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 June 2019 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 11 April 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, cosmetic & specialty products industry.

Accord wishes to provide information on the following substances for consideration at the June 2019 joint meeting of the ACMS-ACCS:

- Arbutin

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

13 May 2019

ACMS-ACCS meeting: June 2019

Arbutin

We note the applicant's proposal to include arbutin as a specific entry in the Poisons Standard and to exempt from scheduling the use of herbs containing arbutin in oral herbal preparations.

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) is used as a skin conditioning agent in cosmetic products.

Arbutin itself is approved for use in cosmetic products in the EU, with listed functions including antioxidant, skin conditioning and skin lightening.

When the cosmetic use of arbutin was previously considered by the NDPSC in 2009[1], the record of reasons states:

> *"The Committee generally agreed that until more robust data was available regarding the actual risk of arbutin, then it remained appropriate to take a conservative approach and control arbutin under the current scheduling for hydroquinone as a derivative (i.e. cosmetic use would be captured by Schedule 2 or 4, requiring cosmetic use to be subject to Therapeutic Goods Administration approval). Members agreed that the scheduling of arbutin could be revisited when sufficient data was available."*

Since the 2009 considerations, new data on the safety of arbutin when used in cosmetics has become available. The European Commission's Scientific Committee on Consumer Safety (SCCS) published 2 opinions relating to the substances α-Arbutin and β-arbutin which came to the following conclusions:

- The SCCS considers the use of α-Arbutin safe for consumers in cosmetic products in a concentration up to 2% in face creams and up to 0.5 % in body lotions[2].

- The SCCS considers the use of β-arbutin to be safe for consumers 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[3].

We support the individual listing of arbutin rather than the current arrangement of being captured as a derivative of hydroquinone, with a cross-reference to arbutin in the index. This will ensure that the requirements for products containing arbutin are clear and more easily identified.

Therefore, we also suggest that the cosmetic use of arbutin can now be reconsidered, to allow its use in line with the findings of the SCCS opinions as detailed above.

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[1] https://www.tga.gov.au/sites/default/files/ndpsc-record-56.pdf
[2] https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_176.pdf
[3] https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_169.pdf