

**Assessment of the risk reduction potential of
hazardous substances in electrical and
electronic equipment on the EU market**

PM 7/15



The Swedish Chemicals Agency is supervisory authority under the Government. We work in Sweden, the EU and internationally to develop legislation and other incentives to promote good health and improved environment. We monitor compliance of applicable rules on chemical products, pesticides and substances in articles and carry out inspections. We review and authorise pesticides before they can be used. Our environmental quality objective is A Non-toxic Environment.

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Foreword

The Swedish Government has in its bill, "Proposition 2013/14: 39 – På väg mot en giftfri vardag – plattform för kemikaliepolitiken" proposed that Sweden should continuously evaluate and identify additional substances that should be regulated by the RoHS Directive. The aim is to contribute to the protection of human health and the environment. Consideration should be given to the particular use patterns and sensitivity of children. The focus should among other things be on electronics for consumer use that generate large amounts of waste and on improving the possibility for profitable and sustainable recycling.

This report is an account of a study with the aim to assess the potential for substitution and to provide data on a few possible candidates for restriction under RoHS. The substances or group of substances preliminary prioritised by the Swedish Chemicals Agency and included in the study were; chlorinated flame retardants; TCEP, TCPP, TDCP, medium chained chlorinated paraffins (MCCP), antimony trioxide and nickel compounds such as nickel sulphate and nickel sulphamate.

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The opinions and recommendations presented in the report are entirely those of the author and do not necessarily reflect the Swedish Chemicals Agency's point of view.

Stockholm, September 2015

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Summary

In 2014 the Swedish Chemicals Agency financed a study with the aim to assess the potential for substitution and to provide data on a selection of possible candidates for restriction under the RoHS Directive (2011/65/EU). The substances and groups of substances preliminary prioritised by the Swedish Chemicals Agency and included in the study were; chlorinated flame retardants; TCEP, TCPP, TDCP, medium chained chlorinated paraffins (MCCPs), antimony trioxide and nickel compounds such as nickel sulphate and nickel sulphamate.

For TDCP and TCPP, the majority is used in the production of foam and the end product is for example furniture and transport vehicles. There are no available data on their presence in electrical and electronic equipment (EEE). There is a trend of decline of the use of TCEP within the EU. The results indicate that TCEP, TCPP and TDCP are not of high priority for inclusion in RoHS Directive.

Medium chained chlorinated paraffins (MCCPs) are hazardous to humans and environment. An estimated volume in EEE is 15,000 tonnes, mainly in PVC cable formulations. There are available substitutes for MCCPs, both as a plasticizer and as a flame retardant.

The study showed that MCCPs could be of interest for a proposal for further substance restrictions under RoHS, because of its hazard properties and volumes of use in electric and electronic equipment.

Antimony trioxide (ATO) is suspected of causing cancer. It is a high volume chemical in EU and 20,000 tonnes per year is used in EEE. There are available substitutes for ATO in different applications, but it can be challenging to replace in demanding applications. A deeper analysis of substitution possibilities, costs for substitution and exposure to ATO from EEE waste needs to be analysed further in order to assess the risk reduction potential of ATO in EEE.

Nickel sulphate and nickel sulphamate are process chemicals for electroplating and not present in the end EEE products. Hence, the results indicate that nickel sulphate and nickel sulphamate are not of high priority for inclusion in RoHS Directive.

Sammanfattning

2014 finansierade Kemikalieinspektionen en studie med syfte att bedöma möjligheten för substitution och att lämna uppgifter för ett urval av möjliga kandidater för begränsning i RoHS-direktivet (2011/65/EU). Ämnena och grupperna av ämnen som preliminärt var prioriterade av Kemikalieinspektionen och som ingick i studien var; klorerade flamskyddsmedel; TCEP, TCPP, TDCP, mellankedjiga klorparaffiner (MCCP), antimontrioxid och nickelföreningar såsom nickelsulfat och nickelsulfamat

Majoriteten av TDCP och TCPP används vid framställningen av skum och slutprodukterna är till exempel möbler och transportfordon. Det finns inga tillgängliga uppgifter om deras existens i elektrisk och elektronisk utrustning (EEE). För användning av TCEP är trenden inom EU på nedåtgående. Resultaten tyder på att det inte är av hög prioritet att infoga TCEP, TCPP och TDCP i RoHS-direktivet.

Mellankedjiga klorparaffiner (MCCP) är farliga för hälsan och miljön. En uppskattad volym i EEE är 15 000 ton, där de främst finns i PVC-kablar. Det finns tillgängliga substitut för MCCP, både som mjukgörare och som flamskyddsmedel.

Studien visade att MCCP kan vara av intresse för ett förslag till ytterligare begränsningar av ämnen enligt RoHS, på grund av dess farliga egenskaper och volymer för användning i EEE.

Antimontrioxid (ATO) misstänks kunna orsaka cancer. Det är en högvolymerkemikalie i EU och 20 000 ton per år används i EEE. Det finns tillgängliga substitut för ATO i olika applikationer, men det kan vara svårt att ersätta i komplexa applikationer. En djupare analys av substitutionsmöjligheter, kostnader för substitution samt exponering för ATO från EEE-avfall måste göras för att det ska gå att bedöma möjligheter till riskreducering för ATO i EEE.

Nickelsulfat och nickelsulfamat är processkemikalier för galvanisering som inte förekommer i slutprodukter i EEE. Resultaten tyder på att det inte är av hög prioritet att infoga nickelsulfat och nickelsulfamat i RoHS-direktivet.

1 List of abbreviations

ATBC	Acetyl tri-n-butylcitrate	NOAEL	No Observed Adverse Effect Level
ATO	Antimony trioxide	PBT	Persistent Bioaccumulative Toxic
BFR	Brominated flame retardants	PE	Polyethylene
CLP	Classification, Labelling and Packaging	PP	Polypropylene
CMR	Carcinogenic, Mutagenic and toxic for Reproduction	PS	Priority score
DEHA	Diethylhexyladipat	PUR	Polyurethane
DEHP	Diethylhexyl phthalate	PVC	Polyvinyle chloride
DIDP	Diisodecyl phthalate	RoHS	Restriction of hazardous substances
DINP	Diisononyl phthalate	SVHC	Substances of Very High Concern
ECHA	European Chemicals Agency	TBBPA	Tetrabromobisphenol A
EEE	Electrical and Electronic Equipment	TCEP	Tris(2-chloro-1-methylethyl) phosphate
RAR	Risk Assessment Report	TCPP	Tris(2-chloroethyl) phosphate
EVA	Ethylvinylacetate	TDCP	Tris[2-chloro-1-(chloromethyl)ethyl] phosphate
FR	Flame retardants	TEHTM	Triethylhexyltrimellitat
LCCPs	Long chained chlorinated paraffines	TOTM	Tris-2-ethylhexyl
LOAEL	Lowest Observed Adverse Effect Level	US EPA	United states Environment protection agency
MCCP	Medium chained chlorinated paraffines	vPvB	Very persistant very bioaccumulative
MOS	Margin of safety	WEEE	Waste electrical and electronic equipment

2 Background

According to the Swedish Government chemical proposition, "*Proposition 2013/14:39 - På väg mot en giftfri vardag – plattform för Kemikaliepolitiken*", Sweden must continually evaluate and identify the additional hazardous substances that should be regulated by Directive 2011/65/EU, on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2). A priority list has been prepared by the European Commission, and from that list, the Swedish Chemicals Agency (KemI) has selected a number of substances that should be the object of a depended assessment, and these sub-stances are thus included in this analysis.

The substances and groups of substances to be included in the survey are:

- Chlorinated flame retardants; TCEP, TCPP, TDCP
- Medium chain chlorinated paraffins, MCCP
- Antimony compounds; antimony trioxide (ATO)
- Nickel Compounds; nickel sulphate and nickel sulphamate

3 Methods

The survey is based on previous information and analyses of the substances, such as scientific articles, chemical reports, classification information from the European chemicals agency (ECHA), as well as information from KemI, Chemsec and companies and providers of Electric and Electronic Equipment (EEE).

The assessment of the risk reduction potential of hazardous substances in EEE is furthermore based on the compiled information in the survey. Specific attention has been given to the methodology proposed in "*Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive*" (January 2014). Article 6(2) of RoHS 2 lays down the minimum information, to be provided by a member state in order to review, amend, or extend the list of restricted substances. Amongst the substance properties, specific attentions have been paid to substances meeting the criteria for;

- Substances classified as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B (CMR substances) in accordance with CLP Regulation (EC) No 1272/2008.
- Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to Regulation (EC) No 1907(2006) REACH Annex XIII (REACH).
- Substances identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that cause an equivalent level of concern as with CMR or PBT/vPvB substances, e.g. endocrine disrupting properties.

In Table 1 in Annex 1 of the report, data on classification, labelling, reported uses (*by the manufacturers and importers within EU*), physical-chemical properties, PBT-properties, environmental fate-data, ecotoxicological and toxicological information, exposure related observations as well as the precautionary statements for safe use are reported.

All data in the table stems from the REACH-registration dossiers submitted to ECHA by manufacturers and importers, by the date indicated as last update.

The studies provided in the REACH-dossiers have undergone a Klimisch rating according to;

- category 1- reliable without restriction (*typically modern GLP study conducted in accordance with technical guideline, compliance with technical appropriate technical guideline such as OECD*).
- category 2 - reliable with restrictions (*typically lack of raw data, no information on substance purity, reliable study but non-GLP compliant*).
- category 3 - not reliable (*typically the underlying data that supports the endpoint is unavailable or is based on an estimation technique, or re-reported briefly, or generated according to a method that is not acceptable in relation to the endpoint in question, relevant methodological deficiencies*).
- category 4 - not assignable (*typically no reference, only a value, or the study did not relate the data to typical environmental conditions*)

The data in Table 1 (Annex 1) are solemnly category 1-3, with a majority in category 1-2.

4 Results

4.1 General results

The assessment of the risk reduction potential for the substances in this study is based on a number of parameters. One parameter of importance for the assessment herein is the volume used of the substance exclusively in EEE in the EU market. Despite efforts to identify volumes associated with EEE products, some of the volume data often reflect other uses. Furthermore, volumes estimates in this study do not take into consideration the volumes entering the EU market from import of goods. As a consequence, the values are underestimates of the total volume of each hazardous substance within EU. A methodology for a higher tier EEE volume estimate for some of the substances has been included in the report.

Moreover, the economic costs for substitution are also relevant for the assessment. Estimations of substitution are rather complex and there are established methods for socio economic analysis and scenario calculation developed within the Authorisation process in Reach and Annex II dossiers for substances within RoHS.

Substitution of a substance is considerable complex, as the substance may be used by various producers and in a wide range of applications. In this study, there are various suggestions for substitutes presented for each substance or group of substances, in order to show the possibilities for substitution. Therefore, within the scope of this study, the focus has not been to estimate the costs for each suggested substitute.

Experiences gained so far in context of the authorization process for Annex XIV-substances in REACH, indicates that the substitution process may span 5-10 years and implicate costs in the 10-100 million €range.

4.2 Chlorinated flame retardants; TCEP, TCPP, TDCP

Substance name	TCEP	TCPP	TDCP
CAS	115-96-8	13674-84-5	13674-87-8
Classification and labelling (GHS)	Carc. 2 H351: “ <i>Suspected of causing cancer.</i> ” Repr. 1B H360: “ <i>May damage fertility or the unborn child.</i> ” Acute Tox. 4 H302: “ <i>Harmful if swallowed.</i> ” Aquatic Chronic 2 H411: “ <i>Toxic to aquatic life with long lasting effects.</i> ”	Acute Tox. 4 H302: “ <i>Harmful if swallowed,</i> ”	Carc. 2 H351: “ <i>Suspected of causing cancer.</i> ” Aquatic Chronic 2 H411: “ <i>Toxic to aquatic life with long lasting effects.</i> ”
Examples of application in EEE	Plastic materials for EEE housings e.g. TV computers	No information	No information
Volumes in EEE	No information	No information	No information

4.2.1 TCEP

Among the three chlorinated compounds reviewed herein, TCEP stands out as the most problematic. However, the REACH dossier for the substance does not contain the complete information and data required for a complete human risk assessment.

For instance, as can be noticed in table 1 (Annex1) under the parameter “Toxicity to reproduction”, the TCEP-dossier does not provide any data on the reprotoxic properties of TCEP. Gulati et al. (1991 and to some extent 1985) provide reprotoxic data sufficient for Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) to propose to ECHA that TCEP should be classified as “Reprotoxic category 1B” (H360).

These studies showed significant impairment of fertility for both sexes in mice during continuous breeding and for two successive generations. Reproductive failure was observed at daily doses of 700 mg/kg bw of TCEP with at best no more than 3 litters produced and with no pups surviving from the last litter produced. The findings were essentially confirmed from the results of a separate cross-over-mating trial in mice at the same dose level.

The reproductive system of male mice appeared to be more sensitive to TCEP treatment as evidenced by less successive reproduction of treated males in comparison to treated females and further by significant male reproductive organ weight reduction and sperm parameter impairment in mice of two different strains. Based on a statistically significant reduction of the number of litters produced by the F0 generation, reduced pregnancy and fertility indices in the F1 generation, and statistically significantly reduced litter size in both the F0 and the F1 generations a NOAEL/fertility of 175 mg/kg bw/d was derived from the study in CD-1 mice with oral administration (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, 2009).

TCEP has thus been included on the ECHA Candidate list (article 59(10)) in 2010 and subsequently been transferred to Annex XIV with a “sunset date” of 2015-08-21.

4.2.2 TCPP

It has been considered that there is sufficient information on structures, physical-chemical properties, toxicokinetics and mutagenic profiles of TCPP and the structurally similar

substances, TCEP and TDCP, to support a qualitative read-across for carcinogenicity. However, differences in the metabolism, target organs, the severity of the effects observed and the potency of the three substances indicates that a quantitative read-across for carcinogenicity from either TDCP or TCEP may not be appropriate.

With regard to reprotoxicity of TCPP (and its structural similarity to TCEP and TDCP), a 2-generation reproductive toxicity study with TCPP found no treatment related differences in several important parameters regarding reprotoxicity such as pre-coital time, mating index, female fecundity index, male and female fertility index, duration of gestation and post-implantation loss.

A-dose of approximately 99 mg/kg for females was considered to be the LOAEL for parental toxicity. This is based on decreased body weight and food consumption seen in mid and high dose parental animals and the effects on uterus weights seen in all dosed F0 animals. For males, a NOAEL of approximately 85 mg/kg is derived for parental toxicity, based on decreased body weights, food consumption and organ weight changes observed at mid and high dose groups (EU RISK ASSESSMENT – TCPP CAS 13674-84-5, 2008).

Neither the data on carcinogenicity nor reprotoxicity has warranted any harmonised classification for TCPP yet.

4.2.3 TDCP

In contrast to the data presented in the REACH-dossier for TDCP, the ECHA Committee on Risk Assessment (RAC) concluded in September 2010, with consensus, that the carcinogenicity data provided by the Stauffer Chemical Company (1981a and b) justified the proposal to classify TDCP as a Carcinogen Category 2 (H351) (harmonized classification). The REACH-dossier instead stated that; “TDCP increased the incidence of commonly occurring benign tumours but did not demonstrate carcinogenic activity in rats”.

Exposure and risks to human and environment

Based on the priority score (PS, EURAM method- EU Risk Ranking Method) with regard to environmental and human health concerns, the EU RAR Committee work on TCEP, TCPP and TDCP concluded that among the three chlorinated alkyl phosphate esters, TCEP has the highest concern followed by TCPP in terms of human health, while TDCP had the highest score with regard to aquatic concerns.

Name	CAS No.	Aquatic PS	Health PS
tris(2-chloroethyl) phosphate (TCEP)	115-96-8	15.3	61.2
tris(2-chloro-1-methylethyl) phosphate (TCPP)	13674-84-5	10.5	58.1
tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP)	13674-87-8	42.6	39.8

Table 1. Priority score regarding environmental and human health concerns (PS, EURAM method- EU Risk Ranking Method).

4.2.4 TCPP

Workplace exposure was the dominant form with regard to TCPP exposure when comparing data from occupational studies with calculations on exposure from consumer products and via environmental exposure. Occupational exposure to TCPP occurred during its manufacture and during the manufacture and cutting of flexible and rigid polyurethane (PUR) foam.

Inhalation of vapours and liquid aerosols and skin contact were the predominant routes of exposure during manufacture of TCPP and manufacture of PUR foam, while inhalation of dust and skin contact are thought to be the predominant routes of exposure during foam conversion and cutting of rigid PUR foam. Oral exposure was not considered to be a significant route of exposure under normal working practices.

The highest inhalation exposure was estimated to be during the manufacture of rigid foam, with the reasonable worst case estimated to be 150 µg/ m³ and the typical exposures estimated to be 20 µg/ m³. During the production of TCPP, the typical inhalation exposure (8 hr TWA) were 25 µg/ m³.

Regarding the occupational exposure scenario for manufacture of TCPP, the MOS (margin of safety) for reasonable worst case dermal exposures for fertility and developmental toxicity were below the minimal MOS (MOS = 50). The conclusion was therefore that there was a need for limiting the risks by risk reduction measures. Most probably, such risk reduction measures are already being applied at the sites producing TCPP.

Uses and volumes in the EU market in EEE

TCEP is mainly used as an additive plasticizer 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. The main industry using TCEP are textiles, furniture and construction, cars, railways and aircrafts.

TCEP have been included in Reach Annex XIV, and as a consequence of inclusion, TCEP cannot be placed on the EU market or be used after the 21st of August 2015 in the EU. No exempted uses for TCEP have been granted; thus, it is assumed that at present the substance is not applied in European manufacture. However, articles containing TCEP can still be imported without restrictions, aside from the duty to communicate information on SVHC in articles (REACH Article 33).

There has been a decline in the manufactured and imported volume of TCEP in EU, which indicate an already declining use of TCEP before the sunset date 21 May 2015. The registration data states a total tonnage of 10 to 100 tonnes per year.

There are to our knowledge no available data on the amounts of TCEP in EEE products in EU. The Swedish Chemicals Agency KemI confirms that TCEP is currently not used in EEE in the Nordic countries. As a consequence of the inclusion of TCEP in the REACH Regulation Authorisation List (Annex XIV), a decrease in use is anticipated. This can be confirmed by KemI's data on the use of TCEP in the Nordic countries in the last years.

However, electronic devices or television sets may contain TCEP as it was used in plastic materials for EEE housings. Although these uses might be considered as "historical uses", as they are not mentioned anymore in the information compilation of ECHA, the EEE products still containing TCEP may still affect consumers as well as having possible impacts in waste treatment and recycling facilities.

For TCPP, the manufactured and imported volume is 10,000 - 100,000 tonnes per year. Registered usages are for example flexible foam, rigid foam, foam granules and rebound PUR foam. Previous data indicates that most TCPP (> 98%) was used as flame retardant in the production of polyurethane (PUR) for the use in construction (e.g. insulation/ fillers) and furniture in the year 2000 (ECHA, 2008).

TDCEP have a manufactured and imported volume of 1,000 - 10,000 tonnes per year, with registered usages such as cutting and handling of foam, foam production with TDCEP,

rebonding and loose crumb. It is found in furniture, transport vehicles, Machinery and equipment.

No information is available to our knowledge regarding volumes of TCPP and TDCP in EEE.

Substitution of TCEP, TCPP and TDCP

Previous studies suggest that non-halogenated flame retardants are safer alternatives to brominated and chlorinated flame retardants, and the following have been suggested to be substitute substances:

- Inorganic flame retardants such as metal hydroxides; e.g. aluminum hydroxide and magnesium hydroxide.
- Phosphorus based flame retardants such as organic and inorganic phosphates, phosphonates and phosphinates
- Nitrogen based flame retardants such as melamine and melamine derivatives. They are often used in combination with phosphorus based flame retardants.

However, as TCEP, TCPP and TDCP are not a high volume substance in EEE in the EU, there are no further attempts to compile information concerning its substitute in EEE products.

Summary

- Among the three chlorinated compounds reviewed herein, TCEP are the most problematic and are classified and labelled as Repr. 1B H360 “May damage fertility or the unborn child.” and Carc. 2 H351: “Suspected of causing cancer.”
- TCEP are included in Annex XIV because of its classification as toxic to reproduction.
- As a result, TCEP cannot be placed on the EU market or be used after the 21st of August 2015. As a consequence of inclusion in Annex XIV there is a decrease in the volume on the EU market.
- There are no available data on the volumes of TCEP, TCPP or TDCP used in EEE on the EU market. Although TCEP are still found in EEE housings, it is not in extensive volumes. The registration data of TCEP is a total tonnage of 10 to 100 tonnes per year and the main industry using TCEP are textiles, furniture and construction, cars, railways and aircrafts.
- The results indicate that TCEP, TCPP and TDCP are not of high priority for inclusion in RoHS Directive.

4.3 Medium chain chlorinated paraffins, MCCP

Substance name	Medium chain chlorinated paraffins, MCCP
CAS	85535-85-9
Classification	Effect on or via lactation H362: “ <i>May cause harm to breast-fed children</i> ”. Aquatic Chronic 1 H410: “ <i>Very toxic to aquatic life with long lasting effects.</i> ” “H400: “ <i>Very toxic to aquatic life.</i> ”
Examples of application in EEE	Plasticizers and flame retardants in cables, soft plastic, PVC, and polyester.
Volumes in EEE	15 000 tonnes

MCCPs meet the criteria for substances of very high concern as defined by REACH. This is due to the fact that MCCPs have endocrine disrupting properties (Cat. 1), and are classified

and labelled; Lact H362 (“*May cause harm to breastfed children*”). They are not considered PBT, but are toxic to aquatic environment with long term effects; H400: (“*Very toxic to aquatic life*”) Aquatic Chronic 1 H410 (“*Very toxic to aquatic life with long lasting effects*”).

Exposure and Risk to humans and Environment:

The main use of MCCPs are secondary plasticizers and as flame retardants in PVC. Although MCCPs have low vapour pressure at ambient temperatures, the vapour pressure is not too low to preclude the possibility of volatilization from plastics and other polymers during their lifecycle. This is of particularly concern for the MCCPs with lower chlorine contents. Its concentration in plastic material is approximately 9-13% and according to Annex XV restriction report for MCCP, it is estimated that significant release will take place during in-service life of MCCPs in plastics.

In addition to volatilization and leaching losses from products, MCCPs may also enter into the environment as particulate losses of polymeric products. Particle losses may occur during the whole lifecycle and it may be the result of tearing and wearing as well as by wind and rain.

As a result of volatilization and particle losses from products during its lifecycle, MCCPs are entering the environment. Once in the environment, MCCPs pose a risk to aquatic environment as they have a high acute toxicity towards aquatic organisms, a high fish bioconcentration factor and are poorly degradable. Previous studies show widespread occurrence in the environment, in biota and in human breast milk.

Human health

The major risks of MCCPs to humans are occupational exposure during the manufacture of products containing MCCP such as PVC, metal working fluids, flame retardants, rubber, etc. Previous measurements of air concentration from workplaces that produce PVC give a maximum value of 1.2 mg/m³. The use of metal working fluids shows even higher levels.

MCCPs are found in the following materials to which consumers could be exposed: in fat liquors used in leather processing, as an additive to adhesive and sealants, use in rubber and plastics, as a plasticizer in paints, as an extreme pressure additive in metal working fluids. Consumer exposure of MCCP in EEE products are mainly from PVC or other plastics in electronics. All above products gives potential risks for consumer exposure. However, in the EU RAR the exposure of consumers from most applications has been considered to be negligible.

In addition to human exposure due to leaching and particle losses there is a potential risk for secondary poisoning of MCCP in food, as the substance has a moderately high bioaccumulation factor. Previous studies have estimated the exposure via the uptake of food, air and drinking water with exposure values of 0,032 mg/kg/day locally and 2,6 x10⁻⁴ mg/kg/day regionally.

Uses and volumes of MCCP in EEE products

The main use of MCCPs are secondary plasticizers and as flame retardants in PVC. Secondary plasticizers are used in combination with primary plasticizers, and cause an enhancement of the plasticizing effects in the polymer. In other plastics than PVC, MCCP are primarily used as a flame retardant additive. As a flame retardant, MCCPs with a high degree of chlorination (e.g. 70-72% wt. Cl) are used, along with a synergist e.g. antimony trioxide. MCCPs with a higher degree of chlorination have a lower volatility than lower chlorinated MCCPs.

MCCP is a high volume production chemical with a manufacture/import volume of 10,000 - 100,000 tonnes per year. In EEE products, total amount is estimated to 15,000 tonnes (Gensch et al. 2014), predominantly used as plasticizer/fire retardant in flexible PVC such as in cable sheathing and insulation. The volume is categorized as medium use volume in EEE, its use is directly related to the use of polyvinyl chloride (PVC).

There are indications of a slight decrease in the use of MCCP partly due to reduced use of DEHP since MCCP are working technically better with DEHP than alternatives as DINP (Annex XV report for MCCP). However, the use of MCCPs seems still to be widespread.

MCCP in waste management

As the major use of MCCPs in EEE products are in PVC cables, the focus lies in disposal of that product category. In the following reasoning, we assume that the waste is treated in accordance with the EU's and national regulations, and that it is not subjected to primitive combustion of electronics in developing countries.

Recycling and incineration of cables

According to previous estimations (ROHS Annex II Dossier, Diethylhexyl phthalate DEHP) the average content of cables in WEEE is 2%, which is approximately 66, 000 tonnes of cables (year 2011). No information is given on the percentage of PVC cables and neither on the recycling rate of PVC cables. It is assumed that one third of PVC resulting from shredding of cables is incinerated, one third is landfilled and one third is sent to mechanical recycling. However, indication is given that recycling of PVC waste resulting from cables will increase.

Whether a restriction of MCCP could affect the use of recycled content of PVC cables is to our knowledge not clear but it is the presence of metals residues in the plastics fraction that prohibits the recycling as cable insulations. The recycled material is used for applications similar to the products of mixed plastics recycling, e.g. poles for roads, industrial floorings and other products substituting concrete and wood products.

During recycling, an important route of exposure of additives in PVC are from shredding or via emission of dust, but to our knowledge there are no information MCCP exposure to workers during cable waste management.

Incineration will likely destroy MCCPs completely, if incineration takes place under controlled conditions. However, if combustion is at lower temperatures or not well functioning incinerators, the chlorine content in MCCP can result in the formation of hazardous polychlorinated dioxins and furans.

Legislation and other mitigating measures

The following textbox is a summary of legislation and other mitigating measures for MCCPs.

MCCP have been substances of concerns for a long time. MCCP was risk assessed according to EU in 2005 and updated 2007. MCCP meets the criteria for substances of very high concern as defined by REACH, due to its endocrine disrupting properties.

MCCP are restricted according to the Toys safety Directive (2009/48/EG) due to its Endocrine disrupting properties (Cat. 1).

MCCP was 1 of 14 prioritized substances in the analysis made by ÖKO-institute in Germany before the revision of RoHS 2.

Furthermore, MCCP are covered by national legislation, restricted and attended in Norway, Germany and UK.

MCCP are also included in 5 of 13 examined companies' lists of hazardous substances that should be phased out or avoided.

MCCP is on the Community Rolling Action Plan (CoRAP 2012 - 2014) as a suspected PBT also fulfilling the concerns of environmental exposure relevant for wide dispersive use and high aggregated tonnage.

Substitution possibilities

In applications where MCCPs are used primarily for their plasticizing effect, there are several available alternatives that could be used. However, such alternatives have been estimated to be more expensive than MCCPs.

Alternatives to MCCP as a plasticizer are:

- Other plasticizers (e.g. DINP) as phthalates, adipates, citrates and organophosphates, trimellitate and epoxidised soybean oil
- Long-chain chlorinated paraffins (LCCPs) have also been suggested to be suitable for some applications.
- Other plastic materials as polyethylene (PE) and polypropylene (PP) and ethyl vinyl acetate (EVA).

Where MCCPs are only used as plasticizer (without a flame retarding function), the phthalates diisononyl phthalate (DINP) and diisodecyl phthalate (DIDP) are mentioned as possible alternatives to MCCPs. DINP is not classified as hazardous, but DINP has shown endocrine disrupting and reprotoxic effects in previous studies (Kvack, 2009; Ghisari, 2009). In addition, DINP have structural similarities to diethylhexyl phthalate (DEHP) which is a candidate substance due to its endocrine disruptive features. DINP is therefore not recommended as suitable substitute to MCCPs. Estimates from 2008 gives the value of around 60% more expensive for using Phthalates (DINP) than MCCPs.

Most adipates are not classified as hazardous according to the CLP Regulation. However, scientific studies of diethylhexyladipat (DEHA), has revealed some toxic effects in animal studies in rats. Citrates are esters of citric acid and are found naturally in the body. They are mostly used as softeners in plastics (vinyl resins) for plastic films, packaging films and "flexible tubing" which contacts with food and medical equipment. Acetyl tri-n-butylcitraate (ATBC) is an example of a citrate used in plastics to enclosures for electrical devices. ATBC

are not classified as hazardous according to CLP but according to previous studies, citrates have showed to be toxic to human cells and to animals.

For some applications, phosphates are proposed as alternatives to MCCPs as these have both plasticizing and flame retarding properties. There are a variety of organophosphates and most are not classified as hazardous. Some of them are self-classified as Aquatic Acute 1; H400; very toxic to aquatic life and Aquatic Chronic H410; very toxic to aquatic life with long lasting effects. However, the softening effect of phosphates is less efficient than that of MCCPs or phthalates. Therefore, higher amounts of phosphate need to be added in the polymer resulting in higher costs. According to previous estimates, alternatives such as phosphate ester plasticizer/flame retardants are about 4 times the price of MCCPs.

Trimellitates are for example tris-2-ethylhexyl (TOTM) and triethylhexyltrimellitat (TEHTM). None of these are classified as hazardous but TOTM has been shown to be toxic in experiments on rats, but at about 20 times the dose of the phthalate DEHP. TEHTM has been shown to have estrogenic effect in an in vitro study (Ter Veld, 2006).

Epoxidised soybean oil ESBO with CAS 8013-07-8, is used in PVC for example in applications related to food products. It serves as a plasticizer and as a scavenger for hydrochloric acid liberated from PVC when the PVC undergoes heat treatment. It is not classified as hazardous according to CLP.

For long-chained paraffines, LCCPs the estimates are 20% to 160% higher price compared to MCCPs (dependent on application and formulation used and by analogy with other uses (2008)). LCCP C18 – 28, with CAS 85535-86- is not classified as hazardous.

The use of plastics with elastic properties is preferred to the use of alternative plasticizers. Suggested alternative polymer materials are polyolefines (polyethylene (PE), polypropylene (PP)) and ethylvinylacetate (EVA). As polyolefines and EVA are not inherently flame retarded, in contrast to PVC, additional flame retardants would need to be added if flame retardancy of the polymer materials is required. In case of substitute the polymer to elastic properties materials, there is also a reduction of other additives found in PVC. PE and PP does not contain hazardous monomers in contrast to PVC and they have a lower amount of hazardous additives compared to PVC.

Alternatives to MCCP as flame retardant are:

- other substances as e.g. trialkyl phosphate, aluminium trioxide in combination with antimony trioxide (for cable sheathing).

In applications where flame-retarding function is needed, additive flame retardants need to be added together with the halogen-free softeners. In cable sheathing, aluminum trioxide together with antimony trioxide as synergist, are suggested as substitute. However, aluminium trioxide together with ATO is not a suitable substitute given ATO's carcinogenic properties. Neither aluminium trioxide nor trialkyl phosphate are classified as hazardous whereas ATO is classified as Carc. 2 H351: "Suspected of causing cancer". For information concerning ATO, see chapter 3.4.

According to previous estimates (Annex XV Restriction report submitted by UK), an average substitution cost for MCCP in PVC would be around €800 per tonne.

Industry and substitution

Swedish "Miljöstyvningsrådet" MSR have done an overall market analysis on companies work with phasing out hazardous substances. According to their report, one telecom industry has all halogenated FR, including MCCP under observation.

MCCP are also included in 5 of 13 examined companies' chemical lists of hazardous substances that should be limited or phased out. One electronic company has phased out MCCP as well as PVC (telephone interview with Chemical manager, Corporate Sustainability Office). Another electronic company confirms that the replacement of MCCP is not technically difficult (mail correspondence).

Summary/ Assessment of the risk reduction potential

- MCCPs are substances of very high concern as they have endocrine disrupting properties (Cat.1)
- They are toxic to aquatic organisms with long lasting effects and previous studies show widespread occurrence in the environment, in biota and in human breast milk.
- MCCPs are assessed as second highest priority according to Study for the Review of the List of Restricted Substances under RoHS2.
- MCCP are used in EEE and predominantly in PVC cables. The total amount is estimated to 15,000 tonnes used in PVC cable formulations.
- MCCP are closely linked to the use of PVC in cables. PVC has been classified to be of the 3rd highest priority and it is therefore previously suggested that these substances should be assessed in parallel or subsequent to the assessment of PVC.
- There are available substitutes for MCCPs, both as a plasticizer and as a flame retardant. However, further analyses need to be conducted for substituting costs for MCCP in various applications.
- According to our and previous results, MCCP are substances that are highly relevant to analyze further for a possible inclusion in the RoHS directive.

4.4 Antimony compounds; Antimony trioxide

Substance name	Antimony trioxide
CAS	CAS: 1309-64-4
Classification	Carc. 2 H351: <i>Suspected of causing cancer</i>
Examples of application	Flame retardant synergist in cables, enclosures for TVs, computers and PCBs.
Volumes in EEE products	20,000 tonnes

Antimony trioxide (ATO) is a possible human carcinogen, according to CLP regulation Carc. 2 - H351 (Suspected of causing cancer via inhalation) and reprotoxic effects have been reported. One in vitro study on bacteria and mammal cells from 2009 indicated that ATO was genotoxic (Asakura, Keiko et al. 2009). ATO is not considered PBT or vPvB and does not fulfil the criteria for a substance of very high concern as defined by REACH.

It has been agreed that the carcinogenic effects are most likely caused by particle overload and impaired lung clearance which leads to the formation of tumours (particle effect, no substance specific effect). ATO is considered a threshold carcinogen with an NOEL of 0.5 mg/m³ (with the critical concentration expected to be 10 times higher). The carcinogenic hazard by inhalation does not apply via dermal or oral exposure.

Exposure and Risk to humans and Environment

Antimony trioxide is a solid at room temperature and handled in powder form, pellet, paste or granules. Due to its hazards features from dust and the suspicion of carcinogenic properties, exposure to workers have been of great concern. 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. As a result, occupational exposure limits of 0.5 mg/m³ antimony trioxide on average have been established in several EU countries. As a consequence of the potential exposure to hazardous powder, ATO is now commercially available in a moistened or pasted form, or encapsulated.

Customers may be exposed to ATO via inhalation and/or skin contact from the use of products containing ATO. As ATO in the final product is often encapsulated in the matrix, the only release is by wear processes (dry abrasion). According to EU-RAR, the inhalation exposure potential to consumers is negligible, as ATO are mixed homogenously into the polymer matrix when used as flame retardant synergist.

ATO may be released to the environment through air emissions and waste water from manufacture, formulation, processing, use and disposal. ATO are present in biomonitoring, have a moderate bioaccumulation potential and are found in all forms of biota, in different fish species from both areas where industry are close and from lakes free of industry. ATO have also been found in drinking water, surface water, ambient air, and soil as well as in plants, birds, mammals, invertebrates from areas close to an antimony smelter, close to an industrialized area, and in agricultural areas. Another exposure route is therefore indirectly via the environment through food, water and soil leading to a continuous exposure to humans throughout the entire life.

The EU-RAR and EU-REACH dossiers confirm that ATO can be safely used throughout its entire lifecycle. US EPA risk assessment addresses effects on ecological receptors from the use of ATO as a synergist in halogenated flame retardants. EPA's final risk assessment indicated no concern for this use of ATO. Based on a review of the available data regarding antimony concentrations in food and environmental media, and biomonitoring data, EPA sets the conclusion that general population exposure to antimony is expected to be low. Because food and water are the primary sources of general population exposure, and the less toxic (i.e., pentavalent) form of antimony predominates in these media, significant human health risks are not anticipated. This conclusion is also supported by recent risk assessments completed for ATO in Canada.

Uses and volumes of Antimony trioxide

The major use of ATO is a synergist for halogenated flame-retardants in e.g. plastics, paints, adhesives, sealants, rubber, and textile back coatings. However, halogenated flame retardants may also be utilized without ATO. It is also used as a flame inhibitor in halogen-containing polymers (such as PVC) where no flame retardants are added. The use of ATO results in a reduced amount of brominated flame retardants needed in an application. According to previous studies it would be beneficial to assess this substance along with brominated flame retardants.

In EEE applications, ATO are used in housings for computers, TV, in printed circuit boards, connectors, plugs and switches, wires and cables, semiconductors encapsulated and other small and large household applications. In addition, antimony trioxide is used as a melting agent in glass-ceramic hobs in household appliances and in glass for TV and PC screens.

Volume

Antimony trioxide is registered under REACH, in a volume of more than 10,000 tonnes per year. According to estimates from 2014 (Gensch et al. 2014), the volume of Antimony trioxide is of medium use volume in EEE with 20,000 tonnes per year.

ATO concentration range in products: 1-10% in non-PVC polymer depending on type of polymer and/or choice of halogenated flame retardants (typical concentration: 3-5%), and 3.5 - 20% in PVC depending on the use of other flame retardants.

The content of antimony trioxide in the final plastic is typically up to 8%, but levels up to 25% are also observed. It is usually used together with additive flame retardants and is mixed into the polymers in a ratio of halogenated flame retardants/ATO of approximately 2:1 to 3:1.

E&E application or component	% SB ending up in end application
Flame retardant synergist	1-7 w%
FR wire and cable	1-5 w%
FR housing for TV, computers	3-7 w%
FR connector & switch etc.	3-7 w%
FR semiconductor encapsulant	1-2 w%

Table 2. Examples of usage and percentage of antimony trioxide in different applications.

Legislation and other mitigating measures

The following textbox is a summary of legislation and other mitigating measures for Antimony trioxide.

Maximum specific migration limit of antimony trioxide from plastics used in contact with foodstuffs is given by Commission Directive 2002/72/EC.

Maximum level of the element antimony in water intended for human consumption is established by the Council Directive 98/83/EC on the quality of water for human consumption.

A maximum level of bioavailability from the application of toys for antimony and other elements is given by the Toys Directive 2009/48/EC.

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. Occupational exposure limits of 0.5 mg/m³ antimony trioxide on average have been established in several EU countries.

Under the Water Framework Directive and the IPPC Directive 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.

Antimony trioxide shall be classified as “heavy metal” in the classification of hazardous waste, according to the Commission decision 2000/532/EC. Maximum air emission limit values for the incineration of waste are established in the Directive 2000/76/EEC of the European parliament and the council.

Leaching limit values for antimony from waste acceptable at landfills for inert waste are given by the council decision 2003/33/EC (Articles 16 of and Annex II to Directive 1999/31/EC).

ATO is included in 10 of the 13 companies' chemical lists of regulated / phased-out substances.

ATO in waste management

The WEEE directive requires that plastics containing brominated flame retardants used in EEE should be separated and not recycled. Most ATO used in EEE will therefore be included in this fraction. The limited recyclability of EEE containing ATO is therefore partly caused by the content of flame retardants in the EEE plastics.

Incineration of plastic waste from EEE products can produce discharges of antimony trioxide distributed among various output fractions, such as emissions, wastewater, ash and slag. Previous studies estimated concentrations of antimony in municipal waste to approximately 10-60 ppm, with large variations. From EEE waste, the concentrations are reported to be in the range from several hundred up to thousands ppm.

ATO may pose a risk to human health and environmental if the electronics are subject to primitive recycling methods, as low combustion temperature favors trivalent antimony which is more hazardous compared to the less toxic pentavalent antimony formed at high combustion temperatures. A deeper analysis of exposure to ATO from waste is needed, e.g. exposure to workers during electronic waste management, in order to assess risk reduction potential of ATO in electrical and electronic equipment.

Substitution possibilities

European Semiconductor Industry Association ESIA (04 Apr 2014) claims that Antimony Trioxide and Tetrabromobisphenol A (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 yet performed, it is linked to critical technology limits and reliability requirements. For example, it is challenging to replace BFRs in demanding applications, such as high speed circuit boards.

ATO is also included in 10 out of 13 examined companies' chemical lists of hazardous substances that should be limited or phased out, and there are examples of companies that already have phased out ATO. One company states that their strategy have been to phase out brominated flame retardants instead of substituting ATO with a new substance in combination with brominated flame retardants.

Alternatives to BFR/antimony trioxide in printed circuit boards are available today on the market, for example in non-BFR circuit board materials. Antimony trioxide may also be substituted to zinc stannate ($ZnSnO_3$, CAS: 12036-37-2), tradename *Flamtard S*, which is used in combination with a brominated flame retardant. Zinc stannate is not classified as hazardous but the substance has been self-classified as H315 Skin Irrit. 2, Causes skin irritation, H319 Eye Irrit. 2, H335 STOT SE 3a. According to the manufacturer, *Flamtard S* is being used increasingly in green, "antimony-free" applications, particularly in the electronics industry. Applications for *Flamtard S* are in PVC systems for cable sheathing, epoxy resins for printed circuit boards, polyamides and surface coatings.

For plastics enclosures in EEE, the International Antimony association (04 Apr 2014) claims that there are no suitable alternatives for ATO: BFR systems. They state that ABS and HIPS plastics are the technically preferred and the most cost effective FR system in polymers for EEE enclosures, and 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). They also addresses that the addition of ATO in combination with halogenated flame retardants allows about 2-3 times less halogenated flame retardants, and they claim that electronic waste which contains ATO can effectively and safely be recycled.

According to previous analyses (RoHS annex II dossier for HBCDD), there are alternatives to brominated flame retardants with less negative properties available for HIPS. Phosphorous based flame retardants are recommended in particular for their technical use and economical feasibility. The table below shows examples of alternative flame retardants in HIPS.

Substance name	CAS	Human health concerns	Environmental concerns	Harmonised (HC) and/or self classification (SC)
Triphenyl phosphate	115-86-6	Chronic toxicant with effects on liver	Readily biodegradable, toxic to aquatic organisms	no HC; SC: Aquatic Acute 1; Aquatic Chronic 1; Aquatic Chronic 4 Eye Irrit. 2;
Resorcinol bis (biphenyl phosphate)	57583-54-7	Chronic toxicant with effects on liver	Inherently biodegradable, may be persistent and bio-accumulative	no HC; SC: Aquatic Chronic 3; Aquatic Chronic 2
Bisphenol A bis (biphenyl phosphate)	5945-33-5	Limited data, likely to be of low toxicity	Poor biodegradable; not bioaccumulative;	HC: aquatic chronic 4; SC: Aquatic Chronic 4
Diphenyl cresyl phosphate	26444-49-5	Chronic toxicant with effects on liver, kidney and blood. Effects on fertility	Readily biodegradable; toxic to aquatic organisms	no HC; SC: Aquatic Acute 1; Aquatic chronic 1; Acute Tox. 4; Aquatic Chronic 2; STOT SE 2;

Table 3. Examples of alternatives to brominated flame retardants in HIPS. Table originates from ROHS ANNEX II DOSSIER FOR HBCDD.

Summary/ Assessment of the risk reduction potential

- ATO are suspected of causing cancer, Carc. 2.
- Antimony trioxide is a high volume chemical in EU and is categorized as a medium use volume in EEE with 20,000 tonnes.
- ATO are used in many different components in EEE products and it is linked to the application of brominated flame retardants.
- The recyclability of EEE plastics containing ATO are linked to its content of brominated FR.
- There are available substitutes for ATO in different applications, but further analyses need to be conducted in order to evaluate best substitute for different applications.
- ATO is found in all biotic compartments as well as in surface water, drinking water and ambient air.
- EU RAR claims that ATO are safely used throughout its entire lifecycle and US EPA indicated no concern on ecological receptors for the use of ATO as a synergist in halogenated flame retardants. Customer exposure of ATO from EEE products is low.
- According to our and previous results, there are indications that ATO is a substance that is relevant to analyse further for a possible inclusion in the RoHS directive. However, a deeper analysis of substitution possibilities and exposure to ATO from EEE waste is needed in order to assess the risk reduction potential of ATO in electrical and electronic equipment.

4.5 Nickel compounds; Nickel sulphate, Nickel sulphamate

Substance name	Nickel sulphate	Nickel sulphamate
CAS	<u>7786-81-4</u>	<u>13770-89-3</u>
Classification	<p>Carc. 1A H350: "May cause cancer." Muta. 2 H341: "Suspected of causing genetic defects." Repr. 1B H360: "May damage fertility or the unborn child." STOT Rep. Exp. 1 H372: "Causes damage to organs" (Specific concentration limits for STOT toxicity). Acute Tox. 4 H302: "Harmful if swallowed." Acute Tox. 4 H332: "Harmful if inhaled." Skin Irrit. 2 H315: "Causes skin irritation." Resp. Sens. 1 H334: "May cause allergy or asthma symptoms or breathing difficulties if inhaled." Skin Sens. 1 H317: "May cause an allergic skin reaction." Aquatic Acute 1 H400: "Very toxic to aquatic life." Aquatic Chronic 1 H410: "Very toxic to aquatic life with long lasting effects."</p>	<p>Carc. 1A H350: "May cause cancer (inhalation route)." Muta. 2 H341: "Suspected of causing genetic defects." Repr. 1B H360: "May damage fertility or the unborn child. Effects via lactation." STOT Rep. Exp. 1 H372: "Causes damage to organs. Affected organs: Respiratory tract Route of exposure: Inhalation." (Specific concentration limits for STOT toxicity). Resp. Sens. 1 H334: "May cause allergy or asthma symptoms or breathing difficulties if inhaled." Skin Sens. 1 H317: "May cause an allergic skin reaction." Aquatic Acute 1 H400: "Very toxic to aquatic life." Aquatic Chronic 1 H410: "Very toxic to aquatic life with long lasting effects."</p>
Examples of application	Used in electroplating Nickel processes.	Used in electroplating Nickel processes.
Volumes in EEE	N/A	N/A

Nickel sulphate and Nickel sulphamate are both hazardous substances as both e.g. may cause cancer, are suspected of causing genetic defects, may damage fertility of the unborn child and causes damage to organs. See also annex 1.

Exposure

Nickel sulphate and Nickel sulphamate are used as process chemicals during production of parts for electrical and electronic equipment. In a surface treatment process, these nickel salts are converted into metallic nickel during a galvanization process. Therefore, they do not occur in EEE products, not during use or during end of life and disposal phase. Therefore there is no exposure of these nickel salts for customers or workers involved with recycling of electrical and electronic waste.

Uses and volumes in EEE products

Nickel sulphate and nickel sulphamate are used in metal surface treatment processes (nickel electroplating, nickel electroforming and nickel electroless technologies), production of batteries, and production of nickel salts. Volumes of nickel sulphate and nickel sulphamate within EU are 10,000 - 100,000 tonnes, and 100 to 1,000 tonnes respectively. There are no available data of volumes used for EEE production in the EU. As RoHS regulates the quantities of hazardous substances present in end EEE product, Nickel sulphate and Nickel sulphamate are not prioritized in this study.

Summary/ Assessment of the risk reduction potential

Nickel sulphate and nickel sulphamate are process chemicals for electroplating. As such, they are not present in the EEE products and are therefore not prioritized in this study. Hence, these substances are not relevant for inclusion in RoHS. However, as nickel compounds are hazardous to human and environment and are found to a great extent in EEE products, it is of interest to analyze them more extensively in order to make an assessment of their risks in EEE products. However, these questions are not included within the scope of this study.

5 Proposed methodology to further assess volumes used in EEE

As pointed out for several of the substances evaluated in this report, the amounts used solemnly in EEE products is still elusive. In order to further refine the risk assessment of these substances in EEE this type of data is necessary.

A significant fraction of EEEs sold within the EU is produced and/or assembled in outside the EU. The amounts of flame retardants entering the EU in imported goods can be considered as highly desirable.

Calculations on volumes of substances in imported goods may be achieved based on data from the Swedish Chemicals Agency's database "Varuguiden", extrapolated to the European market using BNP. In such an approach, estimations on the market share of the various additives (softeners/flame retardants) in relevant materials needs to be taken into account.

A similar approach to estimate volumes on selected substances entering the European market was recently used by the Swedish Chemicals Agency. Volumes of substances may also be estimated based on import data from SCB using the same strategy as above. The extrapolated data for the European market may subsequently be directly compared to data from Eurostat for selected product groups.

6 Summary of the risk reduction potential

The assessment of the risk reduction potential for the hazardous substances in electrical and electronic equipment in the EU market is below.

Chlorinated flame retardants

The chlorinated flame retardants in this study were TCEP, TDCP and TCPP. For two of these TDCP and TCPP, the majority is used in the production of foam and the end product is for example furniture and transport vehicles. There are to our knowledge no available data on their presence in EEE. TCEP are included in the Authorisation list, Annex XIV REACH and there is already a trend of decline of its use within the EU. However, articles containing TCEP can still be imported without restrictions, aside from the duty to communicate information on SVHC. The results indicate that TCEP, TCPP and TDCP are not of high priority for inclusion in RoHS Directive.

MCCP

MCCPs are hazardous to humans and environment and are Substances of very high concern. They have endocrine disrupting properties and are toxic to aquatic organisms with long

lasting effects. Previous studies show widespread occurrence in the environment, in biota and in human breast milk.

An estimated volume in EEE is 15,000 tonnes, mainly in PVC cable formulations. There are available substitutes for MCCPs, both as a plasticizer and as a flame retardant. However, further analyses need to be conducted for substituting costs for MCCP in various applications.

According to our assessment and previous results, MCCP are substances that are highly relevant to analyze further for a possible inclusion in the RoHS directive.

Antimony trioxide

Antimony trioxide is suspected of causing cancer. It is a high volume chemical in EU and is categorized as a medium use volume in EEE with 20,000 tonnes. ATO is used in many different components in EEE products and it is linked to the application of brominated flame retardants. There are available substitutes for ATO in different applications, but it can be challenging to replace in demanding applications.

Exposure to ATO through customer products is low and EU RAR claims that ATO are safely used throughout its entire lifecycle. US EPA indicated no concern for ecological receptors for the use of ATO as a synergist in halogenated flame retardants.

ATO is found in all biotic compartments and in surface water, drinking water and ambient air. According to our and previous results, there are indications that ATO is a substance that is relevant to analyze further for a possible inclusion in the RoHS directive. However, a deeper analysis of substitution possibilities and costs for substitution need to be estimated and evaluated. In addition, exposure to ATO from EEE waste needs to be analyzed further in order to assess the risk reduction potential of ATO in electrical and electronic equipment.

Nickel sulfate and nickel sulphamate

Nickel sulphate and nickel sulphamate are process chemicals for electroplating and not present in the end EEE products, therefore not prioritized in this study. Hence, these substances are not relevant for inclusion in RoHS.

However, as nickel compounds are hazardous to human and environment and are found to a great extent in EEE products, it is of interest to analyze them more extensively in order to make an assessment of their risks in EEE products. However, these questions are not included within the scope of this study.

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Annex 1

Table 1. Repository of data for expert judgment according to the methodology devised in Recital 10, Article 6(1) and 6(2) of RoHS2. All data in the table stems from the REACH-registration dossiers submitted to ECHA by manufacturers and importers, by the date indicated as last update (Regulation (EC) No 1907/2006). The "N/A"-tag either reflects a lack of data or parameters with some kind of scientific rationale for absence.

Substance identification	antimony trioxide, diantimony trioxide, Sb ₂ O ₃	MCCP, Alkanes, C ₁₄₋₁₇ , chloro, Chlorinated paraffin liquid	nickel sulphate, H ₂ O ₄ S.Ni	nickel bis(sulphamidate), Nickel sulfamate, H ₃ NO ₃ S.1/2Ni	tris(2-chloro-1-methylethyl) phosphate, C ₉ H ₁₈ Cl ₃ O ₄ P, TCEP	tris[2-chloro-1-(chloromethyl) ethyl] phosphate, C ₉ H ₁₅ Cl ₆ O ₄ P, TDCP	tris(2-chloroethyl) phosphate, C ₆ H ₁₂ Cl ₃ O ₄ P, TCPP
CAS#	1309-64-4	85535-85-9	7786-81-4	13770-89-3	115-96-8	13674-87-8	13674-84-5
Classification and Labelling (GHS)	Carc. 2 H351: "Suspected of causing cancer".	Effect on or via lactation H362: "May cause harm to breast-fed children". Aquatic Chronic 1 H410: "Very toxic to aquatic life with long lasting effects." "H400: "Very toxic to aquatic life."	Acute Tox. 4 H302: "Harmful if swallowed." Acute Tox. 4 H332: "Harmful if inhaled." Skin Irrit. 2 H315: "Causes skin irritation." Resp. Sens. 1 H334: "May cause allergy or asthma symptoms or breathing difficulties if inhaled." Skin Sens. 1 H317: "May cause an allergic skin reaction." Repr. 1B H360: "May damage fertility or the unborn child."	Resp. Sens. 1 H334: "May cause allergy or asthma symptoms or breathing difficulties if inhaled." Skin Sens. 1 H317: "May cause an allergic skin reaction." Repr. 1B H360: "May damage fertility or the unborn child. Effects via lactation." Muta. 2 H341: "Suspected of causing genetic defects." Carc. 1A H350: "May cause cancer (inhalation route)."	Repr. 1B H360: "May damage fertility or the unborn child." Carc. 2 H351: "Suspected of causing cancer." Aquatic Chronic 2 H411: "Toxic to aquatic life with long lasting effects." Acute Tox. 4 H302: "Harmful if swallowed." Included in REACH Article 59(10), Candidate list since 2010/01/13.	Carc. 2 H351: "Suspected of causing cancer." Aquatic Chronic 2 H411: "Toxic to aquatic life with long lasting effects."	Acute Tox. 4 H302: "Harmful if swallowed."

Substance identification	antimony trioxide, diantimony trioxide, Sb ₂ O ₃	MCCP, Alkanes, C ₁₄₋₁₇ , chloro, Chlorinated paraffin liquid	nickel sulphate, H ₂ O ₄ S.Ni	nickel bis(sulphamidate), Nickel sulfamate, H ₃ NO ₃ S.1/2Ni	tris(2-chloro-1-methylethyl) phosphate, C ₉ H ₁₈ Cl ₃ O ₄ P, TCEP	tris[2-chloro-1-(chloromethyl) ethyl] phosphate, C ₉ H ₁₅ Cl ₆ O ₄ P, TDCP	tris(2-chloroethyl) phosphate, C ₆ H ₁₂ Cl ₃ O ₄ P, TCPP
			<p>Muta. 2 H341: "Suspected of causing genetic defects."</p> <p>Carc. 1A H350: "May cause cancer."</p> <p>STOT Rep. Exp. 1 H372: "Causes damage to organs" (Specific concentration limits for STOT toxicity).</p> <p>Aquatic Acute 1 H400: "Very toxic to aquatic life."</p> <p>Aquatic Chronic 1 H410: "Very toxic to aquatic life with long lasting effects."</p> <p>Labeling: "Danger"</p>	<p>STOT Rep. Exp. 1 H372: "Causes damage to organs. Affected organs: Respiratory tract Route of exposure: Inhalation." (Specific concentration limits for STOT toxicity).</p> <p>Aquatic Acute 1 H400: "Very toxic to aquatic life."</p> <p>Aquatic Chronic 1 H410: "Very toxic to aquatic life with long lasting effects."</p> <p>Labelling: "Danger"</p>	Included in REACH Annex XIV.		
Reported use of substance	<p>"In the production of glass, enamels, functional ceramics and semi-conductors"</p> <p>"use of diantimony trioxide in the production of pigments, paints,</p>	<p>"Metal working fluids; Lubrication at high energy conditions and in partly open process."</p> <p>"Manufacture of preparations,"</p> <p>"Paints and coatings", "Rubber",</p>	<p>"Use of nickel sulphate in the manufacturing of micronutrient additives for biogas production."</p> <p>"Formulation of metal surface treatment products"</p>	<p>"Formulation of nickel compounds"</p> <p>"Metal surface treatment: nickel electroplating, nickel electroforming, electroless nickel plating"</p>	"Coatings"	<p>"Foam production with TDCP."</p> <p>"Cutting and handling of foam with TDCP."</p> <p>"Rebonding"</p> <p>"Loose crumb"</p>	<p>"Flexible foam - Industry applications"</p> <p>"Rigid foam - Industry applications"</p> <p>"Foam granules and rebound PUR foam -</p>

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	<p>coatings, ceramics, brake pads and production and formulation of fine chemicals.</p> <p>“use of diantimony trioxide in PET (films/fibres, resin) production.”</p> <p>“use of diantimony trioxide in the plastics and rubber industry.”</p> <p>“use of diantimony trioxide in the manufacture of flame retarded textiles.”</p> <p>“use use of diantimony trioxide in wood adhesives.”</p> <p>“In a mixture as Flame retarget”</p>	<p>“Furniture manufacture”, “Construction chemicals”,</p> <p>“Lubricants”,</p> <p>“Flame retardants”,</p> <p>“Flame retardant in conveyor belts”,</p> <p>“PVC and Rubber Formulation”,</p> <p>“Sealant/adhesive Formulation”,</p> <p>“Metal Working Fluid Formulation”,</p> <p>“Textile Flame Retardant and Waterproofing Formulation”,</p> <p>“Paint Formulation”</p>	<p>“Metal surface treatment of anodised aluminium sheets.”</p> <p>“Production of Ni-containing pigments from nickel sulphate.”</p> <p>“Production of nickel salts from nickel sulphate.”</p> <p>“Production of batteries using electrodes with nickel containing active materials.”</p> <p>“Metal surface treatment: nickel electroplating, nickel electroforming, electroless nickel plating.”</p> <p>“Selective plating with nickel sulphate.”</p> <p>“Production of nickel-containing glass.”</p> <p>“Manufacture of other non-metallic mineral products, e.g. plasters, cement.”</p>	<p>“General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment”</p> <p>“Selective plating with nickel sulphamate”</p> <p>“Manufacture of computer, electronic and optical products, electrical equipment”</p>			<p>Industry applications”</p> <p>“Manufacture of plastics products, including compounding and conversion”</p> <p>“One component foam”</p>

Substance identification	antimony trioxide, diantimony trioxide, Sb ₂ O ₃	MCCP, Alkanes, C ₁₄₋₁₇ , chloro, Chlorinated paraffin liquid	nickel sulphate, H ₂ O ₄ S.Ni	nickel bis(sulphamidate), Nickel sulfamate, H ₃ NO ₃ S.1/2Ni	tris(2-chloro-1-methylethyl) phosphate, C ₉ H ₁₈ Cl ₃ O ₄ P, TCEP	tris[2-chloro-1-(chloromethyl) ethyl] phosphate, C ₉ H ₁₅ Cl ₆ O ₄ P, TDCP	tris(2-chloroethyl) phosphate, C ₆ H ₁₂ Cl ₃ O ₄ P, TCPP
			<p>"metal surface treatment (nickel electroplating, nickel electroforming and nickel electroless technologies)".</p> <p>"Production of batteries using positive nickel electrodes."</p> <p>"Production of batteries using electrodes with nickel containing active materials."</p> <p>"Selective plating",</p>				
PBT assessment	The substance is not PBT / vPvB	The substance is not PBT / vPvB	N/A, "The PBT and vPvB criteria of Annex XIII to the Regulation does not apply to inorganic substances, such as nickel sulphate."	N/A, "The PBT and vPvB criteria of Annex XIII to the Regulation does not apply to inorganic substances, such as nickel sulphamate."	The substance is not PBT / vPvB; Half-life in surface water = 150d Half-life in sediment = 3000d Half-life in soil = 300d, Log Kow = 2.68	P not vP, "Is P but vP not certain, based on biodegradation testing, it is not readily, but inherently not excluded." Not B and not vB based on: BCF ≤ 2,000 L/kg	The substance is not PBT / vPvB
Phys-chem. properties							
Melting point/freezing point	Melting point; 655 °C	vary between -50°C and +25°C (depending on chlorine content)	≥840 °C (anhydrous form)	Decomposition at 142 °C	N/A	< -20 °C	-51 °C

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Boiling point	1425 °C	N/A, C14-17 chlorinated paraffins start to decompose at around 200°C	N/A	N/A	N/A	326 °C(at higher temperatures decomposition occurs)	> 288 °C (at higher temperatures decomposition occurs)
Density	5.897 g/cm ³	1.1-1.32 g/cm ³ for MCCPs with between 41 - 56% chlorination	3.68 g/cm ³ at 20°C (anhydrous form), 2.07 g/cm ³ at 20 °C (hexahydrate form)	2.25 g/cm ³ at 20 °C	1.39 g/cm ³ at 25 °C	1.51g/cm ³ at 20 °C	1.29 g/cm ³ at 20 °C
Particle size distribution	Total Dustiness (airborne fraction): 18.05 - 178.80mg/g, Mass median aerodyne. $\bar{A}E$ of airborne fraction: MMAD = 4.33 - 35.23 μ m	N/A	N/A	N/A	N/A	N/A	N/A
Vapour pressure	1mmHg at 574°C.	> 0.000001 mm Hg at 20 °C	N/A	N/A, "The melting temperature of the test material was greater than 300°C (see IUCLID section 4.2) and therefore obviated the need for the vapour pressure test."	ca. 0.06125 mm Hg at 25 °C.	0.0000056 Pa at 25 °C	0.0014 Pa at 25 °C
Partition coefficient	N/A	log Pow 5.52 – 8.21 for MCCPs with between 45 - 52% chlorination	N/A	N/A	log Pow = 1.7, at 20 oC.	log Pow = 3.69	log Pow = 2.68
Water solubility	2.76 mg/L (22.2 °C, pH 8.1)	0.005 – 0.027 mg/l at 20 °C	293 g/l at 20°C (anhydrous form) N/A	49.9 – 60 % /w/w), at 20 °C and pH 1.1-1.6	7943 mg/L at 20 °C.	18.1 mg/L 20 °C, pH 6.3	1080 mg/L at 25 oC, pH7
Surface tension	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Flash point	N/A	> 210 °C	N/A	N/A	232 °C, at 1013 hPa	> 245 °C	185-218 °C

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Auto flammability	N/A	N/A	N/A	"The test material has been determined not to have a relative self-ignition temperature below 400°C."	N/A	"Not self-ignitable"	> 400 °C at 1 atm
Flammability	N/A	N/A	Not flammable	"non flammable"	N/A	"In contact with water or damp air, this substance will not react to produce hazardous gases."	No ignition on contact with air
Explosiveness	N/A	N/A	N/A	"The structure of the test material was assessed for chemical groups that imply explosive properties, there are no such groups present in the structure."	N/A	N/A	N/A
Oxidising properties	N/A	N/A	Not oxidising	"The structure of the test material was assessed for chemical groups that would imply oxidising properties. Examples of such groups are nitrates, metal oxides, hypofluorites, difluoroaminopolynitroaryls, perchlorates, bromates and iodites. There are no such groups present in the structure."	N/A	N/A	N/A

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Stability in organic solvents and identity of relevant degradation products	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Dissociation constant	N/A	"study technically not feasible"	N/A	N/A	N/A	N/A	N/A
Viscosity	N/A	90 – 12 000 mm ² /s (static), at 20 °C	N/A	N/A	N/A	Dynamic viscosity of 1715 mPa s at 25 °C	Kinematic viscosity of 68.5 m ² /s at 20 °C
Environmental fate and pathways							
Stability	N/A	N/A	N/A	N/A	N/A	Hydrolysis; At pH 9 and 20 °C, Half-life is ca. 120 days.	Hydrolysis; "Based on this result, it is concluded with no need for further testing in accordance with the OECD guideline, that TCPE is stable in water at pH 4, 7 and 9 at 25°C, with a half-life greater than or equal to one year."
Biodegradation	N/A	inherently biodegradable, 14 % degradation in 14 d (OECD 301D) DT50 in sediment 12-58 d for C16 chlorinated paraffin; 35-69 % Cl under aerobic cond.	N/A	NA/	Biodegradation; "Not readily biodegradable" acc. OECD 301 C Ready Biodegradability: Modified MITI Test (I)	Aerobic biodegradation; "under test conditions no biodegradation observed" (OECD 301 B, Ready Biodegradability:	Not readily biodegradable; "extent of degradation was close to zero at the end of 28 days." (EPA OTS 796.3100,Aerobic

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		DT50 in aerobic soil; 36 h for C14.5 and a C15.4 chlorinated paraffin (43.5 - 50% chlorinated)				CO ₂ Evolution Test) "Very little degradation (<6%) occurred in soil in the 17-week study. There was no inhibition of the soil micro-organisms (OECD 307 Aerobic and Anaerobic Transformation in Soil)	Aquatic Biodegradation)
Bioaccumulation	0.05 mg Sb/kg w.w in crustaceans (BCF = 1000), 0.2 mg Sb/kg w.w. in aquatic plants (BCF = 1 000) BCF in aquatic larvae 43-1150, BCF in fish tissue 15-1000, BCF in algae 0.01-0.67 BSAF = 0.0,34 in Earthworms (<i>L. Terrestris</i>)	BCF = 6660 L/kg in fish (OECD 305), BCF = 349 – 1087 L/kg in fish, with DT50 (depuration) of 15-17 d. BCF = 2.4 – 2.3 in earthworms. BSAF = 0.045 in carrots (C14-17 chlorinated paraffin (52% chlorinated)	BCF = 61 for Phytoplankton grown in culture (25 d-test), BCF = 80 in freshwater macrophytes (plants), BCF = 0.8-4 in fish (180 d-study), BCF = 136 in bivalves (84 d-study), BSAF = 0.75-1.25 in earthworms, BSAF = 0.07 in spinach, 0.08 (cabbage), 0.3 (lettuce), 0.16 (onion), 0.07 (carrot)	See nickel sulphate, for read-across	N/A	BCF = 0.5 for fish in 30-day study	BCF = 0.8 – 2.8 (OECD 305C)
Transport and distribution	Soil adsorption; Koc = 0.125, log Kp(soil) = 1.44-2.08	Log Koc (soil) = 5-5.2 for C16 chlorinated paraffin (34-69 % chlorination)	Log Kp = 3.8 – 4.9 (susp. matter), Log Kp = 3.9 – 4.2 (sediment), Log Kp = 2.06 – 3.76 (soil), Kp =	See nickel sulphate, for read-across	N/A	log Koc = 3.25 (OECD Guideline 106),	Read-cross data from TDCP-dossier; log Koc = 2.24, Koc = 174.

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	Sediment partition; logKp= 4		126 – 1259 (sewage sludge)			log Koc = 4.09 (in sludge). Henrys law constant, H = 0.000396 Pa m ³ /mol at 25 °C	Henrys law constant, H = 0.000124 Pa m ³ /mol at 25 °C
Ecotoxicological Information							
Aquatic toxicity	PNEC(freshwater)= 0.113 mg/L (AF =10), PNEC (marine water)= 0.0113 mg/L (AF = 100), (AF=10)	PNEC (freshwater) = 1 µg/L (AF 10), PNEC(marine water)= 0.2 µg/L (AF = 50)	LC50 (96h) = 15.3 mg/L (fish). NOEC (32 d) = 0.057 mg/l,	See nickel sulphate, for read-across	EC50 (48 h)= 170 mg/L (OECD202 (Daphnia sp. Acute Immobilisation Test), EC50 (72 h)= 450 mg/L, NOEC (72 h)= 72 mg/L (OECD 201 Alga, Growth Inhibition Test)	PNEC(freshwater)= 0.01 mg/L (AF = 50), PNEC(marine water) = 0.001 mg/L (AF =500) NOEC (96 h) = 0.56 mg/L , The 96 hr LC50 was 1.1 mg/L for fish (OECD 203 NOEC (48 h) = 1.6 mg/L for crustaceans (OECD 202). NOEC (21 d)= 0.5 mg/L for crustaceans (OECD 211)	PNEC(freshwater) = 0.64 mg/L (AF = 50), NOEC(96 h) =9.8 mg/l for fish, PNEC (marine water) =0.064 mg/L (AF =500), EC50 (48 h) = 131 mg/L for Crustaceans, NOEC (21 d) = 32 mg/l, for crustaceans. NOEC (72h)= 13 mg/l (green algae)
Sediment toxicity	PNEC sediment (freshwater)= 11.2 mg/kg sediment dw (AF = 10), PNEC sediment (marine water)=2.24 mg/kg sediment dw (AF=50)	PNEC sediment (freshwater)= 13 mg/kg sediment dw (AF =10), PNEC sediment (marine water) = 2.6 mg/kg sediment dw (AF =50)	EC10 (28 d) = 199 mg/kg sediment dw in shrimp. EC10 (28 d) = 388 mg/kg sediment dw (in molluscs),	See nickel sulphate, for read-across	N/A	PNEC sediment (freshwater) =0.83 mg/kg sediment dw (AF = 10) PNEC sediment (marine water) =	PNEC sediment (freshwater) = 2.92 mg/kg sediment dw, PNEC sediment (marine water) = 0.29 mg/kg sediment dw

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						0.166 mg/kg sediment dw (AF =50) NOEC (3 d) = 8.8 mg/kg sediment dw, NOEC (28 d) = 3.9 mg/kg sediment dw for midge (Chironomidae) OECD 218	
Terrestrial toxicity	PNEC soil=37 mg/kg soil dw	PNEC soil= 11.9 mg/kg soil dw (AF = 50)	LC50 (21 d) = 510 mg/kg soil dw (annelide worms), NOEC (28 d) = 30.9 mg/kg soil dw (in Eisenia fetida.), test protocol accd. to ISO 11268-2 (" <i>Effects of Pollutants on Earthworms. 2. Determination of Effects on Reproduction</i> "), NOEC (28 d) = 320 mg/kg soil dw (soil-dwelling springtail)	See nickel sulphate, for read-across	N/A	NOEC (28 d) = 3.9 mg/kg sediment dw (midge), (NOEC (19 d) = > 202 mg/kg soil dw for wheat (OECD 208 Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test), NOEC (90 d) = 20 mg/kg bw with regard to leghorn hen.	PNEC soil = 1.7 mg/kg soil dw (AF = 10), NOEC (28 d) ≥ 196 mg/kg soil dw (earthworm, OECD 222), NOEC (21 d) = ≥ 18 -98 mg/kg soil dw (for green plants, OECD 208). Test on yeast; " <i>Oestrogenic/anti-oestrogenic effects have been investigated by Föllmann and Wober (2006) using the recombinant yeast reporter gene assay and by induction of the alkaline</i>

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							<p><i>phosphatase enzyme in human endometrial cancer Ishikawa cells. This study was used an advanced method to dig out the oestrogenic or anti-oestrogenic effects of TCPP, so the results were fulfilled all validity criteria. No induction of oestrogenic or anti-oestrogenic effects was detected in either of the test systems."</i> (Follman & Weber (2005), "Investigation of cytotoxic, genotoxic, mutagenic, and estrogenic effects of the flame retardants tris-(2-chloroethyl)-phosphate (TCEP) and tris-(2-chloropropyl)-phosphate (TCPP) in vitro ", Toxicology Letters 161 (2006) 124–134</p>
Toxicological information							

Substance identification	antimony trioxide, diantimony trioxide, Sb ₂ O ₃	MCCP, Alkanes, C ₁₄ -17, chloro, Chlorinated paraffin liquid	nickel sulphate, H ₂ O ₄ S.Ni	nickel bis(sulphamidate), Nickel sulfamate, H ₃ NO ₃ S.1/2Ni	tris(2-chloro-1-methylethyl) phosphate, C ₉ H ₁₈ Cl ₃ O ₄ P, TCEP	tris[2-chloro-1-(chloromethyl) ethyl] phosphate, C ₉ H ₁₅ Cl ₆ O ₄ P, TDCP	tris(2-chloroethyl) phosphate, C ₆ H ₁₂ Cl ₃ O ₄ P, TCPP
Acute Toxicity	<i>Inhalation</i> ; LC50=5.20 ±0.16 mg Antimony trioxide/L air (rats in 4 h study). <i>Dermal</i> ; LD50= > 8300 mg/kg bw (rabbits, 168 h)	<i>Oral</i> ; > LD50= 4000 mg/kg bw (rat). <i>Inhalation</i> ; LD50 = > 48170 mg/m ³ air (nominal) (in rats). <i>Dermal</i> ; LD50 = > 10 mL/kg bw (in rabbit)	DNEL = 16 mg/m ³ , acute toxicity (by inhalation), oral; LD50 = 361.9 mg/kg bw (in rats), inhalation; LC50 (4h) = 2.48 mg/L air (in rats)	See nickel sulphate, for read-across	Oral; LD50= 1230 mg/kg bw in rat.	Oral; LD50 = > 2000 mg/kg bw in rat (OECD401 Acute Oral Toxicity), Inhalation; LC50 = > 5.22 mg/L air for rats, (OECD403 Acute Inhalation Toxicity) Dermal; LD50 0 > 2000 mg/kg bw for rats, (OECD 402 Acute Dermal Toxicity)	oral; LD50=2800-4200 mg/kg bw (in rats).inhalation; LC50 = > 7 mg/L air (in rats) dermal; LD50 = > 2000 mg/kg bw (in rats)
Irritation / corrosion	Eyes; "not irritating"	Skin; "slightly irritating", Eyes; "slightly irritating"	Skin; "not irritating", Eyes; "not irritating"	See nickel sulphate, for read-across	Skin; "All animals showed slight erythema that reversed within 24 hours." (OECD404 (Acute Dermal Irritation / Corrosion). Eyes;" Not irritating" (EU Method B.5 Acute Toxicity: Eye Irritation / Corrosion)	Skin; "irritating " on rabbit, (OECD 404 (Acute Dermal Irritation / Corrosion), Eyes; "slightly irritating "(OECD Guideline 405)	Skin;" not irritating" Eyes; "The material is not irritant to eye"
Sensitisation	"Not sensitizing"	"Not sensitizing"	Skin; "sensitizing"	See nickel sulphate, for read-across	read across from TDCP on OECD 429-test.	Skin; "not sensitising ", on Guinea pig (OECD	Skin; "not sensitizing",

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						Guideline 406 Skin Sensitisation)	
Repeated dose toxicity	DNEL (Derived No Effect Level) =0.5 mg/m ³ Oral; NOAEL 1686 mg/kg bw/day (rats), Inhalation; NOAEC = ≤ .51 mg/m ³ air (rats, based on impaired lung clearance)	DNEL (Derived No Effect Level) = 6.7 mg/m ³ (inhalation). Oral; NOAEL = 300 ppm. Additional study; "Administration of Cereclor S52 (a C14-17 chlorinated paraffin; 52% chlorination) by stomach tube to female Sprague-Dawley rats at dose levels up to 1000 mg/kg bw/day for 21 days had no significant effect on the blood clotting system. However, Cereclor S52 appears to cause induction of CYP2B1 and CYP2B2 isozymes in both the normal and menadione-deficient diet groups."	DNEL = 0.05 mg/m ³ , oral; NOAEL = 2.2 mg Ni/kg bw/day (in rats)(OECD 451, in a 104 week-study), inhalation; LOAEC(13 weeks) = 0.056 mg Ni/m ³ (OECD 453), in mouse.	See nickel sulphate, for read-across	N/A	DNEL = 0.327 mg/m ³ , Oral; LOAEL= 5 mg/kg bw/day on rat.	DNEL =5.82 mg/m ³ Oral; LOAEL = 800-2500 ppm,
Genetic toxicity	In vitro (OECD473); positive, substance is considered clastogenic under the conditions of this assay. In vivo (OECD474); negative, No statistically	In vitro (Ames assay OECD 471); negative, the C14-17 chlorinated paraffin (Solvocaffero C1642) was not mutagenic. In vivo (OECD474); negative (C14-17 chlorinated paraffin (42% chlorination)	In vitro; "Nickel sulphate was found not to be mutagenic in the reverse mutation assay using <i>S. typhimurium</i> strains." In vivo; negative, "no effects no cytotoxicity effects on bone marrow	See nickel sulphate, for read-across	In vitro; "negative", Negative in the reverse mutation assay in vitro when tested in <i>Salmonella typhimurium</i> strains TA100,	In vitro; "negative", the substance was not detected as a mutagen in the CECT (chick embryo cytogenetic test). In vivo; "negative", TDCP was negative in the in	In vivo; negative "The test material was not clastogenic and did not induce chromosomal damage in rats."..."

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	significant increase in the incidence of micronuclei was observed in the single or repeated dose study		<i>even at maximum tolerated dose established based on mortality and clinical observations" (in rats)</i>		TA1535, TA1537 and TA98 in a preincubation protocol, with and without metabolic activation (OECD471 (Bacterial Reverse Mutation Assay). In vivo; no data	vivo / in vitro assay for unscheduled DNA synthesis in the livers of male Hsd:SD rats under the conditions of the study (OECD 486 Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells in vivo).	
Carcinogenicity	no evidence of antimony trioxide-induced carcinogenicity (OECD 451)	LOAEL = 125 mg/kg bw/day (actual dose received), based on OECD 451, mouse)	NOAEL (103 weeks)= 2.2-11 mg Ni/kg bw/day (in rats), NOAEC (2 years) = 0.027 mg Ni/m ³ (inhalation), in rats	See nickel sulphate, for read-across	No data	LOAEL (24 months) = 5 mg/kg bw/day in rat. "TDCP increased the incidence of commonly occurring benign tumors but did not demonstrate carcinogenic activity in rats. TDCP is non-genotoxic and may therefore be assumed to be a threshold carcinogen. A LOAEL of 5 mg/kg bw/day was determined."	No data

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Toxicity to reproduction	NOAEL (male testicular toxicity) = > 1200 mg/kg bw/day	NOAEL (parent)= 100 mg/kg bw/day. NOAEL (F1) = 100 mg/kg bw/day. (rats), C14-17 n-alkane, 52% chlorinated	NOAEC (13 weeks) = 0.45 mg Ni/m ³ for parent generation, in rats. "Based on these results, 10.0 mg/kg/day is considered a No-Observed-Adverse-Effect Level (NOAEL) for oral administration of nickel sulfate hexahydrate over two generations in rats."	See nickel sulphate, for read-across	N/A	LOAEL (24 month, parent) = 5 mg/kg bw/day in rat, Effects were noted in the testes, epididymis and seminal vesicles in all animals at 24 months, with a trend for higher incidence in the treated groups. evaluation of the female reproductive system was included in the 2-year carcinogenicity study with TDCP.	LOAEL = 99 mg/kg bw/day (Parent, female), NOEAEL = 85 mg/kg bw/day (parent, male) (OECD 416 2-Generation Reproduction Toxicity Study in rats)
Developmental toxicity / teratogenicity	LOAEC = 2.6 mg/m ³ air (OECD 414). Maternal toxic effects; yes	NOAEL (maternal) = 100 mg/kg bw/day, NOAEL (teratogenicity) = 100 mg/kg bw/day (rabbits), C14-17 chlorinated paraffin (52% chlorinated)(OECD414)	DNEL (Derived No Effect Level) = 0.05 mg/m ³ , teratogenicity (by inhalation)	See nickel sulphate, for read-across	N/A	NOAEL (10 d, maternal) = 25 mg/kg bw/day, NOAEL (10 d, developmental) = 100 mg/kg bw/day, "There were signs of embryo- and fetotoxicity at the high test level which were not expected due to the	NOAEL (maternal) = 1000 mg/kg bw/day, NOAEL (teratogenicity) = 1000 mg/kg bw/day, 70 d-study, OECD 414 (Prenatal Developmental Toxicity Study in rats), "The highest dose in this study, 1000 mg/kg/day, was a NOAEL for

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						maternal toxicity observed."	maternal, fetal, and postnatal toxicity."
Exposure related observations in humans	Lüdersdorf et al., (1987), "Biological assessment of exposure to antimony and lead in the glass-producing industry", Int Arch Occup Environ Health, 59:469-447 Kentner et al. (195); "External and internal antimony exposure in starter battery production", Int Arch Occup Environ Health, 67: 119-123	Thomas et al. (2006), "Short and medium chain length chlorinated paraffins in UK human milk fat", Environment International 32: 34-40.	N/A	N/A	N/A	N/A	N/A
Safe use (precautionary statements)	P202: Do not handle until all safety precautions have been read and understood. P281: Use personal protective equipment as required. P308+P313: IF exposed or concerned: Get medical advice/attention	P201: Obtain special instructions before use. P260: Do not breathe dust. P263: Avoid contact during pregnancy/while nursing. P264: Wash ... thoroughly after handling. P270: Do no eat, drink or smoke when using this product. P273: Avoid release to the environment.	P201: "Obtain special instructions before use." P261: "Avoid breathing dust." P273: "Avoid release to the environment." P280: Wear protective gloves. P308 + P313: IF exposed or concerned: Get medical advice/attention.	See nickel sulphate, for read-across	P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P270: Do no eat, drink or smoke when using this product.	P202: "Do not handle until all safety precautions have been read and understood." P273: "Avoid release to the environment." P281: 2Use personal protective equipment as required." P308+P313: "IF exposed or	P270: "Do no eat, drink or smoke when using this product." P301+P312: "IF SWALLOWED: Call a POISON CENTER/doctor/.../if you feel unwell." P330: "Rinse mouth." P501: "Dispose of contents/container to ..."

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	P405: Store locked up.	P308+P313: IF exposed or concerned: Get medical advice/attention.	P501: Dispose of contents/ container to an approved waste disposal plant.		P273: Avoid release to the environment. P281: Use personal protective equipment as required. P301+P312: IF SWALLOWED: Call a POISON CENTER/doctor/.../ if you feel unwell. P308+P313: IF exposed or concerned: Get medical advice/attention. P391: Collect spillage P405: Store locked up. P501: Dispose of contents/container to ...	concerned: Get medical "advice/attention. P391: "Collect spillage." P405: S2tore locked up." P501: "Dispose of contents/container to ..."	



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