

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	N,N'-Ethylenebis(3,4,5,6-tetrabromophthalimide)
Chemical Group:	
EC Number:	251-118-6
CAS Number:	32588-76-4
Submitted by:	Norway
Date:	17/03/2015

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:	N,N'-ethylenebis(3,4,5,6-tetrabromophthalimide)
IUPAC name:	2,2'-ethane-1,2-diylbis(4,5,6,7-tetrabromo-1H-isoindole-1,3(2H)-dione)
Index number in Annex VI of the CLP Regulation	n.a.
Molecular formula:	C ₁₈ H ₄ Br ₈ N ₂ O ₄
Molecular weight or molecular weight range:	951.47 g/mol
Synonyms/Trade names:	SAYTEX BT93 1,2-bis(tetrabromophthalimido) ethane 2,2'-(1,2-ethandiyl)bis[4,5,6,7-tetrabromo-1h-isoindole-1,3(2h)-dione] BT-93W Ethyl Bis(Tetrabromophthalimide) SynaPro S93; 2,2'-ethane-1,2-diylbis(4,5,6,7-tetrabromo-1H-isoindole-1,3(2H)-dione) Ethylene bis(tetrabromophthalimide) EBTBP

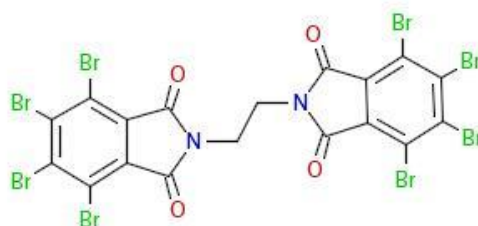
Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

N.a.

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

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

2.2 Self classification

- In the registration:
Not classified.
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
Not classified.

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

No proposal available.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA 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	
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
<p><u>Information from disseminated page:</u></p> <p>Formulation flame retardant preparation Thermoplastic production (masterbatch and compound) Recycling Thermoplastic used in electronic and electrical component and electronic enclosures Thermoplastic used in construction and automotive Wire and cable used in automotive Coating used in textile backcoating Foam production for construction</p> <p>The substance is – among others – used in textile backcoating for fabrics, textiles and apparel. Though low release is stated there is wide dispersive use and consumer exposure cannot be excluded.</p>			

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

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> 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 <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 ¹	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<input checked="" 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 checked="" 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)
<p>1. HH</p> <p>The registration dossier does not provide sufficient information for the evaluation of sensitization, mutagenicity and fertility. The studies submitted for repeated dose toxicity were performed before international guidelines were available. Therefore the toxicity of the substance cannot be sufficiently evaluated and there is a potential risk as exposure of consumers is possible.</p> <p>Based on the relatively large volume and wide dispersive use and the process categories named, there is also a significant potential for exposure of workers, both under production, handling and waste management.</p> <p>2. PBT</p> <p>The substance is expected to adsorb strongly to soil and sediment and to be persistent based on screening test and very persistent based on modeling. There is a general lack of experimental data on the fate of the substance itself and especially its debromination products in the environment. Monitoring data, though scarce, also indicate that the substance is potentially mobile in the environment (reported data from dissemination page). The substance was detected in the receiving environment for leachate water from combined metal recycling and car dismantling factory.</p> <ul style="list-style-type: none"> - A standard bioaccumulation test has been performed, showing low values of bioaccumulation. Solubility is a challenge with this substance and factors such as high log Kow, large size and insolubility are put forward as indications that the substance will not bioaccumulate. However EFSA (2012 http://www.efsa.europa.eu/en/efsajournal/doc/2908.pdf) considered the potential for accumulation to be high in mammals based on modeling. <p>3. Wide dispersive use</p> <p>According to the information on uses, both consumer use and professional use is possible. The substance is also included into or onto matrixes, for example in different plastics and on textiles. Several of the use descriptors relevant for wide dispersive use are listed in the reported data from dissemination page as for example PROC 5, PROC 10, PROC 13, ERC 8c, 8f, 10a and 11a.</p>		

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

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input checked="" type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

-Initially, it is likely that information on sensitization, mutagenicity and fertility will be requested.

- Further tests to investigate the environmental fate of the substance, its metabolites, and debromination products.

Depending on the results of the tests and possible classification, further steps such as information on exposure might be required.

5.5 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
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Due to insufficient information on the fate, behavior and toxicity of the substance a statement on the potential follow-up action can currently not be made.