[redacted]

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 5 February 2018 of the Delegate's interim decisions under subsection 42ZCZP of the *Therapeutic Goods Regulations 1990*, inviting public submissions, with respect to certain substances, addressing a matter raised in section 52E of the *Therapeutic Goods Act 1989*.

Accord provided comments on the following ACCS agenda items for the November 2017 meeting:

- 1-Deoxy-1-(methylamino)-D-glucitol, N-C10-16 acyl derivatives
- Phenyl methyl pyrazolone
- Silver oxide

Please find further comments on these items below.

We look forward to further advice from the Delegate. Should the Delegate require any additional information from Accord at this stage please do not hesitate to contact me on (02) 9281 2322.

Yours sincerely

[unsigned for electronic submission]

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Science & Technical Regulatory Associate

5 March 2018

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ACCS meeting: November 2017

1-Deoxy-1-(methylamino)-D-glucitol, N-C10-16 acyl derivatives

Accord notes the Delegate's interim decision to amend the current Schedule 6 entry for 1-deoxy-1-(methylamino)-D-glucitol N-coco acyl derivatives and include cross reference to cocoyl methyl glucamide, lauroyl methyl glucamide, myristoyl methyl glucamide in the index.

We are extremely concerned with this interim decision for a number of reasons:

1. Recent advice from the Committees on other surfactants (docusate sodium, sodium α-olefin sulfonates and sodium alkyl sulfates) was that *"there is no evidence of a public health risk"* from these kinds of substances, and that a review into the scheduling of all surfactants should take place. We therefore remain unsure as to why a surfactant substance such as *1-Deoxy-1-(methylamino)-D-glucitol, N-C10-16 acyl derivatives* would be on the agenda for consideration by the Committee when a broader review has been flagged. Consideration of this substance for scheduling now, only serves to further perpetuate the inconsistent and piecemeal approach to the risk management of surfactant substances in Australia, and perversely imposes stricter controls on new, less hazardous surfactants when compared with older chemistry such as the lauryl sulfate salts[1].

   There have also been several recent examples of surfactant substances that were considered by the Committees and found not to require scheduling such as docusate sodium, sodium α-olefin sulfonates and sodium alkyl sulfates. It is imperative that a consistent, evidence-based approach is applied to the consideration of surfactant substances.

2. We do not believe that scheduling of this surfactant will lead to a better risk management outcome as the risks of surfactants are already well managed. The public have a good understanding that surfactant-based products such as shampoos, soaps and detergents are irritating to skin and eyes and will instinctively rinse their eyes in case of accidental contact, without being prompted by the label. In fact, if accidental eye contact did occur, attempting to read any instructions on the product label at that stage may prove to be problematic.

   The NICNAS secondary notification report also does not identify any significant public health risks that would require risk management through scheduling of these substances, stating that (our underlining): *"The main risk of eye damage and irritation will be expected from the use of cosmetic products containing the notified chemical. Given the low proposed use concentration in cosmetics (i.e. ≤ 7%), use in rinse-off cosmetics only and likely dilution upon application, <u>significant eye irritation effects are not expected</u>. The eye irritation risk associated with use of the notified chemical in consumer products may be <u>further minimised</u> by the inclusion of appropriate labelling and directions for use to warn against eye contact."*

3. The scheduling of surfactants is out of step with international requirements. As far as we are aware, no other advanced economy has placed restrictions on commonly used surfactants.

The interim decision states that "The primary intent of the existing entry for 1-deoxy-1-(methylamino)-D-glucitol N-C10-16 acyl derivatives is to provide label directions that the eyes

[1] Page 203 of the Poisons Standard March 2018

should be washed if the chemical gets in the eye.". The effect of the schedule entry in practice goes much further than this, requiring significant front-of-pack warnings for spray products, and other products that do not meet the exemptions, including the signal heading POISON as well as other packaging and storage and handling requirements. This level of regulatory intervention for surfactant-based products is completely disproportionate to the low level of risk presented by these products. It is also confusing for consumers when trying to reconcile the actual level of risk of using a product, when such POISON warnings are carried by much more hazardous products.

Accord does not support the scheduling of *1-Deoxy-1-(methylamino)-D-glucitol, N-C10-16 acyl derivatives.* If the delegate believes that these surfactants require scheduling controls, this should be considered in the context of the lauryl sulfate salts entry. As SLS is known to be one of the harshest surfactants in use, we would expect to see higher concentration cut-offs for these less hazardous substances. In order to ensure regulatory consistency, we would also expect the same understanding used when considering SLS to be applied, in that all current uses of the surfactant were excluded from scheduling.

We note that the proposed implementation date is 1 June 2018. This will be approximately 2 months from the date of publication of the final decision and is simply not adequate to accommodate any changes required to the labelling and/or reformulation of products. We request that any scheduling decision that would require such changes include an adequate transition period of at least 12 months, i.e. an implementation date of 1 June 2019 at the earliest. Any changes would affect products currently in the Australian market with an established history of safe use. To our knowledge, there is no evidence that would suggest immediate action is required for the risk management of these substances.

We reiterate our in-principle support for the wider review of the scheduling of surfactant substances as advised by the Committees previously, and look forward to further engagement with the Delegate and the Committees on this matter.

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Phenyl methyl pyrazolone

Accord notes the Delegate's interim decision to create a new Schedule 6 entry for *phenyl methyl pyrazolone* with an exception for use in hair dye and eyebrow/eyelash preparations at a concentration of 0.25 per cent or less after mixing.

We have no objections to aligning the scheduling controls for this substance when used in cosmetics with those of the EU, noting that *phenyl methyl pyrazolone* is included in Annex III of the EU Cosmetics Regulation, allowing its use as a hair dye substance in oxidative hair dye products with an in-use concentration (after mixing under oxidative conditions) not exceeding 0.25%.

As mentioned in our pre-meeting submission, it is important to harmonise any warning statements and safety directions as much as possible with those required in the EU given that the vast majority (if not all) hair dye products in Australia are imported. In the EU Cosmetics Regulation, the following statements are required on the labels of products containing *phenyl methyl pyrazolone:*

- Hair colourants can cause severe allergic reactions.
- Read and follow instructions. *(Which include directions for patch testing)*
- This product is not intended for use on persons under the age of 16.
- Temporary "black henna" tattoos may increase your risk of allergy.
- Do not colour your hair if:
  - you have a rash on your face or sensitive, irritated and damaged scalp,
  - you have ever experienced any reaction after colouring your hair,
  - you have experienced a reaction to a temporary "black henna" tattoo in the past.

The proposed warning statements for Australia (as included in the interim decision) are:

> KEEP OUT OF REACH OF CHILDREN, and
>
> WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use.

While we note that these statements are consistent with those for other S6 hair dye substances, this means that changes to existing labels (which generally follow the EU labelling requirements) will be required. Given the extensive nature of the labelling already required for these products under the EU regulation, and the similarity of the EU warnings with the intent of those proposed, we believe some flexibility could be included in the Schedule entry to allow "words to the effect of" rather than mandating the warning statements verbatim. This flexible approach is already well established in the SUSMP both within specific "reverse scheduling" entries as well as in Appendix E & F where it is noted that *"Standard statements specified in this Appendix may be varied provided that the intent is not changed.".*

We note that the proposed implementation date is 1 June 2019. This will be approximately 14 months from the date of publication of the final decision. If the proposed schedule entry and associated warning statements are aligned with those in the EU as discussed above, this timeframe should be adequate for companies to identify and address any impacts from the scheduling of this substance. If the interim decision is implemented without change, members have advised that a transition period of 24 months would be required to allow for the labelling changes. Any changes would affect products currently in the Australian market with an

established history of safe use. To our knowledge, there is no evidence to suggest immediate action is required for the risk management of this substance.

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Silver oxide

Accord notes the Delegate's interim decision to create a new Appendix B entry for silver oxide when used as a spa/pool sanitiser.

As this approach will ensure that there are no unintended effects on the regulatory status of other silver compounds and/or derivatives which may be used in other sectors, we have no objections to the interim decision.