

MSG on RAC opinion to classify MMA as a respiratory sensitiser

On 18 March 2021, the ECHA Committee for Risk Assessment (RAC) adopted a recommendation to classify Methyl methacrylate (MMA) as a respiratory sensitizer category 1 with the hazard statement H334 (i.e. may cause allergy or asthma symptoms or breathing difficulties if inhaled).

The original proposal was made by France on 26 February 2019. The dossier had been returned to the RAC to reexamine their previous opinion of October 2020 in light of new information presented by industry.

Next Steps

MSG is committed to continuing cooperation with all relevant stakeholders for a complete, transparent re-assessment of MMA. Factors such as potential co-exposure to other chemicals or dust as causation for asthma development, or irritation effects in hyperreactive individuals need to be part of such an assessment.

There are no immediate changes of the harmonized classification, and updates to the Classification, Labelling and Packaging (CLP) Regulation can only be made via Adaptation of Technical Progress (ATP) upon decision by EU Commission. A possible implementation is at the earliest anticipated for 2023.

Grounds for the opinion by RAC

The RAC opinion is based on a number of asthma cases for which occupational exposure to MMA is considered the cause with six positive Specific Inhalation Challenge (SIC) tests that the RAC considers indicative of the involvement of immunological mechanisms.

Industry's response

The Methacrylates Sector Group (MSG), a sector group of Cefic is committed to ensuring health and safety of workers coming and protecting them from harmful levels of exposure to MMA at workplace. We believe, however, that the current evidence presented by RAC have a number of gaps and inconsistencies that need to be addressed before finalization of the decision-making process.

MSG therefore calls on the RAC to reconsider their opinion. MSG and member companies do not consider that the evidence presented is sufficient to show that MMA is a cause for asthma. The evidence comprised reports of occupational asthma claimed to be caused by MMA within National Surveillance databases combined with 6 positive Specific Inhalation Challenge (SIC) tests with MMA judged to prove that MMA caused asthma through an immunological mechanism.

Regarding the clinical cases referenced in the RAC opinion it should be recognized that it is difficult to determine the exact cause of the asthma since limited and insufficient clinical data is available upon which to make this determination.

Furthermore, prior to and during the RAC reviews in October 2020 and March 2021, the Methacrylates REACH Task Force (MRTF) and MSG provided data in written comments that supported the view that MMA



is an classified irritant chemical that exacerbates but does not cause occupational asthma. This is summarized as follows:

In the case of the 6 positive Specific Inhalation Challenge (SIC) tests used as evidence that MMA caused asthma through an immunological mechanism the available clinical science in published peer reviewed literature does not support the claim that Late Asthmatic Responses observed in some of these cases was proof of MMA acting through an immunological mechanism.

It was claimed by RAC that irritation, the more plausible alternative mechanism, could not have occurred during these 6 positive SIC tests on the basis of low average levels being measured during comparable (negative) SIC tests with other products containing MMA. However, since only average levels were measured and not peak concentrations, which are well recognized as responsible for causing irritation, this analogous evidence is not conclusive that irritation could not have occurred in these 6 tests and may have caused the observed symptoms.

Further evidence that high peak exposures capable of causing irritation were likely to have occurred during these 6 SIC tests was provided by the Methacrylates REACH Task Force (MRTF) and MSG in the form of reliable exposure measurements from the German dental industry that demonstrated that despite low average exposure levels, significant peak exposures occur in workplace situations that were being simulated in the SIC tests. This evidence was disregarded without justification.

The observed absence of asthma in major industries, such as cast acrylic sheet manufacture, that are exposed to even higher levels of MMA than those in the industries in which occupational asthma due to MMA is claimed, i.e. dental and artificial nails supports this viewpoint.

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