Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Alcohols, C7-9-iso-, C8-rich
Chemical Group:	
EC Number:	271-231-4
CAS Number:	68526-83-0
Submitted by:	Italy
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

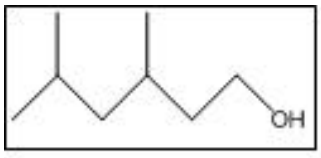
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	Alcohols, C7-9-iso-, C8-rich
IUPAC name:	None available
Index number in Annex VI of the CLP Regulation	No entry
Molecular formula:	CnH2n+1OH (n = 7 to 9)
Molecular weight or molecular weight range:	Ca. 130
Synonyms/Trade names:	None available

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

No entry in the annex VI of the CLP

2.2 Self classification

- In the registration:
  Not classified

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

  Acute tox 4, H302

  Eye damage 1, H318

  Skin Irrit. 2, H315

  STOT SE 3, H336

  Aquatic chronic 3, H412

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)

The exposure assessment has not been performed since the substance has not been self-classified. However in the ECHA C&L Inventory database the substance is self classified as Eye Dam. 1, H318 and Skin Irrit. 2, H315 by other notifiers. Moreover in the CSR the registrants presented the DN(M)EL derivation for several toxicological end-point. Therefore the registrants should develop the exposure scenarios and perform the exposure assessment and the risk characterization for human health. Moreover a justification should be given in the dossier on the reason for deviating from the REACH guidances in the use of the assessment factors for the DN(M)EL derivation. Indeed in the CSR no justification is given for using the ECETOC approach instead of the REACH guidances for risk characterization.

The available developmental toxicity studies show that only slight effects on litter are observed at dose levels inducing maternal toxicity; thus, no specific concerns for developmental toxicity are identified. It is noted that no study covering the full reproductive cycle (i.e., 1- or 2-generation study) is available. Nevertheless, the available data do not point out priority concerns, as no effects on reproductive or endocrine tissues were identified in repeated dose toxicity studies

No clear data are available on the in vivo genotoxicity and carcinogenicity. The Alcohols, C7-9-iso-, C8-rich is a member of the Alkyl Alcohols C6 to C13. In this category the substance 2-ethyl-1-hexanol showed positive results for carcinogenesis. Therefore more information is needed in order to clarify the concern.

In addition in the IUCLID dossier the justification document for the read across approach is missing thus a justification should be provided by 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

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)

5.5 Potential follow-up and link to risk management

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