accord
hygiene, cosmetic & specialty products industry

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: chemicals.scheduling@health.gov.au

Dear Sir/Madam

Public Comment Submission to the July 2015 joint meeting of the Advisory Committee on Medicine Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS)

We refer to the notice published on 28 May 2015 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:

- Methylisothiazolinone (MIT); and
- Methylchloroisothiazolinone (MCI);

for consideration at the July 2015 meeting of the ACMS/ACCS.

Please see the attached submission for details.

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

We look forward to further advice from the ACMS, ACCS and the Delegate. Should the Committees 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]

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Products for healthy living and a quality lifestyle

ACMS/ACCS meeting: July 2015

Methylisothiazolinone (MIT)

Accord has previously provided comments on MIT for the July 2014 meeting of the ACCS. Our submission on MIT to that meeting is provided as Attachment 1.

In addition to the July 2014 meeting submission, we provide the following comments.

- MIT should be exempted from scheduling in both leave-on and rinse off cosmetics and topical therapeutic goods (such as medicated washes and sunscreens) in concentrations up to 100ppm noting that:
    - the EU Regulations currently allow the use of up to 100ppm MIT in both rinse-off and leave-on cosmetics, and
    - the CIR report concluded that it was safe to use MIT at up to 100ppm in rinse-off cosmetics and the safe level in leave-on cosmetics should be determined using a quantitative risk assessment.
- MIT is currently being used in consumer products other than cosmetics i.e. those with incidental and/or unintentional contact in Australia in concentrations up to 1000ppm.
- All industrial preparations would be controlled under the workplace regulatory regime including hazard classification, SDS and labelling requirements.

We also urge the Committees to consider a 24 months transition period for any scheduling decision to allow industry to reformulate products where this may be necessary.

ACCS meeting: July 2014

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.

ACMS/ACCS meeting: July 2015

Methylchloroisothiazolinone (MCI)

Accord notes that the NICNAS IMAP consideration of MCI appears to base its recommendations as though the chemical substance can exist on its own. However, it is our understanding that a major by-product of methylisothiazolinone (MIT) will always be present in the manufacture of MCI. The ratio of MCI to MIT is approximately 3:1.

We therefore respectfully request that the Committees consider scheduling of the MCI/MIT mixture with ratio 3:1 rather than scheduling MCI *per se*.

This approach is consistent with the regulatory treatment internationally of this preservative, where MCI/MIT (3:1 ratio) mixture is used to provide regulatory controls in e.g. the EU. This is also reflective of the industry's use of the preservative, where the concentration calculation is performed on the MCI/MIT mixture.

It is our understanding that MCI/MIT mixture is used as a preservative for the preservative action of the MCI i.e. MIT is not considered an active in this case but a by-product. It is also our understanding that the MCI/MIT mixture can be an effective preservative in cosmetics at 15ppm, provided that there is good hygiene in the manufacturing facility, and it is used by industry in concentrations up to 15ppm in cosmetics.

While we understand that the EU does not allow the use of MCI/MIT mixture in leave-on cosmetics, this is an acceptable practice in the USA, although only in concentrations of 7.5ppm or less. This conclusion was reached by the Cosmetics Ingredient Review (CIR) in 1992 after further sensitisation studies for products containing 15ppm MCI/MIT mixture and for products containing 7.5ppm mixture[1].

Also, we are aware of at least one cosmetic product in Australia with MCI/MIT level at above 7.5ppm (but below 15 ppm), and used in other consumer products i.e. with incidental and/or unintentional contact at up to 50ppm.

For consistency internationally MCI/MIT mixture should be exempted from scheduling when used in leave-on cosmetics at concentrations of 15ppm or less and in leave-on preparations at concentrations of 7.5ppm of less in line with the 1992 CIR report.

We also believe an appropriate exemption is necessary for other consumer products containing low levels of MCI/MIT mixture as a preservative. All industrial products should remain unscheduled noting that they would be controlled under the workplace regulatory controls including hazard classification, SDS and labelling.

For any scheduling decisions on MCI/MIT mixture, we strongly urge the Committees to consider a 24 months transition period to allow industry to reformulate products where this may be necessary.

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[1] http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr114.pdf

accord
hygiene, cosmetic & specialty products industry

The Secretary
Scheduling Secretariat
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Email: chemicals.scheduling@health.gov.au

Dear Sir/Madam

Supplementary Public Comment Submission to the August 2015 joint meeting of the Advisory Committee on Medicine Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS)

We refer to the notice published on 28 May 2015 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 provided information on:

- Methylisothiazolinone (MIT); and
- Methylchloroisothiazolinone (MCI);

for consideration at the July 2015 meeting of the ACMS/ACCS, in our submission dated 25 June 2015.

Since making the submission, Accord has become aware that the EU Scientific Committee on Consumer Safety (SCCS) has adopted a draft opinion on sensitization potential of MIT. The draft is dated 25 June 2015.

We provide this supplementary submission to highlight the new draft opinion of SCCS on MIT. While we note that the public comment period for the August 2015 joint ACMS/ACCS meeting is closed, we hope that this supplementary information will be accepted, given that it highlights new information that has come to light since the close of the public comment period. Further details are provided in the attached submission.

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

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

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Products for healthy living and a quality lifestyle

Yours faithfully

[unsigned for electronic submission]

[redacted]

ACMS/ACCS meeting: August 2015

Methylisothiazolinone (MIT) – supplementary information

The Scientific Committee on Consumer Safety (SCCS) adopted a draft opinion on MIT (sensitisation only) on 25 June 2015. The draft opinion is available from:

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_178.pdf.

Public comment period is open until 1 September 2015.

Accord believes that a careful consideration of both the SCCS draft opinion and the Cosmetic Ingredient Review (CIR) Safety Assessment of MIT (or MI) as used in cosmetics is necessary as the two expert bodies have reached very different conclusions.

As they are both contemporary assessments of MIT, we believe that this is a case of differing opinions from two expert bodies on scientific evidence and the conclusions to be drawn from them, rather than one opinion outdating the other. For example, we have counted that there are 17 references in common i.e. cited in both the SCCS draft opinion and the CIR Safety Assessment, even though the conclusions reached are very different.

The CIR Safety Assessment finalised on 8 October 2014 concluded as follows:

> *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 cosmetic products when they are formulated to be non-sensitizing, which may be determined based on a QRA.*

In comparison, the SCCS draft Opinion adopted on 25 June 2015 concludes as follows:

> ***1. On the basis of the data provided, does the SCCS consider Methylisothiazolinone (MI) to be safe for consumers, when used as a preservative in rinse-off products up to concentration limit of 100 ppm from the view of induction of contact allergy?***
>
> *The information provided does not support the safe use of MI as a preservative in rinse-off cosmetic products up to a concentration limit of 100 ppm from the view of induction of contact allergy.*
>
> *For rinse-off cosmetic products, a concentration of 15 ppm (0.0015%) MI is considered safe for the consumer from the point of view of induction of contact allergy.*
>
> ***2. On the basis of the data provided, does the SCCS consider Metylisothiazolinone (MI) to be safe for consumers, when used as a preservative in leave-on hair products up to concentration limit of 100 ppm from the view of induction of contact allergy?***
>
> *The information provided does not support the safe use of MI as a preservative in leave-on hair cosmetic products up to a concentration limit of 100 ppm from the point of view of induction of contact allergy.*
>
> ***3. Does the SCCS have any further scientific concerns with regard to the use of Methylisothiazolinone (MI) in cosmetic product***

The concerns and opinions raised in SCCS Opinion SCCS/1521/13 (12 December 2013with revision 27 March 2014) remain. The results of the recent Scandinavian study do not support safety of MI in rinse-off products at either 100 ppm or at 50 ppm for elicitation or induction.

It is our understanding that the test data on MIT e.g. HRIPT studies and LLNA are very favourable, showing low likelihood of sensitisation. However, we also understand that there is an increase in the number of patients showing MIT sensitisation. It is also questionable how patients are being sensitised, noting the widespread use of MIT outside the cosmetics sector, and there is an uncertainty in the elicitation and induction doses of MIT.

Given these somewhat contradictory evidence and "unknowns", we believe a careful consideration of all available evidence is warranted for risk management of MIT.

In addition to the scientific evidence provided in the CIR Safety Assessment and the SCCS draft opinion, Accord provides the following industry factors that should be taken into consideration for risk management decisions of MIT.

Effective concentration of MIT in products

MIT is used as a preservative at 100 ppm because it is the dose at which it is effective against bacteria. In some products (non-cosmetic products) it is used at up to 1000 ppm, a dose at which it is effective against fungi. It is our understanding that if the manufacturing facility is pristine i.e. much better than the usual good manufacturing hygiene levels, then 50 ppm may be enough for MIT to be effective against bacteria.

MIT is not an effective biocide at 15 ppm. If the SCCS draft opinion is adopted, this would mean a phase out of MIT from all cosmetic products, except as a by-product in CIT:MIT (3:1) preservative.

Availability and choice of preservatives – need for a broad overview

As noted in our previous submission to the July 2014 consideration of MIT, all preservatives show some level of toxicity. However, it is also recognised that preservatives play an important role in ensuring that every day products are not spoilt – spoilt products or products contaminated with bacteria and other harmful microorganisms can lead to infection and sepsis.

We believe that there is a need to maintain a broad choice of preservatives for formulators of products to choose from, provided that this does not lead to an unacceptable risk. We also believe that narrowing the choice of preservatives can potentially lead to increased risk from exposure to preservatives as more consumers are exposed to products containing a narrower range of preservatives i.e. increased exposure to a single type of a preservative.

In this context, removing MIT entirely from currently available range of preservatives may not be the best risk management option. However, there may be a case for limiting to use of MIT only to certain types of products and to certain concentration levels to ensure that the risk of sensitisation from contact with MIT is minimised.

Timing - final review document vs draft opinion

It must also be noted that the SCCS opinion is currently in draft and will not finalised until after the close of the public comment period. The final opinion is therefore unlikely to be published before the end of this year.

One of the options available to the Committees and the Delegates is to defer the final decision on MIT until the SCCS draft opinion is finalised. However, noting the wide spread use of MIT in all types of use i.e. industrial, consumer and cosmetic, we believe it may be prudent to consult on a detailed proposal for scheduling of MIT prior to finalisation of any decisions.

Transition time for any scheduling decisions

Once again noting the wide spread use of MIT, any scheduling decision on MIT should allow a 24 months transition. Where it is likely that reformulation is required, industry would need minimum 24 months to reformulate their products and phase out existing products.

9 June 2015

Australian Paint Manufacturers' Federation Inc.

The Secretary
Scheduling Secretariat
Department of Health
Therapeutic Goods Administration
GPO Box 9848
CANBERRA ACT 2601

Email: Chemicals.Scheduling@health.gov.au

Dear Sir/Madam

PUBLIC COMMENT SUBMISSION TO THE JULY 2015 MEETING OF THE ADVISORY COMMITTEE ON MEDICINES SCHEDULING (ACMS)

The Australian Paint Manufacturers' Federation (APMF) refers to the notice published on 28 May 2015 inviting public submissions for the July Committee Meeting, with respect to the proposed scheduling of substances under the *Therapeutic Goods Act 1989*.

The APMF is the peak national industry association that represents the surface coatings industry of Australia. Our members manufacture paints and inks.

The APMF wishes to provide information on Methylisothiazolinone (MIT) and Methylchloroisothiazolinone (MCI). Refer to our attached Submission.

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

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

Yours faithfully

UNSIGNED FOR ELECTRONIC SUBMISSION

[redacted]

Australian Paint Manufacturers' Federation Inc.

PROPOSED AMENDMENTS TO THE POISONS STANDARD (CHEMICALS)

JOINT ACCS/ACMS MEETING – JULY 2015

Methylchloroisothiazolinone (MCI)

Methylchloroisothiazolinone (MCI) as a substance is not available, it is only available combined with Methylisothiazolinone (MIT). The combination product is not a mixture of the two individual substances but is synthesised containing both substances. In the mixture the methylisothiazolinone has no biocidal activity due to the low concentration and has no effect on the sensitisation potential of the mixture. The combination of Methylchloroisothiazolinone and methylisothiazolinone, at a ratio of 3:1 is a biocide commonly used by paint, jointing compound, adhesive, sealant and polymer producers. It is already legislated by Safe Work Australia; a concentration of <15ppm methylchloroisothiazolinone/ methylisothiazolinone (3:1) can be present in any finished product or the product must be labelled with R43, May cause sensitisation by skin contact. The mixture is listed in the Safe Work Australia Hazardous Substances Information System (HSIS) under CAS 55965-84-9 as **Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [CAS No. 26172-55-4] and 2-methyl-2Hisothiazol-3-one [CAS No. 2682-20-4] (3:1)**. This limit was adopted by Safe Work Australia in July 2008 following changes to the classification in the EU Dangerous Substances Directive (DSD). The combination of methylchloroisothiazolinone/ methylisothiazolinone at levels of 20-30ppm was the norm for protection of paints, jointing compounds, adhesives, sealants and polymer dispersions in Australia before this classification was changed. No reports of sensitisation from paint applicators or other users have been traced back to the use of this biocide mixture in finished products at these higher levels. After the change to the classification producers in Australia altered their formulations to contain <15ppm to avoid labelling with the R43 risk phrase.

Excluding the use of the mixture in paints, jointing compounds, adhesives and sealants from scheduling is an appropriate outcome as producers of these products already limit the concentration to <15ppm to meet the Safe Work Australia requirements so as to avoid specific labelling. If this is not possible then an exemption at <15ppm for the uses outlined in any schedule in line with the HSIS would be acceptable to the APMF.

Methylisothiazolinone (MIT)

Methylisothiazolinone is a biocide commonly used by paint, jointing compounds, adhesive, sealant and polymer producers following the change in classification of the combined methylchloroisothiazolinone/ methylisothiazolinone (3:1). Methylisothiazolinone is not included in the Safe Work Australia Hazardous Substances Information System (HSIS) nor is it listed in the EU Classification Labelling Packaging (CLP) regulations. However, producers in the EU voluntarily agreed to classify MIT as a sensitiser at 1000ppm (0.1%) in line with labelling requirements for unclassified sensitisers. Correct classification of MIT under the Safe Work Australia guidelines for classifying hazardous chemicals would require manufacturers to include the R43 Risk phrase on their labels if they exceeded the 1000ppm level of MIT. Manufacturers of paint, jointing compounds, adhesives and sealants in Australia are using levels well below this concentration.

Excluding the use of the methylisothiazolinone in paints, jointing compounds, adhesives, sealants from scheduling is an appropriate outcome as producers of these products already limit the concentration to below the labelling requirement of the EU CLP Regulations and the Safe Work Australia requirements. The issue of an effect on consumers from the use of methylisothiazolinone appears to be limited to the use of MIT in leave-on cosmetics and the APMF considers that any scheduling for the use of MIT should be limited only to this use.

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25 June 2015

The Secretary
Scheduling Secretariat
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Email: Chemicals.Scheduling@health.gov.au

Dear Sir or Madam,

Invitation for public comment - ACCS meeting and joint ACCS/ACMS meeting, July 2015
Public consultation on the proposed amendments to the Poisons Standard (Chemicals)

We refer to the invitation seeking comments in relation to the proposed scheduling amendments by the delegate which will be considered by the joint committee of the ACCS and the ACMS.

ASMI would like to provide comment in relation to the methylisothiazolinone (MIT) proposal that has been referred to the July 2015 joint meeting.

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 notes that MIT is used in cosmetic products and in therapeutic goods and is entered as an ingredient on the ARTG. MIT is used as a preservative in topical products, such as sunscreens, antiseptic hand washes, moisturisers, shampoos, conditioners and disinfectants.

ASMI supports harmonisation of requirements with comparable overseas markets and with this in mind, ASMI suggests that MIT should be exempted from scheduling in both leave-on and rinse-off topical products at concentrations up 0.01% (i.e. 100ppm). This limit should apply to both cosmetics and to therapeutic goods and would be consistent with the current MIT levels in these products. This would also be consistent with US recommendations[1] and with current EU regulations[2]. ASMI notes that the SCCS Scientific Opinion[3] on MI, although suggesting a lower allowable limit for topical products, does pre-date the US recommendations.

[1] http://www.cir-safety.org/sites/default/files/mthiaz062014tent_0.pdf
[2] http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32014R1003&from=EN
[3] http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_145.pdf

Should a new scheduling entry for MIT result, then ASMI requests that the Committees allow a 24 month transition period so as to give affected manufacturers sufficient time to reformulate their products if necessary. ASMI requests this timeframe given the difficulties associated with re-formulations affecting preservative systems.

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

29th June 2015

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 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, the scheduling proposal is to list 3-isothiazolone, 2-methyl- Schedule 6 or Schedule 10/Appendix C with concentration exemption cut-offs for preparations containing low concentrations of methylisothiazolinone.

MIT is a preservative which has a long history of safe and effective use in personal care products at concentrations up to 100ppm (0.01%)[1]. However, due to recent increases in reports of sensitisation starting from 2010 in cosmetics in the EU, the chemical has been reassessed by the European Commission Scientific Committee on Consumer Safety (SCCS) and The Cosmetic Ingredient Review (CIR) Expert Panel.

CIR Expert Panel

The CIR Expert Panel has previously considered the safety of MIT (2010) and had concluded that MIT is safe for use in cosmetic formulations at concentrations up to 100ppm. In 2013, the expert panel reviewed newly available clinical data indicating a higher than expected frequency of people with allergic reactions to MIT. Due to this new information, the panel reopened the safety assessment of MIT in order to gather and assess any newly available data.

In June 2014, the expert panel reviewed the safety of Methylisothiazolinone and issued a final report on October 8th, 2014. The Panel reviewed QRAs conducted by Cosmetics Europe and the CIR SSC and took these results into consideration when making their recommendation. The panel recognised that skin sensitisation to MIT depends on the dose of the ingredient per surface area of skin, in addition to the frequency of exposure. For example a shampoo, a baby wipe and a sunscreen will all have different exposure rates and sensitisation potential due to the way these products are used.

The report concluded that Methylisothiazolinone is recognized as safe for use in rinse off cosmetic products in concentrations up to 100ppm (0.01%) and leave-on cosmetic products when they are formulated to be non-sensitizing, which may be determined using a quantitative risk assessment (QRA)[2].

European Commission Scientific Committee on Consumer Safety (SCCS)

The SCCS (Scientific Committee on Consumer Safety), Opinion on Methylisothiazolinone-Submission II, 12 December 2013, SCCS/1521/13, revision of 27 March 2014 is the most current opinion on MIT from the SCCS.

The SCCS opinion is that for leave-on cosmetic products no safe concentrations of MIT for induction or elicitation of contact allergy have been adequately demonstrated.
For rinse off cosmetic products the SCCS has suggested that a concentration cut off of 15ppm is considered safe from an induction of contact allergy view point. No information is available on elicitation of contact allergy.
It is important to note that EU cosmetic regulation has not yet been revised to reflect the SCCS recommendation since the issue of the 2014 report, and MIT is still allowed as a preservative in cosmetics at a concentration up to 100 ppm (.01%) for both leave on and rinse off cosmetic products.

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
European Union	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, EU and NZ, with a maximum allowable cut-off of 100ppm (0.01%).

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Considering the recent reviews by the CIR panel and the SCCS[redacted] acknowledges the need for an appropriate low concentration cut off for MIT in cosmetic products.

[redacted]MIT should be exempted from scheduling in both leave-on and rinse off cosmetics and topical therapeutic goods in concentrations of 100ppm or less noting that:

- the EU cosmetic Regulations currently allow the use of up to 100ppm MIT in both rinse-off and leave-on cosmetics, and
- the CIR report, which is the most recent safety evaluation, concluded that it was safe to use MIT at up to 100ppm in rinse-off cosmetics and the safe level in leave-on cosmetics should be determined using a quantitative risk assessment.

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

3(2H)-isothiazolone, 5-chloro-2-methyl- (MCI)

In response to issues raised in a NICNAS IMAP report for 3(2H)-isothiazolone, 5-chloro-2-methyl-, the scheduling proposal is to list methylchloroisothiazolinone (MCI) in Schedule 6 or Schedule 10/Appendix C with concentration exemption cut-offs for preparations containing low concentrations of methylchloroisothiazolinone.

Our understating is that MCI is almost always found with MIT as a mixture in cosmetics, usually in a 3:1 ratio. Considering the safety of the mixture has been assessed by The Cosmetic Ingredient Review (CIR) Panel and the European Commission Scientific Committee on Consumer Safety (SCCS), JJP proposes that the Committee considers the scheduling of the MCI/MIT mixture with ratio 3:1 rather than scheduling the single ingredient of MCI.

CIR Expert Panel

The CIR Panel has previously reviewed the safety of MCI/MIT (1992) with the conclusion that the mixture, may be safely used in rinse off products at 15ppm or less and 7.5ppm or less for leave on products.[2]

European Commission Scientific Committee on Consumer Safety (SCCS)

The latest SCCS (Scientific Committee on Consumer Safety) Opinion on MCI/MIT is from 2009.

The SCCS conclusion in the 2009 report was that the mixture of MCI/MIT in a ratio of 3:1 does not pose a risk to the health of the consumer when used as a preservative up to a maximum authorised concentration of 15ppm (.0015%) in rinse off cosmetic products, apart from its sensitising potential.

A cut off for leave on cosmetic products has not been proposed by the SCCS.

CURRENT OVERSEAS REGULATORY CLASSIFICATION FOR METHYLCHLOROISTHIAZOLINONE/METHYLISOTHIAZOLINONE

COUNTRY	RESTRICTIONS
European Union	Max concentration in ready for use preparation: 0.0015% (of a mixture in the ration 3:1 of 5-chloro-2-methyl-isothiazol
New Zealand	No specific limits required
USA	No specific limits required
Canada	Methylchloroisothiazolinone is only permitted in combination with methylisothiazolinone. Permitted at concentrations equal to or less than 0.0015% (15 µg/mL or 15 ppm) in rinse-off products and 0.00075% (7.5 µµg/mL or 7.5 ppm) in leave-on products.

The above are key country classifications of MCI when used as a mixture with MIT. Currently, there are restrictions for a maximum of 15ppm (.0015%) in the EU and Canada for rinse off products. Canada also allows up to a maximum of 7.5ppm for leave on products.

[redacted]

Considering the most current reviews by the CIR panel and the SCCS[redacted] acknowledges the need for an appropriate low concentration cut off for MCI/MIT as a preservative mixture in cosmetic products.

[redacted]MCI/MIT as a mixture should be exempt from scheduling for leave-on cosmetics and topical therapeutic goods in concentrations of 7.5ppm or less, and for rinse off cosmetics and topical therapeutic goods in concentrations of 15ppm or less noting that:

- the EU cosmetic Regulations currently allow the use of the mixture up to 15ppm for both rinse-off and leave-on cosmetics, and the latest SCCS opinion recommends a maximum of 15ppm in rinse off cosmetic products.
- the CIR report concluded that it was safe to use MIT at up to 15ppm in rinse-off cosmetics and 7.5ppm in leave on cosmetics.

If a lower concentration cut-off is proposed which impacts products currently on the market, the time required to reformulate should be taken into consideration when

proposing an implementation timeframe. Industry would require 24 months in order to reformulate products and comply with any proposed cut off.

Summary

In summary, [redacted] acknowledges the need for appropriate low concentration cut off for MIT and MCI/MIT mixture in cosmetics and topical therapeutic goods taking into consideration the recent assessments from the European Commission Scientific Committee on Consumer Safety (SCCS) and The Cosmetic Ingredient Review (CIR) Expert Panel.

[redacted]MIT should be exempted from scheduling in both leave-on and rinse off cosmetics and topical therapeutic goods in concentrations of 100ppm or less.
[redacted] to exempt the MCI/MIT mixture from scheduling when used in rinse off cosmetics at concentrations of 15ppm or less and in leave-on preparations at concentrations of 7.5ppm or less.
Should the Committee and Delegate decide to proceed with the proposals, an appropriate transition time of 24 months should be given to allow sponsors and manufacturers to implement the changes for existing products.

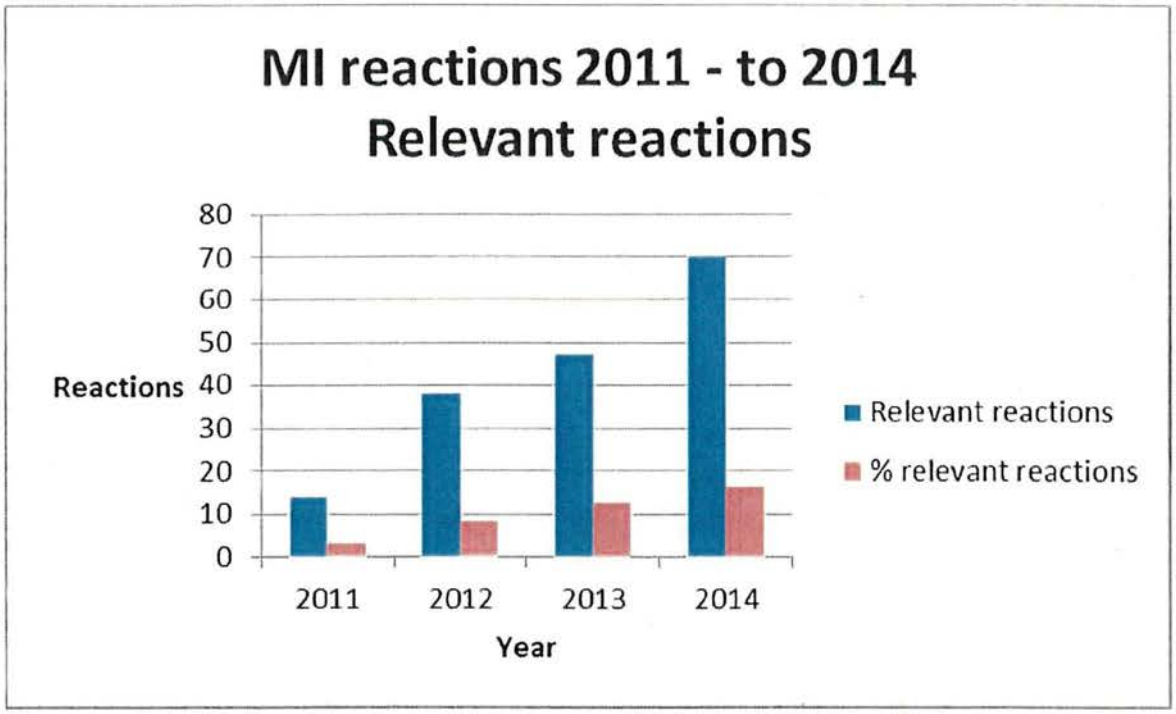
[redacted]

[redacted]

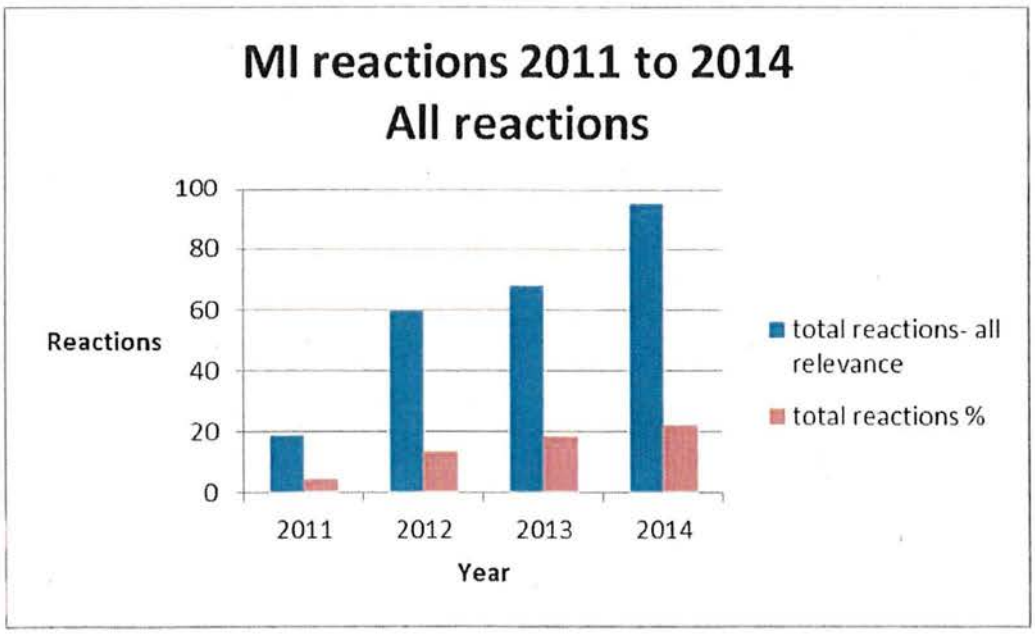
References:

1. International Journal of Toxicology 29(Supplement 3) 187S-213S, 2010 on request
2. Amended Safety Assessment of Methylisothiazolinone as Used in Cosmetics. Final Amended Report. October 8th, 2014. Cosmetic Ingredient Review Expert Panel
3. Opinion on Methylisothiazolinone Submission II. 12 December 2013. Revision of 27 March 2014

[redacted] supplied [redacted] AUSTRALIAN DATA



All reactions



Australasian Journal of Dermatology

Allergic contact dermatitis to methylisothiazolinone: exposure from baby wipes causing hand dermatitis

Journal:	*Australasian Journal of Dermatology*
Manuscript ID:	AJD-2013-0069.R1
Manuscript Type:	Original Research
Keywords:	preservative, allergy, hand, methylchloroisothiazolinone, isothiazolinone, Kathon CG, occupational, cosmetic, moist wipe, wet wipe

Media Statement

SA Health

Wet Wipes Warning

Minister for Health **Jack Snelling** MP is urging members of the public to be more aware of the effects of a preservative, commonly found in baby wipes, following an increase in allergic dermatitis cases in recent times.

The preservative, known as *methylisothiazolinone* (MI), is used to prevent bacterial contamination and is commonly found in personal hygiene products such as baby wipes, moisturisers and cosmetics, as well as industrial products including paint and wallpaper glue.

Allergic dermatitis is a common skin condition which causes an itchy and weeping rash localised to the area in contact with the allergic trigger. It usually develops two or more days after contact with the allergen and lasts as long as contact continues and for a short time afterwards, typically one to two weeks.

Minister Snelling said dermatologists working both in South Australia's hospitals and in the community had seen a significant increase as a result of patch testing. Patch Testing involves a clinician putting a specific allergen directly on the patients skin for 2 days to demonstrate allergy. Australian Patch test clinics have recently recorded up to 10 to15% of all tested patients allergic to Methylisothiazolinone compared with 2-4% in 2005 when this preservative was only used in industrial products. Our figures are comparable with UK,Thailand,German and most recently the Victorian Skin and Cancer combined General and Occupational Patch Test clinics have recorded prevalence approaching 20% of all patients tested. It is of major concern.

"Allergic reactions to MI, such as hand dermatitis, are typically found in mothers and babies who are frequently in contact with baby wipes," Minister Snelling said.

"Dermatologists are now also treating patients who have been exposed to industrial materials following sensitization from cosmetic and personal hygine exposure.

"I would encourage people who may be experiencing a reaction to see a dermatologist, and if it is found that they are allergic to MI, to thoroughly check labelling before purchasing products."

Head of Dermatology at Flinders Medical Centre Dr **Lynne Gordon** said she had seen severe dermatitis caused by Baby wipe type products used for personal hygiene in the elderly,time poor workers "freshening up",anal hygiene as well as the very common hand dermatitis in new mothers.

For more information

Call the Southern Adelaide Local Health Network media line
Telephone: 08 8204 4949

www.twitter.com/sahealthnews www.youtube.com/sahealthaustralia

Government of South Australia
SA Health

While traditionally patients who experience an allergic reaction to MI have had direct skin contact with the preservative, cases are now emerging of airborne allergic reactions where a patient has been exposed to the volatile preservative from a freshly painted room and as a result have a severe dermatitis of the face particularly around the eyes.

Dr Gordon and the Australasian College of Dermatologists are supporting the EU led review of MI levels in a bid to reach an international agreement on optimal concentration levels in products.

"The challenge clinicians face is that there are currently recommended guidelines for the dosage levels of this preservative in Australia, however we believe these levels are too high," Dr Gordon said.

"A positive step forward regarding MI would be to adopt the EU led safe usage levels internationally . This would preclude use in traditional 'leave on' products for example sunscreens,moisturizers and personal hygiene products and adopt lower safe concentrations for' rinse off 'products. This will it is anticipated prevent new cases of sensitization and protect people already sensitized to this allergen. In addition it will be critical for Australia to follow the EU lead to consider accurately label domestic(cosmetic) and industrial products as well as cosmetics containing MI. Product labelling is only mandated in EU countries at present in cosmetics.

"A good example of how this has been managed in the past is with the preservative *parabens* with international experts agreeing on safe usage of this in products."

For more information

Call the SA Health Media Line
Telephone: 08 8226 6488

Government of South Australia
SA Health