



Australian Government

Department of Health
Therapeutic Goods Administration

POISONS STANDARD AMENDMENT No. 1 OF 2014

I, ANTHONY GILL, a delegate of the Secretary to the Department of Health 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 2013 in the manner set out in Schedule 1.

The amendment to the Poisons Standard 2013 as set out in Schedule 1 will commence on 1 February 2014.

(Signed by)

ANTHONY GILL
Delegate of the Secretary to the Department of Health

Dated this 18th day of December 2013

Schedule 1- Amendment to the Poisons Standard 2013

STANDARD
FOR THE
UNIFORM SCHEDULING
OF
MEDICINES AND POISONS

No. 4

AMENDMENT No. 2

Effective Date – 1 February 2014

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The amendments listed in this document are a result of decisions made by the Secretary of the Department of Health or the Secretary's Delegate in November 2013. 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 <http://www.tga.gov.au/industry/scheduling-decisions-final.htm>.

Further inquiries should be directed to:

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

The Secretary of the Department of Health directs that the amendments below be applied to the Standard for the Uniform Scheduling of Medicines and Poisons No. 4 and recommends that these amendments be adopted by the States and Territories with effect from 1 February 2014 unless otherwise stated.

PART 4 – THE SCHEDULES

SCHEDULE 2 – AMENDMENT

HYDROQUINONE – Amend entry to read:

HYDROQUINONE (excluding monobenzone and 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:**

- (a) in hair preparations containing 0.3 per cent or less of hydroquinone; or
- (b) in cosmetic nail preparations containing 0.02 per cent or less of hydroquinone.

SCHEDULE 4 – NEW ENTRIES

AFATINIB DIMALEATE.

DABRAFENIB MESILATE.

DOLUTEGRAVIR.

LURASIDONE.

MIRABEGRON.

OCRIPLASMIN.

PRADOFLOXACIN.

ROMIDEPSIN.

TRAMETINIB DIMETHYL SULFOXIDE.

TRASTUZUMAB EMTANSINE.

VEDOLIZUMAB.

VORTIOXETINE.

SCHEDULE 4 – AMENDMENTS

ALPRAZOLAM – Delete entry.

BUPIVACAINE – Amend entry to read:

BUPIVACAINE **except** when included in Schedule 5.

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; or
- (c) in cosmetic nail preparations containing 0.02 per cent or less of hydroquinone.

LIGNOCAINE – Amend entry to read:

LIGNOCAINE **except**:

- (a) when included in Schedules 2 or 5;
- (b) in dermal preparations containing 2 per cent or less of total local anaesthetic substances per dosage unit; or
- (c) in lozenges containing 30 mg or less of total anaesthetic substances per dosage unit

MONOBENZONE – Amend entry to read:

MONOBENZONE and alkyl ethers of hydroquinone for human therapeutic use or cosmetic use **except** in cosmetic nail preparations containing 0.02 per cent or less of monobenzone or alkyl ethers of hydroquinone.

The following amended entry for tylosin has a delayed implementation date of 1 June 2014.

TYLOSIN – Amend entry to read:

TYLOSIN.

SCHEDULE 5 – NEW ENTRIES

BUPIVACAINE in aqueous gel preparations containing 0.5 per cent or less of bupivacaine, for the dermal spray-on treatment of wounds associated with 'mulesing' of sheep.

LIGNOCAINE in aqueous gel preparations containing 4.5 per cent or less of lignocaine, for the dermal spray-on treatment of wounds associated with 'mulesing' of sheep.

SCHEDULE 5 – AMENDMENTS

3-IODO-2-PROPYNYL BUTYL CARBAMATE (Iodocarb) – Amend entry to read:

3-IODO-2-PROPYNYL BUTYL CARBAMATE (Iodocarb) in preparations containing 10 per cent or less of 3-iodo-2-propynyl butyl carbamate **except**:

- (a) in aqueous preparations not for cosmetic use containing 10 per cent or less 3-iodo-2-propynyl butyl carbamate; or
- (b) in cosmetic preparations (other than aerosolised preparations) containing 0.1 per cent or less of 3-iodo-2-propynyl butyl carbamate.

DELTAMETHRIN – Amend entry to read:

DELTAMETHRIN:

- (a) when impregnated in plastic resin strip material containing 4 per cent or less of deltamethrin;
- (b) in aqueous preparations containing 5 per cent or less of deltamethrin when no organic solvent other than a glycol is present;
- (c) 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;
- (d) in water-dispersible tablets each containing 500 mg or less of deltamethrin in child-resistant packaging; or
- (e) in other preparations containing 0.5 per cent or less of deltamethrin,

except:

- (a) in factory prepared mosquito nets containing 1 per cent or less deltamethrin; or
- (b) in preparations containing 0.1 per cent or less of deltamethrin.

The following amended entry for tylosin has a delayed implementation date of 1 June 2014.

TYLOSIN – Delete entry.

SCHEDULE 6 – NEW ENTRIES

1,2-BENZENEDIOL.

The following amended entry for cocoyl glycinate has a delayed implementation date of 1 February 2015.

COCOYL GLYCINATE in cosmetic preparations **except**:

- (a) in leave-on preparations containing 5 per cent or less of cocoyl glycinate; or
- (b) in wash-off preparations containing 30 per cent or less of cocoyl glycinate and, when containing more than 5 per cent of cocoyl glycinate labelled with a warning to the following effect:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER.

HEXYLOXYETHANOL **except** in preparations containing 10 per cent or less of hexyloxyethanol.

SCHEDULE 6 – AMENDMENTS

3-iodo-2-propynyl butyl carbamate (Iodocarb) – Amend entry to read:

3-iodo-2-propynyl butyl carbamate (Iodocarb) **except:**

- (a) when included in Schedule 5;
- (b) in aqueous preparations not for cosmetic use containing 10 per cent or less of 3-iodo-2-propynyl butyl carbamate (Iodocarb); or
- (c) in cosmetic preparations (other than aerosolised preparations) containing 0.1 per cent or less of 3-iodo-2-propynyl butyl carbamate.

DELTAMETHRIN – Amend entry to read:

DELTAMETHRIN:

- (a) in aqueous preparations containing 25 per cent or less of deltamethrin, when no organic solvent, other than 10 per cent or less of a glycol, is present;
- (b) in wettable granular preparations containing 25 per cent or less of deltamethrin;
- (c) in water-dispersible tablets each containing 500 mg or less of deltamethrin;
- (d) in emulsifiable concentrates containing 11 per cent or less of deltamethrin in a solvent containing 40 per cent or less of acetophenone and 45 per cent or less of liquid hydrocarbons; or
- (e) in other preparations containing 3 per cent or less of deltamethrin,

except:

- (a) when included in Schedule 5;
- (b) in factory prepared mosquito nets containing 1 per cent or less of deltamethrin; or
- (c) in preparations containing 0.1 per cent or less of deltamethrin.

SCHEDULE 7 – AMENDMENT

DELTAMETHRIN – Amend entry to read:

DELTAMETHRIN **except:**

- (a) when included in Schedules 5 or 6; or
- (b) in factory prepared mosquito nets containing 1 per cent or less of deltamethrin; or

(c) in preparations containing 0.1 per cent or less of deltamethrin.

SCHEDULE 8 - NEW ENTRY

ALPRAZOLAM.

PART 5 – THE APPENDICES

APPENDIX D, PARAGRAPH 5 - NEW ENTRY

BENZODIAZEPINE DERIVATIVES, including those separately specified in Schedule 4 and Schedule 8.

APPENDIX E, PART 2 – NEW ENTRIES

POISONS	STANDARD STATEMENT
1,2-BENZENEDIOL (CATECHOL)	A,E1,S1
COCOYL GLYCINATE	E1
HEXYLOXYETHANOL	A,G3,E2,S1

APPENDIX F, PART 3 – NEW ENTRIES

POISONS	WARNING STATEMENT	SAFETY DIRECTION
1,2-BENZENEDIOL (CATECHOL)	51,59	1,4,8
HEXYLOXYETHANOL	2	1,4,8

APPENDIX I – NEW ENTRY

The Second Schedule

Substance	Proportion
HEXYLOXYETHANOL	more than 10 per cent by vol

APPENDIX K – NEW ENTRY

LURASIDONE.

INDEX – NEW ENTRY

CATECHOL

See 1,2-BENZENEDIOL**EDITORIAL AMENDMENTS AND ERRATA****PART 4 – THE SCHEDULES****SCHEDULE 4 – AMENDMENTS**

BESIFLOXACINE HYDROCHLORIDE – Amend entry to read:

BESIFLOXACINE.

LOTEPREDNOL ETABONATE – Amend entry to read:

LOTEPREDNOL.

PASIREOTIDE DIASPARTATE – Amend entry to read:

PASIREOTIDE.

VILANTEROL TRIFENATATE – Amend entry to read:

VILANTEROL

PART 5 – THE APPENDICES**APPENDIX B, PART 3 – AMENDMENT**

BISTRIFLURON – Amend entry to read:

<u>SUBSTANCE</u>	<u>DATE OF ENTRY</u>	<u>REASON FOR LISTING</u>	<u>AREA OF USE</u>
BISTRIFLURON	Feb 2014	a	1.2.2