Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	N-[2-(piperazin-1-yl)ethyl]C18-unsatured-alkylamide
EC Number:	629-767-5
CAS Number:	1228186-18-2
Authority:	Germany
Date:	21/03/2017

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):	N-[2-(piperazin-1-yl)ethyl]C18-unsatured-alkylamide
IUPAC name (public):	(9E)-N-(2-{4-[(9E)-octadec-9-enoyl]piperazin-1-yl}ethyl)octadec-9-enamide
Index number in Annex VI of the CLP Regulation:	N/A
Molecular formula:	N/A
Molecular weight or molecular weight range:	N/A
Synonyms:	N/A

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

Structural formula:

UVCB

1.2 Similar substances/grouping possibilities

None.

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		There is a TPE for this substance regarding the following endpoints: • sub-chronic toxicity (90 d); oral • Reproductive toxicity (pre-natal developmental toxicity) • Bioaccumulation aquatic / sediment A dossier evaluation decision regarding the following endpoints has been issued (decision no. TPE-D-0000002523-80-04/F): • Viscosity (OECD 114) • Repeated dose toxicity (OECD 408) • Developmental toxicity / teratogenicity (OECD 414)

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

There is no harmonised Classification for the substance in Annex VI.

3.1.2 Self classification

- In the registration:

  Acute Tox 4

  Skin Corr 1B

  Skin Sens 1A

  Aquatic Acute 1

  Aquatic Chronic 1

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

  N/A

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Currently, no proposal for harmonized classification and labeling is available for this substance.

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

4.1 Tonnage and registration status

Table: Tonnage and registration status

[1] *Please provide here the date when the dissemination site was accessed.*

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 professionally used in building and construction formulations.

Table: Uses

Part 1:

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

Part 2:

	Use(s)
Uses as intermediate	
Formulation	ERC 2: Formulation of preparations
Uses at industrial sites	
Uses by professional workers	ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix
Consumer Uses	
Article service life	

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 fulfilling the screening criteria for persistence and bioaccumulation as defined in Annex XIII, i.e.

P/vP criterion
The substance is not readily biodegradable. The available simulation study according to OECD 303 A is not relevant for the PBT assessment as the test does not simulate the biodegradation in the environment. Therefore, the substance is considered to be potentially persistent.

B/vB criterion
For the UVCB substance the following log K_{ow} values are available: 5.4, 6.1, 6.7. Consequently, the screening criterion for B/vB is fulfilled. No measured data on bioconcentration in fish are available. The substance is therefore considered to be potentially bioaccumulative.

The substance is a UVCB and the defined constituent approach should be used for the PBT assessment. Therefore all constituents are assessed individually on screening level and the most relevant constituents regarding PBT properties need to be identified. Most of the available experimental data are based on the whole UVCB and the assessment of the single components is missing.

In addition, an NOEC of 0.011 for algae is available, which is very close to the T trigger. This algae test was made with the whole UVCB substance and a T assessment of the single constituents is missing and necessary.

The substance has a relatively high tonnage (100-1000 t/a) and uses include wide dispersive outdoor use resulting in inclusion into or onto a matrix. The likelihood of environmental exposure needs to be assessed.

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)

P/vP criterion
Further evaluation and, if necessary, further testing is required to clarify whether the substance is persistent or very persistent.

B/vB criterion
Further information on bioaccumulation is required to clarify whether the substance is bioaccumulative or very bioaccumulative.

T criterion
Further evaluation and, if necessary, further testing is required to clarify whether the substance is 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, an analysis of risk management options will be carried out, taking into account information on use and exposure. Potential options are the inclusion in the Candidate List with or without Authorisation, but also Restriction.