Danish Ministry of the Environment
Environmental Protection Agency

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	2,3-epoxypropyl o-tolyl ether
EC Number:	218-645-3
CAS Number:	2210-79-9
Authority:	**DK MSCA**
Date:	**22/03/2016**

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

Contents

1 IDENTITY OF THE SUBSTANCE

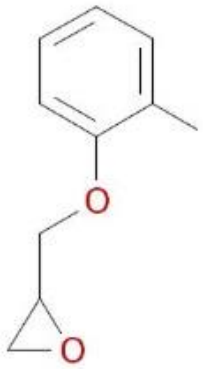
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	2,3-epoxypropyl o-tolyl ether
IUPAC name (public):	2-[(2-methylphenoxy)methyl]oxirane
Index number in Annex VI of the CLP Regulation:	603-056-00-X
Molecular formula:	$C_{10}H_{12}O_2$
Molecular weight or molecular weight range:	
Synonyms:	ARALDITE® DY-K ARALDITE® DY 023 D.E.R.(TM) 723 Epoxy Diluent EPOTEC RD 105

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

Structural formula:



2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☒ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII
Harmonised C&L	☒ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☒ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes / EU legislation	☐ Other (provide further details below)	

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)[1]

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
603-056-00-X	**2,3-epoxypropyl o-tolyl ether**	**218-645-3**	**2210-79-9**	**Skin Irrit. 2 Skin Sens. 1 Muta. 2 Aquatic Chronic 2**	**H315 H317 H341 H411**		Note C

3.1.2 Self classification

- In the registration:
  - Skin Sens. 1 (H317): May cause an allergic skin reaction.
  - Aquatic Chronic 2 (H411): 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:

  Acute Tox. 3 (H331)

  Acute Tox. 4 (H302)

  Acute Tox. 4 (H312)

  Aquatic Chronic 3 (H412)

  Skin Corr. 1B (H314)

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

None

[1] *The ECHA dissemination site was accessed 20.03.2016.*

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per 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
Joint submission		

4.2 Overview of uses

SU 1: Agriculture, forestry and fishing

SU 2a: Mining (without offshore industries)

SU 2b: Offshore industries

SU 5: Manufacture of textiles, leather, fur

SU 6a: Manufacture of wood and wood products

SU 6b: Manufacture of pulp, paper and paper products

SU 7: Printing and reproduction of recorded media

SU 8: Manufacture of bulk, large scale chemicals (including petroleum products)

SU 9: Manufacture of fine chemicals

SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)

SU 11: Manufacture of rubber products

SU 12: Manufacture of plastics products, including compounding and conversion

SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement

SU 15: Manufacture of fabricated metal products, except machinery and equipment

SU 16: Manufacture of computer, electronic and optical products, electrical equipment

SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment

SU 18: Manufacture of furniture

SU 19: Building and construction work

SU 23: Electricity, steam, gas water supply and sewage treatment

SU 24: Scientific research and development

PC 1: Adhesives, sealants
PC 9a: Coatings and paints, thinners, paint removes
PC 9b: Fillers, putties, plasters, modelling clay

According to the Nordic Product Register (SPIN), one or several uses of 2,3-epoxypropyl o-tolyl ether indicate a probable/very probable exposure to consumers and professionals. However, no consumer uses are reported in the registration dossiers.

Table: Uses

Part 1:

☒ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☐ Consumer use	☐ Article service life	☐ Closed system

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)

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[2] ☐ C ☐ M ☐ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[2]	
☐ PBT/vPvB	☐ Suspected PBT/vPvB[2]	☐ 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)

[2] 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

The substance has been tested positive for gene mutations *in vitro* without metabolic activation. *In vivo* a transgenic rodent assay has been conducted, which gave ambigious results. In addition, there is an indication for male germ cell chromosome damage from a dominant lethal assay. Based on these results the substance has been with harmonised classification as MUTA 2 (CLP). Under substance evaluation it will be evaluated if further testing is necessary in order to conclude on germ cell mutagenicity and consequently if the current classification in category 2 is sufficient or if a more stringent classification should be proposed.

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)
Further studies on genotoxicity may be requested.	

5.5 Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
If the substance is concluded to meet criteria for classification as MUTA cat. 1B a proposal for harmonised classification will be submitted.			