

COMMENTS AND RESPONSE TO COMMENTS ON OEL: PROPOSAL AND JUSTIFICATION

All comments and attachments including confidential information received during the consultation have been provided in full to the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the consultation and are also published together with the opinion (after adoption) on ECHA's website. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Last data extracted on 13.12.2021

Substance name: Isoprene

EC number: 201-143-3

CAS number: 78-79-5

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
13.12.2021	Germany	Division 4 - Hazardous Substances and Biological Agents of the Federal Institute of Occupational Safety and Health	National Authority	1
Comment received				
<p>Division 4 - Hazardous Substances and Biological Agents of the Federal Institute of Occupational Safety and Health submits the following comments on the draft scientific report of ECHA for evaluation of limit values for isoprene at the workplace.</p> <p>Chapter 5.3 Occupational exposure, p. 11 The described workplace situation seems to be plausible, although the urgency of deriving a BOELV when reading it is not very obvious: "... lead to some levels of worker exposure" (p. 11) does not really sound like high exposures. There is no measurement data described in the report for the EU, only US data was referred and ECETOC TRA calculations are listed. Both show no significant exceedances of the proposed OEL (if you take the 90th percentile for the measured values, there is no exceedance for the US data).</p> <p>Chapter 9.2 Derived Occupational Exposure Limit (OEL) Values, p. 27 ff The value derived by the ECHA Secretariat corresponds to the German OEL and the MAK value, whereby in Germany a short-term value was derived, which ECHA does not do.</p> <p>Chapter 9.2 Derived Occupational Exposure Limit (OEL) Values, 9.2.1.1 DFG and AGS, p. 27 Editorial remark: in chapter 9.2.1.1, first sentence, reference is made to the documentation of the MAK-Commission (DFG (2005)). However, it must be DFG (2009).</p>				
ECHA/RAC Response				
<p>1. Your comment on no urgency of deriving a BOELV is noted. As explained in the preamble of the Annex, the current activity was carried out based on a request from the Commission on 11 Dec 2020 to ECHA in accordance with the Service Level Agreement (SLA)</p>				

(Ares(2019)18725), to evaluate, in accordance with the Directive 2004/37/EC , isoprene which is classified as a carcinogen Category 1B in CLP legislation.
 2. Thank you.
 3. Thank you; corrected.

Date	Country	Organisation	Type of Organisation	Comment number
03.12.2021	Belgium	Lower Olefins and Aromatics (LOA) REACH Consortium VZW	Company Manufacturer	2

Comment received

1. Agreement with the proposed OEL value.
2. Comment concerned with the last paragraph of section 9.2.1.1 page 27.
3. Editorial comment on section 7.7.1 page 22.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment LOA Isoprene OEL WG FINAL reply to ECHA RAC 25Nov21.pdf

ECHA/RAC Response

1. Thank you.
2. Further text has been added to explain that extrapolation to lower residual risk values would not be relevant since the 3 ppm OEL is based upon endogenous isoprene levels.
3. The recent article of Sathiakumar et al. 2021 was added in section 7.7.1

Date	Country	Organisation	Type of Organisation	Comment number
03.12.2021	Sweden	Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals (NEG)	International NGO	3

Comment received

See attachment

ECHA note – An attachment was submitted with the comment above. Refer to public attachment NEG comments on ECHA Isoprene December 2021.pdf

ECHA/RAC Response

Thank you for the detailed comments. Suggestions presented in your comments are mostly implemented as proposed (see revisions in Annex 1 to the RAC opinion). Please find below explanations for some suggestions not taken on board.

Comment `page14`: Text now acknowledges that IPM3 is measured in urine. The last sentence has not been expanded to explain the conclusions of the article in terms of BMI, sex race etc as no proposal is made for BGV.

Comment `page 26`: The existence or absence of human data is described clearly in each endpoint specific section. ECHA considers that the lack of epidemiological data for certain hazard properties is not such a fundamental lack of information that would prevent deriving an OEL or exposure risk relationship.”

PUBLIC ATTACHMENTS

1. LOA Isoprene OEL WG FINAL reply to ECHA RAC 25Nov21.pdf [Please refer to comment No. 2]
2. NEG comments on ECHA Isoprene December 2021.pdf [Please refer to comment No. 3]