



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 June 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 12 April 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 2018 meeting of the ACMS/ACCS:

- Aliphatic allyl esters

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 (02) 9281 2322.

Yours Sincerely

[unsigned for electronic submission]

Rachael Linklater
Science & Technical Regulatory Associate

10 May 2018

ACMS/ACCS Joint meeting: June 2018

Aliphatic allyl esters

We note the proposal to amend the current Schedule 7 entry for allyl alcohol to exclude allyl esters as its derivatives and to allow low levels of allyl alcohol as an impurity in preparations containing allyl esters at 5% or less. The scheduling proposal refers to the following 9 aliphatic allyl esters:

- 1797-74-6 allyl phenylacetate
- 2835-39-4 allyl isovalerate
- 4728-82-9 allyl cyclohexaneacetate
- 2705-87-5 allyl cyclohexanepropionate
- 123-68-2 allyl hexanoate
- 142-19-8 allyl heptanoate
- 4230-97-1 allyl octanoate
- 68132-80-9 allyl trimethylhexanoate
- 7493-72-3 allyl nonanoate

We strongly support the exclusion of these substances from the Schedule 7 entry for allyl alcohol, as this will allow the use of these globally available fragrance ingredients in domestic and consumer products in Australia. We are also in support of aligning the regulatory treatment of these substances with that already in place in comparable overseas economies.

We note that these substances are currently listed in Annex III of the EU Cosmetics Regulation “List of substances which cosmetic products must not contain except subject to the restrictions laid down” with a specific condition on the permissible level of free allyl alcohol: *“Level of free allyl alcohol in the ester should be less than 0.1%”*. Similarly, the proposed schedule exemption should refer to the level of **free** allyl alcohol (the term “free” is not currently included in the proposal as drafted).

We also note there are no restrictions on the concentration of the esters (provided the level of free allyl alcohol is less than 0.1%) that may be used in cosmetic products marketed in the EU (and other countries which follow the EU Cosmetics Regulation such as the ASEAN countries and New Zealand which are geographically close trading partners).

The proposed amendment as currently worded may result in the inadvertent regulation of substances other than those that have been listed above i.e. that have been identified to be of concern in the IMAP assessment. We would therefore urge consideration of an approach that scheduled only these 9 substances that have been identified as being of concern i.e. listing by CAS number.