

## Justification for the selection of a candidate CoRAP substance

<b>Substance Name (Public Name):</b>	Ethyl methacrylate
<b>Chemical Group:</b>	Acrylates
<b>EC Number:</b>	202-597-5
<b>CAS Number:</b>	97-63-2
<b>Submitted by:</b>	Italy
<b>Published:</b>	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

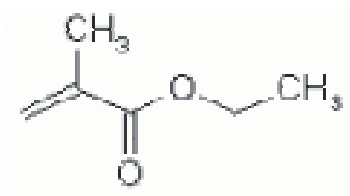
### 1.1 Name and other identifiers of the substance

Table 1: Substance identity

<b>Public Name:</b>	Ethyl methacrylate
<b>EC number:</b>	202-597-5
<b>EC name:</b>	ethyl methacrylate
<b>CAS number (in the EC inventory):</b>	
<b>CAS number:</b>	97-63-2
<b>CAS name:</b>	ethyl methacrylate
<b>IUPAC name:</b>	ethyl methacrylate
<b>Index number in Annex VI of the CLP Regulation</b>	607-071-00-2
<b>Molecular formula:</b>	C <sub>6</sub> H <sub>10</sub> O <sub>2</sub>
<b>Molecular weight or molecular weight range:</b>	114.14
<b>Synonyms:</b>	

**Type of substance**     Mono-constituent     Multi-constituent     UVCB

**Structural formula:**



## 2 CLASSIFICATION AND LABELLING

### 2.1 Harmonised Classification in Annex VI of the CLP

#### CLP criteria:

Flam. Liq. 2; H225: Highly flammable liquid and vapour  
 Skin Irrit. 2; H315: Causes skin irritation  
 Skin Sens. 1; H317: May cause an allergic skin reaction.  
 Eye Irrit. 2; H319: Causes serious eye irritation  
 STOT SE 3; H335: May cause respiratory irritation

#### DSD criteria:

F; R11: Highly flammable  
 Xi; R36 /37/38 Irritant; Irritating to eyes, respiratory system and skin.  
 R43: May cause sensitisation by skin contact

### 2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None.

### 2.3 Self classification

CLP criteria:

Classification by the lead registrant includes those classifications under harmonised classification in annex VI of the CLP except for Eye Irrit. 2 (H319).

DSD criteria:

No self-classification by lead registrant.

In addition to the harmonised classification, the following classifications lacking some of the harmonised endpoints are notified to the Classification and Labelling Inventory:

Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement(s)
Not Classified		
	H225 H315 H317 H319	Highly flammable liquid and vapour Causes skin irritation May cause an allergic skin reaction Causes serious eye irritation
Flam. Liq. 2 Skin Irrit. 2 Skin Sens. 1 STOT SE 3	H225 H315 H317 H335	Highly flammable liquid and vapour Causes skin irritation May cause an allergic skin reaction 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 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)	

The screening process confirms that positive results were observed for skin sensitization in guinea pig test.

The available information on the substance indicates the need for further information for genotoxicity in vivo and carcinogenicity.

In particular the Ames test was negative while weak positive results were observed in the Chromosomal aberration test and mouse-lymphoma assay.

For genotoxicity in vivo and for carcinogenicity study a read across with methyl methacrylate, a structurally similar substance, has been provided in the registration data with negative results on these endpoints.

With the use QSAR toolbox another structurally similar substance has been identified. This substance, ethyl acrylate has shown positive for carcinogenesis and apparently we don't see any possible reason to read across to a substance instead of the other one.

If the read across with methyl methacrylate is not fully justified, further information on carcinogenesis could be requested in order investigate on this endpoint.

#### 3.3 Information on aggregated tonnage and uses

<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa	
<input checked="" type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa		
<input type="checkbox"/> 100,000 – 1000,000 tpa	<input type="checkbox"/> > 1000,000 tpa		
<input type="checkbox"/> Confidential			
<i>Please provide further details</i>			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
<i>Please provide further details</i>			

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

<input type="checkbox"/> Compliance check	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input checked="" 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
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
See 2.1 section	

### 3.5 Information to be requested to clarify the suspected risk

<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 type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Other (provide further details below)	
The available information on the substance indicates the need for further information for genotoxicity in vivo and carcinogenicity.	

### 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)
The available harmonized classification does not cover the carcinogenetic endpoint. The outcome of the Evaluation process could be reclassification.			