Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	Fatty acids, tall-oil, reaction products with 2-[(2-aminoethyl)amino]ethanol
EC Number:	272-902-4
CAS Number:	68919-76-6
Authority:	Germany
Date:	21/03/2017

Cover Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

Table of Contents

1 IDENTITY OF THE SUBSTANCE

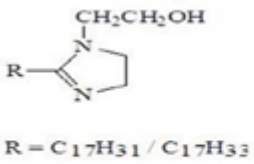
1.1 Other identifiers of the substance

Table: Other Substance identifiers

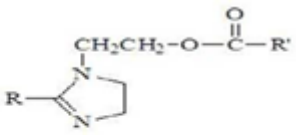
EC name (public):	Fatty acids, tall-oil, reaction products with 2-[(2-aminoethyl)amino]ethanol
IUPAC name (public):	Condensation products of tall-oil fatty acids with 2-[(2-aminoethyl)amino]ethanol
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	Not applicable, UVCB substance containing numerous chemical species
Molecular weight or molecular weight range:	Not applicable
Synonyms:	

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

Structural formula:



R = $C_{17}H_{31}$ / $C_{17}H_{33}$



R = $C_{17}H_{31}$ / $C_{17}H_{33}$

R' = $C_{17}H_{31}$ / $C_{17}H_{33}$

Constituents:
-Mono-condensation products of tall-oil fatty acids with 2-[(2-aminoethyl)amino]ethanol
-Di-condensation products of tall-oil fatty acids with 2-[(2-aminoethyl)amino]ethanol
-Higher condensation products of tall-oil fatty acids with 2-[(2-aminoethyl)amino]ethanol

1.2 Similar substances/grouping possibilities

Not applicable.

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
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restric -tion	☐ Annex XVII
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	
Other processes / EU legislation	☐ Other (provide further details below)	
Further details	A TPE for long-term toxicity to aquatic invertebrates is available.	

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

There is no entry for harmonised classification for this substance in Annex VI.

3.1.2 Self classification

- In the registration:

  Skin Irrit. 2

  Eye Damage 1

  Eye Irrit. 2

  Aquatic Acute 1

  Aquatic Chronic 1

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

  Skin Corr. 1B

  Skin Corr. 1C

  Skin Sens. 1

  Aquatic Chronic 2

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Currently, no proposal for harmonised classification and labelling is available for this substance.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[1]

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

4.2 Overview of uses

The substance is used in the formulation of coatings and inks. The wide dispersive use of these coatings and inks results in inclusion into or onto a matrix. However, the substance is not covalently bound to the matrix and thus, exposure of the environment during processes like spraying or open outdoor cleaning is likely.
In the section on article service life, a low release is assumed. However, since the substance appears to be not covalently bound to the matrix a continuous release to man and environment during the article service life is reasonable. Especially the wide dispersive outdoor use combined with the potential persistence of the substance raises exposure concern for environmental compartments.

Table: Uses

Part 1:

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

[1] *The dissemination site was accessed: 20.09.2016*

Part 2:

	Use(s)
Uses as intermediate	yes
Formulation	ERC 2: Formulation of preparations (coatings and inks)
Uses at industrial sites	ERC 5: industrial use resulting in inclusion into or onto matrix (application of coatings and inks)
Uses by professional workers	ERC 8c, 8f: Wide dispersive indoor/outdoor use resulting in inclusion into or onto matrix (professional application of coatings and inks)
Consumer Uses	ERC 8c, 8f: Wide dispersive indoor/outdoor use resulting in inclusion into or onto matrix (consumer application of coatings)
Article service life	Related to ERC 8c, 8f: ERC 11a, 10a: Wide dispersive indoor/outdoor use of long-life articles and materials with low release

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[3] ☐ C ☐ M ☐ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[2]	
☐ PBT/vPvB	☒ Suspected PBT/vPvB[3]	☐ 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)

[2] 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

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.

The log K_{ow} of the substance (7.5 and 14.8; calc.) is in the range of the screening criterion for bioaccumulation. A BCF of 1887 L/kg was calculated based on a lower log K_{ow} of 7.5; both calculations, log K_{ow} and BCF, do not appear to be in the domain of the models. No measured data on bioconcentration in fish are available. Therefore, the substance is considered to be potentially bioaccumulative (pot. B/vB).

Ecotoxicity assessment for fish is based on read-across with an LC_{50} of 0.3 mg/L (nominal). Evaluation of this result is difficult. For daphnids, a 21 d NOEC of 0.13 mg/L was determined in a recent study. A study on toxicity to aquatic algae is considered technically not feasible by the Registrant(s). A 72 h EC_{50} value of 0.03 mg/L is provided as read-across from a supporting substance.. While the read-across appears reasonable, the given value is an EC_{50} and not a NOEC; furthermore it is close to the trigger value of the T criterion.

The substance is used in the formulation of coatings and inks and it appears to be not covalently bound to the matrix. Due to the wide dispersive use of these coatings and inks, exposure of the environment is likely.

In the section on article service life, a low release is assumed. However, since the substance appears to be not covalently bound to the matrix a continuous release to man and environment during the article service life is reasonable. The wide dispersive outdoor use combined with the potential persistence of the substance raises exposure concern for environmental compartments.

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 ED potential	☐ Other (provide further details below)

Persistence of the substance should be confirmed with further tests on inherent biodegradability.
Lipophilicity and bioaccumulation potential are out of the domain of calculation models; therefore, experimental confirmation of the lipophilicity of individual constitutents of the UVCB and their bioaccumulation behaviour should be provided.
It is acknowledged that experimental testing of ecotoxicity is difficult with a substance of such low water solubility (practically below LOQ), but testing should be based on individual constitutents of the UVCB. A TPE for long-term toxicity to aquatic invertebrates is available.

5.5. Potential follow-up and link to risk management

☐ Harmonised C&L	☒ Restriction	☒ Authorisation	☐ Other (provide further details)
Following to a confirmation of environmental fate and behavior date (Testing Proposals are underway), as well as ecotoxicological information, it appears to be probable that this substance meets the PBT criteria. Such confirmation needs to distinguish between the individual (main) constitutents of the UVCB (i.e. the different condensation products). If the substance (Fatty acids, tall-oil, reaction products with 2-[(2-aminoethyl)amino] ethanol) is identified as a PBT/vPvB substance, an analysis of risk management options will be provided, taking into account information on use and exposure. A potential option is the inclusion in the Candidate List, with or without Authorisation or Restriction.			