

**Substance Name: 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear**

**EC Number: 271-093-5**

**CAS Number: 68515-50-4**

**MEMBER STATE COMMITTEE**

**SUPPORT DOCUMENT FOR IDENTIFICATION OF**

**1,2-BENZENEDICARBOXYLIC ACID, DIHEXYL ESTER,  
BRANCHED AND LINEAR**

**AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS  
CMR<sup>1</sup> PROPERTIES**

**Adopted on 30 May 2014**

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<sup>1</sup> CMR means carcinogenic, mutagenic or toxic for reproduction

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**Substance Name:** 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear

**EC Number:** 271-093-5

**CAS number:** 68515-50-4

- The substance is identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH)<sup>2</sup> owing to the adopted opinion<sup>3</sup> by the Committee for Risk Assessment (RAC) which has agreed that the substance meets the criteria for classification as toxic for reproduction category 1B according to Regulation (EC) No 1272/2008 (CLP)<sup>4</sup>.

**Summary of how the substance meets the CMR (Cat 1A or 1B), PBT or vPvB criteria, or is considered to be a substance giving rise to an equivalent level of concern**

In accordance with Article 37(4) of the CLP Regulation, the Committee for Risk Assessment (RAC) has adopted an opinion for harmonised classification and labelling of *1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear* in June 2013. At RAC-25 the RAC adopted the opinion that *1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear* meets the criteria for classification as toxic for reproduction Repr. 1B, H360FD ("May damage fertility. May damage the unborn child."). The corresponding classification in accordance with Directive 67/548/EEC would be toxic for reproduction Repr. Cat.2, R60-61 ("May impair fertility. May cause harm to the unborn child."). After decision of the European Commission, confirming the classification as Repr. 1B, the new classification will be included in the list of harmonised classifications (Annex VI to the CLP Regulation).

Therefore, *1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear* meets the criteria of Article 57(c) of Regulation (EC) 1907/2006 (REACH Regulation).

**Registration dossiers submitted for the substance:** No

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<sup>2</sup> 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.

<sup>3</sup> Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of 1,2-Benzenedicarboxylic acid, dihexylester, branched and linear EC number: 271-093-5 CAS number: 68515-50-4 CLH-O-000002695-67-03/F Adopted 7 June 2013 <http://echa.europa.eu/documents/10162/18d3ed6d-91c5-48d0-844a-8383ab5723b3>

<sup>4</sup> 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.

## JUSTIFICATION

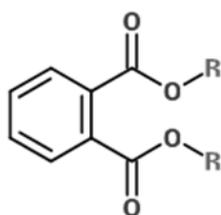
### 1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

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

**Table 1** Substance identity

<b>EC number:</b>	271-093-5
<b>EC name:</b>	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear
<b>CAS number (in the EC inventory):</b>	68515-50-4
<b>CAS number:</b>	68515-50-4
<b>CAS name:</b>	1,2-Benzenedicarboxylic acid, 1,2-dihexyl ester, branched and linear
<b>IUPAC name:</b>	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear
<b>Index number in Annex VI of the CLP Regulation</b>	-
<b>Molecular formula:</b>	$C_{20}H_{30}O_4$
<b>Molecular weight range:</b>	334 g/mol
<b>Synonyms:</b>	Dihexylphthalate, branched and linear Phthalic acid, dihexyl ester, branched and linear Dihexylphthalate, mixed isomers Phthalic anhydride, reaction products with hexanol, branched and linear Esterification of phthalic anhydride and hexanol, branched and linear

#### Structural formula:



R =  $C_6H_{13}$ , branched and linear

## 1.2 Composition of the substance

**Name:** 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear

**Description:** UVCB substance

The CAS number 68515-50-4 represents a reaction product containing branched and/or linear isomers and/or combinations thereof. Two out of many possible isomers found in the UVCB substance *1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear* (CAS number 68515-50-4) are e.g. CAS number 71850-09-4 (di-isohexyl phthalate) and CAS number 84-75-3 (di-n-hexyl phthalate).

Typical concentrations and concentration ranges of the isomers in *1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear* are not known.

## 1.3 Physico-chemical properties

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

## 2 HARMONISED CLASSIFICATION AND LABELLING

The RAC has adopted an opinion<sup>5</sup> at RAC-25 that *1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear* meets the following criteria for classification and labelling:

**Table 2** The RAC opinion on classification and labelling in accordance with Regulation (EC) No 1272/2008 (CLP)

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)		
	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4	Repr. 1B	H360FD	GHS08 Dgr	H360FD			

**Table 3** The RAC opinion on classification and labelling in accordance with Directive 67/548/EEC

Index No	Chemical Name	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4	Repr. Cat. 2; R60-61	T R: 60-61 S: 45-53		

<sup>5</sup> Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of 1,2-Benzenedicarboxylic acid, dihexylester, branched and linear EC number: 271-093-5 CAS number: 68515-50-4 CLH-O-0000002695-67-03/F Adopted 7 June 2013 <http://echa.europa.eu/documents/10162/18d3ed6d-91c5-48d0-844a-8383ab5723b3>

H360FD: May damage fertility. May damage the unborn child.

R60-61: May impair fertility. May cause harm to the unborn child.

### **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**

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(c).*

## **6 CONCLUSIONS ON THE SVHC PROPERTIES**

### **6.1 CMR assessment**

In accordance with Article 37(4) of the CLP Regulation, the Committee for Risk Assessment (RAC) has adopted an opinion for harmonised classification and labelling of *1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear* in June 2013. At RAC-25 the RAC adopted the opinion that *1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear* meets the criteria for classification as toxic for reproduction Repr. 1B, H360FD ("May damage fertility. May damage the unborn child."). The corresponding classification in accordance with Directive 67/548/EEC would be toxic for reproduction Repr. Cat.2, R60-61 ("May impair fertility. May cause harm to the unborn child."). After decision of the European Commission, confirming the classification as Repr. 1B, the new classification will be included in the list of harmonised classifications (Annex VI to the CLP Regulation).

Therefore, *1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear* meets the criteria of Article 57(c) of Regulation (EC) 1907/2006 (REACH Regulation).