

Substance name: N,N-Dimethylacetamide (DMAC) EC number: 204-826-4 CAS number: 127-19-5

MEMBER STATE COMMITTEE SUPPORT DOCUMENT FOR IDENTIFICATION OF

N,N-DIMETHYLACETAMIDE (DMAC)

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

Adopted on 24 November 2011

¹ CMR means carcinogenic, mutagenic or toxic for reproduction

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Substance Name(s): N,N-Dimethylacetamide (DMAC)

EC Number(s): 204-826-4

CAS Number(s): 127-19-5

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 1B under Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 as well as its corresponding classification under Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 as toxic for reproduction category 2.

Summary of how the substance meets the toxic for reproduction 1B criteria

N,N-Dimethylacetamide is listed as index number 616-011-00-4 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the 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 N,N-dimethylacetamide 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

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:	204-826-4
EC name:	N,N-dimethylacetamide
CAS number (in the EC inventory):	127-19-5
CAS number:	127-19-5
CAS name:	Acetamide, N,N-dimethyl-
IUPAC name:	N,N-Dimethylacetamide
Index number in Annex VI of the CLP Regulation	616-011-00-4
Molecular formula:	C ₄ H ₉ N O
Molecular weight:	87.1 g/mol
Synonyms:	Acetdimethylamide
	DMA
	DMAA
	DMAc
	Dimethylamide acetate
	N,N-Dimethylethanamide

Structural formula:

H₃C-N CH

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1.2 Composition of the substance

Name: N,N-Dimethylacetamide

Description: ---

Degree of purity: 99 – 100 % (according to the information received in the registration dossiers)

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
N,N-Dimethylacetamide EC number 204-826-4		99 – 100 %	According to the information received in the registration dossiers

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks	
Information not relevant			Data confidential	

Table 4: Additives

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

1.3 Physico-chemical properties

Property	Value	Remarks	Reference	
Physical state at 20°C and <i>liquid</i> 101.3 kPa		Discussion and the value used for Chemical Safety Assessment (CSA) reported in the endpoint summary	Bornscheuer, U.; Roempp; Georg Thieme Verlag KG; 2008	
Melting/freezing point	-20 °C	idem	Bornscheuer, U.; Roempp; Georg Thieme Verlag KG; 2008	
Boiling point 163 – 165 °C at 760 T		idem	O'Neil, Maryadele J.; The Merck Index; Merck & Co Inc.; Whitehouse Station, NJ, USA; 14th Edition; 2006	
Relative Density	0.9429 at 20 °C		O'Neil, Maryadele J.; The Merck Index; Merck & Co Inc.; Whitehouse Station, NJ, USA; 14th Edition; 2006	
Vapour pressure (p)	100 Pa at 28 °C	idem	Lide, Dacid R.; Handbook of Chemistry and Physics; CRC Press; Boca Raton, London, New York; 88th Edition; 2007-2008	
Water solubility	> 1000 g/l at 20 °C	idem	BASF AG; Dampfdruck, Explosionspunkte, Wassermischbarkeit, Flammpunkt nach DIN EN 22719, Zündtemperatur; Department of safety engineering; 2001	
Partition coefficient n- octanol/water (logP value)	-0.77 at 25 °C	idem	Lide, Dacid R.; Handbook of Chemistry and Physics; CRC Press; Boca Raton, London, New York; 88th Edition; 2007-2008	

Table 5: Overview of physicochemical properties

2 HARMONISED CLASSIFICATION AND LABELLING

N,N-Dimethylacetamide (DMAC) is listed as index number 616-011-00-4 in Annex VI, part 3 of Regulation (EC) No 1272/2008 as follows:

Table 6: 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

International EC No		CAS No	Classification		Labelling				Note
Chemical Identification			Hazard Class and Category Code(s)	Hazard state-ment code(s)	am, Signal	Hazard state- ment code(s)	Suppl. Hazard statement code(s)	Limits, M-factors	S
N,N- Dimethylacetamide	204-826-4	5	Repr. 1B Acute Tox. 4* Acute Tox. 4*	H360D*** H332 H312	GHS08 GHS07 Dgr	H360D* ** H332 H312		Repr. 1B; H360D: C ≥ 5%	

* Indicates that the classification corresponds to the minimum classification for a category

*** 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: 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

International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
N,N-Dimethylacetamide	204-826-4	127-19-5	,	T R: 61-20/21 S: 53-45	Repr. Cat. 2: R61: $C \ge 5\%$	E

Note 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 57(c).

4 HUMAN HEALTH HAZARD ASSESSMENT

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

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

N,N-Dimethylacetamide is listed as index number 616-011-00-4 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) as toxic for reproduction category 1B (H360D: "May damage the unborn child"). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised and classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is toxic for reproduction category 2 (R61: "May cause harm to the unborn child").

Therefore, this classification of N,N-dimethylacetamide 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**

BASF AG; Dampfdruck, Explosionspunkte, Wassermischbarkeit, Flammpunkt nach DIN EN 22719, Zündtemperatur; Department of safety engineering; 2001

Bornscheuer, U.; Roempp; Georg Thieme Verlag KG; 2008

O'Neil, Maryadele J.; The Merck Index; Merck & Co Inc.; Whitehouse Station, NJ, USA; 14th Edition; 2006

Lide, Dacid R.; Handbook of Chemistry and Physics; CRC Press; Boca Raton, London, New York; 88th Edition; 2007-2008

EU, 2006. 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. Official Journal of the European Union, L396: 1-849.

EU, 2007. Corrigendum to 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. Official Journal of the European Union, L136: 3-280.

EU, 2008. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packing of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L353: 1-1355.