Public Consultation 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 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) #11 (July 2014 meeting).

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.

Seven submissions were received. Four submitters provided submissions that related to multiple substances and these have been separately grouped.

List of Submissions

Substance	Total number of public submissions
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 on multiple substances
2-Butenedioic acid (2E)-, di-C12-15-alkyl esters	1 submission on multiple substances
2-Hydroxypropyl methacrylate	1 submission on multiple substances
2-Pentyl cyclopentanol	1 submission on multiple substances
2-Propyl heptanenitrile	1 submission on multiple substances
2,4,7-Decatrienoic acid, ethyl ester	1 submission on multiple substances
3-Hexanone, 2-methyl oxime	1 submission on multiple substances
3-Isothiazolone, 2-methyl (methylisothiazolone)	4 (3 submissions on multiple substances)
Diethylene glycol monomethyl ether [Ethanol, 2(2-methoxyethoxy)]	1 submission on multiple substances
Linear alkylbenzene sulfonates (C10-C16)	2 submissions on multiple substances

Substance	Total number of public submissions
Nickel, soluble salts	1 submission on multiple substances
N-hydroxy- octanamide	2 submissions on multiple substances
Phenol, 2-amino- (O-aminophenol)	1 submission on multiple substances
Phenylenediamines	Nil. 1 multiple submission cover page noted that it had provided submission on this substance, but no further information was provided.
Rosin	1 submission on multiple substances
Tetrahydro-4-methyl-2-phenyl 2H-pyran	1 submission on multiple substances
Toluenediamines	1 submission on multiple substances

Submission on Multiple Substances

One submission was on linear alkylbenzene sulfonates (C10-C16) and 3-isothiazolone, 2-methyl-(methylisothiazolone).

One submission was on 2,4,7-decatrienoic acid, ethyl ester, 3-hexanone, 2-methyl oxime, 3-isothiazolone, 2-methyl-(methylisothiazolone) and nickel.

One submission was on 3-isothiazolone, 2-methyl-(methylisothiazolone) and N-hydroxy-octanamide.

One submission was on 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, 2-butenedioic acid (2E)-, di-C12-15-alkyl esters, 2-hydroxypropyl methacrylate, 2-pentyl cyclopentanol, 2-propyl heptanenitrile, 2,4,7-decatrienoic acid, ethyl ester, 3-hexanone, 2-methyl oxime, 3-isothiazolone, 2-methyl-(methylisothiazolone), diethylene glycol monomethyl ether [Ethanol, 2(2-methoxyethoxy)], linear alkylbenzene sulfonates (C10-C16), N-hydroxy-octanamide, phenol, 2-amino- (o-aminophenol), rosin, tetrahydro-4-methyl-2-phenyl-2H-pyran and toluenediamines.

Scheduling Proposals - ACCS Meeting July 2014 - Methylisothiazolone [SEC=No Protective Marking]

[redacted]: SMP@health.gov.au 17/06/2014 10:20

Cc: [redacted]

No Protective Marking

Good Morning,

I would like to comment on the scheduling proposal for **Methylisothiazolone** (MIT) following NICNAS IMAP Report No 1062. I believe that concerns may have been highlighted because due to MIT use in cosmetics, especially leave on cosmetics where allergic reactions may have been reported. This substance is also widely used in decorative paints in Australia as a biocide having replaced CIT/MIT due to labelling requirements. The surface coatings industry seeks that any cut-offs assigned to MIT is for its use in cosmetics only. If your require any further information, please contact me either direct or by email.

Regards,

[redacted]

[redacted]

[redacted]

APMF

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[redacted]

25 June 2014

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

Email: SMP@health.gov.au

Dear Secretary,

RE: 3-isothiazolone, 2-methyl-(methylisothiazolone)

The Plastics and Chemicals Industries Association (PACIA) is the peak national body representing the chemistry sector in Australia. PACIA members include chemical manufacturers, importers and distributors, logistics and supply chain partners, raw material suppliers, plastic fabricators and compounders, plastics and chemical recyclers and service providers to the sector.

PACIA welcomes the opportunity to provide comment to the ACCS & ACMS meetings in July 2014, specifically in response to the scheduling proposal to list 3-isothiazolone, 2-methyl-(methylisothiazolone).

PACIA would like to take this opportunity to highlight that Methylisothiazolinone is substance that is used in variable preparations with different uses, which was highlighted in the NICNAS IMAP report no.1062. At present there is no indication on the specific schedule or any appropriate cut-off to be applied to preparations. As this chemical is expected to have direct impact to our membership, PACIA would greatly appreciate, if the Advisory Committee on Chemicals Scheduling (ACCS) or the appropriate delegate can keep us informed on any decisions and proposals going forward.

PACIA considers that any decisions going forward, should not have 'a one size fits all applicability', due to the variability in end products and use. At this stage, PACIA has had limited time to consult with members due to the limited timeframe. We will continue to consult with members and provide any further feedback at a later stage if anything warrants further submission in relation to matters as mentioned in section 52E of the Therapeutic Goods Act 1989.

Should you have any questions regarding the content of this submission or require any additional information from PACIA or clarification, please do not hesitate to contact [redacted]

Yours Sincerely,

[redacted]

PLASTICS AND CHEMICALS INDUSTRIES ASSOCIATION ABN: 77 063 335 615
Level 10, 10 Queen Street, Melbourne, Victoria, 3000 Phone: **03 9611 5400** Fax: **03 9611 5499**
PO Box 422 Flinders Lane, VIC 8009 Email: **info@pacia.org.au** Web: **www.pacia.org.au**

02 July 2014

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

Email: SMP@health.gov.au

Dear Secretary,

RE: Supplementary submission on 3-isothiazolone, 2-methyl-(methylisothiazolinone)

The Plastics and Chemicals Industries Association (PACIA) is the peak national body representing the chemistry sector in Australia. PACIA members include chemical manufacturers, importers and distributors, logistics and supply chain partners, raw material suppliers, plastic fabricators and compounders, plastics and chemical recyclers and service providers to the sector.

PACIA welcomes the opportunity to provide comment to the ACCS & ACMS meetings in July 2014, specifically in response to the scheduling proposal to list 3-isothiazolone, 2-methyl-(methylisothiazolone). As indicated in our original submission, PACIA has consulted further and we have made a supplementary submission in relation to matters as mentioned in section 52E of the Therapeutic Goods Act 1989.

PACIA would like to take this opportunity to highlight that Methylisothiazolinone (MI) is a substance that is used in variable preparations with different uses as indicated within our membership. PACIA considers that any decisions going forward, should not have 'a one size fits all applicability', due to the variability in end use products, i.e. the risk associated with cosmetic versus domestic products should be considered separately.

Membership feedback on domestic use of Methylisothiazolinone

The following submission only relates to domestic use products. MI is used as a preservative and an active biocide in domestic and industrial products. The uses range from paints, adhesives, cleaners, polishes, anti-mould sprays, inkjet printer inks, marker pens, caulks and sealants. As indicated within our membership, with limited time to consult, the chemical does not exceed 0.06 % in finished product(s) for the uses indicated above.

NICNAS Risk Characterisation determined for the public

The NICNAS report[1], has indicated that the critical health effect is skin sensitisation in regards to public health risk, which has the potential to pose an unreasonable risk to the public. NICNAS has classified the MI with the following sensitisation criteria within the report;

Approved Criteria (HSIS)	*May cause sensitisation by skin contact (Xi; R43)*
GHS Classification	*May cause an allergic skin reaction - Cat. 1 (H317)*

[1] NICNAS IMAP report no.1062

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Scheduling of domestic products

At dilute use concentrations, no adverse risk is expected with MI for domestic use products. We consider uses which do not have direct application to skin use, should be excluded from scheduling, as the risk is considered to be low in regards to sensitisation. In some uses, it would be undesirable to have skin exposure with products, such as paint, sealants, inks and adhesives, therefore, the user will try to avoid skin exposure of these products. Furthermore, as we currently understand, there is no market restriction globally with the use of MI in domestic or industrial use, nor was any restriction found within the NICNAS IMAP report.

In addition, NICNAS has reported the chemical concentrations used in products are typically reported to be <1 % for domestic use products (based on overseas data), but indication from our membership is that it used at very low concentrations in the domestic environment. The MI level indicated by our members does not trigger any hazardous classification under the Approved criteria or GHS. Also, it should be noted, that sensitisers do not have any additive effect in mixtures, therefore the sensitisation magnitude will remain constant and will not be influenced by other chemicals in mixtures, therefore will not be susceptible to increase.

Conclusion

PACIA considers that any scheduling requirements of products which do not have the purpose of direct skin application, should be excluded from scheduling due to the lower risk profile, compared to those that have intentional skin applications, especially in relation to the sensitiser concerns.

If any cut-off limits are deemed warranted by the Advisory Committee on Chemicals Scheduling (ACCS) for domestic use products in regards to Scheduling, the cut-off limits for Scheduling should be equivalent to those of the Hazardous cut-off triggers within Australia's Hazardous classification scheme(s), as these products do not have an intentional skin application and any skin exposure will occur through accidental application at very low level.

Should you have any questions regarding the content of this submission or require any additional information from PACIA or clarification, please do not hesitate to contact [redacted].

Yours Sincerely,

[redacted]

WACKER

[redacted]

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[redacted]

The Secretary
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Attention: Secretary,

26th June 2014

Submission regards the proposed amendment to the Poisons Standard inclusion of:

3-Isothiazolone, 2-Methyl- (Methylisothiazolone) CAS 2682-20-4

In response to issues raised in a NICNAS IMAP report no. 1062, the Scheduling Proposal is to list 3-Isothiazolone, 2-Methyl- with an appropriate cut-off to exempt from scheduling for preparations containing low concentrations of 3-Isothiazolone, 2-Methyl- (Methylisothiazolone).

http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=1062

Dear Secretary,

Wacker Chemie AG wishes to inform the Advisory Committee on Chemicals Scheduling and the Delegate, that its [redacted] aqueous dispersion products (listed below), contain [redacted] Methylisothiazolinone (MIT), which is part of the Isothiazolinone based biocides present (see below).

[redacted]

The other Isothiazolinone biocides that are also in each of these [redacted] products are:

Benzisothiazolinone (BIT) CAS 2634-33-5
CMIT/MIT 3:1 mixture CAS 55965-84-9

[redacted]

None of these [redacted] products are classified as Skin Sensitisers, as the MIT and BIT concentrations are both well below the cut-off concentration of 0.1%, and there has been no feedback from users that these products have caused skin sensitization issues, when containing [redacted]

Please ensure that IF a specific cut-off concentration below 0.1% is chosen, that this is supported by tox or user data.

[redacted]

26 June 2014

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The Secretary
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Dear Sir/Madam,

RE: Invitation for public comment - ACCS, ACMS and joint ACCS/ACMS meetings, July 2014

I refer to the notice published on 29 May 2014 inviting public submissions, with respect to certain substances, addressing a matter raised in s.52E of the *Therapeutic Goods Act 1989.*

Unilever Australasia is an international manufacturer and marketer of food, home and personal care products and is a market leader in many grocery categories in Australia and New Zealand. Our well known home and personal care brands include: Omo/Persil, Surf, Domestos, Jif, Rexona, Sunsilk, Vaseline and Dove.

Product safety is our top priority. Our home and personal care products are used every day by millions of people around the world. Consumers trust us to provide them and their families with products that are safe. We have a long track-record of collaboration with authorities, poison control centres and our consumers to understand and reduce to a minimum, risks of incidents related to consumer products and their safe use and storage in the home.

Our company is an active member of Accord and we wish to express our full support for Accord's submission in terms of the general regulatory principles conveyed and also more specifically to the following two proposals of interest to Unilever;

- 3-isothiazolone, 2-methyl-(methylisothiazolone); and
- Linear alkylbenzene sulfonates (C10-C16)

We wish to provide information on these two proposals for consideration at the July 2014 meeting of the ACCS. Please find details below.

If the Committee or the Delegate requires any additional information on these matters, please do not hesitate to contact me.

Yours sincerely

[redacted]

3-isothiazolone, 2-methyl- (methylisothiazolone)

Methylisothiazolinone is a commonly used preservative in a range of consumer products. Preservatives are an important ingredient in many consumer products because they help prevent contamination by microorganisms. Without preservatives, bacteria, germs and other organisms could develop, leading to product deterioration, spoilage and safety issues.

It is important for Australia to keep in line with international best practice, particularly where extensive risk assessment has already been carried out. As a global company, we actively encourage regulatory alignment with other comparable jurisdictions including the EU and the US. We also fully support harmonisation of appropriate risk management measures to maximise regulatory effectiveness and to minimise trade barriers.

Linear alkylbenzene sulfonates (C10-C16)

It is important that accurate market data is used as part of the scheduling process, to assess the potential for exposure to these chemicals through the use of laundry detergent products. As such, we have provided information below on the ways in which these substances are currently used in Unilever products.

Linear alkylbenzene sulfonates are widely used across our laundry detergent portfolio at a range of concentrations not exceeding 30%. These substances are used as surfactants in a variety of our detergent product formats including powders, liquids, and capsules containing liquid detergent. Unilever products represent roughly half of the laundry market and the majority of the liquid laundry capsules market in Australia.

Consumer safety is of paramount importance to Unilever. We have a long track-record of collaboration with authorities, poison control centres and our consumers to understand and reduce to a minimum, risks of incidents related to detergents.

Liquid detergent capsules are a relatively new product format. They are practical, convenient, sustainable and safe when correctly stored and used. They need to be handled safely and, as any other household cleaning products, kept away from children.

Globally, Unilever is an active member company of the International Association for Soaps, Detergents and Maintenance Products (AISE). Through AISE, Unilever helped to develop, and was an initial signatory to the *European Industry Product Stewardship Programme for capsules of laundry detergent*. This programme aims at securing safe use and storage of liquid laundry detergent capsules by consumers to ultimately significantly reduce the incidence of accidental exposure, in particular of small children, to these products. More information on the programme can be found on the AISE website: www.aise.eu

In Australia and New Zealand, we have also adopted this programme, and have worked to continuously improve our approach by voluntarily implementing measures on our capsules of liquid detergents such as removing child imagery from our packaging, fitting our boxes with child safety closure systems, adding a very bitter substance to our formulations to minimise ingestion and displaying prominent safety icons.

Unilever is committed to making all our liquid detergent capsules even safer. We are currently exploring additional measures to further address risks of incidents with capsules of detergents. Nonetheless, as for any other detergents, only keeping the product away from children can effectively prevent all instances of accidental exposure.

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26th June 2014

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Dear Sir or Madam,

Re: Invitation for public comment – ACCS, ACMS and joint ACCS / ACMS meetings, July 2014
ASMI Comment – ACCS meeting

We refer to the notice inviting public comment under Regulation 42ZCZK of the Therapeutic Goods Regulations and would like to provide comment on the scheduling proposals that are to be considered by the ACCS and the joint ACCS/ACMS meetings in July 2014. The comments submitted below address matters raised in section 52E of the *Therapeutic Goods Act 1989*, and are in relation to the proposed amendments referred by the delegate for scheduling advice for consideration by the ACCS.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer healthcare 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.

For ease of reference, comments are in the same order as the proposals in the consultation document.

ACCS Agenda – General comments

ASMI notes the many proposals for amendment of schedule entries for various substances in the poisons standard to be considered by the ACCS. The proposals for consideration appear to pertain mainly to the use of the chemicals in cosmetic products, hair dyes and some industrial chemicals. ASMI notes that there is insufficient detail in some of the proposals to allow an adequate assessment of impact on the therapeutic goods industry.

Some of the proposals in the agenda appear to follow from the NICNAS IMAP review process and recommendations, however we are concerned that the possible impact on ingredients entered in the ARTG for use in therapeutic goods may not have been fully considered. ASMI urges the Scheduling Secretariat to ensure that there is adequate co-ordination between the relevant agencies (NICNAS, TGA, APVMA and ANZFA) to ensure that the impact of any potential scheduling amendments on other products is fully considered. ASMI supports the referral to the joint ACCS/ACMS of some scheduling proposals previously considered by the ACCS.

We have reviewed the entire agenda and to the extent possible, have commented on any specific items which are relevant to our members. Some of the proposals do not appear to be relevant to the therapeutic goods industry. However given the limited information provided, the complexity of nomenclature and the large number of possible salts and derivatives, we cannot be certain that no impact exists and we would appreciate the opportunity to provide further comment on any of the agenda items should possible impact be identified following the release of the Delegate's interim decisions.

Proposed scheduling amendments and ASMI comment

Substance	Proposal
2,4,7-decatrienoic acid, ethyl ester	To create a new Schedule 6 and Appendix F entries for 2,4,7-decatrienoic acid, ethyl ester with an appropriate cut-off to exempt from scheduling for preparations containing low concentrations of 2,4,7-decatrienoic acid, ethyl ester.

Comment:
ASMI understands that 2,4,7-decatrienoic acid, ethyl ester may have uses as a surfactant, stabiliser or emulsifier. Although there is no entry on the TGA e-BS site for this ingredient, it is possible that it may be present in proprietary ingredients.

The proposed Schedule 5 or 6 entry is not restricted to cosmetic or industrial products, and no scheduling cut-off is proposed. ASMI is concerned about the possibility that there may be some impact on therapeutic goods, and consideration should be given to drafting the entry so that therapeutic goods are excluded.

Substance	Proposal
3-hexanone, 2-methyl oxime	To create new Schedule 6 and Appendix F entries for preparations containing 3-hexanone, 2-methyl oxime.

Comment:
3-hexanone, 2-methyl oxime may have uses as a perfuming agent. Although there is no entry on the TGA e-BS site for this ingredient, it is possible that it may be present in proprietary fragrance ingredients that may be used in therapeutic goods.

The proposed Schedule 6 and Appendix F entries are not restricted to cosmetic or industrial products, and no cut-off is proposed. Consideration should be given to drafting the entry so that proprietary ingredients that may be part of the ingredients used in therapeutic goods are excluded.

Substance	Proposal
3-isothiazolone,2-methyl (methylisothiazolone)	In response to issues raised in a NICNAS IMAP report no. 1062, the scheduling proposal is to list 3-isothiazolone,2-methyl- with an appropriate cut-off to exempt from scheduling for preparations containing low concentrations of 3-isithiazolone,2-methyl-(methylisothiazolone)

Comment:
ASMI notes that methylisothiazolone (MIT) is entered as an ingredient on the ARTG e-BS website. Its uses are not specified in the ARTG entry, other than it may be used as an excipient in all classes of medicines.

MIT is known to be used in sunscreen preparations as a preservative, providing preservative efficacy against bacterial and fungal species.

Given that there is potential impact on therapeutic goods, ASMI requests that the ACCS consider the impact of any scheduling proposals on therapeutic goods. This may require consideration by the joint ACCS/ACMS.

Australia is a small market globally and some products are manufactured overseas. ASMI does not object to harmonising any cut-offs with comparable regulatory agencies in the EU or USA as appropriate and after providing industry with the opportunity to comment on any specific cut-off. ASMI will consider commenting further on this proposal following the Delegate's Interim Decisions should a specific cut-off be proposed.

Substance	Proposal
Nickel, soluble salts	In response to issues raised in a NICNAS IMAP report nos. 839, 878 and 883, the scheduling proposal is to amend the current Schedule 6 nickel sulfate entry to read nickel, soluble salts.

Comment:
ASMI does not object to the proposed amendment to Schedule 6 to extend the existing entry to include all nickel salts.

ASMI however reserves the right to comment at the post-meeting comment stage, should it become evident that there may be an impact on therapeutic goods, as there are ARTG ingredient entries for nickel salts in the TGA e-BS.

Conclusion
ASMI supports co-ordination between the various agencies to minimise the impact of scheduling changes proposed for cosmetics, personal care products, commercial and industrial products on products such as therapeutic goods, foods and veterinary products.

ASMI requests the ACCS to carefully consider the possible impact of the scheduling proposals on therapeutic goods, and care should be taken to ensure that any amendments are clearly and carefully drafted to exclude any impact on these products.

The ACCS should also allow sponsors adequate time to make changes to formulations and/or labelling if needed; adequate transition times are important to industry, as is the need to allow existing stock in market to be sold through.

As an industry representative, ASMI is a key stakeholder in scheduling matters and we are keen to provide further input as required. We look forward to the Delegate's interim decisions and greater detail on the final scheduling proposals.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

[redacted]

The Secretary
Medicines and Poisons Scheduling
Office of Chemical Safety (MDP 88)
GPO Box 9848
CANBERRA ACT
2601

26th June 2014

Dear Sir/Madam,

RE: Comments on Proposed amendments referred by the Delegate for scheduling advice for consideration by the Advisory Committee on Chemicals Scheduling (ACCS) and the Advisory Committee on Medicines Scheduling (ACMS)

[redacted] would like to provide comments on a number of the proposed amendments referred by the Delegate to the Committee of Chemicals Scheduling (ACCS) and the Advisory Committee on Medicines Scheduling (ACMS).

3-isothiazolone, 2-methyl-(methylisothiazolone)

In response to issues raised in a NICNAS IMAP report no. 1062, the scheduling proposal is to list 3-isothiazolone, 2-methyl- with an appropriate cut-off to exempt from scheduling for preparations containing low concentrations of 3-isothiazolone, 2-methyl- (methylisothiazolone).

MIT is a preservative which has a long history of safe and effective use in personal care products at concentrations up to 0.01%. However, the safety of MIT is currently being reassessed by The Cosmetic Ingredient Review (CIR) Expert Panel and the SCCS EU commission.

The CIR Panel had reviewed the safety of Methylisothiazolinone in 2010. The report concluded that Methylisothiazolinone is recognized as safe for use in cosmetic products in concentrations up to 0.01%[1].

The Cosmetic Ingredient Review Panel has recently released a tentative amended safety assessment report for Methylisothiazolinone. The report was released for public comment on June 20th 2014, with the next panel meeting scheduled for September 8th 2014[4]. The tentative recommendation from the June 20th 2014 CIR is '*The CIR Expert Panel concluded that MI is safe for use in rinse-off cosmetic products at concentrations up to 100 ppm and safe in leave-on cosmetics products when they are formulated to be non-sensitizing, which may be determined based on a QRA'.*

The EU SCCS proposal has been released for public comment with comments due August 2014. The SCCS recommendation is to discontinue the use of MIT in leave-on skin cosmetics and personal care products. For rinse off cosmetics, a concentration of 15 ppm (0.0015%) MIT has been deemed safe from the view of induction of contact allergy.

[redacted]

[redacted]

CURRENT OVERSEAS REGULATORY CLASSIFICATION FOR METHYLISOTHIZOLINONE

COUNTRY	RESTRICTIONS
New Zealand	Max allowed 0.01% for both leave on and rinse off
USA	No specific limits required
Canada	Permitted at concentrations equal to or less than 0.01% for use as a preservative

The above are key country classifications of Methylisothiazolinone. Currently, there are restrictions on the use of Methylisothiazolinone in Canada and NZ, with a maximum allowable cut-off of 0.01%.

[redacted]

Considering the current global discussions, [redacted] that there is a need to reassess the safety of MIT and what an appropriate low concentration cut off would be for cosmetic products. However, considering that work is currently underway in other markets assessing the safety of the ingredient, we suggest that the ACCS defer consideration of scheduling of Methylisothiazolinone until the CIR panel and the SCCS EU commission have made their final recommendations, so that any new findings can be taken into consideration.

Additionally if a concentration cut-off is proposed which impacts products currently on the market, the time required to reformulate such products should be taken into consideration when proposing an implementation timeframe. Industry would require at least 24 months in order to reformulate products and comply with any proposed cut off.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

N-hydroxy- octanamide/ caprylhydroxamic acid

Caprylhydroxamic acid is a chelating agent commonly used in low levels in topical cosmetic and personal care formulations worldwide. Currently this ingredient is used in [redacted] globally at concentrations below 0.3%.

OVERSEAS REGULATORY CLASSIFICATION FOR CAPRYLHYDROXAMIC ACID

COUNTRY	RESTRICTIONS
European Union	Not restricted
New Zealand	Not restricted
USA	Not restricted
Canada	Not restricted

The scheduling proposal for listing refers to an appropriate cut-off to exempt Caprylhydroxamic acid from scheduling for preparations with low concentrations. No actual cut-off has been advised in the meeting agenda.

As other well respected jurisdictions have not restricted the use of this ingredient in cosmetic products our view is that Caprylhydroxamic acid should remain unscheduled for use in cosmetic products regardless of concentration.

Unique Australian requirements should not be set for ingredients in cosmetic products unless a clear safety issue or unacceptable hazard or risk has been identified. A restriction on the use of Caprylhydroxamic acid in cosmetic products in Australia may result an impediment to trade.

Summary

In summary, [redacted] acknowledges the need for consideration of an appropriate low concentration cut off for MIT in cosmetic products, however as work is underway in other markets assessing the safety of the ingredient, we suggest that the ACCS defer consideration of scheduling of Methylisothiazolinone until the CIR panel and the SCCS EU commission have made their final recommendations, so that any new findings can be taken into consideration.

Citral should remain unscheduled as the safety of the ingredient when used in fragrances has been established by IFRA.

Caprylhydroxamic acid should remain unscheduled for use in cosmetic products regardless of concentration.

Additionally, should the Committee and Delegate decide to proceed with the proposals, current cosmetics in the market should not be impacted. Appropriate transition times should be given to allow sponsors and manufacturers to implement the changes for new products.

[redacted]

[redacted]

[redacted]

[redacted]

References:

1. International Journal of Toxicology 29(Supplement 3) 187S-213S, 2010 on request
[redacted]
4. http://www.cir-safety.org/sites/default/files/mthiaz062014tent_0.pdf

[redacted]

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: SMP@health.gov.au

Dear Sir/Madam

Public Comment Submission to the July 2014 meeting of the Advisory Committee on Chemicals Scheduling (ACCS)

We refer to the notice published on 29 May 2014 inviting public submissions, with respect to certain substances, addressing a matter raised in s.52E of the *Therapeutic Goods Act 1989.*

Accord Australasia Limited is the peak national industry association that represents the hygiene, cosmetic & specialty products industry.

Accord wishes to provide information on:

- **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,**
- **2-butenedioic acid (2E)-, di-C12-15-alkyl esters (INCI name Di-C12-15 alkyl fumarate),**
- **2-hydroxypropyl methacrylate,**
- **2-pentyl cyclopentanol,**
- **2-propyl heptanenitrile,**
- **2,4,7-decatrienoic acid, ethyl ester,**
- **3-hexanone, 2-methyl oxime,**
- **3-isothiazolone, 2-methyl- (methylisothiazolone),**
- **Diethylene glycol monomethyl ether [Ethanol, 2(2-methoxyethoxy)],**
- **Linear alkylbenzene sulfonates (C10-C16),**
- **N-hydroxy-octanamide (INCI name caprylhydroxamic acid),**
- **Phenol, 2-amino- (*o*-aminophenol),**
- **Phenylenediamines,**
- **Rosin; resin acids and rosin acids, calcium salts; resin acids and rosin acids, potassium salts; resin acids and rosin acids, sodium salts; rosin, polymerized; rosin hydrogenated,**
- **Tetrahydro-4-methyl-2-phenyl-2H-pyran, and**
- **Toluenediamines.**

for consideration at the July 2014 meeting of the ACCS.

Please see attached submission for details.

We thank the Committee and the Secretariat for the extension to provide comments. It is greatly appreciated.

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Accord is an interested party and stakeholder with regard to the nominated substances and would appreciate being advised of the Committee's considerations and the Delegate's interim decision, with the opportunity for further submission, if appropriate.

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

Yours faithfully

[unsigned for electronic submission]

[redacted]

30 June 2014

ACCS meeting: July 2014

1-propanaminium, N,N,N-trimethyl-3-(octadecyloxy)-, chloride (1:1) (or stearoxypropyltrimonium chloride) and 1-propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(C8-18 and C18-unsatd. acyl) derivs., inner salts (or babassuaminopropyl betaine)

Accord notes that this agenda item relates to two surfactants, stearoxypropyltrimonium chloride and babassuaminopropyl betaine. We understand that technically, both compounds are quaternary ammonium compounds and would be captured under the current schedule entry for quaternary ammonium compounds.

Current schedule entries for quaternary ammonium compounds are as follows:

Schedule 6:

QUATERNARY AMMONIUM COMPOUNDS except:

(a) when separately specified in these Schedules;
(b) when included in Schedule 5;
(c) dialkyl or dialkoyl quaternary ammonium compounds where the alkyl or alkoyl groups are derived from tallow or hydrogenated tallow or similar length (C16/C18) sources; or
(d) in preparations containing 5 per cent or less of such quaternary ammonium compounds.

Schedule 5:

QUATERNARY AMMONIUM COMPOUNDS in preparations containing 20 per cent or less of quaternary ammonium compounds except:

(a) when separately specified in these Schedules;
(b) dialkyl or dialkoyl quaternary ammonium compounds where the alkly or alkoyl groups are derived from tallow or hydrogenated tallow or similar chain length (C16/C18) sources; or
(c) in preparations containing 5 per cent or less of such quaternary ammonium compounds.

Quaternary ammonium compounds are also subject to relevant first aid instructions (Appendix E statements)

We understand that dialkyl and dialkoyl quaternary ammonium compounds, where the alkyl or alkoyl chain length was similar to that derived from tallow, were exempted from scheduling requirements based on their toxicity profile.

We believe that the toxicity of the substance babassuamidopropyl betaine, is significantly different from other quaternary ammonium compounds and warrants separate consideration.

Babassuamidopropyl betaine and other similar, related compounds

Babassuamidopropyl betaine is a zwitterion (a neutral molecule with both negative and positive electrical charge within the molecule), which while technically a quaternary ammonium compound, is not a cationic surfactant like most other quaternary ammonium compounds. Rather, it is an amphoteric surfactant used in cosmetics and consumer products.

In 2010, the Cosmetic Ingredient Review (CIR) published its review of cocamidopropyl betaine and related compounds, which included babassuamidopropyl betaine. The full review document is available from the CIR website: http://www.cir-safety.org/sites/default/files/117_final_capb.pdf.

In its review, the CIR concluded that cocamidopropyl betaine and related compounds were safe for use in cosmetics when formulated to be non-sensitising. The CIR authors believed that the potential for sensitisation was due to impurities rather than the compound itself. The impurities of concern were 3-dimethylaminopropylamine (CAS No. 109-55-7) and amidoamine (cocamidopropyl dimethylamine OR dimethylaminopropyl cocamide; CAS No. 68140-01-2), both known sensitisers.

One of our Members has reported that babassuamidopropyl betaine is used in cosmetic products available overseas at maximum concentration of 16%. Given that there is no restriction on the concentration of the substance in cosmetics in the EU or the USA, we believe that the concentration in some products may be higher.

In the NICNAS assessment of babassuamidopropyl betaine, it was concluded that the substance was classified only as irritating to eyes (with no irreversible effects).

Given these considerations, Accord believes that the current scheduling requirements for quaternary ammonium compounds are too restrictive to apply to babassuamidopropyl betaine and other amidopropyl betaines derived from fatty acids (with carbon chain length of C6-C20).

Accord respectfully suggests excluding fatty acid amidopropyl betaine from scheduling by including them in the list of exclusions in both Schedule 5 and Schedule 6 entries, noting that fatty acids derived from animals also have similar carbon chain length distribution as plant derived fatty acids. The new schedule entries could read:

Schedule 6:

QUATERNARY AMMONIUM COMPOUNDS except:

(a) when separately specified in these Schedules;
(b) when included in Schedule 5;
(c) dialkyl or dialkoyl quaternary ammonium compounds where the alkyl or alkoyl groups are derived from tallow or hydrogenated tallow or similar length (C16/C18) sources;
(d) fatty acid amidopropyl betaines;
(e) in preparations containing 5 per cent or less of such quaternary ammonium compounds.

Schedule 5:

QUATERNARY AMMONIUM COMPOUNDS in preparations containing 20 per cent or less of quaternary ammonium compounds except:

(a) when separately specified in these Schedules;
(b) dialkyl or dialkoyl quaternary ammonium compounds where the alkly or alkoyl groups are derived from tallow or hydrogenated tallow or similar chain length (C16/C18) sources;
(c) fatty acid amidopropyl betaines; or
(d) in preparations containing 5 per cent or less of such quaternary ammonium compounds.

If the Committee is concerned with the sensitisation potential of the impurities, the impurities, 3-dimethylaminopropylamine and amidoamine, can be scheduled with an appropriate cut-off for

exemption from scheduling e.g. 1%, the cut-off concentration for hazard classification for sensitisation in formulation mixtures.

ACCS meeting: July 2014

2-butenedioic acid (2E)-, di-C12-15-alkyl esters (INCI name Di-C12-15 alkyl fumarate)

Accord notes that NICNAS appears to have concluded that di-C12-C15 alkyl fumarate is a skin sensitiser based on an assessment guinea pig skin sensitisation test. We note that there were multiple skin sensitisation studies considered and only the guinea pig skin sensitisation resulted in the conclusion that the substance is a potential skin sensitiser.

Accord is unsure of the basis for the NICNAS conclusion that up to 10% concentration in cosmetic preparations is not expected to pose an unreasonable risk. This NICNAS conclusion appears to have relied on a human skin sensitisation test for formulations containing up to 15% of the substance, which concluded that the test substance was non-sensitising under the conditions of the test.

Accord respectfully requests that the ACCS carefully consider the data for skin sensitisation. We understand that the irritation and skin sensitisation study report which formed the basis of NICNAS conclusions for the substance will be provided to the ACCS for consideration by NICNAS as a confidential document. However, if this is not the case, Accord can provide a copy to the ACCS provided confidentiality can be assured.

It is Accord's view that di-C12-C15 alkyl fumarate does not require scheduling, based on our understanding that the substance does not appear to be a skin sensitiser based on available study results.

ACCS meeting: July 2014

2-hydroxypropyl methacrylate

It is our understanding that 2-hydroxypropyl methacrylate is a monomer that can be used in formulations intended to be applied in liquid form then harden (polymerise) for form a hard coating. Obvious uses for this type of substance/application are mostly in paints, adhesives and in nail polishes.

Accord notes that the NICNAS existing chemicals assessment raised concerns with potential for skin sensitisation.

As cited in the NICNAS assessment report, the Cosmetic Ingredient Review concluded in 2005 that the use of 2-hydroxypropyl methacrylate was safe to use in nail products when skin contact is avoided. Accord also notes that there are no restrictions in the EU for the use of 2-hydroxypropyl methacrylate, and according to the Cosmetics Ingredient database, it is used in "film forming" applications.

One of Accord's Members has identified that the substance is used in their product at up to 25%.

Accord supports aligning the control of 2-hydroxypropyl methacrylate with the EU. Following the EU, there would be no restrictions.

If the Committee decides that it is more appropriate to align with the cosmetic substance controls in the USA then the substance would be unscheduled if a warning statement "avoid contact with skin" is added to the label. If such decision is reached, appropriate transition time should be allowed e.g. for amendments to labels, 12-24 months from the publication of the final decision would be required.

ACCS meeting: July 2014

2-pentyl cyclopentanol

While Accord is unaware of the basis for the proposed scheduling consideration, Accord understands that 2-pentyl cyclopentanol can be used as a fragrance material. Accord is not aware of any other uses of the substance.

In previous submissions, Accord has raised concerns with the consideration of individual fragrance ingredients for scheduling when there is an international body International Fragrance Association (IFRA) assessing and managing the risks of chemicals used as fragrance and flavour. These concerns remain.

We note that we are not aware of any restrictions on 2-pentyl cyclopentanol in the EU, in cosmetics or in any other product preparations, or any restrictions by IFRA. We are also not aware of any restrictions on its use in the USA.

On this basis, Accord respectfully requests that 2-pentyl cyclopentanol remain unscheduled.

ACCS meeting: July 2014

2-propyl heptanenitrile

While Accord is unaware of the basis for the proposed scheduling consideration, Accord understands that 2-propyl heptanenitrile can be used as a fragrance material. Accord is not aware of any other uses of the substance.

In previous submissions, Accord has raised concerns with the consideration of individual fragrance ingredients for scheduling when there is an international body International Fragrance Association (IFRA) assessing and managing the risks of chemicals used as fragrance and flavour. These concerns remain.

We note that we are not aware of any restrictions on 2-propyl heptanenitrile in the EU, in cosmetics or in any other product preparations, or by the International Fragrance Association (IFRA). We are also not aware of any restrictions on its use in the USA.

On this basis, Accord respectfully requests that 2-propyl heptanenitrile remain unscheduled.

ACCS meeting: July 2014

2,4,7-decatrienoic acid, ethyl ester

While Accord is unaware of the basis for the proposed scheduling consideration, Accord understands that 2,4,7-decatrienoic acid, ethyl ester can be used as a fragrance material. Accord is not aware of any other uses of the substance.

In previous submissions, Accord has raised concerns with the consideration of individual fragrance ingredients for scheduling when there is an international body International Fragrance Association (IFRA) assessing and managing the risks of chemicals used as fragrance and flavour. These concerns remain.

We note that we are not aware of any restrictions on 2,4,7-decatrienoic acid, ethyl ester in the EU, in cosmetics or in any other product preparations, or by the International Fragrance Association (IFRA). We are also not aware of any restrictions on its use in the USA.

On this basis, Accord respectfully requests that 2,4,7-decatrienoic acid, ethyl ester remain unscheduled.

ACCS meeting: July 2014

3-hexanone, 2-methyl oxime

While Accord is unaware of the basis for the proposed scheduling consideration, Accord understands that 3-hexanone, 2-methyl oxime can be used as a fragrance material. Accord is not aware of any other uses of the substance.

In previous submissions, Accord has raised concerns with the consideration of individual fragrance ingredients for scheduling when there is an international body International Fragrance Association (IFRA) assessing and managing the risks of chemicals used as fragrance and flavour. These concerns remain.

We note that we are not aware of any restrictions on 3-hexanone, 2-methyl oxime in the EU, in cosmetics or in any other product preparations, or by the International Fragrance Association (IFRA). We are also not aware of any restrictions on its use in the USA.

On this basis, Accord respectfully requests that 3-hexanone, 2-methyl oxime remain unscheduled.

3-isothiazolone, 2-methyl- (methylisothiazolone)

Accord understands that the main reason for the proposal to schedule methylisothiazolone (MIT) arises from its sensitisation potential.

There are many complex issues in scheduling consideration of MIT. We have attempted to list and explain some of these complexities below.

Preservatives - Benefit vs Risk

In scheduling consideration of MIT, it is necessary to consider the benefits of preservatives.

MIT is one of the preservatives available on the market. When preservatives as a group are considered, it is necessary to note that they are chemicals intended to kill microorganisms and all show some level of toxicity. However, without preservatives, products cannot be protected from microorganisms which then raise other health concerns.

Removing any preservative from currently available set of preservatives will require companies to consider whether there are other preservatives available that are as effective for all of their formulations – there is no absolute guarantee that the replacement preservative will be any better in terms of health outcomes i.e. preservative efficacy and/or significantly improved preservative toxicity profile. Research into new types of preservatives necessarily takes time, and again, there is no guarantee that there will be a better health outcome.

For example, we understand that MIT is an effective replacement for parabens, also a preservative. Due to focus on potential yet unproven concerns around parabens, we understand that some companies have removed parabens from their formulation and replaced it with MIT. This leaves an interesting question for these companies if MIT cannot be used as a preservative – whether to go back to using parabens, or find some other preservative (if possible).

Need to consider MIT as a distinct chemical for scheduling

MIT is one of a family of isothiazolone preservatives. We understand from information provided to us that non-chlorinated isothiazolones are less likely to elicit sensitisation reaction. Further, cross sensitisation within the isothiazolone based preservatives does not occur i.e. MIT does not elicit an allergy response from a person sensitised to chloromethylisothiazolinone (CIT).

Accord has been provided a summary of studies into the sensitisation potential of isothiazolinone compounds which provides further details in confidence. Having reviewed the commercial-in-confidence guidelines in Scheduling Policy Framework we are unsure whether this information can be kept confidential once provided to the ACCS. We are happy to provide the information to the ACCS if confidentiality can be retained, noting that the material was provided to us in confidence.

Also, we understand that a combination of different isothiazolone preservatives can be effective while reducing the overall amount of preservatives used. An example of this is the use of benzisothiazolone (BIT) combined with MIT. It is my understanding that MIT is effective against bacteria at around 100ppm, but only effective against fungi at increased levels - up to 1000ppm. BIT however is effective against fungi at around 100ppm. Therefore combination of up to 100ppm of BIT with up to 100ppm of MIT results in a preservative effective against both bacteria and fungi.

Given these consideration, we believe it is necessary to consider scheduling individual preservative separately, excluding salts and derivatives.

Broad range and large number of available products

There is a wide range and a large number of products that use CIT or MIT as a preservative. MIT is also a by-product of CIT (3:1 ratio of CIT:MIT) and the use of CIT as a preservative will necessarily include MIT in the product.

From feedback received, we understand that MIT is used in:

- Cosmetics including shampoos, conditioners, liquid soap, deodorants, hair fixing products, etc.,
- Domestic cleaning products including floor polishes, ironing sprays, stain removers, carpet cleaners, dishwashing liquid, dish washing rinse-aid, anti-mould sprays, etc.,
- Car polishes, emulsion waxes, tyre paints, etc.,
- Paints, adhesives, sealants, patching compounds, etc.,
- Inkjet cartridges and some marker pens, and
- Industrial water treatment products.

As one of our Members has summarised, basically any formulation containing water may have MIT as a preservative. We also note that MIT is on the ARTG and maybe used as a preservative in therapeutic goods.

It is therefore necessary to carve out the products that are not likely to pose a concern e.g. all industrial uses and non-skin contact or no deliberate skin contact products, then have a tiered approach to scheduling for the remainder.

Effective concentration vs “safe” concentration

MIT is a preservative and there is a range of concentrations at which it is effective. Restricting the use of the substance to below the effective level is likely to result in the following outcome:

- MIT is not likely to be used by responsible industry as the allowed levels will not be effective as a preservative, however,
- MIT may be used at allowed levels by some companies which may result in microbial contamination concerns for those products.

As noted above, we understand that MIT is effective against bacteria at around 100ppm, and effective against fungus at around 1000ppm. Product concentrations reported by our Members appear to align with these concentrations - MIT is used in cosmetics at up to 100ppm and in some domestic cleaning products at up to 1000ppm.

The EU Scientific Committee on Consumer Safety (SCCS) published its opinion on MIT and sensitisation on 12 December 2013. A revised version of this report (revision date 27 March 2014) is available from the European Commission website:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_145.pdf.

Since the publication of the SCCS report, the US Cosmetic Ingredient Review (CIR) began evaluating the information relevant to MIT. The CIR published its Tentative Report for Public Comment (Tentative Report) on 20 June 2014. The Tentative Report is available from the CIR website:
http://www.cir-safety.org/sites/default/files/mthiaz062014tent_0.pdf.

It is important to note that there is a significant difference in opinion between the two reviews. The SCCS concluded that up to 15 ppm in rinse-off cosmetics is safe. This concentration is lower than the effective concentration of MIT. The SCCS could not establish a safe leave-on level.

The CIR Tentative Report concluded that up to 100ppm in rinse-off cosmetics is safe, and non-sensitising concentration in leave-on formulations may be determined based on quantitative risk assessment (QRA).

Next Steps

Given the complexity of consideration, we urge the ACCS to consider the following next steps for scheduling consideration.

1. Exclude industrial and other products not intended for direct skin contact from scheduling consideration,
2. Defer the scheduling consideration for cosmetics and domestic products intended for skin contact until the finalisation of the CIR report (expected before the November 2014 meeting of the ACCS),
3. Defer the decision to a joint committee of ACCS and ACMS to ensure that therapeutic goods using MIT as a preservative are also considered,
4. Clarify that the scheduling consideration is for MIT only, and does not apply to other isothiazolone preservatives, and
5. Work with industry to reconcile the issues raised above, including the consideration of reported adverse effects locally.

ACCS meeting: July 2014

Diethylene glycol monomethyl ether [Ethanol, 2(2-methoxyethoxy)]

Accord notes that diethylene glycol monomethyl ether (DEGME) is banned in cosmetics in the EU. It is our understanding that DEGME is currently not used in any cosmetic products in Australia.

We have no objections to including DEGME in the Poisons Standard for cosmetic use and aligning with the EU cosmetics ban. Accord defers to the ACCS to consider the best method for achieving this outcome.

ACCS meeting: July 2014

Linear alkylbenzene sulfonates (C10-C16)

It is Accord's understanding that linear alkylbenzene sulfonates are surfactants used in domestic cleaning products. While NICNAS IMAP report has identified the use of the substance at up to 60%, feedback from Members suggest that the maximum total sum of linear alkylbenzene sulfonates in a product can be higher, at up to 70%.

While sodium dodecylbenzene sulfonates are included in the Poisons Standard, it is a very specific entry i.e. sodium salts with alkyl chain length of 12. We were unable to locate the previous rationale for the inclusion of such a specific schedule entry.

It is our understanding that currently there are unscheduled products on the market containing sodium dodecylbenzene sulfonates in combination with other linear alkylbenzene sulfonates, where the concentration of sodium dodecylbenzene sulfonate is below 30%, however, the total sum of alkylbenzene sulfonates are greater than 30%.

Accord is not aware of any evidence to suggest that the current scheduling controls have failed to adequately manage the risks posed by linear alkylbenzene sulfonates.

Accord further notes that the scheduling proposal is at least in part to manage the risks of alkylbenzene sulfonates when used in liquid laundry capsules.

In 2013, in recognition of the potential risks posed by liquid laundry capsules, Accord, with the aid and support from our Members, and in discussion with the Australian Competition and Consumer Commission (ACCC), finalised the Australian Industry Guideline for Labelling & Packaging of Liquid Laundry Capsules (Industry Guideline). The Industry Guideline is available from the Accord website:
http://www.accord.asn.au/members/resources/submissions/accord_public_statements/australian_industry_guideline_.

Accord is not aware of any evidence to suggest that the Industry Guideline has failed to adequately manage the risks posed by liquid laundry capsules. Given that the industry self-regulation appears to be working, we do not believe that it is necessary, nor appropriate to impose new regulatory requirements.

It is Accord's view that the current scheduling controls should be maintained.

If a change to the current scheduling controls is deemed necessary, further dialogue with affected industry Members is required, including consideration of:

- whether it is appropriate to amend the current Schedule 5 entry for sodium dodecylbenzene sulfonate to a broader alkylbenzene sulfonate entry (and consider calculation method for determining 30% i.e. whether counter ions should be counted in the weight calculation),
- whether it is more appropriate to draft a new schedule entry for alkylbenzene sulfonates, either removing or maintaining the S5 entry for sodium dodecylbenzene sulfonate,
- consideration of exemption from scheduling at higher concentrations if for example child-resistant packaging or other relevant risk controls are applied, and
- appropriate transition time for industry to reformulate, relabel or perhaps remove products from the Australian market, depending on level of risk identified and additional controls.

ACCS meeting: July 2014

N-hydroxy-octanamide (INCI name caprylhydroxamic acid)

Accord understands that there are currently no restrictions on the use of caprylhydroxamic acid in cosmetic preparations in the EU, the USA.

While there are no set restrictions, it is our understanding that caprylhydroxamic acid is a chelating agent in cosmetic preparations used in low concentrations (general <0.5%).

We note that the maximum concentration limitation of 0.3% in cosmetic products has been derived by NICNAS. This limitation appears to have been derived by the use of the repeat dose toxicity study result (NOAEL of 50mg/kg bw/day) and extremely conservative use estimates including:

- 100% dermal absorption of caprylhydroxamic acid,
- Use of every one of below listed products, all containing 0.5% of caprylhydroxamic acid every day;
    - Shower gel,
    - Handwash/soap,
    - Shampoo,
    - Hair conditioner,
    - Body lotion,
    - Face cream,
    - Hand cream,
    - Deodorant (non-spray),
    - Hair styling product,
    - Liquid foundation,
    - Make-up remover,
    - Eye make-up,
    - Mascara,
    - Lipstick, and
    - Eyeliner.

Accord does not believe that the calculations using these assumptions lead to accurate reflection of the risks arising from the use of caprylhydroxamic acid in cosmetics.

Recognising that the caprylhydroxamic acid is generally used in low concentration, and also recognising that there are no controls on the use of the substance internationally with no known adverse incidents to date, Accord believes that it is appropriate to keep caprylhydroxamic acid unscheduled.

ACCS meeting: July 2014

Phenol, 2-amino- (*o*-aminophenol)

Accord understands that 2-aminophenol is a hair dye ingredients that has been included in the banned list in the EU. Feedback from our Members suggests that the substance is either already phased out of use in Australia or is in the process of being phased out.

ACCS meeting: July 2014

Rosin; resin acids and rosin acids, calcium salts; resin acids and rosin acids, potassium salts; resin acids and rosin acids, sodium salts; rosin, polymerized; rosin hydrogenated

From feedback from our Members, Accord understands that at least one of the listed chemicals under this agenda item is used in cosmetics at up to 10%. Accord also understands that there are no restrictions in the EU or the USA for the use of these substances in cosmetics.

Accord notes that rosin is a form of resin derived from plants. Rosin and its derivatives have a long history of a wide range of uses including in food, medicines and consumer products as well as industrial uses.

We also note that colophony (another name for rosin) is included in Appendix B of the Poisons Standard when used as flux.

As far as we are aware, there have been no significant health concerns raised to date with the use of rosin in its varied uses. Based on this information, Accord does not believe scheduling of rosin is required.

ACCS meeting: July 2014

Tetrahydro-4-methyl-2-phenyl-2H-pyran

While Accord is unaware of the basis for the proposed scheduling consideration, Accord understands that tetrahydro-4-methyl-2-phenyl-2H-pyran can be used as a fragrance material. Accord is not aware of any other uses of the substance.

In previous submissions, Accord has raised concerns with the consideration of individual fragrance ingredients for scheduling when there is an international body International Fragrance Association (IFRA) assessing and managing the risks of chemicals used as fragrance and flavour. These concerns remain.

We note that we are not aware of any restrictions on tetrahydro-4-methyl-2-phenyl-2H-pyran in the EU, in cosmetics or in any other product preparations, or by the International Fragrance Association (IFRA). We are also not aware of any restrictions on its use in the USA.

On this basis, Accord respectfully requests that tetrahydro-4-methyl-2-phenyl-2H-pyran remain unscheduled.

ACCS meeting: July 2014

Toluenediamines

From Accord's reading of the NICNAS recommendations from their existing chemicals review of different isomers of toluenediamines, it appears, NICNAS is recommending separate entries for isomers of toluenediamine resulting in:

- Up-scheduling of 2,4-toluenediamine and its salts and 2,6-toluenediamine – currently allowed uses under S6 to move to Appendix C, and
- Down-scheduling 2,5-toluenediamine – include nail polish as allowed use under S6 (currently included in Appendix C).

Accord understands that this is an attempt to align the Poisons Standard with the EU Cosmetics Directive.

Generally speaking, inclusion in Annex II of the EU Cosmetics Directive leads to removal of the substance from cosmetics globally. This is in part due to the size of the EU market, but also due to the adoption of the EU Cosmetics Directive by ASEAN countries and New Zealand.

Feedback from our Members suggests that toluenediamine is used in hair dyes in Australia.

Unfortunately, we were unable to identify (within the consultation timeframe) the specific isomer used, although we suspect that it is most likely 2,5-toluenediamine given the status of other isomers in the EU.

In Australia, we understand that this entry has been carefully developed with extensive industry consultation over time. Further, we do not believe that NICNAS has established any additional safety concerns with respect to the use of these isomers (2,4-toluenediamine and 2,6-toluenediamine) in Australia.

Accord suggests that any change to the schedule entry of toluenediamine to align with the EU consider appropriate transition time for industry e.g. 24 months transition period may be appropriate to give industry transition time if the substances are currently in use. If the substances are not currently in use, the length of the transition period will have no effect i.e. no negative impact.