ROHS Annex II Dossier for DIBP

Proposal for restriction of a substance in electrical and electronic substances under RoHS

Final Version

Substance Name:	Diisobutyl phthalat (DIBP)
EC Number:	201-553-2
CAS Number:	84-69-5
Submitted by:	Oeko-Institut e.V.

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Report for:

The EUROPEAN COMMISSION

DIRECTORATE-GENERAL ENVIRONMENT

Directorate A - Green Economy

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Abbreviations

ASE..... Alkylsulphonic phenylester

ATCB ..... Acetyl tributyl citrate

BBP..... Bis (2-ethylhexyl) phthalate

BCF..... Bio-concentration factor

bw ..... Body weight

CAS ..... Chemical Abstract Service

CMR..... Carcinogenic, Mutagenic or toxic for Reproduction

COMGHA ..... Glycerides, Castor-oil-mono-, hydrogenated, acetates

DBP ..... Dibutyl phthalate

DEHP..... Bis(2-ethylhexyl)phthalat

DIBP ..... Diisobutyl phthalate

DNEL ..... Derived No-Effect Levels

ECHA ..... European Chemicals Agency

ECPI ..... European Council for Plasticisers and Intermediates

EEA..... European Environment Agency

EEE..... Electrical and Electronic Equipment

EPA..... Environmental Protection Agency

ESIS..... European Chemical Substances Information System

HPVC..... High Production Volume Chemical

kPa..... kilo Pascal

LOAEL ..... Lowest-Observed-Adverse-Effect Level

MSW ..... Municipal Solid Waste

NOAEL..... No-Observed-Adverse-Effect Level

PVC ..... Polyvinylchloride

RAC ..... Risk Assessment Committee

REACH ..... Registration, Evaluation, Authorisation and Restriction of Chemical Substances

SEAC ..... Committee for Socio-economic Analysis

SVHC..... Substance of Very High Concern

tpa..... Tonnes per annum

WEEE ..... Waste Electrical and Electronic Equipment

Proposal for including a substance of concern in Annex II of the Directive 2011/65/EC

Substance Name:	Diisobutyl phthalat (DIBP)
EC Number:	201-553-2
CAS Number:	84-69-5

Context

This dossier follows a RoHS Dossier Template for substance assessment prepared by the Austrian Umweltbundesamt GmbH.

The substance assessment of Diisobutyl phthalat (DIBP) is one part of a project within the contract No. ENV/2013/SI2.667381/ETU/A2 implementing Framework Contract No. ENV.C.2/FRA/2011/0020 where a consortium led by Eunomia Research & Consulting has been requested by DG Environment of the European Commission to provide additional information concerning a further substance to be assessed as a candidate for addition to Annex 2 of the RoHS Directive as well as prioritisation of a first shortlist of substances.

RoHS 2 sets the rules for amending the list of restricted substances in Article 6(1). A review and amendment of Annex II is to be considered by the Commission before 22 July 2014, and periodically thereafter. In preparation of the 2014 review, a first study was launched by the Austrian Umweltbundesamt GmbH in 2012. The study identified DIBP as a priority substance for an assessment because in some cases a selective ban of a substance from a larger substance group might drive industry towards the use of a problematic alternative from the very same group.

A draft dossier of DIBP was subject to a targeted stakeholder consultation that ran for eight weeks from 07.02.2014 to 04.04.2014. The corresponding questionnaire and the contributions submitted by stakeholder are available at the following website: http://rohs.exemptions.oeko.info/index.php?id=211.

This dossier will be part of the final report, which is due 26 May 2014 (the project was extended as a result of evidence from stakeholders coming in late to the original project schedule).

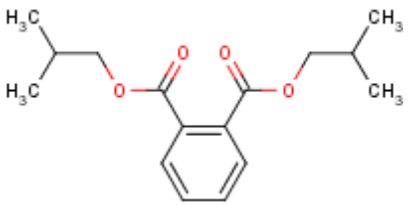
1.0 Identification, Classification and Labelling

1.1 Identification and Physico-Chemical Properties of the Substance

1.1.1 Name, Other Identifiers and Composition of the Substance

Diisobutyl phthalate (DIBP) composition and properties are summarised in Table 1-1.

Table 1-1: Substance Identity and Composition (Source: Annex XV 2009)

Chemical name	**Diisobutyl phthalate (DIBP), 1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester**
EC number	201-553-2
CAS number	84-69-5
IUPAC name	Bis(2-methylpropyl)benzene-1,2-dicarboxylate
Index number in Annex VI of the CLP Regulation	607-623-00-2
Molecular formula	$C_{16}H_{22}O_4$
Molecular weight range	278.35 g/mol
Synonyms	Diisobutyl phthalate; DIBP; 1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester; Bis(2-methylpropyl)benzene-1,2-dicarboxylate
Structural formula	
Degree of purity	–
Remarks	--

1.1.2 Physico-chemical Properties

The physico-chemical properties of DIBP are identified in Table 1-2.

Table 1-2: Overview of Physico-chemical Properties of DIBP (Source: Annex XV 2009)

Property	Value
Physical state at 20°C and 101.3 kPa	Colourless, clear , mostly odourless viscous liquid
Melting/freezing point	-37 °C
Boiling point	320 °C
Vapour pressure	0.01 Pa at 20 °C
Water solubility	20 mg/l at 20 °C
Partition coefficient n-octanol/water (log P_{OW})	logP_{ow}: 4.11
Dissociation constant	-

1.2 Classification and Labelling Status

1.2.1 Classification in Annex VI Regulation No 1272/2008

The Classification, Labelling and Packaging (CLP) regulation[1] ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through classification and labelling of chemicals. For DIBP, there is a harmonised classification and labelling for Reproductive toxicity Category 1B (H360Df: May damage the unborn child; suspected of damaging fertility). For more details, see Table 1-3.

During this Dossier preparation, ECHA launched a consultation on a proposal concerning the removal for the specific concentration limits of the reproductive toxicity of DIBP. The German BAuA (2014) submitted the proposal.[2] The ECHA consultation is shall run until 9 May 2014.

[1] Regulation (EC) No 1272/2008 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 (REACH);
The latest consolidated version from 19.04.2011 of the CLP-Regulation (EC) No 1272/2008 is available under: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2008R1272:20110419:EN:PDF

[2] BAuA Federal Institute for Occupational Safety and Health (2014): CLH report Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2 Substance Name: Diisobutyl phthalate (DIBP);
http://www.echa.europa.eu/documents/10162/59594fc5-519a-4e97-b0f8-7a45b5db04ce

In addition to the harmonised classification, DIBP has been self-classified by manufacturers and/or importers for the following environmental hazards as indicated in the C&L inventory provided by ECHA:[3]

- as Aquatic Acute 1 (H400: Very toxic to aquatic life and H401: Toxic to aquatic life) and
- as Aquatic Chronic 1, 2 and 3 (H410: Very toxic to aquatic life with long lasting effects, H411: Toxic to aquatic life with long lasting effects, H412: Harmful to aquatic life with long lasting effects).

Table 1-3: Classification of DIBP According to Part 3 of Annex VI, Table 3.1 (List of Harmonized Classification and Labelling of Hazardous Substances) of Regulation (EC) No 1272/2008

Index No	International Chemical ID	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard state-ment Code(s)	Picto-gram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
607-623-00-2	diisobutyl phthalate	201-553-2	84-69-5	Repr. 1B	H360Df	GHS08 Dgr	H360Df	--	Repr. 1B; H360Df: C ≥ 25% Repr. 2; H361f: 5% ≤ C < 25%	--

[3] ECHA C&L Inventory database: entry for DIBP; http://clp-inventory.echa.europa.eu/SummaryOfClassAndLabelling.aspx?SubstanceID=14308&HarmOnly=no?fc=true&lang=en

2.0 Legal Status and Use Restrictions

2.1 Regulation of the Substance Under REACH

DIBP was added to Annex XIV - the list of substances subject to authorisation – of the REACH Regulation, No. 1907/2006, on 18 February 2012 (later referred to as Authorisation List). The Annex XIV listing of DIBP appears in Table 2-1 below. As a substance listed in Annex XIV, DIBP cannot be placed on the market or used after the 21st of February 2015 (Sunset date[4]). Specific authorisation will be required from manufacturers, importers or downstream users, to place the substance on the market, use it in preparations or for the production of articles after this date. The latest day for submitting an application to receive such authorisation was 21st August 2013 (Latest application date[5]). No authorisations for exempted uses have been granted as of yet.

It should be noted that the Authorisation List obligations forbidding the use of the substance only apply in EU countries: In practice, this means that EU manufacturers cannot apply listed substances in the production of an article, if an authorisation for exempted use has not been granted. However import of articles (products; components; spare parts; cables) in which the substance is present or has been used during the manufacture, is not limited. The only obligation applying at present where the import of articles is concerned is that the content of such substances in a concentration above 0,1% weight by weight has to be communicated through the product documentation supplied with the product (REACH Article 33).

Table 2-1: Excerpt from the ECHA Authorisation List[6]

Substance Name	EC Number	CAS Number	Sunset date	Latest application date	Exempted (categories of) uses
Diisobutyl phthalate (DIBP)	201-553-2	84-69-5	21 Feb 2015	21 Aug 2013	-

[4] Article 58 (1) (c) defines the significance of the Sunset date specified for substances listed in Annex XIV:
"(i) the date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted (hereinafter referred to as the **sunset date**) which should take into account, where appropriate, the production cycle specified for that use"

[5] Article 58 (1) (c) defines the significance of the **application date** specified for substances listed in Annex XIV:
"(ii) a date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorisation is taken;"

[6] http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list

DIBP is further referred to in REACH Annex XVII – the list of "Restrictions on the Manufacture, Placing on the Market and Use of Certain Dangerous Substances, Mixtures and Articles". It is included in the list of substances of Appendix 6 of the Annex – a list of substances to which Entry 30 applies, which have been found to be "Toxic to reproduction: category 1B (Table 3.1)/category 2 (Table 3.2)". The conditions of restriction relevant in this regard are detailed in the Excerpt of Item 30 in Table 2-2 below.

Table 2-2: Excerpt from the ECHA Restriction List[7]

Column 1 **Designation of the substance, of the group of substances or of the mixture**	**Column 2** **Conditions of restriction**
30. Substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as toxic to reproduction category 1A or 1B (Table 3.1) or toxic to reproduction category 1 or 2 (Table 3.2) and listed as follows: — Reproductive toxicant category 1A adverse effects on sexual function and fertility or on development (Table 3.1) or reproductive toxicant category 1 with R60 (May impair fertility) or R61 (May cause harm to the unborn child) (Table 3.2) listed in Appendix 5 — Reproductive toxicant category 1B adverse effects on sexual function and fertility or on development (Table 3.1) or reproductive toxicant category 2 with R60 (May impair fertility) or R61 (May cause harm to the unborn child) (Table 3.2) listed in Appendix 6	Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30: 1. Shall not be placed on the market, or used, — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: 'Restricted to professional users'. 2. By way of derogation, paragraph 1 shall not apply to: (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles);

[7] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20130701:EN:HTML

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
	(d) artists' paints covered by Directive 1999/45/EC; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.

2.2 Non-governmental Initiatives

DIBP was added to the SIN list in October 2009 (SIN 1.1). "*The SIN (Substitute It Now!) List is an NGO driven project to speed up the transition to a world free of hazardous chemicals. The SIN List 2.1 consists of 626 chemicals that ChemSec has identified as Substances of Very High Concern based on the criteria established by the EU chemical regulation, REACH. The SIN List contains substances that are identified by ChemSec as fulfilling the criteria for Substances of Very High Concern provided by REACH. These are substances that can cause cancer, alter DNA or damage reproductive systems. It also includes toxic substances that do not easily break down, but instead build up in nature - with a potential to cause serious and long-term irreversible effects. The SIN List also contains substances that are identified to give raise on an 'equivalent level of concern'.*"[8]

2.3 Conclusions on Legal Restrictions

DIBP has been included in REACH Annex XIV and Annex XVII. Use of the substance or placing it on the EU market, thus enabling its use as a substance is therefore subject to authorisation according to the procedures in Title VII of REACH. Furthermore, its placing on the market in substance form, as a constituent of other substances or in mixtures, available to the public, is restricted below ≥ 0.02 for gaseous preparations (%vol/vol) or below ≥ 0.1 for other preparations (%w/w)[9].

However, these entries do not restrict the placing on the market of articles containing DIBP and thus the authorisation process has no implications for imported articles (besides the aforementioned duty to communicate information on substances in articles according to REACH Article 33). Therefore, the Danish Competent Authority of

[8] Source: http://www.chemsec.org/what-we-do/sin-list

[9] Thresholds according to Directive 1999/45/EC: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:200:0001:0001:EN:PDF

REACH submitted a Restriction Report in 2011, addressing the four phthalates DEHP, BBP, DBP and DIBP, proposing a new entry 51a in Annex XVII of REACH.[10]

Table 2-3: Wording of Restriction (51a), Proposed in the DEPA 2011 Restriction Report

Column 1 **Designation of the substance, of the group of substances or of the mixture**	**Column 2** **Conditions of restriction**
51a. The following phthalates (or other CAS and EC numbers covering the substance): (a) Bis (2-ethylhexyl) phthalate (DEHP) CAS No 117-81-7 EC No 204-211-0 (b) Dibutyl phthalate (DBP) CAS No 84-74-2 EC No 201-557-4 (c) Benzyl butyl phthalate (BBP) CAS No 85-68-7 EC No 201-622-7 (d) Diisobytyl phthalate (DIBP) CAS No 84-69-5 EC No 201-553-2	1. Articles intended for use indoors and articles that may come into direct contact with the skin or mucous membranes containing one or more of these phthalates in a concentration greater than 0.1% by weight of any plasticised material shall not be placed on the market after (12 months from entry into force). 2. By way of derogation, paragraph 1 shall not apply to the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC, or to medical devices covered under Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC. 3. By way of derogation, paragraph 1 shall not apply to toys. By way of derogation, paragraph 1 shall not apply to childcare articles as regards DEHP, DBP and BBP. 4. By way of derogation, paragraph 1 shall not apply to articles intended to come into contact with food covered by Regulation (EC) No 1935/2004 and specific measures under this regulation, e.g. Commission Regulation (EU) No 10/2011. 5. By way of derogation, paragraph 1 shall not apply to articles intended for use indoors and articles that may come into direct contact with the skin or mucous membranes that were in use in the European Union before (date of entry into force). 6. For the purpose of this entry 'childcare article' shall mean any article intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children. 'Use' shall mean any placing, keeping, storing, hanging, laying, applying, mounting, fixing or other application indoors of articles.

The justification for restriction made in the proposal was based on the combined exposure from the four phthalates that are all classified as reprotoxic category 1B from articles intended for use indoors and articles that may come into direct contact

[10] DEPA – Danish Environmental Protection Agency (2011): Annex XV Restriction Report. Proposal for a restriction. Substance name: Bis(2-Ethylhexyl)phthalate (BBP); Benzyl butyl phthalate (BBP); Dibutyl phthalate (BBP); Diisobutyl phthalate (DIBP). 12. August 2011.

with the skin or mucous membranes. However, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of ECHA, did not support the proposed restriction,[11] which was thus not approved.

The ECHA expects the substitution with other plasticisers, besides the four phthalates DEHP, BBP, DBP and DIBP, to continue at least for uses where the costs are considered to be limited.[12] This is further supported by the requirement in REACH Article 33(1), obliging any supplier of an article containing a substance listed in Annex XIV, and thereby also DIBP, in a concentration above 0.1%, to provide the recipient as a minimum with the name of the substance. In order to be able to submit that information the importer or the supplier is required to identify the concentration of ingredients. Therefore, ECHA assumes that the amount of articles containing the four phthalates will decrease.[13]

[11] ECHA RAC/SEAC Committee for Risk Assessment (RAC) Committee for Socio-economic Analysis (SEAC) (2012a): Opinion on an Annex XV dossier proposing restrictions on four phthalates. Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 15 June 2012) and SEAC's opinion (adopted 5 December 2012).

[12] ECHA RAC/SEAC Committee for Risk Assessment (RAC) Committee for Socio-economic Analysis (SEAC) (2012): Background document to the Opinion on the Annex XV dossier proposing restrictions on four phthalates. 5 December 2012.

[13] Op. cit. ECHA RAC/SEAC (2012)

3.0 Use in Electrical and Electronic Equipment Covered by Directive 2011/65/EC (Annex I)

3.1 Function of the Substance

DIBP is used as a plasticiser in specific applications, for example in PVC, and frequently as a gelling aid in combination with other plasticisers and as a plasticiser for nitrocellulose, cellulose ether and polyacrylate and polyacetate dispersions (Annex XV 2009). These are used in paints, lacquers, varnishes, paper, pulp and boards, as adhesives, binding agents, softeners and viscosity adjusters.[14] DIBP is also used in coatings, e.g. anti-slip coatings; and in epoxy repair mortars.[15]

The European Council for Plasticisers and Intermediates (ECPI) has stated that Diisobutyl phthalate (DIBP) has very similar application properties to Di-n-butyl phthalate (DBP) and may therefore be used to substitute DBP in most, if not all, of its applications.[16] According to other stakeholders, DIBP is one of the main marketed all-round alternatives for DBP.[17] In order to avoid such substitution of one SVHC by another, ECHA proposed to set the sunset date as close as possible to the sunset date of the other phthalates DEHP, BBP and DBP, which were included in REACH Annex XIV prior to the inclusion of DIBP.[18] Possible additional applications based on this unwanted substitution of DBP by DIBP will not be explored in this dossier, among others as the EEE sector is understood not to be concerned: A study of the Danish Environmental Protection Agency in 2010 concluded that the use of DBP in EEE was not deemed essential as technically suitable alternatives are available and already used, even if for some specific non-polymer applications, substitution may be particularly difficult.[19] For more information concerning such cases, please refer to the RoHS DBP dossier prepared by the Austrian Environmental Agency in 2014.[20]

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[14] ECHA European Chemicals Agency (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. 17 December 2010.

[15] Op. cit. ECHA (2010)

[16] http://www.dibp-facts.com/

[17] ECHA European Chemicals Agency (2009): Comments and Response to Comments on Annex XV SVHC: Proposal and Justification, 12.11.2009.

[18] ECHA European Chemicals Agency (2010a): Responses to Comments Document (RCOM) for Diisobutyl Phthalate (EC Number: 201-553-2), 17 December 2010.

[19] DEPA – Danish Environmental Protection Agency (2010): Inclusion of HBCDD, DEHP, DBP, DBP and additive use of TDBPA in annex IV of the Commission's recast proposal of the RoHS Directive, Socioeconomic impacts. Maag, J.; Brandt, K.; Mikkelsen, S.; Lassen, C. COWI A/S. Danish Ministry of Environment, Environmental Project No. 1317 2010.

[20] RoHS DBP dossier (2014): ROHS ANNEX II DOSSIER for DBP, Proposal for restriction of a substance in electrical and electronic substances under RoHS, prepared by the Austrian Environmental Agency; Vienna, January 2014.

Though the use of DIBP in EEE is sometimes mentioned, e.g. present as an additive of polymers like PVC used as wire insulation in electrical articles, cables or power cord of electrical appliance (ECHA Notification Information), DIBP (as well as BBP and DBP) are not reported to be used in cables and wires, probably due to their high volatility. Depending on the specific applications, cables are possibly heated during use and this increases the volatilisation.[21] The latest compilation on phthalates used in end-products, lists DEHP for wires and cables.[22] Based on information from cable manufacturers, besides DEHP, DIDP and DINP are likely the main plasticisers used for cables in the EU.[23]

During the consultation on the draft of this DIBP dossier[24], the contributions of the stakeholders (KEMI Swedish Chemicals Agency, ORGALIME aisbl, Japan Business Council in Europe (JBCE) and the Test & Measurement Coalition) confirmed that DIBP is currently not used in EEE (see Table 3-1).

Table 3-1: Contribution on DIBP Submitted During the Consultation by Order of Submission

Stakeholder (Submission Date)	Summary of the contribution
KEMI Swedish Chemicals Agency (03.04.2014)	„The use of DIBP in EEE cannot be confirmed from the reported areas of use in the SPIN database or the Swedish Products register." Total use of DIBP in the Nordic countries: 37.7 t in 2011 (de-creasing after a peak in 2006 and 2007).
ORGALIME aisbl (04.04.2014)	Referring to the document of the ECHA Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) Opinion on an Annex XV dossier[25] proposing restrictions on four phthalates (DEHP, DBP, DIBP and BBP) as adopted in 2012.

http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex8_RoHS_AnnexII_Dossier_DBP.pdf

[21] Op. cit. DEPA (2011)

[22] Op. cit. ECHA RAC/SEAC (2012)

[23] Op. cit. ECHA RAC/SEAC (2012)

[24] The stakeholder consultation ran for eight weeks from 07 February to 04 April 2014. For more details see the Oeko-Institut's website on RoHs evaluation: Substance assessment of Diisobutyl phthalat (DIBP); http://rohs.exemptions.oeko.info/index.php?id=212. The contributions of the stakeholder submitted during the consultation are posted there.

[25] Annex XV dossier (2009): Proposal for Identification of a Substance as SVHC(CMR), Diisobutyl phthalate; submitted by Germany, August 2009.

Stakeholder (Submission Date)	Summary of the contribution
Japan Business Council in Europe (JBCE) (04.04.2014)	"The JBCE believes that the observations on the use of phthalates as described in the "Committee for Risk Assessment (RAC) Opinion on an Annex XV dossier[26] proposing restrictions on four phthalates (ECHA/RAC/RES-O-0000001412-86-07/F)" is also valid in the EEE sector with a preference for other phthalates over DIBP as well as an overall decline in the use of phthalates." "- To our knowledge DIBP is currently not used and will have no possible use in EEE. Accordingly, the JBCE believe there may be no need to regulate DIBP under RoHS. - Please note that the reason for proposing the restriction of DIBP is "toxic to reproduction", however, the data on reproductive toxicity of the possible alternatives listed in Section 7 are not appropriately referenced. More specifically, there is no data for AES, and the reliability of the data is uncertain about ATBC and COMGHA."
Test & Measurement Coalition (04.04.2014)"	"In general DiBP is not used in sector products at a level which must be reported under REACH. However, as the supply chain reporting is limited to the article-level assessment, an in-depth survey of the supply chain, including SME suppliers of custom parts, would be required to determine homogeneous material level exposure and complications inherent to requiring a substitution of this material."

3.2 Types of Applications

As a plasticiser in dispersion glues and printing inks, DIBP is applied in paper and packaging for food (paper, board, cartons) (e.g. rice, baking mixtures, cheese, bread, nuts) and bottled water.[27]

DIBP has been detected in many consumer products frequently used by children like crayons, bar ends of run bikes, erasers and school bags. [28] 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.[29] Surveys of the Danish EPA on a broad variety of plastic articles containing phthalates

[26] Op. cit. Annex XV dossier (2009)

[27] Op. cit. Annex XV dossier (2009)

[28] Op. cit. Annex XV dossier (2009)

[29] Op. cit. Annex XV dossier (2009)

placed on the Danish Market found DIBP in plastic sandals, bags, oilcloth, swimming pool, balance balls and training balls.[30] Surveys in the Netherlands 2007 and in Germany, Austria and Switzerland in 2007, both found DIBP in 2% of samples of toys and childcare articles.[31]

In an investigation of chemicals in perfumes in February 2005 conducted by Greenpeace, DIBP was found in 20 of 36 perfumes with concentrations ranging from 0.2 - 38 mg/kg.[32] DIBP however is prohibited from use in cosmetic products for its reproductive toxicity. The EU Scientific Committee on Consumer Products suggested that DIBP was present as traces and/or impurities and not used intentionally in the perfumes (SCCP 2007)[33].

3.3 Quantities of the Substance Used

The European chemical Substances Information System ESIS characterizes DIBP as a High Production Volume Chemical (HPVC; quantity exceeds 1000 t/a). The IUCLID Chemical Data Sheet at the ESIS database from 2000 indicates the manufacture and/or use of DIBP in Europe in the range of 10,000 to 50,000 t/a.[34]

There is no new data available on the content of DIBP in (imported) articles.[35]

The ECHA performed a screening of the registration dossiers submitted by producers and importers in 2010. Due to confidentiality aspects, the figures for the three phthalates DBP, DIBP and BBP are aggregated (see Table 3-2 on the next page). It was however noted that DIBP constitutes the largest part of the three phthalates used in the EU.[36] Thus, there are no exact data on the quantity of DIBP used for EU market or imported.

[30] Op. cit. ECHA RAC/SEAC (2012)

[31] Op. cit. ECHA RAC/SEAC (2012)

[32] Op. cit. Annex XV dossier (2009)

[33] SCCP Scientific Committee on Consumer Products (2007): OPINION ON PHTHALATES IN COSMETIC PRODUCTS. 21 March 2007; http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_106.pdf

[34] http://esis.jrc.ec.europa.eu/lib/esis_reponse.php?FROM=LISTE_EINECS&ENTREE=201-553-2

[35] Op. cit. DEPA (2011)

[36] Op. cit. ECHA RAC/SEAC (2012)

Table 3-2: Estimated Production of the Three Phthalates in End-Products Marketed in the EU (all Articles). [37]

	2007			2009–2010		
	EU production for EU market	Import	Total for EU market	EU production for EU market	Import	Total for EU market
DBP, DIBP, BBP	23,000 (27,000 - 4,000)	4,000 + n.d.	27,000 + n.d.	13,000	3,500	16,500

ECHA RAC/SEAC (2012)[38] states that data on plasticisers used in imported products is scarce or lacking for products where production in the EU dominates (e.g. flooring of vinyl); as with a few exemptions it has not been possible to identify the companies responsible for the import. The estimation of quantities of DIBP in import presented in ECHA RAC/SEAC (2012) [39] shows a smaller decline than the amount relevant for EU production, for the EU market. This correlates with the assumption of the Danish Competent Authority that it is not likely that the substitution rate outside the EU has been as high as in the EU. In the EU much work was spent on substitution as a result of the inclusion in Annex XIV of REACH.[40]

However, as DIBP is apparently not used in EEE, this issue will not be further discussed.

[37] Op. cit. ECHA RAC/SEAC (2012)

[38] Op. cit. ECHA RAC/SEAC (2012)

[39] Op. cit. ECHA RAC/SEAC (2012)

[40] Op. cit. DEPA (2011)

4.0 Waste Management of Electrical and Electronic Equipment

Uses of DIBP in EEE have not been identified. It is assumed that the reason for the stated uncommon use of DIBP in EEE is linked with the use of other plasticisers in PVC and other polymers in EEE applications, such as the phthalates DEHP, DBP and BBP. A review of the different routes of waste electrical and electronic equipment (WEEE), aimed at identifying potential releases, has not been performed in light of the limited and possibly non-existent applicability to EEE. Some general information as to the stipulated separate collection (unsorted municipal waste; shipments of WEEE; etc.) is provided below. The identified following 'waste streams' are understood to be of relevance for products potentially containing DIBP :

- Paper and packaging used for foodstuff are considered to fall under packaging waste, which is addressed by Directive 94/62/EC on packaging and packaging waste. The Directive specifies minimum recycling targets (60% by weight for paper and board; 22.5% by weight for plastics, counting exclusively material that is recycled back into plastics).
- Crayons, bar ends of run bikes, erasers and school bags, suckers, plastic spoons and forks, boxes for microwave ovens, disposable cups, plates and bowls are assumed to end up in municipal solid waste (MSW); the European Environment Agency (EEA) published a study in 2013 on the management of municipal solid waste. The treatment of MSW is explained to differ greatly between the various member states in terms of the waste shares that are recycled, landfilled and incinerated (EEA 2013).

4.1 Relevant Waste Management Processes for the WEEE Containing the Substance

This section will not further be discussed as the available data indicate that DIBP is not used in the EEE sector.

4.2 Description of Waste Streams

See Section 4.0.

4.3 Description of Impacts on WEEE Management

See Section 4.1.

5.0 Human Health

DIBP is identified as a substance of very high concern (SVHC) because it meets the criteria for classification as toxic to reproduction in accordance with Article 57 (c) of REACH.

No EU Risk assessment report is available for DIBP. The Annex XV dossier[41] was compiled with the aim of identifying DIBP as a CMR substance. Thus, the Annex XV dossier[42] did not consider toxico-kinetics; acute toxicity; irritation; corrosivity and sensitisation mutagenicity; and carcinogenicity as relevant, whereas repeated dose toxicity and toxicity for reproduction were extensively studied.

The following conclusions were made in ECHA RAC/SEAC (2012):

- The data available on DIBP indicate a low acute toxicity by the oral, intra-peritoneal and dermal route.
- DIBP is understood not to induce skin and eye irritation or skin sensitization, but the available information in this regard is limited.
- For DIBP only a few, rather old and repeated dose toxicity studies are available. A 4-month repeated dose toxicity study reported low body and testis weights and increased liver weights in rats with a 5% diet. The NOAEL was 1% in diet.
- The genotoxic potential of DIBP cannot be determined. There is evidence that shows it may induce DNA damage in human cells *in vitro*.
- For DIBP, no carcinogenicity data are available.
- A few reproductive toxicity studies have been published on DIBP. DIBP has been shown to induce decreased body weight after 1 week oral dosing in rats and mice as well as to have effects on testis weight and testosterone content. Relative testis weight was increased in mice and decreased in rats, while testicular testosterone content was decreased in both species. The adverse effects on the reproductive organs in rats and mice are attributed to an anti-androgenic mode of action. A LOAEL of 125 mg/kg bw/day for DIBP is used in the registration dossier for DIBP, based on histological changes in testes observed at all doses.
- Limited developmental toxicity studies for DIBP are available. At lower doses, it has been shown that DIBP induced decreased foetal weight and increased incidence of undescended testes. The NOAEL was 250 mg/kg bw/day, based on decreased pup weight and increased incidence of undescended testes. Although data for DIBP are limited, the fertility and developmental effects observed are similar to those phthalates with a side chain backbone of carbon side chains of 4-6 carbon atoms in length (C4-6). Therefore, it could be argued

[41] Op. cit. Annex XV dossier (2009)

[42] Ibid. Annex XV dossier (2009)

that DIBP has a similar reproductive toxicity profile to 'transitional' (C4-6) phthalates for which reproductive and developmental effects have been recognised.

5.1 Identification of Hazard Potential

5.1.1 Endpoints of Concern and NOAELS or LOAELs, BMDs

DIBP is not classified for any other human health endpoint besides reproductive toxicity.[43]

Table 5-1: Summary of Human Health Effects of DIBP.[44]

Endpoint	Value
LD50	16000-60320 mg/kgx
NOAEL mg/kg bw	
Reproductive toxicity Effects on male fertility	1000 mg/kg/day
Repeated dose Toxicity NOAEL	1% in diet
Developmental Toxicity NOAEL	250 mg/kg/day (rat)
Genotoxicity	Insufficient data
Carcinogenicity	Insufficient data
Maternal toxicity	NOAEL 250 (rat)
Critical endpoint	Developmental toxicity Dose: 250 mg/kg/day-rat.

5.1.2 Existing Guidance Values (DNELs, OELs, Reference Values)

For the establishment of Derived No-Effect Levels (DNELs), the ECHA Risk Assessment Committee concluded that there is too much uncertainty in the data available to allow a conclusion on humans being less, equally or more sensitive than rats. It was thus suggested not to deviate from the default interspecies factor of 10; for DIBP, the LOAEL of 125 mg/kg bw/day was taken as the starting value for DNEL derivation.[45] In

[43] Op. cit. ECHA RAC/SEAC (2012)

[44] Op. cit. ECHA RAC/SEAC (2012)

[45] Op. cit. ECHA RAC/SEAC (2012)

Table 5-2, the different determined DNELs for oral, inhalative and dermal exposure, as well as the assumed assessment factors for workers and the general population are shown.

Table 5-2: Summary of Human Health Effects of DIBP[46]

Preliminary DNELs	DNEL for critical endpoint, mg/kg/day
Oral	
Workers	350 mg/day Default assessment factors
General population	175 mg/day
Inhalation	
Workers	35 mgm^{-3}
General population	8.75 mgm^{-3}

5.2 Human Exposure Assessment

ECHA RAC/SEAC (2012) performed an in depth exposure assessment of the four phthalates DEHP, BBP, DBP und DIBP. Generally, human exposure by DIBP where consumers are concerned originates from:

- food (food packaging); and
- articles via direct contact; and/ or
- exposure in an indoor environment (indirectly via indoor air or via dust).

Human exposure of workers to DIBP is relevant when the exposure is equal or above the consumer exposure levels. There is greater potential for this:

- during manufacture of articles, through direct dermal contact; or
- through exposure to emissions from e.g. industrial extrusion processes;
- through exposure based on the presence of articles at the production site.

However, as such cases of exposure are not directly related to EEE, this section is not further detailed.

5.2.1 Exposure of Workers of EEE Waste Processing Plants

This section is not further discussed as the available data indicate that DIBP is currently not used in the EEE sector.

[46] Op. cit. ECHA RAC/SEAC (2012)

5.2.2 Exposure of Neighbouring Residents of EEE Waste Processing Plants (WPP)

See section 5.2.1.

5.2.3 Occupational and Consumer Exposure

See Section 5.2.

5.3 Evaluation of Risks of Workers and Neighbouring Residents' of Waste Processing Plants (WPP)

This section will not further be discussed as the available data indicate that DIBP is currently not used in the EEE sector.

5.3.1 Description of Risks Due to Uncontrolled Handling

See Section 5.2

6.0 Environmental Health

There is no environmental assessment available for DIBP:

- No EU Risk assessment report has been conducted for DIBP.
- The Annex XV dossier (2009) did not consider environmental fate properties, since the dossier was targeted at the identification of DIBP as a CMR substance.
- The Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of ECHA did not include any environmental risk assessment conclusions in their review[47].

6.1 Identification of Hazard Potential

ECHA RAC/SEAC (2012)[48] lists the following environmental hazard properties of DIBP (see Table 6-1):

Table 6-1: Environmental Hazard Properties of DIBP as Presented in ECHA RAC/SEAC 2012

Compartment	Hazard / risk conclusions
Water	Fish: LC_{50} (96h) 2500 – 3600 µg/l; Daphnia: LC_{50} 730 – 1100 µg/l Algae: EC_{50} (72h) 1 mg/L, NOEC 0.2 mg/L
Sediment	Unknown
Soil	Unknown
Atmosphere	Unknown
STP	Unknown
Secondary poisoning	Unknown
Bioaccumulation	Log K_{OW} 4.5 Estimated BCF = 800
Persistence	"Phthalate esters undergo 50% ultimate degradation within 28 days in standardised aerobic biodegradation tests with sewage sludge inocula. Biodegradation is expected to be the dominant loss mechanism in surface water, soils and sediments"
Risk assessment conclusions	None identified

[47] Op. cit. ECHA RAC/SEAC (2012)

[48] Op. cit. ECHA RAC/SEAC (2012)

The ECHA RAC/SEAC (2012)[49] thus concludes that DIBP is of potential hazard, based on its aquatic toxicity as it shows ecotoxic effects, (EC_{50}) < 10 mg/l, for two of the endpoints (fish and daphnia). Additionally, the bioaccumulation aspect is classified to be of potential hazard (BCF > 100 or $logK_{ow}$ > 4).

The Annex XV restriction report prepared by the Danish Competent Authority of REACH (DEPA) presents data on the hydrolysis of DIBP (see Table 6-2), originating from a registration dossier on DIBP. According to DEPA (2011), DIBP is not expected to undergo hydrolysis in the environment due to a lack of hydrolysable functional groups.

Table 6-2: Overview of Studies on Hydrolysis[50]

Method	Results	Remarks
Procedure as described in Wolfe et al. (1976) Agric. Food Chem., 24, 1041 and Wolfe et al (1977) Environ. Sci & Tech., 11, 88 Sodium hydroxide induced hydrolysis is monitored by GLC on samples.	Half-life (DT50): t1/2: at 30 °C; Rate constant: 0.0014 ; Type: second order (Units: M-1.s- 1)	2 (reliable with restrictions) weight of evidence experimental result Test material (EC name): diisobutyl phthalate

DIBP is not listed by the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR Convention) as a Chemical for Priority Action, nor as a Substance of Possible Concern. Neither does the Water Framework Directive list DIBP as a priority substance. But the self-classifications of manufacturers and/or importers of DIBP for Aquatic Toxicity (Acute and Chronic, see C&L inventory provided by ECHA) strongly confirm the estimation of ECHA RAC/SEAC (2012)[51] that DIBP is of potential environmental hazard. As DIBP is however not released by EEE, environmental health aspects will not further be discussed.

6.1.1 Endpoints of Concern, NOAECs, Acute, Chronic

The limited data on DIBP for environmental health are discussed in Section 6.0. Thus, this section is not further detailed.

[49] Op. cit. ECHA RAC/SEAC (2012)

[50] Op. cit. DEPA (2011)

[51] Op. cit. ECHA RAC/SEAC (2012)

6.1.2 Potential for Secondary Poisoning and Bioaccumulation

The limited data concerning the potential of DIBP to bioaccumulate is detailed in Table 6-1 and discussed in section 6.1. As specified in Table 6-1, data on secondary poisoning is lacking. Thus, this section is not further detailed.

6.1.3 Guidance Values (PNECs)

See NOAELs and DNELs specified above in Sections 5.1.1 and 5.1.2 respectively.

6.2 Environmental Exposure

ECHA RAC/SEAC (2012)[52] does not contain specific data for environmental exposure of DIBP.

6.2.1 Monitoring Data: Remote Regions, Biota

There are no data available.

6.2.2 Monitoring Data: Waste Management

This section will not further be discussed as the available data indicate that DIBP is currently not used in the EEE sector.

6.2.3 Exposure Scenarios: Waste Management

See Section 6.2.2.

6.3 Evaluation of the Risks for the Environment with Focus on WEEE Management

This section will not further be discussed as the available data indicate that DIBP is currently not used in the EEE sector.

[52] Op. cit. ECHA RAC/SEAC (2012)

7.0 Alternatives

ECHA RAC/SEAC (2012)[53] extensively discusses alternatives to DEHP, BBP, DBP and DIBP referring to availability, human health and environmental risks as well as technical and economic feasibility aspects and concludes that there are technically feasible alternatives available to replace the four phthalates for a very significant part of their use range. As for DIBP however, there are no detailed data on the suitability of the alternatives for specific DIBP applications. Instead, ECHA RAC/SEAC states that in light of the substance similarity, it is assumed that the alternatives for DBP can be used as substitutes for DIBP as well. This assumption is based on the statement of the European Council for Plasticisers and Intermediates (ECPI) concerning the very similar application properties of DIBP compared to DBP.

Table 7-1 shows the substitutes of DBP for various applications that may be relevant for DIBP as well. For applications where DIBP might be applied as a substitute for DBP, please refer to the RoHS DBP dossier (2014) for further detail.

In the following, substitutes that are the main alternatives on the market (1) or for which significant market experience has been gained (2) in at least three applications are shortly elaborated on, as the applications do not concern EEE.

Table 7-1: Alternatives for DBP Proposed by Contacted Manufactures, by Application and with Indication of Market Experience[54]

Application	ASE	GTA	DGD	ATBC	COMGHA
Plasticiser in PVC*	2		1	2	2
Plasticiser in other polymers	2				2
Adhesives	2	2		3	4
Printing inks	2	3		2	3
Miscellaneous					
Sealants	2			3	4
PU foam sealants	2			4	
Nitrocellulose paints	2	3	2	2	
Film coatings	3			3	

[53] Op. cit. ECHA RAC/SEAC (2012)

[54] Op. cit. ECHA RAC/SEAC (2012)

Application	ASE	GTA	DGD	ATBC	COMGHA
Glass fibre production*					4
Cosmetics					2

1: Main alternative on market; 2: Significant market experience; 3: Examples of full scale experience; 4: Pilot/lab scale experience

*It should be noted that though these applications appear in the original table of alternatives for DBP, in light of the available information, it is understood that they are of little relevance for DIBP, so long as it is not used to substitute one of the other three phthalates (DEHP; DBP; BBP).

7.1 Availability of Alternatives

Alkylsulphonic phenylester (ASE)

ASE is a mixture of similar esters of sulfonic acids, phenyl and C10-C18 alkanes (mixture CAS 91082-17-6). It is marketed by Lanxess (formerly Bayer) under the product name Mesamoll.[55] Lanxess has indicated significant market experience for the traditional DEHP, DBP and BBP applications.[56] ASE has a significantly higher price: 75% more expensive than DEHP. ECHA does not have any information on the potential for attaining reduced prices with increased production.[57] It has to be noted that the cost data are on substances and do not relate to applications which might make a difference.

ASE is available and already in use in several products. The substance has been reported by Danish manufacturers to be used in toys. There is experience with the use of ASE as a substitute for the normally used phthalate plasticisers in PVC coated textile fabrics such as e.g. rainwear and workwear.[58]

Acetyl tributyl citrate (ATBC)

ATBC consists of citrate with three ester bonded butyl groups and one acetyl group bonded to the fourth available oxygen atom. It is marketed by Vertellus (formerly Morflex), under the product name Citroflex A-4, and by Jungbunzlauer under the product name CITROFOL® BII.[59] The price of ATBC is significantly higher (200%) than the price of DEHP. This may represent a major impediment for its wider use as alternative to DEHP; DBP and BBP.[60]

[55] Op. cit. ECHA RAC/SEAC (2012)

[56] Op. cit. ECHA RAC/SEAC (2012)

[57] Op. cit. ECHA RAC/SEAC (2012)

[58] Op. cit. ECHA RAC/SEAC (2012)

[59] Op. cit. ECHA RAC/SEAC (2012)

[60] Op. cit. ECHA RAC/SEAC (2012)

ATBC is available and already in use in toys and childcare articles; this has been confirmed by analyses of toys and childcare articles. Furthermore, ATCB is also used in medical devices.[61]

ATBC is effective in solution for coating both paperboard and foil. It is a good plasticiser for vinyl toys. ATBC Special is developed and recommended for medical articles and similar sensitive applications. Thus, ATBC has mostly been used in products used for sensitive purposes such as children's toys medical products and food contact polymers. It is also used in inks, hair sprays and aerosol bandages.[62]

Glycerides, Castor-oil-mono-, hydrogenated, acetates (COMGHA)

COMGHA is a fully acetylated monoglyceride based on hardened castor oil (mixture CAS 736150-63-3). It is marketed by Danisco as GRINDSTED® SOFT-N-SAFE (ECHA RAC/SEAC 2012)[63]. There is research ongoing for manufacture of the substance at lower prices; the company expects that the anticipated lower price will accelerate market acceptance of COMGHA.[64]

COMGHA is approved for use in food contact materials. According to Danisco (2011), commercial experience suggests that the product will be used in both 'sensitive' (food Contact, medical, toys etc.) and technical areas alike (GRINDSTED® SOFT-N-SAFE fact sheet). DIBP specific examples of technical applications are textile dyes and ink applications. So far, COMGHA has not been found to be used in toys and childcare articles and it is not one of the plasticisers reported by Danish manufacturers to be used.[65]

7.2 Hazardous Properties of Alternatives

Table 7-2 provides an overview of the toxicological properties, environmental fate and ecotoxicological effects of the three alternatives presented above. The alternatives are not classified according to the CLP Regulation[66]. ECHA RAC/SEAC (2012)[67] concludes that the alternatives are not worse, as such, than the four phthalates in respect to the human health endpoints as well as in respect to the environmental endpoints, even though some have different negative effects on some of the endpoints:

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[61] Op. cit. ECHA RAC/SEAC (2012)

[62] Op. cit. ECHA RAC/SEAC (2012)

[63] Op. cit. ECHA RAC/SEAC (2012)

[64] Op. cit. ECHA RAC/SEAC (2012)

[65] Op. cit. ECHA RAC/SEAC (2012)

[66] As explained on the ECHA website, in most cases, suppliers are required to decide on the classification of a substance or mixture, termed self-classification. In parallel, classifications appearing in the CLP Regulation are termed harmonized classifications. In some cases, the decision on the classification of a chemical is taken at Community level, bringing about a harmonized classification. Such cases often concern the most hazardous substances. These are usually carcinogenic, mutagenic,

- **ASE** has shown low acute toxicity, negative results for mutagenicity and no effects on fertility. For ASE it is not possible to draw any clear conclusions regarding reproductive toxicity from the available data, and the available data did not show any sign of effect on fertility. As for the environmental fate, ASE is not readily biodegradable and its log K_{OW} (>6) is indicative of significant potential for bioaccumulation. Data on effects of ASE on aquatic organisms are few, however, the data indicates low to very low aquatic toxicity.[68]
- **ATBC** has low acute toxicity, low or slight sensitising, no mutagenic activity and no reproductive effects. Some signs of neurotoxicity were observed. ATBC was not found to be toxic to reproduction. The critical NOAEL is 100 mg/kg based on reduced body weight gain and increased liver weight. As for environmental assessment, ATBC was found to be readily biodegradable as well as ultimately biodegradable; however, there are indications for bioaccumulation potential as well as strong sorption properties i.e. low mobility in soil (BCF = 250 and a K_{OC} = 1,800 have been calculated for ATBC based on water solubility = 5 mg/L). There is potential hazard for aquatic toxicity.[69]
- **COMGHA** has low acute toxicity, no mutagenic activity and no carcinogenic potential. It is not a skin and eye irritant nor a skin sensitizer. COMGHA was shown not to have systemic toxic properties after repeated and chronic oral exposure. COMGHA does not have any adverse reproductive effects, including endocrine disrupting effects, or developmental effects. As for the environmental assessment, COMGHA is readily biodegradable and not expected to persist in the environment. COMGHA shows characteristics of a bioaccumulative substance; however, COMGHA is a glyceride and therefore inherently metabolizable and bioaccumulation is not expected. COMGHA did not show toxicity in aquatic species and is considered harmless to the environment and to environmental organisms.[70]

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toxic for reproduction or respiratory sensitisers. It is mandatory for the suppliers of the respective substance or mixture to apply this harmonised classification and labelling once such a classification is specified in the regulation.

For further detail, see http://echa.europa.eu/web/guest/regulations/clp/classification.

[67] Op. cit. ECHA RAC/SEAC (2012)

[68] Op. cit. ECHA RAC/SEAC (2012)

[69] Op. cit. ECHA RAC/SEAC (2012)

[70] Op. cit. ECHA RAC/SEAC (2012)

Table 7-2: Overview of Toxicological Properties, Environmental Fate and Ecotoxicological Effects of Possible DIBP Substitutes ASE, ATBC and COMGHA[71]

Name of substance	ASE	ATBC	COMGHA
CAS No.	91082-17-6	77-90-7	736150-63-3
Human health			
Acute toxicity O: oral LD50 D: dermal LD50 I: inhalation LC50	O: 26,380-31,650 mg/kg D: > 1,055 mg/kg I: ND	O: > 30 g/kg D: ND I: ND	O: > 2,000 mg/kg D: ND I: ND
Local effects / sensitisation	Skin: No irritation Eye: No irritation	Skin: No or slight irritation Eye: No or slight irritation Not sensitising	Skin: No or slight irritation Eye: No or slight irritation Not sensitising
Subchronic / chronic	NOAEL, 90 days: 228 mg/kg/day (m); 282.6 mg/kg/day (f) (increased kidney weight)	NOAEL, 90 days: 300 mg/kg/day (increased kidney weight); NOAEL, 2 years: 100 mg/kg/day (conservative); NOAEL, 13 weeks: 100 mg/kg/day (m); 300 mg/kg/day (f) (reduced body weight gain, increased liver weights, hepatic hypertrophy)	NOAEL, 90 days: 5000 mg/kg/day
Carcinogenicity	ND	No guideline study available. Existing study reliable with restrictions (lack of detail): No carcinogenicity observed in 2 year oral repeated dose toxicity study	Negative according to the tests performed
Mutagenicity / genotoxicity	Negative (Ames, mammalian cells). Reliable guideline studies for *in vitro* mammalian mutagenicity/genotoxicity. No *in vivo* studies available.	Negative (Ames, mammalian cells, in vivo/in vitro UDS test). Reliable (with some restrictions) guideline studies for *in vitro* mammalian mutagenicity/ genotoxicity. No *in vivo* studies available.	Negative (Ames, chromosomal aberration test) Reliable guideline studies for in vitro mammalian mutagenicity/genotoxicity. No in vivo studies available.
Reproductive toxicity	No reliable data.	Not considered toxic to reproduction (2-generation study) NOAEL: 100 mg/kg/day (parental, offspring) Reliable data available for both reproductive and developmental toxicity. Data for developmental toxicity lack some details.	Negative NOAEL > 1159 mg/kg bw/day
Other	–	Weak signs of neurotoxicity.	–

[71] Op. cit. ECHA RAC/SEAC (2012)

Name of substance	ASE	ATBC	COMGHA
Environmental assessment			
Environmental fate Biodegradation Bioaccumulation Mobility	Not readily biodegradable (31% in 28 d) Bioaccumul.: Log K_{OW} >6 Mobility ND (log K_{OW} indicates low mobility)	Ready biodegradable Bioaccumulation: BCF = 250 (calculated) Mobility: K_{OC} = 1,800 (estimated)	Ready biodegradable Bioaccumulation: Log K_{OW} = 6.4 Mobility: "Immobile in soil"
Ecotoxicity Fish Daphnia Algae	Fish: LC_{50} (96h) >100 mg/L Daphnia: EC_{50} (48h) >1,000 mg/L Algae: EC_{50} (72h) >10 mg/l	Fish: C_{50} (48 h) = 2.8 mg/L; LC_{50} (168h) = 1.9 mg/L Daphnia: EC_{50} (48h) = 7.82 mg/L Algae: EC_{50} (96h) = 0.148 mg/L (calculated)	Fish: NOEC(LC_{10}) (96h) = 0.28 mg/L Daphnia: EC_{50} (48h) = 0.92 mg/L Algae: EC_{50} (72h) = 106 mg/L

The Japan Business Council in Europe (JBCE) noted in its contribution during the stakeholder consultation "the data on reproductive toxicity of the possible alternatives are not appropriately referenced. More specifically, there is no data for ASE, and the reliability of the data is uncertain about ATBC and COMGHA". The JBCE thereby referred to the United States National Library of Medicine, Hazardous Substances Data Bank (HSDB)[72].

7.3 Body of Evidence for Alternatives and Uncertainties

The information on the alternatives is taken from the comprehensive final background document to the Opinion on the Annex XV dossier proposing restrictions on four phthalates (ECHA RAC/SEAC 2012). The information available concerning the three substitutes are presented above.

In short, it is understood that, though the substitutes detailed have been proposed as alternatives for DBP, in light of the similar properties of DBP and DIBP, relevant to various applications, it is expected that they could be used as substitutes for DIBP. Of the proposed substances, the information available shows that experience with their application in products has been gained in various areas. Some alternatives are explained to be substantially more expensive than DBP, however information is lacking to conclude as to their cost in comparison with DIBP. As the cost comparison reflects the cost of the substances themselves, it cannot be concluded how this difference would be reflected in the resulting cost of products using such alternatives. The available information also shows that alternatives have been used as substitutes in a range of products, suggesting that the cost difference has not hindered the phase-out of DBP in these areas of application.

Furthermore, as DIBP is understood not to be present in EEE, it is not anticipated that a restriction of its use through RoHS would result in substitution costs for manufacturers in this sector.

[72] http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB

8.0 Socio-Economic Impact on the Producers of the Substance

The review of socio-economic aspects in ECHA RAC/SEAC (2012) refers to a few areas of possible impacts concerning a possible restriction of the four phthalates DEHP, BBP, DBP and DIBP in the REACH regulation. The information does not allow estimating the possible impacts in relation with the general use of the four phthalates, and thus demarcating what portion of possible impacts can be referred to the applications of DIBP would not be possible, regardless if general applications or EEE applications are to be addressed:

- Where **human health** is concerned, the document points out that though available information demonstrates the four phthalates to have a negative impact in this regard, estimating this impact either quantitatively or qualitatively was not possible. In this regard, for the four phthalates, effects have been reported to be associated with several consequences in terms of human welfare (e.g. infertility/reduced fertility, adverse effects on social behaviour, testicular and breast cancer, sexuality impairment or dysfunctions, learning disabilities, autism and attention deficit hyperactivity disorder (ADHD)), however not allowing the establishment of the degree of such impacts. As other chemical substances have been shown to have similar effects, estimating the degree to which the use of these specific substances in articles would impact human welfare is further complicated.
- As for **environmental impacts**, the report states that the four phthalates have a potential for bioaccumulation and some of them could have effects on aquatic organisms. Their application however, as a plasticiser in articles, generally does not cause environmental problems. Furthermore, it is mentioned that the same potential for bioaccumulation and environmental effects has been recognized for some of the possible alternatives, here too generally not known to cause environmental problems.
- As for **economic impacts**, these are to be viewed in context of the activity at hand:
    - Concerning costs of raw materials, it is understood that the prices of alternatives are not significantly higher than those of the various phthalates, and thus costs related with substitution are not expected to be significant[73]. As an example, prices for substitutes of DEHP are said to be between 0-30% higher. This is further supported with the fact that

[73] It should be noted that this information is based on the ECHA RAC/SEAC (2012) report, which estimated the possible costs of substitution for all 4 phthalates. It is important to note in this regard that the data available on possible alternatives mentioned in Section 7.0 of this report, suggests that the substance cost of some alternatives is significantly higher. That said, the change in cost relates to the cost of the additive itself and is not necessarily reflected in the final costs of substitute-based products. As substitution is said to be underway, it is assumed that the cost of alternative substances has not significantly hindered substitution.

in plasticiser applications, substitution is underway, such as in PVC application of which only 20% still make use of the four phthalates.

- Concerning costs of reformulation, redesign and changes to production processes, available information is explained to contain only limited information on such costs. Similarly, little information is available on possible savings if shorter and more efficient processing can be reached with new plasticisers, as claimed by some manufacturers of alternatives.
- An area of concern is raised regarding the possibility of using recycled soft PVC, which may contain one or more of the four phthalates in concentrations higher than 0.1%. In such cases, some recycled materials could likely not be used any more for the manufacture of articles within the scope of a possible REACH restriction, resulting in a possible adverse economic impact in light of reduced flows of recycled PVC in the EU market.
- The fact that all four phthalates were already on the Authorisation list (Annex XIV) as this estimation was carried out, also explains in part the conclusion that some of the impacts would be less significant, as some of these costs may be assumed to have been incurred in the past.

Due to lack of further information and as DIBP is understood not to be used in electrical/ electronic equipment, the socio-economic impacts relevant for EEE will not be assessed in this dossier in further detail.

8.1 Impact on EEE Users

As DIBP is understood not to be used in electrical/ electronic equipment, the socio-economic impacts on EEE users will not be assessed in this dossier.

8.2 Impact on the Producers of the Substance and on the Producers of EEE and Components Thereof

See above.

8.3 Impact on the Workers in EEE Production and WEEE Treatment

See above.

8.4 Impact on Administration

The Commission's Impact Assessment for the recast of the RoHS Directive [74] extensively discussed the administrative costs for manufacturers and national authorities, stating great potential for reducing administrative costs by e.g. structured cooperation between market surveillance authorities or provisions for conformity assessment (CA) in RoHS. There are no new data available.

Basically, the Commission's Impact Assessment estimates the yearly administrative costs (in particular verification of compliance) make up approximately 67% of total costs, while the share of technical costs amounts to 33%.

The ECHA RAC/SEAC (2012) assumes this also being applicable for the four phthalates, thus they come to a rough estimate monitoring cost for imported articles, that comprise much more than the EEE sector, would be €6-12 million per year.

[74] Commission Staff Working Paper accompanying the Proposal for a Directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) Impact Assessment; Brussels, 3.12.2008; http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52008SC2930&from=EN

9.0 Rationale for Inclusion of the Substance in Annex II of ROHS

Based on the available data, DIBP is currently not used in the EEE sector. The main uses of DIBP are as a plasticiser in dispersion glues and printing inks applied in paper and packaging for food; as a plasticiser in toys and childcare articles; and in a wide range of consumer products (from plastic spoons and forks to plastic sandals) as well as in perfumes.

DIBP is identified as a substance of very high concern (SVHC) because of its reproductive toxicity and was included in REACH Annex XIV. Thus, DIBP cannot be placed on the EU market or be used after the 21st of February 2015 in the EU. No exempted uses for DIBP have been granted. Such specific authorisation for manufacturers, importers or downstream users to place the substance on the market, use it in preparations or for the production of articles had to be applied for before the 21st of August 2013 (latest application date) and it is assumed that at present the substance is not needed for use in European manufacture.

A contribution made by the Swedish Chemicals Agency (KEMI)[75], presents data collected from the Swedish Products Registry and from SPIN[76] concerning the use of DIBP in various products. In their contribution, KEMI state that the use of DIBP in EEE cannot be confirmed from the reported areas in these registries. The provided information furthermore shows a decline in the tonnage use of DIBP in these countries over the past ten years. This decline in the use of DIBP was also confirmed by another stakeholder, and explained as an overall decline in the use of the four phthalates DEHP, DBP, BBP and DIBP (JBCE 2014[77]).

The REACH authorisation route only addresses use within the EU. Articles containing DIBP can still be imported without restrictions, aside from the duty to communicate information on SVHC in articles (REACH Article 33[78]).

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[75] Swedish Chemicals Agency KEMI (2014): Contribution submitted during stakeholder consultation on 03.04.2014, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Diisobutylpthalate/20140403_KEMI_Input_to_PC_RoHS_2014_2_Substance_review_DIBP.pdf

[76] SPIN is a data base on the use of substances in products in the Nordic countries including data for Norway, Finland, Denmark and Sweden; it is available under http://195.215.202.233/DotNetNuke/default.aspx

[77] Japan Business Council in Europe (JBCE) (2014): Contribution submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Diisobutylpthalate/20140404_JBCE_-_Questionnaire_for_substance_prioritisation_DIBP.pdf

[78] This applies for a substance of very high concern in a concentration above 0,1% weight by weight (w/w). Then any supplier of an article shall provide the recipient of the article with sufficient information.
The Test & Measurement Coalition stated that in this regard: “In general DiBP is not used in sector products at a level which must be reported under REACH. However, as the supply chain reporting is

Since it is understood that DIBP is currently not in use in EEE, the main concern, which is in favour of a restriction under the RoHS Directive, is in connection with the possible restriction of the phthalates DEHP, BBP and DBP. DIBP has been stated to be a substitute for DBP (see Section 3.1 above) and could thus potentially be used as a substitute should DBP be restricted. The possibility of substituting one phthalate for another was also understood to be a partial motive for specifying the sunset date of DIBP when it was added to the REACH Annex XIV Authorisation List subsequently to the addition of the other three phthalates[79].

It is therefore concluded that the restriction of DIBP under RoHS should be tied to the decision to regulate DEHP, BBP and DBP under the RoHS Directive. The current REACH Regulation does not prevent the placing on the market of products containing these substances when imported from outside the EU. Thus a restriction of DIBP under RoHS would be aimed at preventing the possible use of DIBP as an alternative for DBP in EEE applications manufactured in countries outside the EU and thereby possibly imported and placed on the EU market.

However, as this is understood to be a subsequent development to a possible restriction of DEHP, BBP and DBP, at present it would be considered a preventive measure. Under the current conditions, this would result in various costs as described below without expected environmental benefit (explained below). It should thus be discussed under what conditions this should lead to a restriction of DIBP under the RoHS Directive.

In this regard, it should be noted that although the restriction of a substance not in use in EEE is not expected to have an impact on the development and manufacture of EEE, administrative costs would still be expected for industry. This is understood to be a result of the need to ensure that the substance is not used in articles (and particularly in articles supplied by the non-EU supply chain) and to specify such information in product documentation. Consequently, if the substance is not in use in EEE, these costs would not be balanced out with benefits arising from a decrease and elimination of use. In parallel, it is assumed that market surveillance activities of the four phthalates are already practiced in light of the REACH obligations, and could provide a basis for monitoring the presence of DIBP in EEE in the future. It is also understood that the four phthalates can be analysed using the same methods, which would mean that monitoring of DIBP should not result in substantial additional costs for such activities[80]. In this sense, an alternative to a restriction at present could be to

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limited to the article-level assessment, an in-depth survey of the supply chain, including SME suppliers of custom parts, would be required to determine homogeneous material level exposure […]."

Test & Measurement Coalition (TMC) (2014): Contribution submitted during stakeholder consultation on 04.04.2014, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Diisobutylpthalate/20140404_TMC_response_to_Oeko_additional_RoHS_substances__2014-0404.pdf

[79] Op. cit. ECHA (2010a)

[80] For instance, a possible analysis method for determination of the phthalates DIBP, DBP, BBP and DEHP in products is extraction with dichloromethane (solvent suitable for liberating phthalates from

condition the restriction with an increase of use of DIBP in EEE, observed in monitoring performed by market surveillance authorities. If in the future an increase in the presence of DIBP is to be observed, the restriction of DIBP in EEE would be reconsidered. It should be noted that market surveillance activities tied with DIBP may need to be enhanced in volume and targeted towards EEE in the future to serve this purpose, though this option would be linked to the monitoring of the other three phthalates in this case.

To conclude, there appears not to be a justification for currently restricting DIBP on its own. If DEHP, DBP and BBP are not to be restricted through RoHS, the consultants do not see a need for the restriction of DIBP in light of its limited applicability to EEE and the low probability for this to change.

There are, however, two options for action, should it be decided to restrict the other phthalates under the RoHS Directive. In both cases, it should be noted that since DIBP is on the REACH Regulation Authorisation List (Annex XIV), its trend of manufacture and use is not expected to change within the EU, whereas for imported goods and components there is a requirement to report its content in such articles to any recipient of the article (manufactures using components containing the substance or importers acquiring products containing the substance for the EU market).

The stricter possibility would be to tie the restriction of DIBP with the restriction of DEHP, DBP and BBP. In this case, if DEHP, DBP and BBP are to be restricted through the RoHS Directive, DIBP would be restricted subsequently. As the main motive for this restriction is to prevent possible substitution of one phthalate with another, it should further be considered if this would not justify grouping the phthalates for the purpose of restriction. The four phthalates DEHP, BBP, DBP and DIBP could be grouped as “classified phthalates” (phthalates on the REACH Authorisation list for the reason of reproductive toxicants category 1B). The grouping of similar substances is mentioned in Article 6 (1) of RoHS 2[81]. The similarity is due to the same classification under REACH and the inclusion on the Authorisation list. Additionally, the four phthalates are Low Molecular Weight (LMW) phthalates (low phthalates include those

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polymer materials such as PVC, followed by gas chromatography of the extracts with mass spectrometric detection (GC-MS).

For further information and examples of analysis results, see Tønning, K.; Jacobsen, E.; Pedersen, E. Nilsson, N. H. (2010): Phthalates in products with large surfaces, Danish Technological Institute, Survey of Chemical Substances in Consumer Products, No. 108 2010; http://www2.mst.dk/udgiv/publications/2010/978-87-92708-71-7/pdf/978-87-92708-70-0.pdf

[81] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast); Article 6(1) says: “In order to review and amend Annex II, the Commission shall take special account of whether a substance, including substances of very small size or with a very small internal or surface structure, or a group of similar substances.”

with 3-6 carbon atoms in their chemical backbone)[82]. In this case the RoHS compliance monitoring of EEE could run the four phthalates in parallel.

The second possibility, which is expected to be more favourable for industry (though with a greater risk for increase of DIBP use in EEE), would be to postpone the decision on the restriction of DIBP, revisiting its necessity based on changes in the trend of use in EEE. In other words, at present DIBP would not be included in Annex II of RoHS and would thus not be restricted for use in EEE through the RoHS Directive. In this case market surveillance of DIBP in EEE would need to be carried out in parallel to the other phthalates[83] in order to monitor changes in the trend of use. Should an increase in use be observed, the restriction would be reconsidered. It would be recommended in this case to revisit the possibility of a restriction from time to time to create an incentive for industry not to phase in DIBP, for instance every 5-7 years. It would further be beneficial in this course of action to reach an agreement with the EEE industry towards a voluntary non-use of DIBP.

[82] European Council for Plasticisers and Intermediates (ECPI): Plasticisers and flexible PVC information centre; http://www.plasticisers.org/en_GB/plasticisers/low-phthalates

[83] Monitorability and analysis methods covering the four phthalates are also discussed in DEPA (2011).

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