Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	2,3-epoxypropyl neodecanoate
Chemical Group:	Organic
EC Number:	247-979-2
CAS Number:	26761-45-5
Submitted by:	Danish Environmental Protection Agency, Strandgade 29, 1401 Copenhagen. Denmark
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

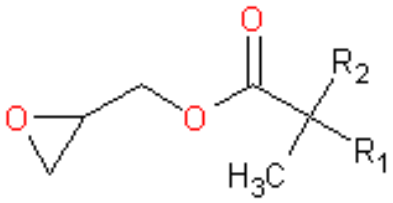
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	2,3-epoxypropyl neodecanoate
IUPAC name:	oxiran-2-ylmethyl 2-ethyl-2,5-dimethylhexanoate
Index number in Annex VI of the CLP Regulation	none
Molecular formula:	$C_{13}H_{24}O_3$
Molecular weight or molecular weight range:	228.3279
Synonyms/Trade names:	Neodecanoic acid, oxiranylmethyl ester

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

Structural formula:



1.2 Similar substances/grouping possibilities

None.

Structural formula:

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification

2.2 Self classification

- In the registration

Aquatic Chronic 2, H411: Toxic to aquatic life with long lasting effects.

Skin Sens. 1, H317: May cause an allergic skin reaction.

Muta. 2 H340: May cause genetic defects. (Route of exposure: Oral)

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

Skin Irrit. 2, H315: Causes skin irritation

Muta. 2, H341: Suspected of causing genetic defects

Carc. 1B, H350: May cause cancer

Aquatic Chronic 2, H413: May cause long lasting harmful effects to aquatic life.

Eye Irrit. 2, H319: Causes serious eye irritation.

STOT SE 3, H335: May cause respiratory irritation

And "Not classified"

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
According to registration (non-confidential): Industrial manufacturing, batch processes, substance transfers, packaging, blending. Used by professional workers. However, according to information in the SPIN database there are indication of exposure to consumers.			

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)

[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

According to information from the registration dossier the substance is mutagenic in-vivo in the TGR assay in bone-marrow and liver tissue. Based on these results the substance is self classified as MUT 2 (CLP). The data for the male germ cell mutant frequencies was incomplete at the time of registration, but is important for evaluation of the mutagenic effects and possible classification as Germ cell Mutagen 1B.

Under substance evaluation the available information relevant for mutagenicity and carcinogenicity will be reviewed. It will be evaluated if the current self-classification by the registrant(s) is sufficient or if a more stringent classification should be proposed. Alternatively, further testing may be required if the available information is judged to be insufficient to conclude on classification.

There are indications from the SPIN database that the substance has a widespread dispersive use and potential for consumer exposure. This should be claified under SEv.

Information from the non-confidential registration-dossier:

OECD 411 (repeated dose , 90 d, dermal) is planned. OECD 414 and OECD 416 are planned

Mutagenicity:

In vitro: OECD 471(Ames): pos. OECD 473: neg.

In vivo: UDS-test: neg. OECD 488 (TGR test): pos.

"The test substance, 2,3 -epoxypropyl neodecanoate was evaluated for its ability to act as a systemic gene-mutagen in an O.E.C.D. test guideline 488 (2011) study conducted in the MutaMouse by the oral gavage rout of exposure. The dose levels of the test substance were: 0, 250, 500 amd 1000 mg/Kg/day. The test substance was shown to be a gene-mutagen in the liver, kidney and bone marrow of the MutaMouse demonstrating that the test substance is a systemic mutagen in mice by the oral route of exposure. In the liver at the high dose level the group mean mutant frequency was 3.1 -fold the mean concurrent vehicle control value."

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)	

CCH: Decision is disseminated on ECHA's website.

TP: OECD Guideline 411 (Subchronic Dermal Toxicity: 90-Day Study) is planned by the registrant and could be ready at mid 2014. OECD 414 (Prenatal Developmental Toxicity Study) and 416 (Two-Generation Reproduction Toxicity Study) are planned.

It is not anticipated that the performance of the studies will interfere with the substance evaluation on mutagenicity/carcinogenicity endpoints.

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)

The data for the male germ cell mutant frequencies is incomplete at the time for the registration of the data, but is important for evaluation of the mutagenic effects.

There are indications that the substance has a widespread dispersive use or there is evidence of frequent or long-term human exposure. However this should be clarified.

4.6 Potential follow-up and link to risk management

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

Based on the outcome of the evaluation, the substance might be classified as Mutagen 1B.