

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name): Methyl vinyl ether
Chemical Group: -
EC Number: 203-475-4
CAS Number: 107-25-5
Submitted by: Latvia
Date: 17/03/2015

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

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1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	methyl vinyl ether
IUPAC name:	methoxyethene
Index number in Annex VI of the CLP Regulation	603-021-00-9
Molecular formula:	C ₃ H ₆ O
Molecular weight or molecular weight range:	58.0791
Synonyms/Trade names:	Methyl vinyl ether; Ethene, methoxy-;

Type of substance Mono-constituent Multi-constituent UVCB

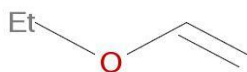
Structural formula:



1.2 Similar substances/grouping possibilities

Methyl vinyl ether was evaluated under OECD HPV programme as part of the chemical category of vinyl ethers. The other category members included in this assessment were ethyl vinyl ether (EC 203-718-4) and Isobutyl vinyl ether (EC 203-678-8).

Structural formula:



IEthyl vinyl ether



Isobutyl vinyl ether

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Table 2: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
603-021-00-9	methyl vinyl ether	203-475-4	107-25-5	Flam. Gas 1 Press. Gas	H220		D U

2.2 Self-classification

- The registration dossiers have applied:
 - Flam. Gas 1 H220: Extremely flammable gas.
 - Liquefied gas H280: Contains gas under pressure; may explode if heated.
 - Aquatic Chronic 3 H412: Harmful to aquatic life with long lasting effects.
- The following hazard classes are in addition notified the aggregated self-classification in the C&L Inventory: None

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa	
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa	
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa	
<input checked="" type="checkbox"/> 100+ tpa		<input checked="" type="checkbox"/> Confidential	
Some tonnage is claimed confidential.			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
The following uses are reported in the registration dossiers: <ul style="list-style-type: none"> Manufacture and distribution of the substance Use as an intermediate (industrial) Manufacture of polymers, resins (industrial) Use as an adhesive/sealant in the health care industry (professional and consumer) 			

4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input checked="" type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
<p>The substance was evaluated as a group with other vinyl ethers in the OECD SIDS report (2006), which can be found at the following link: http://webnet.oecd.org/hpv/ui/handler.axd?id=42289d63-e9ec-4922-8961-553b2ac410e9</p>	

5 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1 Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

5.2 Selection criteria met

- Fulfils criteria as CMR/ Suspected CMR
- Fulfils criteria as Sensitiser/ Suspected sensitiser
- Fulfils criteria as potential endocrine disrupter
- Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
- Fulfils criteria high (aggregated) tonnage (*tpa* > 1000)
- Fulfils exposure criteria
- Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input checked="" type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input checked="" type="checkbox"/> Other (please specify below)
<p>In a prenatal developmental toxicity study (OECD 414) in rats in which methyl vinyl ether was administered via inhalation, a significant reduction in maternal body weight and ecchymosis and ossification issues in the pups were observed. The registrants considered that based on historical control data, the ossification effects observed were not significant. In addition, the registrants noted that the supporting range finding study did not detect any developmental effects. In a combined inhalation repeated dose toxicity study with a reproduction/developmental toxicity screening test with the read-across substance isobutyl vinyl ether, a significant decrease in the live birth index (69 live in the high-dose group versus 115 live in the control) was observed. Further evaluation of the available developmental toxicity data is required to conclude on the developmental toxicity endpoint.</p> <p>The uses in the registration dossier indicate the potential for worker and consumer exposure. Further assessment of the potential for exposure and the adequacy of existing risk management measures are required.</p>		

5.4 Preliminary indication of information that may need to be requested to clarify the concern

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

¹ CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)

Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)

Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

Depending on the outcome of the evaluation, further developmental toxicity data may be required.

Further information on exact uses covered by the exposure scenarios, may be required to ensure the existing risk management measures are adequate.

5.5 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
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Follow up actions will be considered once the hazard and exposure data are evaluated.