BUREAU FOR CHEMICAL SUBSTANCES

SUBSTANCE EVALUATION

CONCLUSION DOCUMENT

as required by REACH Article 48

for

Methanol

EC No 200-659-6

CAS No 67-56-1

Evaluating Member State(s): Poland

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Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2012

Member State concluded the evaluation without the need to ask further information from the the Registrants under Article 46(1) decision.

Please find (search for) further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

The Conclusion document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work.

In order to ensure a harmonised approach, ECHA in cooperation with the Member States developed risk-based criteria for prioritising substances for substance evaluation. The list of substances subject to evaluation, the Community Rolling Action Plan (CoRAP), is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the Registrants concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by the Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. In this conclusion document, the evaluating Member State shall consider how the information on the substance can be used for the purposes of identification of substances of very high concern (SVHC), restriction and/or classification and labelling or for other Community-wide measures. With this Conclusion document the substance evaluation process is finished and the Commission, the Registrants of the substance and the competent authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

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1. CONCERN(S) SUBJECT TO EVALUATION

Methanol was originally selected for substance evaluation in order to clarify suspected risks in regards to:

- Human health/Suspected CMR;
- Exposure/High exposure for workers and the environment, wide dispersive use, consumer use.

Methanol has been proposed for substance evaluation based on Article 44(1) of the REACH Regulation. The substance is produced with high tonnage (> 1000 tons) and its use is wide spread. Methanol is a high production volume chemical with many commercial uses and it is a basic building block for hundreds of chemical products.

Exposure to Methanol is mainly expected via inhalation but can also occur by dermal contact with the substance. Significant exposures are expected e.g. manufacturing of chemical and oil products, solvents, pharmaceutical industry.

Methanol is also present in various professional and consumer products such as paints, varnishes, windshield washer fluid, antifreeze, adhesives, de-icers, cleaning agents. It was evaluated whether or not the use of Methanol in consumer products and at the workplace is safe or if risk management measures are needed.

Methanol was chosen for substance evaluation especially to gain information on the reproductive toxicity and to assess its exposure conditions to decide on the necessity for further Risk Management Measures.

During the evaluation no further concerns to be clarified under substance evaluation process were identified.

However, other risk management measures or follow-up actions are proposed in regards to:

- unintentional uses of Methanol resulting in consumer poisoning (please refer to point 3.1.3),
- classification of Methanol resulting from specific impurities (please refer to point 3.1.4),
- unidentified consumer uses of the Methanol containing products (please refer to point 3.1.4).

2. CONCLUSION OF SUBSTANCE EVALUATION

The available information on the substance and the evaluation conducted has led the evaluating Member State to the following conclusions, as summarised in the table below.

Conclusions	**Tick box**
Need for follow up regulatory action at EU level	
Need for Harmonised classification and labelling	
Need for Identification as SVHC (authorisation)	
Need for Restrictions	X
Need for other Community-wide measures	X
No need for regulatory follow-up action	

3. JUSTIFICATION FOR THE CONCLUSION ON THE NEED OF REGULATORY RISK MANAGEMENT

3.1. NEED FOR FOLLOW UP REGULATORY ACTION AT EU LEVEL

3.1.1. Need for harmonised classification and labelling

Although the need for harmonised classification and labelling has not been indicated in the conclusion chapter above, the following information is essential to clarify why it is considered that additional harmonised classification is not needed.

Evaluation of the data presented in the registration dossier indicated that Methanol affects prenatal development of offspring in mice and rats causing fetotoxic and teratogenic effects. The provided data were sufficient for evaluation and they suggested the possible need for establishing a harmonised classification of Methanol due to developmental toxicity.

In parallel to evaluation process (in September 2012) Italian (IT) MSCA submitted to ECHA Annex XV dossier concerning classification and labelling. Following classification has been then proposed (in addition to existing harmonised classification):

Repr.1B – H360D according to Regulation (EC) 1272/2008

The proposal for classification was based on weight of evidence from the integrated assessment of all the available studies. In animal studies, severe developmental effects were consistently recorded in both rats and mice in the absence of maternal toxicity. In general, prenatal developmental toxicity was evidenced by decreased foetal weight, decreased incidence of live foetuses and increased incidences of resorptions and dead foetuses (relative to concurrent controls), as well as teratogenic effects (neural tube defects, cleft palate and skeletal and visceral malformations).

Opinion of Risk Assessment Committee (RAC) on the IT MSCA's proposal was adopted in September 2014 (RAC-30). According to RAC, based on the available information, there is not sufficient evidence for classifying Methanol for developmental toxicity and classification for developmental toxicity seems not relevant.

3.1.2. Need for Identification as a substance of very high concern, SVHC (first step towards authorisation)

Not applicable.

3.1.3. Need for restrictions

Polish (PL) MSCA has submitted an Annex XV dossier concerning restrictions for Methanol in July 2014.

The reason for which the procedure has been initiated is the occurrence of poisoning cases (including death) among consumers resulting from drinking mixtures containing Methanol such as windshield washing fluids as well as technical ethanol containing Methanol used as a fuel for touristic appliances or a cleaning agent.

In Poland till 1 June 2010 the placing on the market products containing Methanol in the concentration higher than 3.0% by weight for general public was banned by Regulation of Ministry of Economy. In December 2012, the information on the increasing number of Methanol poisonings was submitted by some of the acute poisoning centres, thus verification of this information was commenced in order to determine the extent of this

problem. Between 2001 and 2010, on average 4.5 Methanol poisonings were recorded annually, while this number reached 18 in 2011, 43 in 2012 and 36 in 2013. A very high rate of fatal poisonings was noted – from over 40% to over 60%. Major number of poisonings results from confirmed consumption of windscreen washing fluids.

Methanol poisonings with the extent similar to Poland's occur in Finland. Some accidents were also noted in Lithuania, Estonia, Ireland, UK and Italy.

Thus, following restriction has been proposed:

"*Methanol shall not be placed on the market for supply to the general public:*
- as a substance,
- as a constituent of windshield washing fluids in concentration equal to, or greater than 3.0% by weight,
- as an additive to technical ethanol used as a fuel for touristic cooking appliances or as a multipurpose cleaning agent (methylated spirit, denaturated alcohol, brennspiritus), in concentrations equal to, or greater than 3.0% by weight."

3.1.4. Proposal for other Community-wide regulatory risk management measures

Based on the evaluation, eMSCA decided on the need to transfer the following information to the Enforcement Authorities in MS Countries:

1. The Lead Registrant has declared that use of Methanol in cleaning agents and de-icers liquid products (e.g. windshield fluids) by consumers in the amounts higher than 2.5 % w/w is not currently supported by any Registrant. Thus, it is not an identified use in any of the supply chains of the concerned Registrants.
   The risk characterisation ratios (RCRs) are below 1 indicating no concern for human health (consumers) for the highest concentration of substance in cleaning and de-icers liquid products amounting to 2.5 % w/w, as declared by the Registrants. However, according to the information gathered from Polish database of mixtures, products containing more than 3% w/w are also present on the EU market. The risk characterisation ratios in case of such a high content of Methanol would be higher than 1 indicating concern for human health.
2. The classification and labelling of Methanol due to its health hazards as provided by the Registrants was reviewed based on the classification and labelling as listed in Annex VI, Table 3.1 (List of harmonised classification and labelling of hazardous substances) and of Table 3.2 (list of harmonised classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008. Additionally, registration dossiers of the Lead Registrant and members' dossiers where checked for impurities which may influence classification and labelling of registered substance. Twenty four different impurities have been identified in section concerning detailed composition of registered substance. Seven of them, if present in the declared concentration range, based on entries in Annex VI of Regulation (EC) No 1272/2008 may influence the classification of the registered substance. In such cases, it is not evident that safe use is still demonstrated.

National Enforcement Authorities will be informed by PL MSCA directly via RIPE system or via Enforcement Forum.

3.2. NO FOLLOW-UP ACTION NEEDED

Not applicable.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Follow-up action	Date	Actor
Annex XV dossier for restrictions	July 2014	Poland