

**Annex XV dossier**

**PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A  
CMR CAT 1A OR 1B, PBT, vPvB OR A SUBSTANCE OF AN  
EQUIVALENT LEVEL OF CONCERN**

**Substance Name(s): 1,2-Benzenedicarboxylic acid dipentylester, branched and linear**

**EC Number(s): 284-032-2**

**CAS Number(s): 84777-06-0**

**Submitted by: BAuA  
Federal Office for Chemicals  
Friedrich-Henkel-Weg 1 – 25  
44149 Dortmund  
Germany**

## CONTENTS

1	IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES .....	4
1.1	Name and other identifiers of the substance .....	4
1.2	Composition of the substance .....	5
1.3	Physico-chemical properties .....	6
2	HARMONISED CLASSIFICATION AND LABELLING .....	7
3	ENVIRONMENTAL FATE PROPERTIES .....	8
4	HUMAN HEALTH HAZARD ASSESSMENT .....	8
5	ENVIRONMENTAL HAZARD ASSESSMENT .....	8
6	CONCLUSIONS ON THE SVHC PROPERTIES .....	8
6.1	PBT, vPvB assessment .....	8
6.2	CMR assessment .....	8
6.3	Substances of equivalent level of concern assessment .....	8
	PART II .....	9
	INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS .....	9
1	INFORMATION ON MANUFACTURE, IMPORT/EXPORT AND USES –CONCLUSIONS ON EXPOSURE	9
1.1	Information on Manufacture, Import/Export and Uses .....	9
1.2	Information on Exposure .....	9
2	CURRENT KNOWLEDGE ON ALTERNATIVES .....	10
3	RISK-RELATED INFORMATION .....	10
	REFERENCES .....	11

## TABLES

Table 1: Substance identity .....	4
Table 2: Constituents .....	5
Table 3: Impurities .....	5
Table 4: Additives .....	5
Table 5: Overview of physicochemical properties .....	6
Table 6: Classification according to Annex VI, Part 3, Table 3.1 of Regulation (EC) No 1272/2008 .....	7
Table 7: Classification according to Annex VI, Part 3, Table 3.2 of Regulation (EC) No 1272/2008 .....	7

## **PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR CAT 1A OR 1B, PBT, VPVB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN**

**Substance Name(s): 1,2-Benzenedicarboxylic acid dipentylester, branched and linear**

**EC Number(s): 284-032-2**

**CAS number(s): 84777-06-0**

- 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 category 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 Cat 1B criteria**

1,2-Benzenedicarboxylic acid dipentylester, branched and linear is listed by Index number 607-426-00-1 of 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 toxic for reproduction, Repr. 1B (H360FD: “May damage fertility. May damage the unborn child.”). 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 toxic for reproduction, Repr. Cat. 2 (R60-61;” May impair fertility. May cause harm to the unborn child”).

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**

---

<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

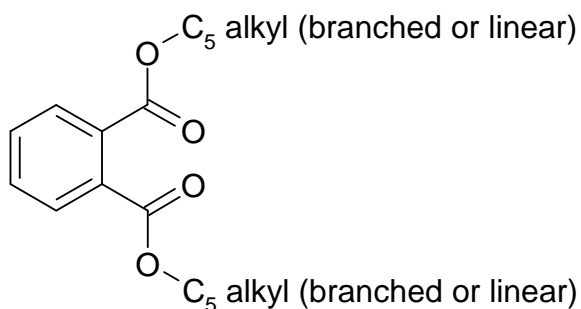
## 1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

## 1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	284-032-2
EC name:	1,2-Benzenedicarboxylic acid dipentylester, branched and linear
CAS number (in the EC inventory):	84777-06-0
CAS number:	84777-06-0
CAS name:	1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear
IUPAC name:	bis-C5-alkyl-(linear and branched)phthalate
Index number in Annex VI of the CLP Regulation	607-426-00-1
Molecular formula:	$C_{18}H_{26}O_4$
Molecular weight range:	306 g/mol
Synonyms:	

## Structural formula:



**1.2 Composition of the substance****Name:** 1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear**Description:** UVCB substance**Degree of purity:** Registration dossiers or other information on concentration ranges are not available.**Table 2: Constituents**

Constituents	Typical concentration	Concentration range	Remarks
1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear 284-032-2			

**Table 3: Impurities**

Impurities	Typical concentration	Concentration range	Remarks

**Table 4: Additives**

Additives	Typical concentration	Concentration range	Remarks

### 1.3 Physico-chemical properties

**Table 5: Overview of physicochemical properties**

Property	Value	Remarks
Physical state at 20°C and 101.3 kPa		
Melting/freezing point		
Boiling point		
Vapour pressure		
Water solubility		
Partition coefficient n-octanol/water (log value)		
Dissociation constant		
[enter other property, if relevant, or delete row]		

No physical and chemical properties could be found in well known databases (e.g. the recommended databases of Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance). Furthermore no registration dossiers are available. Hence no physical and chemical properties could be given.

## 2 HARMONISED CLASSIFICATION AND LABELLING

1,2-Benzenedicarboxylic acid dipentylester, branched and linear is listed by Index number 607-426-00-1 of 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 follows:

**Table 6: 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	EC No	CAS No	Classification		Labelling	
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)
607-426-00-1	1,2-benzenedicarboxylic acid, dipentylester, branched and linear	284-032-2	84777-06-0	Repr. 1B Aquatic Acute 1	H360FD H400	GHS08 GHS09 Dgr	H360FD H400

1,2-Benzenedicarboxylic acid, dipentylester, branched and linear is covered by Index number 607-426-00-1 in 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) as follows:

**Table 7: 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	EC NO	CAS NO	CLASSIFICATION	LABELLING
607-426-00-1	1,2-benzenedicarboxylic acid, dipentylester, branched and linear	284-032-2	84777-06-0	Repr. Cat. 2; R60-61 N; R50	T; N R: 60-61-50 S: 53-45-61

### **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**

1,2-Benzenedicarboxylic acid dipentylester, branched and linear is covered by Index number 607-426-00-1 of 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 toxic for reproduction, Repr. 1B (H360FD: “May damage fertility. May damage the unborn child.”). 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 toxic for reproduction, Repr. Cat. 2 (R60-61;” May impair fertility. May cause harm to the unborn child”).

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.



## 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 and Uses

1,2-Benzenedicarboxylic acid, dipentylester, branched and linear was pre-registered under REACH with indication of registration by 30 November 2010. According to recently performed searches in REACH-IT, there are currently no registrations for this substance. However, it is possible that the substance could be registered at a later date. According to the information available on ECHA's website there have been 70 notifications to the C&L inventory (status on 01.08.2012)<sup>3</sup>. No information could be identified on current annual EU import/export volumes.

Common databases (e.g. SPIN, ESIS) were checked to identify information about tonnage and use. Only one entry from Sweden in 2009 was identified as registered use with a “very narrow range of applications” and no indication of direct exposure (SPIN 2012). Due to their similar physico-chemical properties to other transitional phthalates of carbon backbone lengths of C4-C6 e.g. di-n-butyl phthalate and diisopentyl phthalate concerning for example density (Lide 1997) pentyl phthalates can be used as plasticisers in plastic material (Rein 1937, Schaeffler 2011). The European Chemicals Bureau (ECB) listed 1,2-benzenedicarboxylic acid, dipentylester, branched and linear as a “low production volume chemical” (LPVC). No further information about tonnage and use is available. The database chemical book has listed only one supplier for laboratory chemicals who sells the substance for analytical purposes in small packages of 0.1 g each. Therefore it can be assumed that 1,2-benzenedicarboxylic acid, dipentylester, branched and linear is not manufactured in the Community or placed on the market in quantities of one tonne or more per year.

### 1.2 Information on Exposure

No measured data are available on 1,2-benzenedicarboxylic acid, dipentylester, branched and linear exposure concentration at the workplace.

No information about concentrations of 1,2-benzenedicarboxylic acid, dipentylester, branched and linear in consumer products is available. In general, the presence of this compound in house dust may indicate possible sources. However for 1,2-benzenedicarboxylic acid, dipentylester, branched and linear no information about house dust measurements could be retrieved. A quantification of

---

<sup>3</sup> <http://clp-inventory.echa.europa.eu/SummaryOfClassAndLabelling.aspx?SubstanceID=135961&HarmOnly=no?fc=true&lang=en>

exposure is not possible due to a lack of data. It should be assumed that exposure if at all is very low.

## **2 CURRENT KNOWLEDGE ON ALTERNATIVES**

The effects of phthalates on reproduction appear to be associated predominantly with the transitional phthalates of carbon backbone lengths of C4-C6. In general lower molecular weight phthalates ( $\leq$ C3) and higher molecular weight phthalates ( $\geq$ C7) appeared not to induce developmental effects (Phthalates Hazard Compendium, 2008). However it is noted that there may be exceptions from this general rule and it has to be kept in mind that some low and high molecular weight phthalates show effects at higher levels of exposure. Alternative substances might be phthalates with short or long carbon backbones, depending on the physicochemical property needed.

As there have been no registrations it can be assumed that 1,2-benzenedicarboxylic acid, dipentylester, branched and linear have mostly 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 as alternatives for 1,2-benzenedicarboxylic acid, dipentylester, branched and linear (ECHA, 2009).

## **3 RISK-RELATED INFORMATION**

There are currently no registrations for 1,2-benzenedicarboxylic acid, dipentylester, branched and linear. A risk characterisation is not possible due to a lack of information about possible exposures. It should be assumed that 1,2-benzenedicarboxylic acid, dipentylester, branched and linear is not manufactured in the Community or placed on the market in quantities of one tonne or more per year.

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 their properties, functions and uses, 1,2-benzenedicarboxylic acid, dipentylester, branched and linear might be considered as possible substitutes for already regulated phthalates. In this case, exposure to 1,2-benzenedicarboxylic acid, dipentylester, branched and linear might arise. Possible substitution of hazardous phthalates by 1,2-benzenedicarboxylic acid, dipentylester, branched and linear should be prevented by equal treatment of all phthalates classified as toxic to reproduction. Based on the inherent toxic properties and their classification 1,2-benzenedicarboxylic acid, dipentylester, branched and linear represent hazardous phthalates.

## REFERENCES

### *References to Part I*

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 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.

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

### *References to Part II*

Chemical Book, 2012:

[http://www.chemicalbook.com/Search\\_DE.aspx?keyword=84777-06-0](http://www.chemicalbook.com/Search_DE.aspx?keyword=84777-06-0)

ECHA 2009. Data on manufacture, import, export, uses and releases of Bis(2-ethylhexyl)phthalate (DEHP) as well as information on potential alternatives to its use. The technical work on this report has been led by COWI A/S, supported by IOM and Entec UK Ltd under framework contract ECHA/2008/2.

[http://echa.europa.eu/doc/consultations/recommendations/tech\\_reports/tech\\_rep\\_dehp.pdf](http://echa.europa.eu/doc/consultations/recommendations/tech_reports/tech_rep_dehp.pdf)

ESIS 2012 (European chemical Substances Information System)

<http://esis.jrc.ec.europa.eu/>

Lide 1997: Lide, D.R. (ed.), Handbook of Chemistry and Physics, 78th ed., CRC Press, Boca Raton, Fla, USA.

Phthalates Hazard Compendium, A summary of physicochemical and human health hazard data for 24 ortho-phthalate chemicals. Australian Government Department of Health and Ageing. National Industrial Chemicals Notification and Assessment Scheme:1-72. 2008.

<http://www.nicnas.gov.au/publications/car/Other/Phthalate%20Hazard%20Compendium.pdf>

Rein 1937: H. Rein, Chemiker Taschenbuch, 58th ed., Part II, Springer-Verlag, Berlin 1937.

Schaeffler 2011: Schaeffler Technologies AG & Co. KG, Germany

[http://www.schaeffler.com/remotemedien/media/\\_shared\\_media/supplier/environment\\_1/S132030-1\\_de.pdf](http://www.schaeffler.com/remotemedien/media/_shared_media/supplier/environment_1/S132030-1_de.pdf)

SPIN Database, 2012:

<http://195.215.251.229/DotNetNuke/default.aspx>