



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

POISONS STANDARD AMENDMENT NO.2 OF 2009

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 2009 in the manner set out in Schedule 1.

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

Signed
DR RUTH LOPERT
CHAIR
NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

Dated this 3rd day of August 2009

Schedule 1- Amendments to the Poisons Standard 2009

STANDARD
FOR THE
UNIFORM SCHEDULING
OF
DRUGS AND POISONS

No. 24

AMENDMENT No. 1

Effective Date – 1 September 2009



Australian Government

Department of Health and Ageing

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The amendments listed in this document were finalised at the February and June 2009 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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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.24 and recommends that these amendments be adopted by the States and Territories with effect from 1 September 2009 unless otherwise stated. The amendments arise from decisions made by the Committee at its February 2009 meeting and confirmed at the June 2009 meeting except where separately specified.

PART 4 – THE SCHEDULES

SCHEDULE 2 – NEW ENTRY

(The following entry for guaiphenesin also incorporates an editorial change identified at the June 2009 meeting under item 21.2)

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 not labelled for the treatment of children under 12 years of age.

SCHEDULE 2 – AMENDMENT

(The following entry for hydroquinone also incorporates an editorial change identified at the June 2009 meeting under item 21.2)

HYDROQUINONE – Amend entry to read:

HYDROQUINONE (excluding monobenzone 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** in hair preparations containing 0.3 per cent or less of hydroquinone.

SCHEDULE 4 – NEW ENTRIES

ALPHA1-PROTEINASE INHIBITOR (HUMAN).

AMBRISANTAN.

BAZEDOXIFENE.

CILOSTAZOL.

DAPOXETINE.

ETRAVIRINE.

GEMTUZUMAB OZOGAMICIN.

METHYLNALTREXONE.

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

RIVAROXABAN.

SUGAMADDEX.

TOCILIZUMAB.

SCHEDULE 4 – AMENDMENTS

(The following entry for guaiphenesin also incorporates an editorial change identified at the June 2009 meeting under item 21.2)

GUAIPHENESIN – Amend entry to read:

GUAIPHENESIN for human therapeutic use **except**:

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

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

(The following entry for diethylene glycol also incorporates an editorial change identified at the June 2009 meeting under item 21.2)

† 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

(The following entry for ethylene glycol also incorporates an editorial change identified at the June 2009 meeting under item 21.2)

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

(The following entry for diethylene glycol also incorporates an editorial change identified at the June 2009 meeting under item 21.2)

† 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

(The following entry for ethylene glycol also incorporates an editorial change identified at the June 2009 meeting under item 21.2)

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.

PART 5 – APPENDICES

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

AMBRISANTAN for human use.