

Public Consultation on the Proposed Amendments to the Poisons Standard

The delegates of the Secretary to the Department of Health publish herein all valid public submissions made in response to the invitation for public submission on the interim decisions regarding the proposed amendments to the Poisons Standard (commonly referred to as the Standard for the Uniform Scheduling of Medicines and Poisons - SUSMP). These submissions were considered by the chemicals scheduling and medicines scheduling delegates.

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

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

One submitter provided submission that related to multiple substances.

List of Submissions

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

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: chemicals.scheduling@health.gov.au

Dear Sir/Madam

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

We refer to the notice published on 30 September 2014 of the Delegate's interim decision under subsection 42ZCZP of the *Therapeutic Goods Regulations 1990*, inviting public submissions, with respect to certain substances, addressing a matter raised in section 52E of the *Therapeutic Goods Act 1989*.

Accord provided comments on 3,7-dimethyl-2,6-octadienal isomers (citral, geranial and neral); triethanolamine; and zinc lactate for consideration at the joint meeting of the ACMS and ACCS held in July 2013.

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

Accord notes and supports the Delegate's Interim decisions **3,7-dimethyl-2,6-octadienal isomers (citral, geranial and neral)** and **triethanolamine**, and provides further comments on the Interim Decision of **zinc lactate**. Please see attached submission for details.

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

Yours sincerely

[Unsigned for electronic submission]

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

Tel: 61 2 9281 2322 Fax: 61 2 9281 0366 Website: www.accord.asn.au

Products for healthy living and a quality lifestyle

Delegate's Interim Decision - ACCS/ACMS Joint-meeting: July 2014

1.3 Zinc lactate

Accord notes that the Scheduling Committees have affirmed their recommendation to the Scheduling Delegate for zinc lactate, and the Scheduling Delegate has accepted that recommendation.

We note that reason for the Scheduling Committees' recommendation was based on the "potential risk of ingestion of excessive amounts of zinc in toothpaste, especially in children under 12 years of age". While we understand that there is a risk of chronic effects from over consumption of zinc, the Interim Decision appears overly conservative.

The Delegate also referred the TGA's approval of the use of zinc lactate as a registered and listed toothpaste at 2.5% for use only by adults and children aged 12 years and older. While we note that this creates a consistency between the current TGA controls and the Poisons Standard, it has the potential to create disharmony in the future. It is our understanding that the TGA has not assessed the maximum allowable levels of zinc lactate. The current TGA controls simply reflect the fact that these are the products currently available on the Australian market. The TGA may be requested to assess a product containing a higher concentration of zinc lactate in the future.

However, we understand that the Scheduling Committees are unlikely to consider this matter again. We therefore state our concerns with the risk management conclusion reached by the Scheduling Committees and provide our reasons below.

The recommended daily intake (RDI) of 12 mg/day for adults and 4.5 mg/day for children within the Food Standards Australia and New Zealand (FSANZ) is not the maximum amount under which the consumption should be kept below. It is the recommended daily consumption rate. It is also worth noting that this recommended value varies between countries. For example, the current zinc RDI calculated by the US National Institutes of Health (NIH), Office of Dietary Supplements is summarized below:

Table 1: Recommended Dietary Allowances (RDAs) for Zinc¹

Age	Male	Female	Pregnancy	Lactation
0–6 months	2 mg*	2 mg*		
7-12 months	3 mg	3 mg		
1–3 years	3 mg	3 mg		
4–8 years	5 mg	5 mg		
9–13 years	8 mg	8 mg		
14–18 years	11 mg	9 mg	12 mg	13 mg
19+ years	11 mg	8 mg	11 mg	12 mg

*Adequate Intake

Zinc is an essential mineral required for human body and is found naturally in many foods like shellfish, nuts, meat and legumes. Oysters for example are particularly high in zinc – half a dozen oysters (approximately 84 g) contain approximately 33 mg of zinc² i.e. well above the RDI for adults and children in both US and Australia.

¹ <http://ods.od.nih.gov/factsheets/Zinc-HealthProfessional/#h3>

² <http://ods.od.nih.gov/pubs/usdandb/Zinc-Content.pdf>

Some processed foods in the USDA National Nutrient Database for Standard Reference table³ with high levels of zinc includes cereal (e.g. Kellogg’s All-Bran Complete wheat flakes – 14.99 mg/0.75 cup serve) fast food burgers (e.g. Burger King Double Whopper with cheese – 13.96 mg) and chocolate bars (e.g. Snickers Marathon Double Chocolate Nut bar – 7.46 mg).

This clearly does not mean that consuming foods containing zinc at these levels (above RDI levels) cause chronic health risks.

To address the potential chronic risk from zinc consumption, the US NIH considered the tolerable upper intake levels i.e. the upper level of daily consumption at which chronic effects are unlikely.

Table 3: Tolerable Upper Intake Levels (ULs) for Zinc⁴

Age	Male	Female	Pregnancy	Lactation
0–6 months	4 mg	4 mg		
7-12 months	5 mg	5 mg		
1–3 years	7 mg	7 mg		
4–8 years	12 mg	12 mg		
9–13 years	23 mg	23 mg		
14–18 years	34 mg	34 mg	34 mg	34 mg
19+ years	40 mg	40 mg	40 mg	40 mg

In our previous submission, we have shown that zinc intake from toothpaste, using a conservative estimate is < 20 mg. This is assuming that all the toothpaste used to brush teeth is ingested and assuming that everyone is using adult sized toothbrushes with adult portions of toothpaste.

Molecular weight of zinc lactate: 241.4

Atomic weight of zinc: 65.4

Estimated daily exposure to toothpastes for adults: 2.75g⁵

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

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

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

We also calculated that up to 3% zinc lactate in the product results in < 25 mg (22.3 mg) daily zinc consumption (assuming that all the toothpaste is eaten). If used properly (dispelled after brushing), we calculated < 1 mg zinc consumption from toothpaste containing 2.5% zinc lactate.

In reality, young children use smaller amounts of toothpaste (no more than pea sized portion per brushing), with special care taken with toothpaste containing fluoride⁶. We expect less than half the adult exposure to toothpaste for children.

Given the consideration of the tolerable upper intake level of zinc and the extremely conservative estimate of zinc exposure from toothpaste, we believe that warning statements are unnecessary for toothpaste containing 3% or less zinc lactate. Consuming the entire quantity of toothpaste provides as much zinc as a single serving of some breakfast cereal. We have previously proposed the following schedule entry:

³ <http://ods.od.nih.gov/pubs/usdandb/Zinc-Content.pdf>

⁴ <http://ods.od.nih.gov/factsheets/Zinc-HealthProfessional/#h3>

⁵ Based on the *Notes of Guidance for Testing of Cosmetic Ingredients and Their Safety Evaluation 8th revision* published by the Scientific Committee of Consumer Safety (SCCS) in 2012 (http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_006.pdf)

⁶ http://www.ada.org.au/app_cmslib/media/lib/1103/m297017_v1_policy%20statement%202.2.1.pdf

Schedule 6 – New Entry

ZINC LACTATE in toothpastes **except:**

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

Even if an extremely conservative view was taken, as a minimum there should have been a graded consideration of zinc concentration in toothpaste and application of labelling statement e.g. noting that parents either brush the teeth of or closely supervise young children (between 2-5 years of age) brushing their teeth, no warning statement below 1.5% (approx. 11 mg of zinc exposure based on adult quantity of toothpaste being consumed daily) should be required.