

Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Methacrylic acid, monoester with propane-1,2-diol
Chemical Group:	
EC Number:	248-666-3
CAS Number:	27813-02-1
Submitted by:	France
Published:	20/03/2013

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:	Methacrylic acid, monoester with propane-1,2-diol
EC number:	248-666-3
EC name:	Methacrylic acid, monoester with propane-1,2-diol
CAS number (in the EC inventory):	27813-02-1
CAS number:	27813-02-1
CAS name:	
IUPAC name:	Methacrylic acid, monoester with propane-1,2-diol
Index number in Annex VI of the CLP Regulation	
Molecular formula:	C ₇ H ₁₂ O ₃
Molecular weight or molecular weight range:	144.1684 g/mol
Synonyms:	2-Propenoic acid, 2-methyl-, monoester with 1,2-propanediol; 1,2-Propanediol, monomethacrylate; Methacrylic acid, ester with 1,2-propanediol; Hydroxypropyl methacrylate (HPMA)

Type of substance:

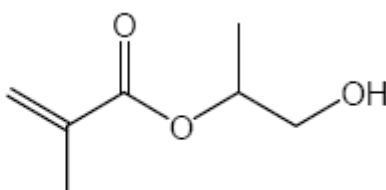
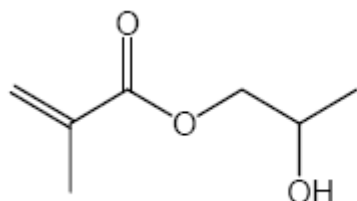
 Mono-constituent

 Multi-constituent

 UVCB

Structural formula:

HPMA is represented by two isomeric structures shown here:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

There is no harmonised classification for the methacrylic acid, monoester with propane-1,2-diol.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

There is no proposal for harmonised classification for the methacrylic acid, monoester with propane-1,2-diol.

2.3 Self classification

The registration data includes the following self classification:

According to CLP criteria:

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

According to DSD criteria:

- Xi; R36 Irritant; Irritating to eyes.
- R43; May cause sensitisation by skin contact

In addition are the following classification(s) included in the Classification and Labelling Inventory:

Skin Irrit.2, H315: causes skin irritation

Muta. 2, H341: Suspect of causing genetic defects

STOT SE 3, H335: May cause respiratory irritation

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)	

Concerns on toxicological properties, exposure and on the risk assessment justify the prioritisation for substance evaluation:

Concern about toxicological proprieties:

- Concern about the **skin sensitisation** potential of the HPMA.

Several tests in experimental animals demonstrate a slight skin sensitisation potential and other studies supported a conclusion of equivocal results. Moreover, many cases of allergic contact dermatitis were reported on workers related to dentistry.

- Concern about the **respiratory sensitisation** potential of the HPMA.

The information provided in the registration data is confused. Several indicators suggest that the HPMA may be a respiratory sensitiser: 1/ Exposure to MMA and HEMA, two close structural analogues of HPMA, have been linked to several cases of occupational asthma. 2/ notifiers have classified MMA as respiratory sensitiser category 1.

Considering the high risk of exposure for workers and those concerns about respiratory sensitization potential, further clarification is therefore considered necessary.

- Concern about the **clastogenic and aneugenic potential** of the HPMA.

Indeed, the HPMA was reported to induce structural chromosome aberrations and polyploidy in an *in vitro* chromosome aberration test performed on mammalian cells.

Only one *in vivo* study with the HPMA is available: the HPMA was found not to be clastogenic in a micronucleus study performed on mice. Since no appropriate second *in vivo* study is provided, and since the HPMA has been classified as a suspected mutagen by several notifiers (CL Inventory), this *in vivo* study seems not sufficient to attest that the HPMA does not induce structural or numeral chromosome aberration *in vivo*.

Concern about exposure:

Several identified uses are linked with a wide dispersive use (ERC 8, and ERC 10).

Many consumer end uses and service life in articles are identified. For example, HPMA is used in paints, finger paints, cosmetics, personal care products, pharmaceuticals, textile dyes...

Concern about the risk assessment:

- Many RCR dermal exposure for the workers are superior to 1.

Although many consumer end use are identified, exposure and risk assessment have not been performed for the consumers. There is no RCR consumer available.

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	
<i>Tonnage band: 10 000 – 100 000 tonnes per annum</i>				
<input checked="" type="checkbox"/> Industrial Use	<input checked="" type="checkbox"/> Professional Use	<input checked="" type="checkbox"/> Consumer Use	<input type="checkbox"/> Closed System	
<p>The HPMA is used as monomer for polymerization or intermediate in synthesis of other chemicals.</p> <p>Industrial uses:</p> <ul style="list-style-type: none"> - Manufacture and use as intermediate - Use in production of formulations - End uses as monomer, intermediate and formulations <p>Professional uses:</p> <ul style="list-style-type: none"> - End uses in formulations <p>Consumer uses:</p> <ul style="list-style-type: none"> - End uses in formulations 				

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	

In order to clarify the HPMA respiratory sensitisation potential, more data on the HPMA or on another member of the hydroxyalkyl methacrylates category could be requested.

In order to clarify the HPMA mutagenic potential, a second *in vivo* chromosomal mutation test on another somatic tissue could be requested.

Further information concerning workers dermal exposure and protection equipments could be requested if the RCR remain superior to 1.

3.6 Potential follow-up and link to risk management

<input type="checkbox"/> Restriction	<input type="checkbox"/> Harmonised C&L
<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details below)

Depends on the outcomes of the substance evaluation process. The substance should be assessed in the context of a best-RMO.