



Natures Organics  
31 Cornhill Street  
Ferntree Gully  
VICTORIA 3156  
Australia

The Secretary  
Scheduling Secretariat  
Department of Health  
MDP 71  
GPO Box 9848  
CANBERRA ACT 2601

Email: [medicines.scheduling@health.gov.au](mailto:medicines.scheduling@health.gov.au) ; [chemical.scheduling@health.gov.au](mailto:chemical.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<sup>th</sup> April, 2020 Consultation: Proposed amendments to the Poisons Standard-ACMS and Joint ACMS/ACCS meetings June 2020.

Natures Organics is an Australian manufacturing company producing a wide range of consumer products including personal care products such as hair shampoos, hair conditioners and bodywashes and household cleaning products such as laundry detergents, dishwashing liquids, floor and surface cleaners. We batch and fill [REDACTED] million litres of these products annually.

Natures Organics wishes to provide information on the following substances for consideration at the June 2020 meeting of the ACMS/ACCS:

- Item 2.3 METHYLISOTHIAZOLINONE and METHYLCHLOROISOTHIAZOLINONE
- Item 2.4 ISOTHIAZOLINONES

Please see the attached submission for details.

We look forward to your consideration of this matter. Should the Committees or Delegates need any further information we will be happy to provide it.

Yours Sincerely

Andrew Gowty  
R&D Manager

15<sup>th</sup> May, 2020

### ACMS/ACCS Joint Meeting: June 2020

- **Item 2.3 METHYLISOTHIAZOLINONE and METHYLCHLOROISOTHIAZOLINONE**
- **Item 2.4 ISOTHIAZOLINONES**

We refer to the proposals to amend the schedule entries for methylisothiazolinone and methylchloroisothiazolinone and to create a new entry for isothiazolinones.

Natures Organic supports the need for regulation of preservatives in consumer products especially those with a known risk such as isothiazolinones with the potential to be skin sensitisers, but we feel that the proposed changes are not appropriate. We are using isothiazolinones as preservatives, at levels we believe are safe and effective, in a range of products under the current regulations.

To require products to be labelled with a warning "Contains isothiazolinones. Repeated exposure may cause sensitisation" without a lower limit seems excessive. Consumers already have information available, being advised of the presence of the preservation agents in rinse off cosmetic preparation through the requirements of the ingredient labelling on cosmetics.<sup>(1)</sup>

Since 2011 we have received only 12 enquiries about our use of isothiazolinones (Benzothiazolinone, Isothiazolinones, Methylisothiazolinone). Of these three were general enquiries and nine were the results a diagnosis of contact dermatitis by a dermatologist, several asking for the isothiazolinones to be removed after seeing it in the ingredients list. This shows both that information about preservatives in our products is already available to the consumer in the form of ingredient lists etc. and that the level of public concern is low.

"In preparations that are not intended for direct application to the skin" is very broad. It covers products as diverse as paints, air fresheners, dishwashing liquids, surface cleaners and laundry liquids, leading to the warning to be applied regardless of the actual risk in use.

The proposed amendments may lead to situations where products have label warnings, but the safety data sheet produced to GHS requirements for these products will not mention any concerns about sensitisation.<sup>(2)</sup>

Methylisothiazolinone and methylchloroisothiazolinone have been assessed by the Cosmetic Ingredient Review, (Final Amended Report Released February 25, 2020)<sup>(3)</sup> which concluded "In most rinse-off products, 15 ppm MCI/MI was not associated with a potential increase risk of skin sensitization induction.", which is the risk that the proposed warning is designed to alert users to.

Benzothiazolinone is not allowed to be used in cosmetic preparations in Europe but mixtures are not classified as sensitisers below 500ppm<sup>(4)</sup> and it is generally regarded to have a low risk of inducing sensitisation except for prolonged contact.



Since there is no lower limit on the proposed entry there is no incentive to minimise the level of isothiazolinones used below 0.05%. The level of risk for different isothiazolinones is not considered in the proposed amendment, so some formulators may use a high level of isothiazolinones within a classification to ensure preservation.

The economic impact on Natures Organics would be severe as we will be faced with a choice of reformulating to other preservatives which could result in a 20% cost increase in some formulas. It would also result in hundreds of hours reformulating and testing for alternatives which may still be a sensitising risk or have other issues compared to isothiazolinones or change the labels for the numerous products containing isothiazolinones, only to change the labels again as we find alternatives.

During the recent worldwide shortage of benzothiazolinone we conducted an urgent search for alternatives and found the options very limited with concerns about efficacy, product stability, environmental fate, human safety and cost. We are continuing to look but expect this to be a long process.

Our experience with isothiazolinone includes laundry products for different uses, some where the consumers are likely to self-identify as having sensitive skin.

While these products are not designed for application to skin some contact will occur in hand washing, handling washed clothes etc.

| Product  | Preservative  | Used Since           | Amount produced 2019  |
|--|---|----------------------|---|
| Purity 2X Laundry Liquids                      |  | May 2016             |  |
| Purity Laundry Liquid 1.25 L                   |   | May 2016             |   |
| Purity Fabric Softener                         |   | October 2012         |   |
| EC Concentrated Laundry Liquid 1 L – Sensitive |   | Before November 2014 |   |

Third party independent Repeat Insult Patch Testing supervised by a dermatologist has been conducted for each of the above products indicating that they are non-irritating.

We also make larger volumes of regular laundry liquid, fabric softeners, cleaners and shampoos.

**In summary:**

We believe that to require products to be labelled with a warning “Contains isothiazolinones. Repeated exposure may cause sensitisation” when only low levels are present is excessive for the types of products that we made, will impose significant costs and may have unintended consequences, eliminating the use of isothiazolinones in some products but allowing the use at higher levels in others.

## REFERENCES

- (1) Ingredient labelling on cosmetics: supplier guide  
<https://www.productsafety.gov.au/publication/ingredients-labelling-on-cosmetics-supplier-guide>
- (2) Globally Harmonised System of Classification and Labelling of Chemicals (GHS)  
United Nations  
Chapter 3.4 Respiratory or skin sensitization
- (3) Cosmetic Ingredient Review, (Final Amended Report Released February 25, 2020)  
<https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR787.pdf>  
or  
<https://www.cir-safety.org/sites/default/files/mcimi122019FAR.pdf>
- (4) HSIS Consolidated List (downloaded 05/03/2018)  
Gives a cut-off of 0.05%, other sources do not but the default cut off for a skin sensitiser class 1 is 0.1%.