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

Email: chemicals.scheduling@health.gov.au

Dear Sir/Madam,

Public Comment Submission to the Delegate's Interim Decisions from the March 2020 meeting of the Advisory Committee on Chemicals Scheduling (ACCS)

We refer to the notice published on 10 June 2020 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, personal care & specialty products industry.

Accord provided comments on the following agenda items for the March 2020 meeting:

- Arbutin
- Picramic acid

Please find our comments on the interim decisions for these substances included below.

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

Yours Sincerely,

[redacted]

Rachael Linklater
Manager, Regulatory Science & Technical

9 July 2020

ACCS meeting: March 2020

Arbutin

We note the Delegate's interim decision to establish new Schedule 6 entries for alpha-arbutin, beta-arbutin and deoxyarbutin (or other arbutin derivates), and a new Schedule 4 entry for beta-arbutin in oral preparations.

The interim decision clarifies the scheduling of arbutin as standalone entries, which is preferable to the current cross-reference arrangement under the hydroquinone entry.

We also note that the exemptions in the Schedule 6 entries for preparations containing alpha and beta arbutin for application to the face and body reflect the European Commission's Scientific Committee on Consumer Safety (SCCS) conclusions that the use of α-arbutin in cosmetic products in a concentration up to 2% in face creams and up to 0.5% in body lotions, and the use of β-arbutin in cosmetic products in a concentration up to 7% in face creams, provided that the contamination of hydroquinone in the cosmetic formulations remain below 1 ppm, are safe for consumers.

As indicated in our pre-meeting submission, we have no objections to aligning the scheduling controls for arbutin when used in topical skincare products, with those of the EU.

We also have no objections to the change in terminology from "cosmetic face creams/body lotions" to "preparations for application to the face/body" and acknowledge that the regulation of products at the therapeutic goods/cosmetic interface is a separate issue to be considered outside of the chemical scheduling process.

We do note that there appears to have been an error in the drafting of the interim decision regarding the Schedule 4 exemption for "herbal preparations containing 500 mg or less beta-arbutin per recommended daily dose." Seemingly this exemption would also need to be included in the Schedule 6 entry for beta-arbutin, in order to exclude such preparations from all scheduling requirements.

ACCS meeting: March 2020

Picramic Acid

We note the interim decision to create a new Schedule 6 entry for picramic acid including its salts with an exemption for hair dye products at a concentration of 0.6 per cent or less of picramic acid after mixing for use when the immediate container and primary pack are labelled with specified warning statements.

We also note that the Schedule 6 cut-off concentration is aligned with that specified in the EU Cosmetics Regulation for picramic acid and sodium picramate.

As indicated in our pre-meeting submission we have no objections to aligning the scheduling controls for picramic acid and sodium picramate, when used in hair dye products, with those for cosmetics in the EU.

The proposed implementation date for this decision is 1 June 2021, which would be approximately 9 months from the date of publication of the final decision. Our pre-meeting comments highlighted the need for an adequate transition period of at least 12 months to allow for any labelling changes and/or reformulation that may be required. As such, we request that the Delegate consider an implementation date of 1 October 2021, which would allow industry ~13 months to accommodate any relabelling or reformulation work required in order to meet the new scheduling requirements. To our knowledge, there is no evidence to suggest immediate action is required for the risk management of this substance.