

## COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public consultation are made available in this table as submitted by the webform. Please note that the comments displayed below may have been accompanied by attachments which are not published in this table.

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**Last data extracted on 17.07.2019**

**Substance name: methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate**

**CAS number: 80-62-6**

**EC number: 201-297-1**

**Dossier submitter: France**

### RESPIRATORY SENSITISATION

Date	Country	Organisation	Type of Organisation	Comment number
26.06.2019	Netherlands		MemberState	1
Comment received				
<p>The DS proposes an Annex VI entry for methyl methacrylate (CAS nr. 80-62-6) as Resp Sens Cat. 1 H334 without subcategory. The DS bases its conclusion on human case studies and epidemiological data obtained from several databases registering occupational disease and public literature. The DS considers the available information too limited for subcategorisation in Cat. 1A or Cat. 1B, since it is largely unknown at what exposure levels humans are sensitised, and the frequency of disease as reported in the public literature and databases may be affected by underreporting.</p> <p>The NL-CA agrees with the DS on the proposed classification as Resp. Sens Cat. 1 H334 without subcategory. The NL-CA considers the available data not sufficient for classification as Resp. Sens Cat. 1A, since there is too limited information available on the concentrations at which sensitisation of the airways occur. We furthermore agree with the DS that it is difficult to distinguish between the clinical symptoms following from the irritant properties of methyl methacrylate and the sensitisation potential of the substance. Nevertheless, the human data in the CLH dossier illustrate several cases of asthma with late reaction in specific inhalation challenge (SIC), pointing to respiratory sensitisation. Please also consider in this respect the publication by Walters et al. (2017). This study supports the association between occupational asthma and exposure to acrylates (among which eight cases occupational asthma caused by predominantly methyl methacrylate reported to the UK SHIELD surveillance scheme between 1989 and 2014).</p> <p>Among the case studies in the CLH report are also several cases of nail salon workers with occupational asthma due to workplace exposure to methyl methacrylate. A recent publication by DeKoven et al. (2017) reports an increasing trend in the incidences of allergic contact dermatitis in this category of professionals visiting their clinic, reflective of a more general trend in nail salon workers due to occupational (meth)acrylate exposure. This trend is of concern also with regard to potential new cases of work-related respiratory sensitisation among nail technicians.</p> <p>DeKoven, S., DeKoven, J., &amp; Holness, D. L. (2017). (Meth) acrylate occupational contact dermatitis in nail salon workers: a case series. <i>Journal of cutaneous medicine and surgery</i>, 21(4), 340-344.</p>				

Walters, G. I., Robertson, A. S., Moore, V. C., & Burge, P. S. (2017). Occupational asthma caused by acrylic compounds from SHIELD surveillance (1989–2014). *Occupational Medicine*, 67(4), 282-289.

Date	Country	Organisation	Type of Organisation	Comment number
25.06.2019	Germany		MemberState	2

Comment received

The CLH proposal for the classification of methyl methacrylate (CAS Nr. 80-62-6) in Resp Sens. 1, H334 is supported. The data presented show that MMA induces asthma in humans, so a classification is justified. Since the human data did not contain a description of the level of exposure, a subcategorization is not possible. However, the dossier could provide more detail on how to ensure that the allergic reaction is specific to the exposure with MMA and did not result from another component of the cement used in dentistry, medicine and nail design.

Date	Country	Organisation	Type of Organisation	Comment number
05.07.2019	Germany	Evonik Röhm GmbH	Company-Manufacturer	3

Comment received

This CLH proposal lacks fundamental scientific standards of ECHA and EUCOM's SCHEER. The weight-of-evidence (WoE) approach of the CLH proposal is thus not balanced and not scientifically justified.

A lack of fundamental understanding was also observed for endpoint specific aspects on respiratory sensitization: Neither obligatory evidence for a biphasic mode of action nor a valid determination of "causation" of the development of asthma in relationship to Methyl Methacrylate (MMA) exposure nor a clear differentiation distinguish between respiratory irritation effects (for which this substance is already classified) against the claimed respiratory sensitization effects was provided in sufficient detail.

Our alternative WoE approach, following the aforementioned standards and based on a broader database, demonstrates clearly a lack of confidence in the CLH proposal that MMA is a causative agent for occupational asthma. Instead, all available evidence reviewed in the literature of sufficient strength confirm that MMA has the potential to aggravate asthmatic symptoms in pre-existing asthmatics.

We thus do not agree to the CLH proposal and, instead, we propose that the current Annex VI entry remains unchanged.

A detailed comment is attached.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2019-07-05\_MMA\_CLH\_comment\_final\_with\_coverletter.pdf

Date	Country	Organisation	Type of Organisation	Comment number
11.06.2019	Finland		MemberState	4

Comment received

Based on the available human data from case reports and epidemiological studies, MMA induces asthma. At present, there are no appropriate animal models for the testing of respiratory sensitisation. However, the evidence in humans indicate that exposure to the substance can lead to specific respiratory hypersensitivity. The data are not sufficient for sub-categorisation. The results meet the criteria for classification as Resp. Sens. 1; H334. FI CA supports the proposed classification of Resp. Sens. 1; H334 for methyl

methacrylate.

PUBLIC ATTACHMENTS

1. 2019-07-05\_MMA\_CLH\_comment\_final\_with\_coverletter.pdf [Please refer to comment No. 3]