

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

**Substance Name (Public Name):** bis(2-ethylhexyl) amine  
**Chemical Group:**  
**EC Number:** 203-372-4  
**CAS Number:** 106-20-7  
**Submitted by:** Portuguese Environment Agency, PT  
**Date:** 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

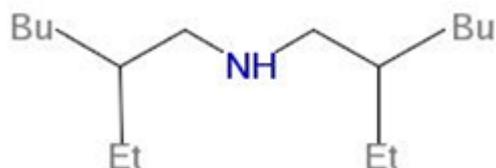
### 1.1 Other identifiers of the substance

Table 1: Substance identity

<b>EC name:</b>	bis(2-ethylhexyl)amine
<b>IUPAC name:</b>	2-ethyl-N-(2-ethylhexyl)hexan-1-amine
<b>Index number in Annex VI of the CLP Regulation</b>	
<b>Molecular formula:</b>	C <sub>16</sub> H <sub>35</sub> N
<b>Molecular weight or molecular weight range:</b>	241.4558 g/mol
<b>Synonyms/Trade names:</b>	

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

**Structural formula:**



### 1.2 Similar substances/grouping possibilities

-

## 2 CLASSIFICATION AND LABELLING

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

Substance is not listed in Annex VI CLP.

### 2.2 Self-classification

- In the registration:
  - Acute Tox. 4 H302: Harmful if swallowed.
  - Acute Tox. 3 H311: Toxic in contact with skin.
  - Acute Tox. 3 H331: Toxic if inhaled.
  - Skin Corr. 1B H314: Causes severe skin burns and eye damage.
  - Eye Damage 1 H318: Causes serious eye damage.
  - STOT Single Exp. 3 H335: May cause respiratory irritation.
  - Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects.
  - M-Factor chronic: 1
- The following hazard classes are in addition notified among the aggregated self-classifications in the C&L Inventory:
 

Acute Tox. 3	H301: Toxic if swallowed.
Acute Tox. 4	H312: Harmful in contact with skin.
Skin Corr. 1C	H314: Causes severe skin burns and eye damage.
Skin Corr. 1A	H314: Causes severe skin burns and eye damage.
Acute Tox. 2	H330: Fatal if inhaled.
Aquatic Chronic 2	H411: Toxic to aquatic life with long lasting effects.

### 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 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 checked="" type="checkbox"/> 100+ tpa		<input type="checkbox"/> Confidential	
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System

The substance is used in preparations that serve as lubricants, greases and release products, as hydraulic fluids, metal working fluids and as intermediate. At industrial sites it is used as intermediate and as processing aid and as extracting agent in functional fluids. The substance is used by professional workers in functional fluids and in laboratories. Uses by professional workers include uses in open systems and outdoor uses.

#### 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)	

#### 5 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

##### 5.1 Legal basis for the proposal

- Article 44(2) a) and c) (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 checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input checked="" type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input checked="" type="checkbox"/> Cumulative exposure
<input checked="" type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p>The substance is fulfilling the screening criteria for persistence and bioaccumulation as defined in Annex XIII.</p> <p><b>P/vP criterion</b> The substance is not readily biodegradable. The available data do not allow assessing degradation in environmental compartments. Therefore, the substance is considered to be potentially persistent.</p> <p><b>B/vB criterion</b> There are no test data on bioaccumulation and the calculations used to assess bioaccumulation are not applicable for surface active substances. Therefore bis(2-ethylhexyl) amine is considered to be potentially bioaccumulative.</p> <p><b>T criterion</b> The registrants classified the substance as Aquatic Chronic 1 (H410). Short-term studies on aquatic ecotoxicology are available for fish. Based on the available data, a definitive conclusion on toxicity cannot be drawn.</p> <p><b>Exposure</b> The lead registrant provides site-specific highly refined exposure scenarios which will not fit for the joint registration. Some Risk Characterization Ratios are relatively high. If the possibility of aggregated exposure and the missing justification are considered, the concern arises, that risks are not adequately controlled.</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

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

<input type="checkbox"/> Information on toxicological properties	<input checked="" type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input checked="" 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)
There is a need to further clarify degradation, bioaccumulation and ecotoxicity of this substance.	

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

<input type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
If the substance is identified as a PBT/vPvB substance or if risks are not adequately controlled, an analysis of risk management options shall be performed, taking into account information on use and exposure.			