

Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name): 2-hydroxyethyl methacrylate

Chemical Group:

EC Number: 212-782-2

CAS Number: 868-77-9

Submitted by: France

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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 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	2-hydroxyethyl methacrylate (HEMA)
EC number:	212-782-2
EC name:	2-hydroxyethyl methacrylate
CAS number (in the EC inventory):	868-77-9
CAS number:	868-77-9
CAS name:	
IUPAC name:	2-hydroxyethyl methacrylate
Index number in Annex VI of the CLP Regulation	607-124-00-X
Molecular formula:	C ₆ H ₁₀ O ₃
Molecular weight or molecular weight range:	130.1418 g/mol
Synonyms:	

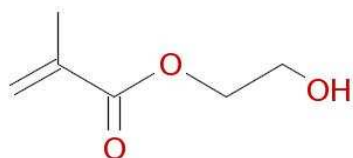
Type of substance:

Mono-constituent

Multi-constituent

UVCB

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Index No. 607-124-00-X

According to CLP:

- Eye Irrit. 2, H319 : Causes serious eye irritation
- Skin Irrit. 2, H315 : Causes skin irritation
- Skin Sens. 1, H317 : May cause an allergic skin reaction

According to DSD:

- Xi; R36/38: Irritating to eyes and skin
- R43: May cause sensitization by skin contact

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None

2.3 Self classification

In addition is the following classification included in the Classification and Labelling Inventory:

- Aquatic Chronic 4, H413: May cause long lasting harmful effects to aquatic life

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

Article 44(1) (refined prioritisation criteria for substance evaluation)

Article 45(5) (Member State priority)

3.2 Grounds for concern

<input checked="" type="checkbox"/> (Suspected) CMR	<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Cumulative exposure
<input checked="" type="checkbox"/> (Suspected) Sensitiser	<input checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> High RCR
<input type="checkbox"/> Suspected PBT	<input type="checkbox"/> Exposure of sensitive populations	<input checked="" type="checkbox"/> Aggregated tonnage
<input type="checkbox"/> Suspected endocrine disruptor	<input type="checkbox"/> Other (provide further details below)	

- Concern about **respiratory sensitisation** of the HEMA.

A small number of case studies not reported in the registration data but available in the scientific literature have linked HEMA with occupational asthma (dentist). In addition, case studies have also linked a close structural analogue of HEMA, the MMA, with occupational asthma. Finally, HPMA another close structural analogue of HEMA has been classified as respiratory sensitiser category 1 by 25 notifiers (CL Inventory). Considering the high risk of exposure for workers and those concerns about respiratory sensitization potential, further clarification are therefore considered necessary.

- Concern about genotoxicity of HEMA.

Positive in vitro mammalian chromosome aberration test in the registration data. Quality and interpretation of the studies is questionable and there is no second appropriate in vivo study. Furthermore, the HPMA, a close analogue of the substance, was reported to induce structural chromosome aberrations and polyploidy in an *in vitro* chromosome aberration test performed on mammalian cells. Also for HPMA, only one *in vivo* study with the HPMA is available and there is no appropriate second in vivo study provided. Finally, the HPMA has been classified as a suspected mutagen by 43 notifiers (CL Inventory).

- Concern about exposure and risk assessment

Many consumer end use are identified, exposure and risk assessment have not been performed for the consumers. Some scenarios are at risks and should be clarified. More information is needed on exposure assessment for workers and consumers.

3.3 Information on aggregated tonnage and uses

<input type="checkbox"/> 1 - 10 t	<input type="checkbox"/> 10 - 100 t	<input type="checkbox"/> 100 - 1000 t	<input type="checkbox"/> 1000 - 10,000 t
<input checked="" type="checkbox"/> 10,000 - 100,000 t	<input type="checkbox"/> 100,000 - 1000,000 t	<input type="checkbox"/> > 1000,000 t	<input type="checkbox"/> Confidential
10,000 - 100,000 tonnes per annum			
<input checked="" type="checkbox"/> Industrial Use	<input checked="" type="checkbox"/> Professional Use	<input checked="" type="checkbox"/> Consumer Use	<input type="checkbox"/> Closed System

3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<input type="checkbox"/> Compliance Check	<input type="checkbox"/> Annex VI (CLP)
<input type="checkbox"/> Testing Proposal(s)	<input type="checkbox"/> Annex XIV (Authorisation)
<input type="checkbox"/> Substance Identification Issues	<input type="checkbox"/> Annex XVII (Restriction)
<input checked="" type="checkbox"/> ESR Programme	<input type="checkbox"/> Other (provide further details below)
<p>Methyl methacrylate (MMA) CAS #: 80-62-6 a structurally related substance, has been evaluated in the framework of 793/93/EC: http://esis.jrc.ec.europa.eu/doc/risk_assessment/REPORT/methylmethacrylatereport024.pdf</p>	

3.5 Information to be requested to clarify the suspected risk

<input checked="" type="checkbox"/> Information on toxicological properties	<input checked="" type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on uses
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Information on physico-chemical properties	
Exact information to be requested should be determined during the substance evaluation	

3.6 Potential follow-up and link to risk management

<input type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Harmonised C&L
<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details below)
Sens. Resp. Harmonised classification not excluded	