



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

POISONS STANDARD AMENDMENT No. 3 OF 2012

I, ANTHONY GILL, a delegate of the Secretary to the Department of Health and Ageing for the purposes of paragraph 52D(2)(a) of the *Therapeutic Goods Act 1989* (the Act) and acting in accordance with the Secretary's power under that paragraph of the Act, hereby amend the Poisons Standard 2012 in the manner set out in Schedule 1.

The amendments to the Poisons Standard 2012 as set out in Schedule 1 commence on 1 September 2012.

(signed by)

ANTHONY GILL
Delegate of the Secretary to the Department of Health and Ageing

Dated this 8th day of August 2012

Schedule 1- Amendment to the Poisons Standard 2012

STANDARD
FOR THE
UNIFORM SCHEDULING
OF
MEDICINES AND POISONS

No. 3

AMENDMENT No. 2

Effective Date – 1 September 2012

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The amendments listed in this document are a result of decisions made by a delegate of the Secretary of the Department of Health and Ageing in May 2012. The basis of these amendments can be found in the 'Reasons for scheduling delegate's final decisions', which can be accessed from the TGA website at www.tga.gov.au/industry/scheduling-decisions.htm.

Further inquiries should be directed to:

The Secretary
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Amendments to the Standard for the Uniform Scheduling of Medicines and Poisons

The Secretary of the Department of Health and Ageing directs that the amendments below be applied to the Standard for the Uniform Scheduling of Medicines and Poisons No. 3 and recommends that these amendments be adopted by the States and Territories with effect from 1 September 2012.

PART 1 – INTERPRETATION

SUBPARAGRAPH 1(1) – NEW ENTRY

“**Free formaldehyde**” includes all hydrated and non-hydrated formaldehyde present in aqueous solution, including methylene glycol.

PART 4 – THE SCHEDULES

SCHEDULE 2 – AMENDMENTS

CICLOPIROX – Amend entry to read:

CICLOPIROX:

- (a) in preparations for dermal use containing 2 per cent or less of ciclopirox **except** in preparations for tinea pedis; or
- (b) in preparations for application to the nails containing 8 per cent or less of ciclopirox.

LORATADINE – Amendment to read:

LORATADINE in solid dose preparations for oral use **except** in preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

- (a) in a primary pack containing 5 dosage units or less; and
- (b) labelled with a recommended daily dose not exceeding 10 mg of loratadine.

SCHEDULE 3 – AMENDMENT

ADRENALINE – Amend entry to read:

ADRENALINE in preparations containing 1 per cent or less of adrenaline **except** in preparations containing 0.02 per cent or less of adrenaline unless packed and labelled for injection.

SCHEDULE 4 – NEW ENTRIES

AXITINIB.

COBICISTAT.

ELVITEGRAVIR.

SCHEDULE 4 – AMENDMENTS

ADRENALINE – Amend entry to read:

ADRENALINE **except**:

- (a) when included in Schedule 3; or

- (b) in preparations containing 0.02 per cent or less of adrenaline unless packed and labelled for injection.

CICLOPIROX – Amend entry to read:

CICLOPIROX except:

- (a) when included in Schedule 2 or 3; or
 (b) in preparations for the treatment of tinea pedis.

LORATADINE – Amend entry to read:

LORATADINE except

- (a) when included in Schedule 2; or
 (b) in solid dose preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:
 (i) in a primary pack containing 5 dosage units or less; and
 (ii) labelled with a recommended daily dose not exceeding 10 mg of loratadine.

SCHEDULE 5 – NEW ENTRIES

CYFLUFENAMID.

SEDAXANE.

SCHEDULE 6 – NEW ENTRIES

FLONICAMID.

ZINC BORATE (excluding its derivatives) for use as an agricultural chemical.

PART 5 – APPENDICES

APPENDIX B – NEW ENTRY

Substance	Date Of Entry	Reason For Listing	Area Of Use
BISTRIFLURON	Sep 2012	a	1.1.2

APPENDIX C – AMENDMENTS

DIETHYLPHTHALATE – Amend entry to read:

DIETHYLPHTHALATE in sunscreens, personal insect repellents or body lotion preparations for human use **except** in preparations containing 0.5 per cent or less of diethylphthalate.

DIMETHYLPHTHALATE – Amend entry to read:

DIMETHYLPHTHALATE in sunscreens, personal insect repellents or body lotion preparations for human use **except** in preparations containing 0.5 per cent or less of dimethylphthalate.