



**Ministry of Environm
and Food of Denmarl**
Environmental
Protection Agency

Risk Management Option Analysis Conclusion Document

Substance Name: Methanol

EC Number: 200-659-6

CAS Number: 67-56-1

Authority: Denmark

Date: 21 June 2016

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA or the Member States may initiate at a later stage. Risk Management Option Analyses and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020¹.

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

¹ For more information on the SVHC Roadmap: <http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation>

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

See section 1 of the RMOA document and section 2 of the Danish LOUS survey for methanol: <http://www2.mst.dk/Udgiv/publications/2013/04/978-87-93026-01-8.pdf>

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

The Danish EPA has conducted a survey of all substances and substances groups listed on the Danish List of Undesirable Substances (LOUS): www.mst.dk/lous (click further for English).

The survey carried out for Methanol provides an overview of the use and the environmental and human health aspects of the substance. The report can be found here: <http://www2.mst.dk/Udgiv/publications/2013/04/978-87-93026-01-8.pdf>

The results of the survey have been used as the main background information for the RMOA as well as feedback from the German Competent Authority.

Conclusions	Tick box
Need for follow-up regulatory action at EU level:	
<i>Harmonised classification and labelling</i>	
<i>Identification as SVHC (authorisation)</i>	
<i>Restriction under REACH</i>	
<i>Other EU-wide regulatory measures</i>	
Need for action other than EU regulatory action	
No action needed at this time	√

Based on the observations reported in the RMOA document the Danish EPA reinforced the risk management of methanol in 2013 in Denmark by providing on site information about safe handling of methanol for consumers when fuelling motor vehicles used in drag racing and speedway sports. Denmark has a long experience on using information to consumers as a risk management measure and has also documented the effectiveness of these initiatives.

Some European countries have problems with methanol-contaminated alcoholic beverages. This prompted Italy to develop a RMOA in May 2010 arguing that a restriction proposal could be a relevant risk management option. Poland finalised a substance evaluation for methanol in the autumn 2015 proposing a restriction and submitted such a proposal in the beginning of this year.

Opinions by the RAC and SEAC committees supporting the restriction as an appropriate measure to address identified risks were presented in the end of last year based on an earlier proposal withdrawn for reasons of non-conformity.

The restriction proposal includes methanol use in windshield washing fluids and use as an additive to technical ethanol for certain applications.

Italy also proposed the elaboration of a proposal for harmonized classification for

reprotoxicity (developmental toxicity), which was submitted in 2012. In an opinion from the Risk Assessment Committee (RAC) dated September 2014 on this proposal (RAC-30), RAC concluded, based on the available information, that there is not sufficient evidence for classifying Methanol for developmental toxicity. Therefore a harmonised classification for developmental toxicity seems not relevant.

Methanol can play a significant role in fuel cells in the future. The use of methanol is expected to reduce carbon dioxide and other exhaust gas emissions as well increase energy efficiency compared to petrol-powered cars. This use of methanol may also be relevant in the EU, if this technology is developed. The environmental and health-related impacts of methanol in fuel cells have not been established. Development of future regulation of fuel-cell technology based on methanol should address risks for health and environment in the EU.

Considering the risk reduction measures already implemented and on their way in the EU, the analysis concludes that methanol does not represent additional unacceptable risk to workers, consumers or to the environment. The Danish EPA considers therefore that there is no need for further regulation of methanol for the time being.