

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: 4,4'-Methylenedi-o-toluidine

EC Number: 212-658-8

CAS Number: 838-88-0

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 (a) of Regulation (EC) 1907/2006 (REACH) owing to its classification as carcinogen 1B¹ which corresponds to classification as carcinogen category 2².

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

4,4'-Methylenedi-o-toluidine is listed by Index number 612-085-00-7 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 carcinogen, Carc. 1B (H350: "May cause cancer"). 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 carcinogen, Carc. Cat. 2; R45 ("May cause cancer").

Therefore, this classification of 4,4'-methylenedi-o-toluidine in Regulation (EC) No 1272/2008 shows that the substance meets the criteria for classification as carcinogenic in accordance with Article 57 (a) 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

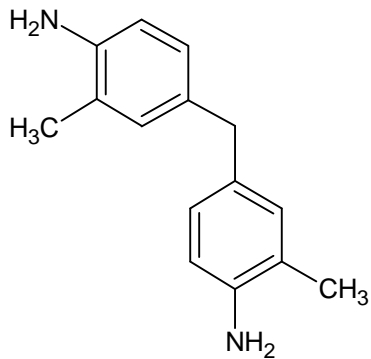
JUSTIFICATION

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:	212-658-8
EC name:	4,4'-Methylenedi-o-toluidine
CAS number (in the EC inventory):	838-88-0
CAS number: Deleted CAS numbers:	838-88-0 54649-88-6
CAS name:	Benzenamine, 4,4'-methylenebis[2-methyl-
IUPAC name:	4,4'-Methanediylbis(2-methylaniline)
Index number in Annex VI of the CLP Regulation	612-085-00-7
Molecular formula:	C ₁₅ H ₁₈ N ₂
Molecular weight range:	226.3 g/mol
Synonyms:	Toluidine, 4,4'-methylenedi-; 2,2'-Dimethyl-4,4'-methylenedianiline; 3,3'-Dimethyl-4,4'-diaminodiphenylmethane; 4,4'-Amino-3,3'-dimethyldiphenylmethane; 4,4'-Diamino-3,3'-dimethyldiphenylmethane; 4,4'-Methylenebis(o-toluidine); 4,4'-Methylenebis[2-methylaniline]; 4,4'-Methylenedi-o-toluidine; Bis(3-methyl-4-aminophenyl)methane; Bis(4-amino-3-methylphenyl)methane; Di(3-methyl-4-aminophenyl)methane

Structural formula:**1.2 Composition of the substance****Name:** 4,4'-Methylenedi-o-toluidine**Description:** ---**Degree of purity:** 95 - 100 5**Table 2: Constituents**

Constituents	Typical concentration	Concentration range	Remarks
4,4'-Methylenedi-o-toluidine 212-658-8		95 - 100 %	According to the information available in the registration dossier

2 Harmonised classification and labelling

4,4'-Methylenedi-o-toluidine is listed by Index number 612-085-00-7 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)		
612-085-00-7	4,4'-methylenedi-o-toluidine	212-658-8	838-88-0	Carc. 1B Acute Tox. 4 * Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350 H302 H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H350 H302 H317 H410		-	

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
612-085-00-7	4,4'-methylenedi-o-toluidine	212-658-8	838-88-0	Carc. Cat. 2; R45 Xn; R22 R43 N; R50-53	T; N R: 45-22-43-50/53 S: 53-45-60-61	-	E

3 Environmental fate properties

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

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 57a.

6 Conclusions on the SVHC Properties

6.1 CMR assessment

4,4'-Methylenedi-o-toluidine is listed by Index number 612-085-00-7 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 carcinogen, Carc. 1B (H350: "May cause cancer"). 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 carcinogen, Carc. Cat. 2; R45 ("May cause cancer").

Therefore, this classification of 4,4'-methylenedi-o-toluidine in Regulation (EC) No 1272/2008 shows that the substance meets the criteria for classification as carcinogenic in accordance with Article 57 (a) 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.