

Substance Name: Formamide

EC Number: 200-842-0

CAS Number: 75-12-7

SUPPORT DOCUMENT FOR IDENTIFICATION OF

FORMAMIDE

**AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS
CMR¹ PROPERTIES**

¹ CMR means carcinogenic, mutagenic or toxic for reproduction.

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Substance Name(s): Formamide

EC Number(s): 200-842-0

CAS number(s): 75-12-7

The substance is identified as substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction category 1 B².

It is proposed to identify the substance(s) as substance(s) of equivalent concern according to Article 57 (c).

Summary of how the substance meets the criteria as category 1B reproductive toxicant.

Formamide is covered by Index number 616-052-00-8 of Regulation (EC) No 1272/2008 in Annex VI, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as toxic for reproduction, Repr. 1B (H360D: "May damage the unborn child."). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is toxic for reproduction, Repr. Cat. 2 (R61;" May cause harm to the unborn child").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance? Yes

² Classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances.

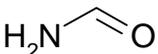
JUSTIFICATION

1 Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	200-842-0
EC name:	Formamide
CAS number (in the EC inventory):	75-12-7
CAS number:	-
CAS name:	Formamide
IUPAC name:	Formamide
Index number in Annex VI of the CLP Regulation	616-052-00-8
Molecular formula:	CH ₃ NO
Molecular weight range:	45.0406 g/mol
Synonyms:	

Structural formula: 

1.2 Composition of the substance

Name: Formamide

Description: mono constituent substance

Degree of purity: $\geq 99.5\%$ ³ (w/w)

Further details on the composition of the substance are confidential and can be found in the technical dossier.

³ Based on the minimum typical content indicated in the registration dossiers (downloaded on 28/02/2010).

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
<i>Formamide,</i> EC number: 200-842-0	>= 99.5%³ (w/w)		

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks
<i>Confidential information</i>			

Table 4: Additives

Additives	Typical concentration	Concentration range	Remarks
<i>Confidential information</i>			

1.3 Physicochemical properties

The physico-chemical properties were taken from the lead registration dossier for formamide (as available on 28/02/2010).

Table 5: Overview of physicochemical properties

Property	Value	Remarks	Reference
Physical state at 20°C and 101.3 kPa	Slightly viscous colourless and odourless liquid		<i>Kirk-Othmer, 1994, Encyclopedia of Chemical Technology, 4th edition, Vol. 11., John Wiley & Sons, New York, USA</i>
Melting/freezing point	2.6°C (275.6 K)		<i>US EPA 2005, EPISuite (v3.12) data assessment, Estimation Programs Interface Suite,™. for Microsoft® Windows, v 3.12. United States Environmental Protection Agency, Washington, DC, USA.</i>
Boiling point	218.3 °C, 1013.3hPa (decomposition starts above 140 °C)	<i>Extrapolated, (decomposition starts above 140 °C)</i>	<i>Körösi G and Kováts E sz. 1981, Density and Surface Tension of 83 Organic Liquids, J. Chem. Eng. Data 26, 323-332</i>
Vapour pressure	0.06 hPa at 20 °C		<i>BASF AG, 1984, BASF AG, ZET/FC, Study-No.: 184.0631.1</i>
Water solubility	1E06 mg/L at 25 °C	<i>EPISuite v3.12 (WSKOW v1.41)</i>	<i>US EPA 2005, EPISuite (v3.12) data assessment, Estimation Programs Interface Suite,™. for Microsoft® Windows, v 3.12. United States Environmental Protection Agency, Washington, DC, USA.</i>
Partition coefficient n-octanol/water (log value)	-0.82 at 25°C		<i>BASF AG, 1984, Determination of Log Pow from Formamid in 1-octanol/water at roomtemperature (25°C), Department of Analytical Chemistry, Report No.: 130365/02</i>
Dissociation constant	pK _a at 20/25°C: -0.48		<i>Kirk-Othmer, 1994, Encyclopedia of Chemical Technology, 4th edition, Vol. 11., John Wiley & Sons, New York, USA</i>
Surface tension	57.46 mN/m at 20°C Based on the chemical structure, no surface activity is expected.	<i>The value is given in the registration dossier for pure Formamide. Furthermore the endpoint can be waived.</i>	<i>Körösi G and Kováts E sz. 1981, Density and Surface Tension of 83 Organic Liquids, J. Chem. Eng. Data 26, 323-332</i>

Viscosity	3.764 mPa s at 20 °C		<i>Kirk-Othmer, 1994, Encyclopedia of Chemical Technology, 4th edition, Vol. 11., John Wiley & Sons, New York, USA</i>
Density	1.13 g/cm ³ at 20 °C		<i>Körösi G and Kováts E sz. 1981, Density and Surface Tension of 83 Organic Liquids, J. Chem. Eng. Data 26, 323-332</i>
Flash point	152 °C at 1013 hPa		<i>BASF AG, 2007, Determination of the flashpoint of formamide, GCT/S - Safety Engineering, Report No. SIK-No. 07/1202</i>
Auto flammability	> 500 °C		<i>Kirk-Othmer, 1994, Encyclopedia of Chemical Technology, 4th edition, Vol. 11., John Wiley & Sons, New York, USA</i>
Flammability	Not flammable; based on the molecular structure and experience in use formamide has no pyrophoric properties; it does not react with water under formation of flammable gases.		
Explosiveness:	Not oxidising; due to the structural composition of the substance it is not considered to be oxidising.		
Stability in organic solvents and identity of relevant degradation products:	In accordance with column 1 of Annex IX, the study does not need to be conducted if the stability of the substance is considered to be critical. Formamide is not considered as critical.		

2 Harmonised classification and labelling

Formamide is covered by Index number 616-052-00-8 of Regulation (EC) No 1272/2008 in Annex VI, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as follows:

Table 6: Classification according to Annex VI, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	Classification		Labelling		
		Hazard Class and Category Code	Hazard statement Code	Pictogram, Signal Word Code	Hazard statement Code	Suppl. Hazard statement Code(s)
616-052-00-8	formamide	Repr. 1B	H360D***	GHS08 Dgr	H360D***	

Hazard statement code: H360D⁴ : May damage the unborn child.

Formamide is covered by Index number 616-052-00-8 of Regulation (EC) No 1272/2008 in Annex VI, Part 3, Table 3.2 (list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) as follows:

Table 7: Classification according to Annex VI, Part 3, Table 3.2 (list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008

Index No	Chemical name	Classification	Labelling
616-052-00-8	formamide	Repr.Cat. 2; R61	T R: 61 S: 53-45

⁴ Hazard statements H360 and H361 indicate a general concern for effects on both fertility and development: 'May damage/Suspected of damaging fertility or the unborn child'. According to the criteria, the general hazard statement can be replaced by the hazard statement indicating only the property of concern, where either fertility or developmental effects are proven to be not relevant.

In order not to lose information from the harmonised classifications for fertility and developmental effects under Directive 67/548/EEC, the classifications have been translated only for those effects classified under that Directive.

3 Environmental fate properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c).

4 Human health hazard assessment

See section 2 on Harmonised Classification and Labelling.

5 Environmental hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c).

6 Conclusions on the SVHC Properties

6.1 PBT, vPvB assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c).

6.2 CMR assessment

Formamide is covered by Index number 616-052-00-8 of Regulation (EC) No 1272/2008 and classified in Annex VI, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as toxic for reproduction, Repr. 1B (H360D: "May damage the unborn child."). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is toxic for reproduction, Repr. Cat. 2 (R61;" May cause harm to the unborn child").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

6.3 Substances of equivalent level of concern assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c).

7 References

REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=oj:l:2006:396:0001:0849:en:pdf>

EU 2008: Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF>