17 December 2010

Background document for Diisobutyl phthalate (DIBP)

Document developed in the context of ECHA's second Recommendation for the inclusion of substances in Annex XIV

1. Identity of the substance

Chemical name:	Diisobutyl phthalate (DIBP)
EC Number:	201-553-2
CAS Number:	84-69-5
IUPAC Name:	bis(2-methylpropyl) benzene-1,2-dicarboxylate

2. Background information

2.1. Intrinsic properties

DIBP was identified as a Substance of Very High Concern (SVHC) according to Article 57(c) as it is classified according to Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 as toxic to reproduction category 2, R61 (may cause harm to the unborn child)[1], and was therefore included in the candidate list for authorisation on 13 January 2010, following ECHA's decision ED/68/2009.

2.2. Imports, exports, manufacture and uses

2.2.1. Volume(s), imports/exports

The world wide production of both DBP (dibutyl phthalate) and DIBP was estimated by a consultant as being 450,000 t/y (cited in Annex XV, 2009). In an authorised IUCLID data sheet from 2000 (Annex XV, 2009) the quantity of DIBP manufactured and/or used in Europe is indicated in the range of 10,000 to 50,000 t/y.

There is no information on imports/exports available.

[1] This corresponds to a classification as toxic to reproduction 1B, H 360Df (May damage the unborn child. Suspected of damaging fertility.) in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (List of harmonised classification and labelling of hazardous substances).

2.2.2. Manufacture and uses

2.2.2.1. Manufacture and releases from manufacture

Companies in Austria, Germany, Italy, Spain and UK were known to manufacture or import DIBP in 2000 (Annex XV, 2009). At present it seems that there is at least one European producer of DIBP but no further information regarding the volume is available (RCOM, 2009).

2.2.2.2. Uses and releases from uses

DIBP is used as a specialist plasticiser and frequently as a gelling aid in combination with other plasticisers and as plasticiser for nitrocellulose, cellulose ether and polyacrylate and polyacetate dispersions. These are used in paints, lacquers, varnishes, paper, pulp and boards, as adhesives, binding agents, softeners and viscosity adjusters (Annex XV, 2009; RCOM, 2009). DIBP is also used in coatings, e.g. antislip coatings, and in epoxy repair mortars (RCOM, 2009). As a plasticiser in dispersion glues and printing inks DIBP is applied in paper and packaging for food (e.g. rice, baking mixtures, cheese, bread, nuts) and bottled water (Annex XV, 2009).

Due to similar application properties it may be used as a substitute for dibutyl phthalate (DBP) (Annex XV, 2009).

DIBP has been detected in many consumer products frequently used by children like crayons, bar ends of run bikes, erasers and school bags. In a Chinese study DIBP has been identified in consumer products such as suckers, plastic spoons and forks, boxes for microwave ovens, milk package bags, disposable cups, plates and bowls. DIBP was found in 20/36 perfumes with concentrations ranging from 0.2 - 38 mg/kg (Annex XV, 2009).

Consumer use of DIBP can also be identified by its existence in house dust (Annex XV, 2009). DIBP was detected in breast milk (RCOM, 2009).

2.2.2.3. Geographical distribution and conclusions in terms of (organisation and communication in) supply chains

Companies in Austria, Germany, Italy, Spain and UK were known to manufacture or import DIBP in 2000 (Annex XV, 2009). At present it seems that there is at least one European producer of DIBP but no further information regarding the volume is available (RCOM, 2009).

There is no further information regarding the formulation and processing sites of DIBP. Presuming a situation similar to that of DBP it can be assumed that formulation and processing take place at about 50-100 major sites, and at an unknown number of smaller installations (ECHA, 2009). DIBP is contained in a wide range of products. Consequently, the use of DIBP can be considered widespread and wide-dispersive.

There is no particular information available as to the complexity of the supply chain. Presuming it is similar to DBP it can be assumed that there might be a large number of companies involved in the further processing and formulation resulting in the final production of a wide range of preparations and articles.

2.3. Availability of information on alternatives[2]

The following information is taken from Annex XV (2009). Please refer to Annex XV (2009) for references cited in Chapter 2.3.

Alternative substances

Structurally, phthalate esters are characterised by a diester structure consisting of a benzenedicarbolic acid head group linked to two ester chains. The structural characteristics of the ester side chains affect the physicochemical and toxicological properties of the phthalate. Reproductive and developmental toxicity appear to be associated predominantly with phthalates of carbon backbone of C3 up to C6 as known for DIBP, DBP, DPP, BBP, DIHP and DEHP. Alternative substances could be searched for in phthalates with shorter or longer carbon backbone lengths (C1, C2 or ≥ C7) or among non-phthalates.

There are some non-phthalate alternative substances (EFSA, 2008; CSTEE, 2004; Heitmann, 2003; Risk & Policys Limited, 2000; Stuer-Lauridsen et al., 2001; TNO, 2001; TNO, 2002):

- adipates, e.g. di (ethylhexyl) adipate (DEHA), diisononyl adipate (DINA),
- citrates, e.g. acetyl tributyl citrate (ATBC),
- cyclohexanedicarboxylic acid esters, e.g. di-(isononyl)-cyclohexane-1,2-dicarboxylate (DINCH),
- terephthalic acid, bis(2-ethylhexyl)ester (DEHT)
- organic phosphates,
- medium chained chloroparaffines (MCCP)
- trimellitates, terepthalates, benzoates, succinates, azelates, sebacates, epoxy plasticisers, alkylsulfonic acid esters, polymeric plasticisers, sorbitol-based plasticisers.

MCCP is a suspected PBT substance, so its suitability as replacement for DIBP is questionable. For the other non-phthalate plasticisers there are currently not enough data available for a comprehensive assessment of their suitability.

Alternative techniques

Alternative techniques or a combination of alternative techniques with other substitution activities may be a solution. According to the draft risk reduction strategy report on DEHP (KEMI, 2006) several alternative techniques are under development:

- "Grafting in order to incorporate subgroups into the polymer structure. In this way copolymers are created that are flexible in themselves and thus without

[2] Please note that this information was not used for the prioritisation.

the need for added plasticisers. […] This technique can only be a possible option for large bulk producers of PVC, who do not need the kind of flexibility in properties/formulations that can be obtained by mixing a standard PVC resin with different plasticisers and other additives."

- "Formulation of PVC with other polymers like EVA and PU. By this technique mixtures of PVC can be obtained with different flexibility without plasticisers."

- "Research about the possibilities to use phthalates fixed within the polymer and not as an additive that can migrate is also taking place."

- Flexible plastics that might be used as alternatives to flexible PVC are polypropylene, polyethylene, ethylene-vinylacetate copolymers (EVA), ethylene propylene diene terpolymers (EPDM), polyurethane (PU) and thermoplastic elastomers.

- Completely different materials than flexible PVC (wood, ceramic, stone, cork, paper, linoleum, caoutchouc non-flexible plastics.) might be considered by producers and also by consumers, e.g. instead of PVC flooring consumers may be decide to have wooden material.

2.4. Existing specific Community legislation relevant for possible exemption

No data available.

2.5. Any other relevant information (e.g. for priority setting)

No data available.

3. Conclusions and justification

3.1. Prioritisation

Verbal-argumentative approach

Given the high volume used and the wide dispersive use pattern (confirmed by monitoring), the substance qualifies on the basis of the prioritisation criteria for prioritisation.

Scoring approach

Score			Total Score
Inherent properties (IP)	Volume (V)	Uses - wide dispersiveness (WDU)	(= IP + V + WDU)
0 (Toxic to reproduction, cat. 2)	9 (Very high volume)	Overall score: 3 * 3 = 9 Site-#: 3 (Use at a high # of sites) Release: 3 (Diffuse environmental releases and uncontrolled consumer exposure (potentially as well uncontrolled worker exposure). Wide dispersive use confirmed by monitoring results.)	18

Conclusion, taking regulatory effectiveness considerations into account

On the basis of the prioritisation criteria the substance qualifies for prioritisation.

Regulatory effectiveness considerations would further support a conclusion that the substance should be prioritised. Diisobutyl phthalate can be used to replace dibutyl phthalate and may as well be suitable to replace other phthalates already recommended for inclusion in Annex XIV.

Therefore, it is suggested to give diisobutyl phthalate priority and recommend it for inclusion in Annex XIV.

4. References

Annex XV (2009): Annex XV report for identification of a substance as SVHC. Submitted by Germany, August 2009. http://echa.europa.eu/doc/consultations/svhc/svhc_axvrep_germany_cmr_diisobutylphthalate_20090831.pdf

ECHA (2009): Dibutyl phthalate. Priorisation and Annex XIV background information. 14 January 2009. http://echa.europa.eu/doc/consultations/recommendations/prioritisations/prioritisation_dbp.pdf

RCOM (2009): "Responses to comments" documents. Document compiled by the German MSCA from the commenting period 31.08.-15.10. 2009. http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2009/rcom_dibp/rcom_dibp_non_conf.pdf