PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR CAT 1A OR 1B, PBT, vPvB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance Name(s): Trixylyl phosphate

EC Number(s): 246-677-8

CAS Number(s): 25155-23-1

Submitted by: Environment Agency Austria on behalf of the Austrian Competent Authority (Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management)

Date: August 5th, 2013

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ABBREVIATIONS

AChE	Acetylcholinesterase
AF	Assessment Factor
BuTTP	Phenol, isobutylenated, phosphate (3:1)
CLP	Classification, labelling and packaging of substances and mixtures
DNEL	Derived No Effect Level
IPPP	Triaryl Phosphate Isopropylated
LMZ	Leningradsky Metallichesky Zavod, Russian power machine building enterprise
LOAEL	Lowest Observed Adverse Effect Level
MCCPs	Medium chain chlorinated paraffins
NOAEL	No Observed Adverse Effect Level
PBT	Persistent, Bioaccumulative, Toxic
PEC	Predicted environmental concentration
POE	Polyolester oil
PPE	Personal Protective Equipment
PU	Polyurethane
PVC	Polyvinylchlorid
RAR	Risk Assessment Report
RCR	Risk Characterisation Ratio
RMM	Risk Management Measures
RPE	Respiratory Protective Equipment
SDS	Safety Data Sheet
SPIN	Substances in Preparations in the Nordic countries
SVC	Saturated vapour concentration
SVHC	Substance of very high concern
TBPP	tris(2,3-dibromopropyl) phosphate
TCP	Tricresyl phosphate
TPE	Thermoplastic elastomers
TXP	Trixylyl phosphate

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR CAT 1A OR 1B, PBT, VPVB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance Name(s): Trixylyl phosphate

EC Number(s): 246-677-8

CAS Number(s): 25155-23-1

- The substance is proposed to be identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction category 1B.

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

Trixylyl phosphate (TXP) is covered by index number 015-201-00-9 of Regulation (EC) No 1272/2008 in Annex VI, Part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) for reproductive toxicity, Rep. 1B (H360F: “May damage fertility”).

Therefore this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as reproductive toxin in accordance with Article 57(c) of REACH.

Registration dossiers submitted for the substance? Yes

PART I

JUSTIFICATION

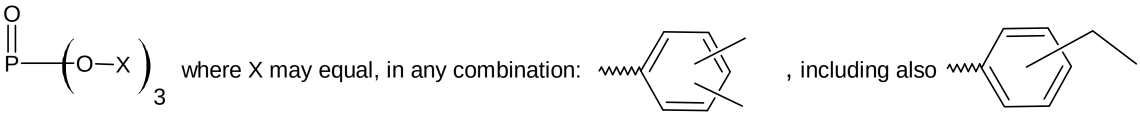
1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	246-677-8
EC name:	Trixylyl phosphate
CAS number (in the EC inventory):	25155-23-1
CAS number: **Deleted CAS numbers:**	25155-23-1 95660-61-0 174956-83-3
CAS name:	Phenol, dimethyl-, 1,1',1''-phosphate
IUPAC name:	Trixylyl phosphate
Index number in Annex VI of the CLP Regulation	015-201-00-9
Molecular formula:	$C_{24}H_{27}O_4P$
Molecular weight range:	410.4425
Synonyms:	Reaction product of phosphorous oxytrichloric acid and xylenols containing tris (dimethylphenyl and/or ethylphenyl) phosphates Trixylenylphosphate Dimethylphenol phosphate (3:1) Phenol, dimethyl-, phosphate (3:1) Phosphoric acid, trixylyl ester Xylenol, phosphate (3:1) Tri-dimethyl phenyl phosphate Tris (dimethylphenol) phosphate Kronitex TXP (Trade name) Phosflex TXP (Trade name) .

Structural formula:



1.2 Composition of the substance

Name: Trixylyl phosphate

Description: Organophosphate, viscous colourless liquid

Degree of purity: confidential

For further details see confidential Annex III, Chapter 1.

1.3 Substance identity

Trixylyl phosphate (TXP) is a UVCB substance containing over 50 different constituents and no additives. It is produced through the reaction of phosphorus oxytrochloride and xylenols. The xylenols (=dimethyl phenols) are present in a distillation fraction of naturally occurring coal tar derivatives which also contains different ethyl phenols. Reaction of the different xylenols and ethyl phenols results in alkylated triphenyl phosphates with a high amount of possible isomers that cannot be easily analysed (see also figure 1). Therefore, the exact composition is unknown. In studies that form the basis for harmonized classification and labelling, the substance was tested as such and the individual constituents are not the basis for the classification.
A more precise chemical naming could be: Reaction product of phosphorous oxytrichloric acid and a mixture of xylenols containing > 95% tri (dimethylphenyl and ethylphenyl) phosphates (ECHA, 2010).

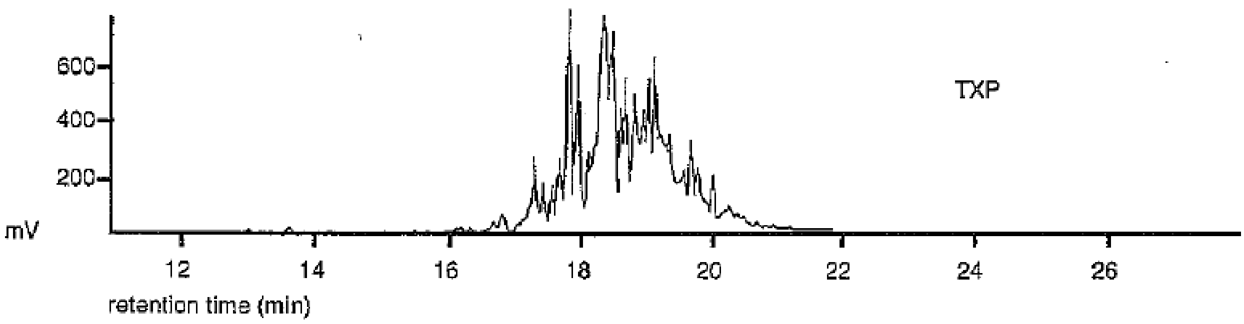


Figure 1: Gas-liquid chromatogram of TXP (Totten, 2000)

According to Nobile (1980), who investigated the composition of two TXP products, the xylyl phosphate isomers (in decreasing order of abundance) 2,5-, 2,3-, 3,5-, 2,4- and 3,4- isomers were present in the products. The 2,6-isomer was not present. Other components identified included 4-ethylphenol, p-cresol, phenol and trimethyl phenol.

None of the xylyl phosphate isomers has a harmonized classification, all but one are notified in the C&L inventory but without a classification for reprotoxicity and they have not been registered yet. For an overview see Table 2.

Table 2: Overview on tris xylenol isomers and their registration and notification status

<table>
<tr><th>CAS No</th><th>Name</th><th>Preregistered (for which deadline)</th><th>Registered</th><th>Annex VI, CLP</th><th>C&L Inventory</th></tr>
<tr><td>121-06-2</td><td>tris (2,6-xylenyl) phosphate</td><td>-</td><td>-</td><td>-</td><td rowspan="5">Skin Irrit. 2
Eye irrit. 2
STOT SE 3
Aquatic Chronic 4</td></tr>
<tr><td>3862-11-1</td><td>tris (3,4-dimethylphenyl) phosphate</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>3862-12-2</td><td>tris (2,4-dimethylphenyl) phosphate</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>65695-97-8</td><td>tris(2,3-dimethylphenyl) phosphate</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>19074-59-0</td><td>tris(2,5-xylyl) phosphate</td><td>+ (2013)</td><td>-</td><td>-</td></tr>
<tr><td>25653-16-1</td><td>tris(3,5-xylyl) phosphate</td><td>+ (2013)</td><td>-</td><td>-</td><td>-</td></tr>
</table>

This SVHC-Dossier (according to REACH Art. 57c) is restricted to the UVCB compound (CAS 25155-23-1). The harmonized classification of TXP is based on studies with Phosflex TXP (one of the commercial names of TXP, CAS 25155-23-1) (ECHA, 2010). Further risk reduction measures therefore relate to the UVCB substance. In case one of the specific isomers mentioned above will be registered, further steps could be considered at a later stage. At the moment only the UVCB is registered.

2 HARMONISED CLASSIFICATION AND LABELLING

TXP is covered by index number 015-201-00-9 in Annex VI, part 3 of Reg. (EC) No 1272/2008 as follows:

Classification according to part 3 of Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008, amended by Regulation (EC) No 618/2012 (3rd ATP):

Index No	International Chemical Identification	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)		
015-201-00-9	trixylyl phosphate	246-677-8	25155-23-1	Repr. 1B	H360F	GHS08 Dgr	H360F			

Classification according to part 3 of Annex VI, Table 3.2 (list of harmonized classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008, amended by Regulation (EC) No 618/2012 (3rd ATP):

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
015-201-00-9	trixylyl phosphate	246-677-8	25155-23-1	Repr. Cat. 2; R60	T R: 60 S: 53-45		

The harmonized classification applies from 1st of December 2013.

3 ENVIRONMENTAL FATE PROPERTIES

Not relevant for this dossier.

4 HUMAN HEALTH HAZARD ASSESSMENT

See section 2 “Harmonised Classification and Labelling” and supplementary information in Annex I.

5 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for this dossier.

6 CONCLUSIONS ON THE SVHC PROPERTIES

Trixylyl phosphate (TXP) is covered by index number 015-201-00-9 of Regulation (EC) No 1272/2008 in Annex VI, Part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) for reproductive toxicity, Rep. 1B (H360F: “May damage fertility”).

Therefore this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as reproductive toxin in accordance with Article 57(c) of REACH.

PART II

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

7 INFORMATION ON MANUFACTURE, IMPORT/EXPORT AND USES – CONCLUSIONS ON EXPOSURE

7.1 Manufacture, import and export

TXP is registered for the tonnage band 1000-10.000 t/year and is manufactured in the EU and imported into the EU. Details on tonnages are given in confidential Annex III, Chapter 2.

7.2 Uses of TXP

7.2.1 Information from registration

According to the registrations TXP is used mainly as functional fluid (fire resistant fluids, hydraulic fluids, lubricants, lubricant additives, grease products, metal working fluid) and as flame retardant in the production of plastics. These uses are described in Annex II, Table 15 (Industrial setting) and 16 (Professionals) by use descriptors.

The registrants advice against consumer use of TXP and state that the substance is not used in the formulation of products intended for consumer use, as these are intended for dedicated professional or industrial applications only.

The products are not readily available to buy off the shelf by consumers (Environment Agency Austria, enquiry, 2013).

7.2.2 Information from literature and websites

TXP belongs to the group of triarylphosphates. TXP is a phosphor-containing flame retardant acting by the formation of a solid surface layer promoted by cross-linking reactions. The formation of the protective layer occurs by the production of phosphoric acid and carbonization via the release of water. The flame retardant creates an effective barrier to heat transfer and diffusion of gases (Papazoglou, 2004).

Apart from the uses described in the registration there are indications of other uses in the literature. Papazoglou (2004) listed TXP for the use in polyurethane, PVC, TPE as well as for coatings and textiles. In addition to these uses internet sources recommend TXP mixtures as plasticizer of vinylite, cellulosic resin and natural and synthetic rubber. It may also be used for anti-mildew cable, electricity and as plasticizer and fire retardant for PVC convey belts, artificial leather and flooring materials[1,2].

Triaryl phosphates in general can be used for many applications in thermoplastics[3]. Weil, 2009 discusses that they may be used as plasticiser but are more costly and somewhat less effective than common dialkyl phthalate plasticizers; therefore only as much triaryl phosphates as needed to pass flammability requirements will be used. TXP has been used where high temperature performance is important or long term heat resistance such as in agricultural (greenhouse) film, or in automobile seating where avoidance of windshield fogging is required (Weil, 2009). TXP has been presented as possible alternative to MCCPs (Medium chain chlorinated paraffins) (UK, 2008).

TXP is commercially available as pure substance or in a mixture. Common trade names, information on composition (as far as available) and recommended uses are exemplary shown in Table 3. See also confidential Annex III., Chapter 3.

Table 3 : Trade names, composition and uses from publicly available sources

Trade name	Info on Composition	Recommended uses	Source
Kronitex® TXP	TXP <= 100	Fire retardant, Plasticiser Recommended specifically for electrical compounds where superior electrical properties, low volatility and resistance are critical to wire and cable applications[4]	SDS Chemtura
Fyrquel L	TXP	Fire resistant LMZ steam turbine fluid	*
Fyrquel EHC®	Mixture butylated and trixylyl phosphate (30-50%)	Electro-hydraulic control (EHC) fluid used in steam turbine control equipment	* SDS ICL industrial products
Syn-O-Ad®8475	TXP	Ashless Antiwear Oil Additive	*
Reolube®	~ 99% TXP	➢ High performance, fire-resistant hydraulic fluid	**

[1] http://www.victory-chem.com/template/p16e.htm

[2] www.made-in-china.com

[3] www.flameretardants-online.com

[4] http://www.chemtura.com/deployedfiles/staticfiles/Kronitex%20TXP%20TDS.pdf/Kronitex%20TXP%20TDS.pdf

Turbofluid 46XC		designed for use in electrohydraulic governor control systems of steam turbines (EHC fluid) ➢ It may also be used for the lubrication of both steam and industrial gas turbines.	
Anvol PE 46 XC	50 – 100% TXP	Fire-resistant hydraulic fluid.	SDS Castrol
DURAD® 120XC	Mixture of tris(methylphenyl) phosphate (>= 50 - <= 100) and trixylyl phosphate (>= 10 - < 20)	Lubricant	SDS Chemtura
Shell Turbo Fluid DR 46	TXP 60,00 - 100,00 %	➢ lubrication oil for main bearings in steam- and gas turbines, generators and cooling pumps. ➢ hydraulic fluid in electrohydraulicgovernor control systems in steam and gas turbines	SDS Shell

* http://icl-ip.com ** http://www.chemtura.com

7.2.3 TXP in mixtures and articles

a. Information from SPIN database:

The SPIN database[6] was searched for information on TXP in products on the national markets of Norway, Sweden, Finland and Denmark. For detailed information see Table 4.

Table 4: TXP in products according to SPIN (2007-2010).

Year	Number of preparations/year [tonnages]			
	SE	FIN	DK	NO
2007	4 [2t]	conf	17 [6t]	9 [0.1t]
2008	4 [0t]	conf	17 [1t]	9 [0.1t]
2009	4 [0t]	conf	13 [5t]	8 [0t]
2010	4 [3t]	conf	12 [0t]	8 [0.1t]
2011	4 [2t]	conf	12 [0t]	9 [0.6t]

conf = confidential: Total quantities and the total number of products have not been reported to SPIN if the substance is contained in less than 4 products and is registered by less than 3 companies.

According to SPIN database TXP was registered in Norway (NO) and Finland (FI) in the years 2008-2011 for the following industrial uses (NACE):

- Manufacture of computer, electronic and optical products (NO)
- Wholesale and retail trade and repair of motor vehicles and motorcycles (FI) (TXP as lubricant for cars and other vehicles)

KemI-stat[5] (a tool for compiling statistical information on the basis of data in the Swedish Chemicals Agency´s products register) shows that the use of TXP is increasing in Sweden (Table 5). 2011 TXP occurred in five products on the Swedish market with a total tonnage of 10.5 tonnes.

Table 5 : Amount of TXP usage according to the Swedish product register

Year	2005	2006	2007	2008	2009	2010	2011
Tonnages	4	4.2	7.7	1.6	1.6	8.6	10.5

b. *Information obtained from questionnaires for registrants*

Further details on uses of TXP obtained from registrants are given in Annex III, Chapter 3 (Environment Agency Austria, enquiry, 2013).

c. *Information from a survey among industry in Austria*

In 2013 an inquiry was carried out by the Austrian Central Labour Inspectorate on the use of TXP. 23 Austrian companies with more than 20 employees in the sector of “manufacture of textiles”, “manufacture of wearing apparel”, “manufacture of rubber and plastic products”, “manufacture of wiring and wiring devices”, “manufacture of leather and related products” and “manufacture of man-made fibres” were contacted. 22 of the companies provided the information that the substance is not used by them.

7.3 Exposure to TXP

The SPIN database has been searched for information on exposure to TXP. SPIN exposure Toolbox[6] (called “Use index”) makes it possible to search for general indicative exposure of the environment and human beings from the use of TXP. Use index is a method where confidential use information is converted into an exposure based index that can be made publicly available. It cannot be used to provide exact quantification on exposure but be considered as an indicative screening tool. The relevant information is given in Table 6.

The probable consumer exposure indicated by the Swedish data is based on the use of TXP as an additive in hydraulic oil and gear oil.

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[5] http://apps.kemi.se/kemistat/start.aspx?sprak=e

[6] http://www.spin2000.net

Table 6: Exposure potential based on data in Nordic product registers[7].

Country	Year	Use Index						Range of use	Article Index [8]
		Surface water	Air	Soil	Waste water	Consumers	Occup		
DK	2009	-	-	x	-	-	-	Very narrow range of applications	
NO	2011	x	-	x	-	x	xxx	Narrow range of applications	Probable use in article productions
SE	2011	x	x	xxx	x	xx	xx	Narrow range of applications	Probable use in article productions

(-)The registered uses do not indicate direct exposure. (x) One or several uses indicate a potential exposure. (xx) One or several uses indicate a probable exposure. (xxx) One or several uses indicate a very probable exposure.

7.3.1 Routes of exposure

7.3.2 Occupational exposure

No measured workplace exposure data are available. Occupational exposure has been estimated by the registrants by the use of ECETOC TRA Worker v2 (partly in version v3). According to the registrants there is significant exposure to TXP during its manufacture, formulation and use.

Annex III, Chapter 4 provides an overview on scenarios and their corresponding tonnages used.

<u>Use in industrial settings:</u>

Calculations indicate dermal and inhalatory exposure of workers to TXP. Examples of scenarios with potentially high exposure are given in Annex III, Chapter 4.

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[7] Note: Registered Use Categories do not include all potential uses of the chemical and possibility for direct exposure can therefore not be excluded. Indirect exposure e.g. exposure of man via the environment or exposure to the environment through waste disposal is not included. Certain product types that may contribute to overall exposure are insufficiently represented in SPIN (articles such as toys, food packaging materials, cosmetic products, medicinal products).

[8] The Article Index indicates if a substance is used in production of articles/goods. The Article Index is based on the use descriptors “Use Category” and “Industrial Category”.

Professional uses:

Professional uses in most cases have a wide dispersive character (outdoor and indoor) resulting in dermal and inhalatory exposure. The substance is applied in mixtures. Examples of scenarios with potentially high exposure are given in Annex III, Chapter 4.

7.3.2.1 National exposure limits

In the EU no national or EU wide workplace exposure limits for TXP have been established up to date. An OEL of 0,1 mg/m^3 exists in Canada-Ontario[9].

7.3.2.2 Exposure concentrations from the CSR and industry

No measured exposure data are available in the CSR and no additional information has been provided in response to an enquiry (Environment Agency Austria, enquiry, 2013).

7.3.2.3 Exposure concentrations from literature

No data available.

7.3.3 Consumer exposure

TXP as functional fluid:

Based on registrants information there is no exposure to consumers. The substance is not used in the formulation of products intended for consumer use, and hence there are no known consumer uses that could result in exposure.

According to one company TXP is used in very low volumes as additive in lubricants for consumers in concentrations below 0.1% (Environment Agency Austria, enquiry, 2013).

TXP may also be used in jet engine oils (Environment Agency Austria, enquiry, 2013). According to information from a SDS concentration of TXP in jet oil is 0.1-1%. Cabin air in commercial aircraft can be contaminated with hydraulic fluids, synthetic jet oils or the compounds released when these fluids are heated/pyrolysed. Modern passenger aircraft use heated air drawn directly from aircraft engines and auxiliary power units for cabin air conditioning ("bleed air")[10]. Exposure of passengers and crew to some level of triaryl phosphates occurs in approximately 23% of monitored flights, whereas higher levels of exposure can occur when engine seals wear or fail (Baker, 2013). The term "aerotoxic syndrome" was proposed in 1999 to describe the association of symptoms observed amongst aircrew exposed to hydraulic or engine oil smoke or fumes (Michaelis, 2010). For TXP no measurements are available in open literature but exposure seems to be possible.

[9] http://limitvalue.ifa.dguv.de/Webform_gw.aspx

[10] http://www.casa.gov.au/wcmswr/_assets/main/cabin/epaaq/epaaq-entire-report.pdf

TXP as flame retardant in plastics:

TXP is registered for the use as flame retardant in plastic production. The production and all uses are claimed to be only industrial. According to information from a report on behalf of the DG Health and Consumers (ARCADIS, 2011) there are indications that TXP might be used in flame retardant articles made of PVC, in which it is additively integrated. The applications listed are wire/cable and furniture made of artificial leather (PVC) available to consumers based on the assumption that flame retardants are commonly used. No specific information on the actual use of TXP for these applications could be provided by the authors. In a tentative risk assessment inhalation (saturated air, dust exposure) was estimated to be the most relevant route of exposure for service life of wires and cables as well as furniture (up to 0.05 mg/m^3). Dermal exposure to TXP in furniture was also calculated resulting in theoretical exposure of 36.5 mg/kg bw/day (see Table 7).

Table 7 : Consumer exposure estimates to TXP (ARCADIS, 2011).

Route of exposure	Exposure estimate (external)	Comment
Service life of wire and cable		
Inhalation	1.43 * 10^{-2} mg/m^3 (SVC)	Due to the very low vapour pressure (<10^{-4} Pa), the saturated vapour concentration has been used as upper bond vapour concentration
Service life of furniture		
Dermal	36.5mg/kg bw/day	1. Tier assessment using ECETOC-TRA (AC6, furniture and a max concentration of 25%)
Inhalation	1.43 * 10^{-2} mg/m^3 (SVC)	Due to the very low vapour pressure (<10^{-4} Pa), the saturated vapour concentration has been used as upper bond vapour concentration
Inhalation	0.0525 mg/m^3 (airborne particulates)	Airborne particulates: When taking the CSOIL[11] (parameter set for human modelling) estimate for particulate matter (dust) in indoor air of 52.5 µg/m^3 into consideration and using a concentration of 1g TXP per g

[11] CSOIL 2000: an exposure model for human risk assessment of soil contamination. RIVM report 711701054/2007

		dust as a unrealistic worst case assumption, due to the lack of measured data.

SVC: Saturated vapour concentration

The exposure assessments are Tier 1 estimates and therefore conservative. For service life of wires and cables as well as furniture, inhalation was estimated to be the most relevant route and one applied exposure model is based on the assumption of saturated air concentration. The exposure model for exposure to airborne particulates assumes that the total amount of dust in indoor air in living areas is TXP due to the lack of data. An overestimation of TXP exposure can be expected. For dermal exposure to TXP in furniture a conservative approach by ECETOC-TRA was used.

The possible uses of TXP in textiles, artificial leather or as plasticizer indicate consumer exposure but no further information is available at this stage. One evidence for its use in wire/cable is given in a technical information for Kronitex® TXP[12], which is specifically recommended for electrical compounds where superior electrical properties, low volatility and resistance are critical to wire and cable applications. Hardcopy devices may be another source of exposure to TXP according to Wensing (2008) conducting a survey of ultrafine-particle release. After precipitation and solvent extraction a semivolatile organic compounds (SVOC) – likely to be TXP – was detected after GC/MS analysis. The amount of TXP correlated with the number of single-page print jobs. It was, however, not clear whether the substance was part of the aerosol and became impacted on the collector plates, or whether gaseous compounds condensed on the collector plates. Release from the fuser unit (a fuser is responsible for fixing the toner on the paper surface; temperatures around 170°C occur during orienting) may play an important role.

The consumer exposure data provided by ARCADIS, 2011, are based solely on assumptions and model calculations. Information from registration indicates that the plastic products manufactured with TXP are used in an industrial environment only. On the basis of this available data it is not possible to substantiate the actual exposure situation for consumers to TXP. No measurements could be found in literature.

Westerdahl (2010) developed a simple model (method used is based on the Fick´s Second Law diffusion) for an initial approximation of emissions of a set of organic chemicals (plastic additives) from products (mostly plastic material) used in Sweden. For TXP an accumulated amount of 70633t and a yearly emission of 847t from the total amount of existing products in Sweden during 2006 have been estimated within this project. According to the authors there is a large probability that the amount of additives in plastics is overestimated as it is assumed that all plastics contain flame retardants, which in practice is not always the case. Additional uncertainties are the minimum and maximum content of additives or the thickness of the plastic

12 http://www.chemtura.com/deployedfiles/staticfiles/Kronitex%20TXP%20TDS.pdf/Kronitex%20TXP%20TDS.pdf

material. Considering the registered tonnage band of 1.000-10.000t, these figures seem extremely high.

Gilbert (1986 as cited in RAR UK, 2009) carried out a survey of the levels of total trialkyl and triaryl phosphates, including TXP, in composite total diet samples (covering 15 commodity food types) representing an average adult diet for eight regions of the UK. The mean total dietary intake of total organic phosphates was estimated to be 0.072-0.105 mg/day. In general, the highest concentrations of total phosphate esters (total triaryl and trialkyl) were in offal and nuts (these food groups have only a low relative importance in the diet). TXP was found to occur in only minor amounts in isolated samples.

7.3.4 Environment

Not relevant for this dossier, see Chapter 9.3.

8 CURRENT KNOWLEDGE ON ALTERNATIVES

8.1.1 Hydraulic fluids [13,14]

One main application of TXP is its use as hydraulic fluid. Although the primary demands on hydraulic fluids are associated with the power transmission, there are many secondary demands, which include heat dissipation, environmental compatibility, lubrication, and corrosion protection (see also Table 10).

Hydraulic fluid ignition often occurs when a leak or break in the hydraulic system, usually operating at high pressures, results in a spray, stream or mist of hydraulic fluid. The fluid may then ignite if it encounters an ignition source such as electrical spark, flame or hot surface (Totten, 2000). Thus, flame retardation is also often required from hydraulic fluids.

Fire resistant fluids in general fall into two basic categories: those that derive their fire resistance from the presence of water and those that exhibit fire-resistant qualities because of their chemical composition or molecular structure. Hydraulic fluids (HF) are a large group of liquids made of many kinds of chemicals. There are different types of hydraulic fluids on the market. Fire-resistant hydraulic fluids are classified by composition according to ISO 6734/4 (Lubricants, industrial oils and related products).

[13] www.substech.com (Substances&Technologies, a free and open knowledge source in Materials Engineering)

[14] Rudnick, 2013

Table 8: ISO classification of fire-resistant hydraulic fluids (Totten, 2000)

Fluid classification	Fluid description
HFAE	Oil-in water emulsions, typically more than 80% water content
HFAS	Chemical solutions in water, typically more than 80% water content
HFB	Water-in-oil emulsion
HFC	Water-polymer solutions, typically less than 80% water (water-glycol fluids)
HFDR	Water-free synthetic fluids consisting of phosphate esters
HFDS	Water-free synthetic fluids consisting of chlorinated hydrocarbon
HFDT	Water-free synthetic fluids consisting of mixtures of HFDR and HFDS
HFDN	Water-free synthetic fluids of other composition than HFDR or HFDS or HFDT
HFDU	Polyol-ester type

Mineral based oils are the most common and low cost hydraulic fluids. Disadvantages are low fire resistance, toxicity and low biodegradability. Phosphate ester based (synthetic) hydraulic fluid (HFDR) possess excellent fire resistance, however they are not compatible with paints, adhesives, some polymers and sealant materials. Polyol ester based synthetic hydraulic fluids (HFDU) are also fire resistant and possess very good lubrication properties but their use is limited by higher costs. Water glycol synthetic hydraulic fluids (HFC) also possess excellent fire resistance, are non-toxic and biodegradable but their temperature range is relatively low and water evaporation has to be considered. Vegetable hydraulic oils have very good lubrication properties and high viscosity index and they are non-toxic and biodegradable. However they have relatively low oxidation resistance.

In general ester based fluids (phosphate esters, polyol esters) have performance and/or safety advantages[15]. They all share the characteristics of being fire resistant and having high flash and fire points as well as high auto ignition temperatures and low heats of combustion, plus having good oxidative stability and extreme pressure wear characteristics. TXP belongs to the group of phosphate esters. In the following potential substitutes of TXP by other phosphate esters or polyol esters are further discussed in more detail.

[15] http://www.fluidcenter.com/phosphate.html

Phosphate esters – Triarylphosphates:

The desired combination of fire resistance (resistance to ignition and burning) and lubrication characteristics are the most important performance parameters associated with phosphate esters and are responsible for their wide use in industrial applications.

Phosphate esters meet most current fire-resistance requirements which arise from the presence of phosphorus in the molecule and they are self-extinguishing when the source of ignition is removed. But only the trisubstituted neutral esters of orthophosphoric acid (triaryl-, trialkyl, alkyl aryl phosphates) have found significant use as synthetic basestocks. Triarylphosphates (like TXP, IPPP, TBPP) have advantages over other phosphate esters. They have the best thermal and oxidative stability and they have boiling points about 400°C and above at atmospheric pressure. In the practical application and use the management of hydrolysis is normally the most important control element as this is the dominant cause of deterioration of phosphate-ester fluids. TXP, IPPP and TBPP normally readily pass the typical limits.

According to industry in certain circumstances tert-butylated triphenyl phosphate (BuTTP, CAS 68937-40-6, EC 273-065-8) may be an alternative hydraulic fluid or additive instead of TXP (Environment Agency Austria. Enquiry, 2013). BuTTP is recommended for use as hydraulic fluid and for production of PVC and flexible foam[16]. The substance is registered for use in lubricants, lubricant additives, greases and metal working fluids as well as starting material for polymer foam production (dissemination database). While BuTTP seems to be one of the least hazardous in the group of phosphate esters (see Table 9, based largely on self-classification) there remain some concerns with potential neurotoxicity and sensitising properties.

[16] http://www.pefrcnet.org/application_examples.asp

Table 9 : Overview on the most common triaryl phosphates used as hydraulic fluid

Substance	CAS	Harmonized Classification	Self-Classification	Environmental risk evaluation UK	Current uses (according to risk evaluation report UK)
TXP	25155-23-1	Repr. 1B	Eye Irrit. 2 Skin Sens. 1B STOT RE. 2 Aquatic Acute 1 Aquatic Chronic 1		*See this Annex XV dossier*
TBPP (tris(2,3-dibromopropyl) phosphate)	126-72-7	No harmonized classification	Acute Tox 4 Skin Irrit 2 Carc 1B Aquatic Acute 1 Aquatic Chronic 1	-	- prohibited by Directive 79/663/EEC for textiles coming into contact with skin

Isopropylphenyl diphenyl phosphate (IPDPP)	28108-99-8	No harmonized classification	Not classified	Readily biodegradable does not meet the P or B criteria proposed classification as R50/53 (corresponding to Aquatic Acute 1 and Chronic 1 H400/H410)	PVC products, polyurethanes, textile coatings, adhesives, paints and pigment dispersions, thermoplastics. Lubricants (additives and base fluids)
tris-(isopropylphenyl) phosphate (IPPP)	26967-76-0		No notification to C&L inventory	Meets the P,B and T criteria (P on the basis of screening data only)	
Phenol, isopropylated, phosphate (3:1)	68937-41-7		Skin Sens. 1 Repr. 2 STOT RE 2 Aquatic Chronic 2		

BuTTP (Phenol, isobutylated, phosphate (3:1))	68937-40-6	No harmonized classification	Aquatic Chronic 1	It does not meet the P or B criteria a lack of adequate data to assess skin sensitizing potential or carcinogenicity proposed classification as R50/53 (corresponding to Aquatic Acute 1 and Chronic 1 H400/H410)	Retardant in engineering, thermoplastics and as a fire-resistant hydraulic fluid [17]

[17] http://a0768b4a8a31e106d8b0-50dc802554eb38a24458b98ff72d550b.r19.cf3.rackcdn.com/scho0809bqui-e-e.pdf

Polyol esters:

Polyolester oil (POE) is a type of synthetic oil formed by the reaction of saturated mono-carboxylic fatty acids with polyhydric alcohols. The most common polyol esters are neopentyl glycol ester, trimethylol propane ester, pentaerythritol ester and dipentaerythritol ester. Polyol esters are good lubricants and additives impair fire resistance by giving the synthetic ester self-extinguishing properties that stop flame propagation. Flash, fire and auto ignition temperatures are very high compared with mineral oils (Totten, 2000). POEs are structurally very similar to natural occurring glycerides found in living systems and in general they are highly biodegradable and provide low ecotoxicity. One negative aspect of POE oils is that they are substantially more hygroscopic than mineral oils (Orszulik, 2008; Lugt, 2012; Bell, 2007; Skoog, 2010).

Polyol esters are compatible with most lubricants at the market and they can operate at temperatures up to 250°C. Therefore they are commonly used for high temperature and high speed applications (Lugt, 2012).

Polyol esters are currently used in refrigeration compressors (replacement of chlorinated hydrofluorocarbons) and in jet turbine engines (Bell, 2007). They are lubricant base fluid for gas turbine oils and may be used for engines, compressors, as gear oil, hydraulic fluid, metal working and rolling oils (Priolube®) (Ash, 2004). They are also offered by the automotive industry as lubricant[18] and for use in rotary screw and vane compressors[19].

Two examples of registered polyol esters with uses a.o. as lubricants and hydraulic fluids are:

Decanoic acid, ester with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol octanoate (CAS 11138-60-6)

Fatty acids, C5-10, esters with dipentaerythritol (CAS 70983-72-1)

They do not have a harmonized classification and have been notified to the C&L inventory as “not classified”, which indicates their benign health and environmental characteristics as compared to other alternatives.

Conclusion:

BuTTP is recommended by industry as possible alternative substance. The substance seems to be the least problematic substance out of the triarylphosphates listed in Table 9. BuTTP has been registered and the submitted data indicate some concern for sensitisation and neurotoxicity, however this has not been evaluated in detail. Polyol esters are attractive due to their predicted low toxicity and good biodegradation. The selection of appropriate alternatives to TXP in general may depend on the characteristics needed (see Table 10). Thermal and chemical stability, compressability, hydrolytic stability, flash point, compatibility with materials, etc. may be important properties to be considered. Additives can be used to improve the anti-friction, chemical and physical properties.

[18] http://www.supercool.ac/products/lubricants/

[19] http://www.ecompressedair.com/compressor-oils/cross-referenced-by-type/polyol-ester-(poe)/iso-grade-68-polyol-ester-oil-(5-gal).aspx

Table 10 : Relative evaluation of viscosity, stability, lubricity and environmental impact (Pawlak, 2003)

Parameter	Phosphate esters	Polyol esters	Mineral oil
Viscosity			
Low temp.	fair/good	very good	fair/good
High temp.	good	good	good
Viscosity index	fair/good	very good	good
Stability			
Thermal	fair	good	good
Oxidative	good	excellent	fair
Hydrolytic	fair	fair	excellent
Volatility	fair/good	good	poor/fair
Lubricity			
No additives	excellent	fair	good
With additive	excellent	good	excellent
Fatigue life	fair	fair/good	fair/good
Environmental performance			
Low toxicity	poor/fair	good	good
Biodegradability	fair	excellent	fair

8.1.2 Flame retardants in Plastics

Flame retardants are a heterogenous group of chemicals with different chemicals properties and different effects on health and the environment. They are able to interrupt the "life cycle of fire" by different mechanisms (Papazoglou, 2004):

- Gas phase mechanism: flame retardant is a radical scavenger that bonds the oxygen or hydroxyl radicals present in the gas phase (e.g. halogenated chemicals).
- Cooling: the flame retardant decomposes in an endothermic reaction and cools the combustion environment and therefore also slows down reaction pathways (e.g. hydrated minerals like alumina trihydrate and magnesium hydroxide).
- Dilution of oxygen concentration: Release of inert gases in a fire environment diluted the active oxygen concentration and decelerates the reaction pathways.
- Solid phase mechanism: (1) cross-linking reactions in the polymer matrix that create an effective barrier to heat transfer and diffusion of gases (e.g. Silicon or phosphorus containing chemicals). (2) Formation of a porous carbonaceous char by the combined action

of a carbon source, a blowing agent/gas release and a catalyst (e.g. systems of alcohols + ammonium compounds + phosphorous compounds).

It is assumed that the mechanism and efficiency of phosphorous flame retardants are influenced and can be optimized by modifying the flame retardant using synergists and adjuvants and by changing the polymeric material (Schartel, 2010).

Aryl phosphate esters themselves are potential replacement for other flame retardants that have already been identified as a risk to health or the environment. They are increasingly successful as halogen-free alternative for various polymeric materials and applications (Environment agency UK, 2009).

TXP is also registered as flame retardant used during the manufacture of plastic products. Furthermore, there is some indication that TXP may be used in consumer products like wire/cable insulation and fire-retardant artificial leather. Artificial leather is normally made by the use of PU or PVC. Therefore alternatives for the use in these materials are also discussed here in general.

Commercially available flame retardants for plastics can be grouped in hydrated minerals, halogenated materials, antimon trioxide, phosphorous additives and intumescent flame retardant systems (foam formation) (Papazoglou, 2004). A short overview on representative chemicals (especially for PU and PVC applications) is given in Table 11. Halogenated materials are not discussed as possible alternatives due to their known hazardous properties.

Table 11 : Examples of common flame retardants in plastics

Substance	**CAS**	**Harmonized Classification**	**Self-Classification (summary of entries)**
Hydrated Minerals			
Aluminium hydroxide	21645-51-2	No harmonized classification	Skin Irrit. 2 Eye Irrit. 2 STOT SE 3
Magnesium Hydroxide	1309-42-8	No harmonized classification	Acute Tox. 4 Skin Irrit. 2 Eye Irrit. 2 STOT SE 3
Antimon trioxide			
Antimon trioxide	1309-64-4	Carc. 2	Eye Dam. 1 Acute Tox. 4 STOT RE 2 Repr. 1A

			Aquatic Chronic 2
Phosphorous Additives			
isopropylphenyl diphenyl phosphate	28108-99-8	No harmonized classification	Not classified
2-ethylhexyl diphenyl phosphate	1241-94-7	No harmonized classification	Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1
isodecyl diphenyl phosphate	29761-21-5	No harmonized classification	Aquatic Acute 1 Aquatic Chronic 1
tert-butylphenyl diphenyl phosphate	56803-37-3	No harmonized classification	Acute Tox. 4 Aquatic Acute 1
tetraphenyl m-phenylene bis(phosphate)	57583-54-7	No harmonized classification	Aquatic Chronic 2
triphenyl phosphate	115-86-6	No harmonized classification	Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1
triisobutyl phosphate	126-71-6	No harmonized classification	Skin Irrit. 2 Skin Sens. 1 Eye Irrit. 2 Resp. Sens. 1 Aquatic Chronic 3
diphenyl tolyl phosphate	26444-49-5	No harmonized classification	Acute Tox. 4 STOT SE 2 Aquatic Acute 1 Aquatic Chronic 1
tert-butylphenyl diphenyl phosphate	56803-37-3	No harmonized classification	Acute Tox. 4 Aquatic Acute 1

Nanocomposites constitute a relatively new development in the area of flame retardancy and can offer significant advantages compared to traditional approaches. The most common nanocomposites are polymer layered silicate structures.

Conclusion:

For the use of TXP in plastic products there are a number of alternatives available, the choice of which depends on the conditions of manufacture (temperature), the acting principle and on the compatibility of the flame retardant with the plastic material and product properties.

8.1.3 Applications with currently no alternatives to TXP

According to information obtained from industry (Environment Agency Austria. enquiry, 2013) no alternatives are currently available for the use of TXP in electro-hydraulic control valve systems in nuclear facilities.

Lubricants in nuclear applications must be able to withstand radiation without significant deterioration and be nonreactive toward reactor materials of construction. Past studies of resistance to radiation for alkyl and aryl phosphates indicated that they were not very stable in such an environment and degrade to form significant amounts of acid (indicator of oxidative and hydrolytic breakdown). Studies with triarylphosphates investigated hydrolytic and oxidation stability as well as physical properties and radiation level of the fluid (radiation level should still be low enough not to require disposal as special waste) after exposure to gamma radiation. The stability of TXP sample is thought adequate for service operation (Totten, 2000).

9 RISK-RELATED INFORMATION – HUMAN HEALTH

9.1 Human Health Effect Assessment

The information on no effect levels for long-term systemic effects of TXP according to the dissemination database[20] is shown in Table 12. For more detailed information on route-to-route extrapolation and assessment factors see confidential Annex III, Chapter 6.

Table 12: DNEL values for workers according to registration

Derived no effect level	
DNEL dermal, long-term, systemic	3.33mg/kg bw/day
DNEL inhalation, long-term, systemic	0.47mg/m^3

The registrants did not derive DNELs for consumers as no exposure is assumed.

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

9.2 Risk characterisation – Human Health

9.2.1 Workers

There is occupational exposure to TXP (see Chapter 7 and Annex III, Chapter 4). The highest worker exposure (dermal and inhalation) is estimated by ECETOC TRA v2 (partly in version v3) in industrial settings for mixing (PROC 5),transfer (PROC 8b), use in closed batch and other batch processes (PROCs 3 and 4), calendering operations (PROC 6), industrial spraying (PROC 7), and roller application or brushing (PROC 10) and for PROC 11 (spraying) for professionals.

According to registrants risk management measures are necessary and in place to reduce exposure. After consideration of all RMMs including personal protection and reducing exposure duration risk characterisation ratios are generally below 1. Further details and examples are given in Annex III, Chapter 7).

9.2.2 Consumers

No consumer uses have been registered. According to the registrants a risk characterisation for consumers is not applicable for the registered uses.

One study (ARCADIS, 2011) indicates that TXP may be used in consumer articles. ARCADIS performed a tentative risk characterisation for the use of TXP in consumer articles. Service life of wire/cable and furniture made of artificial leather, for which flame retardant are commonly used, were chosen for the estimation of consumer exposure. No specific information on the use of TXP for these applications could be provided by the authors. Three sub-scenarios resulted in a risk for consumers; details are shown in Table 13. DNEL´s (consumers) used for this risk characterisation are about 2 orders of magnitude lower than the DNEL´s (workers) used by the registrants (see also Annex III, Chapter 6).

Table 13 : Tentative risk assessment for consumer exposure to TXP (ARCADIS, 2011)

Exposure scenario	Route of exposure	Exposure estimate	DNEL*	RCR
Service life of furniture and service life of wire and cable - Saturated vapour concentration (SVC)	Inhalation	0.014 mg/m^3	0.012 mg/m^3	1.2
Service life of furniture - airborne particulates	Inhalation	0.0525 mg/m^3	0.012 mg/m^3	4.4
Service life of	Dermal	36.5 mg/kg/d	0.007 mg/kg/d	5214

furniture				

* Based on dose-related systemic toxicity and effects on reproductive organs in male and female animals in a combined repeated dose/repro/dev toxicity screening study (exposure time 33/48d) with a LOAEL of 25mg/kg bw. For further details see ARCADIS, 2011.

The presented exposure and risk assessments for the service life of wire/cables and furniture are Tier 1 estimates and considered to be conservative in principle. Referring to the service life of wires and cables, inhalation was estimated to be the most relevant route. The derived RCR was 1.2. The applied exposure model is based on the assumption of saturated air concentration. RCRs below 1 are considered to be more likely under realistic conditions, e.g. if natural ventilation in rooms and other phenomena decreasing the air concentration (e.g. absorption) are taken into account.

Referring to exposure scenario “service life of furniture” an RCR of 4.4 was derived for the inhalation route (considering airborne particulates (dust)) and 5214 for the dermal route (ECETOC TRA (AC6: leather articles, furniture with a max. conc. of 25%)).

The RCR of 4.4 is based on an exposure model assuming that the total amount of dust in indoor air in living areas is TXP due to the lack of data. It is conceivable, that this assumption is likely to be an overestimation and might not fully apply to real conditions. The RCR of 5214 for dermal exposure is significantly above 1. Some relevant aspects resulting in lower exposure levels are not taken into account and could be considered for refinement (e.g. the dislodgeable fraction (transfer of substance from surface to skin). It depends also on the intensity of dermal contact, contact time, concentration, matrix of polymers etc. Given the magnitude of this RCR, a risk cannot be excluded at this stage. However, exposure levels may be highly overestimated in this study.

While the use of TXP as flame retardant in consumer products is possible in principle, the study does not provide evidence that TXP actually is contained in products on the EU market. Apart from this, it is emphasized that the model assumptions used for this study are very conservative and therefore the derived RCRs are questionable.

The potential use of TXP in consumer articles is not supported by the registration. Indications that such uses may result in unacceptable risk are insufficiently evident.

9.3 Risk characterisation - Environment

The present dossier is based solely on concerns for the potential hazards and risks for human health, in particular workers, exposed to TXP. Risks for the environment remain to be carefully assessed. Currently, the PBT status of TXP is analysed by the PBT expert group of ECHA.

Based on available information the registrants propose a self-classification for TXP as H400 and H410 (very acute and chronic toxic to the aquatic life). This finding relies on chronic data for invertebrates while a chronic fish test has been waived. Based on invertebrate data, the registrants derive a PNEC of 0,3 µg/l (freshwater). No PNEC for sediment could be derived because of lack of data. The registrants’ release estimates for the environment purely rely on model calculations (CHESAR). The registrants generally assume for all considered exposure scenarios that waste water is treated on-site with 90% efficiency and that all waste is contained and disposed of as hazardous waste (incinerated). It is thus assumed that there is no significant release to the environment and that all relevant risk ratios are significantly below one.

A risk assessment for TXP carried out by UK (RAR UK, 2009) concludes that TXP may actually be released to the aquatic environment from processes such as manufacturing and formulation. Local

PEC values for surface waters are in the range of ca. 1-4 µg/l for production processes, and significantly lower (factor of 10^{-1} or lower) for formulation processes. These findings are quantitatively supported by monitoring data sampled from British rivers and sewage treatment plants.

Given the relatively weak basis for the derivation of PNECs and the contradiction between the assumptions of the registrants and the UK exposure estimates an in-depth assessment would be required to quantitatively verify the risks derived for the environment.

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ANNEX I

SUPPLEMENTARY INFORMATION ON HUMAN HEALTH AND ENVIRONMENTAL HAZARDS

In addition to the harmonized classification more than 300 C&L notifications received in the C&L inventory[21] display hazards for several endpoints. A summary is given in Table 14.

Table 14: Self classification for TXP in addition to its impairment of fertility.

Hazard Class and Category Code(s)	Hazard Statement Code(s)
Eye Irrit. 2	H319 (Causes serious eye irritation)
Skin Sens. 1B	H317 (May cause an allergic skin reaction.)
STOT RE. 2	H373 (May cause damage to organs (Affected organs: adrenals, testes, epididymides, ovaries, liver (females only))
Aquatic Acute 1	H400 (Very toxic to aquatic life.)
Aquatic Chronic 1	H410 (Very toxic to aquatic life with long lasting effects)

1 NEUROTOXICITY

Organophosphorus compounds are potent neurotoxic chemicals. The primary action is the irreversible inhibition of acetylcholinesterase (AChE), resulting in the accumulation of acetylcholine and subsequent overstimulation of the nicotinic and muscarinic acetylcholine receptors (Abou-Donia, 2003). According to Nannen, 2004 and US EPA, 2010 TXP also inhibits AChE indicating evidence of neurotoxicity.

2 REPEATED DOSE TOXICITY

A combined oral repeated dose and reproductive/developmental toxicity study (Experimur, 2004 as cited in RIVM, 2009) has been carried out with Sprague-Dawley rats (Experimur, 2004) using Trixylylphosphate (Phosflex TXP, purity 99%) administered in a vehicle of corn oil. The study was conducted under GLP and according to OECD guideline 422, using doses of 0, 25, 200 and 1,000 mg/kg bw/day, administered by oral gavage. Groups of eleven rats/sex were exposed at each treatment level, from 2 weeks prior to mating throughout gestation and lactation. Males were dosed

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

for 33 days in total, females for 48 days. The control and high-dose groups included five additional animals/sex, which were used for recovery experiments (3 weeks for females and 4 weeks for males).

No relevant effects were observed on food intake, body weight, clinical observations or functional performance and motor activity. Significant changes in mid- and high-dose groups of both sexes were observed in clinical chemistry, including changes in cholinesterase, alkaline phosphatase and alanine aminotransferase. Except for changes in calcium and phosphatase levels, all changes were completely reversed in the recovery animals.

At 200 and/or 1000 mg/kg bw/day, absolute weight of adrenals, ovaries and liver was increased, whereas weight of the testes, heart and epididymides was significantly decreased. In females, absolute and relative weight of the adrenals was also increased at the lowest dose level (25 mg/kg bw/day). All effects on organ weights were dose-related. In recovery animals, only the liver weight of females was still significantly increased. In both sexes, the weight changes of the reproductive organs were combined with histological changes. In males there was evidence at all dose levels of degeneration of the germinal epithelium of the testes, combined with sloughed epithelial cells in the lumen of the epididymides. In females, mild diffuse hyperplasia of the interstitial cells of the ovaries was observed at all dose levels. Furthermore, histological analysis revealed diffuse cytoplasmic vacuolation of the adrenals in males at all dose levels and females at 200 and 1000 mg/kg bw/day, and mild fatty degeneration of hepatocytes in mid- and high-dosed females. The incidence and severity of all histological changes was decreased in the recovery groups, indicating a reversible mechanism of effects.

Since the histological effects in the adrenals are already present following administration of the lowest dose (25 mg/kg bw/day), a NOAEL cannot be derived based on this study. **LOAEL = 25mg/kg bw/day** (RIVM, 2009).

3 TOXICITY FOR REPRODUCTION

Effects on fertility

In the combined oral repeated dose and reproductive/developmental toxicity study with Sprague-Dawley rats (Experimur, 2004), rats were exposed by oral gavage to doses of 0, 25, 200 or 1,000 mg/kg bw/day of Trixylyl Phosphate from 2 weeks prior to mating throughout gestation and lactation. There was no effect on mating. Gravidity and successful parturition was observed in all animals from the control and low dose group (25 mg/kg bw/day), but was reduced in animals from the mid dose group (200 mg/kg bw/day), where only 2/11 dams underwent parturition. In the high dose group (1000 mg/kg bw/day), none of the ten mated females underwent parturition. Analysis of the uterus revealed only 2 gravid animals in the high dose group, and no additional gravid animals in the mid dose group (besides the 2 that underwent parturition), indicating that the reduced pregnancy rate is mainly the result of decreased fertility and not postimplantation loss.

To determine the cause for the adverse effects on pregnancy observed in the core groups, additional animals from the control and high dose group were left to recover from the trixylyl phosphate exposure. Male recovery rats from the high dose group were used for cross over mating with naïve control females, and recovered rats from the high dose and control groups were used for within group mating. Following both cross over mating and within-group mating, no effects were observed on pregnancy or parturition, suggesting that the effects on fertility are reversible (RIVM, 2009).

Developmental toxicity

In the combined oral repeated dose and reproductive/developmental toxicity study with Sprague-Dawley rats no effects were found on litter size, survival or body weight of the offspring at 25 and 200 mg/kg bw/day. However, a reduced male:female ratio was observed in the highest dose group that resulted in successful parturition. Nevertheless, this is based on only 2 litters in the 200 mg dose group. The reduction in the number of litters at 200 and 1000 mg/kg bw is not considered to be an effect on development because in most cases there were no implants. Except for gross abnormalities, pups were not analysed for e.g. malformations or skeletal retardations (RIVM, 2009).

Conclusions on reproductive toxicity:

Based on **reproductive outcome** RIVM, 2009 established a **NOAEL of 25 mg/kg bw/day**. However, since histological changes in reproductive organs were already observed at the lowest dose level (25 mg/kg bw/day), for **effects on reproductive organs** only a **LOAEL** could be established (**25 mg/kg bw/day**) (RIVM, 2009).

4 PBT-ASSESSMENT

TXP is a proven persistent[22] and toxic[23] substance. For the PBT and vPvB assessment a screening criterion has been established, which is log K_{ow} > 4.5 as then the substance is potentially B or vB. The log K_{ow} of TXP is >6.2. However, based on QSARs and read-across the registrants claim that TXP is not considered as fulfilling the B-criterion. Further investigation will be carried out in the PBT WG at ECHA.

[22] Due to being not readily biodegradable, and having no significant mechanism of hydrolysis the substance is considered to be persistent (dissemination database).

[23] On the basis of effects noted in fish and Daphnia, the substance is deemed to be classified with H400 and H410. The substance is also classified as having concern for reproductive toxicity (dissemination database).

ANNEX II

USES ACCORDING TO REGISTRATION DATA (DISSEMINATION DATABASE)

Table 15: Uses by workers in industrial settings

Identified use name **Tonnages used**	**Substance supplied to that use**	**Use descriptors**
Manufacture of TXP	as such (substance itself)	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 15: Use as laboratory reagent **Market sector by type of chemical product:** PC 16: Heat transfer fluids PC 21: Laboratory chemicals PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents PC 0: Other: solvent PC 24: Lubricants, greases, release products PC 17: Hydraulic fluids

		PC 25: Metal working fluids **Environmental release category (ERC):** ERC 1: Manufacture of substances **Sector of end use (SU):** SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) **Subsequent service life relevant for that use?:** yes
Formulation of Lubricants, Lubricant additives, Greases and metal working fluids with of trixylyl phosphate	as such (substance itself)	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 15: Use as laboratory reagent **Market sector by type of chemical product:** PC 17: Hydraulic fluids PC 24: Lubricants, greases, release products **Environmental release category (ERC):** ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles

		Sector of end use (SU): SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment **Subsequent service life relevant for that use?:** yes
General industrial use of lubricants and greases in vehicles or machinery with trixylyl phosphate, CAS 25155-23-1. Includes filling and draining of containers and enclosed machinery.	in a mixture	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) **Market sector by type of chemical product:** PC 24: Lubricants, greases, release products **Environmental release category (ERC):** ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles **Sector of end use (SU):** SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment **Subsequent service life relevant for that use?:** yes
Application of lubricant to work pieces or equipment by dipping, brushing or spraying (without exposure to heat), e.g. mould releases, corrosion protection, slideways with trixylyl phosphate, CAS 25155-23-1	in a mixture	**Process category (PROC):** PROC 7: Industrial spraying PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers

		(dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring **Market sector by type of chemical product:** PC 24: Lubricants, greases, release products **Environmental release category (ERC):** ERC 9a: Wide dispersive indoor use of substances in closed systems **Sector of end use (SU):** SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment **Subsequent service life relevant for that use?:** yes
Use of lubricants in high energy open processes, e.g. in high speed machinery such as metal rolling / forming or metalworking fluids for machining and grinding with trixylyl phosphate, CAS 25155-23-1	in a mixture	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 17: Lubrication at high energy conditions and in partly open process **Market sector by type of chemical product:** PC 25: Metal working fluids **Environmental release category (ERC):** ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles **Sector of end use (SU):** SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment **Subsequent service life relevant for that use?:** yes

Use at industrial site – Industrial use of trixylyl phosphate, CAS 25155-23-1 within Polymer Mixtures and Compounds – Plastics Manufacture. Manufacturing and use of plastic products within an industrial environment	in a mixture	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles PROC 7: Industrial spraying PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 6: Calendering operations PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles **Market sector by type of chemical product:** PC 32: Polymer preparations and compounds **Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix **Sector of end use (SU):** SU 12: Manufacture of plastics products, including compounding and conversion **Subsequent service life relevant for that use?:** yes

Table 16: Use by professional workers

Identified use name	Substance supplied to that use	Use descriptors
Use of Lubricants, lubricant additives, Greases and metal working fluids used by professionals with trixylyl phosphate, CAS 25155-23-1	in a mixture	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 20: Heat and pressure transfer fluids in dispersive, professional use but closed systems **Market sector by type of chemical product:** PC 17: Hydraulic fluids **Environmental release category (ERC):** ERC 9a: Wide dispersive indoor use of substances in closed systems **Sector of end use (SU):** SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment **Subsequent service life relevant for that use?:** yes
Application of lubricant to work pieces or equipment by dipping, brushing or spraying (without exposure to heat), e.g. mould releases, corrosion protection, slideways with trixylyl phosphate, CAS 25155-23-1	in a mixture	**Process category (PROC):** PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 10: Roller application or brushing PROC 11: Non industrial spraying PROC 13: Treatment of articles by dipping and pouring **Market sector by type of chemical product:** PC 25: Metal working fluids **Environmental release category (ERC):** ERC 9a: Wide dispersive indoor use of substances in closed systems

		Sector of end use (SU): SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment **Subsequent service life relevant for that use?:** yes
Use of lubricants in high energy open processes, e.g. in high speed machinery such as metal rolling / forming or metalworking fluids for machining and grinding with trixylyl phosphate, CAS 25155-23-1	in a mixture	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 17: Lubrication at high energy conditions and in partly open process **Market sector by type of chemical product:** PC 25: Metal working fluids **Environmental release category (ERC):** ERC 8a: Wide dispersive indoor use of processing aids in open systems **Sector of end use (SU):** SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment **Subsequent service life relevant for that use?:** yes

ANNEX III

CONFIDENTIAL DATA