



The Secretary
Scheduling Secretariat
Department of Health
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Dear Sir/Madam

Public Comment Submission to the Delegate's Interim Decisions from 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 10 September 2018 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 is the peak national industry association that represents the hygiene, cosmetic & specialty products industry.

Accord provided comments on the following agenda items for the June 2018 meeting:

- Aliphatic allyl esters

Please find further comments on these items below.

We look forward to further advice from the Delegate. Should any additional information from Accord be required at this stage please do not hesitate to contact me on (02) 9281 2322.

Yours Sincerely

[unsigned for electronic submission]

Rachael Linklater
Science & Technical Regulatory Associate

11 October 2018



ACMS/ACCS Joint meeting: June 2018

Aliphatic allyl esters

Accord notes the Delegate's consideration and interim decision for aliphatic allyl esters which refers to the following 9 substances:

- 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 reiterate our strong support for 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.

As mentioned in our pre-meeting submission, the scheduling of these 9 substances specifically (i.e. by CAS number) is preferred over an unqualified "allyl esters" entry. Please refer to our suggested wording below. The generic nature of the proposed entry makes it difficult for industry to clearly identify those substances which are captured by the schedule entry. Such generic schedule entries have caused significant problems for industry previously by inadvertently regulating substances where no risk to public health has been identified, so should not be perpetuated.

We note several references in the consideration of these substances to maintaining alignment with existing overseas restrictions, however we are concerned that the interim decision as currently worded will not achieve this due to the additional 5% concentration limit proposed for the allyl esters, which would be unique to Australia.

As there are no overseas restrictions in currently in place on the concentration of allyl esters used (provided the level of free allyl alcohol is less than 0.1%), products freely available overseas (both cosmetic and domestic) containing allyl esters above 5% would be Schedule 6 Poisons in Australia. For cosmetics, this means that these products will likely not be available to Australian consumers.

We understand that the proposed 5% cut-off for the allyl esters is in line with the current Therapeutic Goods (Permissible Ingredients) Determination listings for several of these substances but note that Scheduling extends to product categories beyond Listed medicines. Higher concentrations of use would not necessarily pose risks to public health for these different use patterns i.e. domestic products not intended for direct skin contact.

It is not appropriate to extend the regulatory controls for listed medicines to other product categories with very different risk profiles.

Our preference remains alignment with the overseas restrictions for these substances as set out in the IFRA Standards and the cosmetics regulations of the EU, ASEAN economies and New Zealand i.e. the requirement to ensure the level of free allyl alcohol is less than 0.1%.

We have included suggested wording for the schedule entries below:

Schedule 7 - Amend Entry

ALLYL ALCOHOL except

- a. in preparations containing ~~5 per cent or less of~~ allyl esters with 0.1 per cent or less of free allyl alcohol by weight of allyl ester; or
- b. when separately specified in these Schedules.

Schedule 6 - New Entry

ALLYL ESTERS (excluding derivatives) being,

~~allyl phenylacetate (CAS no. 1797-74-6)~~

~~allyl isovalerate (CAS no. 2835-39-4)~~

~~allyl cyclohexaneacetate (CAS no. 4728-82-9)~~

~~allyl cyclohexanepropionate (CAS no. 2705-87-5)~~

~~allyl hexanoate (CAS no. 123-68-2)~~

~~allyl heptanoate (CAS no. 142-19-8)~~

~~allyl octanoate (CAS no. 4230-97-1)~~

~~allyl trimethylhexanoate (CAS no. 68132-80-9)~~

~~allyl nonanoate (CAS no. 7493-72-3)~~

~~in preparations containing 0.1 per cent or less of free allyl alcohol by weight of allyl ester~~
except in preparations when containing 5 per cent or less of allyl esters with 0.1 per cent or less of free allyl alcohol by weight of allyl esters.

Index – New Entry

Schedule 6

ALLYL ESTERS

cross-reference: ALLYL ALCOHOL