

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	2,2'-dimethyl-4,4'-methylenebis(cyclohexylamine)
Chemical Group:	
EC Number:	229-962-1
CAS Number:	6864-37-5
Submitted by:	Germany
Published:	26/03/2014

Note

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

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1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	2,2'-dimethyl-4,4'-methylenebis(cyclohexylamine)
IUPAC name:	4,4'-methylenebis(2-methylcyclohexanamine)
Index number in Annex VI of the CLP Regulation	612-110-00-1
Molecular formula:	C ₁₅ H ₃₀ N ₂
Molecular weight or molecular weight range:	238.41 g/mol
Synonyms/Trade names:	Cyclohexylamine, 4,4'-methylenebis[2-methyl-(6CI,7CI,8CI); 2,2'-Dimethyl-4,4'-methylenebis(cyclohexylamine); 3,3'-Dimethyl-4,4'-diaminodicyclohexylmethane; 3DCM; 4,4'-Diamino-3,3'-dimethyldicyclohexylmethane; 4,4'-Methylenebis[2-methylcyclohexanamine]; 4,4'-Methylenebis[2-methylcyclohexylamine]; Ancamine 2049; Bis(3-methyl-4-aminocyclohexyl)methane; Bis(4-amino-3-methylcyclohexyl)methane; C 260; Ciba 2976; DMDC; Dimethyldicykan; Epicure 113; Eporesit T 58; Hardener SL; JER Cure 113; Laromin C; Laromin C 260; RF 24; Rutapox SL; SIQ-AMIN 1105

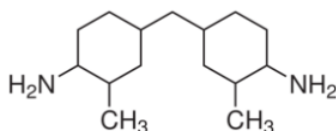
Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

None identified.

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Classification		Labelling		Specific Concentration limits, M- Factors
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	
Acute Tox. 4 *	H302	H302		
Acute Tox. 3 *	H311	H311		
Skin Corr. 1A	H314	H314		
Acute Tox. 3 *	H331	H331		
Aquatic Chronic 2	H411	H411		

Signal Words:

Danger

Pictograms:

GHS06

GHS09

GHS05

2.2 Self classification

- In the registration

The registrants have given the following self classifications in addition to the harmonised classifications:

Classification		Labelling		Specific Concentration limits, M- Factors
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	
Acute Tox. 2	H330	H330		
Eye Dam. 1	H318	H318		

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

No other self-classification than the ones from the registrants are notified.

One group of notifiers has included labelling also with the pictogram GHS07.

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa	
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa	
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa	
<input checked="" type="checkbox"/> 100 + tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input checked="" type="checkbox"/> Confidential	
Some tonnage claimed confidential.			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
For example, the substance is used for the Manufacture of substances, Formulation of preparations, Industrial use resulting in manufacture of another substance and for manufacture of thermoplastics. Further information can be found at the ECHA dissemination portal. Steps occurring in Professional uses are for example mixing or blending in batch processes for formulation of preparations and articles, Non industrial spraying, Treatment of articles by dipping and pouring and Production of preparations or articles by tableting, compression, extrusion, pelletisation.			

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

4.2 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

4.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input checked="" type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
There exists some evidence from in vitro studies and structure activity relation, which indicate the potential of endocrine properties.		

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

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input checked="" type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
Index No. 612-110-00-1	

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

4.5 Preliminary indication of information that may need to be requested to clarify the concern

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input checked="" type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

Information on ED potential needed to clarify the concern may lead to the request of relevant fish toxicity studies including fish sexual development test or fish full life cycle. Further information on the ED potential as well as ecotoxicological data for invertebrate and vertebrates species is needed to clarify the concern.

4.6 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input checked="" type="checkbox"/> Other (provide further details)
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If concern is substantiated a SVHC-identification according to art. 57 f will be proposed.