

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

<b>Substance Name (Public Name):</b>	Fatty acids C18 unsat, reaction products with pentaethylenhexamine
<b>Chemical Group:</b>	
<b>EC Number:</b>	629-732-4
<b>CAS Number:</b>	1224966-13-5
<b>Submitted by:</b>	Lithuania
<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	Similar substances/grouping possibilities	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

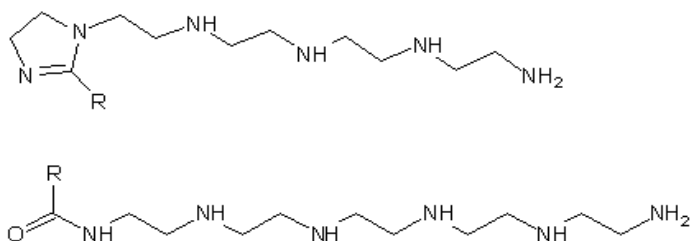
### 1.1 Other identifiers of the substance

**Table 1: Substance identity**

<b>EC name:</b>	-
<b>IUPAC name:</b>	UVCB substance not applicable
<b>Index number in Annex VI of the CLP Regulation</b>	-
<b>Molecular formula:</b>	UVCB substance
<b>Molecular weight or molecular weight range:</b>	>392; ca. 897
<b>Synonyms/Trade names:</b>	-

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

**Structural formula:**



R is fatty alkyl with chain lengths C 18 unsaturated chainlengths

### 1.2 Similar substances/grouping possibilities

None identified.

## 2 CLASSIFICATION AND LABELLING

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

None

### 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)	Pictograms, Signal Word Code(s)	
Skin Corr. 1C	H314	H314		GHS07	M=10 M(Chronic)=1
Skin Sens. 1A	H317	H317		GHS09	
Aquatic Acute 1	H400			GHS05	
Aquatic Chronic 1	H410	H410		Dgr	

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

None

### 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 checked="" 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 checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Closed System
The substance used in closed batch process (synthesis and formulation) and oilfield applications. The substance is used e.g. in adhesives and sealants and as anticorrosive agent.			

## 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 checked="" type="checkbox"/> Sensitiser	Suspected Sensitiser <sup>1</sup>	
<input type="checkbox"/> PBT/vPvB	<input 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 checked="" type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input checked="" 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>There is not enough information about the exposure on workers. Do not dismiss the potential effect of inhalation through respiratory tract. There is a lack of information on exposure on sensitive populations as well. More information about sensitization is needed.</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

#### 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 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)	
<p>Following endpoints addressed:          Reproductive toxicity (pre-natal developmental toxicity)          Sub-chronic toxicity (90-day): oral</p>	

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

<input checked="" type="checkbox"/> Information on toxicological properties	<input checked="" type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input checked="" type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
<p>Information on sensitizing properties (skin/inhalation), SID, exposure and uses.</p>	

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

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>Since the substance has no harmonized classification it is advisable to prepare a dossier on the classification and labeling.</p>			