

## Justification for the selection of a substance for CoRAP inclusion

<b>Substance Name (Public Name):</b>	1-(2-hydroxy-5-nonyl(branched)-phenyl)ethanone oxime
<b>Chemical Group:</b>	
<b>EC Number:</b>	627-083-1
<b>CAS Number:</b>	244235-47-0
<b>Submitted by:</b>	ES CA for Environment (Ministry of Agriculture, Food and Environment)
<b>Published:</b>	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
1.2.1.	Identity of structurally related substances	4
2	CLASSIFICATION AND LABELLING.....	5
2.1	Harmonised Classification in Annex VI of the CLP	5
2.2	Self classification	5
2.3	Proposal for Harmonised Classification in Annex VI of the CLP	5
3	INFORMATION ON AGGREGATED TONNAGE AND USES .....	5
4	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE .....	6
4.1	Legal basis for the proposal	6
4.2	Selection criteria met (why the substance qualifies for being in CoRAP)	6
4.3	Initial grounds for concern to be clarified under Substance Evaluation	6
4.4	Other completed/ongoing regulatory processes that may affect suitability for substance evaluation	7
4.5	Preliminary indication of information that may need to be requested to clarify the concern	7
4.6	Potential follow-up and link to risk management	7

## 1 IDENTITY OF THE SUBSTANCE

### 1.1 Other identifiers of the substance

Table 1: Substance identity

<b>EC name:</b>	-
<b>IUPAC name:</b>	1-(2-Hydroxy-5-nonyl(branched)-phenyl)ethanone oxime
<b>Index number in Annex VI of the CLP Regulation</b>	-
<b>Molecular formula:</b>	C <sub>17</sub> H <sub>27</sub> NO <sub>2</sub>
<b>Molecular weight or molecular weight range:</b>	277.407
<b>Synonyms/Trade names:</b>	Ethanone, 1-(2-hydroxy-5-nonylphenyl)-, oxime, branched

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

**Structural formula:** -

### 1.2 Similar substances/grouping possibilities

2-Hydroxy-5-nonylacetophenonoxim (CAS 59344-62-6) has been provided as a read-across to the registered substance with regard to the short-term toxicity to fish.

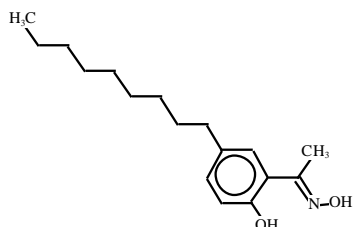
No information on the test material (C-SAT 090071) has been provided regarding the long-term toxicity test to aquatic invertebrates (*Daphnia magna*), alga growth inhibition test and microorganisms.

### 1.2.1. Identity of structurally related substances

**Table 2: Structurally related substance(s) identity**

<b>EC number:</b>	-
<b>EC name:</b>	-
<b>CAS number:</b>	59344-62-6
<b>CAS name:</b>	-
<b>IUPAC name:</b>	2'-HYDROXY-5'-NONYLACETOPHENONE OXIME
<b>Index number in Annex VI of the CLP Regulation:</b>	-
<b>Molecular formula:</b>	C17 H27 N1 O2
<b>Molecular weight or molecular weight range:</b>	277.41
<b>Synonyms:</b>	

**Structural formula:**



## 2 CLASSIFICATION AND LABELLING

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

Not listed.

### 2.2 Self classification

- In the registration

Skin Irritant Cat. 2,  
Skin sensitizer Cat. 1,  
Reproductive toxicant Cat. 2

H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H361 Suspected of damaging fertility or the unborn child.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.

Aquatic Acute 1  
Aquatic Chronic 1

(Specific concentration limits, M-factors: M(Chronic)=1; M=1)

Pictograms, signal word code : GHS08, GHS09, Wng.

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

There are no differences in the classification, just on the labelling:

Aggregated notifications: Pictograms, signal word code : GHS07, GHS09, GHS08, Wng.

### 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 checked="" 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 type="checkbox"/> Confidential	
<input checked="" type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
Industrial use: This substance is exclusively used in mining industries (without off-shore industries). There is no professional or consumer exposure.			

## 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 disruptor
- 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 <sup>1</sup> <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 <sup>1</sup>	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB <sup>1</sup>	<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 checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

<sup>1</sup> 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

It is a low solubility substance (<0.1). According to the information provided, the substance fulfills the criteria T (toxic for reproduction) and P (not vP). Measured Log Kow is 4.8. Concerns on B (read-across measured B: c.a. 138) This issue will be assessed.

Environmental fresh and marine exposure is also indicated. STP effluents are released directly to the marine compartment while fresh water emissions are released only during the wet season. Due to the high aggregated tonnage potential risks on relevant environmental compartments will be accounted.

#### 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 checked="" 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)
Some clarifications are needed, especially on the chronic aquatic environment information on exposure.	

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

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
Follow-up regulatory actions will be set depending on the outcome of the evaluation. That is, further information is needed on the preparation of Annex XV dossier either for the authorization or restriction.			