



**Australian Government**

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**Department of Health**  
Therapeutic Goods Administration

**POISONS STANDARD AMENDMENT No. 2 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 June 2014.

(Signed by)

ANTHONY GILL  
Delegate of the Secretary to the Department of Health

Dated this 9<sup>th</sup> day of May 2014

**Schedule 1 - Amendment to the Poisons Standard 2013**

**STANDARD  
FOR THE  
UNIFORM SCHEDULING  
OF  
MEDICINES AND POISONS**

**No. 4**

**AMENDMENT No. 3**

Effective Date – 1 June 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 April 2014. 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:

The Secretary  
Medicines and Poisons Scheduling Secretariat (MDP88)  
Office of Health Protection  
Department of Health  
GPO Box 9848  
CANBERRA ACT 2601

or by email to [SMP@health.gov.au](mailto:SMP@health.gov.au)

Media Liaison Unit  
Australian Government Department of Health

## **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 June 2014.

### **PART 4 – THE SCHEDULES**

#### **SCHEDULE 2 – NEW ENTRY**

MACROGOLS in preparations for oral use as a liquid concentrate for laxative use.

#### **SCHEDULE 3 – NEW ENTRY**

ESOMEPRAZOLE in oral preparations containing 20 mg or less per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days supply.

#### **SCHEDULE 4 – NEW ENTRIES**

COLLAGENASE CLOSTRIDIUM HISTOLYTICUM.

EMPAGLIFLOZIN.

FEBUXOSTAT.

NORMAL HUMAN IMMUNOGLOBULIN.

SERELAXIN.

SIMEPREVIR.

SOFOSBUVIR.

UMECLIDINIUM.

#### **SCHEDULE 4 – AMENDMENT**

DEANOL for therapeutic use.

ESOMEPRAZOLE **except** when included in Schedule 3.

**SCHEDULE 5 – NEW ENTRIES**

AFOXOLANER for the treatment and prevention of flea infestations and control of ticks in dogs in oral divided preparations each containing 140 mg or less of afoxolaner per dosage unit.

AMINOPYRALID in water soluble gel formulations containing 0.5 per cent or less of aminopyralid.

**SCHEDULE 6 – NEW ENTRIES**

2-CHLORO-6-(TRICHLOROMETHYL)-PYRIDINE.

FLUENSULFONE.

METHYL ETHYL KETONE OXIME **except** in preparations containing 1 per cent or less of methyl ethyl ketone oxime.

FURFURAL **except** in preparations containing 0.1 per cent or less of furfural.

**SCHEDULE 6 – AMENDMENTS**

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

CHROMATES (including dichromates) **except** in paints or tinters containing 5 per cent or less of chromium as the ammonium, barium, calcium, iron, potassium, sodium, strontium or zinc chromate calculated on the non-volatile content of the paint or tinter.

**SCHEDULE 7 – NEW ENTRIES**

BENZIDINE-BASED AZO DYES being:

2,2'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[N-(4-chlorophenyl)-3-oxobutanamide]

CAS No. 94249-03-3

**Acid Red 85 (Acid Fast Red A)**

1,3-Naphthalenedisulfonic acid, 7-hydroxy-8-[[4'-[[4-[[4-methylphenyl)sulfonyl]oxy]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-, disodium salt

CAS No. 3567-65-5

**Direct Black 38**

2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt

CAS No. 1937-37-7

**Direct Blue 2**

2,7-Naphthalenedisulfonic acid, 5-amino-3-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-4-hydroxy-, trisodium salt

CAS No. 2429-73-4

**Direct Blue 6**

2,7-Naphthalenedisulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[5-amino-4-hydroxy-, tetrasodium salt

CAS No. 2602-46-2

**Direct Brown 2**

5-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy- benzoic acid disodium salt

CAS No. 2429-82-5

**Direct Brown 95**

Cuprate(2-), [5-[[4'-[[2,6-dihydroxy-3-[(2-hydroxy-5-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxybenzoato(4-)-], disodium salt

CAS No. 16071-86-6

**Direct Green 1**

2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-6-(phenylazo)-, disodium salt

CAS No. 3626-28-6

**Direct Green 6**

2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-6-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-3-[(4-nitrophenyl)azo]-, disodium salt

CAS No. 4335-09-5

**Direct Red 28 (Congo Red)**

1-Naphthalenesulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[4-amino-, disodium salt

CAS No. 573-58-0

**Direct Red 37**

1,3-Naphthalenedisulfonic acid, 8-[[4'-[(4-ethoxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-7-hydroxy-, disodium salt

CAS No. 3530-19-6

2-NITROTOLUENE.

**SCHEDULE 9 – NEW ENTRY**

3,4-DICHLORO-N- {[1-(  
(DIMETHYLAMINO)CYCLOHEXYL]METHYL}BENZAMIDE

\*AH-7921

**PART 5 – THE APPENDICES****APPENDIX E, PART 2 – NEW ENTRIES**

<b>POISONS</b>	<b>STANDARD STATEMENT</b>
Methyl ethyl ketone oxime	A,E1,S1
Furfural	A,E1,S1

**APPENDIX F, PART 3 – NEW ENTRIES**

<b>POISONS</b>	<b>WARNING STATEMENT</b>	<b>SAFETY DIRECTION</b>
Methyl ethyl ketone oxime	5,28	1,4
Furfural	5	1,4

**APPENDIX I – NEW ENTRY****The Second Schedule**

<b>SUBSTANCE</b>	<b>PROPORTION</b>
CHROMIUM as chromates of ammonia, barium, calcium, iron, potassium, sodium, strontium or zinc	more than 5 per cent

**INDEX – NEW ENTRIES****2-FURANCARBOXALDEHYDE**

*See* FURFURAL

**DEANOL**

*See* 2-(dimethylamino)ethanol, DMEA, DIMETHYL MEA

**2-(dimethylamino)ethanol**

*See* DMEA, DIMETHYL MEA, DEANOL

**DMEA**

*See* DIMETHYL MEA, DEANOL, 2-(dimethylamino)ethanol

**DIMETHYL MEA**

*See* DEANOL, 2-(dimethylamino)ethanol, DMEA

**INTERPRETATION****PART 1 INTERPRETATION – NEW ENTRY**

**“Cosmetic”** means:

- (a) a substance or preparation intended for placement in contact with any external part of the human body, including:
  - (i) the mucous membranes of the oral cavity; and
  - (ii) the teeth;with a view to:
  - (iii) altering the odours of the body; or
  - (iv) changing its appearance; or
  - (v) cleansing it; or
  - (vi) maintaining it in good condition; or
  - (vii) perfuming it; or
  - (viii) protecting it.