

baua:

Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

Federal Institute for Occupational
Safety and Health

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name): Esterification products of 4,4'-
isopropylidenediphenol, ethoxylated
and 2-methylprop-2-enoic acid

EC Number: 609-946-4

CAS Number: 41637-38-1

Authority: Germany

Date: 21/03/2017

Cover Note

This document has been prepared by the evaluating Member State given in the
CoRAP update.

Table of Contents

1	IDENTITY OF THE SUBSTANCE	3
1.1	Other identifiers of the substance	3
1.2	Similar substances/grouping possibilities	3
2	OVERVIEW OF OTHER PROCESSES / EU LEGISLATION	4
3	HAZARD INFORMATION (INCLUDING CLASSIFICATION)	5
3.1	Classification	5
3.1.1	Harmonised Classification in Annex VI of the CLP	5
3.1.2	Self classification	5
3.1.3	Proposal for Harmonised Classification in Annex VI of the CLP	5
4	INFORMATION ON (AGGREGATED) TONNAGE AND USES	6
4.1	Tonnage and registration status	6
4.2	Overview of uses	6
5.	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP SUBSTANCE	8
5.1.	Legal basis for the proposal	8
5.2.	Selection criteria met (why the substance qualifies for being in CoRAP)	8
5.3.	Initial grounds for concern to be clarified under Substance Evaluation	8
5.4.	Preliminary indication of information that may need to be requested to clarify the concern	9
5.5.	Potential follow-up and link to risk management	9

1 IDENTITY OF THE SUBSTANCE

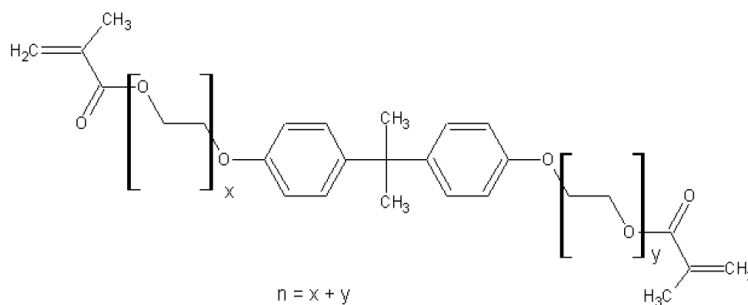
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Poly(oxy-1,2-ethanediyl), α,α' -[(1-methylethylidene)di-4,1-phenylene]bis[ω -[(2-methyl-1-oxo-2-propen-1-yl)oxy]-
IUPAC name (public):	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	$C_{23}H_{24}O_4 (C_2H_4O)_n$
Molecular weight or molecular weight range:	
Synonyms:	Bisphenol A, ethoxylated, dimethacrylated

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

Not applicable.

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 type="checkbox"/> Compliance check, Final decision
		<input type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
	Restriction	<input type="checkbox"/> Annex XVII
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)	
	<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)	
Further details		

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

There is no entry for harmonised classification for this substance in Annex VI.

3.1.2 Self classification

- In the registration:
Aquatic Chronic 4 H413
- The following hazard classes are in addition notified among the aggregated self-classifications in the C&L Inventory:
Skin Irrit. 2 H315
Skin Sens. H317
Eye Irrit. H319
Aquatic Chronic 2 H411

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Currently, no proposal for harmonised classification and labeling is available for this substance.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES¹

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 checked="" 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 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

4.2 Overview of uses

Exposure of the substance is likely to occur by uses of professional workers: Wide dispersive indoor use (in a mixture) resulting in inclusion into or onto a matrix, professional application of formulations. Release of the substance to the environment is also likely to occur by consumer uses: Wide dispersive indoor/outdoor use resulting in inclusion into or onto a matrix, consumer use of formulations as adhesives or sealants.

The substance is used in the formulation of products like adhesives and sealants. The widespread use of these formulations by professionals and consumers results in inclusion into or onto an article. There is potential for release to the environment, i.e. during processes like roller application or brushing. Exposure of the environment during processes like spraying or open outdoor cleaning is likely. In combination with the potential persistency of the substance, this wide dispersive use leads to a concern regarding exposure of the environment.

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 checked="" type="checkbox"/> Closed system
---	---	--	--	--	---	---

¹ The dissemination site was accessed: 20.09.2016

Part 2:

	Use(s)
Uses as intermediate	
Formulation	ERC 2: Formulation into a mixture
Uses at industrial sites	ERC 5: Use at industrial sites leading to inclusion into or onto an article; ERC 6d: Use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into/onto an article)
Uses by professional workers	ERC8c: Wide dispersive indoor use (in a mixture) resulting in inclusion into or onto a matrix; Professional application of formulations
Consumer Uses	ERC 8c, 8f: Wide dispersive indoor/outdoor use resulting in inclusion into or onto a matrix; Consumer use of formulations as adhesives or sealants
Article service life	-

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 ³ <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 ²	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ³	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input 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 type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

² 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 harmonised or registrant self-classification)

Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

The substance is not readily biodegradable. The available data do not allow assessing degradation in environmental compartments. Therefore, the substance is considered to be potentially persistent.

The experimental log K_{ow} of the substance varies with the composition of the constituents in the range of 3.4 – 5.6 (at pH 6.44), and therefore meets the screening criterion for bioaccumulation. No measured data on the bioconcentration factor BCF are available. Therefore, the substance is considered to be potentially bioaccumulative.

The assessment of acute toxicity to aquatic organisms is supported by read-across data with LC/EC₅₀ values around 100 mg/L (nominal). Long-term toxicity to aquatic organisms has been waived.

The substance is used in the formulation of products like adhesives and sealants. There is wide dispersive use of these formulations by professionals and consumers. In combination with the potential persistency of the substance, this wide dispersive use leads to a concern regarding exposure of the environment.

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

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
<p>Further information on biodegradation is required to clarify whether the substance is persistent or very persistent.</p> <p>Further evaluation and, if necessary, further testing is required to clarify whether the substance is bioaccumulative or very bioaccumulative.</p> <p>The read-across approach for ecotoxicity requires further evaluation and, if necessary, testing with the main constituents of the UVCB.</p>	

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)
<p>If the substance is identified as a PBT/vPvB substance, an analysis of risk management options will be carried out, taking into account information on use and exposure. Potential options are the inclusion in the Candidate List with or without Authorisation, but also Restriction.</p>			