

9 December 2011

Substance name: Bis(2-methoxyethyl)phthalate

EC number: 204-212-6 CAS number: 117-82-8

SUPPORT DOCUMENT FOR IDENTIFICATION OF BIS(2-METHOXYETHYL)PHTHALATE 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 bis(2-methoxyethyl) phthalate as a Substance of Very High Concern (SVHC) on the basis of its classification as toxic for reproduction category 1B no comments were received objecting the conclusion that the substance meets criteria set out in Article 57(c). Therefore, in accordance with Article 59 (6), bis(2-methoxyethyl) phthalate 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 bis(2-methoxyethyl) phthalate as SVHC on the basis of Article 57(c) of REACH.

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Substance Name(s): Bis(2-methoxyethyl) phthalate

EC Number(s): 204-212-6

CAS number(s): 117-82-8

• The substance is proposed to be identified as substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction 1B¹ which corresponds to classification as toxic for reproduction category 2².

Summary of how the substance meets the CMR (1A or 1B) criteria

Bis(2-methoxyethyl) phthalate is listed by Index number 607-228-00-5 of Regulation (EC) No 1272/2008 in Annex VI, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as toxic for reproduction, Repr. 1B (H360Df: "May damage the unborn child. Suspected of damaging fertility"). 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 toxic for reproduction, Repr. Cat. 2 (R61;" May cause harm to the unborn child"); Repr. Cat. 3 (R62; "Possible risk of impaired fertility").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance? No.

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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.

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:	204-212-6
EC name:	bis(2-methoxyethyl) phthalate
CAS number (in the EC inventory):	117-82-8
CAS number:	117-82-8
CAS name:	1,2-Benzenedicarboxylic acid, 1,2-bis(2-methoxyethyl) ester
IUPAC name:	Bis(2-methoxyethyl) phthalate
Index number in Annex VI of the CLP Regulation	607-228-00-5
Molecular formula:	$C_{14}H_{18}O_6$
Molecular weight range:	282.29 g/mol
Synonyms:	Di(methoxyethyl) phthalate Bis(methylglycol) phthalate

Structural formula:

1.1 Composition of the substance

Name: bis(2-methoxyethyl)phthalate

Description: mono-constituent substance

Degree of purity: >99.5%³

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks	
bis(2-methoxyethyl) phthalate	≥ 99.5 % (w/w)		Based on C&L notification	

 3 Based on the minimum content indicated in C&L notification

1.2 Physico-chemical properties

Table 3: Overview of physicochemical properties

Property	Value	Remarks	
Physical state at 20°C and 101.3 kPa	practically colourless, oily liquid with very slight odour	Data from Hazardous Substances Data Bank, USA (HSDB, 2010)	
Melting/freezing point	-45 °C	Data from Hazardous Substances Data Bank, USA (HSDB, 2010)	
Boiling point	340 °C (pressure not indicated)	Data from Hazardous Substances Data Bank, USA (HSDB, 2010)	
Tapour pressure 0.00028 mm Hg at 25 °C (est)		Data from Hazardous Substances Data Bank, USA (HSDB, 2010)	
Water solubility	8500 mg/L at 25°C		
Partition coefficient n- octanol/water (log value)	log Pow 1.11 (est) (temperature not indicated)	Data from Hazardous Substances Data Bank, USA (HSDB, 2010)	
Dissociation constant			
Density	1.1596 g/cm³ at 20 °C	Data from Hazardous Substances Data Bank, USA (HSDB, 2010)	
	2.81 x 10 ⁻¹³ atm m ³ /mol at 25 °C (est)	Data from SRC PhysProp Database (2010)	
Flash point	> 100 °C (close cup) (pressure not indicated)	Data from Chemsafe: database (2009)	
Auto ignition temperature (liquids and gases)	no data available		
Flammability upon ignition (solids,gases)	Testing is technically not possible, substance is a liquid	Expert judgment ; BAM 2011	
Flammability (contact with water)	The organic substance does not contain metals or metalloids.	Expert judgment ; BAM 2011	
Pyrophoric properties of solids and liquids The organic substance is known to be stable into contact with air at room temperature for prolonged periods of time (days).		Expert judgment ; BAM 2011	
Explosive properties	There are no chemical groups present in the molecule which are associated with explosive properties.	Expert judgment ; BAM 2011	
Oxidising properties (liquids)	The organic substance contains oxygen, which is chemically bonded only to carbon.	Expert judgment ; BAM 2011	

2 HARMONISED CLASSIFICATION AND LABELLING

Bis(2-methoxyethyl) phthalate is listed by Index number 607-228-00-5 in Annex VI of Regulation (EC) No 1272/2008, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as follows:

Table 4: Classification according to Annex VI, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	Classification		Labelling			Specific Conc.	
		Hazard Class and Category Code	Hazard statement Code	Pictogram, Signal Word Code	Hazard statement Code	Suppl. Hazard statement Code(s)	Limits, M- factors Notes	
607-228- 00-5	bis(2-methoxyethyl) phthalate	Repr. 1B	H360Df	GHS08 Dgr	H360Df			

Hazard statement code: H360Df: May damage the unborn child. Suspected of damaging fertility.

Bis(2-methoxyethyl) phthalate is covered by Index number 607-228-00-5 in Annex VI of Regulation (EC) No 1272/2008, Part 3, Table 3.2 (list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) as follows:

Table 5: Classification according to Annex VI, Part 3, Table 3.2 (list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008

Index No	Chemical name	Classification	Labelling	Concentration Limits	Notes
607-228-00-5	bis(2- methoxyethyl) phthalate	Repr.Cat. 2; R61 Repr.Cat. 3; R62	T R: 61-62 S: 53-45		

3 ENVIRONMENTAL FATE PROPERTIES

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

4 HUMAN HEALTH HAZARD ASSESSMENT

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

5 ENVIRONMENTAL HAZARD ASSESSMENT

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

6 CONCLUSIONS ON THE SVHC PROPERTIES

6.1 PBT, vPvB assessment

Not relevant.

6.2 CMR assessment

Bis(2-methoxyethyl) phthalate is covered by Index number 607-228-00-5 in Annex VI of Regulation (EC) No 1272/2008, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as toxic for reproduction, Repr. 1B (H360Df: "May damage the unborn child. Suspected of damaging fertility"). 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 toxic for reproduction, Repr. Cat. 2 (R61;" May cause harm to the unborn child"); Repr. Cat. 3 (R62; "Possible risk of impaired fertility").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

6.3 Substances of equivalent level of concern assessment.

Not relevant.

7 REFERENCES

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 1907/2006. No

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF

REACH. 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 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:1:2006:396:0001:0849:en:pdf