Justification Document for the Selection of a CoRAP Substance

-Update-

Substance Name (public name):	Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides
EC Number:	931-292-6
CAS Number:	308062-28-4
Authority:	Ireland
Date:	21/03/2017 (UK) 20/03/2018 (1. Update) (UK) 19/03/2019 (2. Update) (IE)

Cover Note

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

1 IDENTITY OF THE SUBSTANCE

The following information is given on the ECHA dissemination website.

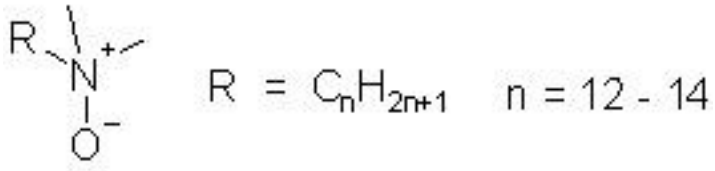
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides
IUPAC name (public):	Amines, C12-14 (even numbered) -alkyldimethyl, N-oxides
Index number in Annex VI of the CLP Regulation:	N/A
Molecular formula:	$(C_nH_{2n+1})(CH_3)_2NO$ with n = 12 - 14
Molecular weight or molecular weight range:	229 ≤ x ≤ 257
Synonyms:	*ADAO_C12-14, Amines, C12-14-alkyldimethyl, N-oxides; Amines, C12-14-alkyldimethyl, N-oxides; AO-1214-LP, Amines oxide, Flavol AO, KAPANOX LO*

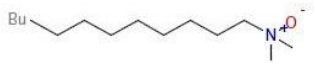
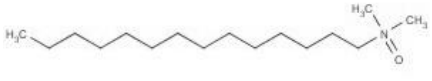
Type of substance ☐ Mono-constituent ☐ Multi-constituent ☒ UVCB

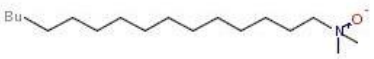
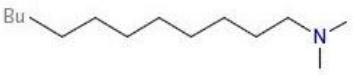
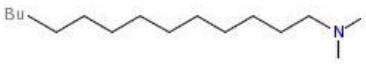
Structural formula:



Other relevant information about substance composition

A number of compositions are given for this UVCB substance which contain between 2 and 6 of the following constituents (all contain the C_{12} & C_{14} amine oxide constituents);

EC Number	Public name	Formula	Structure
216-700-6	Dodecyldimethylamine oxide	$C_{14}H_{31}NO$	
222-059-3	N,N-dimethyltetradecylamine N-oxide	$C_{16}H_{35}NO$	

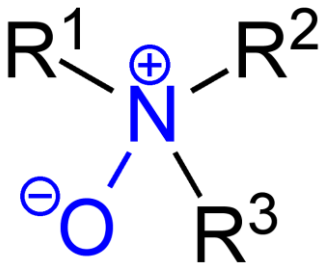
230-429-0	Hexadecyldimethylamine N-oxide	$C_{18}H_{39}NO$	
203-943-8	Dodecyldimethylamine	$C_{14}H_{31}N$	
204-002-4	Dimethyl(tetradecyl)amine	$C_{16}H_{35}N$	
231-765-0	Hydrogen peroxide	H_2O_2	*OH* ——— *OH*
279-420-3	Alcohols, C12-14	NA	*NA*

1.2 Similar substances/grouping possibilities

A number of alkyl amine oxide (AO) substances have been registered under REACH including four of the individual constituents listed above.

The category "amine oxides" has been assessed under the OECD HPV chemical programme.

Structural formula:



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 decision
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ 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)

A compliance check decision was issued to the registrants of amines, C12-14 (even numbered)-alkyldimethyl, N-oxides in July 2017 requesting an *in vitro* mutation study in bacteria (OECD 471), an *in vitro* cytogenicity study (OECD 473 or an *in vitro* micronucleus study (OECD 487), a PNDT study in rabbits (OECD 414) and an extended one-generation reproductive toxicity study without extension to the F2 generation, but including ophthalmological examination of P0 animals (OECD 443). The deadline for submission of the requested studies is the 27 January 2020.

The category *Amine Oxides* has been assessed under the OECD HPV programme. OECD SIDS can be found at: http://webnet.oecd.org/hpv/ui/SIDS_Details.aspx?id=b927b43d-8e91-4ada-80e3-720d634e01c0

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Not applicable – substance does not have a harmonised classification.

3.1.2 Self classification

- In the registration:

Acute Tox. 4 (oral), H302
Skin Irrit. 2, H315
Eye dam. 1, H318
Aquatic acute 1, H400
Aquatic Chronic 2, H411

No additional hazards are listed in the C&L inventory

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Not applicable.

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

*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

ECHA's publicly accessible website (accessed 16/11/2018) gives the following information:

This substance is used in the following products: washing & cleaning products, cosmetics and personal care products, laboratory chemicals, polishes and waxes, metal working fluids and water treatment chemicals.

This substance is used in the following areas: formulation of mixtures and/or re-packaging and agriculture, forestry and fishing. This substance is used for the manufacture of textile, leather or fur.

Release to the environment of this substance is likely to occur from the following industrial uses: formulation of mixtures, in processing aids at industrial sites and manufacturing of the substance. Other release to the environment of this substance is likely to occur from indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners).

[1] *ECHA dissemination site accessed 16/11/2018.*

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	Formulation of preparations (laboratory chemicals; metal working fluids; polishes and wax blends; washing and cleaning products (including solvent based products); water treatment chemicals; cosmetics/personal care products
Uses at industrial sites	Use in detergents
Uses by professional workers	Use in detergents
Consumer Uses	Use in detergents and cosmetic products
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[2]	
☐ 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)

[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

In a combined repeated dose toxicity study with reproductive/ developmental toxicity screening test, an increased incidence of post-implantation and post-natal loss was observed, along with reduced pup weights. In a pre-natal developmental toxicity study, reduced pup weights and increased incidences of foetuses and litters with alterations (linked to reduced ossification) were observed. The registrants have not classified the substance for developmental toxicity. Substance evaluation is required to assess the available data to determine whether classification for developmental toxicity is appropriate.

In the available sub-chronic oral repeated dose toxicity studies, effects in the eyes were noted (moderate to severe bilateral cataracts, lenticular opacities and lenticular lesions). The substance is not classified for repeated dose toxicity. Substance evaluation is required to investigate whether these effects pose a risk to human health. This would involve a detailed assessment of the available studies, and possibly a request for further data on the eye effects.

The substance has both worker and consumer uses. Therefore, there is a need to clarify the hazards and ensure that any risks are properly managed.

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)
Following evaluation of the existing data, additional data may be required to further investigate the eye effects (e.g., detailed histopathological investigations).	

5.5 Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
The substance has consumer uses and there is a high potential for exposure of humans. It is important therefore to ensure that the substance has the appropriate classification and labelling to ensure that the risks are properly managed.			