Public Submissions on the Proposed Amendments to the Poisons Standard

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

The 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 joint committee of ACCS-ACMS #9 (July 2014 meetings).

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

Material claimed to be commercial-in-confidence was considered against the guidelines for the use and release of confidential information set out in Chapter 6 of the Scheduling Policy Framework for Medicines and Chemicals (SPF, 2010), issued by the National Coordinating Committee on Therapeutic Goods. The SPF is accessible at www.tga.gov.au/industry/scheduling-spf.htm.

Two submissions were received. One submitter provided a submission that related to multiple substances and this has been separately grouped.

List of Submissions

Substance	Total number of public submissions
3,7-Dimethyl-2,6-octadienal isomers (CITRAL, geranial and neral)	2 (1 submission on multiple substances)
Triethanolamine	1 submission on multiple substances
Zinc lactate	1 submission on multiple substances

Submission on Multiple Substances

One submission was on 3,7-dimethyl-2,6-octadienal isomers (citral, geranial and neral), triethanolamine and zinc lactate.

accord
hygiene, cosmetic & specialty products industry

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: SMP@health.gov.au

Dear Sir/Madam

Public Comment Submission to the March 2014 joint meeting of the Advisory Committee on Chemicals Scheduling (ACCS) and the Advisory Committee on Medicines Scheduling (ACMS)

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 **citral (also neral and geranial), triethanolamine and zinc lactate** for consideration at the July 2014 joint meeting of the ACCS and ACMS.

Please see the attached submission for details.

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

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 ACCS, ACMS 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]

30 June 2014

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ACCS/ACMS joint-meeting: July 2014

Citral, neral and geranial

In response to a request from the Delegate, Accord provided information relating to the use of citral, neral and geranial in consumer and cosmetic products in Australia. Accord also provided a list of naturally derived plant extracts containing citral, neral and geranial, and the average concentration of the substances in the plant extracts.

If the Delegate decides that scheduling of citral, neral and geranial is necessary based on the information provided and other information available to the Committees and the Delegate, we request that low concentrations are exempted from scheduling. The exemption concentration could be aligned with the International Fragrance Association (IFRA) Standard for citral. We have also previously provided the Standard to the Committees for consideration.

ACCS/ACMS joint-meeting: July 2014

Triethanolamine

We note that triethanolamine was considered at the March 2014 meeting of the ACCS. Accord provided comments on the industrial and cosmetic uses of triethanolamine, but noted that intra dermal application did not fit the definition of cosmetic and such uses should be considered by the ACMS.

The consideration of triethanolamine before the ACMS/ACCS joint Committees for this meeting appears to be focussed solely on the use of triethanolamine in intradermal applications for tattoo removal.

Noting that other uses of triethanolamine have been considered previously, and also noting that no changes to the current industrial uses of triethanolamine were considered necessary at the last meeting of the ACCS, Accord respectfully suggests that any consideration of triethanolamine use be restricted to the intradermal use of triethanolamine in tattoo removal preparations.

ACCS/ACMS joint-meeting: July 2014

Zinc lactate

For the March 2014 ACMS/ACCS pre-meeting consultation, Accord compared the proposed concentration limitations of zinc lactate in toothpaste with allowable zinc concentration levels in complementary medicines with and without RASML statements. The calculation used for the pre-meeting submission was a rough calculation using rounded figures, and the submission did not detail the calculation method perhaps as clearly as it should. For this I apologise to the Committees – unfortunately, we were previously rushed trying to provide comments on such a large number of agenda items at that time.

During the consultation period after the Delegate's Interim Decision, Accord provided further comments on zinc lactate, clearly setting out our proposed amendments to the proposed schedule entry, and the calculation and logic used to derive that value. For the full information, please refer to our submission to the Delegate's Interim Decision.

Accord respectfully requests that the ACMS/ACCS reconsider the scheduling proposal.

[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).

[redacted]

[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]

[redacted]

3,7-dimethy-2,6-octadienal isomers- (CITRAL)
Proposal for a new Schedule 5 entry with a yet to be determined low concentration cut off.

[redacted] the proposal for a new Schedule 5 entry with a yet to be determined low concentration cut off in February 2014. The response has been copied as per below:

Citral is contained in a number of [redacted] on and rinse off cosmetic products, and is usually a part of a proprietary fragrance or flavour rather than an individual ingredient in formulations. As such the concentration of Citral in the proprietary fragrances and flavours used in our products is very low, (0.0001%-0.002%). All fragrances used have been assessed for safety by IFRA.

IFRA are an internationally recognised association which assesses the safety and toxicity of fragrances globally. IFRA works closely with regulators and stakeholders to issue and update comprehensive safety standards. Its members account for 90% of the global production volume of fragrance compounds and the IFRA Code of Conduct prescribes the behaviour that is expected of them. Its comprehensive global compliance programme also

[redacted]

independently spot checks fragranced products to ensure their compliance with the IFRA Code of Practice[2]. The IFRA standard for Citral is attached for your information[3].

[redacted] products undergo rigorous safety testing in humans during their development. Tests may include cumulative irritation studies tested by independent dermatologists, RIPT (repeat insult patch testing), photoallergy and phototoxicity testing. Our formulations which contain Citral are supported by these safety studies.

OVERSEAS REGULATORY CLASSIFICATION FOR CITRAL

COUNTRY	RESTRICTIONS
European Union	The presence of the substance must be indicated on product labelling when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products
New Zealand	The presence of the substance must be indicated on product labelling when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products
USA	No specific limits required
Canada	No specific limits required

The above are key country classifications of Citral. There are no restrictions on use of Citral in any of the 4 key regions listed in the table. The only requirement is for product labelling to include the ingredient when above a certain concentration in the EU and New Zealand. Currently, in Australia, Citral is unscheduled and has no specific labelling requirements when used in cosmetics. Additionally, there are no regulatory or safety issues in the key global markets above that we are aware of for the use of Citral in cosmetic products.

The impact of including cosmetic products containing Citral under schedule 5 of the Poisons Standard would be that products such [redacted], which are considered safe for their intended use by consumers, would be captured and would be required to include strict warning statements on consumer packaging, including the words CAUTION on the front label. This is not appropriate nor warranted for cosmetic baby products which have been used by consumers for many years without any serious safety issues.

In summary, [redacted] view is that Citral should remain unscheduled as the safety of the ingredient when used in fragrances has been established by IFRA. Citral has been used in fragrances contained [redacted] cosmetic products for many years with no known safety issues. Additionally, no other market restricts the use of Citral in cosmetic products. If a Schedule 5 entry is adopted we strongly urge the Committee and the Delegate to exempt the use of Citral in fragrances and flavours contained in cosmetic products. An example would be as per the below:

[redacted]

SCHEDULE 5

3,7-Dimethy-2,6-octadienal isomers (CITRAL, geranial and neral) ***except*** *in preparations for cosmetic use.*

[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]

[redacted]

Summary

[redacted]

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

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

References:

1. [redacted]
2. www.ifraorg.org/
3. IFRA standard for CITRAL
4. [redacted]

[redacted]