Public Consultation on the Proposed Amendments to the Poisons Standard

A delegate of the Secretary to the Department of Health publish herein all valid public submissions made in response to the invitation for public submission on the interim decisions regarding 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 chemicals scheduling and medicines scheduling delegates.

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, 2010), issued by the National Coordinating Committee on Therapeutic Goods. The SPF is accessible at www.tga.gov.au/industry/scheduling-spf.htm.

Two submitters provided submission that related to multiple substances.

List of Submissions

Substance	Total number of public submissions
2-hydroxypropyl methacrylate	1 submission under 'submission on multiple substances'
3-isothiazolone, 2-methyl- (methylisothiazolone)	2 submissions under 'submission on multiple substances'
Diethylene glycol monomethyl ether [Ethanol, 2(2-methoxyethoxy)]	1 submission under 'submission on multiple substances'
Linear alkylbenzene sulfonates (C10-C16)	1 submission under 'submission on multiple substances'
Nickel, soluble salts	1 submission under 'submission on multiple substances'
N-methyl-2-pyrrolidone	1 submission under 'submission on multiple substances'
Phenol, 2-amino- (O-aminophenol)	1 submission under 'submission on multiple substances'
Phenylenediamines	1 submission under 'submission on multiple substances'

Substance	Total number of public submissions
Rosin	1 submission under ‘submission on multiple substances’
Toluenediamines	1 submission under ‘submission on multiple substances’
1-propanaminium, N,N,N-trimethyl-3-(octadecyloxy)-, chloride (1:1) and 1-propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(C8-18 and C18-unsatd. acyl) derivs., inner salts	1 submission under ‘submission on multiple substances’
2-butenedioic acid (2E)-, di-C12-15-alkyl esters (INCI name Di-C12-15 Alkyl fumarate)	1 submission under ‘submission on multiple substances’
2-pentyl cyclopentanol	1 submission under ‘submission on multiple substances’
2-propyl heptanenitrile	1 submission under ‘submission on multiple substances’
2,4,7-decatrienoic acid, ethyl ester	1 submission under ‘submission on multiple substances’
3-hexanone, 2-methyl oxime	1 submission under ‘submission on multiple substances’
N-hydroxy- octanamide (INCI name caprylhydroxamic acid)	2 submissions under ‘submission on multiple substances’
Tetrahydro-4-methyl-2-phenyl 2H-pyran	1 submission under ‘submission on multiple substances’

Submission on Multiple Substances

One submission was on 2-Hydroxypropyl methacrylate, 3-Isothiazolone, 2-methyl-, Linear alkylbenzene sulfonates (C10-C16), Phenol, 2-amino, Rosin, Toluenediamine, 1-Propanaminium compounds, 2-Butenedioic acid (2E)-, di-C12-15-alkyl esters, 2-Pentyl cyclopentanol, 2-Propyl heptanenitrile, 2,4,7-decatrienoic acid, ethyl ester, 3-Hexanone, 2-methyl-, oxime, N-hydroxy octanamide, and Tetrahydro-4-methyl-2-phenyl 2H-pyran.

One submission was on 3-Isothiazolone, 2-methyl- and N-hydroxy octanamide.

The Secretary
Chemical Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: chemicals.schedulinng@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 14 November 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 July 2014 meeting:

- **1.3 – 2-Hydroxypropyl methacrylate,**
- **1.4 – 3-Isothiazolone, 2-methyl- or methylisothiazolone,**
- **1.6 – Linear alkylbenzene sulfonates (C10-C16),**
- **1.9 – Phenol, 2-amino or *o*-aminophenol,**
- **1.11 – Rosin or colophony**
- **1.12 – Toluenediamine**
- **1.13 – 1-Propanaminium compounds,**
- **1.14 – 2-Butenedioic acid (2E)-, di-C12-15-alkyl esters,**
- **1.15 – 2-Pentyl cyclopentanol,**
- **1.16 – 2-Propyl heptanenitrile,**
- **1.17 – 2,4,7-decatrienoic acid, ethyl ester,**
- **1.18 – 3-Hexanone, 2-methyl-, oxime,**
- **1.19 – N-hydroxy octanamide, and**
- **1.20 – Tetrahydro-4-methyl-2-phenyl 2H-pyran.**

We provide additional comments on these substances in this submission. Please find our comments attached.

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

Accord Australasia Limited ACN 117 659 168 ABN 83 205 141 267
Fusion C4.02, 22 – 36 Mountain Street, Ultimo NSW 2007
PO Box 290 BROADWAY NSW 2007

Tel: [redacted] **Fax:** [redacted] **Website:** www.accord.asn.au

Yours sincerely

[Approved for electronic submission]

[redacted]

28 November 2014

ACCS meeting: July 2014

(1.3) 2-Hydroxypropyl methacrylate

Accord supports the Delegate's Interim Decision to include 2-hydroxypropyl methacrylate in nail preparations in Schedule 5, except when labelled 'avoid contact with skin'. However, we would like to seek an extension of the implementation date for this decision to 1 January 2016.

As noted in the Delegate's Interim Decision, long implementation time is necessary to allow for orderly relabelling of any affected products. We note that it is already end of November 2014, approximately 7 months to the implementation date. Christmas and New Year break is included in these 7 moths. We also note that had the Interim Decisions been published on the anticipated date (18 September 2014), industry would have had additional 2 months for compliance i.e. 9 months instead of 7 months.

Given these considerations, we respectfully request that the Delegate consider giving industry additional 6 months for compliance.

ACCS meeting: July 2014

(1.4) 3-Isothiazolone, 2-methyl-, OR methylisothiazolone (MIT)

Accord supports the Delegate's Interim Decision to defer the consideration of methylisothiazolone until the Cosmetic Ingredient Review (CIR) final report has been published.

We note that the CIR final report was published on 8 October 2014. The report is available from: http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR646.pdf.

The CIR report concludes that MIT is safe for use in rinse-off cosmetic products at concentrations up to 100 ppm and safe in leave-on cosmetic products when they are formulated to be non-sensitising, which may be determined based on quantitative risk assessment.

Accord also notes that the EU reached its regulatory decision on the mixture of 5-chloro-2-methylisothiazolin-3(2H)-one and 2-methylisothiazolin-3(2H)-one (CIT:MIT mixture) on 18 September 2014, and published it in the Official Journal of the European Union on 26 September 2014:
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.282.01.0001.01.ENG.

This decision takes into account the 2009 Opinion of the Scientific Committee on Consumer Safety (SCCS) on CIT:MIT mixture.

While MIT appears to have been considered briefly in the context of CIT:MIT mixture consideration, the only amendment made to the MIT entry in Annex V of the Cosmetics Directive was to clarify that MIT should not be used in conjunction with CIT:MIT in the same product as this would change the ratio of CIT:MIT mixture. That is, in the EU, MIT continues to be allowed in cosmetic products in concentrations up to 100 ppm (0.01%). It is our belief that if an urgent action was required based on the SCCS opinion on MIT, the EU Commission would have taken this opportunity to amend the regulation of MIT. Clearly this has not occurred.

ACCS meeting: July 2014

(1.6) Linear alkylbenzene sulfonates (C10-C16)

Accord supports the Delegate's Interim Decision to await the outcomes of the industry self-regulation initiative on laundry capsules containing linear alkylbenzene sulfonates. Accord notes that this is in line with Best Practice Regulation Guidelines, which promotes consideration of non-regulatory approaches to resolve issues before considering whether regulation is required.

(1.9) Phenols, 2-amino OR *o*-aminophenol

Accord supports the Delegate's Interim Decision.

ACCS meeting: July 2014

(1.11) Rosin or colophony

Accord supports the Delegate's Interim Decision to restrict the scheduling of rosin to when it is used as a soldering flux or in flux-cored slder.

ACCS meeting: July 2014

(1.12) Toluenediamine

Accord supports the Delegate's Interim Decision but respectfully requests an extension of implementation date for Schedule 6 amendment only i.e. the new Schedule 6 inclusion for nail polish which includes wording to be included on the label to be exempt from inclusion in Schedule 6.

As noted in the Delegate's Interim Decision, long implementation time is necessary to allow for orderly relabelling of any affected products. We note that it is already end of November 2014, approximately 7 months to the implementation date. Christmas and New Year break is included in these 7 moths. We also note that had the Interim Decisions been published on the anticipated date (18 September 2014), industry would have had additional 2 months for compliance i.e. 9 months instead of 7 months.

Given these considerations, we respectfully request that the Delegate consider giving industry additional 6 months for compliance.

For the new Appendix C entry, it is our understanding that 2,4-toluenediamine is not used in Australia and the inclusion of this substance in Appendix C in February 2015 is not likely to cause a significant concern.

(1.13) 1-Propanaminium compounds

Accord notes that the two 2-propanaminium compounds were considered at the same time. While we accept that 1-propanaminium, N,N,N-trimethyl-3-(octadecyloxy)-, chloride (1:1) (OR stearoxypropyltrimonium chloride) may fit the typical description of a quaternary ammonium compound, we do not agree that this is the case for 1-propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(C8-18 and C18-unsaturated acyl) derivatives, inner salts (OR babassuamidopropyl betaine) and other amidopropyl betaines.

We note that chemically, two substances fit into different categories. While stearoxypropyltrimonium chloride is a cationic surfactant (like most quaternary ammonium compounds), babassuamidopropyl betaine, like other amidopropyl betaines, is a zwitterionic surfactant. That is, amidopropyl betaine is a neutral molecule.

While amidopropyl betaines contain a quaternary ammonium segment within the molecule and may be described by some as a quaternary ammonium compound, it also contains an organic acid segment and may just as well be described as an organic acid. In truth, neither are suitable descriptions of the compound.

Further, we understand that amidopropyl betaines are used in cosmetics as a milder alternative for sodium lauryl sulfates and sodium lauryl ether sulfates, and provides similar foaming properties as these substances.

Noting the chemical structure and use of the amidopropyl betaine, we believe that it would be more appropriate to separately schedule amidopropyl betaine in a separate schedule entry, with controls that are aligned with lauryl sulfates.

This approach would address concerns raised by some of our members that some existing products may become scheduled (S5), noting that due to the differences in chemistry of amidopropyl betaines from typical quaternary ammonium compounds, these may not have been considered quaternary ammonium compounds by some in industry.

It would also be aligning with the Human and Environmental Risk Assessment on ingredients of household cleaning products which concluded that household laundry and cleaning products containing cocamidopropyl betaines raise no safety concerns for the consumers → http://www.heraproject.com/files/45-HH-E101023F-D12F-6A30-DEB0770E9BF8E4D0.pdf.

We also once again note that the Cosmetics Ingredient Review has noted that amidopropyl betaines are safe for use in cosmetics if they are formulated to be non-sensitising (noting that sensitization potential was likely due to an impurity rather than the substance itself → http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr518.pdf.

Accord requests consideration of the following separate schedule entry for amidopropyl betaines to align with lauryl sulfate. This schedule entry allows higher concentrations of the surfactant in wash-off preparations (than quaternary ammonium compounds), while decreasing the amount allowed in leave-on preparations.

Schedule 6

AMIDOPROPYL BETAINES ***except:***

(a) in cosmetic wash-off preparations containing 30 per cent or less of amidopropyl betaine and, if containing more than 5 per cent of amidopropyl betaine, when labelled with a warning to the following effect:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER;

(b) in cosmetic leave-on preparations containing 1.5 per cent or less of amidopropyl betaine.

(c) in other preparations containing 30 per cent or less of amidopropyl betaine and, if containing more than 5 per cent of amidopropyl betaine, when labelled with warnings to the following effect:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER; and

IF SKIN OR HAIR CONTACT OCCURS, REMOVE CONTAMINATED CLOTHING AND FLUSH SKIN AND HAIR WITH RUNNING WATER.

(1.14) 2-Butenedioic acid (2E)-, di-C12-15-alkyl esters

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

(1.15) 2-Pentyl cyclopentanol

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

(1.16) 2-Propyl heptanenitrile

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

(1.17) 2,4,7-Decatrienoic acid, ethyl ester

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

(1.18) 3-hexanone, 2-methyl oxime

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

(1.19) N-hydroxy-octanamide

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

(1.20) Tetrahydro-4-methyl-2-phenyl-2H-pyran

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

[redacted]

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

20th November 2014

Dear sir/Madam

RE: Response to the Invitation to Comment on the Delegates Interim Decision from the July 2014 ACCS #11 meeting

[redacted] provides the following comments on items 1.4 and 1.19 from the ACCS #11 meeting.

1.4 3-Isothiazolone, 2-methyl OR methylisothiazolone

[redacted] supports the Delegates proposal to defer any decision on this chemical until the final US CIR is available. We also support the decision to refer further consideration of this chemical to the joint committee of ACCS and ACMS.

We urge the joint committee to consider appropriate implementation timeframes for any changes made to scheduling of this substance and further clarity on the types of product to be considered.

1.19 N-hydroxy octanamide

[redacted] supports the Delegates interim decision that scheduling for this substance in not required.

Yours faithfully,

[redacted]

[redacted]

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