

**AISE comments to the Commission's newsgroup on
skin sensitising active substances**

“CA meeting participants are invited to reply by 26 January 2021 to these questions:

- 1. To which extent do you consider that the presence of isothiazolinones in treated paints and detergents is a problem? Please specify*
- 2. What could be the impact on the society of a restriction of such substances in treated paints and detergents?*
- 3. How to address those problems in the legal frame of the BPR?”*

20 January 2021 - Draft

Comments from A.I.S.E., the EU detergents and maintenance products industry:

A.I.S.E. would like to refer to the discussions and the work performed in the past years, especially the A.I.S.E.-CEPE workshop on preservation of paints and detergents held in 2019, to which biocides authorities actively participated ([link](#) to presentations and proceedings). Participants recognised that there is an issue related to the future availability of preservatives, and that the use of preservatives in detergents and paints is indispensable in the short/medium term. The workshop was concluded with a recommendation that the Commission works further on the issue, in the form of a CA document to clarify and discuss issues before active substances review.

Additional information on the topic is available from the A.I.S.E. website, and we are available to provide more details if needed:

- A.I.S.E. factsheet on preservatives (Oct. 2018):
https://www.aise.eu/documents/document/20181109153552-aise_factsheet-2018_incanp_final.pdf
- Report on “Economic impact of losing effective in-can preservatives” (Efttec, Aug. 2018)
https://www.aise.eu/documents/document/20181109154448-in-can_preservatives_final_report_16082018.pdf

We would like to stress again that performing proper risk assessment at product authorisation level (and therefore setting appropriate RMM's, if needed), can only be carried out as long as restrictions are not set in the active substance approval regulation, as stated in the joint industry paper tabled at the September CA meeting (CA-Sep20-Doc.7.1.c-2).

To conclude, A.I.S.E. reiterates its request to the Commission to take action and amend the relevant CA documents (for instance CA-Nov14-Doc.6.2 – Final – Conditions on TA in approvals) to prevent that unwarranted restrictions are set for treated articles in skin sensitising active substance approval regulations. A.I.S.E. remains committed to the safe use of preservatives in detergent products and to contribute actively to further work on this topic.

For reference only

AISE contribution to the previous Commission's newsgroup (Oct 2020)

“CA meeting participants are invited to indicate their preference on the implementation of future RMMs for skin sensitisers in detergents or paints by 23 October”

We believe that discussing implementation of RMM's is premature at this stage, since in our view those can only be determined based on the outcome of the end-use specific risk assessments done at biocidal product authorisation level.

It is important to note that there are already relevant mandatory RMM in place for detergents. First, **CLP provides users all required hazard information on the labels, including information on skin sensitisation.**

In addition:

- according to the Commission's note CA-May15-Doc.6.1-Final, labelling provisions of BPR Art. 58(3) should apply to treated articles for which the active substance concerned is skin sensitiser Cat 1 or Cat 1A.
- the Detergent Regulation ((EC) No 648/2004) requires that preservation agents be listed on the label irrespective of their concentration.

We would like to remind that it is common practice to inform consumers via product label about topics such as allergies (e.g. in the food sector). All these requirements in place allow therefore consumers to make informed choices.

Additional RMM's shall only be set if required based on the outcome of risk assessment performed at biocidal product authorisation level, where the different individual uses, including in treated articles, will be assessed. This includes the consideration of the nature of the treated articles and the way these are used. In line with other allergens such as allergenic fragrances (Ref: Basketter DA, Lemoine S, McFadden JP. Skin sensitisation to fragrance ingredients: is there a role for household cleaning/maintenance products? Eur J Dermatol 2015; 25(1): 7-13 doi:10.1684/ejd.2014.2472), skin sensitizing preservatives in detergents are unlikely to be the cause of induction of skin sensitisation due to the extremely low exposure to the allergens.

Although ECHA concluded recently that it is not possible to reach an agreement on the Quantitative Risk Assessment in the short term, it is important that regulatory acceptance discussion begins to allow proper science in this debate.

We would therefore like to reiterate that performing proper risk assessment at product authorisation level, and therefore setting appropriate RMM's, if needed, can only be carried out as long as restrictions are not set in the active substance approval regulation, as stated in the joint industry paper tabled at the September CA meeting (CA-Sep20-Doc.7.1.c-2).

With regard to certain MS's concerns about imported treated articles, we would like to stress that for detergents and maintenance products, importations represent only around 2 % of the total quantity placed on the market in Europe (Source: Euromonitor 2019 and Commission's Trade Market Access Database https://madb.europa.eu/madb/statistical_form.htm). Preserved detergents are only a portion of this figure as it includes formulation types that are not typically preserved (e.g. powder / solid detergents, extreme pH products).

Finally, we wish to recall some conclusions of the A.I.S.E-CEPE workshop on preservation of paints and detergents held last year, to which biocides authorities participated (extract from the workshop proceedings provided below):

- *“With regard to the CMIT/MIT case, it was recognised that there is no legal basis for imposing restrictions in treated articles for use by the general public in case the active is a skin sensitizer. The only reference is a guidance note from 2013 (CA-Sept13-Doc.6.2.a), it was suggested to revise this note . It was also suggested to keep the active substance approval decision as 'open' as possible, demonstrating safe use at biocidal product authorisation level”*

- *“The recommended next step from this break out session was for the Commission to work further on the issue, in the form of a Competent Authorities document to clarify and discuss issues before active substances review, in a similar way as for antifouling active substances (PT21) (CA-March14-Doc.4.2)”.*

To conclude, A.I.S.E. asks the Commission to take action and amend the relevant CA documents (for instance CA-Nov14-Doc.6.2 – Final – Conditions on TA in approvals) to prevent that unwarranted restrictions are set for treated articles in skin sensitising active substance approval regulations. A.I.S.E. remains committed to contribute actively to future debates and work on this topic.