



Justification Document for the Selection of a CoRAP Substance

-Update-

Substance Name (public name):	Reaction Products of C3 alcohols and C3 alkenes obtained as by-products from the manufacture of propan-2-ol by hydration of propylene
EC Number:	701-241-0
CAS Number:	n/a
Authority:	Italy
Date:	22/03/2016 20/03/2018 (1. Update) 19/03/2019 (2. Update)

Cover 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: Other Substance identifiers

EC name (public):	Reaction Products of C3 alcohols and C3 alkenes obtained as by-products from the manufacture of propan-2-ol by hydration of propylene
IUPAC name (public):	
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	A complex and variable combination of hydrocarbons having carbon numbers predominantly in the C3, C6 & C9 chain length and oxygenated organic molecules, predominantly diisopropyl ether and hexanol (branched and linear). See diagram
Molecular weight or molecular weight range:	ca. 96.0
Synonyms:	

Type of substance


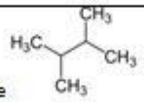
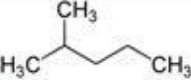

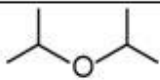
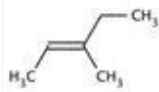

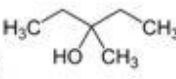
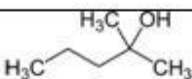
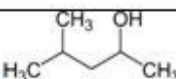
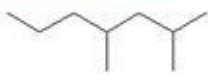
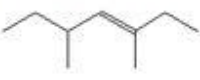
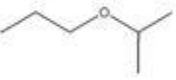
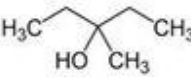
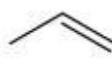

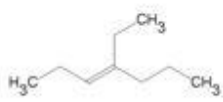
Mono-constituent

Multi-constituent

UVCB

Structural formula:

Main constituents of the Reaction Mass of 2-Methylpentane, Hexanol (branched and Linear) and Diisopropylether.

n-Propanol (NPA) 	2,3-dimethylbutane 
2-methylpentane 	3-methyl pentane 
Isopropyl Ether (IPE) 	3-methyl-2-pentene 
2,3 dimethylbutene 	3-methyl-2-pentanol 
2-methyl-2-pentanol 	4-methyl-2-pentanol 
2,4 dimethylheptane 	3,5 dimethyl-3-heptene 
Propyl isopropyl ether 	3-methyl-3-pentanol 
Propylene 	IPA 
4-ethyl-3-heptene 	

1.2 Similar substances/grouping possibilities

Has read-across been used by the registrant for the concern related endpoints? Yes No

Is the substance a member of a category? Yes No

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input checked="" type="checkbox"/> Compliance check, Final decision
		<input type="checkbox"/> Testing proposal, Final decision
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
Restriction	<input type="checkbox"/> Annex XVII ¹	
Harmonised C&L	<input type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	

¹ Please specify the relevant entry.

	<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment
	<input type="checkbox"/> In relevant Annex
Other processes / EU legislation	<input type="checkbox"/> Other (provide further details below)

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

The substance is not currently listed on Annex VI of CLP Regulation ((EC) No 1272/2008).

3.1.2 Self classification

- In the registration:
 - Asp. Tox. 1 H304
 - Flam. Liq. 2 H225
 - Aquatic Chronic 3 H412
 - STOT SE 3 H336

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

none

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES²

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site*		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa
<input checked="" 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
This substance has 1 active registrations under REACH, 0 Joint Submission(s) and 1 Individual Submission(s).		

*the total tonnage band has been calculated by excluding the intermediate uses, for details see the Manual for Dissemination and Confidentiality under REACH Regulation (section 2.6.11):
https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0

4.2 Overview of uses

This substance is used as a fuel by consumers, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.

Table: Uses

Part 1:

<input checked="" type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
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Part 3: There is high potential for exposure of

<input checked="" type="checkbox"/> Humans	<input checked="" type="checkbox"/> Environment
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² The dissemination site was accessed November 2018.

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 <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 type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ³	
<input type="checkbox"/> PBT/vPvB	<input checked="" 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 checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input checked="" type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> 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

Persistence: At pH4, 7 and 9 there was less than 10% hydrolysis after 120 hours at 50°C when monitoring the isopropyl ether content of the test material, equivalent to a half-life greater than 1 year at 25°C. In a ready biodegradability test conducted according to guideline OECD 310, 22% biodegradation was observed in 28 days. The degradation simulation studies required at this tonnage band have been waived so no definite conclusion on P can be made. The screening criterion for P/vP is met.

Bioaccumulation: The measured water solubility of the substance was found to be dependent on loading and ranged from 0.444-16.9 g/l at nominal loadings between 1 and 100g/l respectively. Log Pow was measured using the HPLC method EU Method A.8 giving values between 0.324 to 4.63. From the chromatographic profile, one component, peak 9, meets the screening criterion for B. The fish bioaccumulation study required at this tonnage band is waived. A summary of QSAR predictions is provided which concludes that ‘highest BCF calculated was 173.9 L/kg, which was associated with the C6 aliphatic constituents’. Based on the measured Pow, some components of the substance are potentially bioaccumulative and this cannot be ruled out without further information, such as further justification of the QSAR predictions or further bioaccumulation testing.

Toxicity: There is insufficient data to determine whether the T criterion is met. Reproductive toxicity and repeated dose toxicity studies are waived. Acute toxicity studies with fish and Daphnia show LC50s in the 10-100 mg/l range based on nominal concentrations. For algae, the 72h ErC50 was 80mg/l (nominal concentration). However, these aquatic toxicity studies all used the WAF approach so the actual toxicity of individual components is unclear. Long-term aquatic toxicity studies are waived.

Exposure and risks: There is wide dispersive use of the substance as a fuel sources, including consumer exposure. Potential risks to consumer are identified.

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

<input checked="" type="checkbox"/> Information on toxicological properties	<input checked="" type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information on ED potential	<input type="checkbox"/> Other (provide further details below)
<ul style="list-style-type: none"> • Further tests to investigate the persistence and bioaccumulation of certain components of the substance. It is difficult to request such information for components of a substance under compliance check. • Substance identity check to determine whether hexane is present • Further tests to investigate long-term toxicity and ecotoxicity, if necessary. • Information on exposure to clarify the risk to consumers 	

5.5 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
Dependent on whether the definitive PBT criteria are met and whether risks to consumers are found.			