Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-methyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate.
Chemical Group:	
EC Number:	260-828-5
CAS Number:	57583-34-3
Submitted by:	NL-CA
Published:	20/03/2013

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

Contents

1 IDENTITY OF THE SUBSTANCE

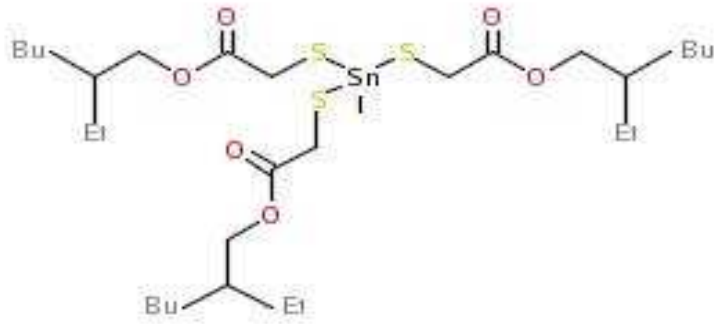
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-methyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate.
EC number:	260-828-5
EC name:	2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-methyl-7-oxo-8-oxa-3 ,5-dithia-4-stannatetradecanoate.
CAS number (in the EC inventory):	57583-34-3
CAS number:	57583-34-3
CAS name:	Not available
IUPAC name:	2-ethylhexyl 10-ethyl-4-({2-[(2-ethylhexyl)oxy]-2-oxoethyl}sulfanyl)-4-methyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecan-1-oate
Index number in Annex VI of the CLP Regulation	Not available
Molecular formula:	$C_{31}H_{60}O_6S_3Sn$
Molecular weight or molecular weight range:	743.7
Synonyms:	

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

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

None

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

Notified proposal from France 19 June 2009:

DSD: Muta. Cat. 3; R68, Repr. Cat. 3; R63, Xn; R21, Xn; R22

RAC-Opinion, adopted 14 September 2011:

CLP: Repr. 2; H361d

DSD: Repr. Cat 3; R63

2.3 Self classification

In the registrations:

CLP:

Acute Tox. 4; H302: Harmful if swallowed.
Acute Tox. 3; H311: Toxic in contact with skin.
Skin Sens. 1; H317: May cause an allergic skin reaction.
Repr. 2; H361: Suspected of damaging fertility or the unborn child
Muta. 2; H341: Suspected of causing genetic defects
STOT Single Exp. 3; H335: May cause respiratory irritation.
STOT Rep. Exp. 2; H373: May cause damage to organs cause the hazard>.
Aquatic Chronic 3; H412: Harmful to aquatic life with long lasting effects.

DSD:

Xn; R21/22 Harmful; Harmful in contact with skin and if swallowed.
R43 May cause sensitisation by skin contact.
Repr. Cat. 3; R63 Possible risk of harm to the unborn child.
Muta. Cat. 3; R68 Possible risk of irreversible effects.
R53 May cause long-term adverse effects in the aquatic environment.

Other notifications to the Classification and Labelling Inventory:

Acute Tox. 4; H312: Harmful in contact with skin.

Acute Tox. 4; H332: Harmful if inhaled.

Aquatic Chronic 4: May cause long lasting harmful effects to aquatic life.

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

☒ Article 44(1) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

3.2 Grounds for concern

☒ (Suspected) CMR	☐ Wide dispersive use	☐ Cumulative exposure
☐ (Suspected) Sensitiser	☐ Consumer use	☐ High RCR
☐ (Suspected) PBT	☐ Exposure of sensitive populations	☒ Aggregated tonnage
☐ Suspected endocrine disruptor	☐ Other (provide further details below)	

This substance has a self-classification with R63 and R68 indicating a concern for developmental toxicity and mutagenicity. The self-classification is based on a limited dataset. Additional data on mutagenicity and reproductive toxicity may show that a more severe classification is required for one or both hazard classes.

The risk assessment is based on a DNEL from the available studies. This may mean that the mutagenicity, which is potentially without a threshold, is not covered by the DNEL. A risk can therefore not be excluded.

3.3 Information on aggregated tonnage and uses

☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☒ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	
☐ 100,000 – 1000,000 tpa	☐ > 1000,000 tpa	
☐ Confidential		
Exact Tonnage:		

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

3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

☐ Compliance check	☐ 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
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	
No data	

3.5 Information to be requested to clarify the suspected risk

☒ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☐ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☐ Other (provide further details below)	
Further information concerning the mutagenicity in germ cells could be requested and further information concerning developmental toxicity. No repro studies are available with the substance itself and only a developmental neurotoxicity study and a screening study with a metabolite which is used by the registrant for read-across.	

3.6 Potential follow-up and link to risk management

☐ Restriction	☐ Harmonised C&L	☒ Authorisation	☒ Other (provide further details)
Classification with R63 and R68 was proposed by France. However, it is likely that a more stringent classification is only possible with additional data. Depending on the results of the additional studies an update of the harmonised classification and the authorization route could be considered. As this substance is a tetra-substituted organostannic compound it is not covered by restriction number 20 part 4, 5 or 6 but only by the limited restrictions in part 1, 2 and 3.			