

Public Submissions on the Proposed Amendments to the Poisons Standard

Notice under subsections 42ZCZL of the Therapeutic Goods Regulations 1990 (the Regulations)

A delegate of the Secretary to the Department of Health publishes herein all valid public submissions made in response to the invitation for public submission on interim decisions on the proposed amendments to the Poisons Standard (commonly referred to as the *Standard for the Uniform Scheduling of Medicines and Poisons* - SUSMP). These submissions were considered by the Advisory Committee on Chemicals Scheduling (ACCS) #9, the Advisory Committee on Medicines Scheduling (ACMS) #10 and the joint committee of ACCS-ACMS #7 (November 2013 meetings).

In accordance with the requirements of subsection 42ZCZL of the Regulations these submissions have had confidential information removed.

Material claimed to be commercial-in-confidence was considered against the guidelines for the use and release of confidential information set out in Chapter 6 of the Scheduling Policy Framework for Medicines and Chemicals (SPF), issued by the National Coordinating Committee on Therapeutic Goods. The SPF is accessible at www.tga.gov.au/industry/scheduling-spf.htm.

Discrete submissions have been grouped by substance. Four submitters provided submissions that related to multiple substances and these has been separately grouped.

List of Submissions

Substance	Total number of public submissions
1,3-Cyclohexadiene-1-carboxylic acid, 4,6,6-trimethyl-, ethyl ester	2 submissions under 'submissions on multiple substances'
2-Amino-5-ethylphenol	2 submissions under 'submissions on multiple substances'
2-Butanone, oxime (also known as methyl ethyl ketone oxime)	1 submissions under 'submissions on multiple substances'
2-Furancarboxaldehyde (furfural)	2 submissions under 'submissions on multiple substances'
2-Nitrotoluene	1 submissions under 'submissions on multiple substances'
3,7-Dimethy-2,6-octadienal isomers (CITRAL, geranial and neral)	4 submissions under 'submissions on multiple substances'
Benzidine-based dyes	2 submissions under 'submissions on multiple substances'

Substance	Total number of public submissions
Aminopyralid	1 submissions under ‘submissions on multiple substances’
C11-C15-secondary, ethoxylated, oxirane and oxirane, ethyl (oxirane)	2 submissions under ‘submissions on multiple substances’
Diethylene glycol monobutyl ether	2 submissions under ‘submissions on multiple substances’
Ethylene glycol monomethyl ether	1 submissions under ‘submissions on multiple substances’
Mercaptoacetic acid	2 submissions under ‘submissions on multiple substances’
Methanol	2 submissions under ‘submissions on multiple substances’
Pentanoic acid, 3-methyl-2-oxo-, ethyl ester	2 submissions under ‘submissions on multiple substances’
Phosphonium, tributyl-octyl-, chloride (1:1)	1 submissions under ‘submissions on multiple substances’
Pyridine, 2-chloro-6-(trichloromethyl)	1 submissions under ‘submissions on multiple substances’
Sulfites - i.e. Salts of sulfurous and disulfurous acids	2 submissions under ‘submissions on multiple substances’
Tetrahydrofuran	2 submissions under ‘submissions on multiple substances’
Triethanolamine	3 submissions under ‘submissions on multiple substances’
Trisiloxane, 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]-	2 submissions under ‘submissions on multiple substances’
Zinc lactate	3 submissions (2 under ‘submissions on multiple substances’)
Cosmetic use Personal care use	3 submissions under ‘submissions on multiple substances’
Ethanol, 2-(dimethylamino)-	2 submissions under ‘submissions on multiple substances’
Salicylic acid	3 submissions under ‘submissions on multiple substances’

Substance	Total number of public submissions
Macrogol	1 submission
Esomeprazole	2 submissions

Submission on Multiple Substances

One submission was on 1,3-cyclohexadiene-1-carboxylic acid, 4,6,6-trimethyl-, ethyl ester, 2-amino-5-ethylphenol, 2-butanone, oxime, 2-furancarboxaldehyde (furfural), 2-nitrotoluene, 3,7-dimethy-2,6-octadienal isomers (CITRAL, geranial and neral), aminopyralid, benzidine-based dyes, C11-C15-secondary, ethoxylated, oxirane and oxirane, ethyl (oxirane), diethylene glycol monobutyl ether, ethylene glycol monomethyl ether, mercaptoacetic acid, methanol, pentanoic acid, 3-methyl-2-oxo-, ethyl ester, phosphonium, tributylloctyl-, chloride (1:1), pyridine, 2-chloro-6-(trichloromethyl), sulfites - i.e. salts of sulfurous and disulfurous acids disuldisulfurous acids, tetrahydrofuran, triethanolamine, trisiloxane, 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]- and zinc lactate.

One submission was on 1,3-cyclohexadiene-1-carboxylic acid, 4,6,6-trimethyl-, ethyl ester, 2-amino-5-ethylphenol, 2-furancarboxaldehyde (furfural), 3,7-dimethy-2,6-octadienal isomers (CITRAL, geranial and neral), benzidine-based dyes, C11-C15-secondary, ethoxylated, oxirane and oxirane, ethyl (oxirane), diethylene glycol monobutyl ether, ethylene glycol monomethyl ether, mercaptoacetic acid, methanol, pentanoic acid, sulfites - i.e. salts of sulfurous and disulfurous acids, tetrahydrofuran, triethanolamine 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]-and zinc lactate, cosmetic use personal care use, ethanol and salicylic acid.

Two submissions on cosmetic use personal care use, ethanol, 2-(dimethylamino)- and salicylic acid.

One submission on cosmetic use personal care use, ethanol and salicylic acid.

One submission on zinc lactate.

Two submission on esomeprazole.

One submission on macrogol.

One submission on 3,7-dimethy-2,6-octadienal isomers (CITRAL, geranial and neral).

The Secretary
Scheduling Secretariat
GPO Box 9848
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Email: SMP@health.gov.au

Dear Sir/Madam

**Public Comment Submission to the Delegate's Interim Decision
under subsection 42ZCZP of the Therapeutic Goods Regulations 1990**

We refer to the notice published on 27 February 2014 of the Delegate's interim decision under subsection 42ZCZP of the *Therapeutic Goods Regulations 1990*, inviting public submissions, with respect to certain substances, addressing a matter raised in section 52E of the *Therapeutic Goods Act 1989*.

Accord provided comments on the following ACCS agenda items for the November 2013 meeting:

- **1,3-cyclohexadiene-1-carboxylic acid, 4,6,6-trimethyl-, ethyl esters;**
- **2-amino-5-ethylphenol;**
- **2-furancarboxaldehyde (furfural);**
- **3,7-dimethyl-2,6-octadienal isomers (citral, geranial and neral);**
- **Benzidine-based dyes;**
- **C11-C15-secondary, ethoxylated, oxirane and oxirane, ethyl (oxirane);**
- **Diethylene glycol monobutyl ether;**
- **Ethylene glycol monomethyl ether;**
- **Mercaptoacetic acid;**
- **Methanol;**
- **Pentanoic acid, 3-methyl-2-oxo-, ethyl ester;**
- **Sulfites – i.e. salts of sulfurous and disulfurous acids;**
- **Tetrahydrofuran;**
- **Triethanolamine;**
- **Trisiloxane, 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]-; and**
- **Zinc lactate.**

Accord also provided comments for consideration for the following agenda items at the joint meeting of the ACMS and ACCS held in November 2013:

- **the cosmetic use and personal care use definition;**
- **ethanol, 2-(dimethylamino)-; and**
- **salicylic acid.**

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Products for healthy living and a quality lifestyle

Accord has reviewed the Interim Decisions & Reasons for Decisions by the Delegate of the Secretary to the Department of Health and Ageing.

Accord provides further comments on the Interim Decisions on these agenda items. Please see attached submission for details.

We look forward to further advice from the Delegate. Should the Committees require any additional information from Accord at this stage please do not hesitate to contact me on [REDACTED]

Yours sincerely

[Approved for electronic submission]

[REDACTED]
Manager, Regulatory and Technical

13 March 2014

ACCS meeting: November 2013

(1.4) Sulfites - i.e. salts of sulfurous and disulfurous acids

Accord supports the Delegate's decision to maintain the current scheduling for sodium and potassium metabisulfite. Accord also supports the Delegate's decision not to schedule any other sulfites.

ACCS meeting: November 2013

(1.5) Benzidine-based dyes

Accord supports the approach of scheduling the specific chemicals assessed by NICNAS through the IMAP process.

We note that while benzidine-based dyes were considered, the scheduling proposal does not include benzidine and its salts. We understand that this is a deliberate decision acknowledging that in the States and Territories that have adopted the Model Work Health and Safety (WHS) legislation, the supply of benzidine and its salts (in concentrations greater than 0.1%) are banned except for genuine research. Those conducting research must also apply for authorisation to use, handle and store benzidine and its salts.

While Accord is supportive of the proposed scheduling approach for benzidine-based dyes, we note that in the annex of the EU Cosmetics Regulation, there are restrictions on the use of benzidine-based azo dyes. We believe an alignment of terminology with the EU may be helpful for industry seeking information.

Accord recommends the amendment in the wording of the Schedule 7 entry to the following:

BENZIDINE-BASED AZO DYES being:

[list chemicals as per the Delegate's Interim Decisions & Reasons].

ACCS meeting: November 2013

(1.6) 2-amino-5-ethylphenol

Accord respectfully requests reconsideration of the decision to include hair dye preparations containing greater than 1 per cent 2-amino-5-ethylphenol (measured as hydrochloride salt) as the decision significantly reduces the concentration of 2-amino-5-ethylphenol in hair preparations in Australia when compared to products available in the EU.

While Accord notes that the EU also restricts the use of 2-amino-5-ethylphenol in hair dye preparations, as highlighted in our pre-meeting submission, the concentration allowed in hair dye preparations in the EU is higher as the EU measures the “on-head” concentration rather than the concentration of the preparation.

It is our understanding that in general, hair dyes are supplied in two parts to be mixed prior to use. The preparation containing 2-amino-5-ethylphenol will be mixed with hydrogen peroxide, generally in a 1:1 ratio i.e. to reach the on-head concentration of 1% 2-amino-5-ethylphenol, the hair dye preparation contains 2% 2-amino-ethylphenol. We note that this is a generalisation and mixtures can be in ratios other than 1:1.

We believe that the scheduling wording to reflect the nature of use of these hair dye preparations to ensure “on-head” concentration of 2-amino-5-ethylphenol of 1% is excluded from scheduling (with appropriate labelling statements).

Accord proposes the following wording:

Schedule 6 – New Entry

2 AMINO 5 ETHYLPHENOL in hair dye preparations except in preparations giving rise to 1 per cent or less on-head concentration of 2-amino-5-ethylphenol when the immediate container and primary pack are labelled with the following statements:

KEEP OUT OF REACH OF CHILDREN; and

WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes and eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5 mm in height.

[also include Appendix E and Appendix F statements as per the Delegate’s Interim Decisions and Reasons.]

Accord also notes the implementation date of 1 February 2015. While this implementation date may be acceptable if the scheduling decision is amended as per our proposal, we note that additional time may be required if we are not aligned with the EU hair dye preparation concentration for this substance. Accord respectfully requests that the Delegate consider an extension of the implementation date to 1 June 2016 to allow full two years transition from the date of publication of the final decision.

ACCS meeting: November 2013

(1.8) Diethylene glycol monobutyl ether

Accord has no objections to the Delegate's Interim Decision to add Appendix E and F statements to the current schedule entry for diethylene glycol monobutyl ether.

However, while Accord has not received any feedback from members on the use of this substance, we note that the implementation date of 1 June 2015 may not be long enough for companies using this substance if any changes are required e.g. to labelling.

Accord respectfully requests a longer transition time, and suggests an implementation date of 1 June 2016.

ACCS meeting: November 2013

(1.9) Ethylene glycol monomethyl ether

In our pre-meeting submission, Accord sought clarification on the identity of the substance being consulted. Accord notes from the Delegate's Interim Decisions and Reasons that the intent was to consult on diethylene glycol monomethyl ether (DEGME) and not ethylene glycol monomethyl ether (EGME). We also note that the intent was to re-consult with the correct name of DEGME listed on the meeting agenda.

For the March 2014 pre-meeting submission, while diethylene glycol monoethyl ether (DEGEE) was listed on the agenda for discussion but DEGME did not appear on the agenda.

Accord provided comments on DEGEE for the March 2014 pre-meeting stating that DEGEE is used extensively in cosmetics. While specific comments on DEGME were not requested, we noted that DEGME is banned in cosmetics in the EU, as also noted in our pre-meeting submission for the November 2013 meeting.

ACCS meeting: November 2013

(1.10) Tetrahydrofuran

Accord supports the Delegate's Interim Decision not to schedule tetrahydrofuran.

ACCS meeting: November 2013

(1.12) 2-furancarboxaldehyde (furfural)

Accord tentatively supports the Delegate's Interim Decision to schedule furfural. We note that the proposed exemption from scheduling should exempt current Australian uses of furfural as a fragrance as it aligns with the International Fragrance Association (IFRA) Standard for furfural.

Accord has one minor administrative suggestion for the referencing of schedule entries. The Delegate's Interim Decisions and Reasons proposes addition of cross referencing in the index for 2-furancarboxaldehyde and furfural. Accord questions the need to cross reference from furfural to 2-furancarboxaldehyde as there is no intention to add a separate schedule entry for 2-furancarboxaldehyde.

ACCS meeting: November 2013

(1.13) Methanol

Accord supports the Delegate's Interim Decision to maintain the current scheduling of methanol.

ACCS meeting: November 2013

(1.14) Pentanoic acid, 3-methyl-2-oxo-, ethyl ester

Accord supports the Delegate's Interim Decision not to schedule pentanoic acid, 3-methyl-2-oxo-, ethyl ester.

ACCS meeting: November 2013

(1.15) Mercaptoacetic acid (thioglycolic acid)

Accord notes the Delegate's Interim Decision and supports the restriction of scheduling of thioglycolic acid to cosmetic use only.

Accord seeks clarification on the intent of the proposed schedule entry.

We note that the wording of the schedule entry in the Delegate's Interim Decision and Reasons does not exclude salts or derivatives. Thioglycolic acid is a simple molecule and inclusion of derivatives in the schedule entry can have unintended consequences of capturing a large number of substances that do not reflect the hazard and risk profile of thioglycolic acid.

Further, while we understand the need to capture salts of thioglycolic acid in the schedule entry based on the toxicity profile of the chemical, again due to the simple nature of the molecular structure, the concentration can vary significantly depending on the counter ion. For example, the molecular weight of potassium thioglycolate is 130 while the molecular weight of thioglycolic acid is 92 i.e. approximately 7% potassium thioglycolate is equivalent to approximately 5% thioglycolic acid when the potassium counter ion is ignored. We do not believe that there is any evidence to suggest that the counter ion plays a part in the toxicity consideration of thioglycolic acid and its salts.

Accord therefore suggests the following amendments to the proposed schedule entry:

Schedule 6 – New Entry

MERCAPTOACETIC ACID *excluding its derivatives* in cosmetic preparations **except:**

- a) when included in schedule 5; or
- b) in preparations containing mercaptoacetic acid and its salts in concentrations of 5 per cent or less (as mercaptoacetic acid).

Schedule 5 – New Entry

MERCAPTOACETIC ACID *excluding its derivatives* in cosmetic preparations containing mercaptoacetic acid and its salts in concentrations of 20 per cent or less (as mercaptoacetic acid), except in preparations containing mercaptoacetic acid and its salts in concentrations of 5 per cent or less (as mercaptoacetic acid).

[Appendix E and F statements as per the Delegate's Interim Decisions.]

Accord also notes that the implementation date of 1 June 2014 does not provide industry with sufficient time to either reformulate or even relabel products currently marketed in Australia. One of our members has noted that if the Delegate's Interim Decision remains unchanged, then several of their products will require re-labelling as a minimum.

Accord requests an extension of the implementation time. A minimum of two years from the final scheduling decision on thioglycolic acid (the implementation date of 1 June 2016) is requested.

ACCS meeting: November 2013

(1.16) 1,3-cyclohexadiene-1-carboxylic acid, 4,6,6-trimethyl-, ethyl esters

Accord supports the Delegate's Interim Decision not to schedule 1,3-cyclohexadiene-1-carboxylic acid, 4,6,6-trimethyl-, ethyl esters.

ACCS meeting: November 2013

(1.17) 3,7-dimethyl-2,6-octadienal isomers (citral, geranial and neral)

Accord notes the Delegate's Interim Decision to seek further information on 3,7-dimethyl-2,6-octadienal isomers. Accord has been requested by the Delegate to provide further information on these fragrances and have provided a summary on the use of the fragrances as well as a summary of adverse event analysis from member companies.

We look forward to further scheduling proposals on these fragrance ingredients.

ACCS meeting: November 2013

(1.18) Zinc lactate

Accord respectfully requests reconsideration of scheduling of zinc lactate.

While Accord is supportive of limiting the scheduling consideration to zinc lactate used in cosmetics, the concentration of zinc allowed in toothpastes is lower than in orally ingested complementary medicines which do not require RASML statements. We note that the scheduling exemption for toothpastes for zinc lactate only applies when a statement “not recommended for children under 12 years of age”. We believe this is an anomaly.

As stated in our pre-meeting submission, currently medicines containing zinc compounds for human internal use in preparations with a recommended daily dose of 25mg or less zinc are excluded from scheduling requirements i.e. there are no scheduling requirements and no labelling requirements. Between 25mg and 50mg, the preparations are exempted when compliant with the requirements of the *Required Advisory Statements for Medicine Labels*.

2.5% zinc lactate in toothpaste equates to approximately 20mg of zinc in the amount of toothpaste used daily by adults. The calculation of this is set out below.

Molecular weight of zinc lactate: 241.4

Atomic weight of zinc: 65.4

Estimated daily exposure to toothpastes for adults: 2.75g¹

% of zinc in zinc lactate = $65.4/241.4 \times 100 = 27\%$

% of zinc in a product containing 2.5% of zinc lactate = $27\% \times 2.5\% = 0.68\%$

Estimated daily exposure to zinc from toothpastes for adults = $2.75g \times 0.68\% = 0.0187g = 18.7mg$

That is, even if the entire quantity of toothpaste containing 2.5% zinc lactate is ingested, the quantity of zinc ingested is below the complementary medicines containing zinc that require no label warnings. In fact, even if the zinc lactate level in toothpaste was increased to 3%, and we assumed ingestion of the full amount of toothpaste, the zinc consumption level falls below 25mg.

Further it is extremely conservative to assume consumption of the full quantity of toothpaste. In most cases, toothpaste is not consumed but expelled after brushing. If we consider dilution factors and rinsing, this equates to approximately 1mg zinc consumption through normal practice of brushing teeth. This calculation is below:

Estimated amount of toothpaste “retained” after dilution and rinsing: 5%¹

Estimated amount of zinc retained after dilution and rinsing = $18.7mg \times 5\% = 0.935mg$

Accord has seen no evidence to suggest that the zinc consumed through brushing teeth poses a higher risk than zinc consumed from taking complementary medicines containing zinc.

Noting that no statements are required on complementary medicines containing zinc at levels up to 25mg, and taking the most conservative approach of assuming that 100% of toothpaste used while brushing teeth is consumed, Accord respectfully requests exemption from scheduling

¹ Based on the *Notes of Guidance for Testing of Cosmetic Ingredients and Their Safety Evaluation 8th revision* published by the Scientific Committee of Consumer Safety (SCCS) in 2012 (http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_006.pdf)

toothpastes containing up to 3% zinc lactate. This should address any concerns with children not expelling toothpaste after brushing, also noting that the amount of toothpaste used by children are also significantly lower (smaller brush heads, smaller mouths, etc.).

Further, noting that ingestion of toothpaste is unlikely in adults (the toothpaste must contain more than 60% zinc lactate to reach 25mg limit of zinc intake when dilution factors are considered) and also noting that higher concentrations of zinc is allowed in complementary medicines containing zinc, Accord respectfully requests exemption from scheduling all toothpastes containing zinc lactate when labelled with “not recommended for children under 12 years of age”.

Accord proposes the following schedule entry:

Schedule 6 – New Entry

ZINC LACTATE in toothpastes **except:**

- (a) in toothpaste preparations containing 3 per cent or less of zinc lactate; or
- (b) toothpastes labelled ‘not recommended for children under 12 years of age’

ACCS meeting: November 2013

(1.19) Triethanolamine

Accord Supports the Delegate's Interim Decision to maintain the current entry for triethanolamine and to consult with the ACMS for the specific use of triethanolamine in intradermal tattoo removal.

As noted in our pre-meeting submission, intradermal applications are therapeutic, not cosmetic. Therefore the ACMS is the most relevant advisory body to consider the issues.

ACCS meeting: November 2013

(1.20) Trisiloxane, 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]-

Accord strongly support the Delegate's Interim Decision not to schedule trisiloxane, 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]-.

We raised concerns with the method of inferring reproductive toxicity potential for this chemical based on 'read-across' from studies with cyclic siloxanes, assuming analogous nature based on similar molecular weights. We are pleased to note that both the ACCS and the Delegate share our concerns.

ACCS meeting: November 2013

(1.21) C11-C15-secondary, ethoxylated, oxirane and oxirane, ethyl (oxirane)

In our pre-meeting submission, Accord raised concerns with the difficulty identifying the chemical with the chemical descriptor used in the notice seeking comments.

Based on the Delegate's Interim Decisions, we understand that the proposal related to a polymer.

Accord supports the Delegate's Interim Decision not to schedule this polymer.

ACCS/ACMS joint-meeting: November 2013

(2.1) Interpretation

Accord supports the Delegate's Interim Decision to include a definition of "cosmetic" in Part 1 of the Poisons Standard. Accord also supports the wording used to define "cosmetic".

ACCS/ACMS joint-meeting: November 2013

(2.2) Ethanol, 2-(dimethylamino)-

Accord has no objections to the Delegate's Interim Decision.

ACCS/ACMS Joint-meeting: November 2013

(2.3) Salicylic acid

Accord support the Delegate's Interim Decision to maintain current scheduling for salicylic acid.



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12 March 2014

The Secretary
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Dear Sir or Madam,

**Re: Invitation for public comment – ACCS and joint ACCS/ACMS Meetings,
Delegate's Interim Decisions & Reasons for Decisions from November 2013 meeting of the ACCS**

We refer to the notice inviting public comment under Regulation 42ZXZS and 42ZCZX of the Therapeutic Goods Regulations 1990 and would like to provide comment on the Delegate's Interim Decisions arising from the November 2013 meeting of the ACCS. The comments submitted below address matters raised in s.52E of the *Therapeutic Goods Act 1989*.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI has considered the Delegate's Interim Decisions and notes that the following proposals have no impact on therapeutic goods and are used mainly in industrial, agricultural or other non-therapeutic settings. We therefore have no further comments in relation to the decisions pertaining to the following substances:

- 1.1 Aminopyralid
- 1.2 Phosphonium, Tributyl-octyl-, chloride (1:)
- 1.3 Pyridine, 2-chloro-6-(trichloromethyl)
- 1.5 Benzidine based dyes
- 1.6 2-amino-5-ethylphenol
- 1.7 2-Butanone, oxime (methyl ethyl ketone oxime)
- 1.8 Diethylene glycol monobutyl ether
- 1.9 Diethylene glycol monomethyl ether
- 1.10 Tetrahydrofuran
- 1.11 2-nitrotoluene
- 1.14 Pentanoic acid, 3-methyl-2-oxo-, ethyl ester
- 1.15 Mercaptoacetic acid
- 1.16 1,3-cyclohexadiene-1-carboxylic acid, 4,6,6-trimethyl-, ethyl ester
- 1.19 Triethanolamine
- 1.20 Trisiloxane, 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]-
- 1.21 C11-C15-secondary, ethoxylated, oxirane and oxirane, ethyl (oxirane)



Some of the Delegate's interim decisions concerned substances that had previously been identified as having potential uses in some therapeutic goods, and ASMI wishes to provide some specific comments in relation to these:

1.4 Sulfites

ASMI supports the Delegate's interim decision that there is no need to amend the current Schedule 5 entry for sodium and potassium metabisulfites.

1.12 Furfural

ASMI supports the Delegate's proposed Schedule 6 entry for Furfural except in preparations containing 0.1% or less of Furfural. The proposed cut-off concentration should accommodate possible use in fragrances used in consumer products and it is unlikely to have any impact therapeutic goods.

1.13 Methanol

ASMI supports the Delegate's interim decision that the current Schedule 5 and 6 entries for methanol are appropriate and no changes are needed.

1.17 3,7-Dimethyl-2,6-octafienal isomers (cital, geranial and neral)

ASMI agrees with the Delegate's interim decision to obtain more information on the uses of these substances and their concentrations and refer again.

1.18 Zinc lactate

ASMI has no further comment on the Delegate's interim decision for zinc lactate.

Thank you for the opportunity to comment on the above interim scheduling decisions. Please contact me if you have any further queries.

Yours sincerely,

A black rectangular box redacting the signature of the QUM Manager.

QUM Manager



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12 March 2014

The Secretary
Scheduling Secretariat
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Dear Sir or Madam,

**Re: Invitation for public comment – ACCS and joint ACCS/ACMS Meetings,
Delegate's Interim Decisions & Reasons for Decisions from November 2013 meeting of the ACMS**

We refer to the notice inviting public comment under Regulation 42ZXZS and 42ZCZX of the Therapeutic Goods Regulations 1990 and would like to provide comment on the Delegate's Interim Decisions arising from the November 2013 meeting of the ACMS. The comments submitted below address matters raised in s.52E of the *Therapeutic Goods Act 1989*.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI has considered the Delegate's Interim Decisions and supports the Delegate's interim decision to amend the SUSMP by including a new Schedule 3 entry for esomeprazole in oral preparations containing 20mg or less per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing no more than 14 days' supply.

Thank you for the opportunity to comment on the above proposal. Please contact me should you have any further queries.

Yours sincerely,



QUM Manager



BETTER HEALTH THROUGH RESPONSIBLE SELF CARE





12 March 2014

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Dear Sir or Madam,

**Re: Invitation for public comment – ACCS and joint ACCS/ACMS Meetings,
Delegate's Interim Decisions & Reasons for Decisions from November 2013 meeting of the
joint ACCS/ACMS**

We refer to the notice inviting public comment under Regulation 42ZXZS and 42ZCZX of the Therapeutic Goods Regulations 1990 and would like to provide comment on the Delegate's Interim Decisions arising from the November 2013 meeting of the joint ACCS / ACMS. The comments submitted below address matters raised in s.52E of the *Therapeutic Goods Act 1989*.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI has considered the Delegate's interim decisions and is pleased to provide the following comments:

2.1 Interpretation

ASMI supports the Delegate's interim decision to include a definition for "cosmetic" in the SUSMP, that is consistent with that currently used in the Industrial Chemicals (Notification and Assessment Act) 1989 and the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991.

The adoption of the definition into Part 1 of the SUSMP may be done in two ways:

- (1) By cross-referencing to the relevant Act, as has been done in the Part 1, Interpretation section of the SUSMP for some other entries, or
- (2) Transposing the relevant definition into Part 1, Interpretation section of the SUSMP.

The definition in the Industrial Chemicals (Notification and Assessment Act) 1989 is as follows:



cosmetic product 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; or

(b) a substance or preparation prescribed by regulations made for the purposes of this paragraph;

But does not include:

- (c) a therapeutic good within the meaning of the Therapeutic Goods Act 1989; or
- (d) a substance or preparation prescribed by regulations made for the purposes of this paragraph.

The Delegate's interim decision document suggests that the definition to be used is an excerpt (as highlighted above, in blue print) from the definition in Industrial Chemicals (Notification and Assessment Act) 1989, and that it excludes parts (b), (c) and (d) of that definition.

ASMI believes that section (c) of the definition, which states that the definition of a cosmetic does not include a therapeutic good, is an important provision that should be retained in the definition to be used in the SUSMP.

For this reason, ASMI believes that the preferred approach to the adoption of a definition for a cosmetic in the SUSMP is by cross referencing the Part 1 definition in the SUSMP to the Industrial Chemicals (Notification and Assessment Act) 1989, i.e by use of approach (1) described above. This approach is already used for other definitions in the SUSMP, e.g. the definitions for a therapeutic good, a veterinary chemical product, and the Required Advisory Statements for Medicine Labels. In all of these examples, the definition is cross-referenced to the relevant reference Act. An advantage of this approach is that any amendments or updates to the reference Act or definition will not require a corresponding amendment to the SUSMP definition.

If for some reason the Delegate does not wish to adopt the cross referencing approach to the inclusion of the definition in the SUSMP, then ASMI suggests that a statement that includes provision (b) of the definition, i.e. that the definition of a cosmetic excludes therapeutic goods, is important for clarity.

2.2 Ethanol, 2-(dimethylamino)- or deanol

ASMI supports the Delegate's interim decision to edit the current Schedule 4 entry for deanol so that it regulates only products for therapeutic use.

2.3 Salicylic acid

ASMI supports the Delegate's interim decision that the current Schedule entries for salicylic acid are appropriate and no changes are needed.

Thank you for the opportunity to comment on the above interim scheduling decisions.
Please contact me if you have any further queries.

Yours sincerely,

A solid black rectangular box used to redact the signature of the QUM Manager.

QUM Manager

Wednesday, 12 March 2014

The Secretary
Medicines & Poisons Scheduling
Office of Chemical Safety (MDP 88)
GPO Box 9848
Canberra ACT 2601
Australia

Dear Sir/Madam

Re: Interim decision to amend Part 4 of the Poisons Standard for Esomeprazole

████████████████████ agrees with the Secretariat and the ACMS to amend the SUSMP by including a new Schedule 3 entry for esomeprazole:

- **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 –Amendment**

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

██████████ agrees with the evaluator, ACMS and the delegate on their comments regarding Esomeprazole down scheduling:

Efficacy

The first-line use of PPIs in general, and esomeprazole in particular, for typical symptoms of gastro-oesophageal reflux disease (GORD) is recognised and supported by good clinical trial evidence and meta-analyses (Cochrane reviews). This is consistent with the current Therapeutic Guidelines that recommends a PPI as first line treatment to provide rapid symptom relief for GORD.

Other members of the class of proton pump inhibitors (PPIs), for example, pantoprazole, rabeprazole, lansoprazole and omeprazole are already included in Schedule 3. PCH agrees that the efficacy of esomeprazole 20mg has been established in clinical trials.

Specifically in relation to esomeprazole, its efficacy for the relief of symptoms of GORD in a dose of 20mg has been very well established. Treatment with esomeprazole has also been shown to improve health-related quality of life.

ACMS also stated that its recommendation for inclusion of a new Schedule 3 entry for esomeprazole is based on the consistency of scheduling with the other PPIs for short-term use for symptomatic relief on the advice of a pharmacist.

Safety

The majority of adverse reactions are mild and transient in nature, and include headache and gastrointestinal symptoms such as pain, diarrhoea, flatulence, nausea/vomiting and constipation. The evaluator stated that the safety of esomeprazole has been well established and is supported by post-marketing experience. *Since omeprazole, which has a very similar benefit-risk profile to esomeprazole, has proved to be safe when used as an S3 medicine, it is highly likely that the same will apply to esomeprazole in a similar dose range. The evidence provided in the submission strongly supports the safety of esomeprazole in a 20mg dose given for up to 14 days.*

ACMS also stated that safety profile is consistent with other PPIs and appropriate for a Schedule 3 entry.

The delegate agreed that esomeprazole was the only Proton Pump Inhibitor (PPI) not listed in Schedule 3 and that the safety profile of esomeprazole is comparable to those PPIs listed in Schedule 3. In addition, the delegate stated that the well-established safety profile of the substance was supported by good clinical trial evidence and is appropriate for Schedule 3 entry.

Overdosage

The evaluator has stated that information on overdose with esomeprazole indicates that the drug causes only minor symptoms such as vomiting, nausea, abdominal pain and drowsiness. Given the wide therapeutic index of esomeprazole, the risk associated with overdose of the OTC product is very low.

Risk Benefit

The evaluator states that [REDACTED] has provided adequate information to support its contention that the benefit-risk balance for OTC esomeprazole is positive. It is generally accepted that there is no evidence of additional risk associated with over-the-counter use of PPIs compared with histamine-2-receptor antagonists, and they are accepted to be more effective. Similar arguments have been made in relation to other PPIs that have been down-scheduled to Schedule 3, and there is no reason to expect that esomeprazole would have any additional issues.

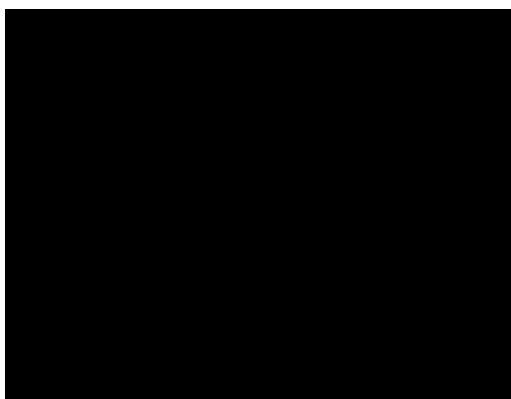
Labelling

The evaluator commented that - *The proposed labelling refers to the trade name [REDACTED] and will be readily distinguishable from the current prescription only product. The information on the carton is clearly laid out in sections that are easy to identify and include the key information on intended use, directions for use, warnings and cautions. The indication on the pack is expressed as "Frequent heartburn (more than twice a week) or acid reflux due to gastro-oesophageal reflux (GORD)". The warnings regarding drug interactions are adequately expressed. The information provided on the pack is comparable to that provided on the pack of the leading OTC omeprazole brand (provided in the submission), and on the packs for the other PPIs that are available OTC.*

The [REDACTED] submission included the European Medicines Agency/Committee for Medicinal Products for Human Use Summary of Opinion for [REDACTED]. As an update to that Opinion, on August 2013 the European Commission granted a Marketing Authorisation for [REDACTED], with non-prescription status in all EU member states for the short-term treatment of reflux symptoms (including heartburn and acid regurgitation) in adults for treatment of up to 14 days.

[REDACTED] agrees with the evaluator, ACMS and delegate recommendation that Esomeprazole is suitable for down-scheduling to a Schedule 3 entry.

Yours sincerely,

A large black rectangular redaction box covering the signature area.

13 March 2014

The Secretary
Medicines and Poisons Scheduling Secretariat (MDP88)
GPO Box 9848
CANBERRA ACT 2601

Email: SMP@health.gov.au

Dear Sir/Madam

**Re: Reasons for scheduling delegate's interim decision and invitation for further comment,
February 2014.**

I refer to the notice published on 27 February 2014, under subsections 42ZCZP of the Therapeutic Goods Regulations 1990, which provides the interim decisions of delegates, the reasons for those decisions and invites further submissions from interested parties.

Please find further comments relating to

1.17 3,7-dimethyl-2,6-octadienal isomers (citral, geranial and neral)

Tisserand R and Young R, in 'Essential Oil Safety' 2nd Ed 2014, note there is up to 20 essential oils or absolutes containing >1% citral.

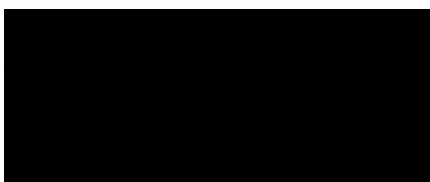
Many of the essential oils are used in aromatherapy and other complementary medicines and marketed or sold as pure oil products or in blends in quantities of between 0.5 to 12%w/w.

Of these the most notable are *Backhousia citriodora* (lemon myrtle), *Leptospermum petersonii* (Lemon scented tea tree), lemongrass, May Chang (*Litsea cubeba*), Verbena and Melissa oils with a citral content of approximately 90, 77, 75, 70, 66 and 60%, respectively.

To a lesser extent Lime, Bergamot, Lemon, Orange (Bitter & Sweet), Geranium, Ginger and Palmarosa oils with citral contents of 5% or less.

By no means is this an exhaustive list, it is merely to highlight the need for a careful and thoughtful approach to the scheduling of the isomers. Many of the aforementioned oils are included in Appendix B of the SUSMP, others are already scheduled, and some have not been considered for scheduling.

Yours faithfully,



Regulatory Affairs Manager

Email: 



The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT
2601

11 March 2014

Dear Sir/Madam,

RE: Interim decisions & reasons for decisions by delegates of the Secretary to the Department of Health.

Johnson & Johnson Pacific Pty Ltd (JJP) would like to provide comments to the Delegate's interim decisions relating to the scheduling proposals which were referred to an advisory committee in November 2013.

Salicylic Acid

JJP supports the interim decision that the scheduling of salicylic acid remains appropriate.

Triethanolamine

JJP supports the interim decision that the current listing of triethanolamine in Schedule 5 remains appropriate. JJP supports the Delegate's interim decision to refer the proposal to a joint Advisory Committee on Chemicals Scheduling (ACCS) and Advisory Committee on Medicines Scheduling (ACMS) meeting if a Schedule 4 listing is proposed for tattoo removal products containing triethanolamine. JJP reserves the right to provide further comment when further information becomes available.

3,7-dimethyl-2,6-octadienal isomers

As some of the 3,7-dimethyl-2,6-octadienal isomers may be components of essential oils, which may be found in therapeutic goods, future scheduling matters relating to the isomers should be considered by both the ACCS and ACMS to ensure the cut-off limit, route of administration, function of the ingredient and possible impact on the therapeutic goods have been considered. JJP reserves the right to provide further comment when further information becomes available.

Definition of Cosmetic

JJP supports the inclusion of the definition of "cosmetic" in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), as the definition is consistent with that used in other relevant legislation.

Yours faithfully,

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Senior Regulatory Associate

Phone: 

Fax: 

Email: 

E-mail Message

From: [REDACTED]
To: [SMP\[SMTP:SMP@health.gov.au\]](mailto:SMP[SMTP:SMP@health.gov.au])
Cc:
Sent: 27/02/2014 at 11:39 AM
Received: 27/02/2014 at 11:39 AM
Subject: RE: Scheduling proposal of Macrogols - Delegate's Interim Decision

Dear Scheduling Secretariat Team,

Thank you for the Delegate's interim decision on the scheduling of liquid Macrogols.

Norgine is currently reviewing the reasons for the decision, and may provide further comment.

Unscheduled MOVICOL Liquid is currently in the supply chain to Australia. Should the Delegate's final decision confirm the interim decision, and the change to macrogol scheduling appear in the next Poisons Standard Amendment in June 2014, what are the TGA's expectations on when Norgine would be expected to have Schedule 2 labelled stock available in the market? Norgine will have to submit an application to the TGA to vary the artwork, and then produce and ship Schedule 2 product from Europe.

I look forward to any advice you can provide.

Best regards

[REDACTED]
Regulatory and Medical Affairs Manager
Australia/New Zealand

Norgine Pty Limited
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] proposal of Macrologols - Delegate's Interim Decision
[SEC=UNCLASSIFIED]

Dear [REDACTED],

Re: Interim Decision for Macrologols

The Scheduling Delegate, after taking into consideration advice from the Advisory Committee on Medicines Scheduling (ACMS), has made an interim decision to include MACROGOLS in preparations for oral use as a liquid concentrate for laxative use in Schedule 2. The Delegate's interim decision includes an implementation date of 1 June 2014 (no more than six months after the publication of the delegate's final decision).

The public notice of the interim decisions on matters referred to the November 2013 ACMS meeting and reason(s) for those decisions will be published on later next week at www.tga.gov.au/industry/scheduling-decisions-interim.htm. You are invited to provide further comment on the Delegate's interim decision. It should be noted that all comments received during the public consultation period (including any comments you wish to provide), will be published on the TGA website. Any commercial-in-confidence and personal details will be removed prior to publication of public submissions and will need to be identified and justified by the party making the submission.

Delegate's final decision

The Delegate will then consider any public comments received on the interim decision and then may confirm, vary or set aside that decision. The public notice of the Delegate's final decision will be available at www.tga.gov.au/industry/scheduling-decisions-final.htm on 27 March 2014.

The Secretariat will write to you again with the Delegate's final decision.

Should you require further information please contact the Scheduling Secretariat via email on smp@health.gov.au or visit the Scheduling website at www.tga.gov.au/industry/scheduling.htm

Regards

The Scheduling Secretariat Team

Scheduling Secretariat | Office of Chemical Safety | Office of Health Protection | Department of Health and Ageing | (02) 6289 2659 | (02) 6289 2650 | MDP 88 GPO Box 9848 CANBERRA ACT 2601 |

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3/04/2014

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[To:](#)
Cc:
Bcc:
Subject: Fw: SUSMP Amendments [SEC=UNCLASSIFIED]
Expiry:

UNCLASSIFIED

From: [REDACTED]
To: [REDACTED]
Date: 02/03/2014 16:33
Subject: SUSMP Amendments [SEC=No Protective Marking]

Hi [REDACTED]

I have been reading with interest the Delegates' reasons for interim decisions published a few days ago.

Most of the proposed amendments are clear, but I find the new entry for zinc lactate in Schedule 6 rather confusing.

The delegate's interim decision appears to be that toothpastes containing more than 2.5% zinc lactate should come within Schedule 6, and that toothpastes containing 2.5% or less of zinc lactate should be labelled "Not recommended for children under 12 years of age". Although not stated, I wonder whether the reason for limiting this warning statement to exempt products is a presumption that the Schedule 6 labelling requirements will discourage toothpaste manufacturers from including more than 2.5% zinc lactate in their products.

I think the Schedule 6 entry would be clearer if it were to read along the following lines:

ZINC LACTATE in toothpastes except in toothpaste preparations containing 2.5 per cent or less of zinc lactate and labelled with the statement:

Not recommended for children under 12 years of age.

It might also be prudent to include an entry in Appendix F Part 1 along the lines "Not recommended for children under 12 years of age." And an entry in Part 3 for zinc lactate in toothpastes.

Your view would be appreciated.

Kind regards

[REDACTED]

UNCLASSIFIED