[redacted]

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

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

Dear Sir/Madam

Public Comment Submission to the March 2020 meeting of the Advisory Committee on Chemicals Scheduling (ACCS)

We refer to the notice published on 20 December 2019 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, personal care & specialty products industry.

Accord wishes to provide information on the following substances for consideration at the March 2020 meeting of the ACCS:

- Arbutin
- Picramic acid (including its salts)

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 or rlinklater@accord.asn.au.

Yours sincerely

[unsigned for electronic submission]

Rachael Linklater
Manager, Regulatory Science & Technical

10 February 2020

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ACCS meeting: March 2020

Arbutin

We note the recent considerations of arbutin at the June 2019 joint meeting of the Advisory Committee on Chemicals and Medicines Scheduling, and support the further consideration of this substance, including the risks and benefits of the use of arbutin in cosmetic and topical dermal therapeutic products.

As noted in our June 2019 submission, arbutin is found as an ingredient itself and as a component of plant extracts like *Arctostaphylos Uva Ursi* (bearberry), *Vaccinium Vitis-Idaea* and *Chimaphila Umbellata*. Bearberry extract (INCI name *arctostaphylos uva ursi* leaf extract).

Internationally, arbutin is used in skin lightening treatments. It is noted to be effective for melasma or chloasma, a skin pigmentation condition that is more common in women. Currently the available treatment for melasma in Australia includes hydroquinone as the active substance.

The European Commission's Scientific Committee on Consumer Safety (SCCS) concluded 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.

The Discussion section of the SCCS opinion for α-arbutin notes that the total internal value of hydroquinone (released from α-arbutin) used for safety assessment related to ochronosis and other end points is 42 times lower than the internal exposure resulting from the use of a product containing 1% hydroquinone, a concentration at which ochronosis may occur. For β-arbutin it is 174 times lower.

We have no objections to aligning the scheduling controls for arbutin when used in cosmetics, with those for cosmetics in the EU.

ACCS meeting: March 2020

Picramic acid (and its salts)

Accord has no objections to aligning the scheduling controls for picramic acid and sodium picramate, when used in cosmetics, with those for cosmetics in the EU.

To avoid confusion, and the inadvertent capture of other substances, we suggest that the scheduling entry specifically identify the substances picramic acid and sodium picramate, along with their respective CAS numbers (rather than the more generic “picramic acid and its salts”).

We note that picramic acid and sodium picramate are included in Annex III of the EU Cosmetics Regulation, permitted for use as a hair dye substance in oxidative and non-oxidative hair dye products with an in-use concentration (after mixing under oxidative conditions) not exceeding 0.6%.

With regard to implementation dates, it is important to recognise that an adequate transition period of at least 12 months must be allowed for any labelling changes and/or reformulation that may be required where no immediate risk has been identified. To our knowledge, there is no evidence to suggest immediate action is required for the risk management of this substance.