Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	**acrylic acid, monoester with propane-1,2-diol**
EC Number:	**247-118-0**
CAS Number:	**25584-83-2**
Authority:	**French MSCA**
Date:	**22/03/2016**

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

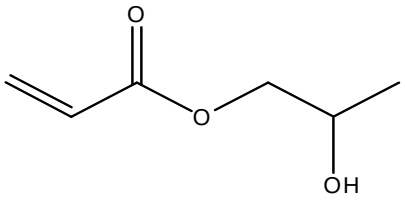
1.1 Other identifiers of the substance

Table 1: Other Substance identifiers

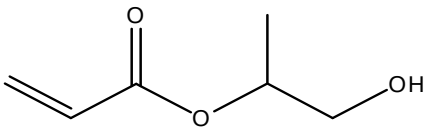
EC name (public):	acrylic acid, monoester with propane-1,2-diol
IUPAC name (public):	Reaction mass of 2-Propenoic acid and 1,2-propanediol
Index number in Annex VI of the CLP Regulation:	607-108-00-2
Molecular formula:	$C_6H_{10}O_3$
Molecular weight or molecular weight range:	130.14
Synonyms:	

Type of substance ☐ Mono-constituent ☒ Multi-constituent ☐ UVCB

Structural formula:



2-Hydroxypropyl acrylate



1-Methyl-2-hydroxyethyl acrylate

Other relevant information about substance composition

This CAS RN represents the commercial product as routinely produced that contains mainly 2-hydroxypropyl acrylate and in a smaller proportion 1-methyl-2-hydroxyethyl acrylate.

Table 2: Constituent

EC number:	220-852-9
EC name (public):	2-hydroxy-1-methylethyl acrylate
CAS number:	2918-23-2
CAS name (public):	2-hydroxy-1-methylethyl acrylate
IUPAC name (public):	2-hydroxy-1-methylethyl acrylate
Index number in Annex VI of the CLP Regulation:	607-108-00-2
Molecular formula:	$C_6H_{10}O_3$
Molecular weight or molecular weight range:	130.14

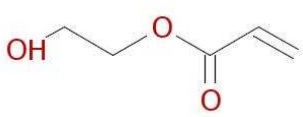
Table 3: Constituent

EC number:	213-663-8
EC name (public):	2-hydroxypropyl acrylate
CAS number:	999-61-1
CAS name (public):	2-hydroxypropyl acrylate
IUPAC name (public):	2-hydroxypropyl prop-2-enoate
Index number in Annex VI of the CLP Regulation:	607-108-00-2
Molecular formula:	$C_6H_{10}O_3$
Molecular weight or molecular weight range:	130.14

1.2 Similar substances/grouping possibilities

Name	CAS No	EC No	Comments
2-hydroxyethylacrylate	818-61-1	212-454-9	Registered
butyl acrylate	141-32-2	205-480-7	Registered

Structural formula:



2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table 4: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☐ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restric -tion	☐ Annex XVII[1]
Harmonised C&L	☒ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes / EU legislation	☐ Other (provide further details below)	

[1] Please specify the relevant entry.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table 5 : 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)		
607-108-00-2	acrylic acid, monoester with propane-1,2-diol	247-118-0	25584-83-2	Acute Tox 3 Skin Corr. 1B Skin Sens. 1	H301/H311/H331 H314 H317	H317: C≥ 0.2%	C and D

3.1.2 Self classification

- In the registration:

  The registrants do not agree with the harmonized classification. They indicated the following classification:

Hazard category	Hazard Statement	
Acute Tox. 4	H302	Harmful if swallowed
Acute Tox. 4	H312	Harmful in contact with skin
Skin Corr. 1B	H314	Causes severe skin burns and eye damage.
Skin Sens. 1	H317	May cause an allergic skin reaction. C≥0.2%
Aquatic Chronic 3	H412	Harmful to aquatic life with long lasting effects.

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

Classification	
Hazard Class and Category Code(s)	Hazard statement code(s)
Eye Dam. 1	H318
Resp. Sens. 1	H334
Not classified (1 notifier)	

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[2]

4.1 Tonnage and registration status

Table 6: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☒ > 1,000+ tpa		☐ Confidential
Joint submission		

4.2 Overview of uses

Acrylic acid, monoester with propane-1,2-diol is used as monomer in polymerization reaction (at registrant's site and downstream users' sites) and as non-monomer reageant in synthesis of substances.

No service-life is considered since residual monomer is considered as an impurity.

Table 7: Uses

Part 1:

☒ Manufacture	☐ Formulation	☒ Industrial use	☐ Professional use	☐ Consumer use	☒ Article service life	☒ Closed system

[2] *Please provide here the date when the dissemination site was accessed.*

Part 2:

	Use(s)
Uses as intermediate	Manufacture and distribution of the substance Manufacture of substances: use as a laboratory reagent Polymerization at registrants sites Polymerization at downstream user sites
Uses at industrial sites	Polymerization at registrants sites and at downstream user sites for bulk, large scale chemicals (including petroleum products), fine chemicals and plastics products. Acrylic acid, monoester with propane-1,2-diol is used as such, as monomers for the manufacture of thermoplastics and as process regulators for polymerisation processes in production of resins, rubbers, polymers. Processes: closed and batch processes, transfers.
Article service life	Noted relevant after polymerization at downstream user sites, but not addressed.

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 (why the substance qualifies for being in CoRAP)

☒ 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 ☐ C ☐ M ☐ R	Suspected CMR[1] ☒ C ☒ M ☐ R	☐ Potential endocrine disruptor
☐ Sensitiser	☒ Suspected Sensitiser[3]	
☐ PBT/vPvB	☐ Suspected PBT/vPvB[1]	☐ Other (please specify below)
Exposure/risk based concerns		
☒ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
☐ Exposure of environment	☒ Exposure of workers	☐ Cumulative exposure
☒ High RCR	☒ High (aggregated) tonnage	☒ Other (please specify below)

[3] 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

Human Health: based on the available information concerning the genotoxicity of the substance, there are still some uncertainties on the genotoxic potential of the substance. Remaining concern is due to equivocal results in *in vitro* assays, and possible missing assays *in vivo*.

Concerning the carcinogenicity, a read-across is proposed in the registration dossier, as for other endpoints. The validity of the read-across should be then assessed.

As for other acrylates, the substance is highly irritative by all routes of exposure and is also classified as a skin sensitizer, therefore it seems necessary to verify if this acrylate is also a respiratory sensitizer.

Exposure:

Release of HPA from products/articles during service life should be investigated. If relevant, non-exposure should be justified or potential exposure and risk for consumers should be characterised.

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

☒ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☒ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☐ Information ED potential	☒ Other (provide further details below)
Information on identity of the substance since there are uncertainties on the identity and the proportion of the constituent of the mixture.	

5.5. Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)