

Annex XV dossier

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR 1A OR 1B, PBT, vPvB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance Name: N-Methylacetamide

EC Number: 201-182-6

CAS Number: 79-16-3

Submitted by: European Chemicals Agency at the request of the European Commission

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- The substance is proposed to be identified as substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction 1B¹ which corresponds to classification as toxic for reproduction category 2².

Summary of how the substance meets the criteria set out in Article 57 (c) of REACH (Repr. 1B).

N-methylacetamide is listed as Index number 616-053-00-3 in 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 N-methylacetamide 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.

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.

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).

PART I

JUSTIFICATION

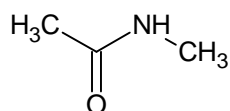
1 Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	201-182-6
EC name:	N-methylacetamide
CAS number (in the EC inventory):	79-16-3
CAS number: Deleted CAS numbers:	79-16-3 1320-47-4
CAS name:	Acetamide, N-methyl-
IUPAC name:	N-Methylacetamide
Index number in Annex VI of the CLP Regulation	616-053-00-3
Molecular formula:	C ₃ H ₇ NO
Molecular weight range:	73.1 g/mol
Synonyms:	Monomethylacetamide Methylacetamide

Structural formula:



1.2 Composition of the substance

Name: N-Methylacetamide

Description: ---

Degree of purity: 99.9 - 100 %

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
N-Methylacetamide 201-182-6		99.9 - 100 %	According to the information available in the registration dossiers

2 Harmonised classification and labelling

N-methylacetamide is listed as Index number 616-053-00-3 in Annex VI, part 3 of Regulation (EC) No 1272/2008 as follows:

Table 3: 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)		
616-053-00-3	N-methylacetamide	201-182-6	79-16-3	Repr. 1B	H360D ***	GHS08 Dgr	H360D ***			

Table 4: 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
616-053-00-3	N-methylacetamide	201-182-6	79-16-3	Repr. Cat. 2; R61	T R: 61 S: 53-45		

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 CMR assessment

N-methylacetamide is listed as Index number 616-053-00-3 in 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 N-methylacetamide 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.

PART II

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

The available use and exposure information is provided in the registration dossiers (authorities with access rights only) or on ECHA's dissemination website³:

<http://echa.europa.eu/information-on-chemicals>

ECHA has not carried out further analysis of this information.

³ Information published by ECHA on the substance can be searched at this site (field "Search for Chemicals" at upper right) by EC number, CAS number or substance name.