

# Methyl isobutyl ketone

(4-Methylpentan-2-one)

Evaluation of the carcinogenicity and genotoxicity

No. 2020/26, The Hague, December 8, 2020

## Executive summary

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Health Council of the Netherlands



The Health Council of the Netherlands assessed whether occupational exposure to methyl isobutyl ketone (MIBK) may induce genotoxic effects and may cause cancer. The assessment is performed by the Subcommittee on Classifying carcinogenic substances – hereafter called the committee – of the Dutch Expert Committee on Occupational Safety of the Health Council. The Health Council has a permanent task in the protection of employees to harmful health effects of substances to which they may be exposed during work. More information on this task can be found on the website [www.gezondheidsraad.nl](http://www.gezondheidsraad.nl).

### **Methyl isobutyl ketone**

MIBK is used for various purposes in manufacturing products. Examples are: as solvent in cosmetic products, paints and lacquers; in the manufacturing of certain medicines; as synthetic flavouring; as component in food contact materials; and, as component in rubber tyres.

### **Assessment of genotoxicity and carcinogenicity**

Based on the available scientific literature, the committee assesses the potential genotoxic and carcinogenic properties of the substance in question. If there are indications for such properties, it recommends classifying the substance in two hazard categories, which represent the grade of evidence that the substance is mutagenic in germ cells (a measure for genotoxicity), and that the substance is carcinogenic. The categories are based on the criteria for assessing hazard categories, as set by the European Commission (EU-guideline (EG) 1272/2008). The recommendation can be used by the State Secretary to decide whether the substance should be listed as mutagenic in germ cells and/or carcinogenic.

### **Recommendation**

There are insufficient indications that MIBK is a mutagen. Therefore, the Committee recommends not classifying MIBK as a germ cell mutagen.

No data were available on the carcinogenicity of MIBK in humans. The substance induced tumours in two animal experiments, one experiment in rats, the other in mice. In male rats, kidney tumours were found, but the carcinogenic mechanism through which they are induced is not relevant for humans. In mice, MIBK induced liver tumours, of which a proposed carcinogenic mode of action is insufficiently investigated to conclude whether or not the findings in mice are relevant to humans. Overall, the committee concludes that there is limited evidence for carcinogenicity of MIBK in animals. It, therefore, recommends classifying the substance as *suspected to be carcinogenic in man*, which corresponds with carcinogenic category 2.



The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is “to advise the government and parliament on the current level of knowledge with respect to public health issues and health (services) research...” (Section 22, Health Act).

The Health Council receives most requests for advice from the Ministers of Health, Welfare and Sport, Infrastructure and Water Management, Social Affairs and Employment, and Agriculture, Nature and Food Quality. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.

Most Health Council reports are prepared by multidisciplinary committees of Dutch or, sometimes, foreign experts, appointed in a personal capacity. The reports are available to the public.

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