

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	iso(C10-C14)alkyl (3,5-di-tert-butyl-4-hydroxyphenyl)methylthioacetate
Chemical Group:	
EC Number:	404-800-4
CAS Number:	118832-72-7
Submitted by:	Germany
Published:	26/03/2014

Note

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

Contents

1	IDENTITY OF THE SUBSTANCE.....	3
1.1	Other identifiers of the substance	3
2	CLASSIFICATION AND LABELLING.....	4
2.1	Harmonised Classification in Annex VI of the CLP	4
2.2	Self classification	4
2.3	Proposal for Harmonised Classification in Annex VI of the CLP	4
3	INFORMATION ON AGGREGATED TONNAGE AND USES.....	4
4	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE	5
4.1	Legal basis for the proposal	5
4.2	Selection criteria met (why the substance qualifies for being in CoRAP)	5
4.3	Initial grounds for concern to be clarified under Substance Evaluation	5
4.4	Other completed/ongoing regulatory processes that may affect suitability for substance evaluation	6
4.5	Preliminary indication of information that may need to be requested to clarify the concern	6
4.6	Potential follow-up and link to risk management	6

1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

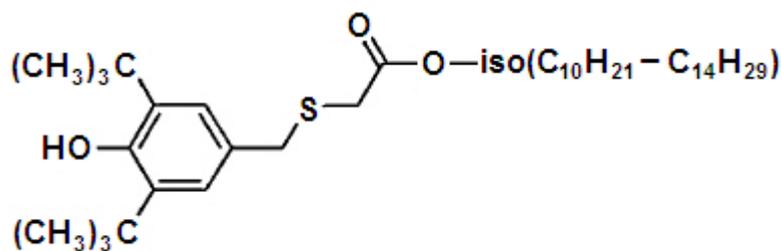
Table 1: Substance identity

EC name:	iso(C10-C14)alkyl (3,5-di-tert-butyl-4-hydroxyphenyl)methylthioacetate
IUPAC name:	iso(C10-C14)alkyl (3,5-di-tert-butyl-4-hydroxyphenyl)methylthioacetate
Index number in Annex VI of the CLP Regulation	607-261-00-5
Molecular formula:	Not available
Molecular weight or molecular weight range:	492.81 g/mol
Synonyms/Trade names:	IRGANOX L 118

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:

one possible structure, as it is "iso(C10-C14)alkyl" the alkyl chain at this position may be C10-C14



1.2 Similar substances/grouping possibilities

--

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Classification		Labelling		Specific Concentration limits, M-Factors
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	
Aquatic Acute 1	H400			
Aquatic Chronic 1	H410	H410		

Signal Words:
Warning

Pictograms:
GHS09

2.2 Self classification

- In the registration

The registrants' classification follows the harmonized classification in Annex VI of the CLP, with the exception that the full registration includes:

M(Chronic)=100.

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

There are no additional hazard classes identified and no other notifiers than the one registrant has given specific M-factor.

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 checked="" 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 type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input checked="" type="checkbox"/> Confidential	
One registration as NONS for which the tonnag is confidential.			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
Uses can be found at the ECHA dissemination portal. Examples are uses as laboratory reagent, Hydraulic fluids, Lubricants, greases, release products and Metal working fluids.			

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

4.2 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

4.3 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 type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input 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>The substance is definitely NOT Ready biodegradable and the assessment of the persistence is obligatory.</p> <p>The substance has a high log Kow value and the assessment of the bioaccumulation is obligatory. This substance has an extreme low water solubility and a extreme high log Kow and consequently the BCF may scientifically not give the correct value to assess the bioaccumulation.</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

4.4 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)	

4.5 Preliminary indication of information that may need to be requested to clarify the concern

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
<p>The registration dossier is missing the assessment of the persistence in the environment and the assessment of the bioconcentration may scientifically not be correct and the registration dossier is missing the PBT-/vPvB-assessment completely.</p>	

4.6 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)