Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	2,2'-methyliminodiethanol
Chemical Group:	Organic
EC Number:	203-312-7
CAS Number:	105-59-9
Submitted by:	UK CA
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

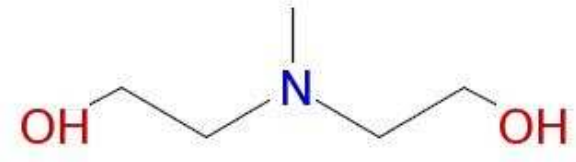
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	2,2'-methyliminodiethanol
EC number:	203-312-7
EC name:	2,2’-methyliminodiethanol
CAS number (in the EC inventory):	105-59-9
CAS number:	105-59-9
CAS name:	Ethanol, 2,2’(methylimino)bis-
IUPAC name:	2,2'-(methylimino)diethanol
Index number in Annex VI of the CLP Regulation	603-079-00-5
Molecular formula:	C5H13NO2
Molecular weight or molecular weight range:	119.16
Synonyms:	Methyldiethanolamin Ethanol, 2,2'-(methylimino)di- (6CI, 8CI) Methyldiethanolamine N-Methyldiethanolamine N-Methyliminodiethanol 2,2'-(Methylimino)diethanol Bis(2-hydroxyethyl) methyl amine N,N-Bis(2-hydroxyethyl)methylamine Methylbis(2-hydroxyethyl)amine Methyliminodiethanol Diethanolmethylamine N-Methylaminodiglycol Eve, Amietol M12, N-METHYLDIETHANOLAMINE (MDEA)

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

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Index number: 603-079-00-5

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

DSD:

Xi; R36 Irritating to eyes

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

Not applicable

2.3 Self classification

In addition to the harmonised classification, the following classifications for other endpoint(s) are notified in the Classification and Labelling Inventory:

STOT SE 3; H335: May cause respiratory irritation

Acute Tox. 4; H302: Harmful if swallowed

Aquatic Chronic 3; H412: Harmful 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)	

Exposure - DNEL for long-term inhalation exposure based on route-to-route extrapolation from dermal data. Further assessment is warranted to confirm that the DNEL provides an adequate basis to assess local and systemic effects from long-term inhalation exposure.

Human Health - A 2-generation study has been read-across from another substance. Reproductive toxicity was observed at the highest dose of 1000 mg/kg bw/day.

An oral screening study is also available for the other substance and again reproductive effects were observed at the top dose of 1000 mg/kg bw/day

Both available developmental toxicity studies are conducted via the dermal route. In addition, the rabbit study was a read across study from another substance and the maximum dose used was only 75 mg/kg bw/day.

An assessment should be made as to whether the dermal route is appropriate; the results from a dermal absorption study raise doubts as release of the substance into the blood was slow.

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

As given on the dissemination site (10,000+).

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

Industrial uses:

Manufacture of 2,2'-methyliminodiethanol (methylDEA)
Formulation of preparations
Application as intermediate in industrial settings
Laboratory work with methylDEA
Use in gas treatment
Use in lubricants and metal working fluids
Use as processing aid (catalyst) in polymerisation reactions
Use as additive in coatings

Professional uses:

Laboratory work with methylDEA
Use in lubricants and metal working fluids
Use as processing aid (catalyst) in polymerisation reactions
Use as additive in coatings
Use as additive in concrete and cement

3.4 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
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	

Annex VI (CLP) see 2.1

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)	

Further information on developmental toxicity may be required.

Repeat inhalation data may be required if there are reasons to consider the current DNELs do not provide an adequate basis to assess long term inhalation exposure.

3.6 Potential follow-up and link to risk management

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

Any follow-up will depend on the outcome of the evaluation.