

**Substance Name: Dihexyl phthalate** 

EC Number: 201-559-5

**CAS Number: 84-75-3** 

# MEMBER STATE COMMITTEE SUPPORT DOCUMENT FOR IDENTIFICATION OF

## **DIHEXYL PHTHALATE**

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

Adopted on 28 November 2013

<sup>&</sup>lt;sup>1</sup> CMR means carcinogenic, mutagenic or toxic for reproduction.

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**Substance Name: Dihexyl phthalate (DnHP)** 

EC Number: 201-559-5

**CAS number: 84-75-3** 

The substance is identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction category  $1B^2$  which corresponds to classification as toxic for reproduction category  $2^3$ .

#### Summary of how the substance meets the CMR Cat 1B criteria

Dihexyl phthalate (DnHP) is listed by Index number 607-702-00-1 in Annex III of Regulation (EU) No 944/2013 amending, for the purposes of its adaptation to technical and scientific progress Annex VI to Regulation (EC) No 1272/2008 (CLP) of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. DnHP is 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 (CLP) is toxic for reproduction, Repr. Cat. 2 (R60-61; "May impair fertility. May cause harm to the unborn child").

Therefore, this classification of DnHP in Annex VI to Regulation (EC) No 1272/2008 (CLP) 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>&</sup>lt;sup>2</sup>Classification in accordance with Annex III of the Regulation (EU) No 944/2013 amending for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

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), OJ L 353, p.1, 31.12.2008.

## **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:	201-559-5
EC name:	dihexyl phthalate
CAS number (in the EC inventory):	84-75-3
CAS number:	84-75-3
CAS name:	1,2-Benzenedicarboxylic acid, 1,2-dihexyl ester
IUPAC name:	dihexyl phthalate
Index number in Annex VI of the CLP Regulation	607-702-00-1
Molecular formula:	$C_{20}H_{30}O_4$
Molecular weight range:	334.46 g/mol
Synonyms:	1,2-Benzenedicarboxylic acid, dihexyl ester (9CI);
	Phthalic acid,dihexyl ester (6CI,7CI,8CI);
	Bis(n-hexyl) phthalate;
	Di-n-hexyl phthalate;
	Dihexylphthalate;
	Jayflex DHP;
	NSC 4817
	DnHP

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 $<sup>^4</sup>$  According to Regulation (EU) 944/2013 amending Annex VI to Regulation (EC) No 1272/2008 (CLP)

#### Structural formula:

## 1.2 Composition of the substance

Name: Dihexyl phthalate

**Description: mono-constituent substance** 

**Degree of purity:** ≥ **80%** (Registration dossiers or other information on concentration ranges are not available)

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
Not relevant for mono-			
constituent substances			

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks	
n.a.				

Table 4: Additives

Additives	Typical concentration	Concentration range	Remarks	
n.a.				

## 1.3 Physico-chemical properties

Due to the fact that dihexyl phthalate is identified as SVHC according to art. 57c no physical and chemical properties are needed for the identification as SVHC. Therefore no physical and chemical properties are given.

#### 2 HARMONISED CLASSIFICATION AND LABELLING

Dihexyl phthalate (DnHP) is listed by Index number 607-702-00-1 in the Regulation (EU) No 944/2013 amending, for the purposes of its adaptation to technical and scientific progress Annex VI to Regulation (EC) No 1272/2008 (CLP) of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. DnHP is classified in Annex VI, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as follows:

Table 5: 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 (CLP)

	Index Internati No onal Chemical Identifica tion	EC No	No	Classification		Labelling				Not es
No				Class and		am, Signal	•		Limits, M - Factors	Limits, rd m H - Factors
607-702- 00-1	dihexyl phthalate	201- 559-5	84-75- 3	Repr. 1B	H360FD	GHS08 Dgr	H360FD			

Dihexyl phthalate (DnHP) is covered by Index number 607-702-00-1 in Regulation (EC) No 1272/2008 (CLP), 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 6: 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 (CLP)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelli ng	Concentration Limits	Note s
607-702- 00-1	dihexyl phthalate	201- 559-5	84-75- 3	Repr. Cat. 2; R60-61	T R: 60- 61 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

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

#### **CMR** assessment

Dihexyl phthalate (DnHP) is listed by Index number 607-702-00-1 in Annex III of Regulation (EU) No 944/2013 amending, for the purposes of its adaptation to technical and scientific progress Annex VI to Regulation (EC) No 1272/2008 (CLP) of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. DnHP is 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 (CLP) is toxic for reproduction, Repr. Cat. 2 (R60-61;" May impair fertility. May cause harm to the unborn child").

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

#### **REFERENCES**

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:l:2006:396:0001:0849:en:pdf

CLP 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

EU Commission Regulation (EU) No 944/2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:261:0005:0022:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:261:0005:0022:EN:PDF</a>