

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

<b>Substance Name (Public Name):</b>	Octene, hydroformylation products, low-boiling
<b>Chemical Group:</b>	-
<b>EC Number:</b>	273-110-1
<b>CAS Number:</b>	68938-03-4
<b>Submitted by:</b>	Slovene CA
<b>Date:</b>	17/03/2015

### **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 1: Substance identity**

<b>EC name:</b>	Octene, hydroformylation products, low-boiling
<b>IUPAC name:</b>	Octene, hydroformylation products, low-boiling
<b>Index number in Annex VI of the CLP Regulation</b>	-
<b>Molecular formula:</b>	Unspecified <i>The complex combination of hydrocarbons produced by the distillation of products from the hydrogenation of isononanal. It consists predominantly of C6 olefins and paraffins and C9 alcohols and aldehydes and boiling in the range of approximately 110°C to 202°C (230°F to 396°F).</i>
<b>Molecular weight or molecular weight range:</b>	n.a.
<b>Synonyms/Trade names:</b>	Oxoöl LS9

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

**Structural formula:** n.a.

### 1.2 Similar substances/grouping possibilities

**Structural formula:** -

## 2 CLASSIFICATION AND LABELLING

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

The substance is not listed in Annex VI, CLP.

### 2.2 Self classification

- In the registration:

• 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)	
Flam. Liq. 2	H225	H225	EUH066	
Asp. Tox. 1	H304	H304		
Skin Sens. 1	H317	H317		
Aquatic Chronic 3	H412	H412		

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

Only the self classification above is notified.

### 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 type="checkbox"/> 1000 – 10,000 tpa	<input checked="" 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 checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
Only used in the market sector Fuel, wide dispersive outdoor use due to ERC 8e (Refueling of cars etc by consumers, Refueling by professional workers, maintenance of combustion engines by professional workers) and 9b (Wide dispersive outdoor use of substances in closed systems, Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities.			

#### 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 checked="" 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)	
TP on Genetic toxicity in vivo.	

#### 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

<b>Hazard based concerns</b>		
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)
<b>Exposure/risk based concerns</b>		
<input type="checkbox"/> Wide dispersive use	<input checked="" 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)
<p><b>Hazard based concerns: PBT/vPvB</b></p> <p>Summary of P assessment:</p> <ul style="list-style-type: none"> <li>• Not expected to undergo hydrolysis</li> <li>• Not readily Biodegradable: 6% after 28 d (CO<sub>2</sub> evolution) (t<sub>1/2</sub> = 315 days)</li> <li>• Considered to be non biodegradable</li> <li>• There are no data available on water or sediment or soil simulation tests</li> </ul> <p>CONCLUSION</p> <p>Definitive criteria for P/vP appear to be met. Screening criteria for P are met, but no data is available to conclude on definitive criteria.</p> <p>Summary of B assessment:</p> <ul style="list-style-type: none"> <li>• log Kow 5.4 -6.2</li> <li>• Only calculations by Episuite were run to determine the BCF-value</li> <li>• The highest calculated BCF-value is for n-Octane: 1220 L/kg</li> <li>• No measured BCF-value is available</li> <li>• A value of around 4.5 or greater is generally accepted as indicating a high potential for bioaccumulation</li> </ul> <p>CONCLUSION</p> <p>Screening criteria for B (e.g. log Kow &gt;4.5) are met, but no data is available to conclude on definitive criteria.</p>		

<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

Summary of T assessment:

- LC50 for freshwater fish: 100 mg/L
- EC50/LC50 for freshwater invertebrates: 12 mg/L
- EC50/LC50 for freshwater algae: 120 mg/L
- No data are available for long-term toxicity to aquatic invertebrates.
- No test data are available for sediment toxicity
- PNEC aqua (marine water): 0.0012 mg/L

CONCLUSION

Neither definitive nor screening criteria for T appear to be met

But: The measured adsorption coefficient of Oxooil LS9 (Log K<sub>oc</sub> 3.2) indicates that there would be a high potential for distribution to sediment. Toxicity to sediment organisms should be tested.

### 5.4 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)
Further tests to investigate the biodegradation and bioaccumulation.	

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

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input checked="" type="checkbox"/> Other (provide further details)
Depending on outcome of the Substance evaluation process (possible: Identification as SVHC).			