

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name): n-butylin trichloride
Chemical Group: organotin
EC Number: 214-263-6
CAS Number: 1118-46-3
Submitted by: FRANCE
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-butyltin trichloride
IUPAC name:	n-butyltin trichloride
Index number in Annex VI of the CLP Regulation	Not assigned
Molecular formula:	C ₄ H ₉ Cl ₃ Sn
Molecular weight or molecular weight range:	282.2 g/mol
Synonyms/Trade names:	<i>Trichlorure de monobutylétain</i> <i>n-butyltin trichloride</i> <i>trichlorure de n-butylétain</i>

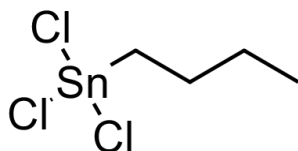
Type of substance

Mono-constituent

Multi-constituent

UVCB

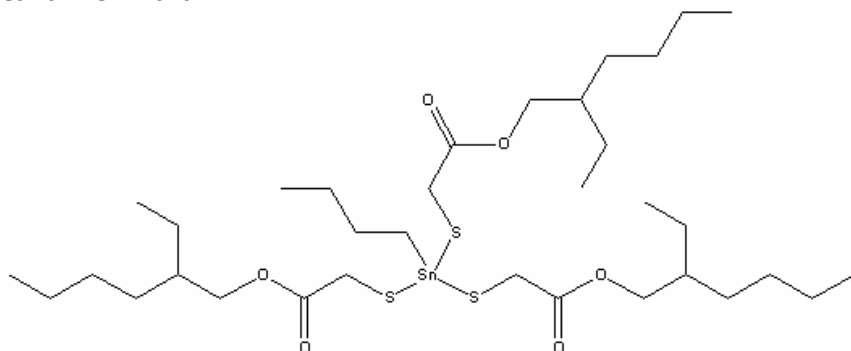
Structural formula:



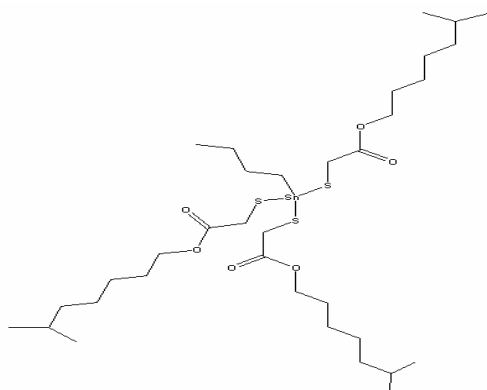
1.2 Similar substances/grouping possibilities

EC name:	2-ethylhexyl 4-butyl-10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate
EC no	248-070-3
IUPAC name:	-
CAS number	26864-37-9
Index number in Annex VI of the CLP Regulation	Not assigned
Molecular formula:	C ₃₄ H ₆₆ O ₆ S ₃ Sn
Molecular weight or molecular weight range:	785.78924 g/mol
Synonyms/Trade names:	2-ethylhexyl 4-butyl-10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate

Structural formula:



EC name:	Triisooctyl 2,2',2''-[(butylstannylidyne)tris(thio)]triacetate
EC nb	247-295-4
IUPAC name:	-
CAS number	25852-70-4
Index number in Annex VI of the CLP Regulation	Not assigned
Molecular formula:	C ₃₄ H ₆₆ O ₆ S ₃ Sn
Molecular weight or molecular weight range:	785.78924 g/mol
Synonyms/Trade names:	triisooctyl 2,2',2''-[(butylstannylidyne)tris(thio)]triacetate

Structural formula:

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

The substance is not included in Annex VI of CLP.

2.2 Self classification

- In the registration:
 - n-butyltin trichloride (MBTC) with dibutyltin dichloride DBTC<0.1% (skin corr 1C H314, Eye Dam 1 H318, STOT SE 3 H335/lungs/inhalation, Aquatic acute 1 H400 M=1, Aquatic chronic1 H410 M=1)
 - MBTC with <0.5% DBTC (**Acute tox 4 H332**, Skin Corr 1C H314, Eye dam 1 H318, **Repr 1B H360**, STOT SE 3 H335/lungs/inhalation, Aq acute 1 H400 M=1, Aq chronic 1 H410 M=1)
 - MBTC with 1% =< DBTC<3% (*Acute tox 4 H332*, Skin Corr 1C H314, Eye dam 1 H318, *Repr 1B H360*, **Muta 2 H341**, STOT SE 3 H335/lungs/inhalation, **STOT RE 2 H373/thymus/oral**, Aq acute 1 H400 M=1, Aq chronic 1 H410 M=1)
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
 - Aquatic chronic 2 H411***
 - acute tox 4 H312***
 - skin corr 1B H314***
 - Acute tox 4 H302***
 - Skin irrit 2 H315***
 - Eye irrit 2 H319***
 - STOT RE 1 H372***

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input 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 checked="" type="checkbox"/> 1000+ tpa		<input type="checkbox"/> Confidential	
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Closed System
Workers exposed in industry (manufacture, formulation, distribution). Professional workers and the general population are both exposed by the major use for coating.			

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 checked="" 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 disruptor
- 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 checked="" type="checkbox"/> M <input checked="" 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 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 checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p><u>Justification of the inclusion in the Co-RAP list of the substance for toxicological concerns:</u></p> <p>Testing proposals submitted (OECD 414 in rabbit) for the reprotoxicity and equivocal studies on developmental toxicity. Self classification for mutagenicity and some positive tests. Final decision on testing proposal 3 October 2012.</p> <p><u>Justification of the inclusion in the Corap list of the substance for environmental concerns:</u></p> <p>SIAR (2006) indicated that MBTC possesses properties indicating a hazard for environment, and that an exposure assessment for environment and risk assessment are necessary.</p> <p>According to data provided in the disseminated dossier of the MBTC, the substance is not readily biodegradable. Therefore, this substance can be considered as P/vP by screening approach. Considering that the potential degradation products must be taken into account in the PBT assessment, clarification is needed on the biodegradability of the MBTC and its potential degradation products. Moreover, data on potential of bioaccumulation of the MBTC need to be clarified. Finally, data showed that MBTC is toxic to aquatic organisms. MBTC belong to organotin substance family, known for their PBT and PE properties.</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 checked="" 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)

5.5 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>MBTC is self classified for the reproductive toxicity as repro 1B H360FD and for mutagenicity as Muta 2 H341 by 31 notifiers on 103 (6 notifiers do not classify).</p>			