

## **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: o-Toluidine**

**EC Number: 202-429-0**

**CAS Number: 95-53-4**

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



## CONTENTS

<b>CONTENTS</b> .....	<b>3</b>
<b>TABLES</b> .....	<b>3</b>
<b>PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR 1A OR 1B, PBT, VPVB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN</b> .....	<b>4</b>
<b>PART I</b> .....	<b>5</b>
<b>JUSTIFICATION</b> .....	<b>5</b>
<b>1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES</b> .....	<b>5</b>
1.1 <i>Name and other identifiers of the substance</i> .....	5
1.2 <i>Composition of the substance</i> .....	6
<b>2 HARMONISED CLASSIFICATION AND LABELLING</b> .....	<b>7</b>
<b>3 ENVIRONMENTAL FATE PROPERTIES</b> .....	<b>8</b>
<b>4 HUMAN HEALTH HAZARD ASSESSMENT</b> .....	<b>8</b>
<b>5 ENVIRONMENTAL HAZARD ASSESSMENT</b> .....	<b>8</b>
<b>6 CONCLUSIONS ON THE SVHC PROPERTIES</b> .....	<b>8</b>
6.1 <i>CMR assessment</i> .....	8
<b>PART II</b> .....	<b>9</b>
<b>INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS</b> .....	<b>9</b>

## TABLES

### 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

## **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: o-Toluidine**

**EC Number: 202-429-0**

**CAS number: 95-53-4**

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).**

o-Toluidine is listed by Index number 612-091-00-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 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**

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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

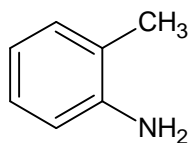
### JUSTIFICATION

#### 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>	202-429-0
<b>EC name:</b>	o-Toluidine
<b>CAS number (in the EC inventory):</b>	95-53-4
<b>CAS number:</b> <b>Deleted CAS numbers:</b>	95-53-4 ---
<b>CAS name:</b>	Benzenamine, 2-methyl-
<b>IUPAC name:</b>	2-Methylaniline
<b>Index number in Annex VI of the CLP Regulation</b>	612-091-00-X
<b>Molecular formula:</b>	C7H9N
<b>Molecular weight:</b>	107.2 g/mol
<b>Synonyms:</b>	1-Amino-2-methylbenzene; 2-Amino-1-methylbenzene; 2-Aminotoluene; 2-Methyl-1-aminobenzene; 2-Methylbenzenamine; 2-Methylphenylamine; 2-Tolylamine; o-Aminotoluene; o-Methylaniline; o-Methylbenzenamine;

**Structural formula:****1.2 Composition of the substance****Name: o-Toluidine****Description: ---****Degree of purity: 95 - 100 %****Table 2: Constituents**

<b>Constituents</b>	<b>Typical concentration</b>	<b>Concentration range</b>	<b>Remarks</b>
o-Toluidine 202-429-0		95 - 100 %	According to the information available in the registration dossiers

## 2 Harmonised classification and labelling

o-Toluidine is listed by Index number 612-091-00-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)		
612-091-00-X	2-aminotoluene o-toluidine	202-429-0	95-53-4	Carc. 1B Acute Tox. 3 * Acute Tox. 3 * Eye Irrit. 2 Aquatic Acute 1	H350 H331 H301 H319 H400	GHS06 GHS08 GHS09 Dgr	H350 H331 H301 H319 H400		-	

**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
612-091-00-X	2-aminotoluene o-toluidine	202-429-0	95-53-4	Carc. Cat. 2; R45 T; R23/25 Xi; R36 N; R50	T; N R: 45-23/25-36-50 S: 53-45-61	-	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**

o-Toluidine is listed by Index number 612-091-00-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 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 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.