SUBSTANCE EVALUATION REPORT

Public Name: **Methanol**

EC Number(s): **200-659-6**

CAS Number(s): **67-56-1**

Submitting Member State Competent Authority:

Bureau for Chemical Substances,

Dowborczykow 30/34, 90-019 Lodz, Poland

Year of evaluation (as given in the CoRAP): 2012

VERSION NUMBER: 3.0 **DATE:** ***17.09.2015***

Conclusions of the most recent evaluation step*	**Tick relevant box(es)**
Concern not clarified; Need to request further information from the Registrant(s) with the draft decision	
Concern clarified; No need of further risk management measures	
Concern clarified; Need for risk management measures; RMO analysis to be performed	**X**

DISCLAIMER

Executive summary

Grounds for concern

Methanol (CAS No: 200-659-6) has been proposed for substance evaluation based on Article 44 of the REACH Regulation.
Methanol was selected to CoRAP due to its high volume and wide dispersive use for both professionals and consumers, high exposure for workers and high release for environment. The exposure to Methanol may cause serious risk to human health.

The aim of evaluation process was to clarify the initial concerns that the manufacture and use of Methanol could pose a risk to human health or the environment.

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 of the reproductive toxicity and to assess its exposure conditions to decide on the necessity for further risk management measures.

During the evaluation also other concerns were identified. The additional concerns were:

- classification and labelling resulting from impurities which may influence classification and labelling of substance
- poisoning cases (including death) occurring among consumers resulting from drinking mixtures containing Methanol such as windshield washing fluids

Procedure

- Evaluation of existing information – from February 2012 to February 2013
- The meeting between the evaluating MSCA and the representatives of the Lead Registrant was held in December 2012. eMSCA informed the Registrants which information might require clarification and what in such a case could be addressed in a possible draft decision. The Registrants declared their willingness to supplement some information on voluntary basis. The draft decision was prepared and then was forwarded to ECHA in February 2013
- 4 April 2013: ECHA sent the draft decision to the concerned Registrants and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision
- The Registrants commented on the draft decision in his letter in May 2013. The Lead Registrant committed to updating the requested information and consequently updated

the registration dossier
- The Registrant submitted an updated dossier to ECHA in August 2013.
- The evaluating MSCA considered the comments and dossier updates received from Registrants concerned. As most of the information requested was addressed in the dossier update the evaluating MSCA modified the Information Required (Section II) and the Statement of Reasons (section III) of the draft decision by removing information requirements fulfilled through the dossier update
- In accordance with Article 52(1) of the REACH Regulation, in March 2014 the evaluating MSCA notified the other MSCAs and ECHA of its modified draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals for amendments to the draft decision within 30 days.
- Subsequently, ECHA and two MSCAs submitted proposals for amendment to the draft decision
- 11 April 2014: ECHA notified concerned Registrants of the proposals for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification
- 22 April 2014: ECHA referred the draft decision as notified to MSCAs and the proposals for amendment subsequently received to the Member State Committee.
- By 12 May 2014, in accordance to Article 51(5), the Registrants provided comments on the proposals for amendment which were submitted to the Member State Committee for further consideration.
- 15 May 2014: Unanimous agreement of MSC on draft agreement document was sought in written procedure
- 26 May 2014: MSC unanimously agreed with the conclusions of eMSCA in the draft agreement document
- eMSCA agreed to remove the only information requirement, as this issue can indeed be addressed directly by enforcement authorities. Thus no decision for asking further information on Methanol was issued by ECHA.

Conclusions

Environment

The eMSCA is of the opinion that further information is not required.

Human Health

Information available in 2012 was carefully reviewed in particular with a focus on reproductive toxicity aspects. Information regarding human health from new Registrant(s) and dossier update have not been taken into account by eMSCA .

Developmental toxicity
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 was considered conclusive and suggested the possible need for establishing a harmonized classification of Methanol for the category of developmental toxicity.
In parallel to evaluation process, Italy has submitted a CLH dossier containing a proposal

together with the justification and background information document.

The Italian proposal for classification was based on weight of evidence from all of the available studies. According to Italian opinion severe developmental effects were consistently recorded in both rats and mice in the absence of maternal toxicity. In general, prenatal developmental toxicity was evidenced in these species 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). Moreover, post-natal effects (some of which were observed at maternally toxic dose levels) included increased neonatal mortality and growth retardation and earlier testis descent. A recent, non-GLP, test guideline compliant study in rabbits (Sweeting et al., 2011) suggested that Methanol may also act as a teratogen in non-rodent species with a metabolic pathway for Methanol more similar to humans, albeit the potency might be lower than in rodents. Moreover, in Macaca fascicularis, Methanol significantly reduced the duration of pregnancy, suggesting that pregnancy also represents a life stage susceptible to Methanol exposure in primates. Classification as Repr. 1B – H360D was therefore proposed by Italy.

The RAC opinion on the proposed harmonized classification and labelling was adopted on 12 September 2014 by consensus. The RAC opinion was made publicly available at http://echa.europa.eu/documents/10162/e9c6d48c-8e53-4282-8d2d-86817cfc17af .

The RAC concludes that, based on the available information, there is not sufficient evidence for classifying Methanol for developmental toxicity.

Fertility and sexual function
The existing data does not indicate that Methanol affects fertility and sexual function in animals.
The provided data is conclusive but it does not warrant classification of Methanol in the end-point on fertility and sexual function

Exposure assessment and risk characterization

Worker Exposure
The exposure scenarios as provided in the updated chemical safety report were carefully reviewed. Further information is not required.

Consumer Exposure
eMSCA does not agree with DNEL proposed by the Lead Registrant for general population and therefore the risk characterisation has been recalculated using DNEL derived by eMSCA. Further information is not required.

- Information on operational conditions, exposure estimations and risk characterisation for exposure scenarios related to consumer use of cleaning agents and de-icers (liquid products)

The Lead Registrant has declared that use of Methanol in cleaning agents and de-icers liquid products (eg. 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 supply chain 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.

- Acute poisonings (with high rate of fatal cases) occurring among alcoholics drinking winter windshield washing fluids (including windshield defrosters) and denaturated alcohol (methylated spirit) as a substitute of consumable alcohol

The proposed restriction by eMSCA is namely to eliminate poisonings caused by consumption of Methanol contained in high concentrations in winter windshield washing fluids (including windshield defrosters) and in denatured alcohol by alcoholics and other person abusing alcohol. These products represent the most common cause of severe Methanol poisonings, which in many cases turn fatal. Winter windshield washing fluids containing alcohol (including windshield defrosters) and denaturated alcohol, which are available in retail, are consumed as a surrogate of consumable alcohol by some alcoholics. The restriction's aim is not to protect workers as they are protected by regulations concerning protection of workers against risk posed by effects caused by chemicals, including OEL, which for Methanol is 260 mg/m^3.

The aim of the proposed restriction is not to protect consumers using winter windshield washing fluids and denaturated alcohol in accordance with their purpose.

It is proposed to establish 3% limit value for Methanol in windshield washing fluids (including windshield defrosters) and denaturated alcohol. The calculation, performed by eMSCA on the basis of lethal oral doses of Methanol in humans, indicates a risk for the human health if a person swallows windshield washing fluids containing high doses of Methanol.

Risk communication, classification and labelling

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 harmonized 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.

Information required

The eMSCA will inform the REACH competent authorities of the respective Member States about the improper classification and labelling in the registration dossiers of the concerned Registrants.

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List of Tables

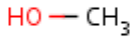
1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1. Name and other identifiers of the substance

Table 1. Substance identity

Public Name:	Methanol
EC number:	200-659-6
EC name:	Methanol
CAS number (in the EC inventory):	67-56-1
CAS number:	67-56-1
CAS name:	Methanol
IUPAC name:	Methanol
Index number in Annex VI of the CLP Regulation	603-001-00-X
Molecular formula:	CH4O
Molecular weight range:	32.0419
Synonyms:	Methanol Methyl alcohol Methyl hydroxide Monohydroxymethane MeOH methanol Methyl Alcohol methyl alcohol

Structural formula:



1.2. Composition of the substance

Name: Methanol

Degree of purity: > 80.0 — 100.0 % (w/w)

Table 2. Constituents

Constituent	Typical concentration	Concentration range
Methanol EC no.: 200-659-6	99.0 % (w/w)	80.0 — 100.0 % (w/w)

Detailed composition of the substance is in the confidential annex.

1.3. Physicochemical properties

Table 3. Physicochemical properties[1]

Property	Value	Remarks
Physical state at 20°C and 101.3 kPa	*Methanol is a clear, colourless liquid that has an alcoholic odour*	*Discussion and the value used for Chemical Safety Assessment (CSA) reported in the endpoint summary*
Melting/freezing point	*-97.8 °C*	
Boiling point	*64.7 °C*	
Vapour pressure	*169.27 hPa at 25°C*	
Surface tension	-	*Based on chemical structure, no surface activity is predicted.*
Water solubility	*>= 1000 g/L*	*Completly miscible in water at 20°C.*
Partition coefficient n-octanol/water (log value)	*log Kow=-0.77*	
Flash point	*9.7 °C at 101325 Pa*	
Flammability	*highly flammable*	*The flammability is deduced from flash point and boiling point, so the substance is a highly flammable liquid.* *Based on chemical structure pyrophoric properties and flammability in contact with*

[1] The references of the values reported in Table 2 will be available in the technical dossier.

		water are not to be expected.
Explosive properties	*non explosive*	*There are no chemical groups associated with explosive properties present in the molecule.*
Self ignition temperature	*455°C at 101325 Pa*	
Oxidising properties	*no oxidising properties*	*Substance is incapable of reacting exothermically with combustible materials.*
Granulometry	*not applicable*	*Substance is marketed or used in a non solid or granular form.*
Stability in organic solvents and identity of relevant degradation products	-	*The stability of the substance is not considered as critical.*
Dissociation constant	-	*The substance does not contain any ionic structure under enviromental conditions.*
Viscosity	*0.54mPa · s (dynamic)*	
Auto flammability	*455°C at 101325 Pa*	
Reactivity towards container material	-	-
Thermal stability	-	-

2. MANUFACTURE AND USES

2.1. Quantities

According to information provided by ECHA, Methanol is registered in the total tonnage band of 10 000 000 - 100 000 000 tonnes per annum.

2.1.1 Manufacturing processes

Methanol production process converts a gaseous mixture of carbon oxides and hydrogen, derived in a steam reforming of a hydrocarbon feedstock, typically natural gas, into Methanol. This mixture is compressed and then reacted over a metal oxide catalyst to give Methanol and by-products, according to the following reactions.
$CO + 2\ H_2 \leftrightarrow CH_3OH$
$CO_2 + 3\ H_2 \leftrightarrow CH_3OH + H_2O$.
The pure product is obtained by fractional distillation. All process steps are performed in closed systems.
According to registration dossiers Methanol is also produced as by-product from the manufacture of polymers and other substances.
On the basis of submitted for the first REACH registration deadline dossiers more than 35 production sites were identified in Europe.

2.2. Identified uses

All uses presented below and evaluated as presented in the registrations dossiers in 2013.

Table 4. Uses at industrial sites

Identifiers	**Use descriptors**
1. Manufacture of the Substance /Use as an intermediate / Use as a process chemical	**Environmental release category (ERC):** ERC 1: Manufacture of substances ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) ERC 6b: Industrial use of reactive processing aids **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity

	for exposure arises PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 15: Use as laboratory reagent
2. Distribution of the substance	**Environmental release category (ERC):** ERC 1: Manufacture of substances ERC 2: Formulation of preparations **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
3. Formulation and (re)packing of substance and mixtures	**Environmental release category (ERC):** ERC 2: Formulation of preparations **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)

	PROC 15: Use as laboratory reagent
4: Use as a fuel in industrial settings	**Environmental release category (ERC):** ERC 8b: Wide dispersive indoor use of reactive substances in open Systems (obsolete) **Process category (PROC):** PROC1: Use in closed process, no likelihood of exposure ; PROC2: Use in closed, continuous process with occasional controlled exposure ; PROC3: Use in closed batch process (synthesis or formulation) ; PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 16: Using material as fuel sources, limited exposure to unburned product to be expected PROC 19: Hand-mixing with intimate contact and only PPE available.
6: Industrial use in cleaning agents	**Environmental release category (ERC):** ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure ; PROC 2: Use in closed, continuous process with occasional controlled exposure ; PROC 3: Use in closed batch process (synthesis or formulation); PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 7: Industrial spraying PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring
8: Use as a laboratory reagent in industrial settings	**Environmental release category (ERC):** ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles **Process category (PROC):** PROC 10: Roller application or brushing;

	PROC 15: Use as laboratory reagent
10: Industrial use in wastewater treatment processes	**Environmental release category (ERC):** ERC 9b: Wide dispersive outdoor use of substances in closed systems **Process category (PROC):** PROC 2: Use in closed, continuous process with occasional controlled exposure
11: Industrial use as oilfield chemical (addition to water based drilling agents)	**Environmental release category (ERC):** ERC 9b: Wide dispersive outdoor use of substances in closed systems **Process category (PROC):** PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities

Table 5 Use by professional workers

Identifiers	**Use descriptors**
5: Use as a fuel in professional settings	**Environmental release category (ERC):** ERC 8b: Wide dispersive indoor use of reactive substances in open systems ERC 8e: Wide dispersive outdoor use of reactive substances in open systems **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 16: Using material as fuel sources, limited exposure to unburned

	product to be expected PROC 19: Hand-mixing with intimate contact and only PPE available.
7: Professional use in cleaning agents	**Environmental release category (ERC):** ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8d: Wide dispersive outdoor use of processing aids in open systems **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 10: Roller application or brushing PROC 11: Non industrial spraying PROC 13: Treatment of articles by dipping and pouring
9: Use as a laboratory reagent in professional settings	**Environmental release category (ERC):** ERC 8a: Wide dispersive indoor use of processing aids in open systems **Process category (PROC):** PROC 10: Roller application or brushing PROC 15: Use as laboratory reagent

Table 6 Uses by consumers

Identifiers	**Use descriptors**
12: Consumer use of cleaning agents and de-icers (liquid products)	**Environmental release category (ERC):** ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8d: Wide dispersive outdoor use of processing aids in open systems **Product Category used:** PC 4: Anti-freeze and de-icing products PC 35: Washing and cleaning products (including solvent based products)

13: Consumer use of cleaning agents and de-icers (spray products)	**Environmental release category (ERC):** ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8d: Wide dispersive outdoor use of processing aids in open systems **Product Category used:** PC 4: Anti-freeze and de-icing products PC 35: Washing and cleaning products (including solvent based products)
14: Consumer use of fuels indoors (Domestic/hobby use e.g in model engines, fuel cells, fondue sets)	**Environmental release category (ERC):** ERC 8b: Wide dispersive indoor use of reactive substances in open systems **Product Category used:** PC 13: Fuels
15: Consumer use of fuels outdoors (gasoline additive)	**Environmental release category (ERC):** ERC 8e: Wide dispersive outdoor use of reactive substances in open systems **Product Category used:** PC 13: Fuels

Technical function of the substance during formulation:

- Solvents
- Intermediates
- Anti-freezing agents
- Laboratory chemicals
- Fuels and fuel additives
- Process regulators, other than polymerisation or vulcanisation processes
- Process regulators, used in vulcanisation or polymerisation processes
- Washing agent
- Stabilisers
- Corrosion inhibitors and anti-scaling agents
- Processing aid, not otherwise listed

2.3. Uses advised against

No information available.

3. CLASSIFICATION AND LABELLING

3.1. Harmonised Classification in Annex VI of the CLP Regulation

Methanol is listed by Index number 603-001-00-X in Annex VI, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as follows:

Table 7. Classification and labelling according to CLP

Index No	International Chemical Identification	Classification		Labelling			Specific Conc. Limits, M-factors
		Hazard Class and Category Code	Hazard statement Codes	Pictogram, Signal Word Code	Hazard statement Codes	Suppl. Hazard statement Code(s)	
603-001-00-X	Methanol	Flam. Liquid 2 Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* STOT Single Exp. 1 Affected organs: Optic nerve (nervus opticus), central nervous system	H225 H301 H311 H331 H370**	GHS02 GHS06 GHS08 Dgr	H225 H373 H315 H318		STOT SE 2; H371: 3% ≤ C < 10% * STOT SE 1; H370: C ≥ 10%

* For certain hazard classes, including acute toxicity and STOT repeated exposure, the classification according to the criteria in Directive 67/548/EEC does not correspond directly to the classification in a hazard class and category under this Regulation. In these cases the classification in this Annex shall be considered as a minimum classification.

** The classification under 67/548/EEC indicating the route of exposure has been translated into the corresponding class and category according to this Regulation, but with a general hazard statement not specifying the route of exposure as the necessary information is not available.

Evaluation of data on toxicity to reproduction provided in the registration dossier suggested that a procedure for establishing a harmonized classification of Methanol for the category of developmental toxicity should be initiating. However during evaluation process on 22 September 2012 IT MSCA submitted Annex XV dossier concerning classification and labelling. Following classification has been proposed (in addition to existing harmonised classification): Repr.1B – H360D according to Regulation (EC) 1272/2008.

RAC opinion on the IT MSCA's proposal was adopted on 12 September 2014 (RAC-30). The RAC is of the opinion that, based on the available information, there is not sufficient evidence for classifying Methanol for developmental toxicity and classification for developmental toxicity seems not relevant.

3.2 Self classification

This section should include information on self-classification(s) reported by the Registrant(s), including any specific concentration limits. Any justification for self classification and information on the variability of self classification (if relevant) can also be included.

However there are numbers of impurities (please refer to confidential annex), specified by the Registrants, listed in annex VI of Regulation (EC) No 1272/2008 which should be taken into account for self-classification by the Registrants. These impurities are relevant for self-classification and for updating of the exposure assessment of Methanol.

The detailed composition of the substance and classification and labelling of identified impurities are in the confidential annex.

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 harmonized 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.

4. ENVIRONMENTAL FATE PROPERTIES

Methanol is readily biodegradable in water, soil and sediments, both under aerobic and anaerobic conditions.
Compared to other loss mechanisms identified, including volatilization and chemical degradation, biodegradation is expected to be the dominant process controlling the fate of Methanol in the soil, groundwater, and surface water environments.
Methanol is degraded in the atmosphere by photochemical, hydroxyl-radical dependent reactions. The estimated elimination half-life is calculated to be about 17.2 days. Due to the high solubility of Methanol in water and its low octanol-water partition coefficient adsorption to soil is considered to be negligible. Given the value of the Henry's Law constant, once in water, Methanol is likely to remain in the aqueous phase. No bioaccumulation is expected.

5. HUMAN HEALTH HAZARD ASSESSMENT

5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

Several data on toxicokinetics has been presented by the Registrants. The data shows that Methanol is readily absorbed after inhalation, ingestion and dermal contact and distributed rapidly throughout the body. The clearance from the body is mainly due to metabolism (up to 98%), with more than 90% of the administered dose exhaled as carbon dioxide. Renal and pulmonary excretion rates contribute to only about 2 – 3%. The metabolism and toxicokinetics of Methanol varies by species and dose. In humans, the half-life time is approximately 2.5 – 3 hours at doses lower than 100 mg/kg bw. At higher doses, the half life can be 24 hours or more (IPCS/WHO, 1977; Kavet and Nauss, 1990).
The mammalian metabolism of Methanol occurs mainly in the liver, where Methanol is initially converted to formaldehyde, which is in turn converted to formate. Formate is converted to carbon dioxide and water. In humans and monkeys, the oxidation to formaldehyde is mediated by alcohol dehydrogenases and basically limited to the capacity of those enzymes. In rodents, the oxidation to formaldehyde predominantly employs the catalase-peroxidase pathway which is of less capacity than the ADH-pathway in humans but on the other hand produces oxygen radicals which may be involved into the developmental effects in rodents which - in contrast to humans - tolerate high Methanol levels without signs of CNS or retinal toxicity. The last oxidation step, conversion of formate to carbon dioxide employs formyl-tetrahydrofolate synthetase a co-enzyme, is of comparably low capacity in primates which leads to a low clearance of formate, possibly also from sensitive target tissues (such as CNS and the retina) (DFG 1999; IPCS/WHO, 1997; Dorman et al., 1994; Medinsky et al., 1997, Medinsky and Dorman, 1995; Mc Martin et al., 1977).
In humans, when exposed to Methanol via inhalation up to an air concentration 65 mg/m3, no increase of blood Methanol is expected. Up to 260 mg/m3 (single or repeated exposure) the Methanol blood level is likely to increase only 2- to 4- fold above the endogenous Methanol concentration in humans, but still remains significantly below 10 mg/L (Lee et al., 1992; NTP, 2003). Up to air concentrations of 1600 mg/m3 the blood Methanol levels increase to a similar extent in rats, monkeys, and humans. However, above this concentration rats show a steep exponential increase which apparently reflects the saturation of the catalase-dependent pathway.
A smaller exponential increase was observed in monkeys, whereas in humans there appears to be a linear relationship between air concentrations and blood Methanol levels.

Baseline levels of formate in blood are about 3 to 19 mg/L (0.07 – 0.4 mM) in humans. Toxic blood formate concentrations are reported to be 220 mg/L and higher (> 5 mM formate). Inhalation of about 1200 mg Methanol/m3 for 2.5 hours contributed only insignificantly to the internal formate pool in monkeys (in the μM-range). This also hold true for folate-deficient conditions. After repeated inhalation of 2600 mg/m3 for 6 hours/day, 5 days/week, for 1 or 2 weeks, monkeys showed no discernible increase in formate concentrations in blood (estimated body burden 200 to 300 mg/kg bw/d). Formate accumulation, however, has been observed in primates upon bolus administration of more than 500 mg Methanol/kg bw (Horton et al., 1992; Medinsky and Dorman, 1995). The critical Methanol dose that saturates the folate pathway in humans is estimated to be ≥200 mg/kg bw. Based on data produced in monkeys, metabolic saturation in humans is also less likely to happen upon inhalation where the dose is distributed over several hours (DFG 1999; IPCS/WHO, 1997; Burbacher et al., 1999).

There is a strong link between saturation (zero-order) kinetics and the onset of acute toxic effects. Exposure levels in humans above 5000 ppm (750 mg/kg bw in the course of 8 hrs) are prone to a zero order kinetic and a strong accumulation of Methanol in the blood. Transient blindness has been reported for exposure levels between 1000 and 5000 ppm. (This saturation point could be reached after oral uptake at lower dose levels.) 10.000 ppm is still tolerated in rodents but would be highly detrimental in humans.

5.2. Acute toxicity

Not evaluated.

5.3. Irritation

Not evaluated.

5.4. Corrosivity

Not evaluated.

5.5. Sensitisation

Not evaluated.

5.6. Repeated dose toxicity

Not evaluated.

5.7. Mutagenicity

Based on the negative results in the in vivo studies submitted by the Registrant, Methanol does not seem to be mutagenic. Furthermore, carcinogenicity studies indicated no evidence of a carcinogenic potential in rats and mice exposed to Methanol. No need for classification based on the available data.

5.8. Carcinogenicity

There are no epidemiological studies of the carcinogenic effects of Methanol. Based on the lack of genotoxic potential and negative results from two inhalation carcinogenicity studies submitted by the Registrants, it is concluded that classification of Methanol as carcinogen is not warranted.

5.9. Toxicity for reproduction

Effects on fertility

The Registrant provided results of the 2-generation study on rats (Takeda, K. and Katoh, N., 1988), one generation study on female monkey (Burbacher, T. et al., 1999) and study of spermatotoxicity of Methanol in mice (Ward, J. B. Et al., 1984).

The existing data does not indicate that Methanol affects fertility and sexual function in animals. This conclusion is in agreement with the opinion expressed in NTP-CERHR Monograph on The Potential Human Reproductive and Developmental Effects of Methanol, September 2003, NIH Publication No. 03-4478.

The provided data is conclusive but does not warrant classification of Methanol for the end-point on fertility and sexual function.

Developmental toxicity

The Registrant provided results of a number of developmental toxicity studies of Methanol on animals acceptable for evaluation.

The data presented in the registration dossier indicates that Methanol affects prenatal development of offspring in mice and rats causing fetotoxic and teratogenic effects.
This conclusion is in line with the following opinions expressed in NTP-CERHR Monograph on The Potential Human Reproductive and Developmental Effects of Methanol, September 2003, NIH Publication No. 03-4478: on Page 99- 100 " Data from animal prenatal exposure studies are sufficient to demonstrate that Methanol is a developmental toxicant following inhalation exposures resulting in blood Methanol levels of 537 mg/L in the mouse and 1,840 mg/L in the rat. Studies in mice sufficiently demonstrated the same developmental pattern of response following oral or inhalation exposures resulting in equivalent blood levels of Methanol. Studies that evaluated neurobehavioral effects in Long-Evans rats exposed prenatally and/or during the neonatal stage are sufficient to demonstrate that Methanol blood levels of 555 mg/L in dams and 1,260 mg/L in offspring are associated with adverse neurological effects. Neurobehavioral studies in primates suggested minor alterations in cognitive function following prenatal exposure to Methanol but due to study limitations, were judged to be insufficient for assessing human hazard."
On page 105 "The Panel concluded that there is sufficient evidence to assume that Methanol could be a developmental toxicant in humans. The Panel also noted that the blood Methanol concentrations that have been associated with developmental toxicity in rodents are in the range associated with formate accumulation, metabolic acidosis, and other signs of acute toxicity in humans."

There is an issue whether developmental toxicity observed in rodents is relevant for humans due to interspecies differences in metabolism of Methanol between rodents and humans (Sweeting N.J et al. Species- and strain-dependent teratogenicity of Methanol in rabbits and mice. Reproductive Toxicology 31 (2011) 50–58).

The provided data are conclusive and sufficient for evaluation and they suggest to initiate a procedure for establishing a harmonized classification of Methanol for the category of developmental toxicity for clarifying the relevance of the rodent data for humans. During evaluation process on 22 September 2012 Italian (IT) MSCA submitted Annex XV dossier concerning classification and labelling. Following classification has been proposed (in

addition to existing harmonised classification): Repr.1B – H360D according to Regulation (EC) 1272/2008.
RAC opinion on the IT MSCA's proposal was adopted on 12 September 2014 (RAC-30). The RAC is of the opinion that, based on the available information, there is not sufficient evidence for classifying Methanol for developmental toxicity and classification for developmental toxicity seems not relevant.

5.10. Other effects

Not evaluated.

5.11. Derivation of DNEL(s) and other hazard conclusions

Discussion
The Registrant has used EU indicative occupational exposure limit values (IOELV) in place of worker DNEL values for risk assessment purposes. The Registrant has set the long-term inhalation DNEL for workers at 200 ppm (260 mg/m3) based on IOEL TWA - 8 hr value and long-term dermal DNEL for workers at 40 mg/kg bw/day.

The IOELVs for Methanol were published in Directive 2006/15/EC establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC. The IOELVs are not mandatory values in the EU and the member states may implement different values (lower, equal or higher) in their national legislations. The MAK level in Germany is of similar magnitude (270 mg/m3) and mainly built on the exposure-effect relations and the established innocuous concentrations in humans; these are related to the limited capacity in humans to convert formic acid into CO2. There is not much difference for this metabolic threshold after single or repeated exposure, hence, the OEL which is mainly based on singular experiences in humans is considered to be valid also for chronic exposure. The scientific rationale of the German OEL has been laid down in: Greim et al., loc. cit.

However in two countries the eight hours national occupational exposure limit value for Methanol (in Poland 100 mg/m3 and in Netherland 133 mg/m3) are lower than proposed by the Registrant DNEL value. eMSCA has examined the basis for lower OEL in Poland and reached the conclusion that it does not have an adequate scientific basis. The Dutch committee recommends a health based occupational exposure limit of 133 mg/m3(100 ppm) for Methanol taking the NOAEL of 1330 mg/m3 (chronic inhalation studies in rats and mice) and applying an assessment factor of 10 for interspecies and intraspecies variation. However the NOAEL was the highest concentration level tested and that exposure was almost continuous. Additionally there are doubts whether animal studies with rodents are suitable for derivation of a DNEL value because of difference in metabolism.

Proposed as a base to derive DNEL, MAK value is consistent with the Indicative Occupational Exposure Limit Value (IOELV) of the European Union. Also in countries such as Denmark, Germany, Sweden, the UK, and the USA, a limit value of 200 ppm (260 mg/m3) is set or recommended. The EU IOEL is based on workplace experiences and describes the dose at which headaches, discomfort / parasthesia have not been observed yet. eMSCA is in the opinion that on the basis of information available in 2012 an OEL of 200 ppm appear to be adequate and therefore uses it for the assessment. Documents submitted in 2013 by Italian MSCA haven't been considered during evaluation process as evaluation was performed in 2012.

Exposure to 260 mg/m3 during a working shift is roughly equivalent to the uptake of 2.6 g/person/day and an internal dose of 40 mg/kg b. w. day which may therefore be considered as a systemic DNEL (40 mg/kg bw/day). The same dose level is also considered as a DNEL for the dermal exposure route, thereby neglecting the high volatility of the material from the skin. The inhalation OEL is predominantly based on resorptive systemic toxicity, however, it is considered to be also protective from local irritation.

Table 8. Hazard conclusions for workers

Route	Type of effect	Hazard conclusion
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level): 260 mg/m³
Inhalation	Systemic effects - Acute	DNEL (Derived No Effect Level): 260 mg/m³
Inhalation	Local effects - Long-term	DNEL (Derived No Effect Level): 260 mg/m³
Inhalation	Local effects - Acute	DNEL (Derived No Effect Level): 260 mg/m³
Dermal	Systemic effects - Long-term	DNEL (Derived No Effect Level): 40 mg/kg bw/day
Dermal	Systemic effects - Acute	DNEL (Derived No Effect Level): 40 mg/kg bw/day
Dermal	Local effects - Long-term	Low hazard (no threshold derived)
Dermal	Local effects - Acute	Low hazard (no threshold derived)
Eyes	Local effects	Low hazard (no threshold derived)

Concerning the DNEL proposed for general population, the OEL value has been divided by the Registrant by a factor of 5. The Registrant has provided following explanation: “To take the intraspecies difference into account, following ECHA's assessment factors for interspecies differences in human, an assessment factor of 5 to derive a worker's DNEL and a factor of 10 to derive a DNEL for the general population accordingly would usually be required (ECHA's 'Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health', page 27). The two standard factors differ by a factor of 2. Since we cannot rule out a possibly wider variability of interindividual sensitivities in the general population regarding the predominant health effect of Methanol, the Lead Registrant decided to accommodate this possibly wider sensitivity with a factor of 5 instead of 2 as a conservative but reasonable.

However according to guidance document R8 (characterization of dose concentration-response for human health), for a same point of departure, assessment factors differ between workers and general population:

- Duration of exposure: 8h/d for worker exposure versus 24h/d for general population
- Intra-species difference: 5 for workers and 10 for general population.

This corresponds to a factor of 6 between DNEL for worker and DNEL for general population. Therefore, the factor of 5 cannot be considered as a conservative approach by evaluator and risk characterisation was recalculated.

A DNEL for oral exposure is not proposed as this would be an exposure route advised against.

Table 9. Hazard conclusions for the general population

Route	Type of effect	Hazard conclusion
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level): 43.3 mg/m³
Inhalation	Systemic effects - Acute	DNEL (Derived No Effect Level): 43.3 mg/m³
Inhalation	Local effects - Long-term	DNEL (Derived No Effect Level): 43.3 mg/m³
Inhalation	Local effects - Acute	DNEL (Derived No Effect Level): 43.3 mg/m³
Dermal	Systemic effects - Long-term	DNEL (Derived No Effect Level): 6.66 mg/kg bw/day
Dermal	Systemic effects - Acute	DNEL (Derived No Effect Level): 6.66 mg/kg bw/day
Dermal	Local effects - Long-term	Low hazard (no threshold derived)
Dermal	Local effects - Acute	Low hazard (no threshold derived)
Oral	Systemic effects - Long-term	
Oral	Systemic effects - Acute	
Eyes	Local effects	Medium hazard (no threshold derived)

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

Not evaluated.

7. ENVIRONMENTAL HAZARD ASSESSMENT

The available information in the registration dossiers (IUCLID section 2-6) and the Chemical Safety Reports (CSRs) were checked for plausibility and indications of additional concerns for Methanol. A throughout and complete quality check and supplementation of the technical dossier (IUCLID dossier) was not performed.

The Registrants provided an environmental exposure assessment referring to the release and corresponding risk management measures applied. The eMSCA concluded that the concern had been clarified and that no further information on environmental hazard and exposure assessment was needed.

7.1. Aquatic compartment (including sediment)

Methanol is the first and simplest member of the series of aliphatic alcohols. Like other non-reactive, non-ionizable organic chemicals ("neutral organics") such as ketones, ethers, alkyl halides, aryl halides and aromatic hydrocarbons Methanol is expected to exert toxicity to aquatic species through simple narcosis.
A large amount of data on the toxicity of Methanol is available for a broad spectrum of aquatic organisms (fish, invertebrates and algae).
All the available data demonstrate consistently the very low acute toxicity to Methanol for aquatic organisms. No fully reliable results and no guideline studies are available concerning long-term toxicity of Methanol to aquatic species. Given the Biological Oxygen Demand of Methanol and its rapid biodegradation, it is indeed difficult to maintain in long-term tests the required levels of oxygen concentration. Due to this aspect, it also difficult to assess the reliability of studies, in which the oxygen concentration is not well documented.
Since Methanol belongs to the category of chemicals acting with a non-specific mode of action (simple narcosis) the chronic toxicity to aquatic organism can be reasonably predicted from data on acute toxicity using an appropriate acute-to-chronic ratio (ACR). An ACR of 10 has been proposed in the literature for such kind of chemicals(see for example Raimondo et al., Environ. Toxicol. Chem. 26, 2007; Roex at al., Environ. Toxicol.Chem. Cryo Letters. 2004 Nov-Dec; 25(6):415-2419, 2000).
Taking into account the toxicity mode of action of Methanol the chronic toxicity to aquatic organisms can be also reasonably predicted using Structure-Activity Relationship models (QSARs). The available information and the results from toxicity estimations indicate a very low chronic toxicity of Methanol to aquatic organisms, with no-effect levels well above the concentrations which are normally used in limit tests on long-tern toxicity.

7.2. Terrestrial compartment

The available experimental data for Methanol are not appropriate for a derivation of PNECsoil. The substance however, exhibits low potential for adsorption, is not bioaccumulative and readily biodegradable in both aerobic and anaerobic environments. Furthermore, results of aquatic tests revealed no harmful effects Methanol, and by thereby suggesting little hazardous potential towards soil organisms. Therefore, the equilibrium partitioning method has been used to assess the hazard potential of Methanol for soil organisms.

7.3. Atmospheric compartment

The substance is not in Annex I of Regulation (EC) 2037/2000 on substances that deplete the ozone layer. The substance does not belong to the green house gases listed in P Forster, PV Ramaswamy et al. Changes in Atmospheric Constituents and in Radiative Forcing. In: Climate Change 2007: The Physical Basis. Contribution of Working Group I to the Fourth Assessment Report of the Intergovernmental Panel on climate Change.

7.4. Microbiological activity in sewage treatment systems

An IC50 value >1000 mg/L for activated sludge is reported in study (1985). This test was performed according to the OECD Guideline 209 (activated sludge, respiration inhibition test) and is considered the most appropriate for assessing the risk for wastewater treatment plant.

7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

No reliable information on acute or chronic effects on birds and wild mammals is available. However, since the substance exhibits low log Pow, secondary poisoning is unlikely to be a relevant exposure route.

7.6. PNEC derivation and other hazard conclusions

Table 9. Hazard assessment conclusion for the environment

Compartment	Hazard conclusion	Remarks/Justification
Freshwater	PNEC aqua (freshwater): 20.8 mg/L	Assessment factor: 10 Extrapolation method: assessment factor
Marine water	PNEC aqua (marine water): 2.08 mg/L	Assessment factor: 100 Extrapolation method: assessment factor
Intermittent releases to water	PNEC aqua (intermittent releases): 1540 mg/L	Assessment factor: 10 Extrapolation method: assessment factor
Sediments (freshwater)	PNEC sediment (freshwater): 77 mg/kg sediment dw	Extrapolation method: partition coefficient The PNEC sediment was derived from the PNEC water using the equilibrium partitioning method.
Sediments (marine water)	PNEC sediment (marine water): 7.7 mg/kg sediment dw	Extrapolation method: partition coefficient The PNEC marine sediment was derived from the PNEC marine water using the equilibrium partitioning method.
Sewage treatment	PNEC STP: 100 mg/L	Assessment factor: 10
Plant		Extrapolation method: assessment factor The IC50 of > 1000 mg/L from the respiration inhibition study

		has been used to derive the PNEC STP because respiration tests using a mixed inoculum are more relevant than tests using a single-species inoculum. Since also tests on growth inhibition with Pseudomonas p. and on inhibition of nitrification are available and they indicate a very low toxicity of Methanol for microorganisms an assessment factor of 10 has been applied in the PNEC derivation.
Soil	PNEC soil: 3.18 mg/kg soil dw	Extrapolation method: partition coefficient The PNEC soil was derived from the PNEC water using the equilibrium partitioning method.
Air		
Secondary poisoning		Due to the low log Pow, secondary poisoning of Methanol is unlikely.

8. PBT AND vPvB ASSESSMENT

Not evaluated.

9. EXPOSURE ASSESSMENT

eMSCA examined whether all identified uses reported in the registration dossier were considered in the Chemical Safety Assessment and in Exposure Scenarios. Furthermore, database of mixtures placed on the market in Poland was used as a reference to identified uses of Methanol. The database was cross-checked to verify whether all of the uses were considered in the Chemical Safety Assessment and subsequently in Exposure Scenarios.

Human health – Worker
Easy TRA and Stoffenmanager tools was used for the exposure calculations.

Human health – Consumer
ConsExpo tool was used for the exposure calculations.

Environment
Methanol has a low toxicity to aquatic and terrestrial organism. It has a very low potential for bioaccumulation and is rapidly biodegradable under aerobic and anaerobic conditions in water soils and sediments. Microorganisms are indeed capable to use Methanol as growth substrate degrading it completely to carbon dioxide and water (mineralization). Together biodegradation, volatilization is an important fate process for Methanol. Methanol rapidly volatilizes from water and from moist and dry soils due to its physico-chemical properties. In the air Methanol is degraded by reaction with hydroxyl radicals produced by photochemical processes.
With regard to potential environmental emissions, about 90% of the worldwide produced Methanol is used as an intermediate. Methanol is in fact a basic building block for chemical synthesis and is therefore used as the starting point for primary, secondary, and tertiary derivatives. The use of Methanol as intermediate includes also the production of biodiesel, where Methanol is consumed in a trans-esterification reaction.
The manufacture of Methanol and its use in the synthesis of these important chemical products occur primarily in large industrial plants under well controlled conditions and where measures to reduce the emissions are implemented. Releases of Methanol during manufacture have been quantified to be < 1 kg per ton of Methanol produced. Similar releases can be predicted for processes, in which Methanol is used as an intermediate in industrial chemical synthesis (IPCS Report on Methanol, World Health Organization, Geneva, 1997).
About 10% of the Methanol produced is used as a solvent, both in chemical processes and in the formulations of products such as cleaning fluids and gasoline blending.
Emissions of Methanol occur primarily from the use as a solvent and are directed mainly to the air. Methanol released from industrial and wide dispersive use into wastewater treatment facilities (both industrial and municipal) is rapidly and completely biodegraded.
Given the very low toxicity of Methanol for aquatic and terrestrial organisms and the rapid and complete degradation in water, soil and air as well as the negligible potential for bioaccumulation, effects due to environmental exposure to Methanol are unlikely, unless it is released to the environment in large quantities through spillages (IPCS Report on Methanol, World Health Organization, Geneva, 1997).

The eMSCA considers the exposure assessment given in registration dossiers (5 August 2013) plausible based on the currently available data.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

Worker Exposure
The exposure scenarios as provided in the updated chemical safety report were carefully reviewed.

Consumer Exposure

- Information on operational conditions, exposure estimations and risk characterisation for exposure scenarios related to consumer use of cleaning agents and de-icers (liquid products)

The Lead Registrant has declared that use of Methanol in cleaning agents and de-icers liquid products (eg. 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 supply chain 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.

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

Following main causes of poisonings with Methanol were indicated by Poisoning Centres in Poland:

1. Incidental consumption of Methanol:

   a) consumption of winter windshield washing fluids (including windshield defrosters), which apart from ethanol contain also Methanol in high concentrations, by alcoholics is the most frequent cause of the poisonings, which in many cases are fatal (sources of Methanol poisonings – Table D.1-5). Such poisonings take place in particular in the situation where a specific country previously applied a restriction of Methanol content in such fluids or where both fluids without Methanol and fluids containing Methanol are placed on the market,

   b) consumption of Methanol added to denaturated alcohol (methylated spirit) by alcoholics is another key cause of the poisonings (source of Methanol poisonings – Table D.1-5). Similarly, as in the case of winter windshield washing fluids, the poisonings also take place in particular in the situation where previously there was a ban on adding Methanol to denaturated alcohol or where both denaturated alcohol containing Methanol and denaturated alcohol without Methanol were placed on the market,

c) fake consumable alcohol to which Methanol has been added purchased at legally operating sales network, is another cause of the poisonings – a large number of poisonings in Poland, the Czech Republic and Slovakia in the years 2012 – 2013,

d) Methanol illegally obtained from such sources as chemical reagents or from industrial sources, also is a cause of the poisonings,

e) Methanol which has been inappropriately stored which is used by general public as a fuel in power-boat sports or in model-making activities can also contribute to the poisonings,

f) winter windshield washing fluids, denaturated alcohol, and anti-freezing fluids can be consumed by children, particularly where they are stored inappropriately, although due to their unpalatable taste, in most cases the consumed quantities are very small and the poisonings are not severe.

2. Conscious consumption of Methanol contained in any of the above-listed products for suicidal purposes.

3. Inhalation of Methanol vapours or Methanol absorption through skin under occupational exposure – OEL for Methanol is 260 mg/m^3.

The restriction proposed by PL MSCA is namely to eliminate poisonings caused by consumption of Methanol contained in high concentrations in winter windshield washing fluids (including windshield defrosters) and in denatured alcohol by alcoholics and other person abusing alcohol. These products represent the most common cause of severe Methanol poisonings, which in many cases turn fatal. Winter windshield washing fluids containing alcohol (including windshield defrosters) and denaturated alcohol, which are available in retail, are consumed as a surrogate of consumable alcohol by some alcoholics. This is encouraged by the difference in price between excisable consumable alcohol and the products in which alcohol is not excisable therefore the price of equivalent quantity of alcohol is considerably lower. In Poland for instance the price of half a litre of the cheapest 40% vodka reaches almost 5 EURO, while the price of 5 litres of the cheapest winter windshield washing fluid containing a similar concentration of ethanol, reaches 2 – 3 EURO. Half a litre of 70% denatured alcohol in Poland costs approx. 1 EURO. Similar price differences also occur in other countries. Additives to ethanol contained in such products, which make it unpalatable for a great majority of people, do not deter many alcoholics from their consumption. A relatively limited availability of consumable alcohol contributes to using this easealy available surrogate of ethanol in some countries, such as Finland. The restriction of Methanol concentration in these products will eliminate incidental Methanol poisonings due to consumption of these products.

The proposed restriction will also prevent some cases of Methanol poisoning in children, who sometimes reach for inappropriately stored coloured winter windshield washing fluids, however this is not the main objective of the restriction as the unpalatable taste of these products contributes to the fact that in most cases the consumed quantities are very small and poisonings are not severe.

The restriction will not eliminate suicidal Methanol poisonings, however it may partly limit

their number. Methanol used as fuel in model-making activities, power-boat sports and in speedway, Methanol used as an additive to bio-fuels and illegally obtained Methanol can be used for suicidal purposes. The restriction will not eliminate nor most likely reduce the number of potential poisonings with fake consumable alcohol with added Methanol and illegally placed on the market.

The restriction's aim is not to protect workers as they are protected by regulations concerning protection of workers against risk posed by effects caused by chemicals, including OEL, which for Methanol is 260 mg/m3.

The restriction's aim is not to protect consumers using winter windshield washing fluids and denaturated alcohol in accordance with their purpose.

Summing up:

— Target group: the restriction is namely to protect people who chronically abuse alcohol, and who use (consume) winter windshield washing fluids (including windshield defrosters) and denaturated alcohol as a surrogate of consumable alcohol. The restriction is not applicable to persons who use these products in accordance with their purpose, nor its aim is to protect the groups that are specifically vulnerable to harmful effects of Methanol.
— Scope: subject of the restriction covers the ban on placing on the market of winter windshield washing fluid and denaturated alcohol available to general public, containing Methanol in concentration equal to, or greater than 3%.
— Exposure route: application concerns oral route exposure. Inhalation or dermal route exposure to Methanol in case of using these products in accordance with their intended purpose is not the subject of the application and is not considered.

Targeted risks in this restriction dossier are acute poisonings (with high rate of fatal cases) occurring among alcoholics drinking winter windshield washing fluids (including windshield defrosters) and denaturated alcohol (methylated spirit) as a substitute of consumable alcohol. The population who faces the risk lives mainly in the northern and central parts of the EU, in the countries were people prefer strong alcohols, but those people do not quit their habits coming into other EU Member States and cases of acute poisonings with denaturated alcohol containing Methanol were noted also in Italy among people from countries of Central Europe. No other Community-wide option was found to appropriately manage the targeted risk. The proposed restriction is expected to eliminate Methanol poisonings in this population.

When there are no restrictions of Methanol content in winter windshield washing fluids (including windshield defrosters) and in denaturated alcohol, poisonings with Methanol contained in these products constitute the highest rate of Methanol poisonings. This is demonstrated by data from Poland and Finland. In Poland, Methanol restriction in consumer products ceased to be effective in June 2010. That resulted in a huge number of poisonings with Methanol namely contained in winter windshield washing fluids and in denaturated alcohol, which started in December 2011. Reintroduction of the restriction in January 2014 considerably reduced the number of the poisonings, although the complete data will be available in the mid-2015. A similar situation was observed in Finland, where withdrawal of the restriction of Methanol content in winter windshield washing fluids in 1994 was accompanied by a considerable increase in the number of poisonings with Methanol contained in these fluids, starting in 1996. Based on the available data in Poland - information on Methanol poisonings in "Silesian Agglomeration" caused by windshield washing fluids:

- 2010: 2 (restriction in force in Poland)
- 2011: 8 (no restriction in Poland)
- 2012: 13 (no restriction in Poland)

we can expect that the ban of using Methanol in such consumer products as the windshield washing fluids should reduce the number of Methanol poisonings by 60 to 90%. The same result we can expect in case of denaturated alcohol poisonings.

It is proposed to established 3% limit value for Methanol in windshield washing fluids (including windshield defrosters) and denaturated alcohol. The calculation, performed by dossier submitter on the basis of lethal oral doses of Methanol in humans, indicates a risk for the human health if consumer swallowing windshield washing fluids containing high doses of Methanol. If windshield washing fluids contain about 30% w/w of Methanol, the dose which can result in death of person (adult, 70 kilograms) is only 90 ml. Based on:

- dossier submitter previous experience (in Poland till 1 June of 2010 the placing on the market for general public mixtures containing Methanol in the concentration higher than 3.0% by weight was banned by Regulation of Ministry of Economy),
- specific concentration limit specified for Methanol in Table 3.2 in Annex VI to CLP (mixtures which contains Methanol in concentration lower than 3.0% are not classified for acute toxicity), it is propose to establish maximum concentration of Methanol in mixtures available for general public (windshield washing fluids/denaturated alcohol) at level of 3.0% w/w. For windshield washing fluids (denaturated alcohol) containing Methanol in concentration of 3.0 % w/w, lethal oral dose is approximately, according to Table B.10-1, 900 ml. There is little likelihood of drinking such high doses of windshield washing fluids or denaturated alcohol.

The proposed maximum concentration limit of Methanol in mixtures available to consumers (windshield washing fluids and denaturated alcohol) - 3% - is also confirmed by the performed risk characterisation in which DNEL value presented in the Methanol registration dossier has been applied.

10.1. Human health

Conclusion: The risk characterisation for human health does not raise further concerns.

10.2. Environment (combined for all emission sources)

Conclusion: The risk characterisation for environment does not raise further concerns.

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Annex: The annex of detailed substance composition is confidential and not included in the public version of this report.