

Substance Name: N,N-dimethylformamide

EC Number: 200-679-5

CAS Number: 68-12-2

MEMBER STATE COMMITTEE

SUPPORT DOCUMENT FOR IDENTIFICATION OF

N, N-DIMETHYLFORMAMIDE

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

Adopted on 29 November 2012

¹ CMR means carcinogenic, mutagenic or toxic for reproduction

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Substance Name(s): N,N-dimethylformamide

EC Number(s): 200-679-5 CAS number(s): 68-12-2

N,N-dimethylformamide is identified as substance meeting the criterion of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction category $1B^2$ which corresponds to classification as toxic for reproduction category 2^3 .

Summary of how the substance meets the CMR (Cat 1A or 1B) criteria

N,N-dimethylformamide (DMF) has been classified as toxic to reproduction (Repr. 1B); H360D "May damage the unborn child" according to Regulation (EC) No 1272/2008 (CLP Regulation) and is included in Annex VI, part 3 (index number 616-001-00-X), Table 3.1 (list of harmonised classification and labelling of hazardous substances). 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) is toxic to reproduction Repr Cat. 2; R61 ("May cause harm to the unborn child.").

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

Registration dossiers submitted for the substance: Yes

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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, OJ L 353, p.1, 31.12.2008

³ Classification in accordance with Regulation (EC) No 1272/2008, Annex VI, part 3, Table 3.2 List of harmonised classification and labelling of hazardous substances (from Annex I to Council Directive 67/548/EEC), OJ L 353, p.1, 31.12.2008

Justification

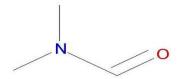
1 Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	200-679-5
EC name:	N,N-dimethylformamide
CAS number (in the EC inventory):	68-12-2
CAS number:	68-12-2
	(deleted CAS registry numbers: 15175-63-0, 15175-77-6, 33513-42-7 and 114057-15-7)
CAS name:	Formamide, N,N-dimethyl-
IUPAC name:	N,N-dimethylformamide
Index number in Annex VI of the CLP Regulation	616-001-00-X
Molecular formula:	C ₃ H ₇ NO
Molecular weight range:	73.0938
Synonyms:	Dimethylformamide
	DMF
	N,N-Dimethylformamide
	Formamide, N,N-dimethyl- (8CI, 9CI)
	DMFA
	N-Formyldimethylamine
	N,N-Dimethylmethanamide
	DMF (amide)

Structural formula:



1.2 Composition of the substance

Name: N,N-dimethylformamide

Description: monoconstituent substance

Degree of purity: \geq 99.9 - < 100.0 % (w/w) (according to the information received in the

registration dossier)

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
N,N-dimethylformamide EC no.: 200-679-5	99.99 % (w/w)	≥ 99.9 - < 100.0 % (w/w)	According to the information received in the registration dossiers.

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks
Information not relevant			Data from the registration dossiers are provided in the confidential Annex 2 of this report.

Table 4: Additives

Additives	Typical concentration	Concentration range	Remarks
None			According to the information received in the registration dossiers

1.3 Physico-chemical properties

Table 5: Overview of physicochemical properties (as reported in the lead registration dossier)

Property	Value	Remarks
Physical state at 20°C and 101.3 kPa	Colorless - yellowish liquid with a faint specific, amine - like odour. The substance origin is organic.	Value used for CSA: liquid
Melting/freezing point	-61°C	Value used for CSA: -61 °C at 1013 hPa
Boiling point	152-153°C at 1013 hPa.	Value used for CSA: 152 °C at 1013 hPa
Vapour pressure	3.77 hPa at 20°C	Value used for CSA: 3.77 hPa at 20 °C
Water solubility	"miscible"	Value used for CSA: 1000 g/L at 20 °C
Partition coefficient n- octanol/water (log value)	-0.85 at 25°C	Value used for CSA: Log Kow (Pow): -0.85 at 25 °C
Dissociation constant	-0.3	Value used for CSA: pKa at 20°C: -0.3

2 Harmonised classification and labelling

N,N-dimethylformamide is listed by Index number 616-001-00-X of Regulation (EC) No 1272/2008 in Annex VI, Part 3, as follows:

Table 6: Harmonised Classification of DMF 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.

INTERNATIONAL CHEMICAL IDENTIFICATION	EC NO	CAS NO	CLASSIFICATION		LABELLING			SPEC. CONC. LIMITS, M- FACTORS
			HAZARD CLASS AND CATEGORY CODE(S)	HAZARD STATEME NT CODE(S)	PICTOGRAM, SIGNAL WORD CODE(S)	HAZARD STATEMENT CODE(S)	SUPPL. HAZARD STATEMENT CODE(S)	
N,N- dimethylformamide; dimethyl formamide	200-679-5		Acute Tox. 4 * Acute Tox. 4 *	H332		H360D *** H332 H312 H319		

^{*)} For certain hazard classes, including acute toxicity and STOT repeated exposure, the classification according to the criteria in Directive 67/548/EEC does not correspond directly to the classification in a hazard class and category under this Regulation. In these cases the classification in this Annex shall be considered as a minimum classification.

***) 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.

Table 7: Harmonised Classification of DMF 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.

International Chemical Identification	EC No	CAS No	Classification	LABELLING	SPEC. CONC. LIMITS	NOTES
N,N- dimethylformamide; dimethyl formamide		68-12-2	Repr. Cat. 2; R61 Xn; R20/21 Xi; R36	T R: 61-20/21-36 S: 53-45		E
			,			

E) Substances with specific effects on human health (see Chapter 4 of Annex VI to Directive 67/548/EEC) that are classified as carcinogenic, mutagenic and/or toxic for reproduction in categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn). For these substances, the risk phrases R20, R21, R22, R23, R24, R25, R26, R27, R28, R39, R68 (harmful), R48 and R65 and all combinations of these risk phrases shall be preceded by the word "Also".

3 Environmental fate properties

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

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 57c.

6 Conclusions on the SVHC Properties

6.1 CMR assessment

N,N-dimethylformamide (DMF) has been classified as toxic to reproduction (Repr. 1B); H360D "May damage the unborn child" according to Regulation (EC) No 1272/2008 (CLP Regulation) and is included in Annex VI, part 3 (index number 616-001-00-X), Table 3.1 (list of harmonised classification and labelling of hazardous substances). 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) is toxic to reproduction Repr Cat. 2; R61 ("May cause harm to the unborn child.").

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