

**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(s): Bis(2-methoxyethyl)phthalate**

**EC Number(s): 204-212-6**

**CAS Number(s): 117-82-8**

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## **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(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 1B<sup>1</sup> which corresponds to classification as toxic for reproduction category 2<sup>2</sup>.

### **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 (a) of REACH.

**Registration dossiers submitted for the substance? No.**

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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

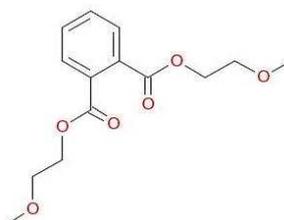
#### 1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

##### 1.1 Name and other identifiers of the substance

**Table 1: Substance identity**

<b>EC number:</b>	204-212-6
<b>EC name:</b>	bis(2-methoxyethyl) phthalate
<b>CAS number (in the EC inventory):</b>	117-82-8
<b>CAS number:</b>	117-82-8
<b>CAS name:</b>	1,2-Benzenedicarboxylic acid, 1,2-bis(2-methoxyethyl) ester
<b>IUPAC name:</b>	Bis(2-methoxyethyl) phthalate
<b>Index number in Annex VI of the CLP Regulation</b>	607-228-00-5
<b>Molecular formula:</b>	C <sub>14</sub> H <sub>18</sub> O <sub>6</sub>
<b>Molecular weight range:</b>	282.29 g/mol
<b>Synonyms:</b>	Di(methoxyethyl) phthalate Bis(methylglycol) phthalate

**Structural formula:**



**1.2 Composition of the substance****Name:** bis(2-methoxyethyl)phthalate**Description:** mono-constituent substance**Degree of purity:** >99.5%<sup>3</sup>**Table 2: Constituents**

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

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<sup>3</sup> Based on the minimum content indicated in C&L notification

### 1.3 Physico-chemical properties

**Table 3: Overview of physicochemical properties**

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

## 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. Limits, M-factors	
		Hazard Class and Category Code	Hazard statement Code	Pictogram, Signal Word Code	Hazard statement Code	Suppl. Hazard statement Code(s)	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.

### **4 HUMAN HEALTH HAZARD ASSESSMENT**

See section 2 on Harmonised Classification and Labelling.

### **5 ENVIRONMENTAL HAZARD ASSESSMENT**

Not relevant.

### **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 (a) of REACH.

#### **6.3 Substances of equivalent level of concern assessment.**

Not relevant.

## PART II

### INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

#### 1 INFORMATION ON MANUFACTURE, IMPORT/EXPORT AND USES – CONCLUSIONS ON EXPOSURE

##### 1.1 Information on Manufacture, Import/Export

Bis(2-methoxyethyl)phthalate (DMEP) has not been registered. Nevertheless it is listed by the database “Chemical Book” (Chemical Book, 2011) and offered for sale by nine EU based suppliers. Consequently, it is not clear whether the substance is used in the EU on an industrial scale. It should be assumed that the amounts offered are below one tonne.

Denmark has reported a total use of approximately 70 tonnes/a between 2004 and 2008 (SPIN, 2011). The European Chemicals Bureau (ECB) listed bis(2-methoxyethyl)phthalate (DMEP) as a “low production volume chemical” (LPVC) (production volume between 10 and 1000 tonnes/a).

##### 1.2 Probable Routes of Occupational Exposure

Bis(2-methoxyethyl)phthalate (DMEP) has an estimated vapour pressure of  $2.3 \times 10^{-4}$  mm Hg (0.0307 Pa) at 25 °C and will exist solely as vapour in the atmosphere. Inhalation exposure therefore is only likely when the substance occurs as an aerosol (e.g. spray applications). Potential occupational exposure to bis(2-methoxyethyl) phthalate through dermal contact or via inhalation could be anticipated if the substance would be used as a constituent of paints, lacquers or varnishes, especially in case of professional use. NIOSH (NOES Survey 1981-1983) has statistically estimated that 68 workers (0 of these were female) were potentially exposed to bis(2-methoxyethyl)phthalate in the US.

According to the main manufacturer of DMEP in the US it was produced in a closed reactor. The airborne concentrations of DMEP in this facility were reported to be below the limit of detection, which is in the range of 0.001-0.005 ppm. Wipe sampling tests confirmed that employee exposure was low (Eastman Kodak Company, 1991).

No monitoring data on occupational exposure to bis(2-methoxyethyl)phthalate in Europe could be found.

##### 1.3 Information on uses and conclusions on exposure

The general global applications of DMEP have included its use as a plasticiser in the production of nitrocellulose, acetyl cellulose, polyvinyl acetate, polyvinyl chloride and polyvinylidene chloride intended for contact with food or drink. DMEP is giving these polymeric materials good light

resistance. Further, it is used as a solvent. DMEP can improve the durability and toughness of cellulose acetate (e.g. in laminated documents (Ormsby, 2005)) and can be used in “enamelled wire, film, high-strength varnish and adhesive. It can also be used in pesticide products internationally” (Canadian Screening Assessment, 2009).

Only limited information regarding DMEP in consumer products in the European marketplace has been identified. The Danish Product Register records DMEP as a plasticiser in the concentration range 0.1–1% in a material used to cover floors. The Swiss Product Register records five consumer products with 1–5 % DMEP. One consumer product is a leather care product e.g. for shoes, the other four consumer products are categorised as “paints, lacquers and varnishes”. The information comes from older records and there are no current registrations of DMEP used in consumer products (personal communication). Baumann et al. (1999) described the application of DMEP as an additive for printer inks (“Kodaflex DMEP”). Cellulose acetate lamination films typically contain 20–30% plasticisers by weight. DMEP and other phthalates are commonly found in laminated documents (Ormsby, 2005).

The Australian NICNAS (2008) has reported about the import of DMEP in balls for playing and exercise, hoppers and children’s toys (e.g. as inflatable water products) (Australian NICNAS, 2008).

There is no information whether the substance is still in use in articles on the EU market.

The presence of DMEP in house dust in investigations performed in the past indicates possible sources of exposure. DMEP was detected in indoor dust collected from vacuum cleaner bags (samples were sieved, and only those particles smaller than 63 µm were analysed) in a survey conducted in 65 apartments in Hamburg, Germany, between 1998 and 2000. DMEP was detected in 49 samples. The highest concentration found was 17 mg/kg (50th percentile = 2 mg/kg; 95th percentile = 8 mg/kg). The authors speculated that the phthalates detected in indoor dust originated from the use of consumer products (Kersten, 2003). Although DMEP was not detected in house dust or upholstery fabrics in Lower Saxony, Germany, in 1999, it was detected in house carpets up to concentrations of 50 µg/kg (Pfordt, 1999).

Information on indoor concentration of DMEP can be obtained from a recent Australian report. Among 10 different dwellings, concentrations of DMEP were in the range of 0.1–2 ng/m<sup>-3</sup> (limit of reporting: <0.1 ng/m<sup>-3</sup>) (Australian Indoor Project, 2010).

In a study recently performed in Austria (unpublished report, personal communication) 10 product samples as well as 10 house dust samples (of commercial and private origin) have been analyzed for their content of DMEP. The limit of detection of 0.04 mg/kg for DMEP was neither exceeded in the product samples nor in the house dust samples.

In conclusion, due to occurrence of DMEP in house dust, consumer exposure from unknown sources might be possible. Nevertheless a quantification of exposure is not possible based on the available data.

## 2 CURRENT KNOWLEDGE ON ALTERNATIVES

Due to the fact that the substance has not been registered it reasonably can be assumed that DMEP has already been replaced by alternatives. Potential alternatives as assessed in the case of bis(2-

ethylhexyl)phthalate (DEHP, CAS No 117-81-7) could also be of interest for DMEP (ECHA, 2009).

### **3 RISK-RELATED INFORMATION**

There are currently no registrations for DMEP. However, it is possible that the substance could be registered at a later date. This probability is realistic because other phthalates are already included in the candidate list and/or banned from several uses. Based on its properties, functions and uses, DMEP might be considered as a possible substitute for already regulated phthalates. In this case, exposure to DMEP, which is currently low, might increase. Possible substitution of hazardous phthalates by DMEP should be prevented by equal treatment of all phthalates classified as toxic to reproduction. Based on the inherent toxic properties of DMEP, its classification and its rapid metabolism to a well-characterized reproductive and developmental toxicant, 2-methoxyethanol, DMEP represents a hazardous phthalate.

## REFERENCES

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