Justification for the selection of a substance for CoRAP inclusion

– UPDATE –

Substance Name (Public Name):	Oxirane, mono[(C12-14-alkyloxy)methyl] derivs.
Chemical Group:	Organic
EC Number:	271-846-8
CAS Number:	68609-97-2
Submitted by:	Ireland
Date:	26/03/2014 updated 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

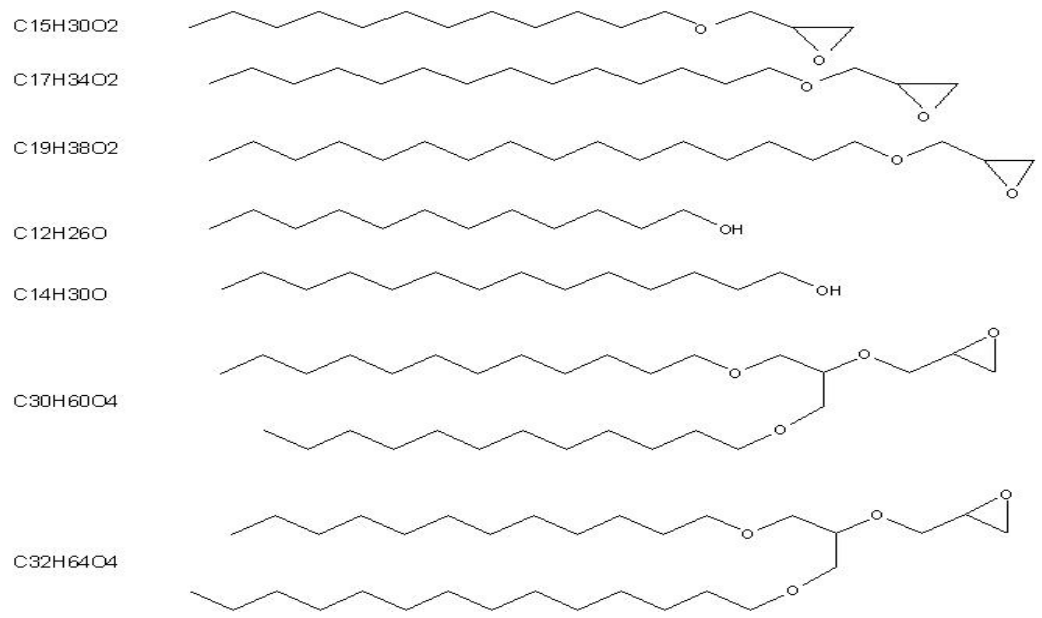
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	Oxirane, mono[(C12-14-alkyloxy)methyl] derivs.
IUPAC name:	Oxirane, 2-((C12-14-alkyloxy)methyl)derivs
Index number in Annex VI of the CLP Regulation	603-103-00-4
Molecular formula:	C15H30O2 + C17H34O2 + C19H38O2 + C12H26O + C14H30O + C30H60O4 + C32H64O4
Molecular weight or molecular weight range:	186-513
Synonyms/Trade names:	

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

Structural formula:



1.2 Similar substances/grouping possibilities

None identified.

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

- Skin Irritation 2; H315: Causes skin irritation.
- Skin Sensitisation 1; H317: May cause an allergic skin reaction

2.2 Self classification

- In the registration data:
  - Skin Irritation 2; H315: Causes skin irritation.
  - Skin Sensitisation 1; H317: May cause an allergic skin reaction

- In addition, the following hazard classes are notified among the self classifications in the C&L Inventory:
  - Aquatic Chronic 2; H411: Toxic to aquatic life with long lasting effects

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

The substance is used as a viscosity adjuster for epoxy resins used in for example in adhesives, sealants, coatings and paints, fillers, putties and pastes.

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 substance has a harmonised classification as a skin sensitiser and there appear to be uses reported in the registration data where worker and consumer exposure is possible. Further assessment of the exposure potential and the adequacy of the existing risk management measures are required.

In a guideline (OECD 471) *in vitro* bacterial gene mutation study (Ames test), a positive result was obtained in *S. typhimurium* strain TA 1535 in the presence and absence of metabolic activation. In a second non-guideline Ames test, ambiguous results were obtained for *S. typhimurium* strains TA100, TA 98 and TA 1535. Negative results were obtained in *in vitro* gene mutation studies on mammalian cells. Results from three *in vivo* studies investigating chromosome aberrations are available, all of which are negative but there is no *in vivo* study addressing gene mutation. Further evaluation of the positive result in the *in vitro* bacterial mutagenicity studies is required in order to determine whether further *in vivo* testing to address gene mutation is required.

No data on the fertility endpoint is reported in the registration data. For the developmental toxicity endpoint, a preliminary dermal developmental toxicity screening study (EPA OTS 798.4420) is reported. No developmental toxicity or maternal toxicity was observed, other than local dermal irritation at site of administration. However, it is noted that there are some limitations with the study, in particular the low number of animals per dose group and the route of administration used. Therefore, given the aggregated tonnage, the potential for worker and consumer exposure and the limited data available on the reproductive toxicity endpoint, further evaluation of the available data is required in order to determine whether additional data to address the fertility and developmental toxicity endpoints is required.

The registration dossier reports a 90-day dermal repeat dose toxicity study on an analogue substance however no justification is provided for the read-across or the choice of route of administration. No systemic effects were observed but local effects at the site of administration were reported. As no other repeated dose toxicity data are reported in the registration data, further evaluation of this study and the derivation of systemic DNELs in the dossier are required.

[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)

Following evaluation of the existing data, additional data to clarify the identified concerns for repeated dose toxicity, mutagenicity and reproductive toxicity may be required.

Further information on uses and/or exposure may be required to clarify whether existing exposure estimates and associated risk management measures are adequate.

5.5 Potential follow-up and link to risk management

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

Difficult to identify at this stage given the limited hazard data available.