

## **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:** 6-Methoxy-m-toluidine [p-cresidine]

**EC Number:** 204-419-1

**CAS Number:** 120-71-8

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



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## **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: 6-Methoxy-*m*-toluidine [p-cresidine]**

**EC Number: 204-419-1**

**CAS number: 120-71-8**

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 1B<sup>1</sup> which corresponds to classification as carcinogen category 2<sup>2</sup>.

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

6-methoxy-*m*-toluidine is listed by Index number 612-209-00-X 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 6-methoxy-*m*-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**

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<sup>1</sup> 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.

<sup>2</sup> 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

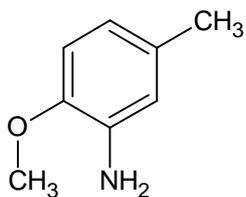
### JUSTIFICATION

#### 1 Identity of the substance and physical and chemical properties

##### 1.1 Name and other identifiers of the substance

Table 1: Substance identity

<b>EC number:</b>	204-419-1
<b>EC name:</b>	6-methoxy- <i>m</i> -toluidine
<b>CAS number (in the EC inventory):</b>	120-71-8
<b>CAS number:</b> <b>Deleted CAS numbers:</b>	120-71-8 ---
<b>CAS name:</b>	Benzenamine, 2-methoxy-5-methyl-
<b>IUPAC name:</b>	2-Methoxy-5-methylaniline
<b>Index number in Annex VI of the CLP Regulation</b>	612-209-00-X
<b>Molecular formula:</b>	C <sub>8</sub> H <sub>11</sub> NO
<b>Molecular weight:</b>	137.2 g/mol
<b>Synonyms:</b>	Anisidine, 5-methyl-; 1-Amino-2-methoxy-5-methylbenzene; 2-Methoxy-5-methylaniline; 2-Methoxy-5-methylbenzenamine; 3-Amino-4-methoxytoluene; 3-Methyl-6-methoxyaniline; 4-Methyl-2-aminoanisole; 5-Methyl-2-methoxyaniline; 5-Methyl- <i>o</i> -anisidine; 6-Methoxy- <i>m</i> -toluidine; Cresidine; Krezidin; <i>m</i> -Amino- <i>p</i> -cresol methyl ether; <i>p</i> -Cresidine

**Structural formula:****1.2 Composition of the substance****Name:** 6-Methoxy-*m*-toluidine**Description:** ---**Degree of purity:** 98 -100 %**Table 2: Constituents**

Constituents	Typical concentration	Concentration range	Remarks
6-Methoxy- <i>m</i> -toluidine 204-419-1		98 - 100 %	According to the information available in the registration dossiers

## 2 Harmonised classification and labelling

6-Methoxy-*m*-toluidine is listed by Index number 612-209-00-X 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)		
612-209-00-X	6-methoxy- <i>m</i> -toluidine; <i>p</i> -cresidine	204-419-1	120-71-8	Carc. 1B Acute Tox. 4 *	H350 H302	GHS08 GHS07 Dgr	H350 H302		-	

**Table 4: Classification according to part 3 of Annex VI, Table 3.2 (list of harmonised 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
612-209-00-X	6-methoxy- <i>m</i> -toluidine; <i>p</i> -cresidine	204-419-1	120-71-8	Carc. Cat. 2; R45 Xn; R22	T R: 45-22 S: 53-45	-	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**

6-methoxy-*m*-toluidine is listed by Index number 612-209-00-X 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 6-Methoxy-*m*-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 website<sup>3</sup>:

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

ECHA has not carried out further analysis of this information.

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<sup>3</sup> 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.