Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether
Chemical Group:	
EC Number:	926-564-6
CAS Number:	
Submitted by:	Germany
Date:	17/03/2015

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	-
IUPAC name:	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether
Index number in Annex VI of the CLP Regulation	N/A
Molecular formula:	Not disseminated
Molecular weight or molecular weight range:	Not disseminated
Synonyms/Trade names:	

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

Structural formula:

Not disseminated.

1.2 Similar substances/grouping possibilities

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2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

The substance is not listed in Annex VI of the CLP regulation.

2.2 Self classification

- In the registration:

  Acute Tox. 4 H302

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

  -

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

There is currently no proposal for harmonised classification registered or under consideration for this substance.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA 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

☒ Industrial use	☒ Professional use	☐ Consumer use	☐ Closed System

The substance is used in the manufacture of thermoplastics, other composite materials, for adhesives & sealants, resulting in inclusion into or onto a matrix, as a composite material, in coatings, rigid foam, adhesives & sealants. The uses include wide dispersive outdoor use, wide dispersive indoor & outdoor use resulting in inclusion into or onto a matrix.

4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

☐ Compliance check, Final decision	☐ Dangerous substances Directive 67/548/EEC
☐ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☐ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	

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[1]	
☐ 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)

The substance is fulfilling the screening criteria for persistence and bioaccumulation as defined in Annex XIII, i.e.

P/vP criterion
The substance is not readily biodegradable and therefore fulfills the screening criterion for persistence.

B/vB criterion

The substance has a log Pow > 4.5 and hence fulfills the screening criterion for bioaccumulation. No measured data on bioconcentration in fish are available. Hence the oligomeric constituents are considered as potentially bioaccumulative.

T criterion

In addition, no long-term studies on aquatic ecotoxicology are available. For a conclusion whether the T-criterion might be additionally fulfilled, information on long-term toxicity for aquatic organisms might also be required.

Endocrine Disrupting Properties

The substance is an UVCB and consists of different structurally related oligomers.

The substance has a relatively high tonnage (100-1000t) and uses include wide dispersive outdoor and indoor use with in inclusion into or onto a matrix. The likelihood of environmental exposure needs to be assessed.

[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

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)

Further information on biodegradation is required to clarify whether the substance is persistent or very persistent.

Further information on bioaccumulation is required to clarify whether the substance is bioaccumulative or very bioaccumulative.

Further evaluation and, if necessary, further testing is required to clarify whether the substance is toxic.

5.5 Potential follow-up and link to risk management

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

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.