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 2020 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 17 April 2020 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 proposed amendments for consideration at the June 2020 joint meeting of the ACMS-ACCS:

- Methylisothiazolinone and methylchloroisothiazolinone
- Isothiazolinones

Please see the attached submission for details.

We look forward to further advice from the Committees and the Delegate. Should the Committees 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

18 May 2020

Accord Australasia Limited ACN 117 659 168 ABN 83 205 141 267
Fusion C4.02, 22 – 36 Mountain Street, Ultimo NSW 2007
PO Box 290 BROADWAY NSW 2007

Tel: 61 2 9281 2322 **Fax:** 61 2 9281 0366 **Website:** www.accord.asn.au

Joint ACCS/ACMS meeting: June 2020

2.3 Methylisothiazolinone and methylchloroisothiazolinone, and
2.4 Isothiazolinones.

Scope of Accord member products affected

Accord member products containing isothiazolinone preservatives that are expected to be impacted by the current scheduling proposals include everyday products such as:

- liquid laundry detergents,
- fabric conditioners ("fabric softeners"),
- dishwashing detergents,
- air care products ("air fresheners") in solid gel, spray and aerosol formulations,
- surface cleaners,
- toilet cleaners,
- shoe care products, and
- APVMA registered household pesticide products.

The isothiazolinones identified by Accord members as being used across this range of products include methylisothiazolinone (MIT), methylchloroisothiazolinone (CIT), benzisothiazolinone (BIT), and octhilinone (OIT). We note that these substances are utilised both individually and in combination depending on the nature of the product.

Accord's comments herein are limited to the product types listed above.

Initial feedback from a limited number of Accord member companies indicates that the current maximum levels of use of isothiazolinone preservatives in these types of products is generally below 0.05% total isothiazolinones.

We also understand that isothiazolinone preservatives are widely used in products such as paints, sealants, jointing compounds and fillers that have a mixture of industrial and consumer use patterns.

Request for deferral

We respectfully request that the Committees' consideration of these agenda items be deferred at this time. They could instead be included on the agenda for the November 2020 meetings.

Any changes to the scheduling of these substances will have significant impact on our member companies operating in the cleaning and hygiene sector. These companies are currently overwhelmed with the COVID-19 response, with their focus firmly on ensuring the continued supply of much needed cleaning and hygiene products, including hard surface disinfectants and hand sanitisers.

Industry is prepared to defend the safety and support the continued use of these substances, but these substances represent a particularly complex case with potentially wide impacts across a number of different product sectors and stakeholder groups. More time is needed to ensure that affected stakeholders can engage with the scheduling process in a meaningful way. Given the types of products affected, we would normally expect a much higher level of engagement from our members on these proposals than we have received to date.

We note that there does not appear to be any evidence that this is a pressing public health issue that would require immediate regulatory action, so a delay would serve to better inform the Committees and the Delegates with more comprehensive input for their considerations.

Preservatives - benefits vs risk

In the scheduling consideration of the isothiazolinone preservatives, it is necessary to consider the essential nature of preservatives in formulated products and the benefits these substances provide. Preservatives are ingredients which are intended to kill microorganisms. As such, all preservatives demonstrate some level of toxicity. However, without preservatives, products cannot be protected from microorganisms during production and throughout their shelf life, which raises other health concerns for consumers using the products. Formulated products are therefore designed to include preserves to ensure that they are fit for purpose, will remain efficacious throughout the duration of their shelf life, and most importantly, will be safe for use.

We need to maintain a suite of available preservatives for formulated products in Australia

Preservatives are an essential component of formulated products. Any scheduling changes that may result in the removal of a substance or a family of related substances from the currently available suite of preservatives, will require substitution with other alternatives. There are no guarantees that the replacement preservative will provide an improved toxicity profile and/or the same level of preservative efficacy (so higher concentrations may be required), making reformulation of preservative systems a complex and difficult task.

Warning labelling to apply at any concentration?

The proposal as currently worded would require inclusion of the prescribed warning statements: CONTAINS ISOTHIAZOLINONES and REPEATED EXPOSURE MAY CAUSE SENSITISATION where isothiazolinones are present at any concentration, even at trace levels, which does not seem to make sense.

The proposals also do not align with the scheduling of other substances based on skin sensitisation potential, where warning statements are required only above established threshold levels. If warning statements are applied to all products the significance of such statements for consumers, and any associated public health benefits, are likely to become diluted.

The proposals for MIT and CIT create a strange anomaly: products containing <0.0015% would not require any warning statements if they were rinse-off cosmetics, but as toilet cleaners, for example, they would require the statement CONTAINS ISOTHIAZOLINONES, REPEATED EXPOSURE MAY CAUSE SENSITISATION. This doesn't make sense given the higher risk of sensitisation for products intended for contact with the skin.

It is also unclear whether the general low concentration exemption (as set out in Part 1 of the Poison Standard) for substances included in Schedules 1 to 6, at a concentration not exceeding 10 mg per litre or 10 mg per kilogram (0.001%) would apply for these substances, given that the proposed wording of the schedule entries refers to "preparations containing 0.05% or less of isothiazolinones in total".

As isothiazolinones are used as preservatives, they may be present in a finished product simply due to carry over from their function in preserving the raw materials that then comprise a formulated product i.e. are only present as incidental ingredients. Such levels would generally be below the 0.001% low concentration exemption mentioned above.

Overseas requirements inconsistent with Australia's risk-based system

We understand that in the EU, non-cosmetic products containing isothiazolinones are subject to hazard-based GHS requirements for labelling, with specific concentration thresholds for classification and additional (different) specific concentration thresholds for labelling for each of the isothiazolinones, regardless of end use.

In Australia, GHS requirements do not extend to domestic and consumer products. Rather, it has been decided that any identified public health risks of such products should be addressed via the SUSMP and State-based legislation, based on a risk assessment process and risk management identification based on end use.

Adequate transition/implementation timing required

When considering these substances, any scheduling decision that would require the reformulation and/or relabelling of existing products already in supply in the Australian market should include a transition period of at least 2 years. This is to allow for any reformulation and related testing required, as well as mitigation of the substantial costs associated with relabelling.

Joint ACCS/ACMS meeting: June 2020

2.3 Methylisothiazolinone and methylchloroisothiazolinone

These comments specific to proposal 2.3 for methylisothiazolinone (MIT) and methylchloroisothiazolinone (CIT) are provided in addition to our comments above.

MIT and CIT only recently considered

With regard to MIT and CIT, these substances were only relatively recently considered for scheduling.

The key toxicological concerns that were identified for these substances related to skin sensitisation risks when used in products intentionally applied to the skin, such as personal care and cosmetic products. These risks were addressed with a staged implementation of scheduling requirements to ensure careful alignment with international approaches and provide adequate transition periods for reformulation of existing products.

As the new scheduling requirements for MIT and CIT have not been in place for very long (the S6 requirements for “other preparations that are not intended for direct application to the skin” were implemented in October 2017, and the latest change for rinse-off cosmetic products was implemented in October 2019) it is important to establish whether further risk management measures for these substances are in fact required at this point in time.

Joint ACCS/ACMS meeting: June 2020

2.4 Isothiazolinones

These comments specific to proposal 2.4 for Isothiazolinones are provided in addition to our comments above.

Differences in skin sensitising potential should be acknowledged and addressed

Grouping together a number of different isothiazolinones with different risk profiles and implementing the same requirements for all does not seem an appropriate, nor risk-based approach. For example, the chlorinated isothiazolinones are regarded as having higher skin sensitising potential than the other isothiazolinones and should therefore be addressed separately.