

## Justification for the selection of a substance for CoRAP inclusion

**Substance Name (Public Name):** bis(2-propylheptyl) phthalate

**Chemical Group:**

**EC Number:** 258-469-4

**CAS Number:** 53306-54-0

**Submitted by:** Germany

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### Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

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## 1 IDENTITY OF THE SUBSTANCE

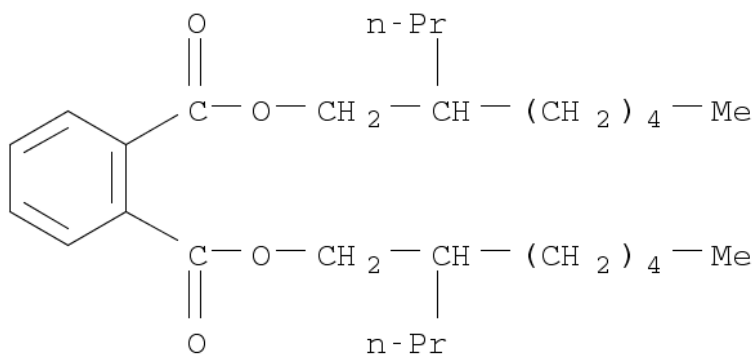
### 1.1 Other identifiers of the substance

Table 1: Substance identity

<b>EC name:</b>	bis(2-propylheptyl) phthalate
<b>IUPAC name:</b>	bis(2-propylheptyl) phthalate
<b>Index number in Annex VI of the CLP Regulation</b>	-
<b>Molecular formula:</b>	C <sub>28</sub> H <sub>46</sub> O <sub>4</sub>
<b>Molecular weight or molecular weight range:</b>	446.66 g/mol
<b>Synonyms/Trade names:</b>	1,2-benzenedicarboxylic acid, di-2-propylheptyl ester; 1,2-Benzenedicarboxylic acid, bis(2-propylheptyl) ester (9CI); Phthalic acid, bis(2-propylheptyl) ester (6CI); Bis(2-propylheptyl) phthalate; Di-2-propylheptyl phthalate; Hexamol DPHP; NSC 17071; Palatinol 10P; dphp

**Type of substance**     Mono-constituent     Multi-constituent     UVCB

**Structural formula:**



### 1.2 Similar substances/grouping possibilities

None identified

## 2 CLASSIFICATION AND LABELLING

### 2.1 Harmonised Classification in Annex VI of the CLP

There is no harmonized classification of bis(2-propylheptyl) phthalate according to Annex VI of Regulation (EC) No 1272/2008.

### 2.2 Self classification

- In the registration

No self-classification is given in the joint registration.

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

No self-classification for bis(2-propylheptyl) phthalate was notified according to Art. 39/40 of the Regulation (EC) No 1272/2008.

### 2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None

## 3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa	
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	<input checked="" type="checkbox"/> 100,000 – 1,000,000 tpa	
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa	
<input type="checkbox"/> <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential	
<i>Please provide further details if appropriate</i>			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
PC 32: Polymer preparations and compounds AC 13: Plastic articles AC 0: Other: Medical Devices Manufacturing of articles, cable and car interiors compounding Industrial: polymer processing, PVC flooring, use as intermediate Professional: polymer processing, use of articles Consumer: use of articles, use in medical devices			

## 4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

### 4.1 Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

### 4.2 Selection criteria met (why the substance qualifies for being in CoRAP)

- Fulfils criteria as CMR/ Suspected CMR
- Fulfils criteria as Sensitiser/ Suspected sensitiser
- Fulfils criteria as potential endocrine disrupter
- Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
- Fulfils criteria high (aggregated) tonnage (*tpa* > 1000)
- Fulfils exposure criteria
- Fulfils MS's (national) priorities

### 4.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR <sup>1</sup> <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input checked="" type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser <sup>1</sup>	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB <sup>1</sup>	<input checked="" type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input checked="" type="checkbox"/> Other (please specify below)

<sup>1</sup> CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)

Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)

Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

Health effects

Repeated dose toxicity: Oral – rat (Wistar), 90-Day study (1995), NOAEL 40 mg/kg/day, LOAEL 200 mg/kg/day (haematology; clinical chemistry; organ weights; histopathology: findings in the pituitary and thyroid glands).

Reproduction: *Developmental toxicity* (2003, rat): gavage exposure gestation day 6-19, Maternal NOAEL 200 mg/kg/day; Developmental NOAEL 200 mg/kg/day (embryo-/fetotoxicity).

*Fertility*: Two-generation study (2009, rat) NOAEL (P, F1 parents) 600 mg/kg, NOAEL (F1, F2 pups) 200 mg/kg; .

Effects in the pituitary and the thyroid gland point to the fact that DPHP may have endocrine disrupting properties.

(b) Wide and dispersive use, consumer and worker exposure

DPHP is an ingredient in consumer preparations e.g. paints and adhesives as well as in consumer articles e.g. toys and childcare articles. The SPIN database (2012) indicates a probable use in article productions. The registration of the substance according to the REACH VO identified the consumer use of plastic articles (AC13) and medical devices (AC1).

It can be assumed that DPHP is used as an alternative for already regulated phthalates. However, the data base is poor and the level of exposure in the population especially for children is unclear.

(c) High aggregated tonnage

**4.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation**

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
<i>Please provide further details when relevant.</i>	

#### 4.5 Preliminary indication of information that may need to be requested to clarify the concern

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

More detailed information on adverse effects on pituitary and thyroid glands is needed.

More information on adverse developmental effects is needed.

#### 4.6 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
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In Entry 52 of Annex XVII it is stated that the substances DINP, DIDP and DNOP "shall not be used as substances or in mixtures, in concentrations of greater than 0.1% by weight of the plasticised material, in toys and childcare articles which can be placed in the mouth by children".

Di-2-propyl heptyl phthalate (DPHP) is a structural isomer of the substance "Di-isodecyl phthalate" (DIDP). DPHP is not covered under the entry 52 of Annex XVII. The uses of the substance may be regulated in the future on a Community-wide basis, if it appears from the information which will become available that it causes unacceptable risks to human health, especially to sensitive subpopulations such as children, or the environment.