Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	**4,4'-Isopropylidenediphenol, ethoxylated (BPA EO)**
EC Number:	**500-082-2**
CAS Number:	**32492-61-8**
Authority:	**FR 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

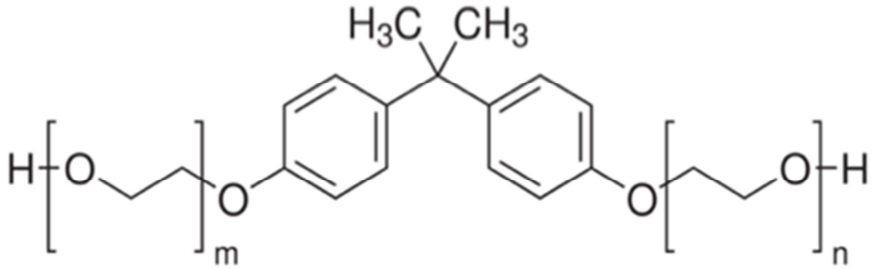
1.1 Other identifiers of the substance

Table 1: Other Substance identifiers

EC name (public):	4,4'-Isopropylidenediphenol,ethoxylated
IUPAC name (public):	2-[4-[2-[4-(2-hydroxyethoxy)phenyl]propan-2-yl]phenoxy]ethanol
Index number in Annex VI of the CLP Regulation:	Not assigned
Molecular formula:	Not applicable for a UVCB
Molecular weight or molecular weight range:	316-448 g/mol
Synonyms:	DIANOL - SIMULSOL

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

Structural formula:



UVCB based on the expected variation of the alkyl chain lenght (n and m).

1.2 Similar substances/grouping possibilities

Structural formula: *Close to BPA,* only the lenght of the chain in para varies, but same biphenyls with 2 methyl.

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table 2: 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
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)	

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

No existing harmonised classification

3.1.2 Self classification

- In the registration:

Aquatic Chronic 3 H412

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
  - Acute Tox. 4 H302
  - Skin Irrit. 2 H315
  - Skin Sens. 1 H317
  - Eye Irrit. 2 H319
  - STOT SE 3 H335
  - Not classified (29 notifiers)

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Not applicable

3.2 Other information

Some *in vitro* mutagenicity result appears equivocal for BPA EO on *in vitro* mammalian chromosome aberration test with metabolic activation and positive result without metabolic activation. These results do not allow a clear conclusion regarding mutagenicity of the substance, so additional data are requested to complete the dossier.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[1]

4.1 Tonnage and registration status

Table 3: 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 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential
Joint submission		

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

4.2 Overview of uses

Table 4: Uses

Part 1:

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

Part 2:

	Use(s)
Formulation	Used in resins in formulation of toner (ink and toner) ; used for production of UV/EB curing resins ; used for production of anti-static agents for plastics ; Formulation of plastics compounded with anti-static agents; Use as a sizing agent for carbon fibre ; Formulation of anti-static agents compounded plastics
Uses at industrial sites	Production of UV/EB curing resins (adhesives, sealants, coatings and paintes, thinners, paint removes, ink and toners) ; Production of resins for toners ; Production of monomers as raw materials for UV/EB curing resins ; Production of anti-static agents ; Molding of the plastic article ; Use for production of sizing agents for carbon fibre ; use as intermediate
Uses by professional workers	Filling and refilling of toners to cartridges ; Maintenance of imaging equipment ; Moulding plastic articles ; Use of carbon fibre ; Laboratory reagent
Consumer Uses	Toner in imaging equipment , laboratory reagent, plastic articles
Article service life	Use of plastic articles; Use of carbon fibre ;

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[2]	
☐ 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)

[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 harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

A concern was identified for genotoxicity, because of equivocal results for chromosome aberration *in vitro*, and no *in vivo* test is available.

Concerning environment, no ED concern was identified for human health but still need to be clarified for environment, in light of the fact that the substance has wide dispersive uses and has an high tonnage.

Additionally the substance has a high aggregated tonnage and has wide dispersive uses.

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)

Environment
BPA EO is a substance inherently biodegradable but not readily biodegradable with a low potential of bioaccumulation and a low aquatic toxicity. The persistent behavior of BPA EO is a concern due to its low degradation. Further analysis regarding biodegradation of BPA EO and identification of its byproducts are needed. If BPA are by-products of BPA EO, a concern for ED could be expected.
As BPA EO is classified as Aquatic Chronic 3 H412 in the registration dossier, an exposure assessment is missing in the dossier.

Human Health
As an in vitro mutagenicity result is equivocal for BPA EO on in vitro mammalian chromosome aberration test with metabolic activation and positive result without metabolic activation. An in vivo toxicological assessment on the mutagenicity of BPA EO is missing in the dossier.

The mutagenicity evaluation might be performed under substance evaluation. While evaluating, an extended one generation study might be requested to obtain information regarding on reproductive and developmental effects of BPA EO.

5.5. Potential follow-up and link to risk management

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