# Justification Document for the Selection of a CoRAP Substance

**Substance Name (public name): 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate**

**EC Number:** 248-227-6

**CAS Number:** 27107-89-7

**Authority:** NL MSCA

**Date:** 22/03/2016

**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

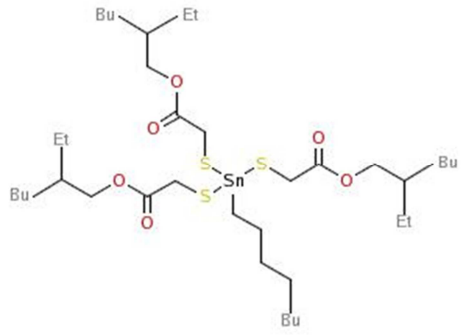
## 1.1 Other identifiers of the substance

**Table: Other Substance identifiers**

| | |
|---|---|
| **EC name (public):** | 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate |
| **IUPAC name (public):** | 2-ethylhexyl 10-ethyl-4-({2-[(2-ethylhexyl)oxy]-2-oxoethyl}sulfanyl)-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecan-1-oate |
| **Index number in Annex VI of the CLP Regulation:** | none |
| **Molecular formula:** | C38H74O6S3Sn |
| **Molecular weight or molecular weight range:** | 841.8956 |
| **Synonyms:** | 8-Oxa-3,5-dithia-4-stannatetradecanoic acid, 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-, 2-ethylhexyl ester;<br>Octyltin tris(2-ethylhexyl mercaptoacetate);<br>10-éthyl-4-[[2-[(2-éthylhexyl)oxy]-2-oxoéthyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatétradecanoate de 2-éthylhexyle;<br>2-Ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate<br>MOTE |

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

**Structural formula:**



## 1.2 Similar substances/grouping possibilities

Tin-carbon bond substances

# 2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

**Table: Completed or ongoing processes**

| | | |
|---|---|---|
| RMOA | ☐ Risk Management Option Analysis (RMOA) | |
| REACH Processes | Evaluation | ☐ Compliance check, Final decision |
| | | ☒ Testing proposal |
| | | ☒ CoRAP and Substance Evaluation |
| | Authorisation | ☐ Candidate List |
| | | ☐ Annex XIV |
| | Restri -ction | ☐ Annex XVII |
| Harmonised C&L | ☐ Annex VI (CLP) (see section 3.1) | |
| Processes under other EU legislation | ☐ Plant Protection Products Regulation<br>Regulation (EC) No 1107/2009 | |
| | ☐ Biocidal Product Regulation<br>Regulation (EU) 528/2012 and amendments | |
| Previous legislation | ☐ Dangerous substances Directive<br>Directive 67/548/EEC (NONS) | |
| | ☐ Existing Substances Regulation<br>Regulation 793/93/EEC (RAR/RRS) | |

| | |
|---|---|
| (UNEP) Stockholm convention (POPs Protocol) | ☐ Assessment |
| | ☐ In relevant Annex |
| Other processes / EU legislation | ☒ Other (provide further details below)<br>List of existing substances subject to transitional measures[2] |

1. ECHA made a decision on 21 September 2012 that an oral sub-chronic toxicity 90d repeated dose toxicity test in rats (TG 408) and an oral rat pre-natal developmental toxicity (TG414) should be performed. Results of these two studies have been included in the CSR. There has been a testing proposal for genetic toxicity in vivio.

2. The UK was the rapporteur for this dossier, in which a potential PBT was raised. This was addressed by a fish BCF study and the concern on PBT was removed. It is concluded by ECHA that no follow-up action at EU level was required.

# 3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

## 3.1 Classification

### 3.1.1 Harmonised Classification in Annex VI of the CLP

None.

### 3.1.2 Self classification

**Octyltin tris (2-ethylhexyl mercaptoacetate)**
Skin Sens. 1B, H317
Aquatic Acute 1, H400
Aquatic Chronic 1, H410
**MOTE >=99 % and DOTE <1%**
Repr 1B, H360 (oral)
Aquatic Acute 1, H400
Aquatic Chronic 1, H410
**MOTE >=97% and 1% =<DOTE <3%**
Repr 1B, H360 (oral)
Aquatic Acute 1, H400
Aquatic Chronic 1, H410
STOT RE 2, H373 (thymus)
**MOTE >=90% and 3% =<DOTE<10%**
Repr 1B, H360 (oral)
Aquatic Acute 1, H400
Aquatic Chronic 1, H410
STOT RE 2, H373 (thymus)
**MOTE >=70% and 10%=<DOTE<30%**
Repr 1B, H360 (oral)
Aquatic Acute 1, H400
Aquatic Chronic 1, H410
STOT RE 1, H372 (thymus)
**MOTE < 70% and DOTE >=30%**
Repr 1B, H360 (oral)

Aquatic Acute 1, H400
Aquatic Chronic 1, H410
Skin Sens. 1A, H317
STOT RE 1, H372 (thymus)
**MOTE < 50% and DOTE >=50%**
Repr 1B, H360 (oral)
Aquatic Acute 1, H400
Aquatic Chronic 1, H410
STOT RE 1, H372 (thymus)
Skin Sens. 1A, H317

### 3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

# 4 INFORMATION ON (AGGREGATED) TONNAGE AND USES

## 4.1 Tonnage and registration status

**Table: Tonnage and registration status**

| **From ECHA dissemination site** | | |
|---|---|---|
| ☒ Full registration(s) (Art. 10) | ☐ Intermediate registration(s) (Art. 17 and/or 18) | |
| Tonnage band (as per 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 |
| Joint submission | | |

## 4.2 Overview of uses

**Table: Uses**

**Part 1:**

| | | | | | | |
|---|---|---|---|---|---|---|
| ☒ Manufacture | ☒ Formulation | ☒ Industrial use | ☐ Professional use | ☐ Consumer use | ☒ Article service life | ☐ Closed system |

**Part 2:**

| | **Use(s)** |
|---|---|
| **Uses as intermediate** | Not listed |
| **Formulation** | Formulation of MOTE in dry-blend formulations<br>Production of dry-blend of MOTE |
| **Uses at industrial sites** | Processing of polymers containing MOTE as a stabiliser through calendering, extrusion, injection and low energy manipulation of plastic articles |
| **Uses by professional workers** | Not listed |
| **Consumer Uses** | Not listed |
| **Article service life** | Service Life of MOTE contained in articles |

# 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)

## 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<br>☐ C ☐ M ☐ R | Suspected CMR[1]<br>☐ 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

MOTE is initially considered as a potential endocrine disruptor. However, the ED concern is not supported by the (eco)toxicological information supplied in the CSR, nor can it be put aside. The details are as follows.

*Toxicological studies*
Three valid studies were available. One was 90d rat dietary repeated dose study. The doses used were nominal concentrations of 0, 200, 500 and 1250 mg/kg diet, corresponding to 0, 13, 32, and 82 mg/kg bw/day for males and 0, 14, 37 and 91 mg/kg bw/day for females. No adverse effects have been observed. Under the conditions of this study the no-observed-adverse-effect level (NOAEL) was placed at the highest level tested, namely 1250 mg/kg diet (≥82 and 91 mg/kg body weight/day for males and females, respectively).
The second study was a test according to OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test). It is concluded that under the condition of this reproduction and developmental toxicity screening study in rats, the oral administration of octyltin tris (2-ethylhexylmercaptoacetate) (MOT(EHMA)) at 200, 500 and 1250 mg/kg diet was well tolerated at all dose-levels. The no adverse effect level (NOAEL) for parental toxicity and fertility toxicity is 1250 mg/kg diet [approx. 72 and 96 mg octyltin tris (2-ethylhexylmercaptoacetate/kg/day) (MOT(EHMA))/kg body weight/day for male and female animals, respectively].
The third study was based TG414 developmental toxicity test in rats exposed to doses of 0 (control), 500 mg/kg diet (low-dose), 1250 mg/kg diet (mid-dose), and 3000 mg/kg diet (high-dose). No adverse effect on thymus weight was observed at the low dose level. The mean absolute and relative thymus weights were decreased (>10 %) in the mid and high dose group. Immunotoxic compounds containing octyltin are known to affect thymus weight in pregnant/lactating females. Therefore, although the decrease in thymus weight in the mid and high dose group did not reach statistical significance, it was considered to be an adverse and test material-related effect. The NOAEL for maternal toxicity was 500 mg/kg diet (corresponding to a daily mean test material intake of 36 mg/kg body weight). In the absence of developmental effects the NOAEL for prenatal developmental toxicity in the rat was 3000 mg/kg in diet (corresponding to a daily mean test material intake of 208 mg/kg body weight).

*Ecotoxicological studies*

Only one valid chronic Daphnia 21d toxicity test was available, with NOEC of 0.036 mg/L for reproduction and growth. No long term fish toxicity data were available.

*The available information did not substantiate, nor could dispute that the substance has endocrine disrupting properties. The data suggest that the substance may induce immunotoxicity indicated by a decrease in thymus weights. A decrease in thymus weight may hint at an endocrine mediated effect. Concern on immunotoxicity is raised and should be further addressed.*

## 5.4 Preliminary indication of information that may need to be requested t 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) |

*The available information points towards potential immune effects of the substance. Further information to eluicidate these effects and the potential mechanism behind these effects should be clarified. Since related substances act via an ED mode of action this concern will be included in the research.*

## 5.5 Potential follow-up and link to risk management

| | | | |
|---|---|---|---|
| ☒ Harmonised C&L | ☐ Restriction | ☒ Authorisation | ☐ Other (provide further details) |
| *The substance is self-classified based on the impurities into Repr 1B, Skin Sens. 1A Harmonised CLP and authorization may be the possible risk management options.* | | | |