

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

### **OUTCOME OF CONSIDERATIONS BY THE NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE AT ITS FEBRUARY 2009 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 February 2009 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 – Editorials and 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/records.htm>. Hard copies of the document can be obtained from the NDPSC Secretariat, by phone on (02) 6160 3200.

The amendments arising from this notice will be incorporated into SUSDP 24 Amendment 1 effective 1 September 2009 (unless otherwise indicated), which should be available for purchase from National Mailing and Marketing Pty Ltd in August 2009, telephone (02) 6269 1035, or using the subscription order form available at <http://www.tga.gov.au/ndpsc/susdp.htm>.

Please note that SUSDP 23, Amendment 3 will soon be available from National Mailing and Marketing Pty Ltd. Please also note that the SUSDP and its amendments are available electronically as the 'Poisons Standard' at the ComLaw website, a link to which can be found at <http://www.tga.gov.au/ndpsc/susdp.htm>.

#### **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.50, 17 December 2008, as substances to be considered for scheduling at the February 2009 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](mailto: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 **24 April 2009** and must address a matter mentioned in Section 52E of the Act and must 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 pursuant to 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 September 2009**, unless otherwise indicated.

##### **Schedule 2 – New Entry**

GUAIPHENESIN in a modified release dosage form of 1200 mg or less of guaiphenesin with a recommended daily dose of 2400 mg or less when labelled not for the treatment of children under 12 years of age.

##### **Schedule 2 – Amendment**

HYDROQUINONE – Amend entry to read:

HYDROQUINONE (excluding monobenzene and other alkyl ethers of hydroquinone included in Schedule 4) in preparations for human external therapeutic or cosmetic use containing 2 per cent or less of hydroquinone **except** hair preparations containing 0.3 per cent or less of hydroquinone.

##### **Schedule 4 – New Entries**

ALPHA<sub>1</sub>-PROTEINASE INHIBITOR (HUMAN).

AMBRISENTAN.

BAZEDOXIFENE.

CILOSTAZOL.

DAPOXETINE.

ETRAVIRINE.

GEMTUZUMAB OZOGAMICIN.

METHYLNALTREXONE.

PHOSPHODIESTERASE TYPE 5 INHIBITORS **except** when separately specified in these Schedules.

RIVAROXABAN.

SUGAMADDEX.

TOCILIZUMAB.

#### **Schedule 4 – Amendments**

GUAIPHENESIN – Amend entry to read:

GUAIPHENESIN for human therapeutic use **except**:

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

HYDROQUINONE – Amend entry to read:

HYDROQUINONE (other than its alkyl ethers separately specified in this Schedule) in preparations for human therapeutic or cosmetic use **except**:

- (a) when included in Schedule 2; or
- (b) in hair preparations containing 0.3 per cent or less of hydroquinone.

#### **Schedule 5 – New Entries**

DIETHYLENE GLYCOL (excluding its salts and derivatives) in preparations containing not less than 10 mg/kg of denatonium benzoate as a bittering agent **except**:

- (a) in paints or paint tinters;
- (b) in toothpastes or mouthwashes containing more than 0.25 per cent of diethylene glycol; or
- (c) in other preparations containing 2.5 per cent or less of diethylene glycol.

PROTHIOCONAZOLE-DESCHLORO **except** in preparations containing 0.5 per cent or less of prothioconazole-deschloro.

PROTHIOCONAZOLE-TRIAZOLIDINETHIONE **except** in preparations containing 0.5 per cent or less of prothioconazole-triazolidinethione.

#### **Schedule 5 – Amendment**

ETHYLENE GLYCOL – Amend entry to read:

ETHYLENE GLYCOL (excluding its salts and derivatives) in preparations containing not less than 10 mg/kg of denatonium benzoate as a bittering agent **except**:

- (a) in paints or paint tinters;
- (b) in toothpastes or mouthwashes containing more than 0.25 per cent of ethylene glycol; or
- (c) in other preparations containing 2.5 per cent or less of ethylene glycol.

#### **Schedule 6 – New Entry**

DIETHYLENE GLYCOL (excluding its salts and derivatives) **except**:

- (a) when included in Schedule 5;
- (b) in paints or paint tinters;
- (c) in toothpastes or mouthwashes containing more than 0.25 per cent of diethylene glycol; or
- (d) in other preparations containing 2.5 per cent or less of diethylene glycol.

#### **Schedule 6 – Amendment**

ETHYLENE GLYCOL – Amend entry to read:

ETHYLENE GLYCOL (excluding its salts and derivatives) **except**:

- (a) when included in Schedule 5;
- (b) in paints or paint tinters;
- (c) in toothpastes or mouthwashes containing more than 0.25 per cent of ethylene glycol; or
- (d) in other preparations containing 2.5 per cent or less of ethylene glycol.

**Schedule 9 – New entries**

1-(8-BROMOBENZO[1,2-B;4,5-B]DIFURAN-4-YL)-2-AMINOPROPANE  
\*(Bromo-Dragonfly)

4-FLUORO-N-METHYLAMPHETAMINE.

N-PHENETHYL-4-PIPERIDONE.

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**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 September 2009**, unless otherwise indicated.

**Appendix C – New entry**

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

**Appendix D, sub-paragraph 6 – New entry**

AMBRISENTAN for human use.

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**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 3 which will come into effect on **1 May 2009** unless otherwise indicated.

NIL

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**PART D – EDITORIALS AND 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 3.

**PART 1, INTERPRETATION – Amendment**

“Australian Code for the Transport of Dangerous Goods by Road and Rail” – Amend entry to read:

**“Australian Code for the Transport of Dangerous Goods by Road and Rail”** means the seventh edition of the document of that name.

## **Part 2 – Labels and containers – Amendment**

Paragraph 16 – Amend entry to read:

### **Paints**

**16.** The requirements of paragraph 7 do not apply to:

- (1) paint (other than a paint for therapeutic or cosmetic use) which:
  - (a) contains only Schedule 5 poisons; or
  - (b) is a First Schedule or Second Schedule paint that is labelled with:
    - (i) the word “WARNING”, written in bold-face sanserif capital letters, the height of which is not less than 5 mm, on the first line of the main label with no other words written on that line; and
    - (ii) the expression “KEEP OUT OF REACH OF CHILDREN”, written in bold-face sanserif capital letters, the height of which is not less than 2.5 mm, on a separate line immediately below the word “WARNING”; and
    - (iii) the appropriate warnings specified for the paint in Appendix F, written immediately below the expression “KEEP OUT OF REACH OF CHILDREN”; and
    - (iv) the name and proportion of the First Schedule or Second 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; or
- (2) a tinter which contains:
  - (a) only Schedule 5 poisons; or
  - (b) a poison included in the First Schedule or Second Schedule to Appendix I, provided that it is labelled with the name and proportion of that poison, and where the poison 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 tinter.

#### **Schedule 4 – Amendment**

ETHYLHEXANEDIOL – Amend entry to read:

† ETHYLHEXANEDIOL for animal use.

#### **Schedule 6 – Amendments**

FORMALDEHYDE – Amend entry to read:

† FORMALDEHYDE (excluding its derivatives) in preparations containing 0.05 per cent or more of free formaldehyde **except:**

- (a) for human therapeutic use;
- (b) in oral hygiene preparations;
- (c) in nail hardener cosmetic preparations containing 5 per cent or more of free formaldehyde;
- (d) in nail hardener cosmetic preparations containing 0.2 per cent or less of free formaldehyde when labelled with the statement:

PROTECT CUTICLES WITH GREASE OR OIL;

- (e) in all other cosmetic preparations; or
- (f) in other preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement:

CONTAINS FORMALDEHYDE.

PARAFORMALDEHYDE – Amend entry to read:

† PARAFORMALDEHYDE (excluding its derivatives) in preparations containing 0.05 per cent or more of free formaldehyde **except:**

- (a) for human therapeutic use;
- (b) in oral hygiene preparations;
- (c) in nail hardener cosmetic preparations containing 5 per cent or more of free formaldehyde;
- (d) in nail hardener cosmetic preparations containing 0.2 per cent or less of free formaldehyde when labelled with the statement:

PROTECT CUTICLES WITH GREASE OR OIL;

- (e) in all other cosmetic preparations; or
- (f) in other preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement:

CONTAINS FORMALDEHYDE.

### **Schedule 7 – New entry**

BENOMYL **except** in paints containing 0.5 per cent or less of benomyl.

### **Appendix A – Amendment**

CHEMISTRY SETS – Amend entry to read:

CHEMISTRY SETS:

- (a) toy, when complying with the requirements of Australian Standard AS 8124.4-2003 *Safety of toys - Part 4: Experimental sets for chemistry and related activities*; or
- (b) for educational use, containing Schedule 5 or 6 poisons in containers of 3 mL or less of each liquid preparation or 5 g or less of each solid preparation in a discrete unit.

### **Appendix B – Amendment**

SOMATOTROPHIN, EQUINE – Delete entry.

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

NICABAZIN - Amend entry to read:

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
NICARBAZIN	Jun 1969	d	2.3

### **Appendix I – Amendment**

Amend Appendix I to read:

This Appendix provides regulations for adoption by the States and Territories.

1. A person must not manufacture, sell, supply or use a First Schedule Paint for application to:
  - (1) a roof or any surface to be used for the collection or storage of potable water; or
  - (2) furniture; or

- (3) any fence, wall, post, gate or building (interior or exterior) other than a building which is used exclusively for industrial purposes or mining or any oil terminal; or
- (4) any premises used for the manufacture, processing, preparation, packing or serving of products intended for human or animal consumption.