

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: chemicals.scheduling@health.gov.au

Dear Sir/Madam

Public Comment Submission to the March 2019 meeting of the Advisory Committee on Chemicals Scheduling (ACCS)

We refer to the notice published on 13 December 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 March 2019 meeting of the ACCS:

- N-methyl-2-pyrrolidone
- Polymer in Durazane 1500

Please see the attached submission for details.

We look forward to further advice from the ACCS and the Delegate. Should the Committee or 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]

Rachael Linklater
Manager, Regulatory Science & Technical

21 January 2019

ACCS meeting: March 2019

N-methyl-2-pyrrolidone

We note the proposal to amend the Schedule 6 entry for N-methyl-2-pyrrolidone to capture cosmetic preparations containing $\geq 2\%$ of the substance.

At this time based on our understanding of the proposal we have no objections and do not expect any significant regulatory impact for our members.

Information available to date indicates that the use of this substance in cosmetic products in Australia is extremely limited, with currently only 1 available product identified (a hair colour removal product).

It is our understanding that while this substance is not currently included in the Annexes to the EU Cosmetics Regulation, it is included in the provisional list of CMRs which are expected to be added to Annex II (prohibited) in the near future. Changes to the Regulation Annexes are usually picked up by other countries that follow the EU model for regulating cosmetic ingredients such as NZ and the ASEAN economies, so similar regulatory action would also be expected in those countries.

For consistency and clarity, it would be useful to include the exception for “cosmetic preparations containing less than 2 per cent of the chemical” in the Schedule 5 entry as well as the Schedule 6 entry as proposed.

Salts and derivatives should be specifically excluded from the schedule entries to avoid inadvertently capturing other substances. There are various other pyrrolidone substances used as cosmetic ingredients, but these do not have the same risks to human health that have been identified for N-methyl-2-pyrrolidone.

ACCS meeting: March 2019

Polymer in Durazane 1500

We note the proposal to create a new Schedule 6 entry for “POLYMER IN DURAZANE 1500 for use in coating wipes” with associated Appendix E & Appendix F entries.

At this time based on our understanding of the proposal we have no objections and do not expect any significant regulatory impact for our members.

We are unsure as to why the tradename of the product has been proposed in the wording of Schedule entry. Given that the chemical name and CAS number for this substance are available in the proposal, and presumably therefore not considered to be confidential business information, these should be used in the schedule entry i.e.

Schedule 6 - New Entry

Cyclosilazanes, di-Me, Me hydrogen, polymers with di-Me, Me hydrogen silazanes, reaction products with 3-(triethoxysilyl)-1-propanamine (CAS number 475645-84-2) for use in coating wipes.

We are not aware of the use of tradenames in any existing schedule entries and support the continued approach of using chemical names and CAS numbers.