Study for the Review of the List of Restricted Substances under RoHS 2

Analysis of Impacts from a Possible Restriction of Several New Substances under RoHS 2

Revised Final Version

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06.08.2014

Report for:

The EUROPEAN COMMISSION

DIRECTORATE-GENERAL ENVIRONMENT

Directorate A - Green Economy

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Contents

Abbreviations

ATO....................Antimony trioxide

AUBA ....Austrian Umweltbundesamt GmbH

CAS....................Chemical Abstract Service

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

DBP ....Dibutyl phthalate

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

DEP ....Diethyl phthalate

DIBP ....Diisobutyl phthalate

ECHA ....European Chemicals Agency

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

ESIS...................European chemical Substances Information System

EEE....................Electrical and Electronic Equipment

EPA....................Environmental Protection Agency

ESIS...................European Chemical Substances Information System

HPVC ....High Production Volume Chemical

IPPC...................Integrated Pollution Prevention and Control Directive

JBCE ....Japanese Business Council in Europe

Kt.......................Kiloton

LPVC..................Low Production Volume Chemical

MCCP ....Medium Chained Chlorinated Paraffins

PBT....................Persistent, Bioaccumulative and Toxic Substances

OSPAR...............Oslo and Paris Conventions for the Protection of the Marine Environment of the North-East Atlantic

PCB ....Printed Circuit Boards

PVC....................Polyvinylchloride

RAC....................Risk Assessment Committee

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

TMC...................Test & Measurement Coalition

SCCNFP.............Scientific Committee on Cosmetic Products and Non-Food Products

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

SIN.....................Substitute It Now! List

SVHC ....Substance of Very High Concern

UPE....................Unsaturated Polyester

vPvB ....very Persistent and very Bioaccumulative Substances

WEEE.................Waste Electrical and Electronic Equipment

1.0 Background and objectives

The RoHS Directive (2002/95/EC) (RoHS 1) has been recast and has now become Directive 2011/65/EU that entered into force on 21 July 2011, repealing Directive 2002/95/EC on 3 January 2013. The RoHS Directive (2011/65/EU) on the restriction of the use of certain hazardous substances in electrical and electronic equipment requires "that EEE placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in Annex II" (i.e. lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers).

Directive 2011/65/EU, referred to as 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, the Austrian Umweltbundesamt GmbH (AUBA) conducted a first study that started in 2012 and ended at the beginning of 2014. The outcome of this study is a methodology for the identification, prioritisation (pre-assessment) and assessment of potentially relevant chemical substances in EEE.[1] AUBA also applied this methodology and produced an inventory of substances, a 24 entries priority substance list, and detailed dossiers for the four substances prioritised already in RoHS 2, Recital 10. These substances are HBCDD (brominated flame retardant), DEHP, BBP and DBP (three phthalate plasticisers), which also scored the highest ranking (together with seven other substances) in the AUBA pre-assessment.

The study also showed that 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 (e.g. substituting one brominated flame retardant for another). This is why the phthalate DIBP, which ranks highest according to the AUBA findings and is a standard substitute for DBP, was also identified for performing an assessment in the current study.

With the contract No. ENV/2013/SI2.667381/ETU/A2 implementing Framework Contract No. ENV.C.2/FRA/2011/0020, 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

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[1] http://www.umweltbundesamt.at/rohs2 provides download documents for the "Study for the Review of the List of Restricted Substances under RoHS 2 Directive" commissioned by DG Environment (European Commission):
Final report;
Annex 1 Manual on the Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive;
Annex 2 ROHS Annex II dossier – Template
Annex 3 EEE substance inventory
Annex 4 Priority List
Annex 5 ROHS Annex II dossier for HBCDD
Annex 6 ROHS Annex II dossier for DEHP
Annex 7 ROHS Annex II dossier for BBP
Annex 8 ROHS Annex II dossier for DBP

candidate for addition to Annex 2 of the RoHS Directive as well as prioritisation of a first shortlist of further substances.

The work has been undertaken by Oeko-Institut, and peer reviewed by Eunomia Research & Consulting. The work has been requested in view of supporting the review of the list of restricted substances under RoHS 2.

Summarising the above, the objectives of this project can be outlined as follows:

- Prepare a substance assessment of Diisobutylphthalat (DIBP), based on the methodology (template) for substance assessment prepared by the Austrian Umweltbundesamt GmbH;
- Provide input concerning quantitative usage data for the 21 priority substances in EEE identified by the Austrian Umweltbundesamt GmbH, or where this is not possible, a magnitude ranking, with a view to a refined prioritisation for future review cycles.

The report includes the following Sections:

Section 2.0 Approach

Section 3.0 Project set-up

Section 4.0 Substance prioritisation

Section A.1.0 Appendix 1: DIBP RoHS Substance Assessment Dossier

2.0 Approach

The initial approach to the various tasks included the review of publically available information from the following sources:

- European Chemicals Agency (ECHA): Documents provided during processes to address chemicals of concern; information provided by the Registered Substance Database[2] and the Classification & Labelling Inventory Database[3];
- Other EU Documents e.g. EU Risk Assessment Reports, Reports from the EU COM;
- Industry information, available on the internet, mainly published on websites of industry associations;
- Results from the Oeko-Institut study in 2008 on Hazardous Substances in Electrical and Electronic Equipment, not Regulated by the RoHS Directive.[4]

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[2] http://www.echa.europa.eu/web/guest/information-on-chemicals/registered-substances

[3] http://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database

[4] Oeko-Institut (2008): Study on Hazardous Substances in Electrical and Electronic Equipment, Not Regulated by the RoHS Directive by Groß, R.; Bunke, D.; Gensch, C.-G.; Zangl, S.; Manhart, A.; Contract

As a second stage, a targeted stakeholder consultation was performed, to collect input from the various stakeholders. It was launched on the RoHS Evaluation website[5], and stakeholders were requested to comment, on the draft dossier of DIBP and on initially compiled information concerning the short list of priority substances. The consultation ran for eight weeks from 07 Febuary 2014 to 04 April 2014. The corresponding questionnaires and the contributions submitted by stakeholders are available at the following website:

- For the "Substance assessment of Diisobutylphthalat (DIBP)" at http://rohs.exemptions.oeko.info/index.php?id=211.
- For the "Compilation and review of quantitative usage information concerning the various substances on the prioritised shortlist" at http://rohs.exemptions.oeko.info/index.php?id=213

Contributions made by stakeholders during the consultation thus provided an important input for reviewing and updating the initial information and data compiled from the sources mentioned above. In some cases the evaluation of the stakeholder contributions led to further consultation including, *inter alia*, engaging with stakeholders in further discussion, further exchanges in order to clarify unclear aspects and to request further information. Meetings were held with the following stakeholders, who requested a meeting to allow the presentation of contributed information and discussion of open issues: The Nickel Institute and the Beryllium Science & Technology Association.

The project was initially scheduled for a period of five months including an eight weeks consultation. The risk of not receiving sufficient input through the stakeholder consultation was identified at an early stage and a further month was added to the schedule. To further reduce this risk, in parallel to the consultation, individual requests for information were sent out to stakeholders identified for the various substances such as manufacturers of substances and compounds; associations of substances, etc. In coordination with the contributors, information acquired in this manner was also posted on the website as part of the stakeholder consultation and provided an important body of information.

3.0 Project set-up

Assignment of project tasks to Oeko-Institut started 27 November 2013. The overall project has been led by Carl-Otto Gensch. The project team at Oeko-Institut consists of the technical experts Yifaat Baron, Markus Blepp, Dirk Bunke and Katja Moch. Eunomia, represented by Adrian Gibbs, have the role of ensuring quality management.

The DIBP Dossier was published on 21 May 2014. As it follows the RoHS Dossier suggested template, it appears in this report in A.1.0 Appendix 1 and not as an integral part of the report.

No. 070307/2007/476836/MAR/G4; Final Report 17 October 2008; http://hse-rohs.oeko.info/fileadmin/user_upload/Documents/RoHS_Hazardous_Substances_Final_Report.pdf

[5] See http://rohs.exemptions.oeko.info/index.php?id=211

4.0 Substance prioritisation

The substances on the prioritised shortlist of the AUBA are presented in Table 4-1. The six different levels of priority are a result of the methodology of the AUBA applying human health & environment criteria and three waste criteria.

In three cases, substances were grouped because of intermediate use and/or a same classification under REACH: the nickel salts, nickel sulphate and nickel sulfamates, the two arsenic compounds di-arsenic pentoxide (i.e. arsenic pentoxide; arsenic oxide) and di-arsenic trioxide, and cobalt dichloride along with cobalt sulphate.

For all substances, prioritized by the AUBA, quantitative usage information has been collected and reviewed.

4.1 Overview of the substances reviewed

Table 4-1: Substances under review with priority as Indicated by the Austrian Umwelt-bundesamt GmbH

Substances	CAS-No	EC-No
Highest priority		
Diisobutylphthalate (DIBP)	84-69-5	201-553-2
Tris(2-chloroethyl) phosphate (TCEP)	115-96-8	204-118-5
Dibromo-neopentyl-glycol	3296-90-0	221-967-7
2,3-dibromo-1-propanol (Dibromo-propanol)	96-13-9	202-480-9
Second highest priority		
Antimontrioxid	1309-64-4	215-175-0
Diethyl phthalate (DEP)	84-66-2	201-550-6
Tetrabromobisphenol A	79-94-7	201-236-9
MCCP (medium chained chlorinated paraffins), C14 – C17: alkanes, C14-17, chloro;	85535-85-9	287-477-0
Third highest priority		
Polyvinylchloride (PVC)	9002-86-2	-
Fourth highest priority		
Nickel sulphate	7786-81-4	232-104-9
Nickel bis(sulfamidate); Nickel sulfamate	13770-89-3	237-396-1

Substances	CAS-No	EC-No
Beryllium metal	7440-41-7	231-150-7
Beryllium oxide (BeO)	1304-56-9	215-133-1
Indium phosphide	22398-80-7	244-959-5
Fifth highest priority		
Di-arsenic pentoxide; (i.e. Arsenic pentoxide; Arsenic oxide)	1303-28-2	215-116-9
Di-arsenic trioxide	1327-53-3	215-481-4
Cobalt dichloride	7646-79-9	231-589-4
Cobalt sulphate	10124-43-3	233-334-2
Sixth highest priority		
Cobalt metal	7440-48-4	231-158-0
Nonylphenol*	84852-15-3 25154-52-3	284-325-5 246-672-0

*4-Nonylphenol, branched and linear

4.2 REACH and CLP Regulation

4.2.1 REACH

Regulation (EC) No 1907/2006 regulates the safe use of chemical substances, and is commonly referred to as the REACH Regulation since it deals with Registration, Evaluation, Authorisation and Restriction of Chemical substances. REACH regulates the use of substances of concern through processes of authorisation and restriction:

- Substances that may have serious and often irreversible effects on human health and the environment can be added to the candidate list to be identified as Substances of Very High Concern (SVHCs). Following the identification as SVHC, a substance may be included in the Authorisation list, available under Annex XIV of the REACH Regulation: “List of Substances Subject to Authorisation”. If a SVHC is placed on the Authorisation list, manufacturers and importers that wish to continue using it, or continue placing it on the market, respectively, must apply for an authorisation for a specified use.
- If the use of a substance (or compound) in specific articles, or its placement on the market in a certain form, poses an unacceptable risk to human health and/or to the environment that is not adequately controlled, the European Chemical Agency (ECHA) may restrict its use, or placement on the market. These restrictions listed in Annex XVII of the REACH Regulation: “Restrictions on the Manufacture, Placing on the Market and Use of Certain Dangerous Substances, Mixtures and Articles”. The provisions of the restriction may be

made subject to total or partial bans, or other restrictions, based on an assessment of those risks.

The following terms are thus used when referring to these processes or substances regulated as a result thereof:

- Annex XIV - the list of substances subject to authorisation by the REACH Regulation, No. 1907/2006
- Annex XVII - Annex XIV - the list of restricted substances of the REACH Regulation, No. 1907/2006
- SVHC – Substances identified as Substances of Very High Concern

Both processes addressing chemicals of concern are performed according to process guidelines, including stakeholder consultations. The documents generated during these processes provide high quality data as they contain industry data that is reviewed by the ECHA and/or Member States.

4.2.1.1 Registered Substances

The manufacturer or the importer of a substance have the responsibility of collecting information on the properties and the uses of substances that they manufacture or import at or above a quantity of one tonne per year. This information is communicated to ECHA through a registration dossier. The ECHA publishes parts of this information in a standardized format in the Registered Substances Database.

There have been different deadlines for the registration of substances based on the usage tonnage. Until now, all substances manufactured or imported in an amount greater than 100 tonnes have had to be registered. The deadline for registration of substances manufactured or imported at a quantity of 1 to 100 tonnes per year is the 31 May 2018.

4.2.1.2 Article 33

REACH Article 33 requires suppliers to report the content of substances identified as SVHC in imported goods and components to any recipient of the article (manufactures using components containing the substance or importers acquiring products containing the substance for the EU market).

4.2.2 CLP Regulation

Regulation No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through classification and labelling of chemicals.

The manufacturers, importers and downstream users must establish the potential risks to human health and the environment of such substances and mixtures before placing them on the market. The substances and mixtures have to be classified according to the identified hazards. The hazardous chemicals have to be labelled according to a standardised system so that workers and consumers know about their effects before they handle them.

If a decision on the classification of a chemical is taken at Community level, it is called a harmonized classification. This process often concerns the most hazardous substances; the CLP regulation covers physical, health or environmental hazards. The harmonized classified substances are listed in Part 3 of Annex VI of the CLP regulation.

The classifications which appear in the substance specific sections have been compiled Table 4-2 below.

Table 4-2: Compilation of classification abbreviations appearing throughout this document

Hazard categories – Hazard statement	Explanation
Human Health Hazards	
Acute Tox. 2 * - H330	Fatal if inhaled
Acute Tox. 3 - H311	Toxic in contact with skin
Acute Tox. 3 * - H301	Toxic if swallowed
Acute Tox. 3 * - H331	Toxic if inhaled
Acute Tox. 4 * - H302	Harmful if swallowed
Acute Tox. 4 * - H332	Harmful if inhaled
Carc. 1A - H350	Category 1A, known to have carcinogenic potential for humans, classification is largely based on human evidence. May cause cancer
Carc. 1A - H350i	May cause cancer by inhalation
Carc. 1B - H350	Category 1B, presumed to have carcinogenic potential for humans, classification is largely based on animal evidence. May cause cancer
Carc. 1B - H350i	May cause cancer by inhalation
Carc. 2 - H351	Category 2, suspected human carcinogens. Suspected of causing cancer
Eye Irrit. 2 - H319	Causes serious eye irritation
Muta. 1B - H340	Germ Cell Mutagens[i] May cause genetic defects
Muta. 2 - H341	Germ Cell Mutagens [ii] Suspected of causing genetic defects
Repr. 1B - H360D	May damage the unborn child
Repr. 1B - H360F	Category 1B, presumed human reproductive toxicant May damage fertility

Hazard categories – Hazard statement	Explanation
Repr. 2 - H361fd	Category 2, suspected human reproductive toxicant Suspected of damaging fertility. Suspected of damaging the unborn child.
Resp. Sens. 1 - H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
Skin Corr. 1B - H314	Causes severe skin burns and eye damage
Skin Irrit. 2 - H315	Causes skin irritation
Skin Sens. 1 - H317	May cause an allergic skin reaction
STOT RE 1 - H372	Causes damage to organs
STOT RE 2 - H373	May cause damage to organs
STOT SE 3 - H335	May cause respiratory irritation
Environmental Hazards	
Aquatic Acute 1 - H400	Very toxic to aquatic life
Aquatic Chronic 1 - H410	Very toxic to aquatic life with long lasting effects
Aquatic Chronic 2 - H411	Toxic to aquatic life with long lasting effects
Aquatic Chronic 3 - H412.	Harmful to aquatic life with long lasting effects
Aquatic Chronic 4 - H413	May cause long lasting harmful effects to aquatic life

Note:
[i] Category 1B is based on:
– positive result(s) from in vivo heritable germ cell mutagenicity tests in mammals; or
– positive result(s) from in vivo somatic cell mutagenicity tests in mammals, in combination with some evidence that the substance has potential to cause mutations to germ cells. It is possible to derive this supporting evidence from mutagenicity/genotoxicity tests in germ cells in vivo, or by demonstrating the ability of the substance or its metabolite(s) to interact with the genetic material of germ cells; or
– positive results from tests showing mutagenic effects in the germ cells of humans, without demonstration of transmission to progeny; for example, an increase in the frequency of aneuploidy in sperm cells of exposed people.
[ii] Category 2 is based on: positive evidence obtained from experiments in mammals and/or in some cases from in vitro experiments, obtained from:
– somatic cell mutagenicity tests in vivo, in mammals; or
– other in vivo somatic cell genotoxicity tests which are supported by positive results from in vitro mutagenicity assays.

4.3 Substance review structure

The following sections (Section 4.4 to 4.19) present the data for each substance, including sub-sections for:

- Classification;
- Uses and quantities;
- A presentation and review of contributions of stakeholders; and

- A summary of the aspects identified as crucial for determining the priority of performing an in depth assessment of the substance as a candidate for restriction under RoHS.

Regarding the sub-sections on *'Classification'*, the status under REACH (SVHC identification or any restrictions under REACH Annex XVII or whether there are on-going processes addressing chemicals of concern), and the harmonized classification are presented. Additionally, if the substances are listed e.g. on the SIN list[6] or on the OSPAR List of Chemicals for Priority Action[7], then this also indicates that there are concerns, and these substances would be expected to be considered by REACH in the future. This information is provided as general background for the substance in question.

The sub-sections on '*Uses and Quantities'* present the data initially compiled for the stakeholder consultation. The availability of qualitative data can be described as follows:

- If substances have been assessed during processes to address chemicals of concern, data on substance applications and amounts is generally available, provided by stakeholders in the past and cross-checked by the ECHA or by National Authorities.
- If there have been no initiatives on ECHA or Member State level, data availability is often limited to the information of the ECHA Registered Substance Database and industry information, available on the internet;
- In cases where substances have not been registered in the EU, even less data is available.

The sub-sections '*Contributions of Stakeholders'* present the main aspects raised in contributions submitted during the consultation in a table format. In most cases, the contributions are cited with correction of spelling and formulation in some cases. In those cases where the extent of the contributions exceeded the space given in the table, a summary is instead presented, which is then indicated by the headline "summary" in the respective field of the table.

Stakeholders generally referred to the EEE sector not specifying single categories of EEE. Only the Test & Measurement Coalition have referred their contributions to category 9 (monitoring and control instruments including industrial monitoring and control instruments).

The data on uses and quantities compiled for the consultation was compared with the stakeholder contributions. The updated information and points identified as relevant for the prioritisation have subsequently been compiled in the sub-sections labelled '*Summary'*. These summaries do not themselves come to a recommendation. This is

[6] 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; http://www.chemsec.org/what-we-do/sin-list

[7] OSPAR List of Chemicals for Priority Action applies the PBT criteria and additional criteria for hazardous substances, such as CMR or chronic toxicity for mammals; http://www.ospar.org/content/content.asp?menu=00940304440000_000000_000000

done at the end in the chapter ‘Priority Recommendations’ within the prioritisation of all substances.

4.4 Tris(2-chloroethyl) phosphate (TCEP)

4.4.1 Classification

TCEP was added to Annex XIV because of its classification as toxic to reproduction (Sunset date: 21/08/2015; latest application date: 21/02/2014; no exempted (categories of) uses granted so far).[8]

TCEP is classified under the CLP Regulation with the following entries:

- Carc. 2 - H351
- Repr. 1B - H360F***
- Acute Tox. 4 * - H302
- Aquatic Chronic 2 - H411

4.4.2 Uses and quantities

TCEP is mainly used as an additive plasticiser and viscosity regulator with flame retarding properties for foams, polyesters and other polymers (e.g. polyurethane, polyvinyl chloride and polyisocyanurate). It is used in plastics, textiles, adhesives, building insulation, coatings, paints and varnishes.[9] The main industrial branches using TCEP are textiles, furniture and construction, as well as cars, railways and aircrafts.[10]

According to ECHA (2010)[11], the manufactured volume of TCEP in EU27 was around 400 t/y in 2010. Accounting the imported and exported quantities, the total use in the EU is assumed to be around 1,000 tonnes per year. The registration data indicates

[8] Article 58 (1) (c) defines the significance of the **sunset date** and **application 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”
“(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 [referred to as **application date**];”
[9] EU RAR (2009): European Union Risk Assessment Report. TRIS (2-CHLOROETHYL) PHOSPHATE, TCEP; July 2009.
[10] ECHA (2010): Background document for Tris (2-chloroethyl) phosphate (TCEP), Document developed in the context of ECHA’s second Recommendation for the inclusion of substances in Annex XIV; 17 December 2010; http://www.echa.europa.eu/documents/10162/f448e657-47e5-43ee-9358-4e2a2c7817cb
[11] Op. cit. ECHA (2010)

much less, namely a total tonnage band[12] of 10 to 100 tonnes per annum.[13] This might indicate an already declining use of TCEP before the sunset date 21 May 2015.

There are no data available on amounts of TCEP in EEE products. However, electronic devices or television sets may contain TCEP as it was used in plastic materials for EEE housings. These uses are discussed in the context of air emissions and consumer exposure.[14] Though these uses might be considered as "historical uses", as they are not mentioned anymore in the information compilation of ECHA, the EEE stock still containing TCEP may still affect consumers as well as having possible impacts in waste treatment and recycling facilities.[15]

4.4.3 Contributions of stakeholders

Two stakeholders, the Swedish Chemicals Agency KEMI and the Test & Measurement Coalition submitted contributions on TCEP. They are cited in the following table. No quantities on the use of TCEP in EEE were provided.

Table 4-3: Stakeholder contributions on TCEP submitted during the consultation

Stakeholder (Submission date)	Uses	Quantities
Swedish Chemicals Agency KEMI (03 Apr 2014)	The use of Tris(2-chloroethyl)phosphate in EEE cannot be confirmed from the reported uses in the SPIN database[16] or the Swedish Products register	Summary Total use of Tris(2-chloroethyl)phosphate in the Nordic countries[17] 2011: 71.4 t (in 2010: 219.2 t)
Test & Measurement Coalition (TMC) (04 Apr 2014)	Chlorinated compounds remain pervasive in EEE. Due to the article-level reporting required to comply with REACH Article 33, there is limited knowledge available on whether custom part plastic sub-components contain TCEP at the homogeneous	-

[12] The total tonnage bands for registered substances are derive from an extraction of the tonnage data from the latest disseminated dossiers of each full (non-intermediate) registration, which are then aggregated and converted to a total tonnage band and published on ECHA's registered substances database; http://echa.europa.eu/web/guest/view-article/-/journal_content/81cace06-43bf-4756-aa10-784f3561ea4c

[13] ECHA Registered Substances Database: Entry for tris(2-chloroethyl) phosphate; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d851c42-6bc0-6ee4-e044-00144f67d249/DISS-9d851c42-6bc0-6ee4-e044-00144f67d249_DISS-9d851c42-6bc0-6ee4-e044-00144f67d249.html

[14] Op. cit. EU RAR (2009)

[15] US TOXNET on TCEP: "Tris(2-chloroethyl)phosphate was detected in the air of a recycling electronic products plant at concentrations ranging from 15-36 ng/cu m in the dismantling hall, 28-34 ng/cu m in shredder during processing of plastics without brominated additives, and 33-38 ng/cu m in the shredder during processing of plastics containing brominated additives(1). Background level of airborne tris(2-chloroethyl)phoshate in a computerized office room was reported as 7.4 ng/cu m(2)."; http://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+2577

[16] SPIN is a database on the use of Substances in Products in the Nordic Countries. The database is based on data from the Product Registries of Norway, Sweden, Denmark and Finland.

[17] The Nordic countries are Sweden, Norway, Denmark and Finland.

Stakeholder (Submission date)	Uses	Quantities
	material level. An in-depth survey of the supply chain, including SME suppliers, is required in order to determine exposure and complications inherent to requiring a substitution of this material.	

Note: Wording as formulated by stakeholders, with correction only for readability where necessary. Views expressed should not be taken to reflect those of the authors of this report.

4.4.4 Summary

The current level of use, of TCEP in EEE across the EU28, could not be verified. The contribution of the Swedish Chemicals Agency KEMI confirms that TCEP is currently not used in EEE in the Nordic counties. The Test & Measurement Coalition suggest that uncertainty exists and proposes performing an in-depth survey of the supply chain based on the reporting requirements of REACH Article 33.

In light of the inclusion of TCEP in the REACH Regulation Authorisation List (Annex XIV), a decrease in use is anticipated, as can be understood to be confirmed by the data presented by KEMI on the use of TCEP in the Nordic countries in the last years. TCEP cannot be placed on the EU market or be used after the 21st of August 2015 in the EU meaning that TCEP will only enter the EU via imported articles. No exempted uses for TCEP have been granted; thus, it is assumed that at present the substance is not applied in European manufacture.

As already mentioned, the REACH authorisation route only addresses use within the EU. Articles containing TCEP can still be imported without restrictions, aside from the duty to communicate information on SVHC in articles (REACH Article 33).

4.4.5 References

ECHA (2010): Background document for Tris (2-chloroethyl) phosphate (TCEP), Document developed in the context of ECHA's second Recommendation for the inclusion of substances in Annex XIV; 17 December 2010; http://www.echa.europa.eu/documents/10162/f448e657-47e5-43ee-9358-4e2a2c7817cb

ECHA Registered Substances Database: Entry for tris(2-chloroethyl) phosphate; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d851c42-6bc0-6ee4-e044-00144f67d249/DISS-9d851c42-6bc0-6ee4-e044-00144f67d249_DISS-9d851c42-6bc0-6ee4-e044-00144f67d249.html

EU RAR (2009): European Union Risk Assessment Report. TRIS (2-CHLOROETHYL) PHOSPHATE, TCEP; July 2009.

Swedish Chemicals Agency KEMI (2014): Contribution submitted during stakeholder consultation on 03.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140403_KEMI_Input_to_PC_RoHS_2014_2_Substance_review_Prioritasion.pdf

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

4.5 Dibromo-neopentyl-glycol

4.5.1 Classification

Dibromo-neopentyl-glycol is not classified under the CLP Regulation; thus there is no harmonized classification. Dibromo-neopentyl-glycol has not been subject to an EU risk assessment nor has it been addressed by a Member State or the ECHA. Thus, the publically available information is scarce.

The self-classification notified by manufacturers and/or importers to the ECHA includes the following entries:[18]

- Acute Tox. 4 - H302
- Eye Irrit. 2 - H319
- Skin Irrit. 2 - H315
- Muta. 2 - H341
- Muta. 1B - H340
- Carc. 1B - H350
- Carc. 2 - H351
- STOT RE 2 - H373
- STOT SE 3 - H335
- Aquatic Chronic 4 - H413

4.5.2 Uses and quantities

Dibromo-neopentyl-glycol is a registered substance under REACH with one registrant that indicates a usage with a total tonnage band of 100 to 1,000 tonnes per year.[19]

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[18] ECHA Classification & Labelling Inventory Database: Entry for 2,2-bis(bromomethyl)propane-1,3-diol; http://clp-inventory.echa.europa.eu/SummaryOfClassAndLabelling.aspx?SubstanceID=70521&HarmOnly=no?DisclaimerAgr=Agree&Index=3296-90-0&ExecuteSearch=true&fc=true&lang=en

[19] ECHA Registered Substances Database: Entry for 2,2-bis(bromomethyl)propane-1,3-diol; http://apps.echa.europa.eu/registered/data/dossiers/DISS-d018e490-d63b-3393-e044-00144f67d249/DISS-d018e490-d63b-3393-e044-00144f67d249_DISS-d018e490-d63b-3393-e044-00144f67d249.html

According to the European chemical Substances Information System ESIS database, it is reported as a low production volume chemical (LPVC).[20]

According to the ECHA Registered Substances Database, the use as reactive flame retardant intermediate in the manufacture of polymer resins is declared, as well as the sectors of end uses:

- SU 12: “Manufacture of plastics products, including compounding and conversion”;
- and the article category related to subsequent service life AC 13: “Plastic articles” are mentioned

These end uses do not allow excluding possible use in EEE.

4.5.3 Contributions of stakeholders

Four stakeholder contributions included information concerning dibromo-neopentyl-glycol. Two of the contributions state that the substance is not in use in EEE whereas the other two did not confirm if the substance is in use or not. According to ICL-IP Europe, dibromo-neopentyl-glycol is used in construction material. For further detail please see the contribution summary in Table 4-4 below.

Table 4-4: Stakeholder contributions on dibromo-neopentyl-glycol submitted during the consultation

Stakeholder (Submission date)	Input
Swedish Chemicals Agency KEMI (03 Apr 2014)	The substance is used in the Nordic countries but only confidential data are available.
ICL-IP Europe (02 Apr 2014)	DBNPG is used solely as a reactive flame retardant in construction, and is used for > 90% in Unsaturated Polyester used for UPE sheets in roofing. DBNPG is not used in EEE products.
Japan Business Council in Europe (JBCE) (04 Apr 2014)	According to the JBCE following substances are not contained in EEE: 2,3-dibromo-1-propanol and Dibromoneopentyl-glycol listed as “highest priority”. EEE manufacturers do not instruct suppliers to use dibromo-neopentyl-glycol.
Test & Measure-ment Coalition (TMC) (04 Apr 2014)	There is limited knowledge available on whether custom parst contain this sub-stance at the homogeneous material level. An in-depth survey of the supply chain, including SME suppliers, is required in order to determine exposure and complications inherent to requiring a substitution of this material.

Note: Wording as formulated by stakeholders, with correction only for readability where necessary. Views expressed should not be taken to reflect those of the authors of this report.

[20] ESIS Data Sheet: Result for EC#: 221-967-7; http://esis.jrc.ec.europa.eu/lib/esis_reponse.php?FROM=LISTE_EINECS&ENTREE=221-967-7

4.5.4 Summary

Although publically available information on dibromo-neopentyl glycol is very scarce, it is understood that low volumes are in use in the EU for the manufacture of plastic articles. Though this could include plastic articles used in EEE, the information provided by stakeholders suggests that this is not the case. It is understood that the low volume of this chemical used in the EU (100 to 1000 tonnes per year) is mainly applied (above 90%) in unsaturated polyester (UPE) used for UPE sheets in roofing.

The information provided by stakeholders during the consultation further suggests that dibromo-neopentyl glycol is either not applied in EEE or applied in small amounts by manufacturers of supplied goods, thus requiring a more comprehensive supplier survey to allow a better quantification.

4.5.5 References

ECHA Classification & Labelling Inventory Database: Entry for 2,2-bis(bromomethyl)propane-1,3-diol; http://clp-inventory.echa.europa.eu/SummaryOfClassAndLabelling.aspx?SubstanceID=70521&HarmOnly=no?DisclaimerAgr=Agree&Index=3296-90-0&ExecuteSearch=true&fc=true&lang=en

ECHA Registered Substances Database: Entry for 2,2-bis(bromomethyl)propane-1,3-diol; http://apps.echa.europa.eu/registered/data/dossiers/DISS-d018e490-d63b-3393-e044-00144f67d249/DISS-d018e490-d63b-3393-e044-00144f67d249_DISS-d018e490-d63b-3393-e044-00144f67d249.html

ESIS Data Sheet: Result for EC#: 221-967-7; http://esis.jrc.ec.europa.eu/lib/esis_reponse.php?FROM=LISTE_EINECS&ENTREE=221-967-7

ICL-IP Europe 2014): Contribution submitted during stakeholder consultation on 02.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140402_ICL_RoHS_OKOinstitute_comments_ICL-IP_Dibromoneopentyl-glycol.pdf

Japan Business Council in Europe JBCE (2014): Contributions submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/index.php?id=213

Swedish Chemicals Agency KEMI (2014): Contribution submitted during stakeholder consultation on 03.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140403_KEMI_Input_to_PC_RoHS_2014_2_Substance_review_Prioritasion.pdf

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

4.6 2,3-dibromo-1-propanol (Dibromo-propanol)

4.6.1 Classification

Dibromo-propanol has the following harmonized classification under the CLP Regulation:

- Carc. 1B - H350
- Repr. 2 - H361f
- Acute Tox. 3 - H311
- Acute Tox. 4 - H302, H332
- Aquatic Chronic 3 - H412.

4.6.2 Uses and quantities

Dibromo-propanol is not registered under REACH and was not expected to be registered by the second deadline, June 1st 2013.[21] This means that, if it is still used, it is used in the EU in quantities lower than 100 tonnes. The European chemical Substances Information System (ESIS) database does not contain any reporting concerning dibromo-propanol submitted by EU Industry.

The major use of 2,3-dibromo-1-propanol is as an intermediate in the production of flame retardants, insecticides, and pharmaceuticals, and it has been used as a flame retardant. 2,3-Dibromo-1-propanol was used in the production of tris(2,3-dibromo-propyl) phosphate, a flame retardant used in children's clothing and other products.[22]

4.6.3 Contributions of stakeholders

The stakeholder contributions submitted during the consultation indicate that 2,3-dibromo-1-propanol is not used in EEE (see Table 4-5). That said, the statement of the Test & Measurement Coalition indicates that the body of knowledge concerning the application of brominated flame-retardants by the EEE supply chain is insufficient to rule out their relevance to this sector.

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[21] http://www.echa.europa.eu/documents/10162/13632/intentions_2013_en.pdf

[22] US National Toxicology Program, Department of Health and Human Services (2011): 2,3-Dibromo-1-propanol, Report on Carcinogens, Twelfth Edition (2011); http://ntp.niehs.nih.gov/ntp/roc/twelfth/profiles/dibromopropanol.pdf

Table 4-5: Stakeholder contributions on dibromo-propanol submitted during the consultation

Stakeholder (Submission date)	Input
European Flame Retardants Association (EFRA) (04 Apr 2014)	We do not have any information about 2,3-dibromo-1-propanol since none of the EFRA member companies manufacture this substance. We thus also believe that its use in E&E should be negligible, if it takes place at all.
Japan Business Council in Europe (JBCE) (04 Apr 2014)	According to the JBCE following substances are not contained in EEE: 2,3-dibromo-1-propanol and Dibromoneopentyl-glycol listed as “highest priority”. EEE manufacturers do not instruct suppliers to use 2,3-dibromo-1-propanol.
Test & Measurement Coalition (TMC) (04 Apr 2014)	Brominated flame retardants not currently restricted under RoHS are still quite pervasive in the supply chain and are frequently noted in supplied article sub-components. As this substance is listed with possible use as a flame retardant for epoxy, polyester, and urethane foams, an in-depth survey of the supply chain, including SME custom part suppliers, would be required to determine exposure and whether substitutions would impact safety or other certifications (e.g. for flame-retarded uses such as epoxy internal to power supplies.)

Note: Wording as formulated by stakeholders, with correction only for readability where necessary. Views expressed should not be taken to reflect those of the authors of this report.

4.6.4 Summary

As 2,3-dibromo-1-propanol is not registered, it is understood not to be used in the EU or to be applied in low quantities; as further information was not obtained through stakeholders, the use volume cannot be concluded.

Though it is used as a flame retardant, its application in the EEE sector is not known to the European Flame Retardant Association, which represents the leading organisations who manufacture, market or use flame retardants in Europe.

On the other hand, the case of 2,3-dibromo-1-propanol suggests that it is not always clear which (brominated) flame retardant is used within the supply chain. The Test & Measurement Coalition states that an in-depth-survey of the supply chain, including SME custom part suppliers, would be required to determine exposure and whether substitution would impact safety or other qualifications (e.g. for flame-retarded uses such as epoxy internal to power supplies).

4.6.5 References

ESIS Data Sheet: Result for EC#: 221-967-7; http://esis.jrc.ec.europa.eu/lib/esis_reponse.php?FROM=LISTE_EINECS&ENTREE=221-967-7

European Flame Retardants Association EFRA (2014): Contribution submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/final_EFRA4_answers_to_Oeko-Institute_survey_on_RoHS_04.04.2014__2_.pdf

Japan Business Council in Europe JBCE (2014): Contributions submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/index.php?id=213

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

US National Toxicology Program, Department of Health and Human Services (2011): 2,3-Dibromo-1-propanol, Report on Carcinogens, Twelfth Edition (2011); http://ntp.niehs.nih.gov/ntp/roc/twelfth/profiles/dibromopropanol.pdf

4.7 Antimony trioxide

4.7.1 Classification

Antimony trioxide is classified under the CLP regulation as Carc. 2 - H351 (Suspected of causing cancer via inhalation). There is no registry of intention to propose it for identification as SVHC. There was a proposal for community-wide measures to reduce risks, submitted by the Swedish Chemicals Agency in 2008. The proposal recommended establishing occupational exposure limit values for antimony trioxide according to Directive 98/24/EEC. Under the Water Framework Directive and the IPPC Directive[23] further measures to reduce the risks to the local environment have been identified (according to the criteria of Regulation (EEC) 793/93) adjacent to some industrial sites.

4.7.2 Uses and quantities

The major use of antimony trioxide is as a synergist for halogenated flame-retardants in plastics, paints, adhesives, sealants, rubber, and textile back coatings. Other uses of antimony trioxide include application as a polymerisation catalyst used in PET resin manufacture and as a clarifying aid in certain glasses, and in pigments.

The use of antimony trioxide as flame retardant synergist in plastics and rubber, may be relevant for EEE applications such as housings for PC, TV and PPC, printed circuit boards, connectors, mouldings, plugs and switches, wires and cables, semiconductors encapsulated, ultra-pure silicon wafers and other small and large household applications. In addition, antimony trioxide is used as a melting agent in glass-ceramic hobs in household appliances also including lamps as well as in glass for TV and PC screens.[24]

[23] The IPPC Directive 2008/1/EC concerning integrated pollution prevention and control has been recasted as the Directive on industrial emissions 2010/75/EU (IED).

[24] Oeko-Institut (2008): Study on Hazardous Substances in Electrical and Electronic Equipment, Not Regulated by the RoHS Directive by Groß, R.; Bunke, D.; Gensch, C.-G.; Zangl, S.; Manhart, A.; Contract No. 070307/2007/476836/MAR/G4; Final Report 17 October 2008; http://hse-rohs.oeko.info/fileadmin/user_upload/Documents/RoHS_Hazardous_Substances_Final_Report.pdf

Antimony trioxide is registered under REACH, indicating a volume of more than 10,000 tonnes per year. According to the Swedish Chemicals Agency in 2008, approximately 25,000 tonnes per year were used in the EU, mainly (>70%) in the production of flame-retarded plastics (PVC and non-PVC).[25] The distribution of these quantities in the EU in 2005 was as follows: use as flame-retardant in plastics (9,200 t); in PVC (8,800 t); in rubber (2,200 t); in textiles (1,750 t); as a catalyst in PET production (950 t); as an additive in glass manufacture (250 t); and in pigments in paint and ceramics (1,100 t).

4.7.3 Contributions of stakeholders

Five stakeholder contributions were made for antimony trioxide, confirming the broad range of use in EEE housings (e.g. computers, TVs etc.) and cables. The contribution of the European Flame Retardant Association EFRA provided detailed input on the advantages of the use of antimony trioxide (ATO), which reduces the amount of brominated flame retardants (BFR) by two to three times. This BFR-ATO system applied in the technically and economically preferred polymers ABS and HIPS provides a high cost-effectiveness.

Table 4-6: Stakeholder Contributions on dibromo-propanol submitted during the consultation

Stakeholder (Submission date)	Uses	Quantities
Swedish Chemicals Agency KEMI (03 Apr 2014)	Relevant to EEE products and applications, but relevant data on used quantities is unclear.	Summary: Data from the Swedish products register in 2011. Product types: Flame retardants, fire protection additive: 177.1 t Raw material f. plastics: 48.4 t Raw material for rubber products: 21.3 t Plastic Construction Materials: 1.7 t Industry sectors: Plastic manufacturing: 162.2 t Electro manufacturing industry: 70.6 t Export: 30.3 t Rubber/plastic products: 24.7 t Metal coating: 11.3 t Total use of Antimony trioxide in the Nordic countries 2011: 713.1 t

[25] Swedish Chemicals Agency (2008): Proposal for Community-wide measures to reduce risks; Diantimony Trioxide; 2008-11-26; http://www.echa.europa.eu/documents/10162/13630/trd_sweden_diantimony_trioxide_en.pdf

Stakeholder (Submission date)	Uses	Quantities
International Antimony Association i2a (04 Apr 2014)	Summary: Further explanation for the following points is provided in annex to the letter: - ATO is a potential inhalation carcinogen - The inhalation hazard disappears once ATO is encapsulated in a polymer matrix - Uses of ATO are safe for human health and the environment - Waste from production and use of ATO is safe - There are no suitable alternatives for ATO:BFR systems for some uses in E&E - WEEE which contains ATO can effectively and safely be recycled. Based on the scientific data we have gathered till now, and on the conclusions of the independent international assessments on ATO, we believe ATO should not be restricted under EU-RoHS. We want to mention that ATO was proposed for inclusion in the 'Restricted Substances'-list under RoHS in 2010; based on scientific data, it was correctly concluded by the regulators at that time to remove ATO from the list. Since then, to our knowledge, no scientific evidence became available supporting a restriction for ATO under EU-RoHS.	
European Flame Retardants Association EFRA (04 Apr 2014)	ATO is mainly used in EEE as flame retardant synergist for halogenated flame retardants (HFR); with a typical ATO-HFR ratio of 1:3), or in polymers containing halogens such as PVC. The addition of ATO in combination with HFRs allows that about 2-3 times less HFRs have to be added to meet the same flame retardancy performance. HFRs in combination with ATO are typically used for E&E housings (e.g. computers, TVs etc.) and cabling. ATO is also used as catalyst in PET production. ATO: The use of Brominated Flame Retardants (BFRs) together with ATO as synergist is for certain applications indispensable. Some examples: - ABS and HIPS are today one of the preferred (technically and economically) polymers for E&E enclosures. The BFR-ATO combination is still one the most cost-effective FR system. Alternatives often do not fulfil the same combination of functionalities as the BFR-ATO system. Replacement by polymer alloys is possible, but this might lead to higher costs and still requires up to 0,5% halogen addition (PTFE).	ATO: in 2005, 24.500 tonnes were used in the EU-15, of which 38% was used for flame retardancy purposes in non-PVC plastics and 36 % in PVC, and 4% in PET production (EU-RAR, 2008). The use as flame retardant synergist in rubber/textile is NOT relevant for EEE. According to Roskill, the EU tonnage (incl. Russia and Ukraine) was 19500 t ATO in 2011. ATO concentration range in products: 1-10% in non-PVC polymer depending on type of polymer and/or choice of HFR (typical concentration: 3-5%), and 3.5 - 20% in PVC depending on the use of other FRs.

Stakeholder (Submission date)	Uses	Quantities
	- The BFR-ATO system is also often the material of choice for thermoplastic elastomers used in cabling for E&E. We see no major trend in replacing BFR-ATO. However, the choice of the flame retardant system in E&E enclosures depends mainly on the choice of the polymer (i.e. virgin polymers or alloys). ATO has been risk assessed by the EU ('EU-RAR'); finalised in May 2008, and the data of EU RAR are approved by the OECD members under the SIAP program (14 October 2008). ATO has been REACH registered in November 2010 (>10000 t/y; http://echa.europa.eu/information-on-chemicals/registeredsubstances). Risk assessments by the Canadian government (2010), the Dutch government (2011) and the U.S. EPA (2013 – draft version) are available as well. ATO is classified in the EU as Carcinogen cat 2- H351 'Suspected of causing cancer via inhalation' (CLP Annex VI). It was agreed by expert toxicologists of TC NEC (Technical Committee for New and Existing Substances) that these effects are most likely caused by particle overload and impaired lung clearance ultimately leading to the formation of tumours (particle effect, no substance specific effect). ATO is considered a threshold carcinogen with an OEL of 0.5 mg/m^3 (with the critical concentration expected to be 10 times higher). The inhalation hazard does neither apply via dermal or oral exposure (cfr. EU-RAR (2008), OECD-SIAP (2008) and 'SCHER opinion on the risks of antimony trioxide in toys' (November 2011)), nor does it apply when ATO is added to a polymer as flame retardant synergist (ATO gets mixed homogeneously into the polymer matrix during the extrusion process, ATO is not present in a respirable form anymore and the inhalation exposure potential to workers and consumers is negligible (cfr. EU-RAR)). The EU-RAR and EU-REACH dossiers confirm that ATO can be safely used throughout its entire lifecycle (production -> disposal). Market and scientific information on ATO is summarized here: http://www.antimony.com/en/antimonycompounds.aspx Publications that might be of interest (factsheets, statements etc.) are available at http://www.antimony.com/en/publications.aspx	

Stakeholder (Submission date)	Uses	Quantities
European Semiconductor Industry Association ESIA (04 Apr 2014)	Antimony Trioxide and TBBPA are used as a flame retardant in the resin for semiconductor manufacturing and remain in final semiconductor device. Antimony Trioxide and TBBPA are already being removed, where possible, through the halogen free program aiming at reducing antimony trioxide and brominated flame retardants. The halogen free program is a voluntary and recognized program within the EEE industry. Where substitutions are not performed yet, it is linked to critical technology limits and reliability requirements.	
Japanese Business Council in Europe JBCE (04 Apr 2014)	The Japanese industry recognizes that Antimontrioxide is largely used. The reason is that these substances have many useful applications in the EEE sector. The accurate numerical value is unidentified, but Japanese industry recognizes that this substance is largely used as assistant agent of flame-retardant. The reason of the use is because we recognize this substance has many advantages for example, it is comparatively safe and is able to give products flame-retardancy effectively at the necessary level of safety of the users.	

Note: Wording as formulated by stakeholders, with correction only for readability where necessary. Views expressed should not be taken to reflect those of the authors of this report.

4.7.4 Summary

Antimony trioxide is used as a synergist together with brominated flame retardants in plastics. For the EEE sector, this is relevant for EEE housings and cables. Of the 24,500 tonnes used in the EU in 2005, about 20,000 tonnes were used in the EEE sector. The use of antimony trioxide is linked to the application of brominated flame retardants.

4.7.5 References

ECHA (2007): DIANTIMONY TRIOXIDE, SUMMARY RISK ASSESSMENT REPORT, Final Report 2008 Sweden; http://www.echa.europa.eu/documents/10162/96ce6735-ec51-42c1-9432-4d8d3f74915f

ECHA Registered Substances Database: Entry for diantimony trioxide; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9eb02d6b-39b7-666e-e044-00144f67d031/DISS-9eb02d6b-39b7-666e-e044-00144f67d031_DISS-9eb02d6b-39b7-666e-e044-00144f67d031.html

EU RAR (2008): Draft European Union Risk Assessment Report. DIANTIMONY TRIOXIDE, November 2008. http://www.echa.europa.eu/documents/10162/553c71a9-5b5c-488b-9666-adc3af5cdf5f

European Flame Retardants Association EFRA (2014): Contribution submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/final_EFRA4_answers_to_Oeko-Institute_survey_on_RoHS_04.04.2014__2_.pdf

European Semiconductor Industry Association ESIA (2014): Contribution submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/20140404_RoHS_ESIA_Substance_Prioritisation_OKO-Institut_ESIA_April_4_2014.pdf

International Antimony Association i2a 2014): Contribution submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140404_Antimony_i2a_letter_to_Oko_institute_ROHS_revision_4_april_2014.pdf

Japan Business Council in Europe JBCE (2014): Contributions submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/index.php?id=213

Oeko-Institut (2008): Study on Hazardous Substances in Electrical and Electronic Equipment, Not Regulated by the RoHS Directive by Groß, R.; Bunke, D.; Gensch, C.-G.; Zangl, S.; Manhart, A.; Contract No. 070307/2007/476836/MAR/G4; Final Report 17 October 2008; http://hse-rohs.oeko.info/fileadmin/user_upload/Documents/RoHS_Hazardous_Substances_Final_Report.pdf

Swedish Chemicals Agency (2008): Proposal for Community-wide measures to reduce risks; Diantimony Trioxide; 2008-11-26; http://www.echa.europa.eu/documents/10162/13630/trd_sweden_diantimony_trioxide_en.pdf

Swedish Chemicals Agency (2008): PROPOSALFOR COMMUNITY-WIDE MEASURES TO REDUCE RISKS, Diantimony Trioxide; 2008-11-26; http://www.echa.europa.eu/documents/10162/13630/trd_sweden_diantimony_trioxide_en.pdf

4.8 Diethyl phthalate (DEP)

4.8.1 Classification

There is no harmonized classification for DEP under the CLP regulation. The Scientific Committee on Cosmetic Products and Non-Food Products SCCNFP (2002) is of the opinion that the safety profile of Diethyl-phthalate supports its use in cosmetic products at current levels. At present, the SCCNFP does not recommend any specific warnings or restrictions under the currently proposed conditions of use.[26]

DEP was added to the SIN list 2.0 in May 2011 because Diethyl phthalate functions as an oestrogen and affects thyroid hormones, skeletal formation, and metabolism.[27]

4.8.2 Uses and quantities

Diethyl Phthalate (DEP) is a plasticiser widely used in tools, automotive parts, toothbrushes, food packaging, cosmetics and insecticide.[28]

Besides the use in polymer preparations and compounds and manufacture of thermo plastics according to ECHA[29], DEP is used through direct addition in cosmetic products and indirectly in fragrances. The material is listed in the inventory of ingredients employed as a solvent and vehicle in fragrance and cosmetic products, as well as a denaturant, and film former.[30]

DEP has been reported as a high Production Volume Chemical (HPVC);[31] ECHA lists a total tonnage band of 1,000 to 10,000 t/y.[32]

4.8.3 Contributions of stakeholders

The stakeholder contributions confirm that DEP is not directly used in EEE; they are presented in Table 4-7.

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[26] SCCNFP (2002): OPINION OF THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD PRODUCTS INTENDED FOR CONSUMERS CONCERNING DIETHYL PHTHALATE adopted by the SCCNFP during the 20th Plenary meeting of 4 June 2002. http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out168_en.pdf

[27] SIN LIST 2.0 (2011): http://www.chemsec.org/what-we-do/sin-list/sin-list-20

[28] European Council for Plasticisers and Intermediates - ECPI (2014): DEP Information Centre. http://www.dep-facts.com/index.asp?page=1

[29] ECHA Registered Substances Database: Entry for diethyl phthalate; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d82880f-aab1-5fcc-e044-00144f67d249/DISS-9d82880f-aab1-5fcc-e044-00144f67d249_DISS-9d82880f-aab1-5fcc-e044-00144f67d249.html

[30] Op. cit. SCCNFP (2002)

[31] ESIS Data Sheet: Result for EC#: 201-550-6; http://esis.jrc.ec.europa.eu/lib/esis_reponse.php?FROM=LISTE_EINECS&ENTREE=201-550-6

[32] Op. cit. ECHA

Table 4-7: Stakeholder contributions on diethyl phthalate (DEP) submitted during the consultation

Stakeholder (Submission date)	Uses
Swedish Chemicals Agency KEMI (03 Apr 2014)	No, the use of DEP in EEE cannot be confirmed from the re-ported uses in the SPIN database or the Swedish Products register.
Japan Business Council in Europe JBCE (04 Apr 2014)	According to the JBCE following substances are not contained in EEE: Diethyl phthalate (DEP) listed as "second highest priority" Therefore it should be reconsidered whether this substance need to be further assessed under RoHS. Based on the methodology it is not clear to the JBCE on which basis DEP has been included: - The substance is not used in EEE - The substance does not fulfil the criteria for substances used in EEE which are hazardous (Step I 2a) - No specific reference was found that DEP causes concern during WEEE management Please note with regard to the above that the JBCE was not able to identify the relevant KEMI report from which information may have been drawn.

Note: Wording as formulated by stakeholders, with correction only for readability where necessary. Views expressed should not be taken to reflect those of the authors of this report.

4.8.4 Summary

DEP is used in the EU in a quantity of 1,000 to 10,000 tonnes per year as a plasticizer in broad applications (tools, automotive parts, toothbrushes, food packaging, cosmetics and insecticides). The assessment and the stakeholder contribution indicate that DEP is not used in EEE.

However, as the scope of RoHS 2 is wider compared to RoHS 1, tools or toothbrushes containing EE components falls under the scope RoHS 2. In this sense, it cannot be concluded without doubt that DEP is not applied in such devices, newly in the scope of RoHS.

4.8.5 References

ECHA Registered Substances Database: Entry for diethyl phthalate; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d82880f-aab1-5fcc-e044-00144f67d249/DISS-9d82880f-aab1-5fcc-e044-00144f67d249_DISS-9d82880f-aab1-5fcc-e044-00144f67d249.html

ESIS Data Sheet: Result for EC#: 201-550-6; http://esis.jrc.ec.europa.eu/lib/esis_reponse.php?FROM=LISTE_EINECS&ENTREE=201-550-6

European Council for Plasticisers and Intermediates ECPI (2014): DEP Information Centre. http://www.dep-facts.com/index.asp?page=1

Japan Business Council in Europe JBCE (2014): Contributions submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/index.php?id=213

SCCNFP (2002): OPINION OF THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD PRODUCTS INTENDED FOR CONSUMERS CONCERNING DIETHYL PHTHALATE adopted by the SCCNFP during the 20th Plenary meeting of 4 June 2002. http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out168_en.pdf

SIN LIST 2.0 (2011): http://www.chemsec.org/what-we-do/sin-list/sin-list-20

Swedish Chemicals Agency KEMI (2014): Contribution submitted during stakeholder consultation on 03.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140403_KEMI_Input_to_PC_RoHS_2014_2_Substance_review_Prioritasion.pdf

4.9 Tetrabromo-bisphenol A

4.9.1 Classification

Tetrabromo-bisphenol A (TBBPA) is classified under the CLP regulation with the following entries:

- Aquatic Acute 1 - H400
- Aquatic Chronic 1 - H410

TBBPA was included in the OSPAR List of Chemicals for Priority Action in 2000. TBBPA is considered to meet all three of the OSPAR criteria for the PBT (persistent, bioaccumulative and toxic) assessment, although it should be acknowledged that it is a borderline case for the bioaccumulation criterion.[33] However, TBBPA does not meet the criteria for a PBT or a vPvB substance under REACH. There is currently no initiative within ECHA concerning TBBPA.

TBBPA was added to the SIN list 1.0 in September 2008 because reprotoxic and endocrine disruptive effects have been reported.[34]

4.9.2 Uses and quantities

The primary use of TBBPA is as a reactive flame retardant in printed circuit boards. It is also used as an additive flame retardant in polymeric material in housings and packaging. These two uses are distinct, and identified as follows.

[33] OSPAR (2011): Background Document on Tetrabromobisphenol-A. http://www.ospar.org/documents/dbase/publications/p00534/p00534_background%20document%20on%20tbbpa_2011%20update.pdf
[34] SIN list database: http://w3.chemsec.org/

TBBPA is used as a reactive component of flame-retarded epoxy and polycarbonate resins, which accounts for approximately 90% of the use of TBBPA. The two main applications for epoxy resins are:

- Epoxy resins in printed circuit boards (rigid or reinforced laminated printed circuit boards most commonly based on glass fibre reinforced epoxy resin (designated FR4-type): used in nearly all types of EEE. From the consultant's prior experience, it can be stated that printed circuit boards (PCB) are mainly imported.
- Epoxy resins to encapsulate certain electronic components, e.g. plastic/paper capacitors, microprocessors: used in plastic/paper capacitors, microprocessors, bipolar power transistors, IGBT (Integrated Gate Bipolar Transistor) power modules, ASICs (Application Specific Integrated Circuits) and metal oxide varistors) on the printed circuit board.

TBBPA is also used as a reactive flame retardant in polycarbonate and unsaturated polyester resins.

TBBPA as an additive flame retardant is mainly used in acrylonitrilecrylonitrile-butadiene-styrene (ABS) resins and accounts for approximately 10% of TBBPA use. It is applied in a wide range of non-EEE applications, but also for encapsulating electrical devices. ABS is widely used for the inner housings of refrigerators.

The information from the Joint Submission of the TBBPA registration at ECHA indicates a total tonnage band of 1,000 to 10,000 tonnes per annum.[35] This is a clear decrease compared to the amounts identified in the Oeko-Institut study in 2008 that estimated the demand for EEE at a total of around 40,000 tonnes per year (based on data for 2003/2005):[36] Thereof, 13,800 tonnes/ year are imported into the EU as the substance itself, 6,000 tonnes/year are estimated for partly finished products (e.g. masterbatch, epoxy resins) and 20,200 tonnes/y for finished products and components. The quantities for the use of TBBP-A as reactive flame retardant were indicated to be ca. 5,850 tonnes per year.[37]

4.9.3 Contributions of stakeholders

Five stakeholder contributions were submitted regarding TBBPA. The detailed contribution submitted by the European Flame Retardants Association (EFRA) indicated quantities of 1,000 to 2,500 tonnes in Europe, of which around 90% is understood to be applied in the manufacture of printed circuit boards[38]. This shows a decline compared to the quantities of the Oeko-Institut report in 2008. The EFRA contribution also discusses substitution.

[35] ECHA Registered Substances Database: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d928727-4180-409d-e044-00144f67d249/DISS-9d928727-4180-409d-e044-00144f67d249_DISS-9d928727-4180-409d-e044-00144f67d249.html

[36] Op. cit Oeko-Institut (2008)

[37] Op. cit. Oeko-Institut (2008)

[38] VECAP The Voluntary Emissions Control Action Programme (2012): MAINTAINING MOMENTUM, European Annual Progress Report 2012; http://www.vecap.info/uploads/report2012.pdf

Table 4-8: Stakeholder contributions on tetrabromo-bisphenol a submitted during the consultation

Stakeholder (Submission date)	Uses	Quantities
Isola GmbH Düren (31 Mar 2014)	Reactive component to obtain a modified epoxy resin of class V0 acc. UL 94 (FR-4 resin); the modified resin is used to produce glass reinforced, copper cladded base materials for the production of printed circuit boards for the electronic industry. Some resin systems can be modified with phosphorous and/or nitrogen components to obtain halogen free systems. ISOLA is missing a clear differentiation be-tween TBBA as additive and TBBA as reactive component.	appr. 500 jatos[39] TBBPA to produce accordingly resin systems. We do not use it as additive!
Swedish Chemicals Agency KEMI (03 Apr 2014)	The use of TBBPA in EEE cannot be confirmed from the information given in the SPIN database or the Swedish Products register.	
IPC – Association Connecting Electronics Industries (03 Apr 2014)	Summary: The IPC submission contains explanations on the following issues: - TBBPA Serves an Important Function in Protecting Human Health, - TBBPA Has Been Found by the European Union to be Safe for the Environment and Human Health, - UBA Should Fully Consider the Life-Cycle Implications of Restricting TBBPA. As the statement concerns the study of the Austrian Umwelbundesamt, it is therefore not presented here.	
European Semiconductor Industry Association ESIA (04 Apr 2014)	Used as a flame retardant in the resin for semiconductor manufacturing and remain in final semiconductor device. Already being removed, where possible, through the halogen free program aiming at reducing antimony trioxide and brominated flame retardants; where substitutions are not performed yet, it is linked to critical technology limits and reliability requirements.	
European Flame Retardants Association EFRA (04 Apr 2014)	Summary: TBBPA used as reactive flame retardant (FR) in printed circuit boards for EEE products and as additive FR in housings (mainly ABS) of EEE products. FR4 Epoxies are the current industry standard and thus the most common type of printed circuit boards today (flammability requirement UL 94 V-1 or V-0); 80-90% of these printed circuit boards are based on brominated epoxy resins, i.e. on TBBPA (best combination of mechanical properties, thermal stability, moisture uptake, electrical performance and cost-effectiveness; low levels of failure during drilling and assembly operations, especially for multi-layer laminates); reaction close to 100%: TBBPA as such is not identifiable any more in the final printed circuit boards.	In 2011, EFRA member companies sold TBBPA in a range of 1,000-2,500 tonnes in Europe according to the 2012 VECAP report. Exact figures cannot be provided due to antitrust rules.

[39] Jatos: It is assumed that the German term „Jahrestonnen“ is meant which means tonnes per year

Stakeholder (Submission date)	Uses	Quantities
	Alternatives in epoxy resins: phosphorus-based flame retardant; most successful solution to date is DOPO (9,10-dihydro-9-oxa-10-phosphaphenanthrene-10-oxide); due to the monofunctional nature of its structure, DOPO has to be reacted into specific multifunctional epoxies; only about 6-7% of the FR-4 printed wiring boards currently on the market are partly based on this technology. Alternatives in ABS: other brominated flame retardants in combination with antimony trioxide, or phosphorus flame retardants; need for change in the polymer and for alloys such as PC/ABS; then necessary equipment change, potentially higher cost and limited material choice. TBBPA subject to the VECAP programme, (aiming in decreasing potential emissions for flame retardants during manufacturing and processing): www.vecap.info	Around 90% of this volume was used in printed circuit boards. We see no major trend in replacing TBBPA in printed circuit boards. It is the flame retardant of choice for this application, as it provides the best combination of technical properties and requirements and economic considerations.
JBCE (04 Apr 2014)	The accurate numerical value is unidentified, but the Japanese industry recognizes that Tetrabromobisphenol A is largely used. The reason of the use is because we recognize this substance has many advantages for example, it is comparatively safe (risk assessment has been already done in the EU, see below*) and is able to give products flame-retardancy effectively at the necessary level of safety of the users. For your information: Canada recently (Nov., 2013) published CEPA Screening Assessment Report on TBBPA and concluded that Canada doesn't need to restrict TBBPA. http://www.ec.gc.ca/ese-ees/BEE093E4-8387-4790-A9CD-C753B3E5BFAD/FSAR_TBBPA_EN.pdf; EU Risk assessment: Communication from the Commission on the results of the risk evaluation and the risk reduction strategies for ...tetrabromobisphenol A; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:152:0011:0020:EN:PDF; COMMISSION RECOMMENDATION 2008/454/EC of 30 May 2008 on risk reduction measures for ...tetrabromobisphenol A; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:158:0062:0064:EN:PDF; 2,2',6,6'-TETRABROMO-4,4'-ISOPROPYLIDENEDIPHENOL (TETRABROMOBISPHENOL-A or TBBP-A) Part II – Human Health; http://echa.europa.eu/documents/10162/32b000fe-b4fe-4828-b3d3-93c24c1cdd51	

Note: Wording as formulated by stakeholders, with correction only for readability where necessary. Views expressed should not be taken to reflect those of the authors of this report.

4.9.4 Summary

The two uses of TBBPA as a reactive and as an additive flame retardant have to be differentiated. The use of TBBPA as a reactive component in flame retarded epoxy resins applied in printed circuit boards accounts for 90% of the TBBPA use. When used as reactive flame retardant it is covalently bound in the polymer and becomes a constituent of the base material.

The quantities of TBBPA used in Europe have decreased substantially to 1,000 to 2,500 tonnes in 2011 compared to the quantity evaluation of the Oeko-Institut in 2008, where the use of TBBPA as a reactive flame retardant was estimated at 5,850 tonnes per year. It has to be stressed that the European PCB industry manufactures speciality and niche products.

The majority of PCBs are imported from China. This means that TBBPA mainly enters the EU in articles and the figures mentioned above are most probably an under estimation as they only represent TBBPA manufactured or acquired for use in manufacture taking place in the EU. The figures above do not include the import of TBBPA contained in partly finished products (e.g. masterbatch, epoxy resins) and in finished products and components. For those amounts, the data from the Oeko-Institut study in 2008 estimating 6,000 tonnes TBBPA per year in partly finished products (e.g. masterbatch, epoxy resins) and 20,200 tonnes TBBPA per year in finished products and components may still be of relevance.

4.9.5 References

ECHA Registered Substances Database: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d928727-4180-409d-e044-00144f67d249/DISS-9d928727-4180-409d-e044-00144f67d249_DISS-9d928727-4180-409d-e044-00144f67d249.html

European Semiconductor Industry Association ESIA (2014): Contribution submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/20140404_RoHS_ESIA_Substance_Prioritisation_OKO-Institut_ESIA_April_4_2014.pdf

European Flame Retardants Association EFRA (2014): Contribution submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/final_EFRA4_answers_to_Oeko-Institute_survey_on_RoHS_04.04.2014__2_.pdf

IPC – Association Connecting Electronics Industries (2014): Contribution submitted during stakeholder consultation on 03.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/20140404_IPC_Comments_on_TBBA_Draft_Screening_Assessment_Report.pdf

Isola GmbH Düren (2014): Contribution submitted during stakeholder consultation on 31.03.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140401_ISOLA_GmbH_Resoponse_to_Questionnaire_TBBA.pdf

Japan Business Council in Europe JBCE (2014): Contributions submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/index.php?id=213

Oeko-Institut (2008): Study on Hazardous Substances in Electrical and Electronic Equipment, Not Regulated by the RoHS Directive by Groß, R.; Bunke, D.; Gensch, C.-G.; Zangl, S.; Manhart, A.; Contract No. 070307/2007/476836/MAR/G4; Final Report 17 October 2008; http://hse-rohs.oeko.info/fileadmin/user_upload/Documents/RoHS_Hazardous_Substances_Final_Report.pdf

OSPAR (2011): Background Document on Tetrabromobisphenol-A. http://www.ospar.org/documents/dbase/publications/p00534/p00534_background%20document%20on%20tbbpa_2011%20update.pdf

SIN list database: http://w3.chemsec.org/

Swedish Chemicals Agency KEMI (2014): Contribution submitted during stakeholder consultation on 03.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140403_KEMI_Input_to_PC_RoHS_2014_2_Substance_review_Prioritasion.pdf

VECAP Voluntary Emissions Control Action Programme (2012): MAINTAINING MOMENTUM, European Annual Progress Report 2012; http://www.vecap.info/uploads/report2012.pdf

4.10 Medium chained chlorinated paraffins (MCCP), C14–C17: alkanes, C14-17, chloro

4.10.1 Classification

MCCP is on the Community Rolling Action Plan (CoRAP 2012 - 2014)[40] as a suspected PBT also fulfilling the concerns of (environmental) exposure relevant for wide dispersive use and high aggregated tonnage.[41] The UK evaluated MCCPs and acquired details on the exact composition of different MCCP products, performing further tests

[40] The community rolling action plan (CoRAP) specifies the substances that are to be evaluated over a period of three years. For more information, see http://www.echa.europa.eu/en/web/guest/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

[41] http://www.echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table?search_criteria=85535-85-9

to verify the PBT status of different formulations, and collecting more information on exposure routes. On 25th February 2014, ECHA decided that further information on the relevant constituents are necessary as there are different commercial MCCP types.[42]

MCCP is classified under the CLP regulation as follows:

- Lact. - H362
- Aquatic Acute 1 - 1 H400
- Aquatic Chronic - H410

4.10.2 Uses and quantities

Some MCCPs are used as secondary plasticizers and as flame retardants in a wide range of especially flexible PVC applications which are subsequently used in various products such as cables, wallpapers, floor coverings, leisure and travel articles.[43] Further MCCPs are used in / applied as metal working fluids, paints and varnishes, adhesives/sealants, leather fat liquors, and carbonless copy paper.[44]

In 2006, approximately 64,000 tonnes of MCCPs were sold in the EU 25. Around 50 % (34,676 tonnes) of the total were applied in the manufacture of PVC; metal working / cutting applications accounted for 8,920 tonnes; rubber/polymers (other than PVC) accounted for 7,077 tonnes; and carbonless copy paper for 89 tonnes.[45]

4.10.3 Contributions of stakeholders

For MCCP, two contributions were submitted during the consultation. The contribution by INEOS Vinyl, the largest producer of MCCPs in the EU, provided detailed estimates concerning the amount of MCCP used in the different applications. Compared to the market data from 2006, there is a decrease in volume used in general and for PVC cable formulations.

[42] ECHA (2014): Decision on Substance Evaluation Pursuant to Article 46(1) of Regulation (EC) No 1907/2006 for alkanes , C14-17, chloro (MCCP, Medium-chain chlorinated paraffins); CAS No 85535-85-9 (EC No 287-477-0); http://echa.europa.eu/documents/10162/03800fac-8153-4dfa-a60f-d1217f0419b2
[43] Norwegian Government (2010): Impact assessment of regulation of medium-chain chlorinated paraffins C14-17 (MCCPs) in consumer products, 05.11.10; http://www.eftasurv.int/media/notification-of-dtr/2010-9018-en.pdf
[44] Op. cit. Oeko-Institut (2008)
[45] UK (2008): ANNEX XV RESTRICTION REPORT; 30th November 2008; http://www.echa.europa.eu/documents/10162/13630/trd_uk_mccp_en.pdf

Table 4-9: Stakeholder contributions on MCCP submitted during the consultation

Stakeholder (Submission date)	Uses	Quantities
INEOS Vinyl (24 Mar 2014)	The main applications are: - Adhesives and sealants c. 1,000 tonnes - Lubricants and metal working fluids, including mineral oils c. 3,000 tonnes - Paints c. 1,000 tonnes - Polyurethane foam c. 8,000 tonnes - Flame retardant in rubber c.1,000 tonnes - Plasticiser/flame retardant in PVC formulations c. 25,000 tonnes In terms of quantities used for electrical and electronic applications we estimate that this is predominantly MCCP used as plasticiser/fire retardant in PVC cable insulation formulations. We think this is probably more than half of the MCCP used in PVC formulations (about 15,000 tonnes used in PVC cable formulations). We think the next largest applications in terms of PVC formulations is for vinyl flooring. We think that the vast majority of the PVC formulations containing MCCPs are recycled at the end of life. MCCPs are very compatible with a wide range of PVC formulation additives so the MCCPs do not impede the recycling of flexible PVC. In the response from ECVM I am sure they will have made reference to the VinylPlus sustainable development programme. Each year VinylPlus issues an independently audited Progress Report. In the 2013 report it was shown that across the EU some 88,477 tonnes of PVC cable insulation was recycled - we therefore believe that most of the MCCPs are being recycled within this cable insulation recyclate. The PVC industry record on Vinyl flooring recycling is also good so much of the remainder of the MCCPs will also be recycled. There was a study by RPA (for UK Government) on substitutes for MCCPs46: In my view the information in this RPA study is still largely valid. As far as I am aware there has not been any development of new alternatives to MCCPs - in fact the choice of possible substitutes for MCCPs has declined - for example, DEHP now requires REACH authorisation and DEHP use is declining rapidly in the market.	Total EU market for MCCPs is about 40,000 tonnes. About 15,000 tonnes used in PVC cable formulations.

[46] RPA (2002), Information on Substitutes for Medium Chain Chlorinated Paraffins, Task 2 Final Report, prepared by Risk & Policy Analysts Limited, for Department for Environment, Food and Rural Affairs

Stakeholder (Submission date)	Uses	Quantities
	There is a cost penalty for using alternatives (this can be significant e.g. phosphate ester plasticiser/flame retardants are about 4 times the price of MCCPs). There are penalties in terms of recyclability. As I said previously MCCPs are very compatible with a wide range of PVC additives so do not complicate flexible PVC recycling. Manchester University has recently conducted a life cycle assessment on MCCPs used in PVC formulations (in accordance with ISO 1400/14040 standards). Compared to possible substitutes in PVC formulations there is a very significant carbon footprint saving by using MCCPs. With regards to occupational exposures to MCCPs in the workplace there was a lot of work done in PVC compounding and product manufacturing operations by the Institute of Occupational Medicine (IOM). Workplace exposures are extremely low and within safe limits by very wide margins.	
KEMI Swedish Chemicals Agency (03 Apr 2014)	The use of MCCP in EEE cannot be confirmed from the reported uses in the SPIN database or the Swedish Products register.	Summary: Data from the Swedish products register; use of MCCP in 2011: Product types: Sealants: 34.4 t Coolants and lubricants for metal forming: 27.6 t Sealants, putty: 18.8 t Lubricants: 2.4 Industry sectors: Export: 47.2 t Construction sector: 44.8 t Retail sales, except of motor vehicles: 8.6 t Wholesale (chemical products): 6.5 t Machinery sector: 3.5 t Total use of MCCP in the Nordic countries 2011: 437.2 tonnes

Note: Wording as formulated by stakeholders, with correction only for readability where necessary. Views expressed should not be taken to reflect those of the authors of this report.

4.10.4 Summary

MCCPs are used as secondary plasticizers, in a wide range of especially flexible PVC applications, used for EEE cable sheathing and insulation. The actual data concerning usage amounts, provided by stakeholders during the consultation, indicates a decrease in the total EU market share of MCCPs, amounting to about 40,000 tonnes, and in the amounts used for PVC cable formulations which are about 15,000 tonnes. In comparison, in 2006, approximately 64,000 tonnes of MCCPs were used in the EU 25 and around 34,676 tonnes of the total were used in PVC.

It has to be noted that the EEE relevant application of MCCP is directly linked to the use of polyvinyl chloride (PVC), which is another substance on the priority shortlist (see Section 4.11).

4.10.5 References

ECHA registered substances database: entry for MCCP; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ebcd9d5-5f92-56b4-e044-00144f67d031/DISS-9ebcd9d5-5f92-56b4-e044-00144f67d031_DISS-9ebcd9d5-5f92-56b4-e044-00144f67d031.html

ECHA (2014): Decision on Substance Evaluation Pursuant to Article 46(1) of Regulation (EC) No 1907/2006 for alkanes , C14-17, chloro (MCCP, Medium-chain chlorinated paraffins); CAS No 85535-85-9 (EC No 287-477-0); http://echa.europa.eu/documents/10162/03800fac-8153-4dfa-a60f-d1217f0419b2

EU Risk Assessment Report (RAR): RISK ASSESSMENT OF ALKANES, C14-17, CHLORO (MEDIUM-CHAINED CHLORINATED PARAF-FINS); Draft of February 2008; http://www.echa.europa.eu/documents/10162/13630/trd_rar_uk_mccp_en.pdf

INEOS ChlorVinyls (2014): Contribution submitted 24.03.2014 during stakeholder consultation; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140324_INEOS_Contribution_RoHS_SC_Substance_Review_MCCP.pdf

Norwegian Government (2010): Impact assessment of regulation of medium-chain chlorinated paraffins C14-17 (MCCPs) in consumer products, 05.11.10; http://www.eftasurv.int/media/notification-of-dtr/2010-9018-en.pdf

Oeko-Institut (2008): Study on Hazardous Substances in Electrical and Electronic Equipment, Not Regulated by the RoHS Directive by Groß, R.; Bunke, D.; Gensch, C.-G.; Zangl, S.; Manhart, A.; Contract No. 070307/2007/476836/MAR/G4; Final Report 17 October 2008; http://hse-rohs.oeko.info/fileadmin/user_upload/Documents/RoHS_Hazardous_Substances_Final_Report.pdf

RPA (2002), Information on Substitutes for Medium Chain Chlorinated Paraffins, Task 2 Final Report, prepared by Risk & Policy Analysts Limited, for Department for Environment, Food and Rural Affairs.

UK (2008): ANNEX XV RESTRICTION REPORT; 30th November 2008; http://www.echa.europa.eu/documents/10162/13630/trd_uk_mccp_en.pdf

Swedish Chemicals Agency KEMI (2014): Contribution submitted during stakeholder consultation on 03.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140403_KEMI_Input_to_PC_RoHS_2014_2_Substance_review_Prioritasion.pdf

4.11 Polyvinyl-chloride (PVC)

4.11.1 Classification

PVC is a polymer and therefore, does not fall under the REACH regulation. There is no harmonized classification under the CLP regulation for PVC.

PVC was classified by the AUBA to be of the third highest priority, in particular because of its high waste relevance.

4.11.2 Uses and quantities

Polyvinyl chloride (PVC) is a widely used chlorinated plastic. It is naturally rigid and in this form is used for many applications, including by the construction industry. PVC generally needs stabilizers to ensure the processing of PVC and to prevent decomposition. In the past mainly lead containing stabilizers were used.

Through the addition of various chemical additives, including plasticisers to make it flexible and soft, PVC can be used in a diverse range of applications. It is the flexible (plasticised) form, in which it is most often used by the electronics industry, mainly as an insulator and coating for electrical cables.

PVC is often applied in telecommunication devices for cable management systems and in business machine housings.[47]

The vinyl chloride monomer chloroethylene (CAS 75-01-4; EC 200-831-0) is registered with an indicated total tonnage band of 1,000,000 to 10,000,000 tonnes per year. In 2012, the European demand for PVC accounted for about 5,000,000 tonnes, where from electrical & electronic products accounted for only a small portion (about 5%).[48]

It is understood that these numbers represent the quantities manufactured or used in European manufacture, and thus remains unclear how much PVC further enters the EU through import of finished articles containing PVC.

[47] Op. cit. Oeko-Institut 2008

[48] PlasticsEurope (2013): Plastics – the Facts 2013, An analysis of European latest plastics production, demand and waste data; http://www.plasticseurope.de/Document/plastics-the-facts-2013-11467.aspx?Page=DOCUMENT&FolID=2

4.11.3 Contributions of stakeholders

PVC received the highest number of stakeholder contributions during the stakeholder consultation. Most of the stakeholders claimed that a differentiation of PVC applications was missing into rigid PVC (without any plasticisers), plasticised PVC containing the three plasticisers DEHP, BBP and DBP and plasticised PVC containing other plasticisers. The European Council of Vinyl Manufacturers (ECVM) provided detailed data on the amounts of PVC used in the EEE sector for manufacturing cables (approximately 330,000 tonnes in 2012).

Table 4-10: Stakeholder contributions on PVC submitted during the consultation

Stakeholder (Submission date)	Uses	Quantities
European Council of Vinyl Manufacturers ECVM (28 Mar 2014)	Herewith a non-exhaustive list of PVC applications - Construction products (pipes and pipe fittings, profiles, boards, roofing and waterproofing membranes, flooring, wall coverings, decorative ceilings, electrical cables, switches and plugs, cable conduits) - Packaging (flexible film, rigid blisters, bottles, crown corks, screw caps, can coating) - Electrical and electronic products (cable sheathings, switches, protective profiles and boxes, battery separators, insulation tape) - Automotive (sealing and anti-corrosion coatings, interior trim, dashboards, steering wheels, etc., cables, truck tarpaulins) - Furniture (laminated in e.g. kitchens and bathrooms, drawers, cushions and artificial leather furniture) - Home (shower curtains, gloves, garden hoses) - Office supplies (binders, book covering) - Leisure and outdoor (luggage, tents, toys, life buoys, inflatable products) - Clothing (artificial leather, rainwear, shoes and shoe soles) - Medical (blood and infusion bags, urine bags, flexible tubing, gloves) - Industrial (hoses, conveyor belts) - Advertisement banners - Miscellaneous (inks, adhesive tape, credit cards) The only significant substitution we are aware of is in bottles, where (at least for water) PVC has been replaced by PET, mainly for appearance reasons.	Obviously, it is not possible to provide detailed statistics for the many applications listed in 4a. To the best of our knowledge, 2012 demand for PVC resin in the EU-27 was 4,900 kt, of which 3,350 kt in building and construction applications (69%), 470 kt in packaging (10%), 150 kt in automotive applications (3%) and 100 kt in E&E (2%). The remaining 16% covers all other uses. Please be aware that cables installed in buildings are counted as a B&C application. Total resin consumption for manufacturing cables was approximately 330 kt.

Stakeholder (Submission date)	Uses	Quantities
	Summary: The second document of the ECVM covered comments on the study of the Austrian Umwelbundesamt and are therefore not presented here.[49]	
CEOE Confederación Española De Organizaciones Empresariales (03 Apr 2014)	Rigid PVC is currently used for cable management systems such as cable trays, cable trunkings and conduits since more than 60 years. More than 95% of these plastics products are manufactured of rigid PVC. Most cable management products are used for electrical installation and are outside of the scope of the RoHS Directive. However, some products are used in Electrical and Electronic Equipment. For some special applications, other substances such as PP (polypropylene), PPO (polyphenilene oxide) and PC+ABS (blends of polycarbonate and ABS) are used. However, these substances are not a real alternative to PVC because their fire behaviour is not the same as PVC and the cost is much more expensive. We think no substitution for PVC is feasible today for most of the applications. Rigid-PVC is used by cable management systems industry since more than 60 years. More than 95 % of these plastic products are manufactured of rigid-PVC. In the current proposal for the priority list PVC is listed as category 3. In the final report of the “Study for the Review of the List of Restricted Substances under RoHS2” Reference: ENV.C.2/ETU/2012/0021 the reason to list PVC as category 3 is that in the 3 defined waste categories plasticisers out of soft- or plasticized-PVC were found if cables are shredded. Here we want to point out that PVC as named in the priority list has not a homogenous composite PVC compounds have to be clustered in: - Rigid PVC (without any plasticisers) - Plasticised PVC containing the 3 mentioned plasticisers - Plasticised PVC containing other than the 3 mentioned plasticisers	It is difficult to us to provide information on this subject.

[49] ECVM (2014): Pre-assessment of PVC for RoHS2; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140328_ECVM_Additional_Info_Pre-assessment_of_PVC_for_RoHS2.pdf

Stakeholder (Submission date)	Uses	Quantities
	Conclusions To evaluate PVC it is absolutely necessary to differentiate between several PVC compounds. No justified reason is seen for considering to adding either rigid PVC nor soft PVC not containing the plasticisers named in category 1 to the list of restricted substances of the European RoHS 2 Directive. Therefore only PVC containing 1 or more of the 3 banned plasticisers should be at the priority list. For cable management system no plasticised PVC containing the 3 mentioned plasticisers is used. Nevertheless the requirements of WEEE and REACH are fulfilled by the respective products. Taking a look to the characteristics of PVC it is classified: - Not to be hazardous according to the EU Regulation on the Classification and Labelling of substances and mixtures - Not to be a Persistent Bio-accumulative and Toxic (PBT) substance or to be a Substance of Very High Concern (SVHC). - Not to be hazardous as waste either. Indeed, although Commission Decision 2001/118/EC2 on the list of wastes mentions plastics waste under several entries which could be relevant for EEE waste (160119, 191204, 200139), none of these has been qualified as hazardous, and there is no specific reference to PVC. The Green Paper on “the environmental issues of PVC” adopted in July 2000 concluded most of the waste management problems are not PVC specific The economical and technical performances, including safety and environmental characteristics of rigid-PVC are outstanding. Some of the characteristics of PVC that make it appropriate for electrical installation equipment are the following: - Electrical insulation - Excellent resistance to many chemical substances - Excellent fire behaviour: no flame propagation and limited heat release in case of fire - Excellent carbon footprint compared to other plastic materials - Very easy recycling inside the producing companies of production waste coming up from starting up the extrusion process as well coming up from different punching processes	

Stakeholder (Submission date)	Uses	Quantities
	Furthermore we want to draw your attention to other sectors of industry where PVC compounds are used: - Rigid-PVC is used since many years to produce of window frames. - Soft-PVC is used for many years to produce as well medical products as floor covering.	
BEAMA (04 Apr 2014)	Used in electrical installation equipment, conduit and trunking for the protection of cables. No substitute. In the final report of the "Study for the Review of the List of Restricted Substances under RoHS2" Reference: ENV.C.2/ETU/2012/0021 the reason to list PVC as category 3 is that in the 3 defined waste categories, plasticisers from soft or plasticized-PVC were found if waste cables are shredded. The page 2 list of this consultation suggests that there is one single "PVC" The UK cable management products industry would like to point out that PVC is a generic name which includes several different types. These are: - Rigid PVC (not containing plasticisers); - Plasticised PVC containing the 3 mentioned plasticisers; - Plasticised PVC containing other than the 3 mentioned plasticisers. Conclusion: Any evaluation of PVC must examine the different types of PVC compounds as any generic approach covering all PVC compounds is inappropriate and could mislead. There is no justification for adding the following to the list of restricted substances contained in the European RoHS 2 Directive: - Rigid PVC, or - Plasticised PVC not containing the plasticisers named in category 1. Only PVC containing 1 or more of the 3 banned plasticisers should be in the priority list, and clearly stated as such i.e. "PVC containing plasticisers X, Y, Z".	
CECAPI (04 Apr 2014)	Electrical installation equipment and more specifically "cable management systems" intended to contain and possibly protect the cables: conduit systems, trunking systems and cable tray. Most of "cable management products" identified in above "a" are not in the scope of RoHS Directive but products are	

Stakeholder (Submission date)	Uses	Quantities
	indirectly concerned by RoHS. A possible conclusion considering that PVC is a hazardous substance can be challenged. For example, the Öko-Institut "Study on Hazardous Substances in Electrical and Electronic Equipment, Not Regulated by RoHS Directive" clearly states in its Final Report dated 17 October 2008 that "PVC itself is not classified as dangerous according to Directive 67/548/EEC." and identifies issues on additives. Additives rather than PVC itself should therefore be investigated.	
Unex aparellaje eléctrico, S.L. (04 Apr 2014)	Summary See contribution of CEOE	See information CEOE
Tehalit GmbH (04 Apr 2014)	Electrical installation equipment, conduit, trunking, trays and ladders for the accommodation and protection of cables. No substitution planned or expected. Summary: For additional information see the statement on differentiation of rigid and plasticized PVC made by CEOE or BEAMA.	The consumption of the German cable management industry is approx. 50.000 tons/year of rigid PVC.
GFI / ZVEI (04 Apr 2014)	Electrical installation equipment, conduit and trunking for the protection of cables. No substitute. Summary: For additional information see the statement on differentiation of rigid and plasticized PVC at e.g. CEOE.	
ESIA (04 Apr 2014)	PVC: is not a substance used in semiconductor devices. It can be an issue for electronic industry (systems) Low halogen products should eliminate PVC use at system level in the coming years. For the Low halogen products (not containing TBBPA or subsequently Antimony Trioxide) although this is the current approach for new product designs, there exists some technologies that cannot be converted due to reliability / product performance requirements.	
JBCE (04 Apr 2014)	The accurate numerical value is unidentified, but the Japanese industry recognizes that Polyvinylchloride (PVC) is largely used. The reason of the use is because we recognize this substance has many advantages for example, it is comparatively safe and has superior performance as material such as flexibility, incombustibility, weatherability.	

Note: Wording as formulated by stakeholders, with correction only for readability where necessary. Views expressed should not be taken to reflect those of the authors of this report.

4.11.4 Summary

This section addresses the substance PVC itself. However, many stakeholders demanded a differentiation between rigid PVC and plasticized PVC where critical additives are contained. Though this aspect may be of relevance for a possible restriction, the amounts of rigid versus flexible/ plasticized PVC within the cable industry could not be clarified, based on the information provided through the consultation. Rigid PVC is not used for cables but for cable management systems (cable trays, cable trunkings and conduits). Stakeholders also contended that a distinction of PVC based on the use of various plasticisers should be made in relation to the use of the phthalates DEHP, BBP,DBP and other plasticisers, or that it is the additives themselves that should be investigated rather than PVC.

The European Council of Vinyl Manufacturers ECVM indicated the European demand for PVC resin in 2012 as 4,900,000 tonnes. Total PVC consumption for manufacturing cables was estimated at approximately 330,000 tonnes.

Further assessment of PVC should consider the distinction between rigid PVC and plasticized or soft PVC with additives. A further aspect of concern is the impact that a restriction of PVC, or of the various additives, may have on the range of use of recycled contact from products placed on the market before the restriction takes effect. In this sense, recycled PVC should also be taken into consideration in future assessments of this substance.

The Oeko-Institut study in 2008[50] mainly identified PVC as hazardous because PVC involved risks associated with its disposal and incineration under uncontrolled conditions. The crucial potential for danger discussed here concerns the emissions of substances such as organic chlorine compounds and the associated emissions of dioxins and furans especially when PVC is disposed and incinerated under sub-standard conditions.

4.11.5 References

BEAMA (2014): Contribution submitted on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/201404040_PVC_BEAMA_Questionaire_Substances_prioritisation_BEAMA_response.pdf

CECAPI (2014): Contribution submitted on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/20140404_Updated_CECAPI_RESPONSE_TO_Questionaire_Substances_prioritisation.pdf

CONFEDERACIÓN ESPAÑOLA DE ORGANIZACIONES EMPRESARIALES (CEOE) (2014): Contribution by submitted on 03.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/2014_04_03_CEOE_reply_to_stakeholder_consultation_for_RoHS.pdf

[50] Op. cit. Oeko-Institut 2008

ECHA Registered Substance Database: Entry for chloroethylene; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d9f2f28-9ebf-4a9f-e044-00144f67d249/DISS-9d9f2f28-9ebf-4a9f-e044-00144f67d249_DISS-9d9f2f28-9ebf-4a9f-e044-00144f67d249.html

European Council of Vinyl Manufacturers ECVM (2014): Contributions submitted on 28.03.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140328_ECVM_replies_to_Questionnaire_for_Substance_Prioritisation_for_RoHS_2.pdf

GFI /ZVEI Gesellschaft zur Förderung der elektrischen Installationstechnik e. V. / Zentralverband der Elektrotechnik- und Elektronikindustrie e. V (2014): Contribution submitted on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/20140404_ZVEI_Antwort_Substances_prioritisation.pdf

Oeko-Institut (2008): Study on Hazardous Substances in Electrical and Electronic Equipment, Not Regulated by the RoHS Directive by Groß, R.; Bunke, D.; Gensch, C.-G.; Zangl, S.; Manhart, A.; Contract No. 070307/2007/476836/MAR/G4; Final Report 17 October 2008; http://hse-rohs.oeko.info/fileadmin/user_upload/Documents/RoHS_Hazardous_Substances_Final_Report.pdf

PlasticsEurope (2013): Plastics – the Facts 2013, An analysis of European latest plastics production, demand and waste data; http://www.plasticseurope.de/Document/plastics-the-facts-2013-11467.aspx?Page=DOCUMENT&FolID=2

Tehalit (2014): Contribution submitted on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/20140404_Tehalit_Questionaire_Substances_prioritisation.pdf

Unex (2014): Contribution submitted on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/20140404_Unex_reply_stakeholder_PVC.pdf

4.12 Nickel sulphate and nickel bis(sulfamidate)/nickel sulfamate

4.12.1 Classification

Both nickel salts, nickel sulphate and nickel sulfamate, are classified under the CLP regulation. Table 4-11 shows the harmonized classification.

There are no ongoing initiatives under REACH concerning these two nickel salts.

Nickel (CAS No 7440-02-0, EC No 231-111-4) and its compounds are subject to the restriction entry 27 of REACH Annex XVII, which restricts the use in jewellery and articles coming in contact with skin.

4.12.2 Uses and quantities

The uses identified in the REACH registrations are listed in Table 4-11.[51] The use of selective plating is relevant for the EEE sector, for which one end use is the manufacture of computer, electronic and optical products and electrical equipment. In the plating processes, both nickel salts are used as intermediates.

Nickel sulphate is a nickel salt with a much higher production and usage volume, 10,000 to 100,000 tonnes per year, whereas nickel sulfamate is only used in amounts of 100 to 1,000 tonnes a year, which is the range of a low production volume chemical.

Table 4-11: Overview on classification, amounts and uses of nickel sulphate and nickel bis(sulfamidate)/nickel sulfamate

	Nickel sulphate	Nickel bis(sulfamidate)/nickel sulfamate
Harmonized Classification: Human Health	Carc. 1A - H350i Muta. 2 - H341 Repr. 1B - H360D*** STOT RE 1 - H372** Acute Tox. 4 * - H332 Acute Tox. 4 * - H302 Skin Irrit. 2 - H315 Resp. Sens. 1 - H334 Skin Sens. 1 - H317	Carc. 1A - H350i Muta. 2 - H341 Repr. 1B - H360D*** STOT RE 1 - H372** Resp. Sens. 1 - H334 Skin Sens. 1 - H317
Environment	Aquatic Acute 1 - H400 Aquatic Chronic 1 - H410	Aquatic Acute 1 - H400 Aquatic Chronic 1 - H410
ECHA: Total Tonnage Band	10,000 - 100,000 t/y	100 – 1,000 t/y
ESIS	HPVC	LPVC
Uses according to Nickel Consortia[52]	Metal surface treatment (nickel electroplating, nickel electroforming and nickel electroless technologies) Production of batteries Production of Ni salts from nickel sulphate	Metal surface treatment (nickel electroforming, nickel electroplating and nickel electroless technologies) Production of batteries Production of nickel salts from nickel sulphate

[51] Nickel Consortia: Nickel Sulphamate; http://www.nickelconsortia.eu/nickel-sulphamate.html?searched=sulphate&advsearch=oneword&highlight=ajaxSearch_highlight+ajaxSearch_highlight1 and Nickel Consortia: Nickel Sulphate; http://www.nickelconsortia.eu/nickel-sulphate.html?searched=sulphate&advsearch=oneword&highlight=ajaxSearch_highlight+ajaxSearch_highlight1

[52] Op. cit. Nickel Consortia

	Nickel sulphate	Nickel bis(sulfamidate)/nickel sulfamate
	Use of nickel sulphate in the manufacturing of micronutrient additives for biogas production Production of nickel-containing pigments	

4.12.3 Contributions of stakeholders

Four stakeholder contributions confirmed the use of both nickel salts in plating processes. The Swedish Chemicals Agency agreed that the nickel salts are relevant to EEE products and applications. The Nickel Institute stresses that nickel salts are only process chemicals and not present in the EEE products as such, as has also been stated by JBCE.

Table 4-12: Stakeholder contributions on nickel sulphate and nickel bis(sulfamidate) / nickel sulfamate submitted during the consultation

Stakeholder (Submission date)	Uses	Quantities
Nickel Institute (01 Apr 2014)	Nickel sulphate and Nickel sulfamate are exclusively used in industrial processes during production of parts for electrical and electronic equipment. Those nickel salts are converted into metallic nickel in surface treatment (i.e. plating) during a galvanization process. They do not occur in electronic and electrical equipment, neither during use nor during end of life. Therefor they neither come into contact with consumers nor with players involved into the collection and recycling of waste electrical and electronic equipment. Therefore, Nickel sulphate and Nickel sulfamate should not be included in the list of priority substances for future review cycles of the RoHS2 Directive. Similarly, they should have also not been included in the Inventory of substances present in EEE and hence should have not been subject to the prioritization scoring exercise performed by the Austrian EPA.	
Swedish Chemicals Agency KEMI (03 Apr 2014)	Yes, relevant to EEE products and applications. Data on used quantities is unclear.	Summary: Nickel sulphate Total quantity in the Swedish Products register: 926.9 ton. Data from the Swedish products register regarding product types

Stakeholder (Submission date)	Uses	Quantities
		and industry sectors where Nickel sulphate was used 2011: Product types: Metal surface treatment products: 21.3 t Electroplating products 8.8 t Industry sectors: Export: 875.5 t Metal coating 44.7 t Manufacture of fabricated metal products: 6.7 t <u>Nickel sulfamate</u> Data from the Swedish products register regarding product types and industry sectors where Nickel sulfamate was used 2011: Product types: Electroplating products; 7.4t Industry sectors: Metal coating; 4.7 t Export 3.5 t
Japanese Business Council in Europe JBCE (04 Apr 2014)	According to the JBCE following substances are not contained in EEE: Nickel sulfate and Nickel sulfamate listed as “fourth highest priority” Nickel sulfate and Nickel bis(sulfamidate) would not be contained in EEE. It would be used in plating process, but is not contained in the plating film which is finally formed.” Nickel sulfate and Nickel bis(sulfamidate) would not be contained in EEE. Such substances would not need to be prioritised under RoHS. The substance restrictions under RoHS don't apply to the substances used or produced in production process, such as intermediate etc., if they are not contained in finished EEEs.	
European Semi-conductor Industry Association ESIA (04 Apr 2014)	Nickel sulfamate is used in plating.	

Note: Wording as formulated by stakeholders, with correction only for readability where necessary. Views expressed should not be taken to reflect those of the authors of this report.

4.12.4 Summary

The EEE specific uses of nickel salts nickel sulphate and nickel bis(sulfamidate)/nickel sulfamate are in metal surface treatment (nickel electroplating, nickel electroforming and nickel electroless technologies). Within these plating processes, as stakeholders explain, nickel salts have intermediate uses, which means that they are converted and not present in the final product as such.

Whereas Nickel sulphate is a high production volume chemical (registration indicates a use of 10,000 - 100,000 tonnes per year), Nickel bis(sulfamidate)/Nickel sulfamate is considered a low production volume chemical (registration indicates a usage of 100 to 1,000 tonnes per year). No specific amounts, used for EEE production in the EU, were provided by stakeholders.

4.12.5 References

ECHA Registered Substance Database: Entry for nickel bis(sulphamidate); http://apps.echa.europa.eu/registered/data/dossiers/DISS-97dc658d-a5d9-1f1e-e044-00144f67d031/DISS-97dc658d-a5d9-1f1e-e044-00144f67d031_DISS-97dc658d-a5d9-1f1e-e044-00144f67d031.html

ECHA Registered Substance Database: Entry for nickel sulphate; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9c845f86-1d61-311e-e044-00144f67d249/DISS-9c845f86-1d61-311e-e044-00144f67d249_DISS-9c845f86-1d61-311e-e044-00144f67d249.html

ESIS Data Sheet: Result for EC#: 232-104-9; http://esis.jrc.ec.europa.eu/lib/esis_reponse.php?FROM=LISTE_EINECS&ENTREE=232-104-9

ESIS Data Sheet: Result for EC#: 237-396-1; http://esis.jrc.ec.europa.eu/lib/esis_reponse.php?FROM=LISTE_EINECS&ENTREE=237-396-1

European Semiconductor Industry Association ESIA (2014): Contribution submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/20140404_RoHS_ESIA_Substance_Prioritisation_OKO-Institut_ESIA_April_4_2014.pdf

Japan Business Council in Europe JBCE (2014): Contributions submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/index.php?id=213

Nickel Consortia: Nickel Sulphamate; http://www.nickelconsortia.eu/nickel-sulphamate.html?searched=sulphate&advsearch=oneword&highlight=ajaxSearch_highlight+ajaxSearch_highlight1

Nickel Consortia: Nickel Sulphate; http://www.nickelconsortia.eu/nickel-sulphate.html?searched=sulphate&advsearch=oneword&highlight=ajaxSearch_highlight+ajaxSearch_highlight1

Nickel Institute (2014): Contribution submitted during stakeholder consultation on 01.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140331-Nickel_Inst._Response_to_RoHS_stakeholder_consultation.pdf

Swedish Chemicals Agency KEMI (2014): Contribution submitted during stakeholder consultation on 03.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140403_KEMI_Input_to_PC_RoHS_2014_2_Substance_review_Prioritasion.pdf

4.13 Beryllium metal

4.13.1 Classification

The harmonized classification under the CLP regulation classifies beryllium metal as:

- Carc. 1B - H350i
- Acute Tox. 2 * - H330
- Acute Tox. 3 * - H301
- STOT RE 1 - H372 **
- Eye Irrit. 2 - H319
- STOT SE 3 - H335
- Skin Irrit. 2 - H315
- Skin Sens. 1 - H317

Because of the classification as Carcinogens, entry 28 of REACH Annex XVII applies to beryllium metals, restricting the use to professional users.

4.13.2 Uses and quantities

Beryllium is registered under REACH, indicating a total tonnage band of 10 to 100 tonnes per year. The publicly available registration information indicates the uses as formulation of beryllium containing alloys at industrial sites. The EEE specific sectors of end use are the manufacture of computer, electronic and optical products, and electrical equipment (SU16).[53]

The Oeko-Institut study 2008 listed the following uses for beryllium metal:

- Beryllium metal and composites: optical instruments, X-ray windows;

[53] ECHA Registered Substance Database: Entry for beryllium; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ea3c1bc-9f6c-1bb2-e044-00144f67d031/DISS-9ea3c1bc-9f6c-1bb2-e044-00144f67d031_DISS-9ea3c1bc-9f6c-1bb2-e044-00144f67d031.html

- Beryllium-containing alloys: current carrying springs, integrated circuitry sockets;

The quantities used in EEE in the EU, mentioned in the 2008 study by stakeholders, accounted for 2 tonnes per year for Beryllium metal and composites and 11.5 tonnes per year for Beryllium containing alloys.[54]

Beryllium is observed as a critical raw material because of the following reasons:[55]

- About 99% of world production originates in US and China;
- Low recycling rate;
- Difficult to substitute – where substitution is possible, it may result in loss of performance.

These aspects are mentioned because the European Commission considers the critical materials[56] as essential to the EU economy and explore different options also on material efficiency, recycling and substitution.

4.13.3 Contributions of stakeholders

The stakeholder contributions submitted during the consultation, namely from the Beryllium Science & Technology Association (BeST), provide a detailed view of the uses, applications and quantities relevant for this substance. The following table presents a summary of this information; the five different documents are available at the Oeko-Institut's webpage for the consultation undertaken within this review (http://rohs.exemptions.oeko.info/index.php?id=213).

All stakeholders stressed the specific properties provided by beryllium, in the respective applications, that could not be substituted without a loss of performance.

Table 4-13: Stakeholder contributions on beryllium metal submitted during the consultation

Stakeholder (Submission date)	Uses	Quantities
Beryllium Science & Technology Association BeST (04 Apr 2014)	**Summary:** **Beryllium Metal (>99%Be) and High Beryllium Alloy (Beryllium Aluminium >60% Be)** Space Exploration / Science: High energy physics experiment	Beryllium metal: 2 -10 t/y; approx. 0.2 t/y in EEE Beryllium-

[54] Op. cit. Oeko-Institut (2008)
[55] European Commission, Enterprise and Industry (2010): Critical raw materials for the EU, Report of the Ad-hoc Working Group on defining critical raw materials; Version of 30 July 2010; http://ec.europa.eu/enterprise/policies/raw-materials/files/docs/report-b_en.pdf
[56] Raw material is labelled "critical" when the risks of supply shortage and their impacts on the economy are higher compared with most of the other raw materials.
Two types of risks are considered: a) the "supply risk" taking into account the political-economic stability of the producing countries, the level of concentration of production, the potential for substitution and the recycling rate; and b) the "environmental country risk" assessing the risks that measures might be taken by countries with weak environmental performance in order to protect the environment and, in doing so, endanger the supply of raw materials to the EU.

Stakeholder (Submission date)	Uses	Quantities
	particle stream guidance beam-pipes; ITER Fusion Reactor main chamber wall lining and neutron blanket material; Medical Isotope production nuclear reactor safety and control linings; Space mounted telescope reflectors; Structural support in space mounted optical benches; Heat shields to protect satellites and orbital telescopes; Audio devices: High fidelity audio loudspeaker diaphragms; Defence & Security: Tank weapon laser targeting mirrors; Aircraft and missile guidance systems; Air launched weapon targeting systems; Medicine: X-Ray windows allowing advances in imaging equipment, diagnostics and laser medicine. **Beryllium-containing alloys; copper and nickel alloys contain from 0.15-2.0 % weight beryllium** Current and signal conductive spring terminals, used in electrical and electronic connectors for communications equipment, mobile phones, cell phone systems; Medical device connections; High reliability automobile electrical and electronic safety related uses in e.g. Air bag triggers; anti-lock brakes; steer by wire; traction controls; dynamic suspension controls; engine sensors; emission control sensors.; Fire suppression sprinkler systems and emergency rescue equipment. **Copper beryllium structural components** are used in such fields as Oil, Gas & Alternative Energy (non magnetic structural components of oil and gas drilling, ex-traction and production equipment, e.g. Directional drilling steering; Blow-out protectors); Thermally conductive, high hardness mold and die applications to reduce cycle time, lower energy consumption and improve dimensional integrity; Energy saving low weight high strength aircraft landing gear bearings	containing alloys: 50 -55 t/y in total; 25 - 28 t/y in EEE
European Semiconductor Industry Association ESIA (04 Apr 2014)	Beryllium metal are used in wires as an alloy element. Beryllium oxide and beryllium metal possess specific physical properties able to confer peculiar characteristics to the semi-conductor devices, therefore they are essential cannot be substituted without changing the semiconductor behaviour.	
Japanese Business Council in Europe JBCE (04 Apr 2014)	Though it is not "beryllium metal" (CAS number 7440-41-7) itself and accurate numerical value is unidentified, but Japanese industry recognizes that beryllium copper, a beryllium alloy, is largely used in EEE. Japanese industry recognizes that beryllium copper (CAS No. 11108-64-8 or 11133-98-5) is largely used in EEE. The reason of the use is because beryllium copper has high conductivity and high strength to contribute to make parts small and lighten, and has durability to be used in the applications in which reliability is indispensable.	

Note: Wording as formulated by stakeholders, with correction only for readability where necessary. Views expressed should not be taken to reflect those of the authors of this report.

4.13.4 Summary

Beryllium metal (>99%Be) and high beryllium alloy (beryllium aluminium >60% Be) are applied in very specific applications. Beryllium-containing alloys (copper and nickel alloys contain from 0.15 - 2.0 % weight beryllium) are used in consumer EEE such as e.g. electrical and electronic connectors for communications equipment, mobile phones, cell phone systems, as well as in medical device connections, fire suppression sprinkler systems and emergency rescue equipment.

The quantities used of beryllium metal accounted for 2 to 10 tonnes per year; thereof approximately 0.2 tonnes per year were used in EEE applications.

The amount of beryllium-containing alloys was indicated by 50 to 55 tonnes per year in total and the use of beryllium-containing alloys in EEE by 25 to 28 tonnes per year.

Compared to the amounts determined in the Oeko-Institit study 2008, the quantities used have doubled in the last years.

Beryllium has been identified as a critical raw material by the European Commission.

4.13.5 References

BeST - Beryllium Science & Technology Association (2014): Contributions submitted on 04.04.2014; http://rohs.exemptions.oeko.info/index.php?id=213

ECHA Registered Substance Database: Entry for beryllium; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ea3c1bc-9f6c-1bb2-e044-00144f67d031/DISS-9ea3c1bc-9f6c-1bb2-e044-00144f67d031_DISS-9ea3c1bc-9f6c-1bb2-e044-00144f67d031.html

European Commission, Enterprise and Industry (2010): Critical raw materials for the EU, Report of the Ad-hoc Working Group on defining critical raw materials; Version of 30 July 2010; http://ec.europa.eu/enterprise/policies/raw-materials/files/docs/report-b_en.pdf

European Semiconductor Industry Association ESIA (2014): Contribution submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/20140404_RoHS_ESIA_Substance_Prioritisation_OKO-Institut_ESIA_April_4_2014.pdf

Japan Business Council in Europe JBCE (2014): Contributions submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/index.php?id=213

Oeko-Institut (2008): Study on Hazardous Substances in Electrical and Electronic Equipment, Not Regulated by the RoHS Directive by Groß, R.; Bunke, D.; Gensch, C.-G.; Zangl, S.; Manhart, A.; Contract No. 070307/2007/476836/MAR/G4; Final Report 17 October 2008; http://hse-rohs.oeko.info/fileadmin/user_upload/Documents/RoHS_Hazardous_Substances_Final_Report.pdf

4.14 Beryllium oxide (BeO)

4.14.1 Classification

The harmonized classification under the CLP regulation for BeO is the same as for Beryllium metal; the classification for carcinogenicity category 1B means that as in the case of Beryllium metal, entry 28 of REACH Annex XVII applies to BeO restricting the use of BeO to professional users.

4.14.2 Uses and quantities

Beryllium oxide is registered under REACH for a total tonnage band of 1 to 10 tonnes per year for production of special industrial ceramic articles. As article categories are related to subsequent service life, the following are relevant for EEE:

- AC 2: Machinery, mechanical appliances, electrical/electronic articles;
- AC 0: Other: Offshore industries, medical and optical products, general manufacturing (machinery, tools, equipment, marine, aeronautic and space transport equipment, nuclear power plants, defence applications, R&D); and
- AC 3: Electrical batteries and accumulators.

The Oeko-Institut study 2008 noted the application of laser bores and tubes for Beryllium oxide ceramics and the amounts of up to 1.5 tonnes per year of beryllium for Beryllium oxide ceramics.[57]

4.14.3 Contributions of stakeholders

Three stakeholders submitted contributions during the consultation. They are presented in Table 4-14. The stakeholder contribution reveals very specific uses of BeO. The Beryllium Science & Technology Association (BeST) that originates from the REACH Beryllium Consortium provided detailed input on the typical applications of BeO, notably high power electronic devices and laser beam guidance, which account for quantities of two to three tonnes per year.

Table 4-14: Stakeholder contributions on beryllium oxide submitted during the consultation

Stakeholder (Submission date)	Uses	Quantities
BeST - Beryllium Science & Technology Association (04 Apr 2014)	Summary: Beryllium oxide ceramic applications (Containing 20% to 37% beryllium) are used in applications that require combinations of: High thermal conductivity; High electrical resistance / insulation; Readily machined and polished; High hardness and strength; Typical Applications are: Substrates for high power electronic devices (e.g. high power transistors; integrated circuitry); Laser beam guidance (e.g for medical surgical devices such as excimer laser bores and tubes)	2 - 3 t/y BeO Powder

[57] Op. cit. Oeko-Institut (2008)

Stakeholder (Submission date)	Uses	Quantities
	Beryllium oxide applied to high-end products and rarely to consumer EEE.	
ESIA (04 Apr 2014)	Beryllium oxide is used as primary constituent of the semiconductor device. Beryllium oxide and beryllium metal possess specific physical properties able to confer peculiar characteristics to the semiconductor devices, therefore they are essential cannot be substituted without changing the semiconductor behaviour.	
JBCE (04 Apr 2014)	According to the JBCE following substances are not contained in EEE: Beryllium oxide listed as "fourth highest priority" BeO would not be used in EEE. Such substance would not need to be prioritised under RoHS. According to the Methodology, and in consideration of the purpose of RoHS, only substances which are used in significant quantity in EEE and whose risk would be considerably reduced by the RoHS should be considered on the restriction under the RoHS.	

Note: Wording as formulated by stakeholders, with correction only for readability where necessary. Views expressed should not be taken to reflect those of the authors of this report.

4.14.4 Summary

Beryllium oxide ceramics are rarely used in consumer electrical and electronic equipment. The main use is in high-end products with long service life. The quantities of Beryllium oxide in the EU are indicated in the stakeholder contributions to account for two to three tonnes per year, which indicates a slight increase compared to the amounts identified by the Oeko-Institut study in 2008 of 1.5 tonnes per year.

Beryllium has been identified as a 'critical' raw material by the European Commission (see section 4.13.2).

4.14.5 References

BeST - Beryllium Science & Technology Association (2014): Contributions submitted on 04.04.2014; http://rohs.exemptions.oeko.info/index.php?id=213

ECHA registered substance database: Entry for beryllium oxide; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ea88471-d27d-627c-e044-00144f67d031/DISS-9ea88471-d27d-627c-e044-00144f67d031_DISS-9ea88471-d27d-627c-e044-00144f67d031.html

European Semiconductor Industry Association ESIA (2014): Contribution submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/20140404_RoHS_ESIA_Substance_Prioritisation_OKO-Institut_ESIA_April_4_2014.pdf

Japan Business Council in Europe (JBCE) (2014): Contributions submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/index.php?id=213

Oeko-Institut (2008): Study on Hazardous Substances in Electrical and Electronic Equipment, Not Regulated by the RoHS Directive by Groß, R.; Bunke, D.; Gensch, C.-G.; Zangl, S.; Manhart, A.; Contract No. 070307/2007/476836/MAR/G4; Final Report 17 October 2008; http://hse-rohs.oeko.info/fileadmin/user_upload/Documents/RoHS_Hazardous_Substances_Final_Report.pdf

4.15 Indium phosphide

4.15.1 Classification

Indium phosphide is at present not classified under the CLP regulation. However, indium phosphide is proposed for a harmonised classification and labelling in light of carcinogenic and reproductive effects.[58]

4.15.2 Uses and quantities

Indium phosphide is not registered under REACH and was not required to be registered by the second deadline on June 1st 2013. This means that indium phosphide may be manufactured and/or used, within the EU, in amounts below 100 tonnes per annum. The European chemical Substances Information System ESIS database[59] does not contain any reporting for indium phosphide by EU Industry.

According to ECHA[60], indium phosphide is used as a semiconductor in electronics. Due to its semiconductor and photovoltaic properties, indium phosphide is primarily used in high power optoelectronic devices such as: [61]

- Laser diodes for fibre optic communications;
- Light Emitting Diodes (LEDs), predominantly to optically transmit data and, to a lesser extent, in LED displays;
- Hetero-junction bipolar transistors for optoelectronic integration;
- Solar cells; and
- High-performance integrated circuits for microelectronics and optoelectronics (lasers and photo-detectors).

[58] ECHA (2010): Background Document to the Opinion of the Committee for Risk Assessment on a Proposal for Harmonised Classification and Labelling of Indium Phosphide; http://echa.europa.eu/documents/10162/56fcaf7e-ed65-4d3c-9e8f-4fddef879789

[59] ESIS European chemical Substances Information System: HPV-LPV Chemicals Information System; http://esis.jrc.ec.europa.eu/index.php?PGM=hpv

[60] Op. cit. ECHA (2010)

[61] IARC International Agency for Research on Cancer (2006): IARC Monographs on the Evaluation of Carcinogenic Risks to Humans; Cobalt in Hard Metals and Cobalt Sulfate, Gallium Arsenide, Indium Phosphide and Vanadium Pentoxide; Volume 86 (2006); http://monographs.iarc.fr/ENG/Monographs/vol86/mono86.pdf

Additionally, indium phosphide is a possible alternative for cadmium in lighting applications in quantum dot based LED technologies, applicable for lighting of displays as well as for solid state lighting.[62]

Indium is defined as a critical raw material by the European Commission.[63] For indium, the high supply risk is mainly due to the fact that more than 81% of the EU's imports of indium originate in China; the recycling possibilities for indium are limited mainly to manufacturing residues, whereas substitution is possible in some applications only.

Emerging technologies contribute to the increasing demand for the raw material.[64] Indium is important for many emerging technologies, including thin-layer photovoltaic cells, displays and white LEDs. The demand for indium in these applications is expected to increase by a factor of eight until 2030.

World production of indium was constant at approximately 200 tonnes per year between 1995 and 1999, and rapidly increased to over 300 tonnes in 2000.[65] The production and the demand for emerging technologies in 2006 as well as an estimated demand for emerging technologies in 2030 are presented in Table 4-15.

Table 4-15: Data for the raw material indium[66]

Raw material production 2006 (t)	Demand from emerging technologies 2006 (t)	Demand from emerging Technologies 2030 (t)
581	234	1.911

4.15.3 Contributions of stakeholders

There was only one submission in relation to indium phosphide during the stakeholder consultation. The European Semiconductor Association stated that *Indium phosphide was used as a primary constituent of the semiconductor device, conferring 'peculiar characteristics to the semiconductor devices, therefore it is essential and cannot be substituted without changing the semiconductor behaviour'.*

[62] Further information is available in the evaluation report of RoHS exemption requests 2013-2 and 2013-5, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/20140422_RoHS2_Evaluation_Ex_Requests_2013-1-5_final.pdf
[63] http://ec.europa.eu/enterprise/policies/raw-materials/critical/index_en.htm
[64] European Commission, Enterprise and Industry (2010): Critical raw materials for the EU, Report of the Ad-hoc Working Group on defining critical raw materials; Version of 30 July 2010; http://ec.europa.eu/enterprise/policies/raw-materials/files/docs/report-b_en.pdf
[65] Op. cit. IARC (2006)
[66] Op. cit. EU COM (2010)

4.15.4 Summary

Indium phosphide is used as a semiconductor in electronics in many emerging technologies, including thin-layer photovoltaic cells, displays and white LEDs. Indium phosphide is so far not registered in the EU, which means that it is used in the EU in amounts of less than 100 tonnes per year.

The demand from emerging technologies in 2006 accounted for 234 tonnes.

Based on earlier experience, the consultants believe that a possible explanation for the lacking REACH registrations is that a large portion of indium phosphide present in EEE placed on the EU market, are imported into the EU as components or products manufactured outside the EU.[67] This could explain the discrepancies between the above mentioned ranges.

Indium is defined as a critical raw material by the European Commission.

4.15.5 References

ECHA (2010): Background Document to the Opinion of the Committee for Risk Assessment on a Proposal for Harmonised Classification and Labelling of Indium Phosphide; http://echa.europa.eu/documents/10162/56fcaf7e-ed65-4d3c-9e8f-4fddef879789

European Commission, Enterprise and Industry (2010): Critical raw materials for the EU, Report of the Ad-hoc Working Group on defining critical raw materials; Version of 30 July 2010; http://ec.europa.eu/enterprise/policies/raw-materials/files/docs/report-b_en.pdf

IARC International Agency for Research on Cancer: IARC Monographs on the Evaluation of Carcinogenic Risks to Humans; Cobalt in Hard Metals and Cobalt Sulfate, Gallium Arsenide, Indium Phosphide and Vanadium Pentoxide; Volume 86 (2006); http://monographs.iarc.fr/ENG/Monographs/vol86/mono86.pdf

European Commission, Enterprise and Industry (2010): Critical raw materials for the EU, Report of the Ad-hoc Working Group on defining critical raw materials; Version of 30 July 2010; http://ec.europa.eu/enterprise/policies/raw-materials/files/docs/report-b_en.pdf

U.S. Geological Survey (2012): Mineral Commodity Summary for Indium, January 2012, http://minerals.usgs.gov/minerals/pubs/commodity/indium/mcs-2012-indiu.pdf

[67] See evaluation report of RoHS exemption requests 2013-2 and 2013-5, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/20140422_RoHS2_Evaluation_Ex_Requests_2013-1-5_final.pdf

4.16 Di-arsenic pentoxide (i.e. arsenic pentoxide; arsenic oxide) and di-arsenic trioxide

4.16.1 Classification

Di-arsenic pentoxide and Di-arsenic trioxide are both listed in Annex XIV because of their carcinogenic properties (both are Carcinogens Category 1A; for both applies the same sunset date: 21/05/2015; the latest application date was 21/11/2013; no exempted (categories of) uses were granted).

4.16.2 Uses and quantities

The ECHA background document[68] for the inclusion on the Authorisation lists considers the volume for Di-arsenic pentoxide, which is relevant for the Authorisation procedure under the REACH regulation as low (< 10 t/y). The uses for wood preservation are covered by the Biocidal Product Regulation. The uses in glass and glass products and uses of other arsenic compounds are all applications as intermediates. The European glass industry trade association has suggested that the substance is not used within Europe.

As for Di-arsenic-trioxide, the ECHA background documents estimate the volume of use in the EU at around 3,900 tonnes per year. The volume of the substance used for non-intermediate uses is approximately 3,000 tonnes per year.[69] There are two major uses of Di-arsenic-trioxide: glass and alloys.

- Alloys: cable sheathing: arsenical lead is also used for cable sheathing; chemical lead, 1% antimonial lead, and arsenical lead are most commonly employed for this purpose; the amount of Di-arsenic-trioxide for this purpose is not very clear (approximately 1,500 tonnes per year);
- Glass and glass products: lighting glass (tubes and bulbs), optical glass, laboratory and technical glassware, borosilicate and ceramic glasses (cookware and high temperature domestic applications), and glass for the electronics industry (LCD panels); the total volume of diarsenic trioxide for glass and enamel processing is estimated at 1,200 tonnes per year;

As for electronic components, diarsenic trioxide is indeed being used within the EU to produce high purity arsenic metal, which is either used to manufacture gallium arsenide semiconductors, or as a dopant to produce special qualities in silicon semiconductors.

[68] ECHA (2009): Diarsenic Pentaoxide, Prioritisation and Annex XIV Background Information, 14 January 2009.
[69] ECHA (2009): Diarsenic Trioxide, Prioritisation and Annex XIV Background Information, 14 January 2009.

Table 4-16: Overview on classification, amounts and uses of di-arsenic pentoxide and di-arsenic trioxide

	Di-arsenic pentoxide	Di-arsenic trioxide
Harmonized Classification: Human Health Environment	Acute Tox. 3 * - H301 Acute Tox. 3 * - H331 Carc. 1A - H350 Aquatic Acute 1 - H400 Aquatic Chronic 1 - H410	Acute Tox. 2 * - H300 Skin Corr. 1B - H314 Carc. 1A - H350 Aquatic Acute 1 - H400 Aquatic Chronic 1 - H410
ECHA	< 10 t/y	4,650 t/y
Relevant uses according to ECHA	Wood preservation; Glass and glass products; Intermediate for other arsenic compounds.	Wood preservation; Glass and glass products; Alloys; Electronic components.

4.16.3 Contributions of stakeholders

The Japanese Business Council in Europe referred to the arsenic compounds in its submission, stating that di-arsenic pentoxide and di-arsenic trioxide would not be contained in EEE.

Table 4-17: Stakeholder contributions on di-arsenic pentoxide and di-arsenic trioxide submitted during the consultation

Stakeholder (Submission date)	Uses
Japanese Business Council in Europe JBCE (04 Apr 2014)	In glass, there are arsenic and an oxide in an amorphous state, but di-arsenic pentoxide and di-arsenic trioxide does not exist as it is. Di-arsenic pentoxide and Di-arsenic trioxide would not be contained in EEE based on our knowledge as EEE manufacturers and glass manufacturers. Such substances would not need to be prioritised under RoHS. The substance restrictions under RoHS don't apply to the substances used or produced in production process, such as intermediate etc., if they are not contained in finished EEEs.

Note: Wording as formulated by stakeholders, with correction only for readability where necessary. Views expressed should not be taken to reflect those of the authors of this report.

4.16.4 Summary

Di-arsenic pentoxide and Di-arsenic trioxide are included in the REACH Regulation Authorisation List (Annex XIV). Di-arsenic pentoxide and Di-arsenic trioxide cannot be placed on the EU market or be used after the 21st of May 2015 in the EU. No exempted uses for Di-arsenic pentoxide and Di-arsenic trioxide have been granted.

As for Di-arsenic pentoxide, no consumer use of articles has been identified. The ECHA considers the volume for Di-arsenic pentoxide, which is relevant for the Authorisation procedure under the REACH regulation as low (< 10 t/y).

As for Di-arsenic-trioxide, there are EEE relevant applications: alloys for cable sheathing and the manufacture of high purity arsenic metal which is either used to manufacture gallium arsenide semiconductors or as a dopant to produce special qualities in silicon semiconductors. The latter application as a doping agent usually results in small amounts of the substance remaining in the material as a trace element. The volume of Di-arsenic-trioxide used for these non-intermediate uses (glass and alloys) is approximately 3,000 tonnes per year.

4.16.5 References

ECHA (2009): Diarsenic Pentaoxide, Prioritisation and Annex XIV Background Information, 14 January 2009.

ECHA (2009): Diarsenic Trioxide, Prioritisation and Annex XIV Background Information, 14 January 2009.

Japan Business Council in Europe (JBCE) (2014): Contributions submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/index.php?id=213

4.17 Cobalt dichloride and cobalt sulphate

The information of the cobalt compounds cobalt dichloride and cobalt sulphate will be presented together because they have the same classification, are both included in the REACH Candidate List and are mostly used as intermediates.

4.17.1 Classification

Cobalt dichloride and cobalt sulphate have both been included in the Candidate list because they are carcinogenic and toxic for reproduction (articles 57a and 57c). On the 20th of December 2011, ECHA recommended including cobalt dichloride and cobalt sulphate in Annex XIV.[70]

Cobalt dichloride and cobalt sulphate are classified under the CLP regulation by the following entries:

- Acute Tox. 4 * - H302
- Skin Sens. 1 - H317
- Resp. Sens. 1 - H334
- Muta. 2 - H341
- Carc. 1B - H350i

[70] ECHA (2011): Third Annex XIV recommendation - 20 December 2011; http://www.echa.europa.eu/documents/10162/13640/3rd_a_xiv_recommendation_20dec2011_en.pdf

- Repr. 1B - H360F ***
- Aquatic Acute 1 - H400
- Aquatic Chronic 1 - H410

4.17.2 Uses and quantities

The information provided by ECHA in the registered substances database show that the focus lies on intermediate use of cobalt dichloride and cobalt sulphate. The results from the ECHA Registered Substances Database are shown in Table 4-18.

For both cobalt compounds, the same usage band is indicated (1,000 to 10,000 tonnes per year). The EEE specific uses of both cobalt compounds are plating processes in surface treatment (used in telecommunication, electronics, storage media, household articles) and the manufacture of inorganic pigments and frits, glass, ceramic ware, varistors and magnets incalcination/sintering processes (for semiconductors used in the manufacture of computer, electronic and optical products, electrical equipment).

Table 4-18: Overview on amounts and uses of cobalt dichloride and cobalt sulphate

ECHA registered substance database	Cobalt dichloride	Cobalt sulphate
Total Tonnage Band	1,000 - 10,000 t/y	1,000 - 10,000 t/y
Intermediate Uses	Manufacture of chemicals and in other wet-chemical processes; Manufacture of cobalt carboxylates and resonates; Manufacture of inorganic pigments, frits, ceramic ware, glass; Plating processes in surface treatment / Passivation processes in surface treatment; Production of textile dyes.	Manufacture of chemicals and in other wet-chemical processes as intermediate Production of cobalt carbonate Manufacture of inorganic pigments & frits, glass, ceramic ware, varistors and magnets (calcination/sintering processes) Production of dyes for textile, leather, wood and/or paper industry Use for chemical pharmaceutical production Battery production Plating processes in surface treatment
Others	Use of water treatment chemicals, oxygen scavengers, corrosion inhibitors Use in fermentation processes, manufacture of reagents and use thereof in scientific research, standard analysis Formulation of Fertilizers and Feed grade material Use in fermentation processes and biogas production Industrial use of cobalt dichloride in humidity indicator cards, plugs and/or bags with printed spots	Use of water treatment chemicals, oxygen scavengers, corrosion inhibitors Formulation of Fertilizers and Feed grade material Manufacture and industrial use of coatings and inks using cobalt sulfate as drier and/or pigment Use in fermentation processes and biogas production

ECHA registered substance database	Cobalt dichloride	Cobalt sulphate
Uses in EEE	Plating processes in surface treatment: telecommunication, electronics, storage media, household articles[71] Manufacture of inorganic pigments & frits, glass, ceramic ware, varistors and magnets (calcination/sintering processes): Semiconductors used in the manufacture of computer, electronic and optical products, electrical equipment	

Source: ECHA Registered Substances Database.

In the context of ECHA's third Recommendation for inclusion of substances in Annex XIV, the Cobalt REACH Consortium provided information on the volumes per sector / use:

Cobalt dichloride: [72]

- In the production of other chemicals: 97%
- In surface treatment: <2%
- As an oxygen scavenger/corrosion prevention in industrial water systems: <1%
- In medicinal products and as trace element in industrial cell culture, <1%
- As animal feed and as component of fertiliser formulation: <<1%
- As humidity indicator: <<<1% (according to a company that provided further information during the consultation, maximum 100 kg/y)
- In the manufacture of inorganic pigments for ceramic products (including glazes) & porcelain manufacture (decolourizing application), no specific tonnage information, assumed low

For the EEE sector, essentially only the use in surface treatment is relevant. Assuming the information indicated above (i.e., <2% of the total of 10,000 t per year) surface treatment accounts for < 200t cobalt dichloride per year; this amount however also covers non-EEE uses.

Cobalt sulphate:[73]

- Manufacture of other chemicals: ~ 90%
- Use in surface treatment: < 5%
- Manufacture of inorganic pigments: <3%

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[71] ECHA (2011): Background document for cobalt dichloride; 20 December 2011; http://www.echa.europa.eu/documents/10162/a002b713-7e1a-46ba-ba54-13763c18fd82 and ECHA (2011): Background document for cobalt(II) sulphate, 20 December 2011; http://www.echa.europa.eu/documents/10162/ef958831-f28c-47f1-b159-ab4a32b53b2f

[72] ECHA (2011): Background document for cobalt dichloride; 20 December 2011; http://www.echa.europa.eu/documents/10162/a002b713-7e1a-46ba-ba54-13763c18fd82

[73] ECHA (2011): Background document for cobalt(II) sulphate, 20 December 2011; http://www.echa.europa.eu/documents/10162/ef958831-f28c-47f1-b159-ab4a32b53b2f

- Manufacture of batteries: <1%
- Manufacture of catalysts: <<1%
- Use as an animal feed supplement: <1%
- Use as an oxygen scavenger/corrosion prevention in industrial water systems: <<1%
- Manufacture of textile dyes: <<1%
- Manufacture of drier and/or pigment in paints/inks: <<1%

Again, for the EEE sector, essentially only the use in surface treatment is relevant. The above indicated <5% of the total of 10,000 tonnes per year. The use of cobalt sulphate in surface treatment thus accounts for < 500 tonnes per year; this amount however also covers non-EEE uses.

4.17.3 Contributions of stakeholders

The stakeholder contributions confirmed that the cobalt compounds are not present in EEE products. Especially the Cobalt Developmental Institute provided detailed input on the different applications and their use amounts; these data are basically the same as the data presented by the ECHA background documents of the two compounds.[74]

Table 4-19: Stakeholder contributions on cobalt dichloride and cobalt sulfate submitted during the consultation

Stakeholder (Submission date)	Uses	Quantities
Swedish Chemicals Agency KEMI (03 Apr 2014)	The use of Cobalt dichloride and Cobalt sulfate in EEE cannot be confirmed from the information given in the SPIN database or the Swedish Products register.	Summary: Cobalt dichloride: Total quantity regarding use in 2011in the Swedish products register: 7.7 tonnes. Total use in the Nordic countries 2011: Used quantities, tonnes per year: confidential Cobalt sulphate: Total quantity regarding use in 2011 in the Swedish products register: 2.9 tonnes Total use in the Nordic countries 2011: 4331 tonnes; partly confidential
Cobalt Developmental Institute (04 Apr 2014)	In EEE uses, cobalt and cobalt compounds are used in semi-conductors, component lead frames, contacts and connectors, printed circuit boards, processors and chipsets, and hard-disk drives. However, the CDI has not to date	

[74] Op. cit. ECHA (2011)

Stakeholder (Submission date)	Uses	Quantities
	collected sufficient data on EEE uses both in terms of the list and description of the uses, and in terms of volumes, to provide details in this consultation. It is not known to the CDI yet, which and how much of each of the three cobalt substances (Co metal, Co sulphate and Co dichloride) are used in each of these applications.	
	Co dichloride is used mainly as an intermediate for the production of chemicals. It is also used in healthcare biotechnology as an essential element in fermentation processes/ industrial cell culture for the synthesis of vitamin B12 and of precursors of biomedical products and in vitro diagnostics. It is also used for the production of biogas. It is added as a trace element to animal feed. A very specific application is the use in hygrometers for the military/ high-tech instrumentation (industrial automotive braking systems, freon lines, control panels) or semiconductor/ electronics packaging. It is also used to prevent corrosion in industrial water systems. There are no consumer applications. The biotechnology applications have no substitute as Co is used as a trace element essential to life and fermentation processes/cell culture. To date no substitute has been found of the use in hygrometers (humidicy indicators) which would maintain the desired technical performance. Information reported to the Cobalt REACH Consortium (CoRC) based on average annual volume manufactured and/or imported in the EU over a 3-year period (2008 to 2010).	On the basis of tonnages reported to the Cobalt REACH Consortium, the annual tonnage of Co dichloride actually manu-factured and/or imported in the EU is less than a third of the range maximum of 10,000. >95% of the total volume of the cobalt dichloride produced/imported in the EU is used for the production of chemicals. The next main use is in surface treatment (general uses - this volume has not been broken down specifically for EEE uses. Other non-EEE uses consist of very low volumes (e.g. <1 % for each use) for corrosion prevention in general for industrial water systems, in healthcare biotechnology as an essential element in cell culture for the industry healthcare sector (biomedicines, vaccines and diagnostics), for the production of biogas or for hygrometers (humidity indicators) for the military/ high-tech instrumentation/ electronics packaging. No (general or EEE) uses of Co dichloride in pigments & frits, glass or ceramic ware were re-ported to the CoRC. The CDI has not received any information on varistors for Co dichloride and use of cobalt in magnets is not known to the CDI. In general Co is used in semi-conductors, component lead frames, contacts and connectors, printed circuit boards, processors and chipsets, and hard-disk drives. However it is not known to the CDI yet which and how much of each of the three cobalt substance are used in each of these applications.

Stakeholder (Submission date)	Uses	Quantities
	Co sulphate is used as an intermediate in the production of other chemicals and in the production of catalysts. It is also used to prevent corrosion in industrial water systems. There are no consumer applications. Information reported to the Cobalt REACH Consortium (CoRC) is based on average annual volume manufactured and/or imported in the EU and represents general (all) uses. It does not cover only EEE uses for which the volumes of Cobalt sulphate in EEE are not known at present.	The volumes of Co sulphate in the EU are reported under REACH in the 1,000-10,000 t/year band, which were provided for the prioritisation of Cobalt sulphate on the Candidate List for Authorisation. In reality the actual total tonnage manufactured and/or imported in the EU is less than a third of the range maximum of 10,000 t/year. In addition, these figures apply to general uses and are not specific to EEE uses, which would there-fore be much lower. The vast majority (>90%) of the EU volume of the cobalt sulphate is used as an intermediate for the production of chemicals. Only small volumes are used in sur-face treatment, pigments and inks, and even less in batteries. <1% is used as an animal feed additive. << 1% is used for corrosion prevention in industrial water systems. It is expected that these volumes will be much lower in EEE uses. In general Co is used in semi-conductors, component lead frames, contacts and connectors, printed circuit boards, processors and chipsets, and hard-disk drives. However it is not known to the CDI yet which and how much of each of the three cobalt sub-stance are used in each of these applications. We have no volume information on specific EEE applications of cobalt sulphate.
Japanese Business Council in Europe JBCE (04 Apr 2014)	Cobalt dichloride would not be used in EEE as long as we know. (It was mainly used in packaging materials as the indicator of desiccant such as silica gel.) Such substance would not need to be prioritised under RoHS. According to the Methodology, and in consideration of the purpose of RoHS, only substances which is used by significant quantity in EEE and whose risk would be considerably reduced by the RoHS should be considered on the restriction under the RoHS. In this consultation and "Study for the Review of the List of Restricted Substances under RoHS2", cobalt dichloride is listed as "the fifth highest	

Stakeholder (Submission date)	Uses	Quantities
	priority". However, according to the Methodology (Annex I thereof), and in the priority list (Annex IV thereof), this substance is ranked as "VII" of the overall priority category. We believe the latter is the accurate result of priority based on the Methodology, and rank should not be altered arbitrary. To avoid misunderstanding, the resulted (original) priority should be applied to substances concerned. (If necessary, a note should be provided as "no substances are identified as the fifth and sixth highest priority")	

Note: Wording as formulated by stakeholders, with correction only for readability where necessary. Views expressed should not be taken to reflect those of the authors of this report.

4.17.4 Summary

For EEE, uses of both cobalt compounds in surface treatment processes are an intermediate use, thus they are not expected to be contained in the final product. The quantities for cobalt dichloride are less than 200 tonnes per year and for cobalt sulphate less than 500 tonnes per year. These volumes have not been broken down specifically for EEE uses.

4.17.5 References

ECHA Registered Substance Database: Entry for cobalt dichloride; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9c82ba1d-3983-63e3-e044-00144f67d249/DISS-9c82ba1d-3983-63e3-e044-00144f67d249_DISS-9c82ba1d-3983-63e3-e044-00144f67d249.html

ECHA (2011): Background document for cobalt dichloride; 20 December 2011; http://www.echa.europa.eu/documents/10162/a002b713-7e1a-46ba-ba54-13763c18fd82

Cobalt Development Institute (2014): Contribution submitted on 04.04.2014; http://rohs.exemptions.oeko.info/index.php?id=213

Swedish Chemicals Agency KEMI (2014): Contribution submitted during stakeholder consultation on 03.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140403_KEMI_Input_to_PC_RoHS_2014_2_Substance_review_Prioritasion.pdf

ECHA Registered Substance Database: Entry for cobalt sulphate; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9c84b590-a1e1-7043-e044-00144f67d249/DISS-9c84b590-a1e1-7043-e044-00144f67d249_DISS-9c84b590-a1e1-7043-e044-00144f67d249.html

ECHA (2011): Background document for cobalt(II) sulphate, 20 December 2011; http://www.echa.europa.eu/documents/10162/ef958831-f28c-47f1-b159-ab4a32b53b2f

Japan Business Council in Europe (JBCE) (2014): Contributions submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/index.php?id=213

4.18 Cobalt metal

4.18.1 Classification

The harmonized classification for cobalt under the CLP regulation is the following:

- Skin Sens. 1 - H317
- Resp. Sens. 1 - H334
- Aquatic Chronic 4 - H413

4.18.2 Uses and quantities

As cobalt is used for the production of inorganic cobalt compounds, the uses of cobalt compounds are also listed for cobalt metal. The additional applications of cobalt metal based on the ECHA Registered Substance Database:[75]

- Use of cobalt in the manufacture of inorganic cobalt substances (intermediate use);
- Use of cobalt in the manufacture of cobalt carboxylates and resonates (intermediate use);
- Manufacture and industrial use of cobalt containing alloys, steels and tools;
- Production of sintered hard metal articles;
- Magnets and magnet systems, materials ,cores and inductive components;
- Manufacture of diamond tools for cutting and or polishing the stone, concrete and asphalt road construction;
- Industrial use of cobalt as catalyst, manufacture of substance as part of a metal catalyst/ inorganic catalyst.

The usage tonnage is indicated to be above 10,000 tonnes per year.

Cobalt is assessed as a critical raw material at EU level because the Democratic republic of Congo has a large share of world production, there is a lack of level playing field regarding primary production, particularly Chinese competition, and there are limited options for substitution. Cobalt is used in emerging technologies such as e.g.

[75] ECHA Registered Substance Database: Entry for cobalt; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9c8246bc-6f29-126a-e044-00144f67d249/DISS-9c8246bc-6f29-126a-e044-00144f67d249_DISS-9c8246bc-6f29-126a-e044-00144f67d249.html

Lithium-ion batteries and synthetic fuels.[76] The raw material production and the demand from emerging technologies for cobalt in 2006 and projected to 2030 are shown in the following table.

Table 4-20: Data for the raw material cobalt

Raw material Production 2006 (t)	Demand from emerging technologies 2006 (t)	Demand from emerging Technologies 2030 (t)
62,279	12,820	26,860

Source EU COM, Enterprise and Industry (2010)[76]

4.18.3 Contributions of stakeholders

Three stakeholders submitted contributions during the stakeholder consultation on cobalt metal. The Cobalt Developmental Institute stated that in general cobalt is used in semiconductors, component lead frames, contacts and connectors, printed circuit boards, processors and chipsets, and hard-disk drives but that it is not clear which and how much of the three cobalt substances (cobalt metal, cobalt dichloride and cobalt sulphate) are used in each of these applications. The Cobalt Development Institute expects the volumes of cobalt metal in EEE to be low.

Table 4-21: Stakeholder contributions on cobalt metal submitted during the consultation

Stakeholder (Submission date)	Uses	Quantities
Swedish Chemicals Agency KEMI (03 Apr 2014)	The use of Cobalt metal in EEE cannot be confirmed from the reported uses in the SPIN database or the Swedish Products register, but cannot be excluded either.	Summary: Product types and industry sectors where Cobalt metal was used 2011: Raw materials for metal production: 347.4 tonnes Fabricated Metal Products Industry: 308.2 tonnes Export 29.6 tonnes Metal coating: 1.5 tonnes Total use of Cobalt metal in the Nordic countries 2008-2011: 2011: 27,101.9 t 2010: 10,209.9 t 2009: 9,836.5 t 2008: 9,394.6 t

[76] European Commission, Enterprise and Industry (2010): Critical raw materials for the EU, Report of the Ad-hoc Working Group on defining critical raw materials; Version of 30 July 2010; http://ec.europa.eu/enterprise/policies/raw-materials/files/docs/report-b_en.pdf

Stakeholder (Submission date)	Uses	Quantities
Cobalt Developmental Institute (04 Apr 2014)	Oeko-Institut have used generic uses for all forms of cobalt. Cobalt metal is mainly used for alloys (e.g. superalloys for gas turbines and hard wearing applications); magnets, hard metals; cutting tools; hard facing alloys; prosthetics and specialist casting alloys. Other uses described by Oeko Institut are largely chemical intermediate forms of cobalt. EEE applications need to be investigated as the CDI is not aware of some of these applications for Cobalt metal. In general Co is used in semi-conductors, component lead frames, contacts and connectors, printed circuit boards, processors and chipsets, and hard-disk drives. However it is not known to the CDI yet which and how much of each of the three cobalt substance are used in each of these applications.	The world annual production of refined cobalt in 2012 was 77,189 (CDI Annual Statistics published on the website), of which approximately 16,500 tonnes was produced in the EU (for all uses). Much of the Co metal is not used in EEE, and therefore we expect the volumes in EEE to be low.
European Semi-conductor Industry Association ESIA (04 Apr 2014)	Cobalt metal is used as primary constituent of the semiconductor device.	

Note: Wording as formulated by stakeholders, with correction only for readability where necessary. Views expressed should not be taken to reflect those of the authors of this report.

4.18.4 Summary

The EEE specific use of Cobalt metal can only be vaguely summarized as uses in semiconductors, component lead frames, contacts and connectors, printed circuit boards, processors and chipsets, and hard-disk drives. The Cobalt Development Institute is not aware which and how much of the three cobalt substance (cobalt metal, cobalt dichloride and cobalt sulphate) are used in each of these applications. The Cobalt Development Institute expects the volumes of cobalt metal in EEE to be low.

As cobalt metal is not proposed for any process to address chemicals of concern within the ECHA, detailed use pattern specifying the quantities are not available.

Cobalt is considered to be a critical raw material in the EU.

4.18.5 References

Cobalt Development Institute (2014): Contribution submitted on 04.04.2014; http://rohs.exemptions.oeko.info/index.php?id=213

ECHA Registered Substance Database: Entry for cobalt; http://apps.echa.europa.eu/registered/data/dossiers/DISS-9c8246bc-6f29-126a-e044-00144f67d249/DISS-9c8246bc-6f29-126a-e044-00144f67d249_DISS-9c8246bc-6f29-126a-e044-00144f67d249.html

European Commission, Enterprise and Industry (2010): Critical raw materials for the EU, Report of the Ad-hoc Working Group on defining critical raw materials; Version of 30 July 2010; http://ec.europa.eu/enterprise/policies/raw-materials/files/docs/report-b_en.pdf

European Semiconductor Industry Association ESIA (2014): Contribution submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/20140404_RoHS_ESIA_Substance_Prioritisation_OKO-Institut_ESIA_April_4_2014.pdf

Swedish Chemicals Agency KEMI (2014): Contribution submitted during stakeholder consultation on 03.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140403_KEMI_Input_to_PC_RoHS_2014_2_Substance_review_Prioritasion.pdf

4.19 Nonylphenol

4.19.1 Classification

Nonylphenol is on the REACH candidate list because of endocrine disrupting effects (equivalent level of concern having probable serious effects on the environment (Article 57 f)). Additionally, nonylphenol is restricted under REACH Annex XVII, Entry 46. This entry states:

> *"Shall not be placed on the market, or used, as substances or in mixtures in concentrations equal to or greater than 0.1 % by weight for the following purposes:*
>
> *(1) industrial and institutional cleaning except:*
>
> - *controlled closed dry cleaning systems where the washing liquid is recycled or incinerated,*
> - *cleaning systems with special treatment where the washing liquid is recycled or incinerated.*
>
> *(2) domestic cleaning;*
>
> *(3) textiles and leather processing except:*
>
> - *processing with no release into waste water,*

- *systems with special treatment where the process water is pre-treated to remove the organic fraction completely prior to biological waste water treatment (degreasing of sheepskin);*

(4) emulsifier in agricultural teat dips;

(5) metal working except: uses in controlled closed systems where the washing liquid is recycled or incinerated;

(6) manufacturing of pulp and paper;

(7) cosmetic products;

(8) other personal care products except: spermicides;

(9) co-formulants in pesticides and biocides.

However national authorisations for pesticides or biocidal products containing nonylphenol ethoxylates as co-formulant, granted before 17 July 2003, shall not be affected by this restriction until their date of expiry."

Nonylphenol (NP) is a priority hazardous substance under the Water Framework Directive (WFD).

Nonylphenol has the following harmonized classification:

- Repr. 2 - H361fd
- Acute Tox. 4 * - H302
- Skin Corr. 1B - H314
- Aquatic Acute 1 - H400
- Aquatic Chronic 1 - H410

4.19.2 Uses and quantities

Nonylphenol is used as an industrial chemical, lubricant, pre- and decomposition product of emulsifiers and detergents. The major quantity use of nonylphenol is in the manufacture of nonylphenol ethoxylates, which are used as surfactants in electrical and electronic engineering industries only to a small extent (surfactants used in coatings for films in EEE and in formulations used to clean printed circuit boards; adhesives).[77] The specific use of nonylphenol and nonylphenol ethoxylates in EEE has neither been considered in the EU RAR (2002)[78] nor in REACH Annex XVII.

The nonylphenol registration data indicates a usage band of 10,000 to 100,000 tonnes per year.[79] However, the Oeko-Institut study in 2008 already stated that in many application areas the use of nonylphenol and nonylphenol ethoxylates has already been phased out as a result of the restrictions specified in item 46 of Annex

[77] Op. cit. Oeko-Institut (2008)
[78] EU Risk Assessment Report, 4-nonylphenol (branched) and nonylphenol, Final report (2002).
[79] ECHA Registered Substances Database: Entry for Phenol, 4-nonyl-, branched; http://apps.echa.europa.eu/registered/data/dossiers/DISS-a0032507-57d5-4c34-e044-00144f67d031/DISS-a0032507-57d5-4c34-e044-00144f67d031_DISS-a0032507-57d5-4c34-e044-00144f67d031.html

XVII to REACH. The known remaining applications are the use as solubilizer in tin electrolytes for printed wiring boards and in curing systems for epoxy resins. End use applications include high temperature resistant module potting, current transformer potting, electrically conductive adhesives and general purpose potting compounds. In EEE, if the use takes place at all, applications are very limited and the quantities of nonylphenol and nonylphenol ethoxylates used are very small.

4.19.3 Contributions of stakeholders

The contribution from the Japanese Business Council in Europe JBCE (04 April 2014) stated that nonylphenol would not be used or contained in EEE:

> *"Based on our knowledge as EEE manufacturers and PCB manufacturers; Nonylphenol would not be contained in EEE. Such substance would not need to be prioritised under RoHS. The substance restrictions under RoHS don't apply to the substances used or produced in production process, such as intermediate etc., if they are not contained in finished EEEs."*

4.19.4 Summary

The use of nonylphenol in the EEE sector could not be clarified during the consultation. The Oeko-Institut study in 2008 already concluded that in the EEE sector, applications are very limited and the quantities of nonylphenol and nonylphenol ethoxylates used are very small. With the inclusion of nonylphenol on the REACH candidate List, this situation will not have changed substantially.

4.19.5 References

Oeko-Institut (2008): Study on Hazardous Substances in Electrical and Electronic Equipment, Not Regulated by the RoHS Directive by Groß, R.; Bunke, D.; Gensch, C.-G.; Zangl, S.; Manhart, A.; Contract No. 070307/2007/4768 36/MAR/G4; Final Report 17 October 2008; http://hse-rohs.oeko.info/fileadmin/user_upload/Documents/RoHS_Hazardous_Substances_Final_Report.pdf

EU Risk Assessment Report, 4-nonylphenol (branched) and nonylphenol, Final report (2002).

ECHA Registered Substances Database: Entry for Phenol, 4-nonyl-, branched; http://apps.echa.europa.eu/registered/data/dossiers/DISS-a0032507-57d5-4c34-e044-00144f67d031/DISS-a0032507-57d5-4c34-e044-00144f67d031_DISS-a0032507-57d5-4c34-e044-00144f67d031.html

4.20 General contributions of stakeholders

There were some general contributions of stakeholders not covering a specific substance; they are summarized in Table 4-22.

Table 4-22: Stakeholder contributions covering general issues not assignable to a specific substance

Stakeholder (Submission Date)	Comments
American Chamber of Commerce to the European Union AmCham EU (04 Apr 2014)	Summary: An assessment of specific substances should not be performed before the RoHS substance methodology has been finalised and agreed. RoHS substance scope should be reviewed periodically (every four years). Only a realistic number of proposals for restriction should be considered at once due to the impact on industry. A large working list is inappropriate and could have a 'black listing' effect; instead limited list to the substances that are explicitly under consideration for identification and assessment. Involvement of stakeholders highly desirable in a transparent and constructive way from the beginning of the process, giving them the possibility to provide input and comments on the substances identified for further assessment for potential restriction under RoHS. Many of the substances identified as priority for assessment are substances of very high concern (SVHC) included in the candidate list and some of them are listed in REACH Authorisation Annex XIV. Special attention should be paid to the further regulatory developments related to these substances under REACH and their interaction with RoHS. A potential RoHS assessment should take into consideration the information submitted in the context of the REACH authorisation procedure and the opinions of ECHA's Committees RAC and SEAC for reasons of consistency and efficient use of existing analysis under REACH. Substances currently identified under RoHS to be of highest priority (DEHP, DBP, HBCDD) are also subject to applications for authorisation that include uses in EEE and one of them focuses specifically on the end of life phase; the currently ongoing assessment by RAC and SEAC will be delivered in the coming months and should be taken into consideration before a decision is made on these substances in the context of RoHS. in-depth RMO analysis of other substances (e.g.: nickel compounds) should be anticipated as well.
Cobalt Developmental Institute (04 Apr 2014)	REACH-RoHS 'harmonisation': The 'Methodology for Identification and Assessment of Substance for Inclusion in the List of Restricted Substances (Annex II) under RoHS2 Directive' published by Oeko Institut in January 2014 (Ref. ENV.C.2/ETU/2012/0021) states in its introduction that 'Another objective of the recast f the RoHS Directive is to harmonise RoHS with other pieces of EU legislation such as chemicals legislation, in particular the [...] REACH Regulation [...] and provisions related to the management of WEE [etc...] '. The CDI welcomes this objective of regulatory coherence which should ensure that the technical elements can enable the 'read across' the two directives. In this context, the CDI expresses its supports to the joint Eurometaux-CEFIC-Orgalime

Stakeholder (Submission Date)	Comments
	position that supports the Commission's initiative to develop a Common Understanding on the implementation of the REACH Regulation and the RoSH2 Directive 2011/65/EU.[80]
Test & Measurement Coalition (04 Apr 2014)	Explanations on the following topics: Specificity of Category 9 industrial equipment; The specific needs of Category 9 industrial taken into account in RoHS 1 and RoHS 2: Exclusion from the scope of RoHS 1; Specific conditions foreseen for Category 9 industrial in RoHS 2; Impossibility of compliance with potential RoHS substance extension; Information about the presence of the priority substances in our products at the homogeneous material level is not yet available; Long term reliability of alternatives should be evaluated for Category 9 Industrial.

Note: Wording as formulated by stakeholders, with correction only for readability where necessary. Views expressed should not be taken to reflect those of the authors of this report.

AmCham addresses the need to be careful with the handling of lists in order to avoid "black lists".

Many other stakeholders noted that the priority list dealt with in this study created confusion in regards to whether the substances will be restricted under RoHS 2 and in which period. Working lists published on the internet can be taken out of context and used differently e.g. as a black list. This confusion could persist as long as the European Commission does not provide a statement clarifying how the various substances are to be regarded at present.

AmCham and CDI addressed the need for harmonization between REACH and RoHS.

As for the recommendation of AmCham to consider the procedures ongoing under REACH in order to use the available information, this approach has been used in this study as explained in earlier sections. The different REACH processes and the opinions of ECHA's Committees RAC and SEAC provide high quality data gained through stakeholder involvement and cross-checked by ECHA and/or Member State Authorities.

The Test & Measurement Coalition claimed in the statement that it would be impossible for companies active in producing Category 9 industrial monitoring and control instruments to comply with a potential RoHS substance extension. The substance prioritization performed in this study did not consider the different categories of EEE as specified in Annex I of RoHS 2. The consultants believe that such concerns may be valid if transition phases of the restriction of new substances have to consider the ability of various industries to adopt processes and technologies as well

[80] The paper from ORGALIME, EUROMETAUX and Cefic COMMENTS ON CARACAL WORKING DOCUMENT: "REACH AND DIRECTIVE 2011/65/EU (RoHS) – A COMMON UNDERSTANDING, Brussels, 7 February 2014 can be downloaded at: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/20140404_3_ORGALIME-EUROMETAUX_Cefic_Comments_REACH-RoHS_Common_Understanding.PDF

as the availability of proven substitutes that could be investigated for this purpose. In this sense, future assessments of substances should look into the aspect of substitution in the context of EEE in order to provide insight into the transition periods that may be relevant for future restrictions.

4.21 Priority recommendations

According to the technical specifications of this project the objective has been *"to quantify the usage of the 21 previously identified priority substances in EEE, or where this is not possible, produce a magnitude ranking, with a view to a refined prioritisation for future review cycles."* Removing substances from the list was not understood to be a relevant recommendation in light of the defined objectives.

For this reason, the consultant's main basis for the refined prioritisation has been based on the use quantities established for each substance in the course of this project. Review of additional literature for the sake of evaluating aspects beyond the quantity usage of substances in EEE, for the purpose of refining the prioritisation, was beyond the scope of the project and only played a role in certain cases.

The following criteria have been the basis of the refined prioritisation:

- Quantities in which the substance is in use in EEE manufacture;
- Quantities present in EEE end products (in cases where substances are used as intermediates or reactive chemicals;
- Possible differences in the use trend of a substance between EU manufacturers and other manufacturers in light of REACH authorisation processes;

It should be noted that although the hazardous priorities of substances have been specified, as found in available literature or as provided by stakeholders, it was beyond the scope of this project to evaluate such classifications for adding this aspect to the prioritisation. Thus, it is possible that despite the risk aspects of a specific substance, it is recommended to be assessed at a later period in time in cases where it is unclear if a restriction is to result in an environmental benefit.

In the cases of indium phosphide, beryllium based compounds and cobalt based compounds, it should be noted that the substances are identified as critical raw materials. Though it is yet to be discussed if such materials are to be regulated through a regulation targeted at hazardous materials, the European Commission considers the critical materials[81] as essential to the EU economy and the Commission may explore such options as it strives to promote material efficiency, recycling and substitution. As all aspects are inherent to the restriction of hazardous materials, it can be followed why the RoHS framework could be used as a tool for realization of

[81] Raw material is labelled "critical" when the risks of supply shortage and their impacts on the economy are higher compared with most of the other raw materials.
Two types of risks are considered: a) the "supply risk" taking into account the political-economic stability of the producing countries, the level of concentration of production, the potential for substitution and the recycling rate; and b) the "environmental country risk" assessing the risks that measures might be taken by countries with weak environmental performance in order to protect the environment and, in doing so, endanger the supply of raw materials to the EU.

these objectives. None the less, the definition of a substance as a critical material has not been a criterion in the refinement of the prioritisation.

Aspects of substances in waste and recyclability were also not the focus of the review and have not been taken into consideration. That said, in some cases, comments have been added to suggest when such aspects are expected to be important for the assessment of a substance under RoHS.

The consultants would also like to clarify that although the availability and applicability of substitutes may play an important role, when the schedule for transition of a restriction is under review, it has not been taken into consideration in this review.

In light of the information presented above, the consultants present a summary of the available quantity usage information and recommendations concerning the assessment of the various substances as presented in Table 4-23 below. The table also provides some commentary to indicate aspects of interest, which should be considered in future assessments of the substances in the context of RoHS.

The recommendations are to be understood as a possibility as to the order of future assessment cycles of the short listed substances and do not reflect if the consultants find a restriction of a substance to be beneficial or not. Where relevant, the body of knowledge enabled through this process is to support both positive and negative decisions concerning new Annex II substances, as well as possible voluntary activity in cooperation with industry.

Table 4-23: Information Summary and Recommendations for AUBA Prioritised Substance Shortlist for Future Assessment Cycles

Substance	Original proposal of AUBA project		Current Project			
	Order of appearance *	Prioritisation	Usage magnitude ranking	Recommendation	Quantity estimation for EEE	Comments
Tris(2-chloroethyl) phosphate (TCEP)	5	Highest priority	Annex XIV substance assumed not to be in use in light of EU use trends - needs to be confirmed in the supply chain, particularly of articles imported from outside the EU. Restriction may be more relevant to ensure that substance is not brought in through import of components and products	Assessment can be made at a later stage in light of the lower relevance to EEE. Main focus would be to realize if there is an impact to competitiveness in light of the Authorisation requirement or if manufacture has just moved elsewhere). It may be beneficial to have a survey of the supply chain in cooperation with industry, to clarify if its use in EEE is relevant and would justify a restriction to ensure the level of environmental safety is the same and whether the different trend of use causes impacts on competition between EU and non EU manufacturers.		
2,3-dibromo-1-propanol	7	Highest priority	Assumed not to be in use in light of EU use trends - needs to be confirmed in the supply chain, particularly of articles imported from outside the EU.	Assessment can be made at a later stage. It may be beneficial to have a survey of the supply chain in cooperation with industry, to clarify if its use in EEE is relevant and would justify a restriction to ensure the level of environmental safety is the same and whether the different trend of use causes impacts on competition between EU and non EU manufacturers.	Apparently not in use	
Dibromoneopentyl glycol	8	Highest priority			Apparently not in use	It remains unclear if this substance is present in components provided by the supply chain, for example when used in flame-retarded uses such as epoxy internal to power supplies.

Substance	Original proposal of AUBA project		Current Project			
	Order of appearance *	Prioritisation	Usage magnitude ranking	Recommendation	Quantity estimation for EEE	Comments
Antimony trioxide	9	Second highest priority	Medium use volume in EEE	Medium priority to assess if environmental benefits justify restriction - check if there are sub-substances that need to be reviewed as with PVC rigid, soft and recycled.	20,000 tonnes	Its use has been explained to reduce the amount of brominated flame retardants needed in an application; For this reason, it would be beneficial to assess this substance along with brominated flame retardants which are to be assessed.
Diethyl phthalate (DEP)	10	Second highest priority	Assumed not to be in use in light of EU use trends - needs to be confirmed in the supply chain, particularly of articles imported from outside the EU.	Assessment can be made at a later stage. It may be beneficial to have a survey of the supply chain in cooperation with industry, to clarify if its use in EEE is relevant and would justify a restriction to ensure the level of environmental safety is the same and whether the different trend of use causes impacts on competition between EU and non EU manufacturers.	Apparently not in use	Unclear if the applications "tools" or "toothbrushes" include electric tools/electric toothbrushes which would be at least in part in scope of the RoHS Directive; if DEP is applied in tools or toothbrushes containing EE components, this justifies higher priority within sub-group

Substance	Original proposal of AUBA project		Current Project			
	Order of appearance *	Prioritisation	Usage magnitude ranking	Recommendation	Quantity estimation for EEE	Comments
Tetrabromo-bisphenol A (TBBPA	11	Second highest priority	Medium use volume in EEE	Medium priority to assess if environmental benefits justify restriction - check if there are sub-substances that need to be reviewed as with PVC rigid, soft and recycled.	1,000 to 2,500 tonnes manufactured and/or used in the EU for EEE manufacture. 6,000-20,200 tonnes may reflect amounts entering the EU through import of components and products.	Substitution has begun where possible; differentiation between TBBA as additive and TBBA as reactive component should be looked into in the assessment; Where used as a reactive component, it may be beneficial to consider the amount of brominated substances that remain in the product in light of the tendency of reactive TBBPA to transform into other compounds. As RoHS restricts the substance that is present in the final product if a restricted substance is not present, the restriction shall have no environmental benefit. In this sense in some cases, it may prove relevant to understand what compounds remain in the product, in light of a compound used in certain processes, and to consider their regulation as a method for reducing the use of the source-compound.

Substance	Original proposal of AUBA project		Current Project			
	Order of appearance *	Prioritisation	Usage magnitude ranking	Recommendation	Quantity estimation for EEE	Comments
Medium-chain chlorinated paraffins (MCCPs)	12	Second highest priority	Medium use volume in EEE	Medium priority to assess if environmental benefits justify restriction - check if there are sub-substances that need to be reviewed as with PVC rigid, soft and recycled.	15,000 tonnes for PVC cable manufacture, smaller quantities may be relevant for other applications despite the lack of such data	Though it may be beneficial to regulate MCCPs as a group of substances, to justify this approach, an assessment should regard various types of MCCPs in light of their various aspects and relevance to EEE. Furthermore, MCCP in recycled content is also an aspect that should be regarded to understand if a restriction could affect the use of recycled content as well as if the use of MCCP in the manufacture of some items facilitates the use of recycled content in manufacture of new products. In light of the relevance of MCCP to PVC, these substances should be assessed in parallel or subsequent to the assessment of PVC, in light of the various links between the two.

Substance	Original proposal of AUBA project		Current Project			
	Order of appearance *	Prioritisation	Usage magnitude ranking	Recommendation	Quantity estimation for EEE	Comments
Poly vinyl chloride (PVC)	13	Third highest priority	High use volume in EEE	Higher priority to assess if environmental benefits justify restriction - check if there are sub-substances that need to be reviewed as with PVC rigid, soft and recycled.	330,000 tonnes	A comprehensive assessment should look into the various types of PVC (rigid and the various flexible types based on plasticiser content - differentiating between the phthalates DEHP, BBP and DBP or other additives) both in terms of relevance for EEE, for substitution and in terms of possible impacts on the environment and on health. Recycled PVC is also an issue of concern, both in terms of the range of uses that recycled content would have should a restriction be decided upon as well as in cases where certain plasticisers are to be restricted, possibly impacting the recyclability of PVC in the future. In this regard, an assessment of PVC in parallel with an assessment of PVC additives would be beneficial.
Beryllium	14	Fourth highest	Low use volume in	Lower priority to assess if environmental benefits justify restriction - check if there	Beryllium metal: 25 to	Should be investigated with

Substance	Original proposal of AUBA project		Current Project			
	Order of appearance *	Prioritisation	Usage magnitude ranking	Recommendation	Quantity estimation for EEE	Comments
metal; (and Beryllium containing alloys)		priority	EEE	are sub-substances that need to be reviewed as with PVC rigid, soft and recycled.	28 tonnes per year Beryllium containing alloys: 0.2 tonnes per year	Beryllium oxide
Beryllium oxide (BEO)	15	Fourth highest priority	Low use volume in EEE	Lower priority to assess if environmental benefits justify restriction - check if there are sub-substances that need to be reviewed as with PVC rigid, soft and recycled.	2 to 3 tonnes per year	Should be investigated with other Beryllium metal
Nickel sulphate	16	Fourth highest priority	Varying use volume with low anticipation for presence in final product in light of intermediate applications	Assessment can be prepared at later stage as restriction aimed at quantities present in end-product and thus impact on use needs to be revisited.	10,000 - 100,000 tonnes in use - not only for EEE	Understood to be applied as an intermediate and thus not present in end-products. May be relevant to restrict converted compounds present in end-products as result of use. In light of similarities, it is proposed to assess this substance along with nickel bis(sulfamidate)/nickel sulfamate.
Nickel sulfamate (=Nickel bis sulfamidate)	17	Fourth highest priority	Varying use volume with low anticipation for presence in final product in light of	Assessment can be prepared at later stage as restriction aimed at quantities present in end-product and thus impact on use needs to be revisited.	100 to 1,000 tonnes in use - not only for EEE	Understood to be applied as an intermediate and thus not present in end-products. May be relevant to restrict

Substance	Original proposal of AUBA project		Current Project			
	Order of appearance *	Prioritisation	Usage magnitude ranking	Recommendation	Quantity estimation for EEE	Comments
			intermediate applications			converted compounds present in end-products as result of use. In light of similarities, it is proposed to assess this substance along with nickel sulphate.
Indium phosphide	18	Fourth highest priority	Low use volume in EEE	Lower priority to assess if environmental benefits justify restriction - check if there are sub-substances that need to be reviewed as with PVC rigid, soft and recycled.	Between 100 and 250 tonnes - uncertainty is high though this is more probably an under estimation as quantities are expected to grow	
Di-arsenic pentoxide; (i.e. Arsenic pentoxide; Arsenic oxide)	19	Fifth highest priority	Annex XIV substance assumed not to be in use in light of EU use trends - needs to be confirmed in the supply chain, particularly of articles imported from outside the EU. Restriction may be more relevant to ensure that substance is not brought in through import of components and products	Assessment can be made at a later stage in light of the lower relevance to EEE. Main focus would be to realize if there is an impact to competitiveness in light of the Authorisation requirement or if manufacture has just moved elsewhere). It may be beneficial to have a survey of the supply chain in cooperation with industry, to clarify if its use in EEE is relevant and would justify a restriction to ensure the level of environmental safety is the same and whether the different trend of use causes impacts on competition between EU and non EU manufacturers.	Below 10 tonnes per year	

Substance	Original proposal of AUBA project		Current Project			
	Order of appearance *	Prioritisation	Usage magnitude ranking	Recommendation	Quantity estimation for EEE	Comments
Di-arsenic-trioxide; (i.e. Arsenic trioxide)	20	Fifth highest priority	Annex XIV substance assumed not to be in use in light of EU use trends - needs to be confirmed in the supply chain, particularly of articles imported from outside the EU. Restriction may be more relevant to ensure that substance is not brought in through import of components and products	Assessment can be made at a later stage in light of the lower relevance to EEE. Main focus would be to realize if there is an impact to competitiveness in light of the Authorisation requirement or if manufacture has just moved elsewhere). It may be beneficial to have a survey of the supply chain in cooperation with industry, to clarify if its use in EEE is relevant and would justify a restriction to ensure the level of environmental safety is the same and whether the different trend of use causes impacts on competition between EU and non EU manufacturers.	3,000 tonnes per year used as intermediates and not necessarily present in articles placed on the market	Mainly relevant when used as a dopant in the manufacture of semiconductors - possibly not present in products placed on the market above trace amounts, if this is true, motive for restriction would be to remove competitive impacts between EU manufacture and import. According to the current RoHS applicability to content in the final product, this aim could not be captured in a restriction.

Substance	Original proposal of AUBA project		Current Project			
	Order of appearance *	Prioritisation	Usage magnitude ranking	Recommendation	Quantity estimation for EEE	Comments
Cobalt dichloride	21	Fifth highest priority	Varying use volume with low anticipation for presence in final product in light of intermediate applications; Annex XIV definition pending		Less than 200 tonnes per year not necessarily all for EEE	Mainly used as intermediate in small amounts and not expected in the end products. Addition to Annex XIV of REACH is in discussion and could mean that use shall be relevant in the future in the production of imported products and not in the EU. If substance not present in end product, competitive impacts could not be handled through RoHS restriction. May be relevant to restrict converted compounds present in end-products as result of use.

Substance	Original proposal of AUBA project		Current Project			
	Order of appearance *	Prioritisation	Usage magnitude ranking	Recommendation	Quantity estimation for EEE	Comments
Cobalt sulphate	22	Fifth highest priority	Varying use volume with low anticipation for presence in final product in light of intermediate applications; Annex XIV definition pending		Less than 500 tonnes per year not necessarily all for EEE	Mainly used as intermediate in small amounts and not expected in the end products. Addition to Annex XIV of REACH is in discussion and could mean that use shall be relevant in the future in the production of imported products and not in the EU. If substance not present in end product, competitive impacts could not be handled through RoHS restriction. May be relevant to restrict converted compounds present in end-products as result of use.
Cobalt metal	23	Sixth highest priority	Low use volume in EEE	Lower priority to assess if environmental benefits justify restriction - check if there are sub-substances that need to be reviewed as with PVC rigid, soft and recycled.	Quantities not known but expected to be low	Substance probably used in EEE, however main concern is in light of being a critical raw material and less in light of hazardous properties. Thus despite possible relevance to EEE, assessment can be delayed to a later time, whereas the main aspect is to understand if restriction shall have environmental

Substance	Original proposal of AUBA project		Current Project			
	Order of appearance *	Prioritisation	Usage magnitude ranking	Recommendation	Quantity estimation for EEE	Comments
						benefits that shall justify costs. In this sense, priority is lower despite use trend. It may make sense to investigate along with other cobalt compounds.
Nonylphenol	24	Sixth highest priority	Annex XVII substance with restrictions applying both to EU and non EU production	Assessment can be made at a later stage in light of the lower relevance to EEE. Main focus would be to realize if there is an environmental impact still expected from restriction.	Low quantities	Possibly in use only as an intermediate and not present in the final product, meaning that RoHS regulation would have little impact on use. The current restriction may have already enabled a large portion of phase out where possible, thus again meaning that remaining reductions could be low if at all.

*Note: *The Austrian UBA prioritisation referred to 24 substances, however 5 substances (Number 1-4 and 6), for which a substance assessment has been carried out, have been removed from the list in this table. Namely: Di-(2-ethylhexyl)phthalate (DEHP); Di-n-butyl phthalate (DBP); Butyl benzyl phthalate (BBP); Diisobutyl phthalate (DIBP); Hexabromocyclododecane (HBCDD), all of which originally appeared in the highest priority.*

Concerning substances for which data does not allow clarifying without doubt that they are not in use in articles supplied to manufacturers through the supply chain, it is suggested to prepare a supply chain survey. To ensure that such a study would be effective and would not just be a variation of the current study, it is recommended to cooperate with industry so that over a longer period, the supply chain can be questioned as to the use of various substances in articles. In this regard, to facilitate cooperation, it would be important that industry have assurance that where potentially restricted substances are not present in EEE, a restriction could be avoided or altered to voluntary agreements not to phase-in the use of substances over time. On the basis of earlier projects, the consultants would further like to comment that a longer period would be needed to allow industry to seek and receive information from the supply chain as to use, especially where the suppliers must contact their suppliers and sub-suppliers in order to provide information.

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.

May 2014

Report for:

The EUROPEAN COMMISSION

DIRECTORATE-GENERAL ENVIRONMENT

Directorate A - Green Economy

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Disclaimer

Contents

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).

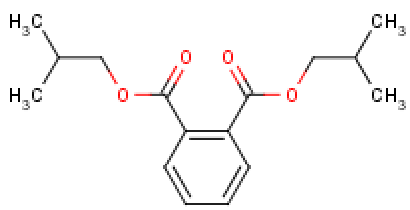
1.0 Identification, Classification and Labelling

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})	$\log P_{ow}$: 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 statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement 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]

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[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 manu-facturers, 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 al-ternatives 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

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[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.

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[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 $\log K_{ow}$ > 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, mamma-lian 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 back-ground 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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