Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides
Chemical Group:	
EC Number:	264-120-7
CAS Number:	63393-96-4
Submitted by:	Italian Competent Authority
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

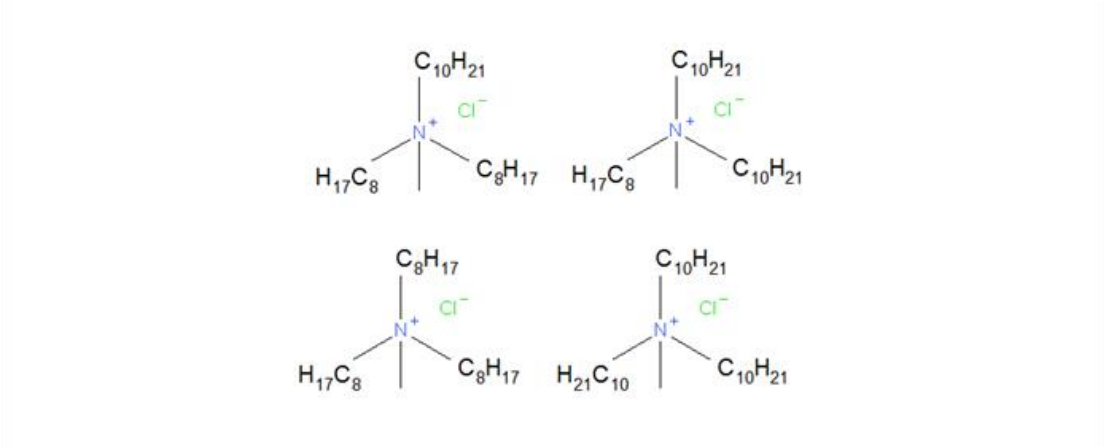
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides
IUPAC name:	Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides
Index number in Annex VI of the CLP Regulation	
Molecular formula:	Unspecified
Molecular weight or molecular weight range:	ca. 403.0 — ca. 487.0
Synonyms/Trade names:	

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

Structural formula:



1.2 Similar substances/grouping possibilities

Structural formula: -

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

None.

2.2 Self classification

- In the registration

Acute Tox. 4, H302: Harmful if swallowed.
Skin Corr. 1C, H314: Causes severe skin burns and eye damage.
Aquatic Acute 1, H400: Very toxic to aquatic life.
Aquatic Chronic 1, H410: Very toxic to aquatic life with long lasting effects.
M-Factor acute: 10

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

Skin Irrit. 2, H315

Eye Dam. 1, H318

Skin Corr. 1B, H314

Acute Tox. 3, H301

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

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

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 assessment

There are two screening tests on biodegradation, whose results are in contradiction: a RA from Amines, tri-C8-10-alkyl and a QSAR estimation. Data waiving for the simulation tests (water/sediment and soil) are reported. Therefore, according to CSR, further information is necessary to conclude on the P or vP properties in the context of the PBT Assessment.

Based on a BCF calculation using QSAR estimation (BCF = 1778 L/Kg), the substance is considered to be not bioaccumulative. Considering that this data is very close to cut-off value of 2000 L/Kg and there is a lack of QSAR documentation of the applied method in the technical dossier, bioaccumulation assessment should be better clarified.

The waiving provided for chronic testing on fish and invertebrates is not valid: risk assessment shows a potential risk in several exposure scenarios, confirming the need for further assessment of chronic toxicity. Only a long-term testing on "algae and cyanobacteria" is provided (ErC10 = 0.138 mg/l), however the short term toxicity value on fish (LC50 = 0.094 mg/l) seem to prove that "algae and cyanobacteria" is not the more sensitive trophic level. Moreover, the acute toxicity on fish reveals that the substance potentially meet the criteria for T. To refer the substance to definitive T evaluation, chronic studies in all trophic levels have to be performed.

Risk assessment

In absence of any ecotoxicological data for soil and sediments compartments the PNECs were calculated using the equilibrium partitioning method. In that case, for substances with a logKow greater than 5, the PEC/PNEC ratio should be increased by a factor of 10 to account for uptake via ingestion of soil and sediments. The correct RCRs reveal, for some exposure scenarios, values greater than 1, providing that risks are not controlled, therefore the CSA process should be refined by improving information on both hazard or exposure assessment.

[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)

In relation to the PBT assessment, definitive studies on biodegradability and bioaccumulation are required to conclude on the P and B properties of the substance. The assessment of T properties requires information on chronic toxicity in all trophic levels.

As regards exposure, information are required to justify the not default release factors and clarify the adopted operational conditions (OCs) and risk management measures (RMMs).

Moreover, information on the water solubility of the substance are needed to explain the discordant data reported in the CSR. Although the experimental water solubility value is 1023 mg/l, the substance is defined as highly insoluble in water, justifying several data waiving for ecotoxicological studies.

5.5 Potential follow-up and link to risk management

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

The potential regulatory outcome of the clarification of the concern: Annex XV for SVHC identification.