Justification for the selection of a candidate CoRAP substance

Substance Name (Public name):	2-aminoethanol
EC Number:	205-483-3
CAS Number:	141-43-5
Submitted by:	Bureau for Chemical Substances, Poland
Published:	20/03/2013

NOTE

This document has been prepared by Poland CA but the evaluating Member State was changed to United Kingdom in the CoRAP update for 2014-2016.

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1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	205-483-3
EC name:	2-aminoethanol
CAS number (in the EC inventory):	141-43-5
CAS number:	141-43-5
CAS name:	
IUPAC name:	2-aminoethanol
Index number in Annex VI of the CLP Regulation	603-030-00-8
Molecular formula:	C2H7NO
Molecular weight or molecular weight range:	61,08 g/mol
Synonyms:	Ethanol, 2-amino- ; ethanolamine

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

Structural formula:

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Classification according to part 3 of Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008:

Classification		Labelling		Specific Conc. Limits, M-factors	Notes
Hazard Class and Category Code(s)	**Hazard statement Code(s)**	**Pictogram, Signal Word Code(s)**	**Hazard statement Code(s)**		
Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * Skin Corr. 1B	H332 H312 H302 H314	GHS05 GHS07 Dgr	H332 H312 H302 H314	STOT SE 3; H335: C ≥ 5 %	

H332: Harmful if inhaled.

H312: Harmful in contact with skin.

H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

Classification according to part 3 of Annex VI, Table 3.2 (list of harmonized classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008:

Classification	Labelling	Concentration Limits	Notes
Xn; R20/21/22 C; R34	C R: 20/21/22-34 S: (1/2-)26-36/37/39-45	C; R34: C ≥ 10 % Xi; R36/37/38: 5 % ≤ C < 10 %	

R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.

R34: Causes burns.

R36/37/38 Irritating to eyes, respiratory system and skin.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None proposed.

2.3 Self-classification

The registrants follow the harmonised classification in section 2.1 and in addition include the following self classifications:

STOT Single Exp. 3; H335: May cause respiratory irritation.

Aquatic Acute 2; H401: Toxic to aquatic life.

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

In addition to the harmonised and self classifications given above, is the following classification(s) notified to the Classification and Labelling Inventory:

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

Carc. 1B; H350: May cause cancer.

Acute Tox. 3; H301: Toxic if swallowed.

Eye Dam. 1; H318: Causes serious eye damage.

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

Aquatic Acute 1; H400: Very toxic to aquatic life.

The following Supplementary Hazard Statement is also given by a group of notifiers:

EUH071: corrosive to the respiratory tract

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 was selected due to its hazard potential (respiratory sensitizer), exposure profile (used in personal care products) and tonnage.

2-Aminoethanol has a large production volume, widespread use in manufacturing with high exposure for workers, wide dispersive use with high release for environment and is in consumer goods. The substance is toxic by every (oral, dermal, inhalation) route. There is insufficient information regarding the carcinogenicity of 2-aminoethanol.
The substance is identified in the list of agent causing occupational asthma from the CSST (Commission de la santé et de la sécurité du travail) (updated April 2010).

2-Aminoethanol is potential persistent, respiratory sensitizer and neurotoxic substance.

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	
☐ <1 . . . . . >+ tpa	☐ Confidential	

Please provide further details if appropriate

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

2-Aminoethanol is used as feedstock in the production of detergents, emulsifiers, polishes, pharmaceuticals, corrosion inhibitors, chemical intermediates.
The identified uses of the substance are wide-dispersive industrial use (e.g. in manufacture of substances, in formulation of preparations, as laboratory reagent, as ph-regulators, flocculants, precipitants, neutralisation agents, metal working fluids), professional use (e.g. lubricants, greases, release products, washing and cleaning products and as laboratory reagent) and consumer use (e.g. Washing and cleaning products (including solvent based products), cosmetics, personal care products, biocidal products).

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 substance is identified in the list of agent causing occupational asthma from the CSST (Commission de la santé et de la sécurité du travail) (updated April 2010).

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)	

Detailed evaluation of the available data may lead to further information requirements.

Information related to the identified uses and exposure scenarios as well as information needed to refine exposure assessment and risk management measures.

3.6 Potential follow-up and link to risk management

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

Depending on outcome of the substance evaluation.
A potential follow up action of the evaluation will be refinement of the RCR and in consequence risk management measures to limit exposure.