Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Amides, C18-unsatd., N-[3-(dimethylamine)propyl]
Chemical Group:	
EC Number:	800-353-8
CAS Number:	1379524-06-7
Submitted by:	Germany
Date:	17/03/2015

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

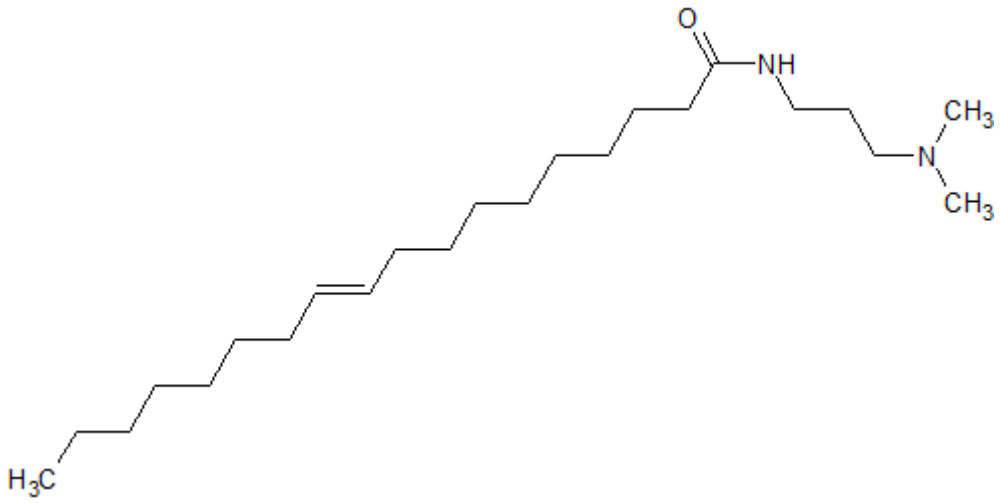
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	-
IUPAC name:	Amides, C18-unsatd., N-[3-(dimethylamine)propyl]
Index number in Annex VI of the CLP Regulation	
Molecular formula:	$C_{23}H_{46}N_2O$
Molecular weight or molecular weight range:	367 g/mol
Synonyms/Trade names:	

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

Structural formula:



1.2 Similar substances/grouping possibilities

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2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

The substance is not listed in Annex VI, CLP.

2.2 Self classification

- In the registration:

  Aquatic Chronic 1 H410

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

  Aquatic acute 1 H400

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA 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

☒ Industrial use	☒ Professional use	☐ Consumer use	☐ Closed System

The substance is used as an emulsifier for formulation of bitumen emulsions. The emulsions are in wide dispersive use for road building purposes. The two common types of the application are:

a) Asphalt emulsion mix which include uses as asphalt emulsion, slurry and asphalt emulsion, coldmix, and where the bitumen emulsion and stone aggregate are mixed in an asphalt plant and poured on the road surface
b) Asphalt emulsion distribution, where the bitumen emulsion is spread on the road surface after which the stone aggregate is spread into the emulsion.

4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

☐ Compliance check, Final decision	☐ Dangerous substances Directive 67/548/EEC
☐ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☐ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	

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[1]	
☐ 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)

PBT/vPvB Assessment

Based on the available data, it cannot be concluded whether the substance is fulfilling the screening criteria for PBT/vPvB as defined in Annex XIII.

Environmental Exposure

Uses need to be described in a level of detail that it is understandable for what purpose the substance is used, which processes are carried out with the substance and how these processes are operated that the release is limited to the release factor reported in the CSR. Derivations from the default release factors of the ERCs need to be reasonably justified.

Assumptions and explanations in the environmental exposure scenarios of the different registrants are partly insufficient or not comprehensible. This relates among other reasons to the following:
The description of the operational conditions is not always without any doubt in sense of containment of the processes and whether or not the life cycle steps occur indoor/outdoor.
The CSR do not contain a sound justification for the input parameters used for exposure assessment. For example this refers to the use of spERCs for exposure assessment without further information on operational conditions. In those cases it is not possible to verify the practicability of the spERC.

The registrants also did not provide a sufficient life cycle description. For example, there is no information regarding wastes from the different life cycle steps. Furthermore, information on emissions during service life of the paved roads is not clearly defined.

A retraceable environmental risk assessment is missing for several uses, as the registrants sometimes set the releases to the different compartments (and in result also the PECs) to "zero" with the argument that the releases are "negligible" but then fail to provide further justifications.
Some of the exposure scenarios in the CSRs provide (as a result of calculated PECs) a RCR close to 1 for single environmental compartments, whereas other registrants for the same use assume no risk for the environmental compartments because of "zero" emission.

[1] 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

☐ 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)

Further information on biodegradation may be required to clarify whether constituents of the substance are persistent or very persistent.
If the substance is persistent, further information on bioaccumulation might be required to clarify whether the substance is bioaccumulative or very bioaccumulative.
If the substance is persistent and bioaccumulative, further information on ecotoxicity is required to clarify whether the substance is toxic.

For the assessment of environmental exposure further information on operational conditions and emissions are required. More information is needed on the life cycle steps of the substance.

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.