Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	4,4'-methylenebis[N,N-bis(2,3-epoxypropyl)aniline]
Chemical Group:	Tetraglycidylated epoxy resin.
EC Number:	249-204-3
CAS Number:	28768-32-3
Submitted by:	Danish Environmental Protection Agency, Strandgade 29, 1401 Copenhagen. Denmark
Published:	20/03/2013

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	4,4'-methylenebis[N,N-bis(2,3-epoxypropyl)aniline]
EC number:	249-204-3
EC name:	4,4'-methylenebis[N,N-bis(2,3-epoxypropyl)aniline]
CAS number (in the EC inventory):	249-204-3
CAS number:	28768-32-3
CAS name:	4,4'-Methylenebis(N,N-bis(2,3-epoxypropyl)aniline)
IUPAC name:	4-[[4-[bis(oxiran-2-ylmethyl)amino]phenyl]methyl]-N,N-bis(oxiran-2-ylmethyl)aniline
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	$C_{25}H_{30}N_2O_4$
Molecular weight or molecular weight range:	422.5 – 422.6
Synonyms:	-

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

Structural formula:

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

None listed.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None proposed.

2.3 Self classification

CLP criteria:

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

Muta. 2; H341: Suspected of causing genetic defects.

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

67/548/EEC self classification:

N - dangerous for the environment ; R51/53 - toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Muta. Cat. 3; R68 - possible risk of irreversible effects.

R43 - may cause sensitisation by skin contact.

C&L inventory additionally includes the following classifications:

Acute Tox. 4; H302: Harmful if swallowed.

Acute Tox. 4; H312: Harmful in contact with skin.

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

Aquatic Chronic 2; H412: Harmful to aquatic life with long lasting effects.

Aquatic Chronic 2; H410: Very toxic to aquatic life with long lasting effects.

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

☐ Article 44(1) (refined prioritisation criteria for substance evaluation)

☒ Article 45(5) (Member State priority)

3.2 Grounds for concern

☒ (Suspected) CMR	☒ Wide dispersive use	☐ Cumulative exposure
☐ (Suspected) Sensitiser	☐ Consumer use	☐ High RCR
☐ (Suspected) PBT	☐ Exposure of sensitive populations	☐ Aggregated tonnage
☐ Suspected endocrine disruptor	☐ Other (provide further details below)	

According to information from the registration dossier the substance is mutagenic in-vitro. Five in-vivo tests have been performed in bone-marrow and spermatogonial cells with both positive, negative and one ambiguous result. Negative results are reported in all spermatogonial tests, but it is positive in some somatic mutagenicity tests, and it is therefore considered to be mutagenic in rodents. Based on these results the registrant has self classified the substance as MUT 2 (CLP).

The substance has positive QSAR predictions for mutagenicity and cancer:
(Q)SAR screening:
Human health:
– Positive predictions for MUT and CARC in Danish DQDB
– Positive predictions for MUT and CARC in CAESAR
– Positive predictions for developmental toxicity in CAESAR
– Negative predictions for developmental toxicity submitted by MOLCODE

No studies on carcinogenicity have been conducted.

Under substance evaluation available information relevant for mutagenicity and carcinogenicity will be reviewed. It will be evaluated if the current self-classification by the registrant 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.

3.3 Information on aggregated tonnage and uses

☐ 1 – 10 tpa	☐ 10 – 100 tpa	☒ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	
☐ 100,000 – 1000,000 tpa	☐ > 1000,000 tpa	
☐ Confidential		

Please provide further details

☒ Industrial use	☒ Professional use	☐ Consumer use	☐ Closed System

Industrial Uses:
Adhesives formulation and filling cartridges
Adhesives application
Industrial production of carbonfibre composites etc.

Professional use:
Professional end-use of adhesives

Laminating processes

3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

☐ Compliance check	☐ 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
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	

Testing proposal examination of the substance has resulted in a request for further testing, which includes tests on reproductive toxic effects. However before testing it would be appropriate to assess the possible genotoxic effects closely, as these effects have influence on the specific reproductive toxicity testing requirement.

According to REACH, Annex IX, 8.7. the reproductive toxicity studies do not need to be conducted if the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented.

3.5 Information to be requested to clarify the suspected risk

☒ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☒ Information on exposure
☐ Information on ecotoxicological properties	☒ Information on uses
☐ Other (provide further details below)	

The substance evaluation may result in a request for further studies on genetic toxicity.

Further information on exposure (including potential for consumer use and wide dispersive use) may also be requested.

3.6 Potential follow-up and link to risk management

☐ Restriction	☒ Harmonised C&L	☐ 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.