

Substance Name: 4,4'-methylenedi-*o*-toluidine

EC Number: 212-658-8

CAS Number: 838-88-0

SUPPORT DOCUMENT FOR IDENTIFICATION OF

4,4'-METHYLENEDI-O-TOLUIDINE

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

¹ CMR means carcinogenic, mutagenic or toxic for reproduction

CONTENTS

1	IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES	5
1.1	NAME AND OTHER IDENTIFIERS OF THE SUBSTANCE	5
1.2	COMPOSITION OF THE SUBSTANCE	6
2	HARMONISED CLASSIFICATION AND LABELLING	7
3	ENVIRONMENTAL FATE PROPERTIES	8
4	HUMAN HEALTH HAZARD ASSESSMENT	8
5	ENVIRONMENTAL HAZARD ASSESSMENT	8
6	CONCLUSIONS ON THE SVHC PROPERTIES	8
6.1	CMR ASSESSMENT	8

TABLES

Table 1: Substance identity	5
Table 2: Constituents	6
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	7
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	7

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The substance is identified as substance meeting the criteria of Article 57 (a) of Regulation (EC) 1907/2006 (REACH) owing to its classification as carcinogen 1B² which corresponds to classification as carcinogen category 2³.

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

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.

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).

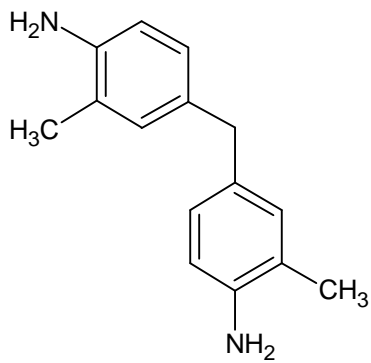
JUSTIFICATION

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- <i>o</i> -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(<i>o</i> -toluidine); 4,4'-Methylenebis[2-methylaniline]; 4,4'-Methylenedi- <i>o</i> -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 %

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
4,4'-methylenedi- <i>o</i> -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- <i>o</i> -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- <i>o</i> -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").

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