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): Dihexyl phthalate

EC Number(s): 201-559-5

CAS Number(s): 84-75-3

Submitted by: **BAuA**

Federal Office for Chemicals

Friedrich-Henkel-Weg 1 – 25

44149 Dortmund

Germany

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Substance Name(s): Dihexyl phthalate

EC Number(s): 201-559-5

CAS number(s): 84-75-3

- The substance is proposed to be identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to the favourable opinion of the REACH committee on the draft Commission Regulation (EU) amending, for the purposes of its adaptation to technical and scientific progress Annex VI to Regulation (EC) No 1272/2008 (CLP) which provides that Dihexyl phthalate should be classified as toxic for reproduction category 1B in accordance with the CLP Regulation (Regulation (EC) 1272/2008).

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

Dihexyl phthalate (DnHP) is listed by Index number 607-702-00-1 in the draft Commission Regulation (EU) 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. The Committee established under the Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) gave its favourable opinion on the draft Regulation via written procedure in May 2013. DnHP will be 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) will be toxic for reproduction, Repr. Cat. 2 (R60-61;” May impair fertility. May cause harm to the unborn child”).

Therefore, even though the substance is not yet listed in Annex VI of CLP (Regulation (EC) 1272/2008) there is evidence based *inter alia* on the favourable opinion of the REACH Committee on the draft Commission Regulation amending, for the purposes of its adaptation to technical and scientific progress Annex VI to Regulation (EC) No 1272/2008 (CLP) that DnHP meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance? No

PART I

JUSTIFICATION

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

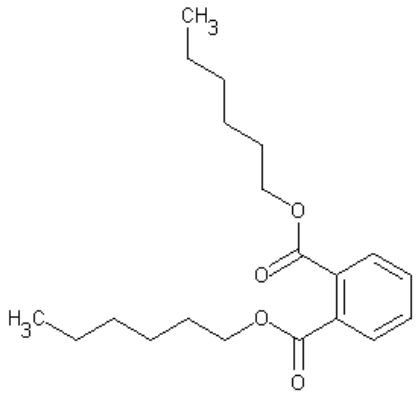
1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	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[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

[1] According to draft Commission Regulation (EU) correcting 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 draft Commission Regulation (EU) 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. The Committee established under the Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) gave its favourable opinion on the draft Regulation via written procedure in May 2013. DnHP will be classified in Annex VI, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as follows:

Table 5: Future 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 No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific 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)		
607-702-00-1	dihexyl phthalate	201-559-5	84-75-3	Repr. 1B	H360FD	GHS08 Dgr	H360FD			

Dihexyl phthalate (DnHP) will be 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: Future 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	Labelling	Concentration Limits	Notes
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.

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

Dihexyl phthalate (DnHP) is listed by Index number 607-702-00-1 in the draft Commission Regulation (EU) 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. The Committee established under the Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) gave its favourable opinion on the draft Regulation via written procedure in May 2013. DnHP will be 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) will be toxic for reproduction, Repr. Cat. 2 (R60-61;” May impair fertility. May cause harm to the unborn child”).

Therefore, even though the substance is not yet listed in Annex VI of CLP (Regulation (EC) 1272/2008) there is evidence based *inter alia* on the favourable opinion of the REACH Committee on the draft Commission Regulation amending, for the purposes of its adaptation to technical and scientific progress Annex VI to Regulation (EC) No 1272/2008 (CLP) that DnHP 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

Dihexyl phthalate 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, which can be explained by a tonnage lower than 100 tpa. However, it is possible that the substance could be registered at a later date. Registration is expected to follow as soon as the substance is listed in Annex VI of the CLP regulation as toxic for reproduction, Repr. 1B in case DnHP is manufactured in the Community or placed on the market in quantities of 1 ton or more per year.

The substance has not been reported by EU Industry as an HPVC or LPVC according to the previous existing substances regulation (ESIS). No further information on current annual EU manufacture and import/export volumes have been identified. Chemical book (2012) listed eight suppliers in Europe, thereof three in Germany and four in the United Kingdom.

It should be assumed that DnHP is not manufactured in the Community or placed on the market in quantities of 100 tonnes or more per year.

1.2 Information on Consumer Uses

The SPIN database (2012) lists for 2009 “one or several uses that indicate a potential exposure” with a “very narrow range of applications” in consumer mixtures in Sweden. Further information about use categories is not available in the database.

In the Material Safety Data Sheet of the Physical and Theoretical Chemistry Laboratory (chemexper.net 2012) the use of dihexyl phthalate is recorded as “plasticizer for cellulose & vinyl plastics”.

DnHP can be used in the making of plastisols that are subsequently used in the manufacture of automobile parts (air filters, battery covers) and dip-moulded products (tool handles, dishwasher baskets). Commercial phthalate substances containing DnHP may be added to the PVC utilised in the manufacture of flooring, canvas tarps, and notebook covers. Substances containing DnHP may also be used in traffic cones, toys, vinyl gloves, weather stripping, flea collars, shoes, and conveyor belts used in food packaging operations (NTP 2003). Due to its similar physico-chemical properties to other transitional phthalates of carbon backbone lengths of C4-C6 dihexyl phthalate can possibly be used as a substitute to these phthalates (Phthalates Hazard Compendium 2008). C4 to C6 side chain phthalates with 3 to 6 carbon atoms in their backbone are used in applications where high solvating plasticisers and stain resistance are required, for example, foamed leather cloth and flooring (Plasticisers 2012).

The DK-EPA (2012) has analysed cell phone covers, work gloves/household gloves, sleeping mats, handbags made of synthetic leather, and sneakers. DnHP has not been found in any of these products. Pfordt et al. (1999) has reported the results of measurements in textiles (swaddling clothes, bathrobe, t-shirts, pantyhose, beach dress, upholstery fabric, carpets). Only small amounts (0.01 - 0.03 mg/kg) were detected in three of these products.

1.3 Information on Consumer Exposure

Only a few measurements of consumer products including mixtures and articles can be identified. In these products the concentration of DnHP was mostly below the detection limit. However, the collected samples are not representative and a quantification of exposure is not possible based on the current data.

The presence/absence of DnHP in house dust is also an indicator for possible phthalate sources. Only two house dust studies of DnHP in Europe can be identified. No (Pfordt et al. 1999) and low (Watson et al. 2006) concentrations (< 4 µg/g), respectively, were detected.

In conclusion, the data available have not proven to be sufficient to conclude on consumers' exposure. It should be assumed that consumer 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 phthalates of carbon backbone lengths of C4-C6. In general lower molecular weight phthalates (<=C3) and higher molecular weight phthalates (>=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.

Depending on the functionality needed chemicals like citrates (biodegradable and not toxic), adipates, phosphates (resistant to ignition and burning), trimellitates (exceptional thermal properties.), etc. could be used as alternatives of dihexyl phthalate. Potential alternatives as assessed in the case of the restriction proposal for bis(2-ethylhexyl)phthalate (DEHP, CAS No 117-81-7), Benzyl butyl phthalate (BBP, CAS No 85-68-7), Dibutyl phthalate (DBP, CAS No 84-74-2), and Diisobutyl phthalate (DIBP, CAS No 84-69-5) could be of interest for dihexyl phthalate (ECHA 2009, 2012).

3 RISK-RELATED INFORMATION

There are currently no registrations for dihexyl phthalate, which can be explained by a tonnage lower than 100 tpa. A risk characterisation is not possible due to a lack of information about possible exposure. 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. Registration is expected to follow as soon as the substance is listed in Annex VI in case DnHP is manufactured in the Community or placed on the market in quantities of 1 tonne or more per year. Based on its properties, functions and uses, dihexyl phthalate might be considered as a possible substitute for already regulated phthalates. In this case, exposure to dihexyl phthalate might rise. Possible substitution of hazardous phthalates by dihexyl phthalate should be prevented by equal treatment of all phthalates classified as toxic to reproduction. Based on the inherent toxic properties and its future classification dihexyl phthalate represents a hazardous phthalate.

REFERENCES

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