend entries to read:

DEXCHLORPHENIRAMINE in oral preparations **except**:

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

DIPHENHYDRAMINE – Amend entries to read:

DIPHENHYDRAMINE in oral preparations **except**:

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

DOXYLAMINE – Amend entries 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.

PHENIRAMINE – Amend entries to read:

PHENIRAMINE in oral preparations **except**:

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

TRIPROLIDINE – Amend entries to read:

TRIPROLIDINE in oral preparations **except**:

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

Schedule 4 – Amendment

DEXTROMETHORPHAN – Amend entry to read:

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

DEXTRORPHAN – Amend entry to read:

DEXTRORPHAN (excluding its stereoisomers).

FRUSEMIDE – Amend entry to read:

FUROSEMIDE (frusemide).

METHOTRIMEPRAZINE – Amend entry to read:

LEVOMEPRMAZINE.

The following editorial changes to the entry for paracetamol relate to the decision from the February 2008 NDPSC meeting (Resolution 2008/52 - 25).

PARACETAMOL – Amend entry to read:

PARACETAMOL:

- (a) when combined with aspirin or salicylamide or any derivative of these substances **except** when separately specified in these Schedules;
- (b) in slow release tablets or capsules containing more than 665 mg of paracetamol;
- (c) in non-slow release tablets or capsules containing more than 500 mg of paracetamol;
- (d) in individually wrapped powders or sachets of granules each containing more than 1000 mg of paracetamol; or

- (e) for injection.

The following editorial changes to the entry for piper methysticum relate to the decision from the February 2008 NDPSC meeting (Resolution 2008/52 - 21).

PIPER METHYSTICUM – 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 7 – Amendment

EPIDERMAL GROWTH FACTOR – Amend entry to read:

EPIDERMAL GROWTH FACTOR **except** in preparations for human therapeutic use.

Appendix E – Part 2 – Amendment

Maldison – Amend entry to read:

POISON

STANDARD STATEMENTS

Malathion at 20 per cent or lessA

Appendix F – Part 1 – New Entry

Warning Statement 102 – Amend entry to read:

- 102. Unless a doctor has told you to, don't use [*this product / name of the product*]:
For more than a few days at a time
With other medicines containing aspirin or other anti-inflammatory medicines
If you have asthma

In children under 12 years of age
In children 12-16 years of age with or recovering from chicken pox, influenza or fever
If you are pregnant.

Appendix F – Part 3 – Amendment

Hydrocortisone – Amend entry to read:

POISON	WARNING STATEMENTS	SAFETY DIRECTIONS
Hydrocortisone		
(a) for dermal use when included in Schedule 2 or 3.	38,72,73,74,75	
(b) for topical rectal use when included in Schedule 2 or 3.	38,75	

Tranexamic acid – delete entry.

Appendix J – Part 2 – Amendment

CHOLECALCIFEROL – Amend entry to read:

POISON	CONDITION
Colecalciferol.....	1
