[redacted]

The Secretary
Scheduling Secretariat
Department of Health
MDP 71
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Dear Sir/Madam

Public Comment Submission to the Delegate's Interim Decisions from the November 2018 joint meeting of the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS)

We refer to the notice published on 7 February 2019 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 Australasia Limited is the peak national industry association that represents the hygiene, cosmetic & specialty products industry.

Accord provided comments on the following agenda items for the November 2018 meeting:

- Napthalene
- Salts of boric acid
- Atranol and chloratranol
- Solvent yellow 33

Please find further comments on naphthalene and salts of boric acid below.

We note that interim decisions have not been made for atranol and chlororatranol and for solvent yellow 33 as the delegate is seeking further advice on how to most appropriately schedule skin sensitisers. If we can provide any assistance on this matter, feel free to contact me.

We look forward to further advice from the Delegates. Should the Committees or the Delegates require any additional information from Accord please do not hesitate to contact me on [redacted]

Yours Sincerely

[unsigned for electronic submission]

Rachael Linklater
Manager, Regulatory Science & Technical

7 March 2019

ACMS/ACCS Joint meeting: November 2018

Napthalene

We note the interim decision to include naphthalene for domestic use in Schedule 10, with an exemption for preparations “enclosed in a device which in normal use, prevents removal or ingestion of its contents”.

We are extremely concerned that the interim decision as currently drafted inadvertently captures ***all*** domestic use products containing naphthalene, extending far beyond the scope of the scheduling consideration which focussed on the public health risks from domestic mothball products.

The interim decision would result in domestic use products such as solvents, coatings, adhesives and surfactants, and even diesel becoming Schedule 10 poisons (prohibited). This would have significant regulatory impact on a large number of products, making them unavailable to consumers in Australia. This seems a disproportionate effect given that no public health concerns have been raised with these uses of naphthalene and naphthalene containing products.

The conclusions in the interim decision indicate that the Delegate’s intent was to capture only domestic mothball products that are not packaged appropriately. To achieve this outcome, the wording of the new Schedule 10 entry must be amended to include reference to “preparations in block, ball, disc, pellet or flake form for domestic moth/insect repellent use” or similar in the entry.

For consistency with the existing Schedule 6 entry for naphthalene, derivatives should also be excluded from the new Schedule 10 entry.

We suggest the following wording:

> *Schedule 10 - New Entry*
>
> *NAPHTHALENE (excluding derivatives) in preparations in block, ball, disc, pellet or flake form for domestic moth/insect repellent use **except** when enclosed in a device which, in normal use, prevents removal or ingestion of its contents.*

It would also aid compliance to include a reference in the index entries for camphor and naphthalene to the specific packaging requirements for these substances detailed in Part 2.7.

We note the proposed implementation date for this decision is 1 June 2019. This would be approximately 5 weeks from the date of publication of the final decision. If the wording of the new Schedule 10 entry is amended such that only domestic use mothball products that do not meet the packaging requirements of 2.7 are affected, we have no objections to this short transition period.

We also support the comments on the proposed scheduling of this substance made by our sister association Chemistry Australia.

ACMS/ACCS Joint meeting: November 2018

Salts of boric acid

We note the interim decision to amend the Schedule 5 entry for boric acid and remove the entries for the four individual salts of boric acid that were due to be implemented on 1 June 2019.

We have previously indicated our preference for the scheduling of the four salts specifically (i.e. by CAS number) over an unqualified “all salts” entry, in order to help facilitate compliance and make it easier for industry to easily identify those substances which are captured.

If separate entries by CAS number are not supported in this case, other ways of easily identifying the substances intended to be captured by the Schedule entry should be considered i.e. by adding the four borate salts (sodium borate, potassium borate, MEA-borate, MIPA-borate) to the index with cross-references to the boric acid entry.

The concentration cut-off for the exemption for non-cosmetic preparations (other than insect baits) is now expressed as a percentage of boric acid instead of boron, though the effective concentration remains the same. We note that this change provides consistency with the exemptions for cosmetic products, based on the EU Cosmetics Regulation.

We note the proposed implementation date for this decision is 1 February 2020. This would be approximately 9 months from the date of publication of the final decision. Products already in the Australian market, particularly those imported from countries that do not follow the EU Cosmetics Regulation, may require reformulation and/or labelling changes. The process of implementation of the required labelling changes for these substances is also exacerbated by the changes to the previous final decision published in April 2018 which companies may have already started working towards. An adequate transition period of at least 12 months, preferably 24 months, is necessary to accommodate these changes. To our knowledge, there is no evidence that would suggest immediate action is required for the risk management of these substances.