Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	p-(2,3-epoxypropoxy)-N,N-bis(2,3-epoxypropyl)aniline
Chemical Group:	Glycidylated p-amino-phenol
EC Number:	225-716-2
CAS Number:	5026-74-4
Submitted by:	Danish Environmental Protection Agency
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

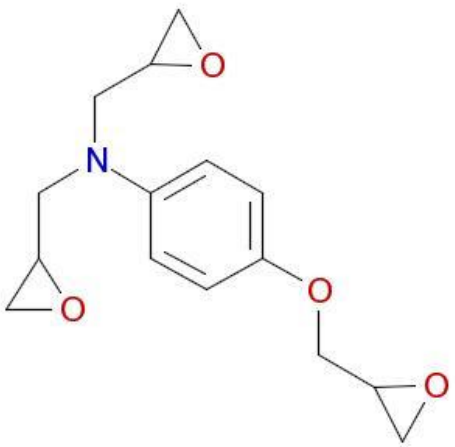
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	p-(2,3-epoxypropoxy)-N,N-bis(2,3-epoxypropyl)aniline
IUPAC name:	4-(oxiran-2-ylmethoxy)-N,N-bis(oxiran-2-ylmethyl)aniline
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	$C_{15}H_{19}NO_4$
Molecular weight or molecular weight range:	277.3
Synonyms/Trade names:	*Araldite MY 0510; Araldite MY 0500*

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

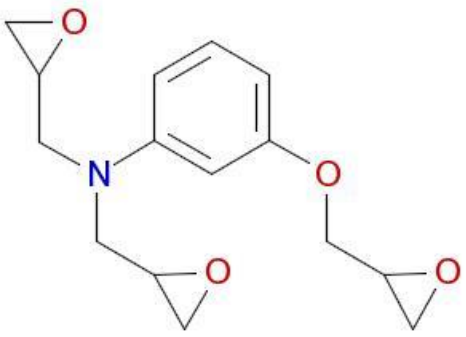
Structural formula:



1.2 Similar substances/grouping possibilities

EC name:	m-(2,3-Epoxypropoxy)-N,N-bis(2,3-epoxypropyl)aniline
EC Number:	275-662-9
IUPAC name:	3-(Oxiran-2-ylmethoxy)-N,N-bis(oxiran-2-ylmethyl)aniline
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	$C_{15}H_{19}NO_4$
Molecular weight or molecular weight range:	277.3
Synonyms/Trade names:	*Araldite MY 0600; Araldite MY 0610*

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Not listed.

2.2 Self classification

- Self-classification in registration dossier:

  Acute Tox. 4, H302: Harmful if swallowed.
  Skin Irrit. 2, H315: Causes skin irritation.
  Skin Sens. 1, BH317: May cause an allergic skin reaction.
  Muta. 2, H341: Suspected of causing genetic defects.
  Aquatic Acute 2, H401: Toxic to aquatic life.
  Aquatic Chronic 2, H411: Toxic to aquatic life with long lasting effects.

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

Classification[1]	**Hazard statement**	**Number of notifiers** (May2014)
Acute Tox. 4	H302	68
Acute Tox. 4	H312	5
Skin Irrit. 2	H315	121
Skin Sens. 1	H317	121
Muta. 2	H341	77
Aquatic Chronic 2	H411	75
Eye Irrit. 2	H319	48
STOT SE 3	H335	44
Carc. 2	H351	43
Aquatic Chronic 2	H411	1

[1]Number of Aggregated Notifications: 13 Number of notifiers: 122 (1.9.2014)

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None proposed.

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

According to the information from the registration dossier the substance is used as an intermediate, to industrial formulation, application of adhesives and composite repair, resin transfer moulding, resin infusion industrial prepreg/wetpreg manufacturing via automated impregnation, prepreg processing, filament winding, pultrusion, seamless moulding paste and casting. All uses are either related to the formulation of industrial products or the direct industrial use of the substance.

However, according to the Nordic Product Register (SPIN database) there is also professional use of the substance.

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)	

A testing proposal was put forward by the registrant for a mammalian erythrocyte micronucleus test (OECD guideline 474). The proposed study will be performed with the m-isomer of the substance and used for read-across to the p-isomer. According to the registrant the study has been requested by a non-European authority for registration outside Europe.

An additional testing proposal for a repeated dose 90-day oral toxicity in rodents according to OECD Guideline 408 has been put forward by the registrant. The proposed study will also be performed with the m-isomer of the substance and used for read-across to the p-isomer. The study has been requested by a non-European authority for registration outside Europe.

Furthermore a testing proposal by the registrant for a two-generation reproduction toxicity study (OECD 416) has been put forward. It is proposed that the study will be performed with the m-isomer of the substance and is intended to be used for read-across to the p-isomer.

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)

[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 an *in vitro gene- and chromosomal mutagen* (OECD Guideline 473 and 476 with and without metabolic activation). Two *in vivo* (none according to OECD Guidelines) tests have been carried out in bone marrow (DNA damage and/or repair and chromosome aberration) cells with positive results.

No studies on carcinogenicity have been concluded.

(Q)SAR screening:

- Positive predictions for a variety of MUT and CARC models in Danish DQDB within the applicability domain of the individual models

Under substance evaluation the available information relevant for mutagenicity and carcinogenicity should be reviewed. It should be evaluated if the current self-classification by the registrant is sufficient or if a more stringent classification should be proposed.

In addition, the exposure potential to workers (and potentially also consumers) should be further investigated. Further testing may be required if the available information is judged to be insufficient to conclude on the initial concern for *in vivo* gene and chromosome mutagenicity (including germ cell mutagenicity) and carcinogenicity.

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)

The substance evaluation may result in a request for further mutagenicity and as appropriate at a later stage also carcinogenicity studies as well as a request for further exposure information including on possible exposure of consumers and workers.

5.5 Potential follow-up and link to risk management

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

Depending on the outcome of the substance evaluation it might be relevant to put forward a proposal for harmonized classification.

Later and depending of new information to potentially be requested it may in addition be relevant to consider proposals for restriction and/ or inclusion on the Candidate List.