

## NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

### PRE-FEBRUARY 2003 SCHEDULING MEETING NOTICE

#### Notice under Regulations 42ZCU of the *Therapeutic Goods Regulations 1990*

The Chair of the National Drugs and Poisons Schedule Committee (NDPSC) hereby gives notice that the next meeting of the NDPSC will be held on 25-27 February 2003. Substances to be considered for scheduling by the NDPSC are open for public comment.

Accordingly, public submissions are invited on those substances mentioned below which are to be considered for scheduling at the October meeting. Public submissions must address a matter(s) mentioned in section 52E of the *Therapeutic Goods Act 1989* and received by the closing date. Public submissions must also include the name of the person making the submission and a contact address. Persons making a submission in regard to a substance where a Schedule 3 classification may be an outcome are invited to provide additional comment on inclusion of that substance in Appendix H - Schedule 3 Poisons Permitted to be Advertised. Inclusion in Appendix H may be a consequential consideration of the Committee following a decision to include a substance in Schedule 3.

Public submissions should be made to:

The Secretary  
National Drugs and Poisons Schedule Committee  
PO Box 100  
WODEN ACT 2606

Facsimile: 02-6270 4353; or e-mail: [NDPSC@health.gov.au](mailto:NDPSC@health.gov.au)

The closing date for submissions is **COB 5 February 2003**.

The NDPSC, in making a decision in relation to the classification and scheduling of a substance, must consider all valid public submissions made by the closing date which address a matter(s) mentioned in section 52E of the Act. Public submissions that reserve the right to comment on a scheduling proposal or are made after the closing date need not be considered by the NDPSC.

The post-February 2003 meeting notice will invite further public submissions on substances which are the subject of an amendment to the Schedules at the February 2003 meeting. However, the invitation will be restricted to those who make a valid public submission in relation to the substance in response to this pre-meeting notice.

Further information may be obtained from the NDPSC Secretariat on 02-6270 4400 during business hours or by e-mailing [NDPSC@health.gov.au](mailto:NDPSC@health.gov.au).

To promote timely communications with stakeholders, the NDPSC has created an e-mail subscription list. Subscribers will be notified by e-mail of new information on the NDPSC website including pre- and post-meeting gazette notices, Record of the Reasons, advice on the publication of the SUSDP and other information relating to NDPSC operations. For further information follow the “**Subscribe by email:**” link at:

<http://www.health.gov.au/tga/docs/html/ndpsc/ndpsc.htm>

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## SUBSTANCES TO BE CONSIDERED FOR SCHEDULING

### 1. FORESHADOWED DECISIONS FROM PREVIOUS MEETING

No items.

### 2. SUBSTANCES REFERRED BY THE NATIONAL REGISTRATION AUTHORITY FOR AGRICULTURAL AND VETERINARY CHEMICALS

- 2.1 Fenbuconazole - consideration of scheduling.
  - 2.2 Morantel tartrate - consideration of scheduling.
  - 2.3 *Bacillus sphaericus* strain 2362 - consideration of scheduling.
  - 2.4 Cadusafos - consideration of scheduling.
  - 2.5 Marbofloxacin - consideration of scheduling.
  - 2.6 Ivermectin – consideration of scheduling.
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### 3. OTHER AGRICULTURAL/VETERINARY, INDUSTRIAL AND DOMESTIC CHEMICALS

- 3.1 Tin organic compounds (dibutyl tin laurate, dibutyl tin oxide, dibutyl tin diacetate) in or with paints - consideration of scheduling.
  - 3.2 Lithium in pigments – consideration of a cut-off to exempt when present as an excipient.
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### 4. ANTIBIOTICS FOR CONSIDERATION FOLLOWING RECOMMENDATIONS OF THE JOINT EXPERT ADVISORY COMMITTEE ON ANTIBIOTIC RESISTANCE (JETACAR)

- 4.1 Avoparcin - consideration of scheduling.
  - 4.2 Bacitracin - consideration of scheduling.
  - 4.3 Cuprimyxin - consideration of scheduling.
  - 4.4 Erythromycin - consideration of scheduling.
  - 4.5 Hygromycin - consideration of scheduling.
  - 4.6 Nalidixic acid - consideration of scheduling.
  - 4.7 Nisin/antibiotic substance - consideration of scheduling.
  - 4.8 Spiramycin - consideration of scheduling.
  - 4.9 Virginiamycin - consideration of scheduling.
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## **5. SUBSTANCES REFERRED BY THE AUSTRALIAN DRUG EVALUATION COMMITTEE**

- 5.1 Tadalafil - consideration of scheduling.
  - 5.2 Etoricoxib - consideration of scheduling.
  - 5.3 Valdecoxib - consideration of scheduling.
  - 5.4 Pegfilgrastim - consideration of scheduling.
  - 5.5 Telithromycin - consideration of scheduling.
  - 5.6 Bosentan - consideration of scheduling.
  - 5.7 Dutasteride - consideration of scheduling.
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## **6. OTHER PHARMACEUTICALS**

- 6.1 Lansoprazole - consideration of scheduling of oral preparations.
  - 6.2 Ketoprofen - consideration of scheduling of topical preparations.
  - 6.3 Dextromethorphan - consideration of scheduling of modified-release liquid preparations.
  - 6.4 Orlistat - consideration of scheduling.
  - 6.5 Nabilone - consideration of scheduling of oral preparations.
  - 6.6 Beclomethasone - consideration of scheduling of intranasal preparations.
  - 6.7 Mitragynine - consideration of scheduling.
  - 6.8 Pseudoephedrine - consideration of scheduling of undivided, combination and slow release preparations in S2.
  - 6.9 Collagen, hyaluronic acid, polylactic acid – consideration of including products for implantation in the Schedule 4 entries.
  - 6.10 Iron compounds - consideration of the proposed amendment to the S2 entry to clarify the cut-off for iron oxides when present as an excipient to read "...10 mg or less of iron oxides".
  - 6.11 Oxedrine (also known as synephrine, which is a component in various *Citrus* species, principally *C. aurantium* and in some cacti, eg, *Coryphantha macromeris* and *Dolichotele spp.*) – consideration of scheduling.
  - 6.12 Clobetasone, alclometasone and hydrocortisone in S3 – consideration of proposal to limit the entries to allow single-active formulations only.
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## **7. TRANS-TASMAN HARMONISATION MATTERS**

- 7.1 Dextromethorphan - consideration of proposal to include a pack size limit in Schedule 2.
  - 7.2 3-aminobenzoic acid ethyl ester methanesulphonate – consideration of proposal to delete entry from the SUSDP.
  - 7.3 Orthocaine – consideration of proposal to delete entry from the SUSDP.
  - 7.4 Benzamine - consideration of proposal to delete entry from the SUSDP.
  - 7.5 Ibuprofen - consideration of a dose limit for undivided oral preparations in Schedule 2.
  - 7.6 Selenium sulfide- consideration of scheduling preparations for topical use.
  - 7.7 Silver sulfadiazine - consideration of scheduling.
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**MATTERS EXPECTED TO LEAD TO AN AMENDMENT OF PARTS 1-3 OR PART 5 OF THE SUSDP, FOR WHICH THE NDPSC INVITE PUBLIC SUBMISSIONS.**

**8. OTHER MATTERS FOR CONSIDERATION**

- 8.1 Requirement for Part 2, Clause 7 (1) (d) – proposal to delete the requirement for WS 23 for certain types of pool chemicals.
  - 8.2 Sodium hydroxide and potassium hydroxide – proposal to amend the Appendix F, Part 3 requirement for Safety Direction No. 28.
  - 8.3 Orlistat – consideration of inclusion in Appendix H.
  - 8.4 Lansoprazole – consideration of inclusion in Appendix H.
  - 8.5 Sodium phosphate, sodium picosulfate or macrogol 3350 - consideration of inclusion in Appendix H.
  - 8.6 Boron Trifluoride, Bifluorides and Hydrosilicofluoric acid - Appendix F, Part 3 - amendment of WS 91 under Schedules 6 and 7, to WS 93.
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**9. PROPOSED APPENDIX B**

**APPENDIX B**

**SUBSTANCES CONSIDERED NOT TO REQUIRE CONTROL BY SCHEDULING**

[This appendix should be read in conjunction with Appendix A]

**INTRODUCTION**

At various times, the NDPSC has considered substances for which the available information suggests that inclusion in the Poisons Schedules is not necessary or not the most appropriate means of controlling the risk to public health.

Listing in Appendix B indicates that a decision has been taken not to list substances anywhere in the Schedules, either for a specific purpose, or generally. It is an inclusive, but not an exhaustive, list ie. there may be substances not included in the Schedules, and not included in Appendix B, which may be hazardous or non-hazardous, but have not been considered in relation to the need for scheduling.

Substances may be included in Appendix B because they have intrinsically low toxicity, or where other factors suggest that the potential public health risk would be minimal. Factors which are considered when determining an Appendix B entry include:

- The toxicology profile was adequately characterised and not consistent with inclusion in any of the Schedules;
- The use, purpose or product presentation minimised any hazard to the public such as to not require scheduling; or
- The public access was limited such that scheduling was inappropriate or unnecessary.

The list has been developed from current scheduling files and historical records. For transparency, where the reason for entry and/or purpose or use for the substance was apparent in the consideration, this has been included in the columns “Reason for Entry” and “Area of Use”

Inclusion in Appendix B will not prevent reconsideration of the scheduling of a substance where adverse information becomes available about the Appendix B entry for that substance.

The NDPSC considers applications for scheduling. Applications for entry into Appendix B will not be accepted.

## **PART 1**

### **REASONS FOR ENTRY**

- a Low Toxicity.
- b Use pattern restricts hazard.
- c Presentation/packaging restricts hazard.
- d Industrial use only

## **PART 2**

### **AREAS OF USE**

- 1. Agricultural
  - 1.1 Herbicide
  - 1.2 Insecticide
    - 1.2.1 Insecticide for codling moth
  - 1.3 Fungicide
    - 1.3.1 On seed fungicide
- 1.4 Bird Repellent
- 1.5 Fertiliser
- 1.6 Plant Growth Regulator
- 1.7 Insect Pheromone
- 1.8 Mushroom Bactericide
- 1.9 Acaricide
- 2. Veterinary
  - 2.1 For animal use
  - 2.2 Treatment of mastitis in cows
  - 2.3 Coccidiostat
  - 2.4 Feed additive

- 2.5 Antiseptic
- 2.6 Scabicide
- 2.7 Anthelmintic
- 2.8 Vitamin/Mineral
  
- 3. Domestic
  - 3.1 Aromatherapy
  - 3.2 Food additive
  - 3.3 Cosmetic
  - 3.4 Human use
  - 3.5 Miticide
  
- 4. Industrial
  - 4.1 Water Treatment
  - 4.2 Biological control agent
  
- 5. Environmental
  - 5.1 Mosquito control
  
- 6. Human therapeutic use
  - 6.1 Diagnostic agent
  - 6.2 Medical device
  - 6.3 Antiseptic
  - 6.4 Sunscreen
  - 6.5 External Use
  - 6.6 Laxative
  - 6.7 Antiseborrheic
  - 6.8 Cytoprotective
  - 6.9 Vitamin/Mineral
  - 6.10 Eye Drops
  
- 7. General
  - 7.1 Any use.
  - 7.2 Excipient
  - 7.3 Synergist
  - 7.4 Flux
  - 7.5 Pesticide
  - 7.6 Insect Repellent
  - 7.7 Solvent
  - 7.8 Disinfectant
  - 7.9 Preservative
  - 7.10 Antioxidant
  - 7.11 Resin Activator/Accelerant
  - 7.12 Sweetener Artificial
  - 7.13 Food additive

## PART 3

### SUBSTANCES CONSIDERED NOT TO REQUIRE CONTROL BY SCHEDULING

As at November 2002

SUBSTANCE	DATE OF ENTRY	REASON FOR LISTING	AREA OF USE
AGROBACTERIUM RADIOBACTER	Nov 1989	a	1
ALCOHOL, DEHYDRATED	Aug 2000	b	6
ALUM	May 1997	a	7.1
ALUMINIUM AMMONIUM SULFATE	May 1997	a	7.1
ALUMINIUM POTASSIUM SULFATE	May 1997	a	7.1
ALUMINIUM SILICATE	Nov 1974	a	7.1
ALUMINIUM tris (ETHYLPHOSPHONATE)	Aug 1986	a	1
AMINACRINE	Aug 1999	b	6.3
AMMONIUM PHOSPHATE	Nov 1974	a	7.1
AMMONIUM THIOSULPHATE	Nov 1974	a	7.1
AMPROLIUM	Jun 1969	a	2.3
AMYL ACETATE	Nov 1974	a	7.1
ASPARTIC ACID	-	a	6
ASULAM	May 1986	a	1
BACILLUS THURINGIENSIS (excluding endotoxin)	May 1992	a	5.1
BACULOVIRUS CYDIA POMONELLA (Codling Moth Granulosis Virus)	Oct 2002	a	1.2.1
BENFLURALIN	-	a	1.1
BENSULFURON-METHYL	Aug 1987	a	1
BENTONITE	Jun 2002	a	7.1
BENZYL BENZOATE	Aug 1989	a	1,3,4
BETAINE HYDROCHLORIDE	Nov 1974	a	7.1
BIFENAZATE	Oct 2002	a	1.9
BISMUTH SUBNITRATE	Nov 1999	b, c	2.1
BIURET	Nov 1974	a	2.4
BOVINE SOMATOTROPHIN	May 1992	a	2
BROMACIL	Aug 1987	a	1
BROMOPROPYLATE	Nov 1994	a	1
BUPIRIMATE	Nov 1990	a	1
BUTAFENACIL	May 2000	a	1
BUTOXPOLYPROPYLENE GLYCOL	Nov 1974	a	7.7
CARBETAMIDE	Aug 1991	a	1
CARBOXIN	Aug 1987	a	1

CARFENTRAZONE-ETHYL	Aug 1998	a	1
CETYL ALCOHOL	Nov 1974	a	7.1
CHAMOMILE OIL	Feb 2000	a	3.1
CHINA CLAY	Nov 1974	a	7.1
CHLORFLURENOL	Feb 1974	a	1.6
CHLORHEXIDINE	Nov 1974	a	7.8
CHLORIDAZON	May 1988	a	1
CHLOROXYLENOLS	Feb 1975	a	7.8
CITRONELLA OIL	Feb 2000	a	7.1
CLARY SAGE OIL	Feb 2000	a	7.1
CLOPIDOL	Nov 1974	d	2.3
COBALT NAPHTHENATE	-	d	7.1
COLOPHONY	Feb 1997	b	7.4
CROSPVIDONE	Aug 1996	a	2
CULICINOMYCES CLAVOSPORUS	Nov 1982	a	5.1
CYCLAMIC ACID	Nov 1971	a	7.1
CYCLOHEXANE	Nov 1974	a	7.7
CYCLOHEXANOL ACETATE	-	a	7.7
CYROMAZINE	Nov 1980	a	2
DIAVERIDINE	Jun 1969	d	2.3
DICLAZURIL	Nov 2001	a	2.3
DIETHYL CARBONATE	-	a	7.1
DIFLUFENICAN	Feb 1987	a	1
DIKEGULAC-SODIUM	Mar 1980	a	1.6
DIMETHICONE		a	7.1
DIMETHYL ETHER	Nov 1988	d	4
d-PHENOTHRIN	Feb 1982	a	7.5, 1.2
DIPHENYLAMINE	Feb 1988	a	1
DIPROPYLENE GLYCOL MONOMETHYL ETHER	Nov 1987	a	4
DIURON	Nov 1987	a	1
DOCUSATE SODIUM (DIOCTYL SODIUM SULFOSUCCINATE)	Feb 1970	a	7.1
2,2-DPA	Nov 1989	a	1
EPSIPRANTEL	Nov 1991	a	2
ETHAMETSULFURON-METHYL	Nov 2000	a	1.1
ETHOPABATE	Jun 1969	d	2.3
ETHYL ACETATE	Nov 1974	a	7.1
ETHYL ALCOHOL	Nov 1974	a	7.1
ETHYLBUTYLACETYL- AMINOPROPIONATE	Aug 2000	a	3.4
ETHYL BUTYRATE	-	a	7.1
ETHYL LACTATE	-	a	7.1

ETHYL METHACRYLATE	Nov 1974	a	7.1
FENFURAM	May 1977	a	1.3.1
FENHEXAMID	Feb 1999	a	1
FENOXYCARB	Feb 1988	a	1
FIR NEEDLE OIL (Canadian)	Feb 2000	a	7.1
FIR NEEDLE OIL (Siberian)	Feb 2000	a	7.1
FLUFENOXURON	Feb 1997	a	1
FLUMETSULAM	Feb 1992	a	1
FLUOMETURON	Aug 1989	a	1
FLUTOLANIL	Nov 2001	a	1.3
FLUROXYPYR	May 1986	a, c	1
FULLERS EARTH	Nov 1974	a	7.1
GERANIUM OIL	Feb 2000	a	7.1
GIBBERELIC	Nov 1974	a	1.6
HELIOTHIS NUCLEAR POLYHEDROSIS VIRUS	May 1981	a	1.2
HEXAFLURON	Nov 1988	a	1
HEXYL ACETATE		a	7.7
HEXYTHIAZOX	Feb 1988	a	1
HUMAN OSTEOGENIC PROTEIN-1 (OP-1)	Aug 2001	b	6.2
HYDROPRENE	Feb 1988	a	1
HYDROXYPROPYL CELLULOSE	Nov 1982	a	7.1
ICODEXTRIN	Nov 2000	b	6
INDOLE-3-ACETIC ACID	Feb 1985	b	1.6
ISOPRENE ALCOHOL	-	a	7.1
IPRODIONE	Feb 1997	a	1
ISOSTEARYL ALCOHOL ETHOXYLATE	Nov 1999	a	5.1
JUNIPER BERRY OIL	Feb 2000	a	7.1
KAOLIN	Nov 1974	a	7.1
KRESOXIM-METHYL	Aug 1999	a	1
KUNZEA OIL	Feb 2000	a	7.1
LAURYL ALCOHOL 91-DODECANOL)	Nov 1974	a	7.1
LAVANDIN OIL	Feb 2000	a	7.1
LAVENDER OIL	Feb 2000	a	7.1
LEAD, METALLIC	-	a	7.1
LEMONGRASS OIL	Feb 2000	a	7.1
LEPIDOPTEROUS SEX PHEROMONES	Nov 1990	a	1
LIMONENE (DIPENTENE)	June 2002	a	7.1
LINSEED FATTY ACIDS	Aug 1990	a	2.1
LINURON	Feb 1990	a	1
LIQUORICE, DEGLYCYRRHISINISED	May 1999	a	7.1
MALEIC HYDRAZIDE	Nov 1992	a	1
MANGANESE DIOXIDE	May 1999	b	1

MESOLSULFURON-METHYL	Feb 2002	a	1.1
METARHIZIUM ANISOPLIAE	Feb 2000	b	4.2
METHOPRENE	Aug 1987	a	1
METHOXYFENOZIDE	Nov 2000	a	1
METHYL ACETATE	-	a	7.7
METHYL BENZOQUATE	Nov 1974	d	2.3
METHYL p-HYDROXYBENZOATE	Nov 1974	a	7.9
METSULFURONMETHYL	Nov 1985	a	1.1
NAPROPAMIDE	Aug 1987	a	1
NAPHTHYL ACETAMIDE	Nov 1974	a	1.6
n-BUTYL BUTYRATE	-	a	7.1
n-BUTYL LACTATE	-	a	7.1
NEROLI OIL	Feb 2000	a	7.1
NICABAZIN	Jun 1969	d	2.3
NISIN	Jul 1987	d	7.1
NORFLURAZON	Nov 1983	a	1.1
NOVALURON	Nov 2000	a	1
OCTYL ALCOHOLS	Nov 1974	a	7.1
ORANGE OIL, SWEET	Aug 2000	a	7.1
OXABETRINIL	Feb 1987	a	1
OXYFLUORFEN	May 2001	a	1
PALMAROSA OIL	Feb 2000	a	7.1
PATCHOULI OIL	Feb 2000	a	7.1
PENCYCURON	Aug 1994	a	1
PEPPERMINT OIL	Feb 2000	a	7.1
PHENMEDIPHAM	May 1989	a	1.1
PHYTASE	Feb 1996	a	2.4
PICLORAM	Aug 1987	a	1
PICOLINAFEN	May 2000	a	1
PINUS SYLVESTRIS (PINE NEEDLE) OIL	Feb 2000	a	7.1
PIPERONYL BUTOXIDE	Aug 1991	a	7.5
POLOXALENE	Nov 1974	a	7.1
POLYHEDROSIS VIRUS OF HELICO ZEA OCCLUSION BODIES	Nov 1996	a	1
POLY (GNRF) OVALBUMIN	Feb 1990	a	2
PORCINE SOMATOTROPHIN	Nov 1991	c	2
PROCYMIDONE	Feb 1991	a	1.3
PROPYLENE GLYCOL	Nov 1974	a	7.1
2-PROPYLENE GLYCOL 1-MONOMETHYL ETHER	Nov 1987	a	4
POLY DIALLYL DIMETHYL AMMONIUM CHLORIDE (PolyDADMAC)	Nov 1997	a	4.1
POLYSORBATE 20	May 2001	a	1

PROPAMIDINE	Nov 1992	d	6.10
PROPYL ACETATES	-	a	7.1
PSEUDOMONAS FLUORESCENS	May 1985	a	1.8
PYRIMETHANIL	Feb 1996	a	1
PYRIPROXYFEN	Aug 1994	a	1
QUASSIA	Nov 1974	d	6, 2.1
QUINOXYFEN	Nov 2001	a	1.3
ROSEMARY OIL	Feb 2000	a	7.1
SAGE OIL (Spanish)	Feb 2000	a	7.1
SANDALWOOD OIL	Feb 2000	a	7.1
SEAWEED & UNFRACTIONED SEAWEED EXTRACTS	Feb 1985	d	1.5
SIMAZINE	Nov 1987	a	1.1
SOMATOTROPIN, EQUINE	Feb 1997	b	2
SUCRALFATE	Aug 1982	a	6.8
SULESOMAB	Jun 2002	b	6.1
SULFOSULFURON	Feb 1998	a	1
SULPHATED POLYSACCHARIDES	-	a	7.1
TANNIC ACID	Dec 1965	a	7.1
TANNIC ACID/BENZYL ALCOHOL PRODUCT	Nov 1993	a	7.1
TERBACIL	Aug 1987	a	1
THAUMATIN	Nov 1990	a	3.2
THIDIAZURON	Nov 1989	a	1
TRIASULFURON	Feb 1988	a	1
TRICHODERMA HARZIANUM	May 1996	a	1
(Z)-9-TRICOSENE	Aug 1991	a	1
TRIETHYLENE GLYCOL	Nov 1974	a	7.1
TRIFLOXYSULFURON	Feb 2002	a	1.1
TRIFLURALIN	Aug 1990	a	1
TRIFORINE	Aug 1987	a	1
UREA	Nov 1974	a	7.1
<sup>13</sup> C-UREA	May 2001	a	6.1
VETIVER OIL	Feb 2000	a	7.1
VINYL ETHER	Nov 1987	b	6
VITAMIN K	Jul 1963	a	6.9, 2.8
XANTHOPHYLL ( , -CAROTENE-3,3'-DIOL; LUTEIN; VEGETABLE LUTEIN; VEGETABLE LUTEOL; BO-XAN)	Nov 1974	a	7.1
YLANG YLANG OIL	Feb 2000	a	7.1
ZINC NAPHTHENATE	-	a	1.3