Ministry of Environment and Food of Denmark
Environmental Protection Agency

ANALYSIS OF THE MOST APPROPRIATE RISK MANAGEMENT OPTION (RMOA)

Substance name: Methanol
EC number: 200-659-6
CAS number: 67-56-1

Submitted by: Denmark
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Cover Note

The Danish EPA has conducted a survey of all substances and substance 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 this RMO as well as feedback from the German Competent Authority.

Contents

1. Background

The Danish EPA has conducted a survey of all substances listed on the Danish List of Unwanted Substances (LOUS).

The survey carried out for methanol provides an overview of the use and the environmental and human health aspects of the substance. The results of the survey have been used as the main background information for this RMOA.

The most important EU regulations include:

- REACH, where methanol has been subject to a substance evaluation finalised in September 2015 by Poland
- There is a pending restriction proposal under REACH for methanol in windshield washing fluids and use as an additive to technical ethanol for certain applications elaborated by Poland
- The EU has laid down limit values for the content of methanol in alcoholic beverages
- The EU has laid down limit values for the use of the food additives aspartame (E 951) and dimethyl dicarbonate (E 242), which both release methanol during degradation
- Methanol has a harmonised classification for acute toxicity in category three and a specific target organ toxicity after a single exposure in category one
- Criteria for ecolabelled products in the EU and in the Nordic countries include restrictions on the content of methanol, as there are restrictions on the VOC content
- Upon a Parliamentary questionThe European Commission has dismissed a raise of the limit of 3% methanol content in fuels
- Working with methanol or work which involves a risk of being exposed to methanol is covered by the EU directives on safety and health at work
- Methanol has a limit value for pollution of the air which can be inhaled at the workplace

2. Objectives for (further) risk management

Based on the available data and assessments the following concerns are identified:

Besides misuse no concerns for health and environment appear when current risk management is adhered to. However the following observation points have been noted:

- In a Finish risk assessment (Finish Institute of Occupational Health. “Development of initial REACH exposure scenarios for methanol”, Helsinki 2008, Translation 2009, Funded by the Finnish Work Environment Fund) concern was concluded for the use of methanol based fuels in hobby activities like speedway motorcycling for exposure through skin.

3. Available information

3.1 Human health Risk assessment

Methanol is toxic for humans, because it causes damage to the eyes, and, at worst, it can cause blindness or death. Methanol is readily absorbed through ingestion and through dermal contact and inhalation.

There is only little data available on the effects of chronic exposure to methanol. Studies on toxicity for human beings are complicated by the fact that methanol is more toxic to human beings than to animals.

The toxicity of methanol is due to a toxic metabolite formate. The toxicity in humans is influenced by the person's content/status of folate, as folate increases the rate of formate detoxification. Certain groups are therefore particularly sensitive, as they typically have a folate deficiency. These can include pregnant women, the elderly or alcoholics. Methanol occurs naturally in humans, animals and plants.

Several exposure assessments have been carried out in Finland on different exposure scenarios to non-natural methanol sources. The assessments found that there was a need to use protective equipment in the following scenarios:

- Manufacturing of products with methanol, and as solvents in extraction processes,
- Use of methanol in waste water treatment,
- Use of methanol as a fuel in speedway, drag racing etc.

Human beings are primarily exposed to methanol in their working environment and to some extent through food, and because the body naturally produces methanol. The Danish Working Environment Authority's regulations include requirements to avoid unnecessary exposure. Preventive measures must be assessed case-by-case, and this may result in requirements for ventilation and use of personal protective equipment.

Methanol is classified as hazardous on the basis of acute effects on human health. The current management of the very large quantities of methanol therefore poses a potential risk in health and safety at work and the challenges in health and safety require close compliance with health and safety regulations.

To address the potential risk, Italy has proposed a new classification of methanol as being 'toxic to reproduction'. The background information for this proposal should be evaluated and commented bearing in mind that methanol is less toxic for animals than for human beings and that classification is often based on animal studies. It should also be taken into account that folate-deficient individuals might be at greater risk from inhalation of low concentrations of methanol, compared to normal individuals.

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.

A number of EU countries (Italy, Finland, Poland and the Czech Republic) have experienced a number of deaths from ingestion of methanol-contaminated alcoholic beverages. Enquiries at the Danish Poison Information Centre have not revealed such cases in Denmark. This prompted Italy to develop a RMOA discussing a restriction proposal in May 2010.

A certain group of consumers in Denmark may be exposed to methanol in such high concentrations that it poses a health risk. These include consumers who have been granted an exemption to use methanol-based fuels in speedway, drag racing etc. according to a Danish dispensation scheme for certain recreational organizations to use methanol as a fuel. The identified risk is based on observations in a Finnish occupational health study, where they found that – if not wearing gloves – there could be a risk related to methanol spillage on the skin when filling the methanol tanks. Possible data in the registration dossiers or any preliminary results from the substance evaluation has not been investigated in this context.

Methanol intake from the diet is primarily from methanol containing foodstuff with the food additives aspartame and dimethyl dicarbonate. Fruit and fruit wines have a high content of methanol, and in addition to this, methanol is released in the body in connection with degradation of aspartame (E 951) and dimethyl dicarbonate (E 242).

Aspartame and dimethyl dicarbonate are both allowed in aromatised drinks in quantities of 600 mg/L and 250 mg/L, respectively. A person drinking 1 litre of soft drink with the two additives will ingest 60 mg of methanol from aspartame and 120 mg methanol from dimethyl dicarbonate, corresponding to 1 and 2 mg/kg respectively. Both aspartame and dimethyl dicarbonate have recently been risk assessed by the European Food Safety Authority, but this assessment has not been included in the survey. The two substances have been found unproblematic to human health, as the amount of methanol released has been assessed with regard to the intake from fruit and endogenous processes in the body. The survey does not challenge this conclusion.

In an older report, WHO assessed that if methanol is used as a fuel, it should be denatured and contain a colour additive to avoid misuse. The use of methanol as a fuel is expected to increase, as China in particular will base parts of its transport sector on this fuel. In EU, methanol is likely to become a component in fuel cells, as it can generate hydrogen, which on reaction with oxygen can be converted into electricity.

3.2 Environmental risk assessment

Methanol is readily degraded in the environment. Generally 80% of methanol is degraded within five days in standard biodegradation tests, and is typically a growth substrate for micro-organisms which degrade methanol into carbon dioxide and water. Methanol is of low toxicity to aquatic and terrestrial organisms and does not bioaccumulate.

The IPCS under WHO concludes that effects related to environmental exposure to methanol are unlikely to be observed, unless methanol is released into the environment in large quantities. The IPCS suggests that care should be taken to prevent spills of methanol, especially spills to the surface water. An EU Directive regulating spills from companies handling at least 500 tons/year and the safe transport of methanol is in force.

It is likely that consumption of methanol will increase significantly at global level. However, this will mainly be in China and in other countries where methanol is expected to be used as a fuel in the transport sector.

There are not the same expectations for an increase in consumption in the EU. Upon request from industry, the European Commission has not proposed to increase the limit already set for methanol in fuel.

The Danish EPA has no indication that methanol poses a problem in the waste sector, as it is either reused in production or degraded completely during incineration.

In conclusion the overall assessment from the Danish EPA is that methanol does not pose a risk to the environment.

3.3 Alternatives

Alternatives to the most important uses of methanol have been investigated:
There are no relevant alternatives to methanol in the production of glue.

It is possible to use other types of alcohols than methanol in the production of biodiesel, but none of these are as efficient as methanol. Methanol is the only alcohol used for this purpose worldwide.

In certain cases ethanol can be used as an alternative to methanol when used as a solvent. The use of ethanol can be advantageous in production, and the substance is of lower acute toxicity compared to methanol.

As a part of the large scale Danish research program, BioRec, at Center for Energy Resources Engineering, alternatives to methanol in the oil and gas industry have been investigated. Methanol is used as a gas-hydrate inhibitor in oil and gas pipelines, and promising results have been attained by using proteins from beetles as a sustainable alternative. The findings have been published in several peer reviewed articles for instance in Daraboina et al 2015.

4. Identification of risk management options

Risk Management Options that can be initiated by Member State Competent Authorities under REACH or CLP:

- Substance evaluation
- Harmonised C&L

- Inclusion in the candidate list and eventual inclusion in Annex XIV
- Restrictions

National Risk Management Options:

- Information campaign for exposed population at risk

5. Assessment of the identified risk management options

The Danish EPA assessed in 2013 that the following observation points were relevant to address:

- There may be individuals in Denmark who are exposed to methanol through their hobby, e.g. as a fuel for speedway and drag racing. This exposure is possible through a legal exemption to the Danish regulations only prohibiting methanol solutions in concentrations of more than 10% being sold to the general public. Therefore there may be a health risk via dermal exposure if use of the compound is not in accordance with recommendations on the label (use of protective gloves). However, the information available does not give reason for proposing a restriction, since investigating exposure in relation to the specific use in Denmark and across Europe in order to document evidence for risk is estimated not to be feasible.

- Some European countries have problems with methanol-contaminated alcoholic beverages. This has prompted Italy to develop a RMOA in May 2010 arguing that a restriction proposal could be a relevant risk management option in their view. They also proposed that they would make a proposal for harmonized classification for reprotoxicity. This could in the future make methanol a possible candidate for SVHC list in REACH.

- 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.

6. Conclusions on the most appropriate (combination of) risk management option(s)

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.

7. References

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