Annex XV dossier

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR CAT 1 OR 2, PBT, vPvB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance Name: Tris (2-chloroethyl) phosphate

EC Number: 204-118-5

CAS Number: 115-96-8

- *It is proposed to identify the substance as a CMR according to Article 57 (c).*

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

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EC Number: 204-118-5

CAS number: 115-96-8

- *It is proposed to identify the substance as a CMR according to Article 57 (c).*

Summary of how the substance meets the CMR (Cat 1 or 2), PBT or vPvB criteria, or is considered to be a substance of an equivalent level of concern

According to Article 57 (c) of Regulation 1907/2006 (the REACH Regulation) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC may be included in Annex XIV. Tris (2-chloroethyl) phosphate (TCEP) has been classified as toxic to reproduction (Repr. Cat. 2) according to Directive 67/548/EEC by Commission Directive 2009/2/EC amending, for the purpose of its adaptation to technical progress, for the 31st time, Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

Therefore, TCEP meets the criteria for classification as toxic for reproduction category 1 or 2 under Directive 67/548/EEC and accordingly may be included in Annex XIV.

This classification as Repr. Cat. 2 will also be included in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 by a Commission Regulation amending, for the purposes of its adaptation to technical progress, for the first time Regulation 1272/2008. This Commission Regulation was adopted on 10 August 2009 (publication and entry into force of this Regulation is expected to be in September/October 2009).

The corresponding classification in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (list of harmonised classification and labelling of hazardous substances) will be Repr. 1B.

Registration number(s) of the substance or of substances containing the substance:

Not available.

JUSTIFICATION

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

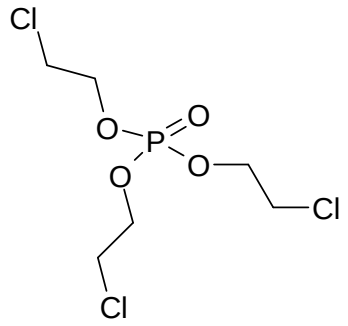
1.1 Name and other identifiers of the substance

Chemical Name:	Tris(2-chloroethyl) phosphate
EC Name:	204-118-5
CAS Number:	115-96-8
IUPAC Name:	Tris(2-chloroethyl) phosphate

1.2 Composition of the substance (EU RAR draft, 2008)

TCEP is physically and not chemically bound within the polymer matrix.

Chemical Name:	Tris(2-chloroethyl) phosphate
EC Number:	204-118-5
CAS Number:	115-96-8
IUPAC Name:	Tris(2-chloroethyl) phosphate
Molecular Formula:	$C_6H_{12}Cl_3O_4P$
Structural Formula:	



Molecular Weight:	285.49 g/mol
Typical concentration (% w/w):	Degree of purity > 99.5 % (w/w)
Concentration range (% w/w):	-
Identity and percentage (w/w) of impurities:	water
Additives	-

1.3 Physico-chemical properties

Table 1: Summary of physico- chemical properties, from EU RAR draft (2008)

REACH ref Annex, §	Property (IUCLID 5 section)	IUCLID 5 section	Value	[enter comment/reference or delete column]
VII, 7.1	Appearance/physical state/colour	4.1	liquid	
VII, 7.2	Melting point/freezing point	4.2	< -70 °C	Akzo Nobel (10.05.2000)
VII, 7.3	Boiling point	4.3	decomposition at 320 °C at 1013 hPa	Akzo Nobel (06.07.2000)
VII, 7.4	Density	4.4	1.4193 g/cm^{3}at 25 °C	Akzo Nobel (15.06.2000)
VII, 7.5	Vapour pressure	4.6	43 Pa at 136.9 °C 0.00114 Pa at 20 °C (extrapolated)	Akzo Nobel (06.07.2000)
VII, 7.6	Surface tension	4.10	not determined	
VII, 7.7	Water solubility	4.8	7820 mg/l at 20 °C	Hazelton Europe (18.04.1994)
VII, 7.8	Partition coefficient	4.7 partition coefficient	logPow = 1.78	Hazleton Europe (20.04.1994)
VII, 7.9	Flash point	4.11	200 °C at 1013 hPa	Courtaulds Chemicals (1996)
VII, 7.12	Auto flammability	4.12	480 °C	Hoechst AG (1994)
VII, 7.10	Flammability	4.13	not extremely flammable not highly flammable not flammable	CHEMSAFE
VII, 7.11	Explosiveness	4.14	not explosive (structural reasons)	
VII, 7.13	Oxidizing properties	4.15	not oxidizing (structural reasons)	

2 MANUFACTURE AND USES

Not relevant for this type of dossier.

3 CLASSIFICATION AND LABELLING

3.1 Classification in Annex VI of Regulation (EC) No 1272/2008

According to Article 57 (c) of the REACH Regulation, substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC may be included in Annex XIV. The classification of tris (2-chloroethyl) phosphate (TCEP) according to Directive 67/548/EEC was updated by the 31st Adaptation to Technical Progress (31st ATP; Commission Directive 2009/2/EC)[1] as follows:

Index Number: 015-102-00-0

Classification

Carc. Cat. 3; R40

Repr. Cat. 2; R60

Xn; R22

N; R51-53

Labelling

T; N

R: 60 – 22 – 40 – 51/53

S: 53 – 45 – 61

Specific concentration limits: none

This classification will be included in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008[2] by a Commission Regulation amending, for the purposes of its adaptation to technical progress, for the first time Regulation 1272/2008. This Commission Regulation has been adopted on 10 August 2009 (publication and entry into force of this first ATP is expected to be in September/October 2009[3]).

[1] COMMISSION DIRECTIVE 2009/2/EC of 15 January 2009 amending, for the purpose of its adaptation to technical progress, for the 31st time, Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

[3] Pursuant to Article 53(1) of Regulation 1272/2008 this Commission Regulation was adopted in accordance with the regulatory procedure with scrutiny involving both the Council of the EU and the European Parliament.

According to the first ATP to Regulation (EC) No 1272/2008, the corresponding classification in Annex VI, part 3, Table 3.1 of this Regulation (EC) No 1272/2008 (list of harmonised classification and labelling of hazardous substances) will be as follows:

Index Number: 015-102-00-0

Hazard Class and Category Code(s):

Carc. 2

Repr. 1B

Acute Tox. 4 *[4]

Acute Tox. 4 *

Aquatic Chronic 2

Hazard Statement Code(s):

H351

H360F***[5]

H302

H411

3.2 Self classification(s)

Not relevant for this dossier.

[4] Minimum classification for a category is indicated by the reference * in the column "Classification" in Table 3.1.The reference * can also be found in the column 'Specific concentration Limits and M-factors' where it indicates that the entry concerned has specific concentration limits under Directive 67/548/EEC (Table 3.2) for acute toxicity. These concentration limits cannot be "translated" into concentration limits under this Regulation, especially when a minimum classification is given. However, when the reference * is shown, the classification for acute toxicity for this entry may be of special concern.

[5] In order not to lose information from the harmonized classifications for fertility and developmental effects under Directive 67/548/EEC, the classifications have been translated only for those effects classified under that Directive. These hazard statements are indicated by the reference *** in Table 3.1.

4 ENVIRONMENTAL FATE PROPERTIES

Not relevant for this type of dossier

5 HUMAN HEALTH HAZARD ASSESSMENT

5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

Not relevant for this type of dossier

5.2 Acute toxicity

Not relevant for this type of dossier

5.3 Irritation

Not relevant for this type of dossier.

5.4 Corrosivity

Not relevant for this type of dossier.

5.5 Sensitisation

Not relevant for this type of dossier.

5.6 Repeated dose toxicity

Not relevant for this type of dossier

5.7 Mutagenicity

Not relevant for this type of dossier

5.8 Carcinogenicity

Not relevant for this type of dossier

5.9 Toxicity for reproduction

5.9.1 Effects on fertility

5.9.2 Developmental toxicity

5.9.3 Human data

5.9.4 Other relevant information

5.9.5 Summary and discussion of reproductive toxicity

Based on available animal data tris(2-chloroethyl)phosphate (TCEP) is identified as reproductive toxicant. Treatment of mice resulted in significant impairment of reproductive success of both sexes and of male reproductive organs and of sperm parameters [EU RAR draft, 2008]. Therefore, TCEP is classified and labelled for its effects on fertility as **Repr. Cat. 2; R 60** according to Directive 67/548/EEC or **Repr. 1B** according to the 1st ATP of the CLP regulation (EC (No.) 1272/2008Details on reproductive toxicity: Oral administration of TCEP revealed significant impairment of reproductive capacity and fertility for both sexes during continuous breeding and for two successive generations in CD1- mice. The reproductive system of male mice appeared to be more sensitive to TCEP treatment than that of females. A significant reduction of the number of litters produced by the F0 generation, reduced pregnancy and fertility indices in the F1 generation, and reduced litter size in F0 and F1 generation. A **$NOAEL_{fertility}$** of **175 mg/kg bw/day** was derived [Mice Gulati and Chapin, 1991, cited in EU RAR draft,2008]. There are no human data on reproductive toxicity.

5.10 Other effects

Animal studies:

Specific endpoint studies considering neurotoxicity have been evaluated within the EU RAR draft, 2008 (see Chapter 4.1.2.6.1.2). Besides kidneys and liver, also the brain appeared to be one of the main sites of toxicity in animal studies after repeated oral application of tris(2-chloroethyl) phosphate (dose range 22 to 700 mg/kg bw/d in rats and up to 1500 mg/kg bw/d in mice). A dose- and sex-dependent (more severe in female rats) neuronal necrosis in the hippocampal and thalamal region of the brain was observed. The NOAEL for brain effects (hippocampal lesions) was established to be 44 mg/kg bw/day in F344 rats (NTP 1991; Matthews 1993). In an acute delayed neurotoxicity study with White Leghorn hens no evidence of neurotoxicity could be observed after two oral administrations (day 1 and 3 weeks later) of 14.2 g/kg bw/day TCEP (Stauffer Chemical Company, 1979). Key animal studies considering neurotoxic effects are summarized in TABLE 2.

Table 2: Key studies for brain toxicity data (rats, hens) after repeated exposure to TCEP Table modified from EU RAR draft, 2008

Study design: Species, strain (male/female) Exposure route Exposure duration Dose	Non-neoplastic effects (selected) at LOAEL NOAEL	Reference
F344/N rat (10m/10f) Oral Gavage 16/18 weeks (f/m), 5 d/wk 0, 22, 44, 88, 175, 350 mg/kg bw/d	350 mg/kg bw/d: mortality: 4/10 (m), 3/10 (f) periodic convulsion during week 12 (f) ↑** liver and kidney weights, rel (m) ↓ brain, thymus, abs (f) neuronal necrosis, loss of neurons in the brain (f:10/10; m: 2/10) ≥175 mg/kg bw/d: in the brain: neuronal necrosis (10/10 f) loss of neurons (8/10 f) **↓** serum cholinesterase activity (f)** ≥44 mg/kg bw/d: ↑** liver and kidney weights, rel (f) $NOAEL_{sys}$ for brain lesions: (m): 175 mg/kg bw/d (f): 88 mg/kg bw/d	NTP, 1991 Matthews, 1990
F344/N rat (10m/10f) Oral Gavage 66 weeks (interim sacrifice), 5 d/wk 0, 44, 88 mg/kg bw/d rat	88 mg/kg bw/d: ↓** AP (f), ↓** ALAT (f) ↑** liver and kidney weights, rel (m) renal tubule adenoma (1/10m) brain: local necrosis, accumulation of inflammatory cells, reactive gliosis, endothelial hypertrophy (3/10 f) $NOAEL_{sys}$ for brain lesions (f): 44 mg/kg bw/d	NTP, 1991 Matthews, 1993
F344/N rat (60m/60f) Oral Gavage 103 weeks, 5 d/wk 0, 44, 88 mg/kg bw/d rat	88 mg/kg bw/d: ↓** survival (m/f); ↑** focal hyperplasia of tubule epithelium of the kidney (m:24/50; f: 16/50) ↑** degenerative lesions in the brain (f) ↑ lesions in the brain (m) 44 mg/kg bw/d: ↑** focal hyperplasia of tubule epithelium of the kidney (m:2/50; f: 3/50) $LOAEL_{sys}$ for kidney lesions (m/f): 44 mg/kg bw/d $NOAEL_{sys}$ for brain lesions (m/f): 44 mg/kg bw/d	

White Leghorn Hens (18 test animals, 10/negativ and 10/positiv control group) Oral by stomach tube 2 treatments (on day 1 and again 3 weeks later) 0, 14200 mg/kg bw	14200 mg/kg bw: mortality (4/18) ↓** body weight cessation of egg production feather loss NOAELsys: not derived	Stauffer Chemical Company, 1979

↑**: statistically significant increase compared with controls ($p<0.01$);↑ increase compared with controls, no statistically significant but possibly of toxicological relevance; ↓**: statistically significant decrease compared with controls ($p<0.01$); m: male; f: female; AP: Alkaline phosphatase; ALAT: Alanine aminotransferase; $LOAEL_{sys}$: lowest observed adverse effect level for systemic effects; $NOAEL_{sys}$: no observed adverse effect level for systemic effects

Study not included in the EU RAR draft, 2008

Female Fisher-344 rats (age 75 days) were exposed to 275 mg/kg of TCEP by gavage (Tilson et al., 1990). A single exposure to TCEP results in a severe and specific pattern of damage to hippocampal neurons. Most pronounced was the damage to cells of the CA1 hippocampal pyramidal cells with lesser damage to CA4, CA3, and CA2 pyramidal cells. TCEP – induced seizures following a characteristic time-dependent pattern including wet-dog shakes, facial twitching, myoclonic motions of the jaws, forelimb clonus, and whole body jerks. Exposed rats were impaired in performing a repeated acquisition task in the water maze. A single dose of TCEP caused deficits in learning up to 3 weeks after exposure, Additional treatment with atropin and chlordiazepoxide showed a protective (seizure-related and neurohistological) effect.

Effects on humans:

One case study for human TCEP exposure has been mentioned within the EU RAR draft, 2008. A five year old girl developed neurogenic defects after TCEP exposure (sleeping room equipped with wood panelling treated with 3% TCEP). Shortly after the house was renovated, the clinical status improved.

A study conducted by the Austrian Umweltbundesamt (UBA 2008, Band 182) investigated the influence of indoor air pollution on children's health in nine full-time schools. Boys (n = 225) and girls (n = 224) at the age of 5 to 9 living in urban (86%) and rural (14%) environment have been included in this survey. 252 parameters (e.g. industrial chemicals, metals, volatile organic carbons) have been analyzed in air, house dust and particulate matter. TCEP was measured in house dust (n = 19, Table 16) and particulate matter PM_{10} and $PM_{2.5}$ (n = 86, Table 17). TCEP could be recovered from nearly all analyzed house dust (100%) and particulate matter samples (97% in 2006, 100% in 2007). The TCEP concentration in the household dust was in the range of 0.59 and 35 mg/kg. Cognitive skills were tested using Standard Progressive Matrices (SPM) (Spearman 1938, Raven 1938). The achieved score of the SPM test is an indicator for cognitive skills, but independent from education and socio-cultural environment. Interestingly, a high correlation was found between TCEP concentration in PM_{10}, $PM_{2.5}$ and house dust and the decline of cognitive skills (-0.69, -0.68, -0.73, n = 436, boys: girls = 50%:50%, study participation = 73.1%). However, confounding factors such as spending too much time in front of the television or lack of encouragement where not considered.

Summary:

Specific endpoint studies considering neurotoxicity have been evaluated within the EU RAR draft, 2008 (see Chapter 4.1.2.6.1.2). Besides kidneys and liver, also the brain appeared to be the main target organ of toxicity in animal studies after repeated oral application of tris(2-chloroethyl) phosphate (dose range 22 to 700 mg/kg bw/d in rats and up to 1500 mg/kg bw/d in mice). A dose- and sex-dependent neuronal necrosis in the hippocampal and thalamal region of the brain was observed, which was more severe in female rats compared to male rats. The **NOAEL** for **brain** effects (hippocampal lesions) was established to be **44 mg/kg bw/day** in F344 rats (NTP 1991; Matthews 1993). TCEP was administered orally for 103-weeks. In an acute delayed neurotoxicity study with White Leghorn hens no evidence of neurotoxicity could be observed following two oral administrations (day 1 and 3 weeks later) of 14.2 g/kg bw/d TCEP (Stauffer Chemical Company, 1979). One case study for human TCEP exposure has been mentioned within the EU RAR draft, 2008. A 5 year old girl developed neurogenic defects after TCEP exposure (sleeping room equipped with wood panelling treated with 3% TCEP). Shortly after the house was renovated, the clinical status improved. In a study conducted by the Austrian Umweltbundesamt (UBA 2008, Band 182 refer to Chapter 1.4.1.1.) a high correlation between TCEP concentrations in particulate matter (indoor: PM_{10}, $PM_{2.5}$) and house dust and the decline of cognitive skills of children has been obtained.

5.11 Derivation of DNEL(s) or other quantitative or qualitative measure for dose response

Not relevant for this type of dossier

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Not relevant for this type of dossier.

7 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for this type of dossier

8 PBT, VPVB AND EQUIVALENT LEVEL OF CONCERN ASSESSMENT

8.1 Comparison with criteria from annex XIII

8.2 Assessment of substances of an equivalent level of concern

Neurological effects of TCEP have been shown in various studies. These are summarised in Section 5.10.

8.3 Emission characterisation

8.4 Conclusion of PBT and vPvB or equivalent level of concern assessment

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

1 INFORMATION ON EXPOSURE

1.1 Production volumes

According to IPCS (1998) all commercial TCEP is produced by the reaction of phosphorus oxychloride with ethylene oxide followed by subsequent purification. TCEP was produced in 1998 in the EU15 in quantities of about 2000 t/a (EU RAR draft, 2008). Up-to-date information given by industry revealed that there is no production in Europe[6] anymore and processing has been reduced, but marketing of TCEP-containing articles and preparations is still relevant for the EU.

Past trends

According to the maximum range of production/import for 1991/1992, given in the IUCLID-database, an amount of 10.500 t/a was relevant at that time for the European market. TCEP production and use have been in decline since the 1980s as its historic use in rigid and flexible polyurethane foams and systems have been substituted by other flame retardants. According to IPCS (1998) global consumption of TCEP peaked at over 9.000 t in 1989 but had declined to below 4.000 t by 1997. In 1998, the EU tonnage was 2.040 t of which 1.950 t were produced in the EU, 580 t imported and 490 t exported.

Present situation

According to the EU RAR draft, 2008 there was no production of TCEP in the EU15 in 2001/2002. There are three companies importing a total amount of 1.150 t TCEP in the EU (partly from Russia and Poland[7]). All of these importers are exclusively traders of TCEP. No specific information on formulation or processing could be obtained. However, the importing companies provided information on fields of application of their sales. These data are used in the calculation of the environmental exposure.

A tonnage of 143 t was exported outside the EU15 in 2002. The total EU tonnage present can be estimated to be **1007 t/a**. This quantity is used in the risk assessment.

The rapporteur of the EU RAR 2008 received information from Poland[8] in 2005. This information has been provided voluntarily. It is used as additional information only. Production is estimated as 300 to 500 t for 2004, of which export to outside the EU is about 300 to 400 t for the same time period.

TCEP is also formed as a reaction by-product in the manufacture of other commercial flame retardants in which TCEP is present as impurity (Tris(2-chloro-1-methylethyl)phosphate (TCPP); Tris[2-chloro-1-(chloromethyl)ethyl]phosphate (TDCP); 2,2-bis(chloromethyl)trimethylenebis(bis(2-hloroethyl)phosphate)]). Risk assessment reports for TCPP, TDCP and V6 have been finalized under the Existing Substance Regulation program (ESR).

[6] Referring to countries of the European Union before enlargement at 1st May 2004.

[7] In the context of this Risk Assessment (EU RAR draft, 2008) , Russia and Poland are considered as being outside the EU.

[8] Accession to EU in May 2004.

This additional amount of TCEP is considered only in the calculation of the regional background concentration.

Up-dated information from Product Register Data (based on EU RAR draft, 2008 and SPIN database)

The SPIN database (Substances in Preparations in the Nordic countries) was searched for information on TCEP in products on the national markets of Norway, Sweden, Finland and Denmark. In the EU RAR draft, 2008 the information on the number of preparations and tons was indicated for the year 2001 and 2003 (Table 3). In this SVHC dossier the information provided is up-dated and concerns the years 2006 and 2007. (Table 4):

Table 3: TCEP in products according to SPIN for 2001and 2003

country	2001		2003	
	number of preparations	Tonnage	number of preparations	tonnage
Norway	13	1104	8	1285
Sweden	11	9	12	9
Finland	14	306	7	0.2
Denmark	25	190	13	4

In total 2001: 1.069,0 tons

In total 2003: 1.298,2 tons

Table 4: TCEP in products according to SPIN for 2006 and 2007

country	2006		2007	
	number of preparations	tonnage	number of preparations	tonnage
Norway	7	133,9	8	170,6
Sweden	5	48	5	47
Finland	9	271,9	9	123,8
Denmark	8	0,4	8	0,3

In total 2006: 454,2 tons

In total 2007: 341,7 tons

Within the EU RAR draft, 2008 it is mentioned, that the above tonnages (2001, 2003) seem unrealistically high compared to the total identified EU tonnage. The reason is the way the data are recorded in SPIN:

The total amount of a substance included in the SPIN database is the added quantity of the substance in all products without the amount substances exported. Therefore, if a substance is registered first as the

imported raw material and then again as part of the final preparation the quantity will be counted twice. Substances which are imported and then used for the formulation of chemical products, which is very often the case in the Nordic countries, will thus be accounted for with up to double the actual amount.

Another factor giving a distortion of the quantity value is when concentration has been registered as an interval. In such cases the upper limit has been chosen for calculations of the substance amount in Denmark, Finland and Norway. Depending on how wide the allowed interval is in the different countries the discrepancy between the given value and the true value will vary. For example, the tonnage interval given for Norway in 2001 ranges from 61 t (min) to 1.104 t (max).

Therefore, the tonnages in (Table 3, Table 4) have to be considered as overestimations.

The tonnages notified in Denmark and Finland went down considerably between 2001 and 2003. Norway showing a notably high tonnage compared to the other countries in 2001 registered an even higher tonnage in 2003. Reasons may be due to the data recording explained above. However, it has to be noted that TCEP was notified as being present in consumer products in 2001 and 2002 but not in 2003. In 2007, TCEP was notified as being present in consumer preparations in Norway (170,6 tons).

1.1.1 Estimation of TCEP quantities from pre-registration data

An excerpt from pre-registration shows that more than one-hundred companies pre-registered TCEP 335 times. In order to obtain an estimation of TCEP quantities in the next years, pre-registration data were analyzed. The results of the pre-registered tonnages and companies are summarized in Table 5.

Table 5: Estimation of TCEP Tonnages according to pre-registration data

	Total t/a
No. of companies pre-registrations	335
min t/a acc. no. of pre-registrations	10.820
max t/a acc. no. of pre-registrations	72.200
min t/a acc. no. of companies	7.217
max t/a acc. no. of companies	36.170

For pre-registration each company had to indicate the tonnage band (1-10 t/a, 10-100 t/a, 100-1.000 t/a, and 1.000+ t/a), where the actual amount of produced and / or imported TCEP will be given. For the estimation of annual tonnages each tonnage band (minimum and maximum amount) is multiplied with the number of pre-registrations or with the number of companies and then summed up to give the total amount of imported and / or produced tonnage of TCEP per year.

Very few companies have pre-registered TCEP in more than one tonnage band. To consider the fact that one company has pre-registered the same substance several times for the same tonnage band only one pre-registration for one company was taken into account to estimate the annual tonnages (Table 5.). It might be correct that one company registered several times, if the holding company is composed of different legal entities in Europe. In that case each legal entity must pre-register the phase-in substances that they produce or import (refer to Guidance on Data sharing, page 20). For the calculation of the total tonnage sum, the amount of more than 1.000 t/a was set to 1.000 t/a.

This estimate results in a minimum of **7.200 t/a** and a maximum of 72.000 t/a of TCEP imported and/ or produced in Europe. Even the minimum tonnage estimate is significantly higher than the total EU

tonnage of **1.007 t/a**, which was used in the risk assessment (EU RAR draft, 2008). It should be considered, that tonnages from pre-registration data are highly uncertain.

Conclusion:

The estimate of the pre-registration data indicates a total EU volume in the range of **7.200 t/a** to 72.000 t/a. This estimate is higher than the total EU tonnage of **1.007 t/a** used within the EU RAR draft, 2008, nevertheless it has to be taken into account that the pre-registration data are highly uncertain. The total volume according to the SPIN database (Norway, Sweden, Finland and Denmark) is decreasing since 2001 from 1.069,0 tons to 341,7 tons in the year 2007. Given the discrepancies of the available production/import data the future trend of the total EU volume of TCEP remains difficult to predict.

Polybrominated biphenols (PBB) and polybrominated diphenyl ethers (PBDE) including Decabromodiphenyl ether (DecaBDE) are banned for use in electrical and electronic products by the ROHS Directive 2002/95/EC[9]. DecaBDE was earlier exempted from the ROHS-Directive but the exemption is repealed by 1 June 2008[10]. Therefore, the import/production or use of alternative flame retardants like e.g. TCEP might increase. In this context, it should be noted that the Scientific Committee on Health and Environment (SCHER, 2006) recommended already before monitoring the production/use volume, as the PEC/PNEC ratios are below, but close to 1.

[9] DIRECTIVE 2002/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

[10] Ruling of the European Court of Justice in Joined Cases C-14/06 and C-295/06: Annulment of the exemption for DecaBDE (Point 2 of Commission Decision 2005/717/EC) while maintaining its effects until 30 June 2008. As a consequence of this ruling electrical and electronic equipment placed on the European Community market after 1 July 2008 must not contain DecaBDE above the maximum concentration value of 0.1 % by weight in homogenous material. As a result of the ruling, economic operators should consider 30 June 2008 the final cut-off date for placing new electric and electronic goods containing the substance on the market.

1.2 Information on uses

According to EU RAR draft, in 2008 TCEP is mainly used as an additive plasticiser and viscosity regulator with flame-retarding properties for polyurethane, polyesters, polyvinyl chloride and other polymers.

Past trends

Historically the largest field of application of TCEP (80-90 % of the quantity produced) was concerned with reducing the brittleness, and the simultaneous flame-resistant finishing, of polyurethane in the production of celled, rigid or semi-rigid foam. The addition of 10 % TCEP relative to the finished foam is sufficient to achieve a clear flame retardant effect (GDCh, 1987).

On a small scale TCEP was also used as an intermediate for the production of wax additives (GDCh, 1987).

In GDCh (1987) further application fields of TCEP (10 – 20 % of total quantity) are given[11]:

- Acetyl cellulose (10 - 70 % TCEP)
  - paints and varnishes
  - thermoplastics (foils, extrusion)
- Ethyl cellulose (foils)
- Nitrocellulose (paints and varnishes)
- Polyvinyl acetate (paints and varnishes)
- Polystyrole (adhesives for polyurethane foam)
- Polyvinyl chloride (20% TCEP at max.)

Present situation

There are indications that the market and respective application fields have changed over the past 15 years.

Currently TCEP is mainly used in the production of unsaturated polyester resins (~ 80 %). Other fields of application are acrylic resins, adhesives and coatings. The main industrial branches to use TCEP as a flame-retardant plasticiser are the furniture, the textile and the building industry (roof insulation); it is also used in the manufacture of cars, railways and aircrafts (EU RAR draft, 2008).

Other utilisation of TCEP is represented by flame resistant paints and varnishes, e.g. for polyvinyl acetate or acetyl cellulose and the use as a secondary plasticiser for polyvinyl chloride to suppress the flammability resulting from plasticisers such as phthalates.

[11] This information is only given for illustrative purposes.

One company supplied quantitative information about the type of product and the application areas of their sales in 2002 (Table 6, source: EU RAR draft). However, these data are only representative for ~ 44 % of the total tonnage.

Table 6: Fields of application given by one company (representing 44 % of EU tonnage)

Type	Application are	%
Unsaturated polyester resin	Building industry, e.g. roofing	83
Others (unknown)	Unknown	9
Adhesives	Building industry	5
Acrylic resin	Roadside safety barriers	2
Cellulose acetate	Transport	1
Paints (wood and roofings)	Building industry, e.g. fire protection of wood	< 1
Polyurethane foam	Furniture	< 1
Textile coating	Upholstery	0

Specific information is given for 44 % of the total tonnage specifying that 1 % of that tonnage goes into paints. 5 % is used for intermediates, 94 % in polymer industry. The rapporteur tried unsuccessfully to get specific use information on the remaining quantity (56 %).

One importer indicated unsaturated polyester resins (75 - 80 %) and flexible foam (20 – 25 %) as application fields of their sales whereas another company stated that no TCEP was used in any foam anymore. More detailed information was not available.

The fraction of TCEP used in paints and varnishes is somewhat unclear. The above Table 6 lists a quantity of < 1 % in paints. There is no use of TCEP in paints and varnishes listed in the SPIN data base (see tables Table 7). Industry stated that there has been a move of the paint industry away from that use since TCEP was classified as toxic several years ago. A survey by the European Council of Paints, Printing Inks and Artists' Colour Industry (CEPE, 2002) amongst its members showed that 3 out of 10 companies responding still use TCEP in paints in Europe, without specifying any quantities. An update of this information by CEPE (2004) states that the total volume of TCEP in paints in the EU amounted to 10 t in 2003. The representativeness of that statement could not be verified. It is further stated that no new company has started the use of TCEP in paints after 2002, leaving three companies continuing the use of TCEP in paint manufacturing in 2003/2004.

The information given by a new EU member state specifies use of TCEP in polyurethane foams and unsaturated polyester resins. Uses of TCEP in paints are not known.

The lead company commented on the unresolved issue of use of TCEP in consumer paints (Akzo Nobel, 2004). It is stated, that there is no need to put TCEP into consumer paints since there is no regulation governing the flammability of domestic paints. In view of the higher costs of TCEP compared to other plasticisers like phthalates TCEP would not be used as plasticisers in consumer paints. The largest coating manufacturer in the world confirmed that no flame retardants are formulated into domestic paints. Professional paints need for certain uses flame retardant properties, however these are specialised products.

It can be assumed that no TCEP is formulated into consumer paints. Furthermore, no TCEP use in paints is given either in the SPIN database or in the data provided by the new member state. CEPE stated a total use of about 10 t/a of TCEP in EU for industrial paints. This corresponds to 1 % of the total EU tonnage in accordance with the specific information given for the 44 % of the EU tonnage. Summarising all this information the Rapporteur of the EU RAR draft, 2008 proposes to carry over the information on 44 % of the EU tonnage to the total amount resulting in the following scenarios.

Table 7: Tonnages in various scenarios

	total tonnage in application
polymers	94 % (947 t/a)
intermediate	5 % (50 t/a)
paints	1 % (10 t/a)

The resulting total mass balance and the respective industrial and use categories are shown in Table 8

Table 8: Main, industrial and use categories of TCEP

Main category (MC)	**Industrial category (IC)**	**Use category (UC)**	**Mass balance [in % of use]**
Use resulting in inclusion into or onto a matrix (II)	Polymers industry (11)	Flame retardants and fire preventing agents (22)	94
Use resulting in inclusion into or onto a matrix (II)	Paints and varnishes industry (14)	Flame retardants and fire preventing agents (22)	1
Non dispersive use (I)	Chemical industry (3)	Intermediate (33)	5

SPIN database

Main industrial use categories (2001) are given as "Manufacture of rubber and plastic products" (Norway, 538 t, 5 preparations; Finland, 403 t, 5 preparations) and "Manufacture of chemicals and chemical products" (Norway, 41 t, 4 preparations). Specifying the technical use of these preparations, "Adhesives, binding agents" (Norway, 5 preparations) and "Flame retardants and extinguishing agents" (Denmark, 4 preparations) are identified as the main fields of application.

Main industrial use categories (2007) is given as "Manufacture of rubber and plastic products" (Norway, 44 t, 3 preparations; Sweden, no number is indicated). Following further use categories (2007) are indicated for Finland: “Manufacture of rubber and plastic products”, “Manufacture of motor vehicles, trailers and semi-trailers”, and “Manufacture of furniture”; manufacturing n.e.c. No tons and number of preparations are indicated.

For Finland additional use categories (UC62) are indicated (2007): Flame retardants and extinguishing agents, Insulating materials and others.

Conclusion on uses

Given these contradicting statements it is difficult to determine a quantitative breakdown of usage reflecting the present situation in Europe.

1.3 Information on exposure – Environmental and human health monitoring data

The main focus within this section is to present Austrian monitoring data which demonstrate the distribution of TCEP in various environmental compartments. These data are also compared to other European monitoring data. For this purpose the risk assessment report (EU RAR draft, 2008) and some new studies are included as well. In the EU RAR draft most monitoring data were measured in Germany, partly in areas of small size and often done as one-time sampling. The representativeness of these data might be questionable. In the EU RAR draft, measured TCEP concentrations in surface waters (0.01 – 0.3 µg/l) are of comparable magnitude to the modelled $PECreg_{water}$ (0.087 µg/l). In contrast, measured sediment concentrations are scarce and a comparison with predicted concentrations cannot be made.

TCEP is present in products available for consumers such as furniture, textiles, flame resistant paints and toys. It is used in the manufacture of cars, railways and aircrafts and in the textile and building industry (e.g. roofing). The main routes of occupational exposure are by dermal and inhalation contact. Babies are at risk with respect to sucking on toys taking into consideration the carcinogenic properties of TCEP and the effects after repeated oral administration (EU RAR draft, 2008).

Measured Austrian concentrations of TCEP in surface water, influent and effluent of wastewater treatment plants, sediment, house dust and particulate matter (PM2.5, PM10) are summarized in Table 9 to Table 17.

1.3.1 Environmental monitoring data

Mean values and median values are calculated by the so called minimum approach. More than 50% of individual analysed values need to exceed the limit of quantification (LOQ) to calculate a median or mean. Values below the limit of detection (LOD) were set to 0 for the statistical analyses and values below the LOQ were set to LOQ. No special laboratory precautions are necessary to measure TCEP.

1.3.1.1 Measured concentrations of TCEP in the influent and effluent of Austrian wastewater treatment plants (WWTP)

TCEP concentrations in the influent/effluent of Austrian sewage treatment plants (STPs) are presented in Table 9 and Table 10, respectively. In the influent TCEP was detected in concentrations up to 510 ng/l. Influent and effluent samples taken in 2008 were retrieved from the same wastewater treatment plant. The number of positive findings was 100%. It should be noted, that the TCEP concentration in the influent depends on various factors such as the percentage of industrial discharges, weather conditions or population equivalents. Effluent concentrations of TCEP were found in concentrations up to 1.600 ng/l. In all analysed samples TCEP was detected. No relevant elimination of TCEP occurred during wastewater treatment (of the same WWTP) when comparing the mean influent and effluent values of TCEP in samples analysed in 2008. This WWTP (n = 4) receives municipal (50%) and industrial (50%) wastewater. All other wastewater treatment plant samples were retrieved from municipal WWTPs.

Table 9: Concentration of TCEP [ng/l] in wastewater (influent) from an Austrian wastewater treatment plant

Date	No. measured values	No. of positive findings [%] *	LOD	LOQ	Min	Max	Median minimum approach	Mean minimum approach	Ref.
June – August 08	4	100	16	32	110	510	205	258	unpublished data

all values in [ng/l]
Abbreviations: limit of quantitation, LOQ; Min. Minimum; Max. Maximum; limit of detection, LOD; Ref., Reference;
* measured values > LOQ; n.d. not detected

Table 10: Concentration of TCEP [ng/l] in Austrian wastewater (effluent)

Date	No. measured values	No. of positive findings [%] *	LOD	LOQ	Min	Max	Median minimum approach	Mean minimum approach	Ref.
July 04	16	100	15	30	43	1.600	91	191	Martinez-Carballo et al. 2007
June – August 08	4	100	16	32	110	520	165	240	unpublished data

all values in [ng/l]
Abbreviations: limit of quantitation, LOQ; Min. Minimum; Max. Maximum; limit of detection, LOD; Ref., Reference;
* measured values > LOQ; n.d. not detected

In general, TCEP must be considered as non-biodegradable and the elimination in sewage treatment plant is set to zero in the EU RAR draft as a realistic worst case scenario (EU RAR draft, 2008). Monitoring data determined the elimination efficiency in two wastewater treatment plants (WWTPs). During the wastewater process no elimination of TCEP was observed (Meyer and Bester, 2004).

In the EU RAR draft influent and effluent concentrations in sewage treatment plants are available especially for Germany (EU RAR draft, 2008). Measured TCEP influent concentrations range from 220 ng/l (MUNLV NRW, 2003) up to 986 ng/l (Fries and Püttmann, 2003). The effluent concentrations measured are in the range from < 50 mg/l up to 600 ng/l found in samples from WWTPs in Germany (ARGE, 2000).

Summary

TCEP concentrations found in the influent from Austrian sewage treatment plants range from 110 up to 510 ng/l (median = 91 ng/l). In Germany, TCEP influent concentrations were twice as high as in Austrian treatment plants. TCEP concentrations found in the Austrian effluents were in the range of 43 ng/l to 1.600 ng/l. In Germany, maximum TCEP concentrations of 600 ng/l have been detected. Summarizing all data (EU RAR draft, 2008; Austrian monitoring data), TCEP influent concentrations are in the range of 110 up to 986 ng/l and in the range of 43 ng/l up to 1600 ng/l for the effluent.

1.3.1.2 Measured concentrations of TCEP in surface water and sediment from Austria

TCEP concentrations in Austrian surface water and sediment are presented in Table 11 and Table 12**.**

Table 11: Concentration of TCEP [ng/l] in Austrian surface water

Date	No. measured values	No. of positive findings [%] *	LOD	LOQ	Min	Max	Median minimum approach	Mean minimum approach	Ref.
Jul. 05	10	100	3,5	7	11	360	44	86	unpublished data

all values in [ng/l]
Abbreviations: limit of quantitation, LOQ; Min. Minimum; Max. Maximum; limit of detection, LOD; Ref., Reference;
* measured values > LOQ; n.d. not detected

TCEP could be detected in all analysed surface water samples (n = 10; rivers: Danube, Liesing and Schwechat). TCEP was found in concentrations between 11 (minimum) and 360 ng/l (maximum). The concentrations are in the same range as the samples analysed from the river Rhine (GDCh, 1987 and Knepper and Karrenbroch, 1996). No strong conclusion can be drawn as the number of measured values is very low.

TCEP concentrations in surface water from EU RAR draft, 2008

Germany

TCEP values measured (1972 – 1986) concerning the river Rhine (Germany and Dutch locations) are in the range of 0.1 µg/l to 1 µg/l (GDCh, 1987). At Cologne (Rhine), Knepper and Karrenbrock (1996) analyzed TCEP. The TCEP concentrations were between 50 and 300 ng/l. For the river Elbe TCEP concentrations were found in the range of 10 to 220 ng/l (ARGE, 2000). Fries and Püttmann (2003) monitored TCEP in the Oder river, mean values ranged from 30 ng/l (March 2000) to 282 ng/l (March 2001). In July 2001 the measured concentrations were generally higher (554 – 1236 ng/l). In an early study TCEP was monitored at the Rivers Rhine, Elbe, Main, Oder, Nidda and Schwarzbach (Fries and Püttman, 2001). TCEP concentrations ranged from non-detectable (< 1 ng/l) up to 220 ng/l (n = 51, March and November 2000). The authors noted a decreasing trend in TCEP surface water concentration compared to TCEP concentrations of 138 to 3000 ng/l measured previously. Prösch et al. (2002) measured TCEP in 29 bath lakes (Mecklenburg-Vorpommern). TCEP was not detectable in 18 lakes (detection limit: 0.01 µg/l). The maximum concentration was 0.09 µg/l which is assumed to originate from a contaminated site.

Italy

TCEP concentrations were in the range from < 10 ng/l up to 293 ng/l (Galassi, 1991) at one station at River Po and two marine stations in the Adriatic Sea (April to August 1988).

United Kingdom

Monitoring data for the Midland region near Derby/UK was supplied for the years of 1990 to 2003 (Environment Agency, 2003). Measurements were taken around two locations presumably discharging TCEP. At one of the sites a company used to produce a flame retardant. The other location received effluent of a textile finishing company. Both companies have closed down in recent years however TCEP can still be detected. Whereas in early 1990s maximum values of up to 4 mg/l were measured, TCEP concentration has been constantly < 5 µg/l since around 1998 (90 percentile of all values: 3.55

µg/l). Values from January 2004 to July 2005 from the same region showed a 90 percentile of 1.03 µg/l (Environment Agency, 2005).

Non - EU countries

TCEP was detected in 60% of surface water samples (streams across 30 U.S. states) and the maximum concentration was 0.54 µg/l (Kolpin et al., 2002).

Summary

Austrian surface water concentrations of TCEP are in the range from 11 to 360 ng/l. Similar TCEP concentrations have been found in German rivers. TCEP was found in concentrations of 0.05 and 0.3 µg/l in the river Rhine. For the tributaries (Rhine), including the rivers Neckar, Main, Mosel, Lahn und Ruhr, concentrations ranging from 0.18 to 1.3 µg/l were determined.

Table 12: Concentration of TCEP [µg/kg dwt] in Austrian sediment samples (Danube, Ybbs, Schwechat, and Liesing)

Date		No. measured values	No. of positive findings [%] *	LOD	LOQ	Min	Max	Median minimum approach	Mean minimum approach	Ref.
Sediment	Aug 01	14	28,5%	3,5	7,7	n.d.	160	-	-	unpublished data
Sediment	Aug 04	6	0%	3,5	7,8	n.d.	<7.8	-	-	unpublished data

all values in [µg/kg/dw]
Abbreviations: limit of quantitation, LOQ; Min. Minimum; Max. Maximum; limit of detection, LOD; Ref., Reference; dry weight dwt;
* measured values > LOQ; n.d. not detected

Sediment samples were taken from the river Danube Ybbs, Schwechat and Liesing. The maximum concentration found was 160 µg/kg (dry weight). The number of sediment samples with positive findings of TCEP was 28.5% in 2001 and zero in 2004. No strong conclusion can be drawn as the number of measured values was very low. No mean values and median values could be calculated as less than 50% of individually analysed values exceeded the limit of quantification (LOQ).

TCEP concentrations in sediment samples from EU RAR draft, 2008

TCEP concentrations for 10 sediments from 5 German rivers in Lower Saxony are reported (Niedersächsisches Landesamt für Ökologie, 1997). The measured concentrations ranged from min. 5.4 to max. 15.0 µg/kg (dry weight). The median value is 8.3 µg/kg (dry weight, n = 10). Concentrations of 0.5 – 100 µg/kg (dry weight) were monitored in the sediment of the river Elbe (ARGE, 2000). In sediment samples of the 3 great rivers Rhine, Danube and Neckar in Baden-Wuerttemberg (Germany) were analyzed for TCEP (Metzger and Möhle, 2001). TCEP was not detectable in 6 out of 12 sites allocated at different spots of the rivers (detection limit: 20 µg/kg dry weight). The maximum concentration found was 188 µg/kg (dry weight).

Summary

The maximum TCEP concentration in Austrian sediment samples was160 µg/kg dwt. In Germany, the maximum TCEP concentration was 188 µg/kg dwt (EU RAR draft, 2008).

1.3.2 Human Exposure

This chapter is based on the information given in the EU RAR draft (2008), additional data are specifically mentioned.

1.3.2.1 General information

TCEP is liquid and can be considered as a non-volatile substance with a low vapor pressure of 0.00114 Pa (20°C), which results in low maximum possible air-concentrations of the gaseous form under normal conditions. The main use of TCEP is the production of unsaturated polyester resin (83%)[12]. TCEP is physically and not chemically bound within the polymer matrix. A migration test in an aqueous medium conducted by the Danish EPA, 2004 draft has shown that the TCEP is easily dissolved and migrates into the solution (tested on a cube designed for babies). It could also migrate to the surface during process steps especially those performed at higher temperatures. In addition, TCEP can be released by abrasion and becomes part of the dust fraction. The latter is divided into two parts, house dust and airborne dust. Therefore, dust burden reflects the sum of all the sources (Sagunski & Roßkamp, 2002).

The human population can be exposed to TCEP via the workplace and from the use of consumer products. OELs for TCEP are not established in the EU.

Oral exposure can be referred to dust intake, due to hand-to-mouth behavior, contamination of articles for daily use, e.g. toys which can be put into the mouth. This pathway of exposure may play a particular role for children and is covered by hand-to-mouth activities.

Inhalation exposure takes place by inhaling airborne particles, and dermal exposure can occur from direct contact with e.g. furniture coverings, as well as with house dust and airborne dust.

[12] Fields of applications have been given by one company (representing 44% of EU tonnages)

1.3.2.2 Occupational exposure (EU RAR draft, 2008)

For TCEP three occupational exposure scenarios are regarded to be relevant.

Scenario 1: Production of TCEP

Scenario 2: Use of TCEP at ambient temperatures for the production of polymers and formulations

Scenario 3: Use of formulations and products containing TCEP

TCEP is produced (scenario 1) and is used for the production of formulations (scenario 2). The use of TCEP-containing formulations (scenario 3) includes spray application (scenario 3a) and applications without formation of aerosols (scenario 3b). Beside inhalation exposure, dermal exposure (potential and actual) is assessed for each scenario.

Inhalation exposure is to be expected if processes are performed at elevated temperatures or if dusts containing TCEP are formed. Industry states that process at elevated temperature do not occur because of the degradation of TCEP at elevated temperatures and that the substance or products containing the substance do not occur in a powdery state.

In general, the number of exposed workers is not known for any of these scenarios. Since no information on exposure levels is available, the assessment of inhalation and dermal exposure is based on model estimates. It is not possible to correct the inhalation, because the composition of the applied formulations is generally not known. EASE estimate for the pure substance in consideration of the percentage of TCEP.

OELs have not yet been established at EU level.

Recycling:

There is no information concerning the exposure during recycling of plastic waste. Generally, the recycling of halogenated flame retardants is problematic, because of the possible release of halogenated compounds into the environment. There are two possibilities in recycling of plastic waste: incineration and shredding. It is supposed that mixtures of different plastics are recycled together.

Scenario 1 (Production of TCEP)

Only limited confidential information from a Polish company is available. TCEP is produced by the catalytic addition of ethylene oxide and phophoryl chloride in closed systems. The product is pure after cleaning and catalyst removal. Workplace monitoring data are not available; therefore model calculations have been performed with EASE.

Table 13: Summary of exposure levels in the production of TCEP (Scenario 1)

Workplace operation	**Exposure by inhalation (mg/m^3)**	**Dermal exposure (mg/person/day)**
Scenario 1A: Production and further Processing	Reasonable worst case: 1.2 (E)	420 (E)

E) Estimated by EASE: input parameters (Exposure by inhalation: 20°C, closed system, significant breaching, local exhaust ventilation present, vapor pressure < 1 Pa, dermal exposure: non dispersive use, direct handling, intermittent)

Conclusions for inhalative and dermal exposure (Scenario 1):

Exposure levels of 0 – 1.2 mg/m^3 (8-h TWA) predicted by the EASE model are used to assess the risks of inhalative exposure. 1.2 mg/m^3 should be taken as representing the reasonable worst case situation. It is to be assumed that the substance is applied daily. Consequently, the duration and the frequency of exposure to TCEP are assumed to be daily and for the entire length of the shift. The assessed exposure level (incl. duration of exposure) is representative for the Polish company. For assessing the health risks from daily dermal exposure in the area of production and further processing, an exposure level of 42 – 420 mg/person/day should be taken. This exposure assessment is based on information provided by the companies that unsuitable gloves are worn and takes into account the possible dermal exposure under actual workplace conditions. Exposure to the eyes is largely avoided by using eye protection.

Scenario 2 (Use of TCEP at ambient temperature for the production of formulations)

TCEP is used as plasticizer in different formulations containing various other substances (e.g. polyvinyl acetate) in different resins (e.g. for glues) and in polymers (e.g. polyurethane).
The concentration of TCEP in this formulation is 5 up to 16%. Higher concentrations (up to 40%) are possible in the starting polymer mixture. According to information from the representative company, TCEP is neither handled in powdery formulations nor at elevated temperature.

Table 14: Summary of exposure levels in the use of TCEP at ambient temperature for the production of formulations (Scenario 2)

Workplace operation	**Exposure by inhalation (mg/m^3)**	**Dermal exposure (mg/person/day)**
Scenario 2: Production of Polymers and of Formulations	Reasonable worst case: 1.2 (E)	420 (E)

E) Estimated by EASE: input parameters (Exposure by inhalation: 20°C, closed system breaching or non-dispersive use, vapor pressure < 1 Pa, dermal exposure: non dispersive use, direct handling, intermittent)

Conclusions for inhalative and dermal exposure (Scenario 2):

In general for vapour pressures below 1 Pa the result of the EASE estimate is 0 – 1.2 mg/m^3 (0 – 0.1 ppm), independent of the use pattern “closed system” (with the possibility to be breached), “non-dispersive use”, or “wide dispersive use”. It is to be assumed that the substance is processed daily, so the duration and the frequency of exposure to TCEP are assumed to be daily and for the entire length of the shift. For assessing the health risks of daily dermal exposure in the area of production of polymers and formulations, an exposure level of 42 – 420 mg/person/day should be taken. This exposure assessment is based on the assumption that suitable gloves are not worn. It cannot be presupposed, that eye protection is regularly used.

Scenario 3 (Use of formulations and products containing TCEP)

The use of TCEP is assumed to be restricted to cases where flame retarding properties are necessary e.g. textile, building/construction and furniture industry (adhesives, glues, paints, lacquers,..). The concentration of TCEP in end products is assumed to be ≤ 25%. The application of e.g. paints and the preparation of paints and cleaning are relevant for the occupational exposure.

Table 15: Summary of estimated exposure levels in the Use of formulations and products containing TCEP (Scenario 3)

Workplace operation	Exposure by inhalation (mg/m^3)	Dermal exposure (mg/person/day)
Scenario 3a: Spraying Scenario 3b: Techniques without producing droplets of aerosols	8.3 (*) 1.2 (E)	< 2500 (**) 210 (E)

*) Analogue data were used for inhalation exposure: according to the revised TGD were used (EU RAR draft, Appendix IC) based on: 25% TCEP; **) Analogue data were used for dermal exposure: refer to EU RAR draft, 2008 page 29 E) Estimated by EASE: input parameters (Exposure by inhalation: 20°C, non-dispersive use, vapor pressure < 1 Pa, dermal exposure Scenario 3a: T = 20°C, wide dispersive use, direct handling, intermittent, TCEP content ≤ 25%, exposed area of 210-1050 mg/person/day; dermal exposure Scenario 3b: T = 20°C, non dispersive use, direct handling, intermittent, TCEP content ≤ 25%, exposed area of 21-210 mg/person/day)

Conclusion for inhalative and dermal exposure (Scenario 3):

Inhalation exposure has to be assessed for the use of formulations containing TCEP (e.g. paints, flame-retardant formulations, glues) in fields with lower protection levels, e.g. in small and medium sized companies. The concentration of TCEP is assumed to be ≤ 25 %. For assessing the risks of inhalation exposure during spray application, **8.3 mg/m³** should be taken if spraying techniques are applied (Scenario 3a). In case of activities without the formation of droplet aerosols, **1.2 mg/m³** should be taken as representing the reasonable worst case situation (Scenario 3b). The duration and frequency of exposure to TCEP are assumed to be daily and for the entire length of the shift. For assessing the risk of daily dermal exposure during painting works and use of glues and adhesives, an exposure level of **< 2500 mg/person/day** should be taken (analogous data, scenario 3a). The dermal exposure takes into account a reasonable worst case estimate of 10000 mg on an exposed area of 840 cm² (both hands) and the TCEP content in formulations of ≤ 25 % (direct skin contact during spraying). For uses without the formation of aerosols, dermal exposure is considerably lower: **210 mg/person/day** (Scenario 3b).

Study not included in the EU RAR draft, 2008:

Recently a study by Mäkinen et al. (2009) investigated the respiratory and dermal exposure to organophosphorus flame retardants (FRs) and tetrabromobisphenol A at five work environments. TCEP was quantified in a circuit factory (A), furniture workshop (B), two different electronic dismantling facilities (C, D), a computer classroom (E) and offices at sites (A-C). Organophosphorus compounds including TCEP were quantified by GC/MS from air samples. In addition the dermal exposure was assessed with patch and hand wash samples. TCEP was a universal contaminant of the work air and was present in more than 75% of the work air samples at sites C and E, and in more than 50% at sites B and D. The highest TCEP concentration (geometric mean) was found at a Finnish dismantling and sorting facility (personal air samples: 450 ng/m^3, 100% frequency of detects; stationary air samples 50 ng/m^3, 75% frequency of detects; patch samples: 0.4 ng/cm^2, 67% frequency of detects). In general, high concentrations in personal air samples were accompanied by high FR levels in the patch samples.

At the moment, there are no limit values for dermal exposure to FRs. Since the extent of penetration of the compounds through the skin is not known, the effects of the doses are difficult to estimate.

Summary of Occupational exposure levels (EU RAR draft, 2008)

Inhalation exposure levels in the production of TCEP (scenario 1) and the use of TCEP at ambient temperature for production and formulation (Scenario 2) are 1.2 mg/m^3. Dermal exposure was estimated via EASE to be 420 mg/person/day. For Scenario 3a (Spraying) and 3b (Techniques without producing droplets of aerosols) following exposure levels were obtained. For the exposure by inhalation 8.3 and 1.2 mg/m^3 for Scenario 3a and 3b were calculated. Dermal exposure for Scenario 3a was set < 2500 and for 3b 210 mg/person/day.

1.3.2.3 Consumer exposure

TCEP is released from a number of sources which have been treated with flame retardants e.g. timber, foam rubber, carpets, plastic materials (electronic devices, TV, car interior), glues and lacquers. TCEP is a non-volatile substance, which does not appear in its gaseous form under normal conditions. Therefore, it is released primarily by abrasion and becomes part of the dust fraction. The latter is divided into two parts, house dust and airborne dust. Dust burden therefore reflects the sum of all the sources (Sagunski & Roßkamp, 2002).

Oral exposure can be referred to dust intake, due to hand-to-mouth behaviour, contamination of articles for daily use, e.g. toys which can be put into the mouth. This pathway of exposure may play a particular role for children and is covered by the hand-to-mouth activities. Inhalation exposure takes place by inhaling airborne particles, and dermal exposure can occur from direct contact with e.g. furniture coverings, as well as with house dust and airborne dust.

Absorption rates in this approach include the desorption of TCEP from dust and the subsequent absorption in the GI-tract or in the lungs and were set to 100% as a worst case approach.

1.4.3.1. Measured concentrations of TCEP in house dust and particulate matter

A study conducted by the Environment Agency Austria (UBA 2008, Band 182) investigated the influence of indoor air pollution on children's health in nine full-time schools. Boys (n = 225) and girls (n = 224) at the age of 5 to 9 living in urban (86%) and rural (14%) environment have been included in this survey. 252 parameters (e.g. industrial chemicals, metals, volatile organic carbons) have been analyzed in air, house dust and particulate matter. TCEP was measured in house dust (n = 19,Table 16) and particulate matter PM_{10} and $PM_{2.5}$ (n = 86, Table 17). TCEP could be recovered from nearly all analyzed house dust (100%) and particulate matter samples (97% in 2006, 100% in 2007). The TCEP concentration in the house dust was in the range of 0.59 and 35 mg/kg. In the EU RAR draft ,2008 983 house dust samples were statistically analyzed. The 95th percentile of distribution is 11.9 mg/kg, and the median 0.6 mg/kg (EU RAR draft, 2008).

Table 16: Concentration of TCEP [mg/kg] in Austrian house dust

sample type	Date	No. measured values	No. of positive findings [%] *	LOD	LOQ	Min.	Max.	Median minimum approach	Mean minimum approach	Ref.
Household dust	2006	6	100%	0,05	0,1	1,2	13	2,6	4,8	UBA 2008, Band 182
Household dust	2007	13	100%	0,05	0,1	0,59	35	1,4	5,4	UBA 2008, Band 182

all values in [mg/kg]
Abbreviations: limit of quantitation, LOQ; Min. Minimum; Max. Maximum; limit of detection, LOD; Ref., Reference;
* measured values > LOQ; n.d. not detected; n.a. not available

Table 17: Concentration of TCEP [ng/Nm3] in particulate matter (PM) from Austria

sample type	Date	No. measured values	No. of positive findings [%] *	LOD	LOQ	Min.	Max.	Median minimum approach	Mean minimum approach	Ref.
PM 10/PM 2,5	2006	25	100%	0,07	0,14	0,14	28	2,8	9,2	UBA 2008, Band 182
PM 10/PM 2,5	2007	61	97%	0,07	0,14	n.d.	64	2,7	9,3	UBA 2008, Band 182

all values in [ng/Nm^3]
Abbreviations: limit of quantitation, LOQ; Min. Minimum; Max. Maximum; limit of detection, LOD; Ref., Reference; particulate matter, PM
* measured values > LOQ; n.d. not detected; n.a. not available

Consumer Exposure (EU RAR draft, 2008)

House dust:

In an interlaboratory comparative study published by Ingerowski et al. (2001), TCEP dust concentrations have been measured in approximately 1000 German households by three different laboratories using identical methodology. These data and the data from Sagunski (1997) correspond to each other. The dust concentration ranges between 0 and 121 µg/kg, which is in agreement with a number of other - studies (Becker et al. (2002), Bürgi (2002), Hansen et al. (2000), Kersten & Reich (2003), Marklund et al., 2003, Salthammer & Wensing (2002)).

The data published by Ingerowski et al. were taken to use the data (983 dust samples taken in German households) to perform a log-logistic distribution[13]. The 95th percentile of this distribution is 11.9 mg/kg, and the median 0.6 mg/kg. This distribution covers also the highest values reported by Marklund et al. (2003) in libraries and the other studies mentioned.

Freeman & Adgate (2003) have estimated a maximum load of ~ 5.0 mg of dust per hand in 1 - 4 year old children. Taking the 98th percentile of TCEP dust concentration reported by Ingerowski et al. (18 ng/mg of house dust), then the total dermal exposure via this pathway would account for ~ 0.18 µg per day (both hands). This value is only applicable for children; the burden resulting from this estimation is 0.018 µg/kg of bodyweight, considering a child having a bodyweight of 10 kg.

Airborne dust:

The airborne dust concentrations of TCEP as determined in the same study lies between 0 and a maximum of 6000 ng/m³, which is in agreement with other authors (Hansen et al., 2000, Bürgi, 2002). Data revealed a log-normal distribution[14] with a 95th percentile of 134 ng/m³, and a median of 10 ng/m³. This distribution covers also room air concentrations of max. 30 ng/m³ published by Otake et al. (2001), without specification of dust adsorption, as well as those measured in cars by Wensing et al. (2003).

Toys: A migration test in an aqueous medium conducted by the Danish EPA, 2004 draft has shown that the TCEP is easily dissolved and migrates into the solution (tested on a cube designed for babies).

Summary house dust

The TCEP concentration in the house dust was in the range of 0.59 and 35 mg/kg (UBA 2008, Band 182). In the EU RAR draft (2008) 983 house dust samples were statistically analyzed. The 95th percentile of distribution is 11.9 mg/kg, and the median 0.6 mg/kg (EU RAR draft, 2008) are within the range of data found in the Austrian study.

[13] RiskLoglogisticAlt(50%;0,61;90%;8,02; 95%;11,86; RiskTruncate(0;121))

[14] @RISK formula: RiskLogNormalAlt(10%;5; 50%;10; 90%;40; RiskTruncate(0;6000))

Table 18: Conclusions Consumer exposure (inhalative, dermal, oral and total body burden)

Consumer exposure (according to EU RAR draft, 2008)		
Inhalative	Reasonable worst case: 0.6 µg/m^3 (*)	0.4 µg/kg (adults) 0.96 µg/kg (children)
Dermal	Reasonable worst case: Upholstery 3.9 µg/kg bw/day	House dust: 0.02 µg/kg bw/day (children) Different sources (total): app. 4 µg/kg bw/day 10 µg/kg bw/day (children)
Oral (dust uptake)	0.0033 µg/kg bw/day (adult) 0.2 µg/kg bw/day (3-yr old child) 240 µg/kg bw/day (babies)	
Total body burden	Female adults approx. 4.5 µg/kg bw/day (+) Child 11µg/kg bw/day Baby (3 months) 240 µg/kg bw/day (‘)	

(*) value 98th percentile from Ingerowski et al. 2001, major part is bound to dust and the degree of desorption is not known; (+) reasonable worst case, all paths; (´) sucking on toys, all other paths can be neglected

1.3.2.4 Indirect exposure via the environment

Indirect TCEP exposure (local and regional) to humans via the environment can be through food, drinking water and air.

For the local concentrations the default scenario for the formulation of paints is used, representing the local worst case. This scenario is compared to an average intake due to exposure via the regional background concentration. The following input parameters were selected:

annual average local PEC in surface water:	13.59 µg/l
annual average local PEC in air:	0.0038 µg/m³
local PEC in grassland:	8.66 µg/kg
local PEC in porewater of agricultural soil:	18.1 µg/l
local PEC in porewater of grassland:	4.18 µg/l
local PEC in groundwater under agricultural soil:	18.1 µg/l

regional PEC in surface water:	0.0871 µg/l
regional PEC in air:	2.27 x 10^{-4} ng/m³
regional PEC in agricultural soil:	0.061 µg/kg
regional PEC in pore water of agriculture soil:	0.0295 µg/l

The resulting total daily doses are:

$$\mathbf{DOSE_{tot\_local} = 5.842\ \mu g \cdot kg_{b.w.}^{-1} \cdot d^{1}}$$

$$\mathbf{DOSE_{tot\_regional} = 0.0111\ \mu g \cdot kg_{b.w.}^{-1} \cdot d^{1}}$$

The calculated doses comprise the following routes:

Table 19: Routes of exposure (regional and local model)

Route	regional model, percentage of total dose	local source model; percentage of total dose
drinking water	22.4	8.85
Air	<0.01	0.01
Stem	66.8	85.9
Root	2.38	2.77
Meat	<0.01	<0.01
Milk	0.02	<0.01
Fish	8.38	2.48

The stem is the main route of exposure for the regional and local approach.

However, it has to be noted, that the applied model calculations are of preliminary nature (i.e. according to TGD “state of the art” methods serving screening purposes) and have to be revised as soon as further information becomes available.

2 INFORMATION ON ALTERNATIVES

2.1 Alternative substances

According to Sagunski et al, 2000 and SCHER (SCHER, TCPP 2007) the use of TCEP is substituted by the alternative flame retardant Tris(2-chlorpropyl)phosphat (TCPP).

2.1.1 TCPP Volumes

TCPP is produced at four sites within the EU. Production volumes are above 30,000 tonnes/year and have increased in recent years due to the substitution of TCEP by TCPP. The EU RAR includes information from industry indicating that the replacement has been completed for all the applications for which replacement is possible. TCPP is also mentioned as a potential candidate for the substitution of brominated flame retardants.

The RAR indicates that no further increases in the production/consumption volumes are expected; but the SCHER (SCHER, TCPP 2007) has no information for addressing this specific point. TCPP is an additive (physically combined with the material being treated) flame retardant; mostly (over 98%) used as a flame retardant in the production of PUR for use in construction and furniture.

2.1.2 Harmonised Classification and Labelling

An Annex XV dossier proposing a harmonised classification and labelling for TCPP has been prepared by the rapporteur Ireland and submitted to ECHA, to be discussed by the Risk Assessment Committee (RAC). In this Annex XV C&L dossier the rapporteur proposes no classification for the harmonised classification endpoints (i.e. CMRs or respiratory sensitiser). The RAC decided not to discuss Annex XV dossiers proposing “no classification” as they would not be collected in a list, comparable to Annex VI of the CLP regulation. The Commission Working Group on the Classification and Labelling of Dangerous Substances Meeting on Environmental Effects of Existing Chemicals, Pesticides & New Chemicals agreed that TCPP did not meet the criteria for classification as dangerous for the environment on 28-30 September 2005. Industry self classifies TCPP as Xn; R22.

2.1.3 Risk related information on TCPP (according to EU-RAR, 2006)

Environment

Conclusion (ii) The conclusion of the assessment of the risks to the **atmosphere, aquatic and terrestrial ecosystem, and micro-organisms in sewage treatment plants** is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied.

Human Health

Conclusion (iii) Workers

The RAR for TCPP concluded that there is a need for limiting the risk associated with reasonable worst case dermal exposure of workers to TCPP, during the manufacture of TCPP (worker scenario 1) in relation to fertility and developmental toxicity. As a result of these conclusions, a strategy for

limiting these risks is required. Therefore, a transitional Annex XV dossier "Strategy for Limiting the Risk" was submitted by Ireland on the 1st December 2008.

Environment

The environmental part of the RAR (EU-RAR, on TCPP was reviewed by SCHER (SCHER, TCPP 2007) and adopted during the 19th plenary of 20 September 2007.

A European Union Risk Assessment Report[15] (RAR) (HSA/EA, 2008) was carried out for TCPP in accordance with Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances.

The SCHER had difficulties for accepting that only 40% of the substance is available for release; nevertheless, as all PEC/PNEC ratios are below 0.4 this situation does not affect the conclusions as PEC/PNEC ratios would remain under 1 even for a 100% availability, still leading to conclusion ii) for all environmental compartments for the current production/consumption data. The SCHER stressed that significant parts of the exposure assessment are based on confidential data, and therefore have not been checked by the committee; therefore, the committee did not comment on the acceptability of the conclusions. The low potential for bioaccumulation based on a fish BCF confirms that TCPP cannot be considered as a PBT or vPvB substance. SCHER had no information for addressing if further increases in the production/consumption volumes should be expected or not.

Conclusion

Industry has already substituted particular uses of TCEP with TCPP (Tris(2-chlorpropyl)phosphat). It should be noted, that not all uses of TCEP could be identified within the EU RAR, 2008 and it might be difficult to replace all uses by TCPP or other flame retardants. An in depth research on alternative substances for TCEP is necessary to find appropriate substitutes.

2.2 Alternative techniques

3 RISK-RELATED INFORMATION

Information concerning the risk for human health and the environment is summarized from the risk assessment report (EU RAR draft, 2008).

Human health

Conclusions are summarized and have been drawn for workers, consumers and man exposed indirectly via the environment.

Workers

Conclusion (iii) there is a need for limiting the risk; risk reduction measures which are already being applied shall be taken into account.

[15] Work on the RAR began before enlargement of the EU to 27 Member States in 2006. Therefore the conclusions of the risk assessment are based on information regarding the former EU of 15 member states.

For TCEP three occupational exposure scenarios are evaluated. TCEP is produced (Scenario 1) and is used for the production of formulations (Scenario 2). The use of TCEP-containing formulations (Scenario 3) includes spray application (Scenario 3a) and applications without formation of aerosols (Scenario 3b). The overall result of risk assessment indicates that current exposure levels (inhalation and dermal contact) are too high for all occupational exposure scenarios.

From the toxicological point of view, concern mainly derives from the carcinogenic properties of TCEP. In addition, chronic toxicity and partly fertility impairment gives reason for concern.

Measures selected for risk reduction should be able to substantially reduce TCEP exposure of workers. Special emphasis should be given to the "spray application" scenario (dermal contact and inhalation).

With respect to risk assessment for carcinogenicity **inhalation exposure** at the workplace should be reduced to a level of **less** than **0.2 mg/m^3**. It is recommended to establish an occupational exposure limit (OEL) for TCEP.

Concerning skin contact, **dermal exposure** should be controlled to be **less** than **2 mg/person/day**. Against this background it needs to be carefully considered whether gloves could be able reduce sufficiently reduce the dermal exposure from TCEP.

Consumers

Conclusion (iii) there is a need for limiting the risk; risk reduction measures which are already being applied shall be taken into account.

Ad iii) Risk reduction measures are required for babies with respect to the scenario sucking on toys taking into consideration the carcinogenic properties of the substance and the effects after repeated oral administration.

Humans exposed via the environment

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

Strategy for limiting the risk for workers and consumers

The strategy for limiting the risks for workers is to establish at a community level occupational exposure limit (OEL) values for TCEP according to Directive 98/24/EEC[16] or Directive 2004/37/EC[17] as appropriate. The strategy for limiting the risks for consumers is to consider at Community level marketing and use restrictions in Council Directive 76/769/EEC (Marketing and Use Directive) for the use of TCEP in sucking toys for babies (refer to section OTHERS).

[16] OJ L 131, 05.05.1998, p. 11

[17] OJ L 158, 30.04.2004, p. 50

Environment

Conclusion (ii) The conclusion of the assessment of the risks to the **atmosphere, aquatic and terrestrial ecosystem, and micro-organisms in sewage treatment plants** is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient

This conclusion is reached for the following all life cycle steps to all environmental compartments, to the function of waste water treatment plants and to secondary poisoning via the food chain.

TCEP does not meet the PBT and vPvB criteria.

3.1. Environmental Effects Assessment (EU - RAR draft, 2008)

3.1.1 $PNEC_{aqua}$

Despite remaining problems regarding the plausibility of widely differing effect values resulting from growth inhibition tests with algae, the lowest effect concentration refers to this group. As the available studies are regarded as valid and no reason for the conflicting results can be given, it is proposed to use the lowest effect value based on growth rate for the derivation of the $PNEC_{aqua}$. As explained above, the 48h-values are preferred to the 72h-values. Therefore, the 48h-ErC10 of 0.65 mg/l found by (Kühn et al., 1989WaBoLu res. Report N° 106 03 052/01) for *Scenedesmus subspicatus* is used as basic value. Long-term tests with species from two trophic levels are available. Therefore an assessment factor of 50 can be regarded as suitable. However, as from the effect values for *Scenedesmus subspicatus* found by Kühn et al. it can be concluded, that algae are the most sensitive species to TCEP (EC_{50}-value is a factor of 18 to 90 lower than EC_{50}/LC_{50} values from fish and daphnids found in short-term tests), and it is therefore not expected that in a long-term test with fish an effect value below 0.65 mg/l will be found, an assessment factor of 10 is justified according to the Technical Guidance Document TGD (EC, 2003):

$PNEC_{aqua}$ = 0.65 mg/L / 10 = 65 µg/L

3.1.2 $PNEC_{Sediment}$

No information about TCEP effects on sediment organisms could be found. Consequently, only a provisional $PNEC_{sed}$ can be determined based on equilibrium partitioning according to TGD using a $K_{susp\text{-}water}$ of 3.655:

$$\mathbf{PNEC_{sed}} = \frac{3.655 \bullet 0.065 \bullet 1000}{1150} = \mathbf{0.2\ mg/kg\ ww}$$

3.1.3 $PNEC_{marine}$

There is not enough information available to exclude the possibility of sites being located at the sea. TCEP is not degradable and shows limited sorption (98.6 % released to water from WWTP). The concentration in seawater can be estimated to be about 10 % of that in freshwater. As the marine PNEC will be 10 % of the freshwater PNEC, the overall marine PEC/PNEC ratios will be similar to those for freshwater. Due to the low BCF values bioaccumulation is not expected and the assessment of secondary poisoning is not considered necessary. In view of all arguments above, there is no need for a marine risk assessment.

3.1.4 $PNEC_{micro\text{-}organisms}$

For the effects assessment for microorganisms in sewage treatment plants the PNECwwtp is calculated by applying an assessment factor of 100 on the EC_{50} from the OECD 209 (Akzo, 1990c) respiration inhibition test (3.2 g/L) according to the EC, 2003:

$PNEC_{micro\text{-}organisms}$ = 32 mg/L

3.1.5 $PNEC_{soil}$

On the basis of the various effect values reported (supplemented by information of merely indicative value) higher plants may be regarded as being somewhat more sensitive to TCEP than susceptible invertebrates. Regarding invertebrates, the available information points to notably higher susceptibility of arthropods compared to earthworms. The poor data on *Pardosa* do not allow

drawing further detailed conclusions with respect to a higher sensitivity of insects or spiders. On the whole, the data point to similar susceptibility.

Long-term tests are available for springtails and soil microorganisms. No significant differences in sensitivity between *Folsomia* and bacteria can be derived from the respective test results for 28 d exposure.

However, since the available information on *Folsomia* covers a broader spectrum of effects, the lowest effect value reported for this species is chosen as reference value for the $PNEC_{soil}$ derivation (28 d LC_{10} = 19.3 mg/kg dw for adults, assumed to represent a NOEC).

According to the TGD an assessment factor of 50 has to be applied to this value.

$PNEC_{soil}$ = 19.3 mg/kg (dry weight)/ 50 = 0.386 mg/kg (dry weight)

$PNEC_{soil}$ = 0.341 mg/kg (wet weight)

3.1.4 Secondary poisoning

Since there is no indication of bioaccumulation of TCEP, a risk characterization for exposure via the food chain is not necessary.

No ecotoxicological data are available for the atmosphere.

3.1. 5 PBT-assessment

It can be concluded that TCEP meets the **P/vP**- and the **T**-criteria. The **B**-criteria is not fulfilled. Overall TCEP does not meet the PBT (persistent, bio-accumulative, toxic) and vPvB (very persistent and very bio-accumulative) criteria.

3.2 Comparison of Austrian environmental monitoring data with effect data

Micro-organisms in sewage treatment plants

The mean concentration of TCEP found in the Austrian influent/effluent (258/191-240 ng/l) is far below the $PNEC_{WWTP}$ value (32 mg/l, EU RAR draft, 2008).

Surface waters

The maximum monitored value (0,36 µg/l) in Austrian surface waters is well below the $PNEC_{aqua}$($PNEC_{aqua}$ = 65 µg/l).

3.3. Human health Effects assessment (EU RAR draft, 2008)

General aspects

Kidneys appear to be the most sensitive organ for repeated exposure for TCEP. 12 mg/kg bw/d (Takada et al. 1989) is considered as LOAEL for kidney lesions (tumor formation) and was used for risk characterization. TCEP revealed significant impairment of reproductive capacity and fertility during continuous breeding and for 2 successive generations in mice for both sexes. An oral $NOEAL_{fertility}$ of 175 mg/kg bw/ was derived from the studies with mice (Gulati and Chapin, 1991). There are no human data on reproductive toxicity.

3.3.1 Toxicokinetics (absorption, distribution, and elimination)

The substance is well absorbed (> 90% of the dose) and distributed in rats after oral administration. Metabolites [bis(2-chloroethyl) carboxymethylphosphate, bis (2-chloroethyl)hydrogen phosphate and bis(2-chloroethyl) -2-hydroxyethyl-phosphate glucuronide] in urine were identical in rats and mice. For the risk characterization absorption is set to 100%.

3.3.2 Acute Toxicity

TCEP has demonstrated moderate toxicity (oral LD_{50} rats: 430-1230 mg/kg bw). The inhalation toxicity seems to be low as judged on the basis of test results with rats that survived an 8-hours exposure to saturated substance aerosols or an 1-hour exposure to a nominal concentration of 25.7 mg/l. Acute dermal toxicity in the rabbit is low, the dermal LD_{50} value was detected to be > 2150 mg/kg bw. Information on human experience with TCEP is not available. The substance is classified as "harmful" according to EEC classification guidelines and labelled with "R 22, Harmful if swallowed".

3.3.3 Irritation

TCEP is not considered to be a skin and eye irritant.

3.3.4 Corrosivity

TCEP is not a corrosive substance.

3.3.5 Sensitisation

An animal skin sensitisation study (Buehler Test) showed no skin sensitising potential of TCEP. Based on all information on the three structurally related chloroalkyl phosphates (results of animal testing, similarity in physicochemical data and chemical structures, as well as alkylating properties of TCEP, TCPP and TDCP) it is concluded that TCEP should be non-sensitizing to humans.
No information is available on the respiratory sensitisation potential of TCEP and the other two chloroalkyl phosphates. Human data on sensitizing properties of TCEP are not available

3.3.6 Repeated dose toxicity

Kidneys appear to be the most sensitive organ in Scl:ddY mice for repeated exposure for TCEP. 12 mg/kg bw/d (Takada et al. 1989) is considered as LOAEL for kidney lesions (tumor formation) and was used for risk characterization.

3.3.7 Mutagenicity

There is no relevant evidence for mutagenicity of TCEP.

3.3.8 Carcinogenicity

From animal data it is obvious that there is a carcinogenic potential of TCEP (NTP 1991, Matthews 1993, Takada et al., 1989). Carcinogenic potential of TCEP in rats and mice was demonstrated for the oral route. TCEP caused primarily benign tumors but also malignant tumors in the kidney of rats and in mice (LOAEL of 12 mg/kg bw/d, no NOAEL). Tumor formation after TCEP treatment was observed in the liver of male in Scl:ddY mice, and in Harderian gland of B6C3F1 female mice, respectively. Kidney data were considered to provide a clear evidence of TCEP induced carcinogenic activity in male Scl:ddY mice. For risk characterization purposes a LOAEL of 12 mg/kg bw/d is brought forward for tumor formation. The carcinogenic effect of TCEP is thought to be related to non-genotoxic (epigenetic) mechanisms. According to the decision of the EU C&L WG TCEP is be classified as a carcinogen, category 3 and labelled as Harmful, Xn, R 40.

3.3.9 Toxicity for reproduction

TCEP revealed significant impairment of reproductive capacity and fertility during continuous breeding and for 2 successive generations in mice for both sexes. An oral $NOEAL_{fertility}$ of 175 mg/kg bw/ was derived from the studies with mice (Gulati and Chapin, 1991). There are no human data on reproductive toxicity. Based on the available animal data TCEP is identified as a reproductive toxicant with a significant toxic potential adverse to fertility. Treatment of mice resulted in significant impairment of reproductive success of both sexes and of male reproductive organs and of sperm parameters. Therefore, TCEP is classified and labelled as reproductive toxicant Cat. 2, R 60. No significant toxicity to embryo-/fetal development has been revealed from TCEP treatment in pregnant rats.

Risk Assessment Human health

Conclusion (iii)

According to the EU-RAR (2008) the conclusion is that for **workers** there is a need for specific measures to limit the risk. This conclusion was reached because of concerns for repeated dose toxicity and carcinogenicity as a consequence of inhalation and dermal exposure arising from all exposure scenarios. In addition, concerns for fertility as a consequence of dermal exposure arising from exposure scenarios 1 (production), 2 (processing to formulations), 3a (use of formulations with spray application) and 3b (use of formulations without aerosol formation).

For **consumers** there is also a need for specific measures to limit the risks. This conclusion is reached because of concerns for babies for repeated dose toxicity and carcinogenicity as a consequence of oral exposure arising from sucking on toys.

Conclusion (ii)

The conclusion for **humans exposed via the environment** is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to **human health (physico-chemical properties)** is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

OTHER INFORMATION

Tris (2-chloroethyl) phosphate, (TCEP) is on the 2nd priority list under Council Regulation (EEC) No 793/93 on the Control and Evaluation of the Risks of Existing Substances with Germany as Rapporteur. The final draft risk assessment report used herein was received from former ECB and has not been published at the ECB website. It is foreseen to publish the final RAR in September 2009 (personal communication).

The draft environmental EU RAR on TCEP proposes a conclusion (ii) for all environmental compartments.

The Scientific Committee on Health and Environment (SCHER) agrees with the conclusions of the EU RAR draft. The Committee (SCHER, 2006) adopted their opinion on the RAR (environmental part) on the 4 July 2006. In addition, SCHER agrees that TCEP is a non-PBT substance, thus it lacks the bio-accumulation potential. Nevertheless, it should be considered that the PEC/PNEC ratios are below, but close to 1. SCHER recommends monitoring the production/use volume.

According to the EU RAR draft, 2008 a conclusion (iii) is obtained for workers and consumers.

For **workers** there is a need for specific measures to limit the risk. This conclusion was reached because of concerns for repeated dose toxicity and carcinogenicity as a consequence of inhalation and dermal exposure arising from all exposure scenarios (scenarios 1: production, 2: processing to formulations, 3a: use of formulations with spray application and 3b: use of formulations without aerosol formation).

For **consumers** there is also a need for specific measures to limit the risks. This conclusion is reached because of concerns for babies for repeated dose toxicity and carcinogenicity as a consequence of oral exposure arising from sucking on toys.

A draft recommendation for TCEP was given at the 14th Risk Reduction Strategy (RRS) meeting in October 2007 (14th RRSM, 2007).

The strategy for limiting the risks for workers as proposed by the German rapporteur was to establish at community level occupational exposure limit values (OELs) for TCEP according to Directive 98/24/EEC[18] or Directive 2004/37/EC[19] as appropriate. The strategy for limiting the risks for consumers was to consider at Community level marketing and use restrictions in Council Directive 76/769/EEC (Marketing and Use Directive) for the use of TCEP in sucking toys for babies.

At the 15th Risk Reduction Strategy (15th RRSM, 2008) the Commission concluded that the draft recommendation on TCEP was endorsed with revisions by the meeting. It was agreed to establish a community level OEL and the marketing and use restrictions for the use of TCEP in sucking toys. The Commission is to finalize and progress to publish it.

[18] OJ L 131, 05.05.1998, p. 11

[19] OJ L 158, 30.04.2004, p. 50

Due to the classification of the substance as reprotoxic cat 2 in the 1st ATP of the CLP regulation, the Commission may apply Article 68 paragraph 2 and amend Annex XVII following the Committee procedure; setting restrictions for sucking toys for babies.

The revised Toys Directive[20] will regulate the use of all substances classified as CMR in toys present in concentrations above 0.1%. For concerns arising from concentrations below this value specific restrictions under Annex XVII might be considered. At the moment no Member State has (pre)-notified an intention to prepare an Annex XV restriction dossier.

At the 2nd CARACAL meeting (15-16 June, 2009) the work plan for future restrictions (including TCEP) was discussed.

TCEP is mentioned on the priority list of European Trade Union Confederation (ETUC). This list proposes substances of very high concern (SVHC) and should encourage industry to develop safer substances, improve the protection of workers, consumers and the environment.

The Government of Canada has conducted a science-based evaluation of TCEP. TCEP was identified in the categorization of the *Domestic Substances List* as a high priority for action under the Challenge (Draft Screening Assessment, Environment Canada, Health Canada, 2009[21]). TCEP was considered to pose intermediate potential for exposure to individuals in Canada.

Literature

Note that no re-evaluation was conducted of those references which are cited in this Annex XV dossier and which were taken from the Risk Assessment Report for TCEP (EU RAR draft, 2008). The last full literature survey for the RAR was carried out in 2006 (human health and environmental part) with subsequently conducted targeted searches. For the present dossier no comprehensive literature survey was carried out, but focus was given to exposure related data (especially monitoring data).

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