[redacted]

The Secretary
Scheduling Secretariat
Department of Health
MDP 71
GPO Box 9848
CANBERRA ACT 2601

Email: medicines.scheduling@health.gov.au; chemicals.scheduling@health.gov.au

Dear Sir/Madam

Public Comment Submission to 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 31 August 2018 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 the following substances for consideration at the November 2018 meeting of the ACMS/ACCS:

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

Please see the attached submission for details.

We look forward to further advice from the ACMS, ACCS and 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]

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28 September 2018

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ACMS/ACCS Joint meeting: November 2018

Napthalene

We note the application from a private applicant to reschedule naphthalene from Schedule 6 to Schedule 7 based on concerns around poisonings from mothball products.

We note that naphthalene was last considered for scheduling in 2011, where similar concerns were raised. At that time, concerns regarding compliance with APVMA labelling requirements for moth-repellent products formed part of the Delegate's considerations.

While naphthalene is used in mothballs in Australia, it is much more predominantly used in industrial products and processes i.e. as a solvent, in dyes, heat transfer fluid, additives, coatings, textiles, binders, adhesives and surfactants. It is also an impurity in liquid hydrocarbons such as diesel (hence the current exemption).

Adding all forms and uses of naphthalene to Schedule 7 as proposed would present significant issues for industry. It would mean that industrial products consisting of and/or containing naphthalene (other than liquid hydrocarbons where it is present as an impurity) would be inadvertently captured and required to comply with the Schedule 7 requirements, including licensing. It would become extremely difficult, if not impossible to continue marketing these products. This seems a disproportionate effect given that no public health concerns have been raised with these industrial uses of naphthalene and naphthalene containing products.

As the applicant has raised public health concerns around the use of naphthalene specifically in domestic mothball products, any changes to the current scheduling for naphthalene, if considered appropriate (and presumably based on new evidence available since the previous consideration), must be limited to addressing this particular use pattern only i.e. naphthalene in ball, block, disc, pellet or flake form for domestic use.

ACMS/ACCS Joint meeting: November 2018

Salts of boric acid

We note the scheduling proposal initiated by a delegate of the Secretary of the Department of Health to amend the schedule entries for boric acid and 4 borate salts:

- Sodium borate
- Potassium borate
- MEA-borate
- MIPA-borate

As included in our previous recent submissions on these substances, Accord members have advised that these 5 substances are used at very low concentrations in cosmetics as buffering/viscosity controlling agents (sodium borate), as enzyme stabilisers in domestic detergent products and as corrosion inhibitors in industrial products.

Our previous comments emphasised the importance of aligning scheduling with existing overseas regulations, such as those in the EU Cosmetics Regulation for cosmetic products and retaining current levels of availability for other uses. These remain important factors for consideration.

The final decision issued in April 2018 differed somewhat from the interim decision issued, and as such stakeholders were unable to comment on the final wording of the schedule entries and warning statements. This meant that some inconsistencies with existing overseas requirements for cosmetics were unfortunately included and may also affect non-cosmetic products.

Along with these inconsistencies, the new proposed wording for the schedule entries as currently drafted is very complex. We have included below suggestions for simplifying the schedule entries and ensuring consistency with existing overseas requirements (schedule entries in full below with suggested changes in red text):

- Inclusion of the word “cosmetic” in the exemptions for talc, oral and other cosmetic preparations, as these align with the EU Cosmetics regulation and should only apply to cosmetic products.
- Clarification that the cut-off concentrations for the cosmetic exemptions is calculated as that of boric acid (not boron as currently drafted) to align with the EU Cosmetics regulation.
- Removal of the words “(THIS PRODUCT/INSERT NAME OF PRODUCT)” from the warning statements, as this is unnecessary, does not add any benefit, and is additional to what is required overseas.
- Correction of substance names in the entries for potassium borate, MEA borate and MIPA borate (perhaps a copy/paste error?).

We are concerned with the proposed new Appendix F entry for these substances, as the warning statements proposed are not consistent with the schedule entries for these substances e.g.

The warning statement “DO NOT USE (THIS PRODUCT/INSERT NAME OF PRODUCT) IN CHILDREN UNDER 3 YEARS” is required to meet the exemptions for cosmetic products, but if this statement is not applied, then the preparation is a Schedule 5 poison and the Appendix F statement of “CAUTION - Do not use for children under 2 years unless a doctor has told you to” applies. This is not consistent and does not make sense and should therefore be amended for consistency or removed.

The proposed Appendix F warning statements do not seem consistent with the risk profile of a Schedule 5 substance:

- 77 (may cause birth defects) or
- 46 (WARNING - contains boric acid which causes birth defects in laboratory animals. Women of child bearing age should avoid contact with boric acid)

Currently, these statements only apply to Schedule 4 and Schedule 7 substances. The previous final decision for these substances noted: *No or limited data of oral, dermal and inhalation toxicity and genotoxicity or carcinogenicity. Overall, evidence from studies considered shows toxicity in these areas is low in humans.* These statements should therefore be reviewed or removed.

Depending on the extent of any changes, an adequate transition period will be required to allow for any reformulation and/or labelling changes that would be required for products already in the Australian market.

Proposed schedule entries with suggested changes in red text:

Schedule 5 - Amend Entry

BORIC ACID except:

a. when included in Schedule 4; or

b. in preparations, other than insect baits, containing 1 per cent or less calculated as boron; or

c. in hand cleaning preparations when labelled with a warning to the following effect:

   DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; and if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words: NOT TO BE USED ON PEELING OR IRRITATED SKIN; or

d. in cosmetic talc preparations containing 5% or less ~~calculated as boron~~ when labelled with a warning to the following effect:

   DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; and if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words: NOT TO BE USED ON PEELING OR IRRITATED SKIN); or

e. in cosmetic oral ~~hygiene~~ preparations containing 0.1% or less ~~calculated as boron~~ when labelled with a warning to the following effect:

   NOT TO BE SWALLOWED. DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; or

f. in other cosmetic preparations~~, other than insect baits,~~ containing 3% or less ~~calculated as boron~~ when labelled with a warning to the following effect:

   DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; and if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words: NOT TO BE USED ON PEELING OR IRRITATED SKIN.

Schedule 5 - New Entries

SODIUM BORATE (CAS No. 1330-43-4) except:

a. when included in Schedule 4; or

b. in preparations, other than insect baits, containing 1 per cent or less calculated as boron; or

c. in hand cleaning preparations when labelled with a warning to the following effect:

DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; and if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words: NOT TO BE USED ON PEELING OR IRRITATED SKIN; or

d. in cosmetic talc preparations containing 5% or less of sodium borate (calculated as boric acid) when labelled with a warning to the following effect:

   DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; and if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words: NOT TO BE USED ON PEELING OR IRRITATED SKIN); or

e. in cosmetic oral hygiene preparations containing 0.1% or less of sodium borate (calculated as boric acid) when labelled with a warning to the following effect:

   NOT TO BE SWALLOWED. DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; or

f. in other cosmetic preparations containing 3% or less of sodium borate (calculated as boric acid) when labelled with a warning to the following effect:

   DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT) IN CHILDREN UNDER 3 YEARS~~; and if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words: NOT TO BE USED ON PEELING OR IRRITATED SKIN.

POTASSIUM BORATE (CAS No. 1332-77-0) except:

a. when included in Schedule 4; or

b. in preparations, other than insect baits, containing 1 per cent or less calculated as boron; or

c. in hand cleaning preparations when labelled with a warning to the following effect:

   DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; and if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words: NOT TO BE USED ON PEELING OR IRRITATED SKIN; or

d. in cosmetic talc preparations containing 5% or less of ~~sodium~~ potassium borate (calculated as boric acid) when labelled with a warning to the following effect:

   DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; and if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words: NOT TO BE USED ON PEELING OR IRRITATED SKIN); or

e. in cosmetic oral hygiene preparations containing 0.1% or less of ~~sodium~~ potassium borate (calculated as boric acid) when labelled with a warning to the following effect:

   NOT TO BE SWALLOWED. DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; or

f. in other cosmetic preparations containing 3% or less of ~~sodium~~ potassium borate (calculated as boric acid) when labelled with a warning to the following effect:

   DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; and if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words: NOT TO BE USED ON PEELING OR IRRITATED SKIN.

MEA-borate (CAS No. 26038-89-9) except:

a. when included in Schedule 4; or

b. in preparations, other than insect baits, containing 1 per cent or less calculated as boron; or

c. in hand cleaning preparations when labelled with a warning to the following effect:

DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; and if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words: NOT TO BE USED ON PEELING OR IRRITATED SKIN; or

d. in cosmetic talc preparations containing 5% or less of ~~sodium~~ MEA-borate (calculated as boric acid) when labelled with a warning to the following effect:

   DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; and if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words: NOT TO BE USED ON PEELING OR IRRITATED SKIN); or

e. in cosmetic oral hygiene preparations containing 0.1% or less of ~~sodium~~ MEA-borate (calculated as boric acid) when labelled with a warning to the following effect:

   NOT TO BE SWALLOWED. DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; or

f. in other cosmetic preparations containing 3% or less of ~~sodium~~ MEA-borate (calculated as boric acid) when labelled with a warning to the following effect:

   DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; and if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words: NOT TO BE USED ON PEELING OR IRRITATED SKIN.

MIPA-BORATE (CAS No. 26038-90-4 and 68003-13-4) except:

a. when included in Schedule 4; or

b. in preparations, other than insect baits, containing 1 per cent or less calculated as boron; or

c. in hand cleaning preparations when labelled with a warning to the following effect:

   DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; and if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words: NOT TO BE USED ON PEELING OR IRRITATED SKIN; or

d. in cosmetic talc preparations containing 5% or less of ~~sodium~~ MIPA-borate (calculated as boric acid) when labelled with a warning to the following effect:

   DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; and if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words: NOT TO BE USED ON PEELING OR IRRITATED SKIN); or

e. in cosmetic oral hygiene preparations containing 0.1% or less of ~~sodium~~ MIPA-borate (calculated as boric acid) when labelled with a warning to the following effect:

   NOT TO BE SWALLOWED. DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; or

f. in other cosmetic preparations containing 3% or less of ~~sodium~~ MIPA-borate (calculated as boric acid) when labelled with a warning to the following effect:

   DO NOT USE ~~(THIS PRODUCT/INSERT NAME OF PRODUCT)~~ IN CHILDREN UNDER 3 YEARS; and if the concentration of free soluble borates exceeds 1.5% (as boric acid), with the words: NOT TO BE USED ON PEELING OR IRRITATED SKIN.

ACMS/ACCS Joint meeting: November 2018

Atranol and chloratranol

We note the proposal to create new Schedule 10 entries for the substances atranol and chloroatranol.

Atranol and chloroatranol are naturally occurring components of treemoss and oakmoss extracts, which are used as components in fragrance materials. The global IFRA standards for treemoss and oakmoss extracts[1] stipulate that levels of atranol and chloroatranol should each be below 100 ppm in tree/oak moss extracts.

For cosmetic products in the EU, the decision was made recently to include atranol and chloroatranol in Annex II - List of substances prohibited in cosmetic products[2]. This becomes effective from 23 August 2019 for "placing products on the Union market" i.e. import/manufacture and 23 August 2021 for "making available on the Union market" i.e. product on-shelf.

It is important to note that under the EU Cosmetics Regulation[3] (Article 17) traces of prohibited substances are permitted under certain provisions:

> "The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3."
>
> [Article 3: A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use…]

As naturally occurring components of botanical extracts, the presence of small quantities of atranol and chloroatranol in these extracts may be technically unavoidable. A Schedule 10 entry would not allow for the low-level presence of these substances as impurities which may prove problematic and would also impose stricter restrictions on these substances than other overseas regulations and regulatory measures, making compliant overseas products non-compliant in Australia.

An acceptable cut-off level for these substances should be determined in acknowledgement of their nature as naturally occurring components of botanical extracts. This cut-off should be aligned with the IFRA Standards i.e. 100ppm (0.01%).

Any new Schedule entries "prohibiting" these substances should be limited to cosmetic use only, as this is where the risks to human health have been identified.

If concerns exist around the contact allergen risks of atranol and chloroatranol as components of treemoss and oakmoss extracts for non-cosmetic products, the provisions of the IFRA standards i.e. the concentration limits in finished products could be replicated in the SUSMP to manage these risks.

The implementation date should be no sooner than that for cosmetics "being made available" in the EU and ASEAN economies i.e. August 2021.

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[1] http://www.ifraorg.org/en-us/standards-library/s/moss#.W61_93szaos

[2] https://eur-lex.europa.eu/eli/reg/2017/1410/oj

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1538110444055&uri=CELEX:02009R1223-20180801

ACMS/ACCS Joint meeting: November 2018

Solvent yellow 33

We note the proposal to create a new Schedule 10 entry for solvent yellow 33.

In the EU for cosmetic products (and other economies that follow the EU regulation such as NZ and the ASEAN countries), this substance is currently prohibited for use as a hair dye colourant, and 'not to be used in products applied on mucous membranes' when used in other cosmetic products.

We have no objections to aligning the Australian regulatory treatment of this substance with existing overseas regulations. However, the wording of the proposed entry should be clarified such that it only applies to cosmetic products, given the potential different risk/benefit consideration for therapeutic goods:

> Schedule 10 - New Entry
>
> SOLVENT YELLOW 33 for use in cosmetic products applied to mucous membranes (the oral cavity, on the rim of the eyes and genital region), and in hair dye preparations.

Given the overseas status of this substance for use in cosmetics, it is unlikely that it is widely used in Australia. Nonetheless, keeping in mind the human health concerns, an adequate transition period is required to allow for action to be taken for any products already in the Australian market