

Substance Name: 4,4'-oxydianiline and its salts

EC Number: 202-977-0

CAS Number: 101-80-4

SUPPORT DOCUMENT FOR IDENTIFICATION OF

4,4'-OXYDIANILINE AND ITS SALTS

**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	9
4	HUMAN HEALTH HAZARD ASSESSMENT	9
5	ENVIRONMENTAL HAZARD ASSESSMENT	9
6	CONCLUSIONS ON THE SVHC PROPERTIES	9
6.1	CMR ASSESSMENT	9

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	8

Substance Name: 4,4'-oxydianiline and its salts

EC Number: 202-977-0

CAS number: 101-80-4

The substance is 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 1B² which corresponds to classification as carcinogen category 2 and mutagen category 2³.

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 and its salts 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 and its salts 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

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).

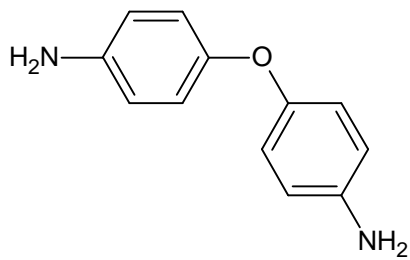
JUSTIFICATION

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:	202-977-0
EC name:	4,4'-oxydianiline
CAS number (in the EC inventory):	101-80-4
CAS number: Deleted CAS numbers:	101-80-4 121509-79-3, 928208-61-1
CAS name:	Benzenamine, 4,4'-oxybis-
IUPAC name:	4,4'-Oxydianiline
Index number in Annex VI of the CLP Regulation	612-199-00-7
Molecular formula:	C ₁₂ H ₁₂ N ₂ O
Molecular weight range:	200.2 g/mol
Synonyms:	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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
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 and its salts 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 and its salts 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.