

## **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-Oxydianiline**

**EC Number: 202-977-0**

**CAS Number: 101-80-4**

**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>6</b>
<b>1.1 Name and other identifiers of the substance</b> .....	<b>6</b>
<b>1.2 Composition of the substance</b> .....	<b>7</b>
<b>2 HARMONISED CLASSIFICATION AND LABELLING</b> .....	<b>8</b>
<b>3 ENVIRONMENTAL FATE PROPERTIES</b> .....	<b>10</b>
<b>4 HUMAN HEALTH HAZARD ASSESSMENT</b> .....	<b>10</b>
<b>5 ENVIRONMENTAL HAZARD ASSESSMENT</b> .....	<b>10</b>
<b>6 CONCLUSIONS ON THE SVHC PROPERTIES</b> .....	<b>10</b>
<b>6.1 CMR assessment</b> .....	<b>10</b>
<b>PART II</b> .....	<b>11</b>
<b>INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS</b> .....	<b>11</b>

## TABLES

Table 1: Substance identity .....	6
Table 2: Constituents .....	7
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 .....	8
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 .....	9

## **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-Oxydianiline**

**EC Number: 202-977-0**

**CAS number: 101-80-4**

The substance is proposed to be identified as substance meeting the criteria of Article 57 (a) and 57 (b) of Regulation (EC) 1907/2006 (REACH) owing to its classification as carcinogen 1B and mutagen 1B<sup>1</sup> which corresponds to classification as carcinogen category 2 and mutagen category 2<sup>2</sup>.

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

4,4'-oxydianiline is listed by Index number 612-199-00-7 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") and mutagen, Muta. 1B (H340: "May cause genetic defects"). 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") and mutagen, Muta. Cat. 2, R46 ("May cause heritable genetic damage").

Therefore, this classification of 4,4'-oxydianiline in Regulation (EC) No 1272/2008 shows that the substance meets the criteria for classification as carcinogenic and mutagenic in accordance with Article 57 (a) and 57 (b) 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**

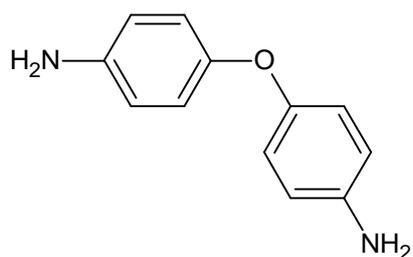
## **JUSTIFICATION**

# 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>	202-977-0
<b>EC name:</b>	4,4-oxydianiline
<b>CAS number (in the EC inventory):</b>	101-80-4
<b>CAS number:</b> <b>Deleted CAS numbers:</b>	101-80-4 121509-79-3, 928208-61-1
<b>CAS name:</b>	Benzenamine, 4,4'-oxybis-
<b>IUPAC name:</b>	4,4'-Oxydianiline
<b>Index number in Annex VI of the CLP Regulation</b>	612-199-00-7
<b>Molecular formula:</b>	C <sub>12</sub> H <sub>12</sub> N <sub>2</sub> O
<b>Molecular weight range:</b>	200.2 g/mol
<b>Synonyms:</b>	Aniline, 4,4'-oxydi-; 1-Amino-4-(4-aminophenoxy)benzene; 4,4'-Diaminobiphenyl ether; 4,4'-Diaminobiphenyl oxide; 4,4'-Diaminodiphenyl ether; 4,4'-Diaminodiphenyl oxide; 4,4'-Diaminophenyl ether; 4,4'-Oxybis(aniline); 4,4'-Oxybis[benzenamine]; 4,4'-Oxydianiline; 4,4'-Oxydiphenylamine; 4-(4-Aminophenoxy)phenylamine; 4-Aminophenyl ether; Bis(4-aminophenyl) ether; Bis(p-aminophenyl) ether; Di(4-aminophenyl) ether; Oxybis(4-aminobenzene); Oxydi-p-phenylenediamine; Oxydianiline; p,p'-Diaminodiphenyl ether; p,p'-Oxybis[aniline]; p,p'-Oxydianiline; p-Aminophenyl ether

**Structural formula:**

## 1.2 Composition of the substance

**Name:** 4,4'-Oxydianiline

**Description:** ---

**Degree of purity:** 98 – 100 %

**Table 2: Constituents**

Constituents	Typical concentration	Concentration range	Remarks
4,4'-Oxydianiline 202-977-0		98 – 100 %	Information according to the available registration dossiers.

## 2 Harmonised classification and labelling

4,4'-oxydianiline is covered by Index number 612-199-00-7 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)		
612-199-00-7	p-aminophenyl ether 4,4'-oxydianiline and its salts	202-977-0	101-80-4	Carc. 1B Muta. 1B Repr. 2 Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Aquatic Chronic 2	H350 H340 H361f *** H331 H311 H301 H411	GHS06 GHS08 GHS09 Dgr	H350 H340 H361f *** H331 H311 H301 H411		-	

**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**

<b>Index No</b>	<b>International Chemical Identification</b>	<b>EC No</b>	<b>CAS No</b>	<b>Classification</b>	<b>Labelling</b>	<b>Concentration Limits</b>	<b>Notes</b>
612-199-00-7	p-aminophenyl ether 4,4'-oxydianiline and its salts	202-977-0	101-80-4	Carc. Cat. 2; R45 Muta. Cat. 2; R46 Repr. Cat. 3; R62 T; R23/24/25 N; R51-53	T; N R:45-46-23/24/25-62-51/53 S: 53-45-61	-	

### **3 Environmental fate properties**

*Not relevant for the identification of the substance as SVHC in accordance with Articles 57 a and b.*

### **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 a and b.*

## **6 Conclusions on the SVHC Properties**

### **6.1 CMR assessment**

4,4'-oxydianiline is listed by Index number 612-199-00-7 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") and mutagen, Muta. 1B (H340: "May cause genetic defects"). 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") and mutagen, Muta. Cat. 2, R46 ("May cause heritable genetic damage").

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