Justification for the selection of a substance for CoRAP inclusion

- Update -

Substance Name (Public Name):	bis(2-ethylhexyl) tetrabromophthalate
Chemical Group:	
EC Number:	247-426-5
CAS Number:	26040-51-7
Submitted by:	Sweden
Date:	17/03/2015 19/03/2019 (1. 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

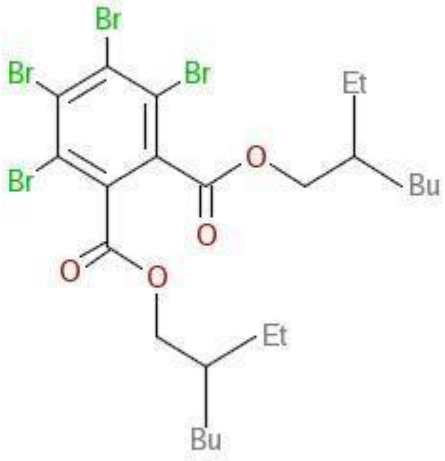
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	bis(2-ethylhexyl) tetrabromophthalate
IUPAC name:	bis(2-ethylhexyl) 3,4,5,6-tetrabromophthalate
Index number in Annex VI of the CLP Regulation	
Molecular formula:	$C_{24}H_{34}Br_4O_4$
Molecular weight or molecular weight range:	706.1404 g/mol
Synonyms/Trade names:	bis(2-ethylhexyl) tetrabromophthalate 1,2-bis(2-ethylhexyl) 3,4,5,6-tetrabromobenzene-1,2-dicarboxylate

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

Structural formula:



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, CLP.

2.2 Selfclassification

- In the registration:

Classification		Labelling		Specific Concentration limits, M-Factors
Hazard Class and Category Code(s)	**Hazard Statement Code(s)**	**Hazard Statement Code(s)**	**Supplementary Hazard Statement Code(s)**	
Not Classified				

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

Classification		Labelling		Specific Concentration limits, M-Factors
Hazard Class and Category Code(s)	**Hazard Statement Code(s)**	**Hazard Statement Code(s)**	**Supplementary Hazard Statement Code(s)**	
Eye Irrit. 2	H319	H319		

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

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3 INFORMATION ON AGGREGATED TONNAGE AND USES [1]

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
***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		

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

Information from disseminated page:

Formulation of preparations, formulation in materials
Use of plastics, masterbatch or compound in extrusion applications
Use of plastics, masterbatch or compound in calendering applications
Use in the production of rubber articles: Compounding and conversion
One Component Foam (spray can / dose can)
Laboratory use
Service life of plastic or rubber articles (indoor and outdoor)

Additive flame retardant and one of two brominated chemicals in Firemaster 550, the primary replacement for pentaBDEs in polyurethane foam. The substance is also used as a flame
retardant and as a plasticizer for flexible polyvinylchloride and for use in wire and cable insulation, film and sheeting, carpet backing, coated fabrics, wall coverings and adhesives: http://www.miljodirektoratet.no/old/klif/publikasjoner/2871/ta2871.pdf

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)	

[1] *The dissemination site was accessed August 2018.*

CCH : Sub-chronic toxicity study (90-day), In vitro gene mutation study in bacteria, Screening study for reproductive/developmental toxicity and Bioaccumulation in aquatic species requested. Deadline 23 November 2018.
TPE: Developmental toxicity / teratogenicity study (OECD 474) requested. Deadline 5 october 2016.

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)

Further explanation and justification for the concerns:

1. Suspected PBT/vPvB[1] :

- The low hydrolysis half-life-value used (14.7 days, 20°C, pH 7) is not sufficient to say that the substance is not persistent. Hydrolysis product is tetrabromophthalic acid, which meets screening P criterion. Transformation products and impurities have not been assessed on their PBT properties. The substance itself meets potentially P/vP screening criterion. Further the substance is detected in top predators in remote areas, indicating the potential for persistence in the environment and probably potential for long range transport.
- The bioaccumulation test is not performed to the OECD standard; and yields a BMF of 0.012/0.014. The substance is detected in top predators and other animals in remote areas, including polar bear, ringed seal, glaucous gull, kittiwake, common eider and Atlantic cod, Brown Trout, Harbor Seal, Brünnich's Guillemot and capelin, indicating the potential for bioaccumulation. The values reported for the substance in biota are often low, which harmonizes well with the tonnage band. However, related to the BMF value supplied from the registration, there should not be any detectable BEHTBP in biota
- All aquatic toxicity test performed above water solubility. Waiving for terrestrial toxicity tests seems unreasonable since environmental exposure is expected (ERC 8f).

[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 InventorySuspected 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

2. Potential endocrine disruptor: Structural similarity to DEHP (117-81-7: harmonized classification repr 1B). See SVHC support document for DEHP, http://echa.europa.eu/documents/10162/b8395d41-b6d5-427c-8294d46997e8835d. In vitro tests demonstrate potential for endocrine effects, see https://pubchem.ncbi.nlm.nih.gov 3. Wide dispersive use : PROC 10 and 15, ERC 8a, 8c, 8f, 10a and 11a Exposure of environment : Detected in top predators in remote areas (see above) 4. Other: A gap in the standard information requirements for subchronic toxicity has been identified which might be addressed by performing a compliance check prior to the substance evaluation.

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 test to investigate the environmental fate, impurities and degradation products - Further tests to investigate ecotoxicological properties and endocrine disruption Also, a gap in the standard information requirements for subchronic toxicity has been identified.	

5.5 Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
Depending on outcome of the Substance evaluation process			