



9 December 2011

Substance Name(s): 2-Methoxyaniline, o-anisidine
EC Number(s): 201-963-1
CAS Number(s): 90-04-0

SUPPORT DOCUMENT FOR IDENTIFICATION OF

2-METHOXYANILINE, o-ANISIDINE

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

NOTE

During the public consultation, in accordance with Article 59 (4) of the REACH Regulation, on the proposed identification of 2-methoxyaniline as a Substance of Very High Concern (SVHC) on the basis of its classification as carcinogenic category 1B no comments were received objecting the conclusion that the substance meets criteria set out in Article 57(a). Therefore, in accordance with Article 59 (6), 2-methoxyaniline has been included in the Candidate List by ECHA.

The present support document comprises Part I (Justification) of the Annex XV dossier for identification of 2-methoxyaniline as SVHC on the basis of Article 57(a) of REACH.

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Substance Name(s): 2-methoxyaniline

EC Number(s): 201-963-1

CAS number(s): 90-04-0

- The substance is proposed to be identified as substance meeting the criteria of Article 57 (a) of Regulation (EC) 1907/2006 (EU, 2006; REACH Regulation) owing to its classification as carcinogen 1B¹ which corresponds to classification as carcinogen category 2².

Summary of how the substance meets the criteria as category 1B carcinogen.

2-Methoxyaniline is covered by index number 612-035-00-4 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the 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 and 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 the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as carcinogen in accordance with Article 57 (a) of REACH.

Registration dossiers submitted for the substance?

Yes

¹ 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.

² 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).

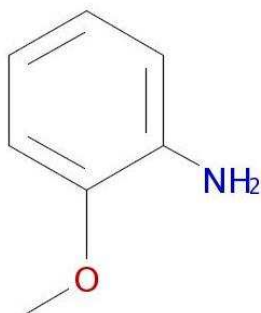
Justification

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:	201-963-1
EC name:	2-methoxyaniline, o-anisidine
CAS number (in the EC inventory):	90-04-0
CAS number:	90-04-0
CAS name:	Benzenamine, 2-methoxy-
IUPAC name:	2-methoxybenzenamine
Index number in Annex VI of the CLP Regulation	612-035-00-4
Molecular formula:	C ₇ H ₉ NO
Molecular weight range:	123.15 g/mol



Structural formula:

1.2 Composition of the substance

Name: 2-methoxyaniline, o-anisidine

Description: mono-constituent substance

Degree of purity: > ca. 99 % w/w³.

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
<i>o-anisidine</i>	> ca. 99 % w/w.		

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks
<i>Name and EC number</i>			

Table 4: Additives

Additives	Typical concentration	Concentration range	Remarks
<i>Name and EC number</i>			

Further details on the composition of the substance are confidential and can be found in the technical dossier.

³ Based on the minimum typical content indicated in the registration dossiers (downloaded on 24/11/2010)

1.3 Physico-chemical properties

Table 5: Overview of physicochemical properties⁴

Property	Value	Remarks
Physical state at 20°C and 101.3 kPa	light red to yellow liquid (20°C, 1,013 hPa) with a faintly aromatic odor. It becomes brownish on exposure to air.	Data from European Union Risk Assessment Report on o-anisidine (RAR, 2002)
Melting/freezing point	5 - >7 °C	Data from European Union Risk Assessment Report on o-anisidine (RAR, 2002)
Boiling point	224 – 225 °C pressure not indicated	Data from European Union Risk Assessment Report on o-anisidine (RAR, 2002)
Vapour pressure	0.02 - 0.05 hPa at 20 °C	Data from European Union Risk Assessment Report on o-anisidine (RAR, 2002)
Water solubility	15 g/L at 20°C	Data from European Union Risk Assessment Report on o-anisidine (RAR, 2002)
Partition coefficient n-octanol/water (log value)	log Kow 1.18 (measured) temperature not indicated	Data from European Union Risk Assessment Report on o-anisidine (RAR, 2002)
Dissociation constant		
Density	1.0923 - 1.1 g/cm ³ at 20°C	Data from European Union Risk Assessment Report on o-anisidine (RAR, 2002)
Flash point	107 °C (<i>closed cup</i>)	CHEMSAFE (2009)
Flammability upon ignition (solids)	Testing can be waived, substance is a liquid.	BAM 2.2 (2011)
Flammability in contact with water	Testing can be waived in accordance with REACH Column 2 of Annex VII, 7.10, because the organic substance does not contain metals or metalloids.	BAM 2.2 (2011)
Pyrophoric properties	Testing can be waived in accordance with REACH Column 2 of Annex VII, 7.10, because the organic substance is known to be stable into contact with air at room temperature for prolonged periods of time (days).	BAM 2.2 (2011)
Explosive properties	Testing can be waived in	BAM 2.2 (2011)

⁴ The references of the values reported in Table 5 will be available in the technical dossier.

	accordance with REACH Column 2 of Annex VII, 7.11, because there are no chemical groups present in the molecule which are associated with explosive properties.	
Auto-ignition temperature (Liquids and Gases)	430 °C (DIN 51794)	CHEMSAFE (2009)
Oxidising properties	Testing can be waived in accordance with REACH Column 2 of Annex VII, 7.13, because the organic substance contains one oxygen atom which is chemically bonded only to carbon.	BAM 2.2 (2011)

2 HARMONISED CLASSIFICATION AND LABELLING

o-Anisidine is classified and labelled as follows:

Table 6: Classification and labelling according to Annex VI of Regulation (EC) 1272/2008, Table 3.1 (EU, 2008)

Index No	International Chemical Identification	Classification		Labelling			Specific Conc. Limits, M-factors
		Hazard Class and Category	Hazard Statement Code(s)	Pictogram, Signal Word	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	
612-035-00-4	2-methoxyaniline, o-anisidine	Carc. 1B Muta. 2 Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 *	H350 H341 H331 H311 H301	GHS06 GHS08 Dgr	H350 H341 H331 H311 H301		

* minimum classification

Hazard statement codes:

H350: May cause cancer

H341: Suspected of causing genetic defects

H331: Toxic if inhaled

H311: Toxic in contact with skin

H301: Toxic if swallowed

Table 7: Classification and labelling according to Regulation (EC) 1272/2008, Table 3.2 (EU, 2008)

Index Number:	CAS No.	Classification	Labelling
612-035-00-4	90-04-0	Carc. Cat. 2; R45 Muta. Cat. 3; R68 T; R23/24/25	T R:45-23/24/25-68 S: 53-45

3 ENVIRONMENTAL FATE PROPERTIES

Not relevant for the identification of the substance as SVHC in accordance with Article 57(a).

4 HUMAN HEALTH HAZARD ASSESSMENT

Not relevant for the identification of the substance as SVHC in accordance with Article 57(a).

5 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for the identification of the substance as SVHC in accordance with Article 57(a).

6 CONCLUSIONS ON THE SVHC PROPERTIES

6.1 PBT, vPvB assessment

Not relevant for this dossier.

6.2 CMR assessment

o-Anisidine is covered by index number 612-035-00-4 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the 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 and 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 the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as carcinogen in accordance with Article 57 (a) of REACH.

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6.3 Substances of equivalent level of concern assessment.

Not relevant for this dossier.

REFERENCES

BAM 2.2 (2011): Expert judgement by BAM Federal Institute for Materials Research and Testing, Division 2.2, Berlin, Germany.

CHEMSAFE (2009): Database that contains safety characteristic data for fire and explosion prevention, evaluated and recommended by experts at BAM and PTB. CHEMSAFE is a joint project between BAM (Federal Institute for Materials Research and Testing, Berlin), PTB (Physikalisch-Technische Bundesanstalt, Braunschweig) and DECHEMA (Gesellschaft für Chemische Technik und Biotechnologie e.V., Frankfurt am Main).

Cosmetics Directive 76/768/EEC. Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (Cosmetics Directive). http://ec.europa.eu/consumers/sectors/cosmetics/documents/directive/index_en.htm

EU (2006): Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=oj:l:2006:396:0001:0849:en:pdf>

EU (2008): Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

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RAR (2002): European Union Risk Assessment Report. o-Anisidine.

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