

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	2-ethyl-2-[[[1-oxoallyl]oxy]methyl] - 1,3-propanediyl diacrylate
Chemical Group:	
EC Number:	239-701-3
CAS Number:	15625-89-5
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

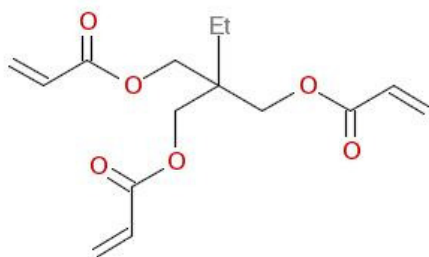
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	2-ethyl-2-[[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl diacrylate
IUPAC name:	2,2-bis(prop-2-enoyloxymethyl)butyl prop-2-enoate
Index number in Annex VI of the CLP Regulation	607-111-00-9
Molecular formula:	C ₁₅ H ₂₀ O ₆
Molecular weight or molecular weight range:	296.3157
Synonyms/Trade names:	TMPTA, GM63C00(TMPTA), AgiSyn 2811 Trimethylolpropane-triacrylate

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

Structural formula:

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the 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.

Signal word: Warning Pictogram: GHS07

2.2 Self classification

- In the registration
Only the harmonised classification is given.
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
 - Resp. Sens. 1; H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 - STOT SE 3; H335: May cause respiratory irritation.
 - Aquatic Chronic 2; H411: Toxic to aquatic life with long lasting effects.
 - Not Classified

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 checked="" 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 type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential	
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
<ul style="list-style-type: none"> - Production of chemicals / Manufacture of the substance - Formulation of preparations / industrial formulation of the substance - Industrial use of the substance as cross-linking agent in rubbers (tyres, GRG) and plastics - Industrial use of process regulators for polymerization processes in production of resins, rubbers, polymers - Industrial use resulting in inclusion into or onto a matrix - industrial application of formulations - industrial manufacture of polymers - industrial use as intermediate - professional wide dispersive use of reactive substance in open systems - professional wide dispersive indoor use of reactive substances in open systems - professional application of formulations 			

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

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

4.2 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 disruptor
- Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
- Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)
- Fulfils exposure criteria
- Fulfils MS's (national) priorities

4.3 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 type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input checked="" 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 checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input 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 checked="" type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
Respiratory sensitization has not been assessed in the dossier but some cases of occupational asthma are reported in the literature (Quirce et al., 2011; several references in the article). Moreover, some RCR indicated in the dossier are enough close to one (<i>for inhalation exposure of industrial workers</i>) to be examined under SEv.		

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

4.4 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 type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
As far as we know, no regulatory process has been engaged that could affect suitability for substance evaluation.	

4.5 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 checked="" type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
Information on toxicological properties: to assess the respiratory sensitization potential of the substance	
Information on exposure and uses: to investigate high RCRs and uses such as artificial nail application and thermal activated papers used in point of sale terminals (reported cases of occupational asthma).	

4.6 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)
Dependent on outcome of SEv.			