

## **Annex XV report**

# **PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57**

**Substance Name: Diisohexyl phthalate**

**EC Number: 276-090-2**

**CAS Number: 71850-09-4**

**Submitted by: Sweden**

**Date: 2019-08-05**

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## **PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57**

**Substance name:** diisohexyl phthalate

**EC number:** 276-090-2

**CAS number:** 71850-09-4

- The substance is proposed to be identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification<sup>1</sup> in the hazard class toxic for reproduction category 1B<sup>2</sup>.

### **Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation**

According to an adopted opinion from RAC (ECHA, 2017), diisohexyl phthalate meets the criteria for classification in the hazard class:

- Toxic for reproduction category 1B in accordance with Article 57 (c) of the REACH Regulation.

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

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<sup>1</sup> The substance does not yet have a harmonised classification, but according to an adopted opinion from RAC (ECHA, 2017), the substance meets the criteria in the hazard class toxic for reproduction, category 1B. The substance is included in the draft ATP 14 to CLP Annex VI to be decided in 2019.

<sup>2</sup> Classification in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008

## PART I

### Justification

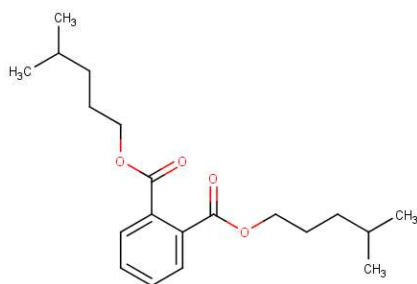
#### 1. Identity of the substance and physical and chemical properties

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

**Table 1: Substance identity**

<b>EC number:</b>	276-090-2
<b>EC name:</b>	diisohexyl phthalate
<b>CAS number (in the EC inventory):</b>	71850-09-4
<b>CAS number: Deleted CAS numbers:</b>	
<b>CAS name:</b>	
<b>IUPAC name:</b>	1,2-bis(4-methylpentyl) benzene-1,2-dicarboxylate
<b>Index number in Annex VI of the CLP Regulation</b>	
<b>Molecular formula:</b>	C <sub>20</sub> H <sub>30</sub> O <sub>4</sub>
<b>Molecular weight range:</b>	
<b>Synonyms:</b>	

##### Structural formula:



##### 1.2 Composition of the substance

**Name:** diisohexyl phthalate

**Description:** organic

**Substance type:** mono-constituent

### **1.3 Identity and composition of structurally related substances (used in a grouping or read-across approach)**

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

### **1.4 Physicochemical properties**

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

## **2. Harmonised classification and labelling**

According to an adopted opinion by RAC (ECHA, 2017) the substance diisohexyl phthalate meets the criteria for classification in the hazard class toxic for reproduction category 1B (May damage fertility. May damage the unborn child) in accordance with the CLP Regulation<sup>3</sup>.

The substance is included in the draft ATP 14 to CLP Annex VI.

## **3. Environmental fate properties**

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

## **4. Human health hazard assessment**

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

## **5. Environmental hazard assessment**

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

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<sup>3</sup> Classification in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008.

## **6. Conclusions on the SVHC Properties**

### **6.1 CMR assessment**

According to the adopted opinion by RAC (ECHA, 2017) the substance diisohexyl phthalate meets the criteria for classification in the hazard class toxic for reproduction category 1B (May damage fertility. May damage the unborn child)<sup>4</sup>.

The substance therefore fulfils the criteria in accordance with Article 57 (c) of the REACH Regulation.

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<sup>4</sup> Classification in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008.

## Part II

### 7. Registration and C&L notification status

#### 7.1 Registration status

**Table 2 Registration status**

From the ECHA dissemination site <sup>5</sup>	
Registrations	<input type="checkbox"/> Full registration(s) (Art. 10) <input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)

No registration is submitted.

#### 7.2 CLP notification status

**Table 3: CLP notifications**

	CLP Notifications <sup>6</sup>
Number of aggregated notifications	-
Total number of notifiers	-

There are no notifications for diisohexyl phthalate in the CL Inventory database.

<sup>5</sup> ECHA dissemination site. Available at <https://www.echa.europa.eu/web/guest/substance-information/-/substanceinfo/100.069.152> (accessed 11 July 2019).

<sup>6</sup> C&L Inventory database, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> (accessed 22 May 2019).



## 8. Total tonnage of the substance

The substance is not registered. No information is available.

**Table 4: Tonnage status**

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18)	Not registered/No information
Tonnage information from public sources other than registration dossiers (if available)	No information

## 9. Information on uses of the substance

Since the substance is not registered there is no information on uses available on ECHA's website. However, the substance is a component (the branched form) of 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear (EC 271-093-5; CAS 68515-50-4) which might be used as a substitute for other low/transitional molecular weight phthalates of carbon backbone lengths of C4-C6 already included in Annex XIV or recommended for inclusion in Annex XIV<sup>7</sup>. According to the Annex XV report for 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear (EC 271-093-5; CAS 68515-50-4), there are indications for potential use of the substances in the same types of applications (e.g. as sealant, plasticiser in polymers etc)<sup>8</sup>.

## 10. Information on structure of the supply chain

No information is available.

## 11. Additional information

### 11.1 Substances with similar hazard and use profiles on the Candidate List

A number of substances, structurally similar to diisohexyl phthalate, namely bis(2-ethylhexyl) phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP) and 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear, are already included in the Candidate list because of harmonised Repr.1B classification. Diisohexyl phthalate might have similar uses as the other phthalates, or could be used as substitute for the phthalates that are included in the Candidate List. Based on the above, a grouping approach can be used for diisohexyl phthalate with other structurally similar phthalates to prevent regrettable substitution.

<sup>7</sup> E.g. DEHP (EC 204-211-0), DBP (EC 201-557-4), BBP (EC 201-622-7).

<sup>8</sup> Annex XV report for 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear: <https://echa.europa.eu/documents/10162/7c5c54dc-e0bb-4d8b-b759-437044f82af8>

## REFERENCES

### References for Part I

- EU (2006). 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. Official Journal of the European Union, L396: 1-849.
- EU (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packing of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L353: 1-1355.
- ECHA (2017). RAC Opinion proposing harmonised classification and labelling at EU level of diisohexyl phthalate, Adopted 9 June 2017. Available at <https://echa.europa.eu/documents/10162/66be881a-6813-9d40-4c16-df3ffca768b6> (accessed on 11 July 2019).

### References for Part II

- ECHA (2014). Annex XV report 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear. Available at <https://echa.europa.eu/documents/10162/7c5c54dc-e0bb-4d8b-b759-437044f82af8> (accessed on 11 July 2019).
- ECHA (2019). Diisohexyl phthalate. Information published on ECHA's website: <https://www.echa.europa.eu/web/guest/substance-information/-/substanceinfo/100.069.152> (accessed on 11 July 2019).