



Substance name: 1-methyl-2-pyrrolidone
EC number: 212-828-1
CAS number: 872-50-4

**MEMBER STATE COMMITTEE
SUPPORT DOCUMENT FOR IDENTIFICATION OF**

1-METHYL-2-PYRROLIDONE

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

Adopted on 20 May 2011

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LIST OF ABBREVIATIONS

CAS	Chemical Abstracts Service
CLH	Harmonised Classification and Labelling
CSR	Chemical Safety Report
CMR	Carcinogenic, mutagenic or toxic for reproduction
ECHA	European Chemicals Agency
EU	European Union
MSCA	Member State Competent Authority
NMP	N-Methyl Pyrrolidone
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation and Authorisation of Chemicals
vPvB	Very Persistent and very Bioaccumulative

Substance Name: 1-methyl-2-pyrrolidone

EC Number: 212-828-1

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- 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 B¹ which corresponds to classifications as toxic for reproduction category 2².

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

N-methyl-2-pyrrolidone is listed as entry 606-021-00-7 of Regulation (EC) No 1272/2008 as amended and adapted to technical and scientific progress by Regulation (EC) No 790/2009, as of 1 December 2010 and classified 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 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 the substance in Regulation (EC) No 1272/2008 as amended and adapted to technical and scientific progress by Regulation (EC) No 790/2009 shows that the substance meets the criteria for classification as toxic for reproduction, in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance? Yes

¹ 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 as amended and adapted to technical and scientific progress by Regulation (EC) No 790/2009.

² 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) as amended and adapted to technical and scientific progress by Regulation (EC) No 790/2009.

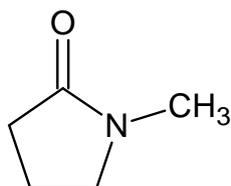
JUSTIFICATION

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:	212-828-1
EC name:	1-methyl-2-pyrrolidone
CAS number (in the EC inventory):	872-50-4
CAS number:	872-50-4
Deleted CAS numbers:	53774-35-9, 57762-46-6, 26138-58-9
CAS name:	2-Pyrrolidinone, 1-methyl-
IUPAC name:	1-Methylpyrrolidin-2-one
Index number in Annex VI of the CLP Regulation	606-021-00-7
Molecular formula:	C ₅ H ₉ NO
Molecular weight range:	99 g/mol
Synonyms:	1-Methyl-2-pyrrolidinone 1-Methyl-5-pyrrolidinone 1-Methylazacyclopentan-2-one 1-Methylpyrrolidone AgsolEx 1 M-Pyrol Microposit 2001 N 0131 N-Methyl- α -pyrrolidinone N-Methyl- α -pyrrolidone N-Methyl- γ -butyrolactam N-Methyl-2-ketopyrrolidine N-Methyl-2-pyrrolidinone N-Methyl-2-pyrrolidone N-Methylbutyrolactam N-Methylpyrrolidone NMP NSC 4594 Pharmasolve Pyrol M SL 1332

Structural formula:**1.2 Composition of the substance****Name:** 1-methyl-2-pyrrolidone**Description:** ---**Degree of purity:** ≥ 80 - ≤ 100 %**Table 2: Constituents**

Constituents	Typical concentration	Concentration range	Remarks
1-Methylpyrrolidin-2-one		≥ 80 - ≤ 100 %	

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks
Information not relevant			

Table 4: Additives

Additives	Typical concentration	Concentration range	Remarks
None			

1.3 Physicochemical properties

Table 5: Overview of physicochemical properties³

Property	Value	Remarks
Physical state at 20°C and 101.3 kPa	Liquid, colourless with ammonia-like odour	Harreus (2005)
Melting/freezing point	-24.4 °C	Harreus (2005)
Boiling point	204.3 °C at 101.3 kPa	Harreus (2005)
Vapour pressure	0.04 kPa at 25 °C	Lide (1994)
Density	1.028 g/cm ³ at 25 °C	Harreus (2005)
Water solubility	completely miscible with water	Harreus (2005)
Partition coefficient n-octanol/water (log value)	-0.54 at 25 °C	ECHA (2011) Domanska and Lachwa (2002)
Surface tension	52.9 mN/m at 25 °C and 0.1 vol. % 50.1 mN/m at 50 °C and 0.1 vol. % 50.8 mN/m at 25 °C and 1 vol. % 48.0 mN/m at 50 °C and 1 vol. % 48.3 mN/m at 25 °C and 10 vol. % 44.6 mN/m at 50 °C and 10 vol. %	García-Abuín et al. (2008)
pH value	7.7 – 8 Concentration: 10 % aqueous solution	Harreus (2005)
Viscosity	1.796 mPa s at 20 °C	Harreus (2005)
Refractive index	1.469 at 25 °C	Harreus (2005)
Flash point	91 °C (DIN 51758)	Harreus (2005)
Auto-Ignition Temperature	245 °C (DIN 51794)	Harreus (2005)

³ The references of the values reported in Table 5 are available in the technical dossier.

2 HARMONISED CLASSIFICATION AND LABELLING

Pursuant to the first ATP to Regulation (EC) No 1272/2008 (Commission Regulation (EC) No 790/2009) as of 1 December 2010, 1-methyl-2-pyrrolidone is listed with index number 606-021-00-7 in Annex VI, part 3 of Regulation (EC) No 1272/2008 (list of harmonised classification and labelling of hazardous substances) with the following classification:

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

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
606-021-00-7	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	212-828-1	872-50-4	Repr. 1B Eye Irrit. 2 STOT SE 3 Skin Irrit. 2	H360D*** H319 H335 H315	GHS08 GHS07 Dgr	H360D*** H319 H335 H315		Repr. 1B; H360D: C ≥ 5 % STOT SE 3; H335: C ≥ 10 %	

Repr. 1B, H360D***⁴ May damage the unborn child.
 Eye Irrit. 2 H319 Causes serious eye irritation.
 Skin Irrit. 2 H315 Causes skin irritation.
 STOT Single Exp. 3 H335 May cause respiratory irritation.

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
606-021-00-7	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	212-828-1	872-50-4	Repr. Cat. 2; R61 Xi; R36/37/38	T R: 61-36/37/38 S: 53-45	Repr. Cat. 2; R61: C ≥ 5 % Xi; R36/37/38: C ≥ 10 %	

Repr. Cat. 2; R61 May cause harm to the unborn child.
 Xi - R36/37/38 Irritating to eyes, respiratory system and skin.

⁴ According to Annex VI (Part 1, entry 1.2.3): H360 and H361 indicate a general concern for effects on both fertility and development: 'May damage/Suspected 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. These hazards statements are indicated by reference *** in Table 3.1.

3 CONCLUSIONS ON THE SVHC PROPERTIES

3.1 PBT, vPvB assessment

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

3.2 CMR assessment

Pursuant to Regulation (EC) No 1272/2008 as amended and adapted to technical and scientific progress by Regulation (EC) No 790/2009, as of 1 December 2010, N-methyl-2-pyrrolidone is listed as entry 606-021-00-7 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as toxic for reproduction category 1B¹. Its 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 category 2².

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

3.3 Substances of equivalent level of concern assessment

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

4 REFERENCES

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