Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Dioctyltin oxide
Chemical Group:	organometallic
EC Number:	212-791-1
CAS Number:	870-08-6
Submitted by:	AT, EE
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:	Dioctyltin oxide
IUPAC name:	Stannane, dioctyloxo-
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	$C_{16}H_{34}OSn$
Molecular weight or molecular weight range:	361.1506
Synonyms/Trade names:	AI3-61965 , BRN 4131181; Di-n-octyl-zinn oxyd; Di-n-octyl-zinn oxyd; Di-n-octyltin oxide; Dioctyloxostannane; Dioctyltin oxide EINECS 212-791-1; NSC 140743; Stannane, oxodioctyl- Tin, dioctyl-, oxide; Tin, dioctyloxo-

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

Structural formula:

1.2 Similar substances/grouping possibilities

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Structural formula:

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2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification entry of the substance in table 3.1 in Annex VI of CLP exists.

2.2 Self classification

- In the registration

Repr. 2; H361: Suspected of damaging fertility or the unborn child
STOT Rep. Exp. 1 (Thymus); H372: Causes damage to organs

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

Aquatic Chronic. 4; H413: May cause long lasting harmful effects to aquatic life
Repr. 2, H361: Suspected of damaging fertility or the unborn child
STOT Rep. Exp. 1 (thymus), H372: causes damage to organs through prolonged and repeated exposure
STOT Rep. Exp. 2 (Immune System); H373: May cause damage to organs through prolonged or repeated exposure

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

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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

Following product categories are listed in the registration, in which dioctyltin oxide is used:
PC 1: Adhesives, sealants
PC 9a: Coatings and paints, thinners, paint removes
PC 9b: Fillers, putties, plasters, modelling clay
PC 14: Metal surface treatment products, including galvanic and electroplating products
PC 15: Non-metal-surface treatment products
PC 19: Intermediate
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents
PC 21: Laboratory chemicals
PC 23: Leather tanning, dye, finishing, impregnation and care products
PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids
PC 31: Polishes and wax blends
PC 32: Polymer preparations and compounds
PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids
PC 35: Washing and cleaning products (including solvent based products)
PC 0: Other: K35000, P15500, P15900

Sectors of end use are: manufacture of textiles, leather, fur, wood and wood products, pulp, paper and paper products, manufacture of fine chemicals, formulation [mixing] of preparations and/or re-packaging (excluding alloys), manufacture of rubber products, manufacture of plastics products, including compounding and conversion, manufacture of other non-metallic mineral products, e.g. plasters, cement, manufacture of fabricated metal products, except machinery and equipment, manufacture of computer, electronic and optical products, electrical equipment, general manufacturing, e.g. machinery, equipment, vehicles, other transport equipment, manufacture of furniture, building and construction work, electricity, steam, gas water supply and sewage treatment, scientific research and development.

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)

[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

Human health:

Reproductive effects:
The registrants referred to an OECD guideline 422 study (combined toxicity study with the Reproduction/Developmental Toxicity Screening Test). The outcome of the studies demonstrates adverse effects on the reproductive systems. A data waiving argument based on exposure considerations for further developmental and/or teratogenicity testing is given by the registrants. It has to be verified if this data waiving argument is justified, and if the self-classification of the registrants as Repr. Tox. 2 based on the GHS criteria is appropriate.
An *in vitro* toxicokinetic study to evaluate the hydrolysis from dioctyl tin to DOTC under gastric conditions was applied. The registrant's state that the outcome of the study is not meaningful, since dioctyltin oxide was extremely insoluble and only partially hydrolysis occurred. However, information on formation of DOTC would be helpful in regard of the adverse effects on the reproductive system.

Potential endocrine disruptor
While the acute toxicity of the substance seems to be low, a rather low no observed adverse effect level (NOAEL) for repeated dose toxicity was deduced based on adverse effects on the thymus of dioctyl tin oxide exposure. Based on GHS criteria, the registrants classify the substance as STOT RE Cat. 1, H372: cause damage to thymus through prolonged or repeated exposure effects. There is evidence from literature, that organic tin oxide compounds have the potential to disrupt endocrine systems. Since, dioctyltin oxide has adverse effects on the thymus and there is also evidence that the reproductive system is adversely affected the endocrine disruptor potential of dioctyl tin oxide has to be addressed in the chemical safety assessment.

Environment:

Bioaccumulation
The estimated log Kow value for dioctyltin oxide is 9.26 (KOWWIN v1.68), but due to the lack of validity for organometalls the value is questionable and the registrant assigned the study with Klimisch 3. A BCF test with dioctyl tin bis(2-ethylhexylthioglycate) in fish is available (Bouwman, 2010). The surrogate used is considered to hydrolyse to dioctyltin oxide. The BCF was determined to be 1294 µg/L. But for substances with extremely low water solubility testing via water is extremely difficult and a dietary test is preferred, but not available. It is unknown (according to the CSR) if growth dilution and lipid normalisation have been performed. If these 2 factors have been not taken into account, the BCF value would be higher. In addition, limitations in the sensitivity of the method were recorded. A detailed evaluation and perhaps re-calculation of the original study data is necessary.
With respect to bioaccumulation, this study (Bouwman, 2010) was evaluated in depth by UK EPA (http://www.echa.europa.eu/documents/10162/13628/dichlorodioctylstannane_pbtfactsheet_en.pdf). Both dioctyltin bis(2-ethylhexylmercaptoacetate) and 2,2-dioctyl-1,3,2-oxathiastannolan-5-one (DOTTG) are expected to hydrolyse rapidly to form dioctyltin hydroxide/ dioctyltin oxide (DOTO), which indicates that the measured BCF refers to the common hydrolysis product. UK concludes that "Overall, although the results of this study do not lead to the determination of a definitive value for the BCF of dioctyltin bis(2-ethylhexyl mercaptoacetate) or its hydrolysis products, they nevertheless provide strong evidence that the BCF is well below the 2,000 l/kg cut-off for a bioaccumulative substance in relation to the Annex XIII criteria. The available data suggest that the BCF is perhaps around 1,000 l/kg as a maximum."

Persistence
The substance is not readily biodegradable, showing 1.9% O_2 consumption after 28 days (OECD 301F) and 1.9% after 31 days (EU Method C.4-D). Further evaluation of the biodegradability is required. Simulation tests are not available. The registrant considered further testing unnecessary, as no exposure of the substance is anticipated.

Toxicity (Environment)
Acute aquatic toxicity information is available for fish, daphnia. L(E)C50 values were higher than the water solubility (acute LC50 fish is > 0.09 mg/L > water solubility; acute EC50 48h > 0.21 mg/L > water solubility). The algae study is considered not valid due to the lack of reporting; therefore the NOEC of 0.00097 cannot be used for derivation of the PNEC and the risk assessment. Chronic data for fish and daphnia are not available and have been waived. The water solubility of the substance indicated in the registration dossier is very low, but the substance might be stable in the environment (not readily biodegradable) and exposure of aquatic environment cannot be completely excluded. Therefore, long-term toxicity to aquatic organisms testing are relevant and should be requested based on the results of this screening. Toxicity to terrestrial organisms has been waived due to exposure considerations, although the substance is highly adsorptive and persistent and the substance. As the substance is used in many sectors, for many uses also in consumer products, exposure to the environment and appropriate risk management are expected to be relevant. It needs to be assessed, if this justification for data waiving is justified.
Due to the classification of DOTO in the registration as Repr. 2; H361: Suspected of damaging fertility or the unborn child and STOT Rep. Exp. 1 (Thymus); H372: Causes damage to organs the T criterion is fulfilled.
As for human health, there is also a need for this organo-tin compound to be evaluated regarding the endocrine disrupting potential for the environment.

Exposure
Based on the high tonnage and many uses of this substance, exposure of man and environment is a potential concern. After having concluded on the toxicological and ecotoxicological properties of this substance, it needs to be assessed, if the proposed risk management in the registration dossiers are sufficient and/or if more data on exposure are required.

Conclusion:
Dioctyltin oxide is a potential candidate substance to be included in the CoRAP list. There are concerns in regard to adverse effects on the development, which have to be in-depth assessed during substance evaluation. Furthermore, developmental toxicity effects and toxic effects on the thymus related to repeated dioctyltin exposure (at already low doses) indicate that dioctyltin oxide might be an endocrine disruptor. Dioctyltin oxide is not readily biodegradable and might persist in the environment. Although, data indicate that dioctyltin oxide does not bio-accumulate, the persistence of the substance needs to be clarified, since it is highly (eco)toxic and there is potential release to the environment.

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)

5.5 Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☒Authorisation	☐ Other (provide further details)
Depending on the outcome of substance evaluation, further risk management options such as a harmonized classification and/or authorization might be necessary.			