



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR EMPLOYMENT, SOCIAL AFFAIRS AND INCLUSION
Working Conditions and Social Dialogue
Health and Safety at Work Unit, EU-OSHA

The Advisory Committee on Safety and Health at Work

Opinion

Opinion on an EU Binding Occupational Exposure Limit Value (BOEL) for

Isoprene

**under the Directive on the protection of workers from the risks related to
exposure to carcinogens, mutagens or reprotoxic substances at work
(2004/37/EC)**

Doc. 004/23

Adopted on 22/09/2023

Isoprene

This Opinion is one of a series of chemical specific Opinions adopted by the ACSH in support of the forthcoming Commission proposal on amending the Directive on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (2004/37/EC).

In the meeting of the Working Party of Chemicals on 11th - 12th May 2023 and 5th-6th September 2023, in three technical meetings with the consultant and two technical exchange meetings on 17th and 29th August the report findings together with the RAC opinion (ECHA/RAC/OEL-O-0000007102-87-01/F from 18 March 2022) on Isoprene were discussed.

The three Interest Groups recognise that exposure of workers to Isoprene as a non-threshold carcinogen is of relevance. Therefore, they agree that exposure of workers to Isoprene should be addressed at EU level.

The three Interests Groups agreed the following points concerning the limit value for Isoprene:

- Isoprene (n-methyl-(1,3) butadiene) is classified as Carc. 1B and Muta. 2, but is also endogenously formed in the human body.
- The limit value of 8,5 mg/m³ proposed by RAC was derived by taking into account the naturally occurring endogenous isoprene levels in humans.
- The OEL should be set at 8,5 mg/m³ and can enter into force without any transitional measures.

Taking into consideration:

- Due to the differences in the metabolism, extrapolation from animal data to humans was not considered to be an appropriate approach by RAC.
- Beyond the RAC proposal of 8,5 mg/m³ a theoretical linear ERR derived from animal data point to a cancer risk of 4:100,000 at 1,3 mg/m³. Based on the current available exposure data this level seems to be feasible in the sectors in which isoprene is known to be used.
- OELs under the CMRD are always set without prejudice to the minimization principle and the hierarchy of controls. Knowing that isoprene is mainly used in closed systems, exposure levels below 8,5 mg/m³ and even 1,3 mg/m³ can be achieved and must therefore be maintained by industry.

The ACSH recommends the Commission to adopt as soon as possible the below new BOELV for Isoprene under Directive 2004/37/EC. The ACSH believes that this will facilitate the high level of protection by securing a level playing field now and further on.

Annex:

EC No	CAS No	NAME OF THE CHEMICAL AGENT	LIMIT VALUES				Notation	Transitional measures
			8 hours		Short-term			
			mg/m³	ppm	mg/m³	ppm		
201-143-3	78-79-5	Isoprene	8.5	3	-	-	-	-