Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	bis(2-ethylhexyl) amine
EC Number:	203-372-4
CAS Number:	106-20-7
Authority:	Portuguese Environment Agency, PT
Date:	17/03/2015 21/03/2017 (withdrawn) 19/03/2019 (update)

Cover 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

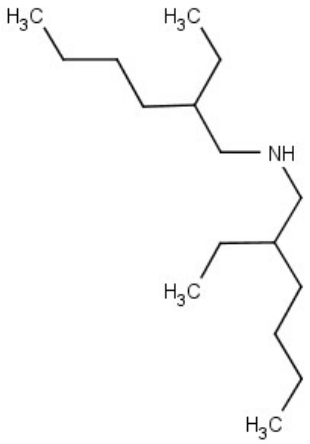
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Bis(2-ethylhexyl)amine
IUPAC name (public):	2-ethyl-N-(2-ethylhexyl)hexan-1-amine
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	$C_{16}H_{35}N$
Molecular weight or molecular weight range:	241.4558 g/mol
Synonyms:	

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

Structural formula:



Other relevant information about substance composition

1.2 Similar substances/grouping possibilities

Has read-across been used by the registrant for the concern related endpoints? ☐ Yes ☒ No

Is the substance a member of a category? ☐ Yes ☒ No

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA		☐ Risk Management Option Analysis (RMOA)
REACH Processes	Evaluation	☒ Compliance check, Final decision
		☐ Testing proposal, Final decison
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII[1]
Harmonised C&L		☐ Annex VI (CLP) (see section 3.1)
Processes under other EU legislation		☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009
		☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments
Previous legislation		☐ Dangerous substances Directive Directive 67/548/EEC (NONS)
		☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)
(UNEP) Stockholm convention (POPs Protocol)		☐ Assessment
		☐ In relevant Annex

[1] Please specify the relevant entry.

Other processes / EU legislation	☐ Other (provide further details below)

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Substance is not listed in Annex VI CLP.

3.1.2 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. 2 H330: Fatal if inhaled.
  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.
  Aquatic Chronic 2 H411: Toxic to aquatic life with long lasting effects.

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[2]

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site *		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☒ 1+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential
Joint submission		

*the total tonnage band has been calculated by excluding the intermediate uses, for details see the Manual for Dissemination and Confidentiality under REACH Regulation (section 2.6.11): https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0

4.2 Overview of uses

Table: Uses

Part 1:

☒ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☐ Consumer use	☐ Article service life	☐ Closed system

Part 2:

	Use(s)
Uses as intermediate	Uses at industrial sites.
Formulation	Industrial formulation of lubricant additives.

[2] *Dissemination site was accessed on 1st June 2018.*

Uses at industrial sites	Use as intermediate not under strictly controlled conditions.
Uses by professional workers	Use in functional fluids (closed and open systems) including outdoor uses.
Consumer Uses	
Article service life	

Part 3: There is high potential for exposure of

☐ Humans	☒ Environment

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

Hazard based concerns		
CMR ☐ C ☐ M ☐ R	Suspected CMR[1] ☐ C ☐ M ☐ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[3]	
☐ PBT/vPvB	☒ Suspected PBT/vPvB[1]	☐ Other (please specify below)
Exposure/risk based concerns		
☐ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
☒ Exposure of environment	☐ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☐ High (aggregated) tonnage	☐ Other (please specify below)

[3] 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)

The substance is fulfilling the screening criteria for persistence and bioaccumulation as defined in Annex XIII of REACH Regulation.

P/vP criterion

The available experimental results are conflicting, and the available data do not allow assessing degradation in environmental compartments. Therefore, the substance is considered to be potentially persistent.

B/vB criterion

There are no test data on bioaccumulation and the estimation models used to assess bioaccumulation are not adequate for the substance, with the exception of the model BCFBAF v3.01 (EPI Suite v4.11) with an estimated BCF of 2402 L/kg. Therefore bis(2-ethylhexyl) amine is considered to be potentially bioaccumulative.

T criterion

The registrants classified the substance as Aquatic Chronic 1 (H410). Long-term data on aquatic ecotoxicology are available for invertebrates and algae (NOEC >0.01 mg/L). Based on the available data, a definitive conclusion on toxicity cannot be drawn.

Therefore, it is considered necessary to assess this substance in order to conclude if further information is required and if the substance constitutes a risk to the environment.

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

☐ Information on toxicological properties	☐ Information on physico-chemical properties
☒ Information on fate and behaviour	☐ Information on exposure
☒ Information on ecotoxicological properties	☐ Information on uses
☐ Information on ED potential	☐ Other (provide further details below)
There is a need to further clarify degradation, bioaccumulation and ecotoxicity of this substance.	

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

5.5 Potential follow-up and link to risk management

☐ Harmonised C&L	☒ Restriction	☒ Authorisation	☐ 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.