Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	3,6,9,12-tetraazatetradecamethylenediamine
Chemical Group:	organic
EC Number:	223-775-9
CAS Number:	4067-16-7
Submitted by:	Czech Republic
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 3
1.1 Name and other identifiers of the substance 3

2 CLASSIFICATION AND LABELLING 4
2.1 Harmonised Classification in Annex VI of the CLP 4
2.2 Proposal for Harmonised Classification in Annex VI of the CLP 4
2.3 Self classification 4

3 JUSTIFICATION FOR THE SELECTION 5
3.1 Legal basis for the proposal 5
3.2 Grounds for concern 5
3.3 Information on aggregated tonnage and uses 5
3.4 Other completed/ongoing regulatory processes 6
3.5 Information to be requested to clarify the suspected risk 6
3.6 Potential follow-up and link to risk management 6

1 IDENTITY OF THE SUBSTANCE

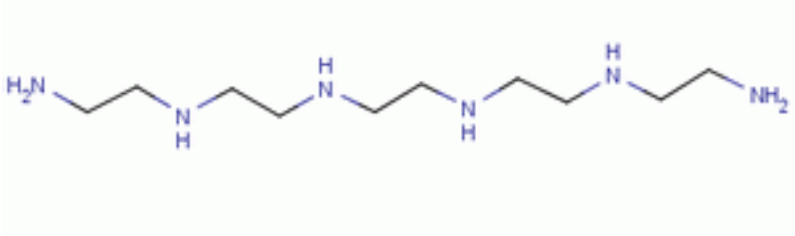
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	3,6,9,12-tetraazatetradecamethylenediamine
EC number:	223-775-9
EC name:	3,6,9,12-tetraazatetradecamethylenediamine
CAS number (in the EC inventory):	4067-16-7
CAS number:	4067-16-7
CAS name:	Pentaethylene hexamine
IUPAC name:	Pentaethylenehexamine
Index number in Annex VI of the CLP Regulation	612-064-00-2
Molecular formula:	C10H28N6
Molecular weight or molecular weight range:	-
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

CLP:

- Skin Corr. 1B; H314: Causes severe skin burns and eye damage.
- Skin Sens. 1; H317: May cause an allergic skin reaction.
- Aquatic Acute 1; H400: Very toxic to aquatic life.
- Aquatic Chronic 1; H410: Very toxic to aquatic life with long lasting effects.

DSD:

- C; R34 Corrosive; Causes burns.
- R43; May cause sensitization by skin contact
- N; R50-53; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None

2.3 Self classification

In addition to the harmonised classification, the following classifications are given in the registration data and in the C&L Inventory:

According to **CLP**:

- Acute Tox. 4; H302: Harmful if swallowed.
- Acute Tox. 4; H312: Harmful in contact with skin.
- Eye Damage 1; H318: Causes serious eye damage.

Additional classifications according to 67/548/EEC (**DSD**):

- Xn; R21/22 Harmful in contact with skin and if swallowed.

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)	

The substance is a known sensitiser. The uses indicate potential for inhalation exposure e.g. PROCS 7 and 10. No information on the potential for respiratory sensitisation has been indicated in the registration data. The potential for respiratory sensitisation could be examined via the SEV process. Even though there is an ongoing TP examination on this dossier, also for HH endpoints, this substance could be considered for the SEV process due the potential of this type of substance i.e. ethyleneamines to cause respiratory sensitisation.

The substance is classified as Corr. 1B, however the uses and the exposure of the substance is at low concentrations and it is possible to get sensitised from being exposed to low concentrations where irritation of the respiratory tract does not occur.

It would be possible to request via SEV more information about the possible potential (or the lack thereof) for respiratory sensitisation. Information on cytokine fingerprinting could provide useful information on the respiratory sensitisation potential (no standard/regulatory guidelines available for this endpoint.

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

Intermediate substance, other manufacturing processes. Used in wood preservative as a biocidal product. Use in e.g. air care products. Use of ethylenamines in consumer preparations:
PC 1: Adhesives, sealants
PC 9b: Fillers, putties, plasters, modelling clay

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)	
The ongoing testing proposal process is for the endpoints dissociation constant, viscosity, pre-natal developmental toxicity and two-generation reproductive toxicity study.	

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)	
Due to the sensitising properties of the substance and exposure to workers/consumers via inhalation route, more information on the substance potential to cause respiratory sensitization (or the lack thereof) could be requested e.g. human data/case reports from persons exposed to the substance and/or non-regulatory accepted test e.g. cytokine fingerprinting.	

3.6 Potential follow-up and link to risk management

☐ Restriction	☒ Harmonised C&L	☐ Authorisation	☐ Other (provide further details)
The harmonized classification does not cover respiratory sensitization. The outcome of the evaluation could be reclassification.			