Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Quaternary ammonium compounds, di-C16-18-alkyldimethyl, chlorides
Chemical Group:	
EC Number:	295-835-2
CAS Number:	92129-33-4
Submitted by:	Italy
Published:	26/03/2014

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:	Quaternary ammonium compounds, di-C16-18-alkyldimethyl, chlorides
IUPAC name:	N-C16-C18(even numbered)-alkyl-N,N-dimethyl-C16-C18(even numbered)-alkyl-1-aminium chloride
Index number in Annex VI of the CLP Regulation	
Molecular formula:	R2N+(CH3)2, Cl- with R is fatty alkyl with chainlengths C16-C18 (even numbered)
Molecular weight or molecular weight range:	>494; <550
Synonyms/Trade names:	Quaternary ammonium compounds, bis(hydrogenated tallow alkyl)dimethyl, chlorides Quaternary ammonium compounds, di-C14-18-alkyldimethyl, chlorides

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

1.2 Similar substances/grouping possibilities

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Not included

2.2 Self classification

- In the registration:

Self classification for TECHNICAL GRADE of the substance:

Hazard Class and Category	Hazard Statement code(s)	Hazard Statement(s)
Flam. Liq. 3	H226	Flammable liquid and vapour.
Skin Corr. 1C	H314	Causes severe skin burns and eye damage.
Eye Dam. 1	H318	Causes serious eye damage.
Aquatic Acute 1	H400	Very toxic to aquatic life.
Aquatic Chronic 1	H410	Very toxic to aquatic life with long lasting effects.

Self classification for SOLVENT FREE version of the substance:

Hazard Class and Category	Hazard Statement code(s)	Hazard Statement(s)
Eye Dam. 1	H318	Causes serious eye damage.
Aquatic Chronic 1	H410	Very toxic to aquatic life with long lasting effects.

- In addition are the following hazard class notified to the C&L Inventory:

Skin Irrit. 2	H315	Causes skin irritation

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

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
Tonnage band is reported in ECHA dissemination site and in the registration dossier.		

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

In the registration dossier (update to 2011/07/05) only industrial uses (referred to ES1 and ES2 with ERC1 and ERC3 listed) are reported; no professional and consumer uses are reported.

In ECHA disse**m**ination site (last update March 2013) the following identified uses are listed:

Formulation of cosmetic products - PROC 15: Use as laboratory reagent

Industrial application of coatings - PROC 10: Roller application or brushing; PROC 13: Treatment of articles by dipping and pouring

Professional application of coatings - PROC 10: Roller application or brushing - ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix

Consumer use of cosmetic products - PC 39: Cosmetics, personal care products - ERC 8a: Wide dispersive indoor use of processing aids in open systems

Some identified uses lead to wide dispersive outdoor and indoor use.

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

☒ Article 44(2) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

4.2 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

4.3 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)

Concern about exposure/risk

QUATs fulfill criteria for high aggregated tonnage (tpa≥1000). According to ECHA dissemination site, some identified uses lead to wide dispersive outdoor and indoor use (e.g. Professional application of coatings and Consumer use of cosmetic products). In the registration dossier, some information on exposure is lacking. In view of the QUATs are not ready biodegradable and persistent in soil, a more in depth assessment of terrestrial compartment exposure may be needed. Therefore, the registrant may be requested to provide a refinement of exposure and risk assessment, also taking into account wide dispersive use scenarios and in consideration of the substance self classification as Aquatic Chronic 1 (H410).

Furthermore since the substance is self-classified for eye damage (H318) and skin corrosion (H314) and is used by consumers and professionals, a refinement of exposure and risk assessment may be requested to the registrants.

[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

4.4 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)	

QUATs are existing biocidal active substance currently under programme referred to Art. 16(2) of the Biocidal Product Directive 98/8/EC.

QUATs (DHTDMAC) are used as ingredient in cosmetic products. However, consumer uses of cosmetics are covered by the Cosmetic Regulation (EC) No 1223/2009 and Cosmetics Directive 76/768/EEC, respectively, and therefore risk characterization for these uses could not be included in this assessment.

4.5 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)

4.6 Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)

It depends on the outcome of substance evaluation with regard to the need for a refined environmental exposure and risk assessment.