Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Imidazolium compounds, 2-C17-unsatd.-alkyl-1-(2-C18-unsatd. amidoethyl)-4,5-dihydro-N-methyl, Me sulfates
Chemical Group:	
List Number:	931-745-8
CAS Number:	
Submitted by:	Sweden
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

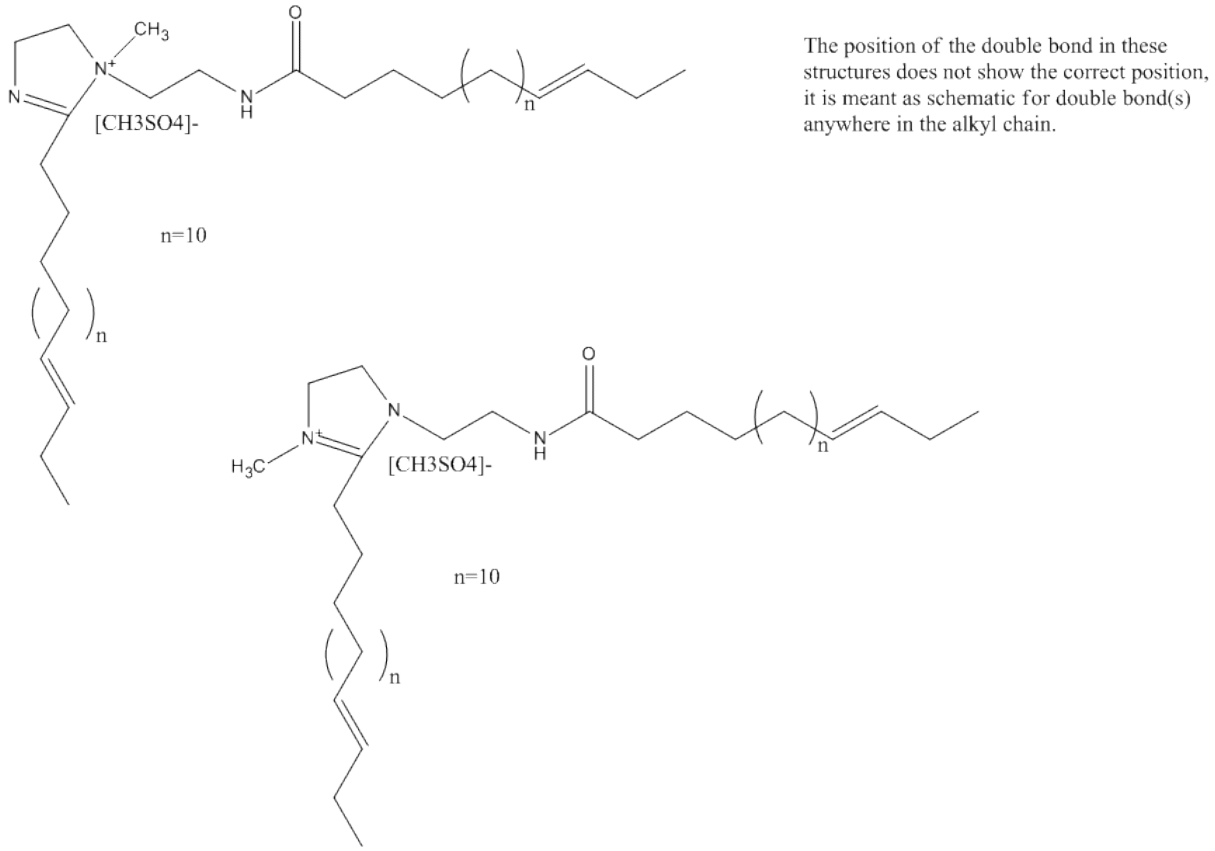
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	-
IUPAC name:	Imidazolium compounds, 2-C17-unsatd.-alkyl-1-(2-C18-unsatd. amidoethyl)-4,5-dihydro-N-methyl, Me sulfates
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	Molecular formula cannot be given as substance is a mixture.
Molecular weight or molecular weight range:	
Synonyms/Trade names:	

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

Structural formula:

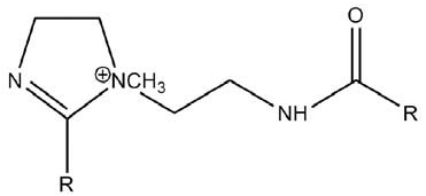


The position of the double bond in these structures does not show the correct position, it is meant as schematic for double bond(s) anywhere in the alkyl chain.

1.2 Similar substances / grouping possibilities

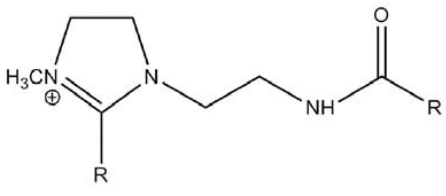
Imidazolium compounds, 2-(C15-17(odd numbered), C17-unsatd. alkyl)-1-[2-(C16-18(even numbered), C18-unsatd. amido)ethyl]-4,5-dihydro-N-methyl, Me sulfates)

Structural formula:



$[CH_3SO_4]^{\ominus}$

Structure #1



$[CH_3SO_4]^{\ominus}$

Structure #2

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

None

2.2 Self classification

- In the registration (given for "oleic-acid based IQAC, DMS quaternised")

  Skin Irrit. 2; H315: Causes skin irritation.
  Eye Irrit. 2 ; H319: Causes serious eye irritation.
  Aquatic Acute 1; H400: Very toxic to aquatic life.
  Aquatic Chronic 1; H410: Very toxic to aquatic life with long lasting effects.

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

  None. Not listed in the C&L inventory.

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
Please provide further details if appropriate		

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

WDU:
Anti-static agents
Softeners
Surface active agents

Professional and consumer uses

Polishes and wax blends
Fabrics, textiles and apparel
Paper articles

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)

Water solubility: 2.2 ± 0.4 mg/L

P:

4.4 — 12.7 % after 28 d (CO_2 evolution) (not readily biodegradable).

P screening criterion is met. However, evidence is presented that an analogue is rapidly biodegradable.

Hydrolysis:

Hydrolysis of the test item was studied in the dark at 20ºC, 50 ºC and 60 ºC in sterile aqueous buffered solutions at pH 4 (acetate buffer), pH 7 (phosphate buffer) and pH 9 (borate buffer) for 5 days according to EC C.7 (OECD 111). The half-lives of the test item were at pH 4: > 1 year at 25 °C, at pH7 2.9 days at 20°C, 2.5 days at 25°C, 27 hours at 50 °C and 16 hours at 60 °C, respectively. At pH 9 the half life was 1.2 days at 20 °C.

No information provided on hydrolysis products.

B:

Log Kow > 5.7

Only calculated BCF = 71, BCF R-A = 10.7

Concl. from Reg on a calculation: “A n-octanol/water partition coefficient log Kow=12.94 at 25°C was calculated using EPIWIN v3.20, KOWWIN v1.67. Due to missing information about the applicability of the calculation model in respect to the substance under investigation the result should be treated with care.”

However correlation between log Kow and BCF is not linear for substances with high molecular weight and high log Kow. Therefore the lower limit of the n-octanol/water-partition coefficient (log Know = 5.7) was used for the assessment as a conservative approach.

Log Koc >5.6 (strongly adsorptive to soil, sediments and suspended matter)

T:

Fish: LC50 = 1.8 mg/l (based on a.i. content of 75%; 2.4 mg/L nominal)

Long-term fish test waived

Daphnia: EC50 = 87 µg/L (95% CL: 75 - 100 µg/L)

Long-term R-A: The 63d NOEC of >100 µg/L was determined in a 21-day-reproduction test with Daphnia magna over 3 generations. Daphnids were exposed to the effluent of the activated sludge unit containing the degradation products of partially unsaturated IQAC, DMS quaternised.

[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

Algea: NOEC (72h) = 79 µg/L yield Oleic-acid based IQAC, DMS quaternized is toxic for the environment. Sediment and terrestrial toxicity tests waived. High RCRs: for sediment: <1 and for agricultural soil > 1 for various scenarios.

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)	
Testing proposal was terminated on administrative grounds. (Endpoint: Sub-chronic toxicity (90-day): oral)	

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)
Could clarify risks to soil and sediment compartment, consider toxicity testing. Consider bioaccumulation potential and biodegradability of all components.	

4.6 Potential follow-up and link to risk management

☐ Harmonised C&L	☒ Restriction	☒ Authorisation	☐ Other (provide further details)
Please provide further details/explanation.			