

## Justification for the selection of a substance for CoRAP inclusion

**Substance Name (Public Name):** Cyclohexylamine

**Chemical Group:**

**EC Number:** 203-629-0

**CAS Number:** 108-91-8

**Submitted by:** Belgium

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### 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:	Cyclohexylamine
IUPAC name:	Cyclohexanamine
Index number in Annex VI of the CLP Regulation	612-050-00-6
Molecular formula:	C <sub>6</sub> H <sub>13</sub> N
Molecular weight or molecular weight range:	99.1741
Synonyms/Trade names:	

Type of substance     Mono-constituent     Multi-constituent     UVCB

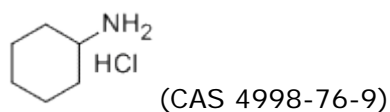
Structural formula:



### 1.2 Similar substances/grouping possibilities

Many studies were performed with cyclohexylamine hydrochloride

Structural formula:



## 2 CLASSIFICATION AND LABELLING

### 2.1 Harmonised Classification in Annex VI of the CLP

Flam. Liq. 3; H226: Flammable liquid and vapour

Acute Tox. 4; H302: Harmful if swallowed

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

Skin Corr. 1B; H314: Causes severe skin burns and eye damage

Repr. 2; H361f: Suspected of damaging fertility

### 2.2 Self classification

- In the registration

The registrant has given the harmonised classification in Annex VI, but selfclassified the Acute Tox 4\* to Acute Tox 3 based on compound specific data:

Acute Tox. 3; H301: Toxic if swallowed

Acute Tox. 3, H311: Toxic in contact with skin

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

Eye Dam. 1; H318: Causes serious eye damage

Aquatic Chronic 3; H412: Harmful to aquatic life with long lasting effects

Flam. Liq. 2; H225: Highly flammable liquid and vapour

Met. Corr. 1; H290: May be corrosive to metals

Skin Irrit. 2; H315: Causes skin irritation

### 2.3 Proposal for Harmonised Classification in Annex VI of the CLP

NA

### 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 checked="" 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 type="checkbox"/> <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential	
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
<u>Industrial uses:</u> Manufacture of substances Use for formulation of preparations Use as intermediate in chemical synthesis Formulations containing the substance as a water treatment chemical Formulations containing the substance as cutting oil Laboratory chemical Corrosion inhibitor  <u>Professional uses:</u> Use of formulations containing the substance as cutting oil Laboratory chemical Formulations containing the substance as water treatment chemical			

### 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 checked="" type="checkbox"/> R	Suspected CMR <sup>1</sup> <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	Suspected Sensitiser <sup>1</sup>	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB <sup>1</sup>	<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 checked="" type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p>Toxicity for reproduction : classified Repr. Category 2 but there is limited information on the studies. It is said that there are negative observed effects as increase incidence of testicular atrophy, retardation of offspring development, reduced litter size. Some further information would be needed to clarify the concern and to check whether a more severe classification would be appropriate.</p>		

### 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 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)	
Information on other completed/ongoing regulatory processes was not found.	

<sup>1</sup> 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 checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input checked="" type="checkbox"/> Other (provide further details below)

Toxicity for reproduction :

Studies in rats and mice with insufficient documentation that are of limited validity and therefore do not allow final evaluation.

⇒ Need for more information on the tests and the results of the studies

Some additional studies might be needed to clarify the reprotoxic properties of the substance.

In general, there are many studies with limited validity present in the dossier.

#### 4.6 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
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Depending on the outcome of the evaluation any of the above mentioned risk management measures could be initiated if warranted.