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Environmental risk evaluation report: 2-Ethylhexyl diphenyl phosphate (CAS no. 1241-94-7)

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Steve Killeen

Head of Science

Executive summary

An environmental risk assessment has been carried out for 2-ethylhexyl diphenyl phosphate (CAS no. 1241-94-7) on the basis of available information and using the methods of a European Technical Guidance Document. In Europe this substance is mainly used as a flame retardant plasticizer in flexible PVC, and also in rubber, polyurethanes, photofilms, paints, pigment dispersions, adhesives and textile coatings.

Potential risks are identified for most or all areas of use for the surface water (fresh and marine), sediment (fresh and marine) and soil compartments and for secondary poisoning in the terrestrial food chain. Risks are also indicated for some uses through the freshwater and marine food chains and for humans exposed through the environment.

Emission estimates are based on information from a number of generic sources, including emission scenario documents and other risk assessments, so they could be refined with more specific information for the substance itself. However, some of the risk characterisation ratios are high and it is unlikely that such information will be sufficient to remove all of the risks identified.

The assessment could also be refined through further toxicity testing with sediment and terrestrial organisms. In each case it is likely that three long-term studies would be required. The actual need for testing is closely linked with that for the other triaryl and alkyl/aryl phosphates considered as part of this project. A suggested testing strategy for the group as a whole is outlined in a separate overview document.

The risks to waste water treatment plant and air from production and all uses are low. A low risk is also indicated for regional sources for surface water and soil.

2-Ethylhexyl diphenyl phosphate does not meet the criteria for a persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substance.

Introduction

This report is one of a series of evaluations covering a group of related substances that represent the major aryl phosphate ester products used in Europe:

Triphenyl phosphate
Trixylenyl phosphate
Tricresyl phosphate
Cresyl diphenyl phosphate
Tris(isopropylphenyl) phosphate
Isopropylphenyl diphenyl phosphate
Tertbutylphenyl diphenyl phosphate
2-Ethylhexyl diphenyl phosphate
Isodecyl diphenyl phosphate
Tetraphenyl resorcinol diphosphate

A further substance is known to be commercially available, but it has already been assessed under the Notification of New Substances (NONS) Regulations. Information is also available on some (possibly obsolete) triaryl phosphates that are not thought to be supplied in the EU. This information is summarised in Annex A, but the risks from these products have not been assessed. Information for the group as a whole has also been used in this assessment, where appropriate, to fill any gaps in the database for this particular substance. Annex B discusses the read-across of data between the various phosphate esters considered.

This group was highlighted for assessment during preliminary work for a review of flame retardants (eventually published as Environment Agency 2003), particularly because they are potential replacements for other flame retardants that have already been identified as a risk to health or the environment. Regulators need to understand the potential consequences of such market switches before substantial replacement takes place. These assessments are not intended to provide a basis for comparison between the different aryl phosphates themselves; such a comparison would require consideration of a wider range of factors than are included here (such as human health risks, efficacy, recycling potential and costs). The assessments have been produced as part of the UK Coordinated Chemical Risk Management Programme (UKCCRMP) (http://www.defra.gov.uk/environment/chemicals/ukrisk.htm).

The methodology used in the report follows that given in an EU Technical Guidance Document (TGD)[1] for risk assessment of existing substances. The scientific work was mainly carried out by the Building Research Establishment Ltd (BRE), under contract to the Environment Agency. The review of mammalian toxicity data for the assessment of non-compartment specific effects was carried out by the Institute of Environment and Health, under contract to the Department for Environment, Food and Rural Affairs (Defra).

[1] This document has recently been replaced by similar guidance for the REACH Regulation.

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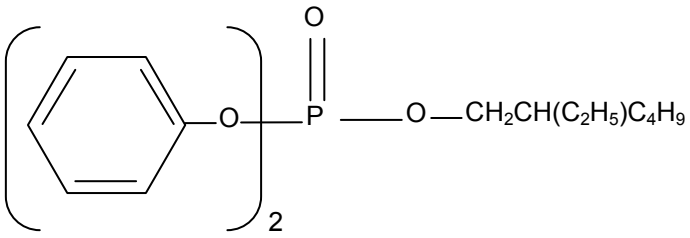
1 General substance information

1.1 Identification of the substance

This assessment considers the following commercial substance.

CAS No:	1241-94-7
EINECS No:	214-987-2
EINECS Name:	2-Ethylhexyl diphenyl phosphate
Molecular formula:	$C_{20}H_{27}O_4P$
Molecular weight:	362.4 g/mol
Structural formula:	



Other names, abbreviations, trade names and registered trademarks for this substance include the following.

EHDP
Diphenyl 2-ethylhexyl phosphate
Disflamoll DPO®
Phosflex 362®
Phosphoric acid, 2-ethylhexyl diphenyl ester
Santicizer 141®

The term diphenyl octyl phosphate (CAS Number 115-88-8) may have also been used in the past for this type of product.

Some of the trade names and trademarks may refer to older products no longer supplied to the EU, or products produced outside the EU, but these are included in the report as they are sometimes referred to in the open literature.

The name 2-ethylhexyl diphenyl phosphate is used in this assessment.

1.2 Purity/impurity, additives

1.2.1 Purity/impurities

Commercial 2-ethylhexyl diphenyl phosphates were reported to be more than 90 per cent pure (Saeger *et al.* 1979, Ferro 2002) and 94.5 per cent pure (Muir and Grift 1981), with a triphenyl phosphate content of less than 4 per cent (Ferro 2002).

Bayer (2002) reported that another commercial product contained 1.5 per cent triphenyl phosphate.

1.2.2 Additives

Additives are not thought to be present in commercially supplied products, although some aryl phosphate ester products are sometimes supplied as blends with other (halogenated) flame retardants.

1.3 Physico-chemical properties

Detailed test reports were not available for review, and so the validity of many of the reported values for physico-chemical properties is not always clear.

1.3.1 Physical state (at normal temperature and pressure)

Commercial 2-ethylhexyl diphenyl phosphate is a clear, oily liquid at room temperature (Ferro 2002). Bayer (2002) indicates that another commercial product is a clear, almost colourless liquid.

1.3.2 Melting point

The melting point (pour point) of commercial 2-ethylhexyl diphenyl phosphate is below -54°C (Ferro 2002). A pour point of -60°C is reported for another commercial product (Bayer 2002). Muir (1984) gives the melting point for 2-ethylhexyl diphenyl phosphate as -80°C. The Japanese Chemicals Evaluation and Research Institute (CERI 2003) report a melting point of -54°C for 2-ethylhexyl diphenyl phosphate.

A melting/pour point of -60°C is assumed in the assessment.

1.3.3 Boiling point

Wightman and Malalyandi (1983) determined the boiling point at reduced pressure of a pure sample of 2-ethylhexyl diphenyl phosphate to be 181°C at 0.6 mmHg (80 Pa). The paper also quotes a further literature value of 232°C at 6 mmHg (800 Pa). Ferro (2002) reported a reduced pressure boiling point of 239°C at 1,330 hPa (10 mmHg) for a commercial 2-ethylhexyl diphenyl phosphate and indicated that decomposition of the product occurred under these conditions. Bayer (2002) gives a boiling point of 225°C at 500 Pa for another commercial product determined using the DIN 53 171 method. IUCLID (2000a) and CERI (2003) report a boiling point value of 375°C at atmospheric pressure (101,325 Pa).

Further boiling points are reported by Boethling and Cooper (1985) as 230°C at 5 mmHg (667 Pa) and 150°C at 0.2 mmHg (26.7 Pa). Bayer (2002) reports that the decomposition temperature for a commercial 2-ethylhexyl diphenyl phosphate is around 240°C.

A boiling point of 375°C at atmospheric pressure is assumed in the assessment.

1.3.4 Density

Shankwalkar and Cruz (1994) reported a relative density of 1.07 at 20°C for a commercial 2-ethylhexyl diphenyl phosphate. A similar relative density of 1.09 at 20°C is reported by Ferro (2002) for a commercial 2-ethylhexyl diphenyl phosphate product and Bayer (2002) gives a density of 1.085 g/cm^3 at 20°C (determined by the DIN 51 757 method) for another commercial product.

A relative density of 1.07-1.09 at 20°C is assumed in the assessment.

1.3.5 Vapour pressure

The vapour pressure at ambient temperature is an important physico-chemical property for environmental risk assessment because it is used to estimate both the distribution of a substance in the environment and the volatile releases from products.

No reliable data appear to be available for 2-ethylhexyl diphenyl phosphate at temperatures around 20-25°C. However, information on boiling points at reduced pressure (see Section 1.3.3) and at elevated temperatures is available.

Ferro (2002) reported the vapour pressure for a commercial 2-ethylhexyl diphenyl phosphate product to be 27 Pa at 150°C and 213 Pa at 200°C. A vapour pressure of 10 Pa at 150°C is reported in IUCLID (2000b) for another commercial product. Muir (1984) gives a vapour pressure of 0.5 mmHg (67 Pa) at 100°C; however, this value appears to be out of line with other data and so is not considered further here.

The vapour pressure (or boiling point at reduced pressure) of a pure substance is related to the temperature within a limited temperature range according to the simplified Clapeyron-Clausius equation:

$$\log (\text{vapour pressure}) = [\Delta H_v/2.3RT] + \text{constant}$$

where vapour pressure is in Pa
ΔH_v = heat of vapourization in J/mol
R = the universal gas constant 8.314 J/mol K
T = temperature in K

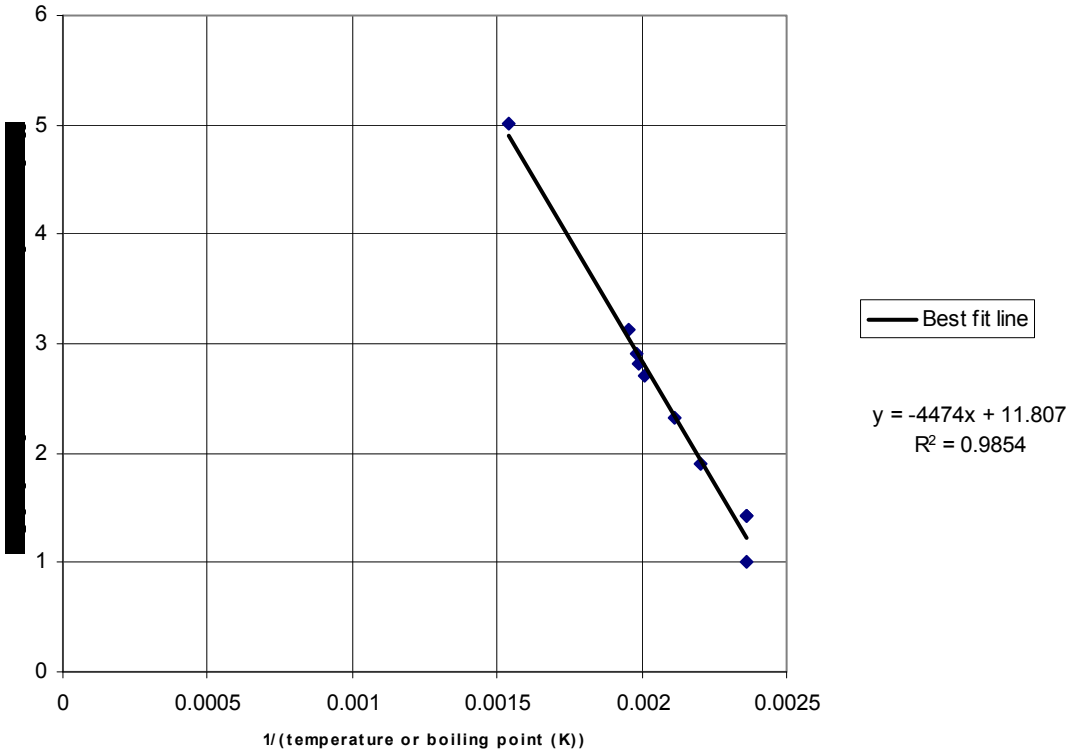
Figure 1.1 shows a plot of log (vapour pressure or reduced pressure (Pa)) against 1/(temperature or boiling point (K)) for the available data. The plot corresponds to the following regression equation:

$$\log (\text{vapour pressure (Pa)}) = [-4474 \times 1/(\text{temperature (K)})] + 11.807$$

From the slope of the plot, the value of ΔH_v for 2-ethylhexyl phosphate is estimated to be -85,553 J/mol.

Using this equation, the vapour pressure of 2-ethylhexyl phosphate is estimated as 3.4×10^{-4} Pa at 20°C, 6.2×10^{-4} Pa at 25°C, 17 Pa at 150°C and 223 Pa at 200°C. The value for ΔH_v may vary with temperature and so could introduce further errors in extrapolating the data obtained at elevated temperatures to ambient temperatures.

Figure 1.1 Plot of log (vapour pressure or reduced pressure (Pa)) against 1/(temperature or boiling point (K)) for 2-ethylhexyl diphenyl phosphate



A vapour pressure (at 25°C) of 1.88×10^{-7} mmHg (2.5×10^{-5} Pa) can be estimated for 2-ethylhexyl diphenyl phosphate from its structure using the Syracuse Research Corporation MPBPWIN (version 1.28) software (modified Grain method). Boethling and Cooper (1985) estimated a vapour pressure of 1.4×10^{-5} to 3.0×10^{-5} mmHg (1.9×10^{-3} to 4.0×10^{-3} Pa) at 25°C from the boiling point of 2-ethylhexyl diphenyl phosphate (Grain method).

The vapour pressure of 2-ethylhexyl diphenyl phosphate is taken to be 3.4×10^{-4} Pa at 20°C and 6.2×10^{-4} Pa at 25°C in this assessment.

1.3.6 Water solubility

The Research Institute for Chromatography (RIC 2004) determined the solubility of a commercial 2-ethylhexyl diphenyl phosphate using a slow stirring method. Distilled water was stirred in a large glass vessel with a coated stirrer bar, with the vessel isolated from the stirrer plate to avoid temperature effects. The stirring rate used, 100 rpm, was low enough to avoid the formation of a vortex. After the water was stirred for 24 hours, a drop of 4 µl of the substance (4.3 mg) was added to the water surface, where it formed a single drop. Water was sampled from the bottom of the vessel through a tap at 2, 5, 9 and 19 days after the addition of the substance, with three samples taken each time. Samples were extracted with cyclohexene, and the cyclohexene layer analysed by GC-MS. The mean concentration after two days was 36.2 µg/l, and at five days was 50.6 µg/l. After this time, the concentrations reduced with time, and extra peaks were observed in the chromatograms, presumably indicating decomposition.

Saeger *et al.* (1979) determined the solubility of a commercial 2-ethylhexyl diphenyl phosphate using a shake flask method. The substance used was a commercial product consisting of more than 90 per cent 2-ethylhexyl diphenyl phosphate. In the

experiment, 25 ml of the phosphate ester was added to 500 ml of purified water and shaken for 48 hours. The solution was then allowed to stand for one week in the dark before the aqueous phase was centrifuged at 20,000 g for one hour to remove droplets of undissolved substance. The aqueous phase was extracted twice with methylene dichloride and the extracts were analysed for 2-ethylhexyl diphenyl phosphate by a gas chromatography (GC) method (the centrifugation/extraction/analysis steps were carried out in duplicate and gave a mean relative average deviation of 13 per cent). The solubility of the substance tested was determined to be 1.9 mg/l at room temperature.

IUCLID (2000a) reports a water solubility of 0.38 mg/l for 2-ethylhexyl diphenyl phosphate from an unpublished industry study. The entry notes that the composition of the current product is different from that of the test substance used in this test.

Hollifield (1979) estimated a water solubility for octyl diphenyl phosphate of 0.14 mg/l at 24°C using a nephelometric technique. The method involved dissolving the substance in a water miscible solvent (ethanol or acetone) and measuring the turbidity of dilutions of increasing amounts of this solution in water. A turbidity curve was then constructed and extrapolation of this curve to the blank value provided an estimate of the water solubility of the substance. This substance would be expected to be closely related to 2-ethylhexyl diphenyl phosphate.

A water solubility of around 0.067 mg/l at 25°C can be estimated for 2-ethylhexyl diphenyl phosphate using the Syracuse Research Corporation WSKOW version 1.30 software (the estimate is based on a log K_{ow} of 5.73).

The commercial product contains a proportion of the more soluble triphenyl phosphate, and so the results have to be interpreted with care. The RIC (2004) study is considered to be the most appropriate from which to derive a solubility for the substance, and so a water solubility of 51 µg/l at room temperature is assumed in this assessment.

1.3.7 Octanol-water partition coefficient (log K_{ow})

The octanol-water partition coefficient of a 2-ethylhexyl diphenyl phosphate has been determined using a shake flask method (Saeger *et al.* 1979). The substance used was a commercial product consisting of above 90 per cent 2-ethylhexyl diphenyl phosphate. In the study, the substance was dissolved in n-octanol (at least two concentrations were tested between 100 mg/kg and 10,000 mg/kg) and 100 ml of this solution was shaken with 500 ml of purified water for 48 hours in the dark. The mixture was then allowed to stand for seven days in the dark before the concentration in the water phase (based on the sum of the major components of the product found in the gas chromatography trace) was determined (as only small amounts of the test substance were found to partition into the water phase, the concentration of the substance in the n-octanol phase was taken to be the starting concentration). The partition coefficient obtained was 534,000 (log K_{ow} = 5.73).

Renberg *et al.* (1980) determined the octanol-water partition coefficient for a 2-ethylhexyl diphenyl phosphate (the same substance as used by Saeger *et al.* 1979 above) using high performance thin layer chromatography (HP-TLC). The log value determined was 5.00, which is in reasonable agreement with that measured above.

A log K_{ow} of 6.30 can be estimated for 2-ethylhexyl diphenyl phosphate from its structure using the Syracuse Research Corporation Log K_{ow} (version 1.60) software.

A log K_{ow} of 5.73 is used in this assessment

1.3.8 Hazardous physico-chemical properties

Ferro (2002) reports a flash point (open cup) of 224°C for a commercial 2-ethylhexyl diphenyl phosphate. Bayer (2002) reports a similar flash point (open cup) of above 223°C for another commercial product determined using the ISO 2592 method.

The substance is reported to be non-flammable (Ferro 2002). Bayer (2002) reports that the ignition temperature for a commercial 2-ethylhexyl diphenyl phosphate is above 500°C using the DIN 51 794 method.

No information could be located for explosivity or oxidising properties of this substance (Ferro 2002).

1.3.9 Other relevant physico-chemical properties

Surface tension

The surface tension of a commercial 2-ethylhexyl diphenyl phosphate is reported to be 0.0367 Nm at 23°C (Ferro 2002).

Henry's law constant

Based on the water solubility of 51 µg/l and a vapour pressure of 6.2×10^{-4} Pa at 25°C, the Henry's law constant for 2-ethylhexyl diphenyl phosphate can be estimated as 4.44 Pa m^3/mol.

A Henry's law constant of 2.48×10^{-7} atm m^3/mol (0.025 Pa m^3/mol) at 25°C is estimated for 2-ethylhexyl diphenyl phosphate from chemical structure (bond contribution method) using the Syracuse Research Corporation HENRYWIN (version 3.00) software.

Muir *et al.* (1985) measured the Henry's law constant for ^{14}C-labelled 2-ethylhexyl diphenyl phosphate using a gas sparging technique. The test was carried out at 25°C using a one-litre water column containing 10-100 µg/l of the test substance. The column was sparged with nitrogen at a flow rate of 200 ml/min for up to 46 hours and the amount of test substance present in the gas was determined at various time intervals. A mean Henry's law constant of 5.49 Pa m^3/mol was determined from the slope of the first order volatilisation curve. This value is slightly higher than the value obtained from the water solubility and vapour pressure of 2-ethylhexyl diphenyl phosphate. The purity of the substance used in the test was not given in the paper, but the substance was synthesised from ^{14}C-labelled ethylhexanol and phenol. As ^{14}C was used to determine the amount of test substance volatilised in this study, the presence of any ^{14}C impurity more volatile than the 2-ethylhexyl diphenyl phosphate could have adversely affected the results of this test.

A Henry's law constant of 4.44 Pa m^3/mole at 25°C is used in this assessment. This value is consistent with available water solubility and vapour pressure data, and is in good agreement with the value measured directly.

1.3.10 Summary of physico-chemical properties

The physico-chemical properties of 2-ethylhexyl diphenyl phosphate are summarised in Table 1.1. Most of the data have been obtained with commercial products and so some properties may vary depending on the actual composition of the products.

Table 1.1 Summary of environmentally relevant physico-chemical properties of 2-ethylhexyl diphenyl phosphate

Property	Value
Melting point	-60°C (pour point)
Boiling point (at atmospheric pressure)	375°C
Relative density	1.07-1.09 at 20°C
Vapour pressure	3.4×10^{-4} Pa at 20°C and 6.2×10^{-4} Pa at 25°C
Water solubility	51 µg/l at room temperature
Octanol-water partition coefficient (log value)	5.73
Henry's law constant	4.44 Pa m^3/mol at 25°C

2 General information on exposure

2.1 Production

There are two known European production sites (one of which – Solutia UK Limited, Newport, Gwent, UK – operates under a toll agreement with Ferro) and one additional European supplier. Information on production volume and market size is therefore confidential. It is possible that other companies may supply this substance, but no further information is available for this report.

2.2 Use

2.2.1 General introduction

Triaryl phosphate flame retardants were first commercialised in the early twentieth century for use in flammable plastics such as cellulose nitrate and later for cellulose acetate (Weil 1993). Use in cellulose products is still significant but the largest area of application is now in plasticized vinyl polymers. The main applications of these products are in wire and cable insulation, connectors, automotive interiors, vinyl moisture barriers, furniture upholstery, conveyor belts (for mining) and vinyl foams.

In addition to their use as flame retardants in polymer systems, triaryl phosphates are also used as fire-resistant hydraulic fluids, lubricants and lubricant additives (Weil 1993). Small amounts are also reported to be used as non-flammable dispersing media for peroxide catalysts.

Alkyl diphenyl phosphate products were originally developed to improve low temperature flexibility in PVC over that obtained with triaryl phosphates. Alkyl diphenyl phosphates are slightly less efficient as flame retardants than triaryl phosphates, but generally result in lower smoke formation when PVC is burned (Weil 1993).

2.2.2 Uses of 2-ethylhexyl diphenyl phosphate

The main use of 2-ethylhexyl diphenyl phosphate is as a flame retardant/plasticizer in flexible PVC. The substance has been approved for use in certain food packaging applications in the United States (Weil 1993).

Information on sales of 2-ethylhexyl diphenyl phosphate in the EU has been provided by the relevant supplier companies for the year 2001. The exact figures are confidential, however the main current uses of the substance are in PVC, rubber, polyurethanes, photofilms, paints, pigment dispersions, adhesives and textile coatings.

3 Environmental exposure

This assessment has been prepared in accordance with the principles of Council Regulation (EEC) 793/93 (the Existing Substances Regulation or ESR)[2] and the methods laid down in Commission Regulation (EC) 1488/94[3], which is supported by a Technical Guidance Document or 'TGD' (EC 2003). The European Union System for the Evaluation of Substances (EUSES) computer program[4] (v2.0.3) implements the TGD models. The EUSES output file for this assessment is confidential because of the information it contains on tonnage and use pattern.

The assessment carried out here is generic, representing a *realistic worst case approach* for a hypothetical environment that broadly reflects average European conditions. It uses a number of assumptions (such as a fixed river dilution level), and further details can be found in the TGD. The assessment is based on estimated sales figures for Europe and some site-specific information. Since these are confidential, the calculations are presented in the Confidential Annex, but they are discussed qualitatively in the report as appropriate.

3.1 Environmental fate and distribution

3.1.1 Degradation

Abiotic degradation

Atmospheric photo-oxidation

A rate constant for reaction of 2-ethylhexyl diphenyl phosphate with atmospheric hydroxyl radicals of 39.8×10^{-12} cm^3/molecule s can be estimated from its structure using the Syracuse Research Corporation AOP (version 1.86) software. This program implements the method recommended in the Technical Guidance Document for estimating the rate constant.

Using an atmospheric hydroxyl radical concentration of 5×10^5 molecules/cm^3, a half-life for the reaction in air is estimated to be 9.7 hours.

Hydrolysis

No information appears to be available on the hydrolysis of 2-ethylhexyl diphenyl phosphate. By comparison with other aryl phosphates, hydrolysis of 2-ethylhexyl diphenyl phosphate would be expected to occur, particularly under alkaline and acidic conditions, but it is not currently possible to estimate the rate of this reaction in the environment for 2-ethylhexyl diphenyl phosphate.

Photolysis

IUCLID (2000a) reports the results of an unpublished study into the aqueous photolysis of 2-ethylhexyl diphenyl phosphate. The test was carried out according to the ASTM

[2] O.J. No L 084, 05/04/1993 p. 0001–0075.
[3] O.J. No L 161, 29/06/1994 p. 0003–0011.
[4] Available from the European Chemicals Bureau, http://ecb.jrc.ec.europa.eu/.

E47.06 Task Group on Aqueous Photolysis, Draft Method No. 8, 7-19-81. The substance was tested at a concentration of 1 mg/l at 22.5°C using natural sunlight (end of August in St. Louis, United States (latitude 38 degrees 37 minutes and 44 seconds)). The total number of sunlight hours during the 14-day exposure period was 235 hours and a half-life of above 24 days was reported for the substance. This shows that direct photolysis in the environment is unlikely to be a significant degradation mechanism for 2-ethylhexyl diphenyl phosphate in the environment.

Biodegradation

Bayer (2002) and IUCLID (2000a) state that 67 per cent degradation after 28 days was seen in a modified MITI-biodegradation test (ISO DP 9408) based on an unpublished study. The inoculum used was predominantly communal waste water. The extent of degradation seen was 0 per cent by day 10, 17 per cent by day 14, 58 per cent by day 18, 61 per cent by day 20, 65 per cent by day 26 and 67 per cent by day 28. Thus, based on the results of this test, the substance can be considered to be readily biodegradable meeting the ten-day window.

The Japanese Chemicals Evaluation and Research Institute (CERI 2003) also report the results of a MITI (I) ready biodegradation test using 2-ethylhexyl diphenyl phosphate. The test was carried out for 28 days at 25°C using an initial activated sludge concentration of 30 mg/l and an initial test substance concentration of 100 mg/l. The average percentage degradation (as determined by biochemical oxygen demand (BOD)) over three replicates was one per cent. Analysis for the test substance was also performed at the end of the test. This showed that an average of five per cent had degraded during the test. The results of this test appear to be out of line with the bulk of the biodegradation data available for this substance.

IUCLID (2000a) reports the results of another unpublished biodegradation study. The test was an OECD 301B Modified Sturm ready biodegradation test. The concentration of 2-ethylhexyl diphenyl phosphate tested was 20 mg/l and the inoculum was adapted activated sludge. The extent of degradation seen was 82 per cent after 28 days, measured as CO_2 evolution. Although the test system used normally measures the ready biodegradability of a substance, as an adapted inoculum was used in this test, the results can only be interpreted as indicating that the substance is inherently biodegradable, rather than readily biodegradable.

Another unpublished ready biodegradation test for 2-ethylhexyl diphenyl phosphate carried out with an adapted activated sludge inoculum is reported in IUCLID (2000a). This test was apparently based on the EPA 40CFR D796.3100 method and measured CO_2 evolution. The concentration of the substance tested was 30 mg/l and the extent of degradation seen after 28 days was 62 per cent. Again, as an acclimated inoculum was used in this test the results are interpreted as indicating that the substance is inherently biodegradable.

Saeger *et al.* (1979) (the same results appear to have been reported by Carson *et al.* 1990) determined the biodegradation of a commercial 2-ethylhexyl diphenyl phosphate using various test systems. The substance used was a commercial product consisting of above 90 per cent 2-ethylhexyl diphenyl phosphate. The first test investigated the primary degradation of the test substance using a river die-away method. The water used in the test was settled Mississippi River water. The test substance (at a concentration of 1 mg/l) was added to the water and the test vessels (bottles) were sealed with a foil-lined cap and stored in the dark at room temperature. Sterile control solutions (containing the same concentration of test substance) and positive control solutions (containing linear alkyl benzene sulphonate) were also run. At various times during the study, a bottle was removed and the amount of the phosphate ester present

was determined (the gas chromatographic method used analysed the sum of the major components present in the test substance). The results showed that the test substance underwent primary degradation in the test system with almost complete degradation in around 10-21 days. No significant degradation was seen in the sterile controls. Carson *et al.* (1990) reported the degradation at the end of the study as 84-99 per cent based on parent compound (primary degradation) and 56-68 per cent for ultimate mineralisation.

The second part of the study investigated the primary degradation of the test substance using a semi-continuous activated sludge (SCAS) unit. The method used was based on the Soap and Detergent Association procedure (Soap and Detergent Association 1965 and 1969). The activated sludge used in the test was of domestic origin and the vessels used had an operating volume of 1.5 litres. The test substance was added to the unit at a rate of 3 mg/l per 24-hour cycle. The units were operated for a period of 22 weeks and samples of the mixed liquor were removed at weekly intervals and the concentration of the phosphate ester present was determined. The results indicated an equilibrium removal rate of 74 ± 9 per cent in the test system. To investigate the loss by volatilisation, the off-gases were passed through a series of scrubbers. No significant loss by volatilisation (below 0.5 per cent per cycle) of the phosphate ester was seen.

The final part of the study investigated the ultimate mineralisation of the test substance using a degradation method based on the modified Sturm method. An acclimated bacterial seed was prepared by incubation of 100 ml of settled supernatant from a SCAS unit with 20 mg of one of eleven phosphate esters (including the test substance), 50 mg of yeast extract and 900 ml of standard biological oxygen demand (BOD) water for 14 days in the dark at room temperature. At the end of the incubation period, a combined acclimated seed was prepared by mixing samples from each acclimation bottle and this was used as seed for the inherent biodegradation test. In the test 500 ml of the composite seed was added to 5,500 ml of BOD water and the substance was then added to the bottle (initial concentration 21.6 mg/l). During the test, CO_2-free air was continually bubbled through each bottle and the CO_2 evolved determined. Control bottles (receiving no test substance) were also run. The amount of CO_2 evolved from the control bottles was around 10-15 per cent of that of the bottles containing the test substance and the results were corrected for this background CO_2 level. CO_2 evolved from the test substance (expressed as a percentage of the maximum theoretical amount) was 37 per cent after seven days and 82 per cent after 28 days. Thus, the substance can be considered inherently biodegradable based on the results of this test.

IUCLID (2000a) also reports the results of an unpublished OECD 302A Modified SCAS inherent biodegradability test. The concentration of the substance tested was 5 mg/l and 50-85 per cent degradation was seen within a 24-hour period.

Carson *et al.* (1990) also reported results for the biodegradation of a commercial 2-ethylhexyl diphenyl phosphate in microcosm tests. The tests were carried out using lake water and sediment collected from the littoral region of a spring-fed freshwater lake in 5- or 10-gallon aquaria. The sediment was screened (1.3 cm) and placed to a depth of 8 cm in the aquaria. Twenty-two litres of lake water were then added to the aquaria and the system was allowed to stabilise for six weeks. After this time, core chambers were created within the aquaria by inserting glass cylinders through the water column and sediment and the test substance was added to each chamber (concentration not clear). Sterile control chambers were created by adding formaldehyde to the chamber. The percentage ultimate degradation seen in the test (mineralisation) was reported to be 5 to 24 per cent, but it is not clear over what time frame this test was carried out.

IUCLID (2000a) give the results of an unpublished study investigating the mineralisation of ^{14}C-labelled 2-ethylhexyl diphenyl phosphate in lake water or a lake water/sediment system. The test was carried out for 31 days using test concentrations

of 0.05 mg/l and 0.5 mg/l using either lake water alone or a water/sediment core. The rate of biodegradation was monitored by $^{14}CO_2$ evolution and the rate was found to be higher in water alone than in the water/sediment core. The total amount of mineralisation was 56 to 68 per cent after 31 days in water at an initial concentration of 0.05 mg/l and 60 to 67 per cent after 31 days in water at an initial concentration of 0.5 mg/l. The degradation seen after 31 days in the water/sediment system was 15 to 23 per cent at 0.05 mg/l and 5 to 13 per cent at 0.5 mg/l.

The results of an unpublished river die-away study using both a commercial 2-ethylhexyl diphenyl phosphate product and a pure sample of 2-ethylhexyl diphenyl phosphate are also given in IUCLID (2000a). The substances were tested at a concentration of 0.05 and 0.5 mg/l in Mississippi River water. The tests carried out with the commercial product gave primary degradation half-lives of 0.46 days at 0.05 mg/l and 0.8 days at 0.50 mg/l (a total of 96 per cent primary degradation was seen within 20 days). The pure sample of 2-ethylhexyl diphenyl phosphate was also found to undergo rapid primary biodegradation with the concentration decreasing from 0.41 mg/l at day zero to 0.085 mg/l at day one, 0.080 mg/l at day two, 0.025 mg/l at day three and below 0.05 mg/l at day seven.

IUCLID (2000a) reports the results of experiments carried out by Kincannon and Lin (1985). The tests were carried out with a sandy loam soil (2 per cent clay, 29 per cent silt and 69 per cent sand, pH 7.1, water content 25 per cent) and a clay loam (27 per cent clay, 45 per cent silt and 24 per cent sand, pH 7.2, water content 25 per cent). The concentration of the substance tested was 425 mg/kg in the sandy loam and 578 mg/kg in the clay loam and the half-life for (primary) degradation at 20°C was determined to be 24-58 days in the sandy loam (a total of 77 per cent degradation was seen after 97 days) and 23 days in the clay loam (a total of 90 per cent degradation was seen after 76 days).

The effect of temperature and redox potential on the degradation of several phosphate esters, including 2-ethylhexyl diphenyl phosphate, in two natural sediments has been investigated by Muir *et al.* (1989). The 2-ethylhexyl diphenyl phosphate tested was ^{14}C-labelled (labelling on the phenyl rings) mixed with a purified non-labelled 2-ethylhexyl diphenyl phosphate. The sediment samples used in the study were collected from a eutrophic farm pond and the Red River, Winnipeg (both samples were from agricultural areas remote from industry). The pond sediment consisted of 75 per cent clay, 24 per cent silt and one per cent sand and had an organic carbon content of 3.7 per cent and a pH of 7.6 and the river sediment consisted of 48 per cent clay, seven per cent sand and 43 per cent silt and had an organic carbon content of 2.3 per cent and a pH of 7.7.

The aerobic sediment experiments were carried out using either loosely capped flasks (static test) or respirometer flasks with air flowing through the system (1-2 ml/minute). The sediments incubated under anaerobic conditions (in respirometer flasks under a nitrogen flow (1-2 ml/minute)) were amended with one per cent by weight of microcrystalline cellulose to provide an additional source of carbon. The degradation experiments were carried out using around 10 g (dry weight) of sediment in dechlorinated water (sediment:water ratios of either 1:10 (static test) or 1:20 (respirometer flask)). Each sediment sample was pre-incubated for 21 days at the intended experimental temperature prior to the addition of the test substance. The concentration tested was either 0.1 mg/l (static test) or 0.05 mg/l (respirometer flasks) and the substance was added as 0.1 ml of a solution in acetone. All experiments were carried out in duplicate for up to 64 days and sterile controls were also run to investigate the abiotic degradation of 2-ethylhexyl diphenyl phosphate under the conditions used. The aerobic experiments were incubated with a 16:8 hours light:dark photoperiod (using low intensity light) whereas the anaerobic experiments were incubated in darkness. The microbial biomass present in the test systems was between 9×10^6 to 32×10^6 colony-forming units (CFU)/g in the experiments with river sediments.

The microbial biomass present in the aerobic pond respirometer sediments was found to decline from 42×10^6 CFU/g to 0.3 CFU/g over the 64-day period. The total microbial biomass (aerobic and facultative anaerobic heterotrophs) present in the N_2-purged respirometer experiments was 5.3×10^6 CFU/g after three to eight days and 24×10^6 after 30-40 days, but the number of strict anaerobes present was around eight to forty times less, and so the incubations were not strictly anaerobic. The results of the experiments are summarised in Table 3.1.

The results suggest that degradation of 2-ethylhexyl diphenyl phosphate was characterised by slow oxidation of the parent compound and rapid transformation of the resulting polar products. Initially, most of the 2-ethylhexyl diphenyl phosphate added to the system adsorbed onto the sediment phase but by the end of the experiment the amount of extractable radioactivity associated with the sediment phase had decreased substantially. This low extractability is likely due to the extensive degradation of the ^{14}C-labelled aromatic rings and to irreversible sorption of the parent compound and degradation products to the sediment. Detailed analysis of the sediment extracts by GC, high performance liquid chromatography (HPLC) and reverse-phase TLC with autoradiography indicated that the major portion of the extractable radioactivity was as unchanged parent compound 2-ethylhexyl diphenyl phosphate, with low levels of degradation products, including diphenyl phosphate, also present. Less than three per cent of the extractable residue in river sediments had TLC retention factors greater than the parent compound. Evolution of $^{14}CO_2$ was a major degradative pathway for 2-ethylhexyl diphenyl phosphate under both air and N_2 aeration, and mineralisation was five-fold higher in pond than in river sediments. Judging by the high recovery of radiolabel from autoclaved pond sediments after 64 days, degradation of 2-ethylhexyl diphenyl phosphate appeared to be entirely due to microbial activity.

The amount of parent substance remaining at the end of the tests ranged from two per cent (aerobic pond sediments after 64 days) to 54 per cent (anaerobic river sediments after 40 days). Half-lives of around 5 days were determined at 10-20°C.

Muir and Grift (1983) investigated the degradation of ^{14}C-labelled 2-ethylhexyl diphenyl phosphate in river sediment incubated under both aerobic and anaerobic (nitrogen atmosphere) conditions for up to 64 days. The tests were carried out using 50 g (wet weight) of sediment in 250 ml of dechlorinated water. Few other experimental details of this test are available. The results are summarised in Table 3.2. The reaction was followed by determining the amount of ^{14}C that could be extracted from the sediment (by refluxing with aqueous methanol) and the amount that could not be extracted from the sediment. The extractable ^{14}C was found to be mainly in the form of unchanged 2-ethylhexyl diphenyl phosphate and diphenyl phosphate. The identity of the radioactivity in the unextractable fraction was not determined. Based on these results around 53 per cent primary degradation of the 2-ethylhexyl diphenyl phosphate occurred in 64 days under aerobic conditions and around 22 per cent primary degradation occurred in 64 days under anaerobic conditions.

Table 3.1 Effect of temperature and redox potential on degradation of ^{14}C-2-ethylhexyl diphenyl phosphate in sediments

Test system	Sediment	Temp.	Time (days)	Amount of ^{14}C present (% of applied)							Estimated half life[c] (days)
				Sediment – extractable[a]	Sediment – non-extractable	Water – extractable[b]	Water – non-extractable	CO_2	Total	Percentage of total as parent cpd.	
Aerobic static test system	Pond	25°C	0.25	86.7	10.4	1.2	n/a		98.3		5.3 ± 2.4
			64	32.0	17.6	0.8	6.3		56.7		
		10°C	0.25	76.6	11.8	0.9	1.9		91.2		4.5 ± 0.7
			64	31.8	8.3	<0.1	2.7		42.8		
		2°C	0.25	72.1	3.6	0.9	n/a		75.8		19.1 ± 13.3
			6	75.9	2.6	0.6	n/a		79.1		
	River	25°C	0.25	75.2	0.9	0.7	0.8		77.5		4.5 ± 2.4
			40	26.2	21.0	0.2	17.8		65.3		
Aerobic respirometer	Pond	25°C	8	62.7	10.9	15.7	n/a	3.3	92.6	19.7	
			64	12.2	49.6	1.9	n/a	22.8	86.5	2.0	
	River	25°C	3	59.0	9.3	4.7	n/a	0.1	73.4	43.5	
			40	62.5	10.1	8.3	n/a	4.4	85.2	36.9	
Anaerobic respirometer	Pond	25°C	8	81.9	4.0	3.6	n/a	0.5	89.8	29.0	
			64	69.1	2.9	1.9	n/a	8.3	82.2	4.2	
	River	25°C	3	76.6	1.5	1.7	n/a	0.1	79.8	76.6	
			40	81.2	2.4	3.0	n/a	1.0	87.7	54.2	
Autoclaved sample (aerobic static test system)	Pond	25°C	64	74.7	1.4	1.3	1.9				

Source: Muir *et al.* (1989).

Notes: a) Extracted with aqueous methanol to recover undegraded phosphate ester and any diaryl phosphate degradation products.
b) Extracted with dichloromethane to recover undegraded phosphate ester.
c) Half-life estimated based on the data obtained over days 0-6 for pond sediment and days 0-10 for river sediment. The half-life refers to the disappearance of the parent compound from the sediment phase.

Table 3.2 Degradation of ^{14}C-labelled 2-ethylhexyl diphenyl phosphate in aerobic and anaerobic river sediments

Sediment type	Incubation time	Extractable radiolabel (%)			Unextractable radiolabel (%)
		As 2-ethylhexyl diphenyl phosphate	As metabolites	Total	
Aerobic	32 days	75.1	10.9	86.0	14.0
	64 days	46.9	20.1	67.0	33.0
Anaerobic	32 days	76.5	20.7	97.2	2.8
	64 days	78.3	13.6	91.9	8.1

Source: Muir and Grift (1983).
Notes: a) The main metabolite found was diphenyl phosphate.

Summary of degradation

Abiotic degradation

No information appears to be available on the hydrolysis of 2-ethylhexyl diphenyl phosphate.

Based on the information available for other aryl phosphates (for example, see the risk evaluation report for triphenyl phosphate in this series), significant hydrolysis of the substance would be expected to occur only under alkaline (pH 8-9 and above) and acidic conditions.

Products of the initial hydrolysis would be expected to be either phenol and 2-ethylhexyl phenyl phosphate or 2-ethylhexanol and diphenyl phosphate. The diphenyl or alkyl phenyl phosphates would be expected to be more resistant to further hydrolysis than the parent compound.

It is not possible to estimate the likely rate of hydrolysis of 2-ethylhexyl diphenyl phosphate in the environment, but the rate is expected to be slow except possibly at high or low environmental pHs. A hydrolysis rate of zero will therefore be used in this assessment. However, in some acidic or alkaline environments, hydrolysis could become significant and so the effect of inclusion of a hydrolysis rate on the predicted concentrations is considered in Annex C.

The available information indicates that direct photolysis of 2-ethylhexyl diphenyl phosphate in the environment is likely to be slow, and so for the purposes of this assessment the rate is assumed to be zero.

Atmospheric photo-oxidation of 2-ethylhexyl diphenyl phosphate is predicted to occur with a half-life of around 9.7 hours. This reaction is taken into account in the risk assessment.

In summary, the abiotic rate constants and half-lives assumed in the assessment are as follows, and the importance of hydrolysis to the overall conclusions of the risk assessment is considered further in Appendix D.

Hydrolysis	$khydr_{water}$ = 0 d^{-1}	half-life = infinite
Photolysis	$kphoto_{water}$ = 0 d^{-1}	half-life = infinite
Atmospheric photo-oxidation	k_{OH} = 3.98×10^{-11} cm^3/molecule s	half-life = 9.7 h

Biodegradation

The most likely pathway for biodegradation of aryl phosphates is the initial hydrolysis of the phosphate ester to form orthophosphate and corresponding phenolic compounds or alcohols, which then undergo further biodegradation (Saeger *et al.* 1979).

There is at least one standard ready biodegradation test showing that the substance can be considered readily biodegradable, meeting the 10-day window. Recommended biodegradation half-lives for sewage treatment, surface water and soil from the Technical Guidance Document are summarised below (Kp_{soil} = 28 l/kg).

	Rate constant	Half-life
Sewage treatment plant	$k = 1\ h^{-1}$	0.7 hours
Surface water	$k = 4.7\times10^{-2}\ d^{-1}$	15 days
Soil	$k = 2.3\times10^{-3}\ d^{-1}$	300 days
Sediment	$k = 2.3\times10^{-4}\ d^{-1}$	3,000 days

There are, however, a number of screening studies that need to be considered with respect to the biodegradation rate of this substance in the environment.

For surface water, almost complete primary degradation was seen in around 10-21 days and in less than 7 to 20 days river die-away tests. However, tests looking at ultimate mineralisation found 56-68 per cent mineralisation in around 31 days. The temperature of these tests is not reported, but the data indicate that the default degradation half-life for water given above may be too short.

Tests carried out in sediment-water systems have shown that the mineralisation rate is slower than in water alone, with 5 to 23 per cent mineralisation in 31 days in one study. Another study found 53 per cent primary degradation in 64 days under aerobic conditions and 22 per cent primary degradation after 64 days under anaerobic ones.

Primary degradation half-lives of 23 to 58 days at 20°C have been determined in soil.

Although there are problems in extrapolating laboratory-determined degradation half-lives to the situation in the environment (owing to different temperatures, concentrations and so on), it is clear that the default degradation half-life of 15 days given above may not be applicable for this substance. To take this into account the mineralisation half-life for surface water is assumed to be 50 days (the default half-life for a readily biodegradable substance that does not meet the 10-day window) in this assessment, as this appears to fit better with the screening data. The default mineralisation half-life of 300 days for soil appears to be in reasonable agreement with available data, but the one for sediment of 3,000 days appears to be overly conservative. This default half-life for sediment effectively assumes that no mineralisation occurs in the anaerobic phase, which makes up to 90 per cent of the sediment used in the TGD. However, there is evidence that this substance (and other triaryl phosphates; see the risk evaluation report for triphenyl phosphate in this series) is actually mineralised under anaerobic conditions, and so for this reason, the half-life in sediment is assumed to be 300 days (the same as soil). This is in reasonable agreement with the data available for sediment.

The rate constants and half-lives for surface water, sediment and soil used in the assessment are summarised below.

	Rate constant	Half-life
Surface water	$k = 1.4\times10^{-2}\ d^{-1}$	50 days
Soil	$k = 2.3\times10^{-3}\ d^{-1}$	300 days
Sediment	$k = 2.3\times10^{-3}\ d^{-1}$	300 days

3.1.2 Environmental partitioning

Adsorption

Muir and Grift (1981) determined a suspended matter-water adsorption coefficient (Kp_{susp}) of 12,389 l/kg for 2-ethylhexyl diphenyl phosphate. The substance used in the test was ^{14}C-labelled 2-ethylhexyl diphenyl phosphate (labelling on the phenyl groups) mixed with a commercial 2-ethylhexyl diphenyl phosphate product (purity 94.5 per cent) and the test was carried out by stirring a solution of the test substance (24 μg/l) in river water (pH = 8.1; suspended matter content 30 mg/l) for three hours at 10°C. After this time the suspended solid phase and water phases were separated by centrifuge (10,000 g for 30 minutes) and the level of radioactivity in both phases was determined.

A K_{oc} value of 16,040 l/kg can be estimated for 2-ethylhexyl diphenyl phosphate from its structure using the Syracuse Research Corporation PCKOC version 1.63 software which employs a molecular connectivity index method.

Chapter 4 of the Technical Guidance Document recommends the following equation for estimating K_{oc} from log K_{ow} for phosphates.

$$\log K_{oc} = 0.49 \times \log K_{ow} + 1.17$$

Using this equation for 2-ethylhexyl diphenyl phosphate (log K_{ow} of 5.73) results in an estimated K_{oc} value of 9,499 l/kg. The resulting partition coefficients for soils and sediments calculated using the methods given in the Technical Guidance Document are shown below.

K_{oc}	9,499 l/kg		
Kp_{sus}	950 l/kg	$K_{susp\text{-}water}$	238 m^3/m^3
Kp_{sed}	475 l/kg	$K_{sed\text{-}water}$	238 m^3/m^3
Kp_{soil}	190 l/kg	$K_{soil\text{-}water}$	285 m^3/m^3

As can be seen, the estimated value for Kp_{susp} is much lower than found in the Muir and Grift (1981) experiment above. The actual value of Kp_{susp} will depend to some extent on the organic carbon content of the suspended particulates used. This information is not available for the Muir and Grift (1981) study and so it is not possible to back-calculate the data to give a K_{oc} value.

A K_{oc} value of 9,499 l/kg (and the associated partition coefficients for the various phases) is used in this risk assessment as these are derived using the recommended methods given in the Technical Guidance Document. However, this approach may underestimate the actual adsorption of the substance.

Volatilisation

Muir *et al.* (1985) carried out experiments investigating the volatilisation from and distribution in an artificial pond (15-17 m^2 area and 0.5 m depth) over a total of 360 days. The substance tested was ^{14}C-labelled 2-ethylhexyl diphenyl phosphate which was added to give an initial water concentration of 50 μg/l. The air above the pond was sampled continuously for the first five days of the experiment at heights of 5, 10 and 20 cm and the maximum concentration found was 32 ng/m^3 above the centre of the pond. The paper also estimated (using a two-resistance model) that the potential cumulative losses by volatilisation accounted for a total of around eight per cent of the total radioactivity added by day 21. The results of the study are summarised in Table

3.3. The half-life of the substance in the water and sediment phase was estimated to be 0.52 and 79 days respectively based on parent compound analysis.

The estimated Henry's law constant for 2-ethylhexyl diphenyl phosphate is 4.44 Pa m^3/mole at 25°C. This indicates that volatilisation from water may be significant in some circumstances.

Table 3.3 Distribution of ^{14}C-labelled 2-ethylhexyl diphenyl phosphate in an artificial pond

Time	Distribution (as percentage of initial amount applied)			
	Water	Sediment	Air[a]	Biota
1 hour	79.6	-		-
18 hours	25.5	62.3	4.8	1.7
7 days	4.0	31.7	7.6	0.2
21 days	4.5	34.2	8.0	<0.1
105 days	<2.0	30.0	-	0.3
360 days	-	24.0	-	-

Source: Muir *et al.* (1985).
Notes: a) Values for air represent theoretical cumulative total using a two-resistance model.

Fugacity modelling

The potential environmental distribution of 2-ethylhexyl diphenyl phosphate has been studied using a generic level III fugacity model. The physico-chemical properties used and the results of the modelling exercise are shown in Table 3.4.

The model used was a four-compartment model (EQC version 1.01, May 1997) that has been circulated for use within the Organisation for Economic Cooperation and Development (OECD) High Production Volume (HPV programme. The model was run four times with a nominal release rate of 1,000 kg/hour initially entering the air, soil or water compartments in different proportions.

The results of the model show that only a very small amount of the 2-ethylhexyl diphenyl phosphate released to the environment will be in the air compartment at steady state. When the substance is released to air it distributes mainly to the soil compartment, presumably by atmospheric deposition. When it is released to soil, the substance generally remains in the soil, with only a small fraction distributing to the water and sediment compartment. When released to water, the substance is likely to distribute mainly to the sediment phase at steady state, but a small fraction is also predicted to remain in the water phase.

Table 3.4 Results of generic level III fugacity model for 2-ethylhexyl diphenyl phosphate

Input data	Value				
Vapour pressure	3.4×10^{-4} Pa at 20°C				
Water solubility	51 µg/l				
Log K_{ow}	5.73				
Atmospheric half-life	9.7 hours				
Half-life in water	50 days				
Half-life in soil and sediment	300 days				
Emission rate	**Model results at steady state**				
	Amount in air	**Amount in soil**	**Amount in water**	**Amount in sediment**	**Overall residence time/persistence**
1,000 kg/hour to air 1,000 kg/hour to soil 1,000 kg/hour to water	0.079%	75.6%	2.45%	21.9%	207 days
1,000 kg/hour to air 0 kg/hour to soil 0 kg/hour to water	1.27%	93.6%	0.52%	4.63%	37 days
0 kg/hour to air 1,000 kg/hour to soil 0 kg/hour to water	4×10^{-5}%	99.9%	0.005%	0.05%	432 days
0 kg/hour to air 0 kg/hour to soil 1,000 kg/hour to water	0.02%	1.34%	9.94%	88.7%	151 days

The behaviour of 2-ethylhexyl diphenyl phosphate during waste water treatment has been estimated using the EUSES model (assuming the substance is readily biodegradable and either meeting or not meeting the 10-day window). Using a K_{oc} of 9,499 l/kg (see above) and a Henry's law constant of 4.44 Pa m^3/mol at 25°C (see Section 1.3.9), the following behaviour is predicted:

	Meets 10-day window	Does not meet 10-day window
Degraded	51.0%	36.1%
Adsorbed to sludge	40.0%	43.3%
Volatilised to air	0.89%	1.63%
To effluent	8.13%	19.0%

For sewage treatment, two SCAS studies showed equilibrium removal rates of 74 per cent and 50-85 per cent over a 24-hour period. These removal rates are lower than might be expected for a substance classified as readily biodegradable (meeting the 10-day window). Although it is difficult to compare the results from a SCAS test directly with the EUSES estimates, it is apparent that the EUSES estimates assuming the substance does not meet the 10-day window are in better agreement with the available data than the other estimates and so these values are used in the PEC calculations.

3.1.3 Bioaccumulation and metabolism

Measured data

The uptake and accumulation of 2-ethylhexyl diphenyl phosphate in rainbow trout (*Oncorhynchus mykiss*) fry was studied by Muir and Grift (1981, 1993). The substance used in the test was ^{14}C-labelled 2-ethylhexyl diphenyl phosphate (labelling on the phenyl groups) mixed with a commercial 2-ethylhexyl diphenyl phosphate product (purity 94.5 per cent).

In the uptake and accumulation part of the test, rainbow trout fry (0.1-0.2 g) were exposed to one of two test substance concentrations (50 or 5 μg/l nominal concentrations) in one of four test waters (river water (pH 8.1), dechlorinated tap water or dilutions (1:3 and 2:3) of river water with dechlorinated tap water) at 10°C. At various times during the test (0.5, 1.5, 4.5, 7, 13 and 24 hours) three fish were removed from each replicate and analysed for the presence of radiolabel. These indicated that the concentration had fallen to 40-44 per cent of the initial concentration by 24 hours. Tissue distribution of the radiolabel was explored in a similar way except that the fish used were 150-300 g and these were exposed to 60 μg/l of the test substance for ten hours in dechlorinated tap water followed by 36 hours in clean water. Finally, the depuration of radiolabel from rainbow trout was studied by exposing fry (0.1-0.2 g) to a test substance concentration of 5 or 50 μg/l in dechlorinated tap water for 12 hours and then transferring the fish to a 40-litre tank with a constant flow of dechlorinated tap water. Samples of fish (three per time point) were analysed at various times during the depuration period (24, 48, 148, 240 and 432 hours).

During the 24-hour uptake experiment, the concentration of ^{14}C-label present in the water phase was found to have fallen to 40-44 per cent of the initial concentration in both the 5 μg/l and 50 μg/l exposure groups. The rate of uptake of ^{14}C by rainbow trout was found to be different in river water compared with tap water. The initial rates of uptake (estimated over the first seven hours of uptake) are shown in Table 3.5 and were found to be lower in river water than in dechlorinated tap water. It was thought that the difference between the initial rates of uptake could be explained by adsorption of the test substance onto suspended matter present (the concentration of suspended matter was 30 mg/l in the river water). The depuration experiments showed that elimination of radioactivity from the fish was initially rapid but slowed after about 148-240 hours of depuration. Based on the initial uptake rate constant (determined over the first seven hours of uptake) and depuration rate constants (determined over the first 148 hours of depuration), a bioconcentration factor (BCF) of 1,147-1,481 l/kg (average value 1,314 l/kg) was determined for 2-ethylhexyl diphenyl phosphate in dechlorinated tap water.

Table 3.5 Uptake of ^{14}C-labelled 2-ethylhexyl diphenyl phosphate by rainbow trout

Water type	Exposure conc. (μg/l)	Observed initial uptake rate ng/(g hour)	Initial rate constant for uptake (hour^{-1})	Depuration rate constant (hour^{-1})	BCF
Dechlorinated tap water	5	139 ± 15	45.8 ± 24.8	0.0297 ± 0.0027	1,481 ± 704
	50	1,310 ± 96	35.0 ± 22.1	0.0294 ± 0.0019	1,147 ± 651
2:1 Dechlorinated tap:river water	5	135 ± 12			
	50	1,224 ± 111			
1:2 Dechlorinated tap:river water	5	93 ± 16			
	50	1,134 ± 72			
River water	5	98 ± 16			
	50	1,026 ± 94			

Source: Muir and Grift (1981).

The results of the tissue distribution studies are summarised in Table 3.6. The results indicate that the highest rate of uptake of radiolabel was associated with the liver, kidney, pyloric caeca, and intestine, with much lower levels of radiolabel present in muscle, gill filaments, blood and brain. High levels of radioactivity were also found in the intestine during the depuration phase of the experiment, but it was not clarified whether this radioactivity was associated with the gut contents or the intestinal wall. Parent compound analysis of the various fish tissues indicated that substantial metabolism of the 2-ethylhexyl diphenyl phosphate was occurring in the fish, with diphenyl phosphate formed as a major metabolite.

The Japanese Chemicals Evaluation and Research Institute (CERI 2003) carried out an 8-week bioconcentration study with 2-ethylhexyl diphenyl phosphate using carp (*Cyprinus carpio*; 4.1 per cent lipid content). The test was carried out using a continuous flow system at two exposure concentrations (0.1 and 0.01 mg/l). The bioconcentration factors obtained were 433-735 l/kg at 0.1 mg/l and 194-426 l/kg at 0.01 mg/l. The ranges reported most probably reflect the bioconcentration factors calculated at various time points during the experiment (determinations are usually made at two-weekly intervals in this type of study).

Uptake and accumulation of ^{14}C-labelled 2-ethylhexyl diphenyl phosphate (labelled on the phenolic rings) by duckweed (*Lemna minor*) was investigated by Lockhart *et al.* (1983). Distilled water or river water was used to dilute a concentrated nutrient solution in order to produce the test medium. The tests were carried out under static conditions by adding the test substance and 30 duckweed fronds to 50 ml of the test medium. At various time periods during the study (4, 24, 48 and 96 hours) the fronds were counted and plants and water were analysed for the presence of ^{14}C. The BCF values determined were 283 l/kg in the experiment with distilled water and 254 l/kg in the experiment with river water.

Table 3.6 Tissue distribution in rainbow trout exposed to an initial 2-ethylhexyl diphenyl phosphate concentration of 60 μg/l

Time (hours)	Tissue	Total conc. of radiolabel (mg/kg)	Identity of radiolabel (% of total)			
			2-Ethylhexyl diphenyl phosphate	Diphenyl phosphate	Not identified	Un-extractable
Uptake part of experiment						
4	Liver	10.25	30.4	11.4	57.8	0.4
	Muscle	0.44	82.6	not analysed	not analysed	0.5
	Intestine	4.14	19.6	4.7	75.5	0.2
10	Liver	3.29	31.5	35.9	29.2	3.4
	Muscle	0.34	90.1	not analysed	not analysed	1.9
	Intestine	2.97	9.7	41.4	43.0	5.9
Depuration part of experiment						
2	Liver	1.81	22.8	39.8	31.5	5.9
	Muscle	0.50	45.8	15.3	37.0	1.9
	Intestine	13.30	1.7	24.7	72.5	1.1
26	Liver	1.36				
	Muscle	0.11	61.3	36.2	0	2.2
	Intestine	4.25	2.5	11.9	84.7	0.9

Source: Muir and Grift (1981and 1983).

Bayer (2002) gives a BCF of 1,600 l/kg for a commercial 2-ethylhexyl diphenyl phosphate but the basis behind this value is unclear.

IUCLID (2000a) reports a BCF of 934 l/kg for 2-ethylhexyl diphenyl phosphate with *Lepomis macrochirus* from an unpublished study. The concentration of the test substance used was 4.83 μg/l and the exposure period was 36 days at 22°C. The highest concentration in whole fish found in the study was 4.3 mg/kg, giving a BCF of 934 l/kg. The concentration in muscle alone was lower (2.3 mg/kg at 28 days). The depuration half-life was determined to be five days, with a 90 per cent clearance time of seven days.

Muir *et al.* (1985) determined the uptake of ^{14}C-labelled 2-ethylhexyl diphenyl phosphate by *Pimephales promelas* in an artificial pond. The pond was 15-17 m^2 in area, with a depth of 0.5 m, and the substance was added to the pond water to give an initial concentration of 50 μg/l. The maximum concentration of ^{14}C in the fish was determined eight hours after addition of the test substance to the pond and an approximate BCF of 413 l/kg was reported at this time. After this time, the concentration of the test substance in fish declined, reflecting the decline in the concentration present in the water phase in the experimental pond. The same study also investigated the uptake of the test substance by invertebrates (*Chironomus tentans*) larvae. The larvae were found to accumulate ^{14}C, either via pore water or from the sediment itself, and the maximum concentration found in the organism was 7.28 mg/kg at day 14. The authors estimated a concentration factor (based on the measured concentration of the 2-ethylhexyl diphenyl phosphate present in sediment) of 11 at day 49, with the factor generally being below 10 over days 21 to 70.

A similar study of the bioconcentration of 2-ethylhexyl diphenyl phosphate in fathead minnow (*Pimephales promelas*) was carried out by Muir *et al.* (1982). In this study fish were exposed to an initial ^{14}C-labelled 2-ethylhexyl diphenyl phosphate concentration

of 60 μg/l in a small, shallow, artificial pond (2.5 × 4 m^2 and 0.5 m deep). The pond water had a pH of 8.62 and a total suspended solids concentration of 11 mg/l. The bottom sediments were silty clays which had a pH of 6.8 and six per cent organic matter content. The pond was stocked with 200 fish for two weeks prior to addition of the test substance (in small volumes of ethanol). A similar pond acted as control. Fish were sampled at regular intervals up to 15 weeks after addition of the test substance and both the fish and water phases were analysed for the presence of radiolabel. The results for the first ten days are summarised in Table 3.7. The concentration of 2-ethylhexyl diphenyl phosphate in the water was found to decrease rapidly with a half-life of less than 24 hours (as a result of degradation and/or volatilisation and/or adsorption onto sediment and/or uptake into biota). The maximum concentration of radiolabel in the fish was found after 10-24 hours exposure and the BCF was in the range 170-465 l/kg (the highest value was obtained at 240 hours post-treatment). The same study evaluated the concentrations of radiolabel in duckweed (*Lemna minor*) and cattails (*Typha* sp.) present in the pond. The maximum BCF for duckweed was found to be 62 l/kg, and the level of radioactivity in the plant was found to be similar at one hour and ten days after exposure began. The BCF for cattails was less than 1 l/kg ten days after the start of exposure. The fact that the exposure concentration was not maintained during this experiment limits its usefulness in deriving steady-state BCF values.

Muir (1984) reports the results of unpublished work by Huckins and Petty (1982) showing that the major route of metabolism of 2-ethylhexyl diphenyl phosphate in rainbow trout (*Oncorhynchus mykiss*) is O-dealkylation to yield diphenyl phosphate. Diphenyl phosphate is then eliminated either as the compound itself or as a conjugate.

Table 3.7 Distribution of radioactivity with time in an artificial pond initially exposed to 60 μg/l of ^{14}C-labelled 2-ethylhexyl diphenyl phosphate

Time hours	Distribution of radioactivity (as percentage of initial amount added; values in [ ] refer to the actual concentration present)					
	Water	Sediment (0-3 cm depth)	Duckweed	Cattails	Fish	Total
1-4	[63.5 μg/l]					
10	74% [36.8 μg/l]	30% [138 μg/kg dry wt.]	2.0% [2,143 μg/kg wet wt.]	[4 μg/kg wet wt.]	2.9% [8,070 μg/kg wet wt.]	108.9%
24	36% [26.0 μg/l]	32% [162 μg/kg dry wt.]	1.7% [2,031 μg/kg wet wt.]	[5 μg/kg wet wt.]	2.0% [10,250 μg/kg wet wt.]	71.7%
48	19% [16.8 μg/l]	33% [211 μg/kg dry wt.]	0.8% [1,775 μg/kg wet wt.]	[12 μg/kg wet wt.]	2.5% [4,004 μg/kg wet wt.]	55.3%
72	28% [14.4 μg/l]	31% [147 μg/kg dry wt.]	0.6% [1,370 μg/kg wet wt.]	[9 μg/kg wet wt.]	1.3% [2,750 μg/kg wet wt.]	60.9%
120	20% [12.2 μg/l]	41% [181 μg/kg dry wt.]	0.4% [766 μg/kg wet wt.]	[42 μg/kg wet wt.]	0.2% [1,740 μg/kg wet wt.]	61.6%
240	10% [6.3 μg/l]	39% [149 μg/kg dry wt.]	0.2% [735 μg/kg wet wt.]	[43 μg/kg wet wt.]	3.0% [1,530 μg/kg wet wt.]	52.2%

Source: Muir *et al.* (1982).

No data is available on the accumulation of 2-ethylhexyl diphenyl phosphate from food.

Calculated data

For the terrestrial food chain, the EU TGD requires a BCF for earthworms. No experimental data were available for this endpoint and so an earthworm BCF value was estimated using the following equation given in the TGD.

$$BCF_{earthworm} = 0.84 + 0.012\ K_{ow} / RHO_{earthworm}$$

where $RHO_{earthworm}$ = density of the earthworm = 1 kg/l
K_{ow} = octanol-water partition coefficient

Using a log K_{ow} value of 5.73, the $BCF_{earthworm}$ was estimated as 6,445 l/kg. This value is used in the assessment.

Summary of accumulation

Several studies cover the bioconcentration of 2-ethylhexyl diphenyl phosphate in fish. Some studies are limited in their usefulness for risk assessment as the concentration was not maintained adequately during the study (and so the resulting BCF does not represent a steady-state value) or the result was based on ^{14}C-measurements (and so may lead to an overestimate of the bioconcentration factor if extensive metabolism was occurring in the fish). The available values are summarised in Table 3.8.

Table 3.8 Summary of bioconcentration factors for 2-ethylhexyl diphenyl phosphate

BCF (l/kg)	Species	Comment	Rel.	Reference
1,600	Unknown	Details unknown	4	Bayer (2002)
426-735	*Cyprinus carpio*	Eight-week flow-through study based on parent compound analysis	2	CERI (2003)
934	*Lepomis macrochirus*	36-day study	4	IUCLID (2000a)
1,147-1,481 (mean 1,314)	*Oncorhynchus mykiss*	Twenty-four hour study. BCF determined by initial rate method over first seven hours. Based on ^{14}C determinations. Concentration fell by 40-44 per cent over 24 hours. Substantial metabolism had occurred.	2	Muir and Grift (1981 and 1993)
170-465	*Pimephales promelas*	A 240-hour study. Based on ^{14}C measurements using an artificial pond. The concentration of water was not maintained during the study.	3	Muir *et al.* (1982)

The data show BCFs in the range 426-934 l/kg based on parent compound analysis, with a slightly higher value of 1,314 l/kg based on ^{14}C-analysis. There are no details on how the value of 1,600 l/kg was determined (it is possible this is an estimate since no species is given). Since extensive metabolism of the test substance was apparent in tests using ^{14}C, the BCF for 2-ethylhexyl diphenyl phosphate itself is assumed to be 934 l/kg. Although this value is from an unpublished study and so cannot be fully validated, it is supported by the value of 735 l/kg determined by CERI (2003).

The log K_{ow} value of 2-ethylhexyl diphenyl phosphate is 5.73. Using the methods recommended in the TGD, a BCF for fish of 14,808 l/kg is predicted. This value is much higher than those determined in the more reliable studies.

A BCF of 934 l/kg is used in this risk assessment for 2-ethylhexyl diphenyl phosphate.

In addition to a BCF, the TGD also requires a biomagnification factor (BMF) to be taken into account. For 2-ethylhexyl diphenyl phosphate, the default BMF would be one based on the BCF value determined above.

Using a log K_{ow} value of 5.73 and the methods recommended in the TGD, the $BCF_{earthworm}$ is estimated as 6,445 l/kg. The reliability of this estimate is unknown.

3.2 Environmental releases

3.2.1 General discussion

Releases from the production and use of 2-ethylhexyl diphenyl phosphate have been estimated using a number of sources such as the default methods from the TGD and the Emission Scenario Document (ESD) on plastics additives (OECD 2004). In the absence of specific information on the substance, the ESD is considered to be a reasonable basis for emission estimation; the TGD default values are intended for use as realistic worst case values in the absence of other data. Hence, the estimates from these sources will have some degree of uncertainty. The actual calculations are considered confidential as they are based on confidential production and use figures.

The producers of 2-ethylhexyl diphenyl phosphate provided information on the amounts used by representative large customers, and this was used in the local estimates of emissions from use. Some additional information on waste treatment and cleaning at a small number of user sites was also provided; this information did not contradict the assumptions made on the basis of the ESD.

3.2.2 Releases from production

Releases from production sites were estimated from specific information provided by the manufacturing companies. The results are included in Table 3.10.

3.2.3 Releases from use (processing)

PVC

Emissions from the use in PVC and other polymeric materials were estimated using the methods outlined in the Emission Scenario Document on plastics additives (OECD 2004). The ESD provides methods for estimating releases from three stages:

- handling of raw materials;
- compounding – the blending into the polymer of additives;
- conversion – the forming of the polymer into finished articles.

The first two stages are assumed to take place together. There are companies which compound the plastics and then sell them on to converters, so separate calculations

are carried out for the two as well as for the case where compounding and conversion take place together. The emission factors in the ESD are derived from information on a model substance, di(2-ethylhexyl)phthalate (DEHP), and are modified according to the relative properties of this substance and the substance of interest. The main property affecting emissions is the vapour pressure of the substance. 2-Ethylhexyl diphenyl phosphate has a higher vapour pressure than does DEHP, and is classed as of high volatility according to the criteria in the ESD[5]. The ESD also uses the particle size of the substance when estimating possible releases from raw materials handling. 2-Ethylhexyl diphenyl phosphate is supplied as a liquid (Section 0).

Emission factors derived for PVC using the ESD methods are (depending on the type of product):

- Compounding (including raw materials handling): 0 to 0.025 per cent to air, 0.01 to 0.035 per cent to waste water.
- Conversion: 0.025 to 0.125 per cent to air, 0.025 to 0.125 per cent to waste water.

For rubber, polyurethanes, photofilms and pigment dispersions, emission factors are:

- Compounding (including raw materials handling): 0.025 per cent to air, 0.035 per cent to waste water.
- Conversion: 0.025 per cent to air, 0.025 per cent to waste water (for pigment dispersions, conversion losses are assumed to be covered by those from the plastics into which they are included, so the conversion factor is zero).

Textile coatings

This use produces PVC coatings on fabrics, and as such can be considered to be a plastics process. The ESD on plastics additives (OECD 2004) provides information on release factors for this use and these are used in the assessment. The emission factors used are:

- Compounding (including raw materials handling): 0.01 per cent to water.
- Conversion: 0.125 per cent to air, 0.125 per cent to water.

Paints

Emissions from the blending (formulation) of paints and their application were estimated using TGD default values of 0.1 per cent to air and 0.3 per cent to water for formulation, and 0.1 per cent to water for application. This assumes that the paints containing the substance are used in industry rather than by the general public.

Adhesives

Information from risk assessments on other substances were used to estimate emissions from formulation into adhesives. These are considered to be negligible.

[5] 'High volatility' is used in comparison to DEHP which is of 'medium volatility'. All phosphates assessed in this series have vapour pressures considered low for organic substances.

3.2.4 Releases over lifetime of products

2-Ethylhexyl diphenyl phosphate is used in products which are expected to have long service lives. These are therefore potentially important sources of emission.

Possible losses from PVC and other polymeric materials through leaching and volatilisation are considered in this section. A limited amount of information relevant to the release of 2-ethylhexyl diphenyl phosphate is available, and is included here, but estimates are based on the methods outlined in the Emission Scenario Document (OECD 2004) and also take into account the approaches used in the risk assessment of other substances (for example, the risk assessment on medium-chain chlorinated paraffins carried out under the Existing Substances Regulation (ECB 2005)). The approach taken also considers the release of polymer particulates (waste remaining in the environment) over the lifetime of products and at disposal as appropriate; this is based on the treatment of this area in other risk assessments such as that on medium-chain chlorinated paraffins.

In the absence of information on the types of polymeric materials in which the pigment dispersions are used, a release of five per cent to cover the service life and losses on disposal (see below) is assumed.

Leaching loss

Braden and Wright (1983) investigated the weight loss after immersion in distilled water for 812 days from a soft acrylic lining material used for acrylic dentures. The acrylic material was plasticized with 2-ethylhexyl diphenyl phosphate and at the end of the 812-day experiment, a weight loss of 1.17 per cent, based on the original weight of the polymer used in the experiment, had occurred. This figure measures the loss of plasticiser and any other additives present in the original polymer. The amount of 2-ethylhexyl diphenyl phosphate originally present in the polymer was not given.

The above information is not suitable for deriving emission factors for this assessment. Factors from the ESD on plastics additives are used in the assessment for emissions from PVC and rubber products, textiles and adhesives. Compared to the model substance DEHP in the ESD (which is of low solubility), 2-ethylhexyl diphenyl phosphate is classed as a medium solubility substance, and so the factor is increased to account for this. The factor most widely used is 0.25 per cent over the lifetime of the product, but is higher for some types of product. One exception to this relates to some uses of PVC in the external environment, where factors of up to14 per cent loss over the lifetime are used.

The polyurethanes and photofilms in which 2-ethylhexyl diphenyl phosphate is used are not considered likely to come into contact with water in the course of their normal use, so leaching emissions from this use are negligible.

Emission factors for paints are also based on the ESD, with leaching of 0.75 per cent per year (based on external use of the paints).

Volatile loss

The stability of, and volatile loss from, several commercial aryl and alkyl/aryl phosphate products has been studied using a combination of differential scanning calorimetry (DSC) and thermogravimetric analysis (TGA) under both a nitrogen atmosphere (Shankwalkar and Cruz 1994) and an oxygen atmosphere (Shankwalkar and Placek 1992). The results of the studies are summarised in Table 3.9.

Table 3.9 Thermal degradation temperature and weight loss of aryl and alkyl/aryl phosphates

Phosphate ester	Experiments under an oxygen atmosphere				Experiments under a nitrogen atmosphere		
	Start of thermal degradation	1% weight loss	5% weight loss	10% weight loss	Start of thermal degradation	5% weight loss	10% weight loss
Triphenyl phosphate	>400°C	188°C	236°C	252°C			
Tricresyl phosphate	215°C	184°C	255°C	252°C	333°C	272°C	306°C
Trixylenyl phosphate	210°C	224°C	268 °C	286°C	311°C	276°C	302°C
Isopropyl phenyl diphenyl phosphate[a]	210-215°C	200-218°C	239-265°C	263-288°C	311-314°C	264-282°C	293-307°C
Tertbutyl phenyl diphenyl phosphate[a]	295-305°C	213-234°C	262-277°C	280-295°C	338-347°C	274-278°C	305-306°C
2-Ethylhexyl diphenyl phosphate	200°C	90°C	220°C	229°C	257°C	226°C	231°C
Isodecyl diphenyl phosphate	165°C	93°C	213°C	235°C	264°C	233°C	246°C

Notes: a) Data for three (nitrogen atmosphere) or four (oxygen atmosphere) different grades.

The results under a nitrogen atmosphere show that the triaryl phosphates start to decompose at temperatures of around 310-350°C, whereas the alkyl diphenyl phosphates tested start to decompose at a temperature of around 260°C. The decomposition temperatures under an oxygen atmosphere are significantly lower. For all the substances tested, significant weight loss occurs at temperatures below that at which decomposition starts, indicating a loss of the substance by volatilisation at elevated temperatures.

These data do not allow emission factors for the service life to be estimated. The factors from the ESD on plastics additives are used, as applied in the risk assessment of medium-chain chlorinated paraffins as appropriate. These are applied to articles from PVC, polyurethanes and rubber, and to textiles and adhesives. Volatile losses from products occur at ambient temperatures, and at these temperatures 2-ethylhexyl diphenyl phosphate is considered to have a high vapour pressure in relation to DEHP, the reference compound. The appropriate factor from the ESD is therefore that for high volatility substances or 0.25 per cent over the lifetime of the product. An exception to this is where the use is in thin films, where a higher value of 18 per cent over the lifetime is used for paints. For photofilms, the thin film factor is used but assuming only limited exposure to air over the lifetime (see the assessment on triphenyl phosphate). The emission factor used is 0.079 per cent over the lifetime.

Waste in the environment

This considers the loss of substance in particles of plastic material from articles in use. The approach is the same as that used in the risk assessment for medium-chain chlorinated paraffins (ECB 2005). For use in PVC, a loss of zero to 3.125 per cent of the material over the lifetime of the products or articles is assumed, depending on the use of the products, together with a further two per cent loss on disposal at the end of the service life. For textiles and adhesives, two per cent loss during service life and two per cent loss on disposal are assumed. For rubber and polyurethanes, no waste generation during the lifetime is assumed, but two per cent loss on disposal is assumed. For paints a loss of 2 to 5 per cent on disposal is assumed. As noted above, losses of pigment dispersions are taken as five per cent across the whole of service life and disposal. Photofilms are assumed not to release plastic material to the environment.

In the calculations, the substance in these particles is assumed to be available in the environment; this is likely to be an overestimate, but there are no actual data to indicate how much may be available.

3.2.5 Other sources of release

There is a small quantity of 2-ethylhexyl diphenyl phosphate which is not allocated to one of the three use areas. It has been assumed that this amount is in fact used in these areas, but passes through a longer supply chain and hence its use is not known to the major producers and suppliers who provided the information. To deal with this, an overall emission factor was derived from the estimated releases from the quantity allocated to specific uses. This factor was applied to the unallocated tonnage, and the release divided between the different compartments in the same ratio as for the allocated tonnage. These releases appear in the summary Table 3.10 under ‘miscellaneous uses’.

3.2.6 Summary of environmental releases

The estimated environmental releases of 2-ethylhexyl diphenyl phosphate are summarised in Table 3.10.

Table 3.10 Summary of estimated environmental releases of 2-ethylhexyl diphenyl phosphate

Life cycle stage		Local (kg/day)			Regional (kg/year)			Continental (kg/year)		
		Air	**Water**	**Soil**	**Air**	**Water[a]**	**Soil**	**Air**	**Water[a]**	**Soil**
Production			135			13,500 to surface water[b]				
			2						<72 to surface water[b]	
PVC – 1	Raw materials handling and compounding		0.17							
	Conversion	2.08	2.08							
	Raw materials handling, compounding and conversion	2.08	2.25		c	c		c	c	
	In service losses				189	189		1,699	1,699	
	Waste in the environment				3.8	950 to surface water[d]	2,861	34.3	8,548 to surface water[d]	25,748
PVC – 2	Raw materials handling and compounding	0.122	0.17							
	Conversion	0.609	0.609							
	Raw materials handling, compounding and conversion	0.731	0.779		c	c		c	c	
	In service losses				45.5	45.5		410	410	
	Waste in the environment				0.36	90.1 to surface water[d]	271	3.26	811 to surface water[d]	2,443

Table 3.10 continued.

Life cycle stage		Local (kg/day)			Regional (kg/year)			Continental (kg/year)		
		Air	**Water**	**Soil**	**Air**	**Water[a]**	**Soil**	**Air**	**Water[a]**	**Soil**
PVC – 3	Raw materials handling and compounding	0.09	0.126							
	Conversion	0.45	0.45							
	Raw materials handling, compounding and conversion	0.54	0.576		c	c		c	c	
	In service losses				5,940	82.5		53,460	743	
	Waste in the environment				0.54	134 to surface water[d]	403	4.84	1,205 to surface water[d]	3,628
PVC – 4	Raw materials handling and compounding	0.0625	0.0875							
	Conversion	0.0625	0.0625							
	Raw materials handling, compounding and conversion	0.125	0.15		c	c		c	c	
	In service losses				12.5			112.5		
	Waste in the environment				0.02	4.98 to surface water[d]	15	0.18	44.8 to surface water[d]	135

Table 3.10 continued.

Life cycle stage		Local (kg/day)			Regional (kg/year)			Continental (kg/year)		
		Air	**Water**	**Soil**	**Air**	**Water[a]**	**Soil**	**Air**	**Water[a]**	**Soil**
PVC – 5	Raw materials handling and compounding	0.0625	0.0875							
	Conversion	0.0625	0.0625							
	Raw materials handling, compounding and conversion	0.38	0.40		c	c		c	c	
	In service losses				51.25	1,486 to surface water[d]		461	13,376 to surface water[d]	
	Waste in the environment				0.78	194 to surface water[d]	585	7.03	1,749 to surface water[d]	5,269
PVC – 6	Raw materials handling and compounding	0.0625	0.0875							
	Conversion	0.313	0.313							
	Raw materials handling, compounding and conversion	0.38	0.40		c	c		c	c	
	In service losses				7.5	420		67.5	3,780	
	Waste in the environment				0.2	49 to surface water[d]	149	1.79	445 to surface water[d]	1,339

Table 3.10 continued.

Life cycle stage		Local (kg/day)			Regional (kg/year)			Continental (kg/year)		
		Air	**Water**	**Soil**	**Air**	**Water[a]**	**Soil**	**Air**	**Water[a]**	**Soil**
PVC – 7	Raw materials handling and compounding	0.0625	0.0875							
	Conversion	0.3125	0.3125							
	Raw materials handling, compounding and conversion	0.375	0.40		c	c		c	c	
	In service losses				12.5	362.5 to surface water[d]		112.5	3,263 to surface water[d]	
	Waste in the environment				2.7	675 to surface water[d]	2,033	24.4	6,075 to surface water[d]	18,299
Photographic film	Raw materials handling and compounding	0.125	0.175							
	Conversion	0.125	0.125							
	Raw materials handling, compounding and conversion	0.25	0.50		c	c		c	c	
	In service losses				74.7			672		
	Waste in the environment									

Table 3.10 continued.

Life cycle stage		Local (kg/day)			Regional (kg/year)			Continental (kg/year)		
		Air	**Water**	**Soil**	**Air**	**Water[a]**	**Soil**	**Air**	**Water[a]**	**Soil**
Textiles/fabric coating	Raw materials handling and compounding		0.05							
	Conversion	0.625	0.625							
	Raw materials handling, compounding and conversion	0.625	0.675		c	c		c	c	
	In service losses				65.75	65.75		591.75	591.75	
	Waste in the environment				1.04	258 to surface water[d]	778	9.3	2,325 to surface water[d]	7,003
Pigment dispersion	Raw materials handling and compounding	0.125	0.175							
	In service losses/waste in the environment				0.15	37.4 to surface water	113	1.35	336 to surface water	1,013
Paints and coatings	Formulation	0.533	1.6		c	c		c	c	
	Processing		0.008							
	Losses during service life				3,200	840 to surface water		28,800	7,560 to surface water	
	Waste remaining in the environment				1.56	387 to surface water	1,167	14	3,487 to surface water	10,503

Table 3.10 continued.

Life cycle stage		Local (kg/day)			Regional (kg/year)			Continental (kg/year)		
		Air	**Water**	**Soil**	**Air**	**Water[a]**	**Soil**	**Air**	**Water[a]**	**Soil**
Poly-urethane	Raw materials handling and compounding	0.125	0.175							
	Conversion	0.125	0.125							
	Raw materials handling, compounding and conversion	0.25	0.30		c	c		c	c	
	In service losses				16.25			146.25		
	Waste in the environment				0.13	32.25 to surface water[d]	97	1.17	290 to surface water[d]	874
Rubber	Raw materials handling and compounding	0.125	0.175							
	Conversion	0.125	0.125							
	Raw materials handling, compounding and conversion	0.25	0.30		c	c		c	c	
	In service losses				12.5	25		112.5	225	
	Waste in the environment				0.1	24.7 to surface water[d]	74.4	0.89	222 to surface water[d]	669
Adhesives	In service losses				22.5	1,820 to surface water		203	16,378 to surface water	
	Waste in the environment				0.32	80 to surface water	240	2.88	716 to surface water	2,157

Table 3.10 continued.

Life cycle stage	Local (kg/day)			Regional (kg/year)			Continental (kg/year)		
	Air	**Water**	**Soil**	**Air**	**Water**	**Soil**	**Air**	**Water**	**Soil**
Miscellaneous				463	143 + 261 to surface water	410	4,164	1,288 + 2,345 to surface water	3,692
Total				11,498	23,981	9,198	92,345	79,461	82,855

Notes: a) Regional and continental emissions to water are split 80:20 between wastewater treatment and direct discharge to surface water, except where noted.
b) Emissions calculated from site-specific data, after wastewater treatment (sludges from production sites are incinerated, calculating the values after treatment allows this to be reflected in the emission estimates).
c) Values for individual steps are confidential, but are included in the total figure.
d) Releases as waste in the environment and from service life in some uses are assumed to go directly to surface water.

3.3 Environmental concentrations

3.3.1 Aquatic environment (surface water, sediment and waste water treatment plant)

Calculation of PECs

Predicted environmental concentrations (PECs) for surface water and sediment were estimated with the EUSES 2.0.3 program using the data summarised in the previous sections as input. The concentrations predicted for water and sediment are shown in Table 3.11.

Table 3.11 Summary of predicted local concentrations for the aquatic compartment

Scenario		PEC_{local}			
		Microorganisms in sewage treatment plant (mg/l)	Surface water - emission episode (µg/l)	Surface water - annual average (µg/l)	Sediment (mg/kg wet wt.)
Production of 2-ethylhexyl diphenyl phosphate		1	0.19	0.19	0.04
PVC – 1	Compounding	0.02	1.76	1.48	0.37
	Conversion	0.2	19.6	16.2	4.07
	Combined compounding and conversion	0.21	21.2	17.5	4.4
PVC – 2	Compounding	0.02	1.76	1.48	0.37
	Conversion	0.06	5.87	4.86	1.22
	Combined compounding and conversion	0.07	7.46	6.16	1.55
PVC – 3	Compounding	0.01	1.35	1.14	0.28
	Conversion	0.04	4.38	3.63	0.91
	Combined compounding and conversion	0.05	5.56	4.6	1.15
PVC – 4	Compounding	8.31×10^{-3}	0.99	0.85	0.21
	Conversion	5.93×10^{-3}	0.76	0.65	0.16
	Combined compounding and conversion	0.01	1.58	1.33	0.33
PVC – 5	Compounding	8.31×10^{-3}	0.99	0.17	0.21
	Conversion	5.93×10^{-3}	0.76	0.76	0.16
	Combined compounding and conversion	0.01	1.58	1.33	0.33

Table 3.11 continued.

Scenario		PEC_{local}			
		Microorganisms in sewage treatment plant (mg/l)	**Surface water - emission episode (μg/l)**	**Surface water - annual average (μg/l)**	**Sediment (mg/kg wet wt.)**
PVC – 6	Compounding	8.31×10^{-3}	0.99	0.49	0.21
	Conversion	0.03	3.1	1.3	0.64
	Combined compounding and conversion	0.04	3.92	1.61	0.81
PVC – 7	Compounding	8.31×10^{-3}	0.99	0.41	0.21
	Conversion	0.03	3.1	1.01	0.64
	Combined compounding and conversion	0.04	3.92	1.24	0.81
Photo-graphic film	Compounding	0.02	1.81	1.52	0.38
	Conversion	0.01	1.34	1.34	0.28
	Combined compounding and conversion	0.03	2.98	2.48	062
Rubber	Compounding	0.02	1.81	1.52	0.38
	Conversion	0.01	1.34	1.13	0.28
	Combined compounding and conversion	0.03	2.98	2.48	0.62
Poly-urethane	Compounding	0.02	1.81	0.18	0.38
	Conversion	0.01	1.34	1.34	0.28
	Combined compounding and conversion	0.03	2.98	2.48	0.62
Textiles/ fabric coating	Compounding	4.75×10^{-3}	0.64	0.17	0.13
	Conversion	0.06	6.02	0.19	1.25
	Combined compounding and conversion	0.06	6.49	5.36	1.35
Pigment dispersions	Production of dispersions	0.02	1.81	1.52	0.38
Paints	Formulation	0.15	15.1	12.5	3.14
	Application	7.59×10^{-4}	0.25	0.17	0.05
Adhesives		negligible	negligible	negligible	negligible

The predicted regional concentrations are 0.17 μg/l for surface water and 0.037 mg/kg wet weight for sediment.

Predicted concentrations were also calculated for the marine environment, using the EUSES program. These are included in Table 3.12. Note that the production calculation is not for the same site as that for freshwater.

Table 3.12 Summary of predicted concentrations for the marine environment

Scenario		PEC_{local}		
		Marine water - emission episode (μg/l)	**Marine water - annual average (μg/l)**	**Marine sediment (mg/kg wet wt.)**
Production of 2-ethylhexyl diphenyl phosphate		28[a]	14.2 [a]	5.8[a]
PVC – 1	Compounding	0.85	0.70	0.18
	Conversion	10.3	8.44	2.13
	Combined compounding and conversion	11.1	9.13	2.3
PVC – 2	Compounding	0.85	0.70	0.18
	Conversion	3.02	2.48	0.63
	Combined compounding and conversion	3.86	3.17	0.8
PVC – 3	Compounding	0.64	0.53	0.13
	Conversion	2.23	1.84	0.46
	Combined compounding and conversion	2.85	2.35	0.59
PVC – 4	Compounding	0.45	0.37	0.09
	Conversion	0.32	0.27	0.07
	Combined compounding and conversion	0.76	0.62	0.16
PVC – 5	Compounding	0.45	0.02	0.09
	Conversion	0.32	0.32	0.07
	Combined compounding and conversion	0.76	0.62	0.16
PVC – 6	Compounding	0.45	0.18	0.09
	Conversion	1.56	0.61	0.32
	Combined compounding and conversion	1.99	0.77	0.41
PVC – 7	Compounding	0.45	0.14	0.09
	Conversion	1.56	0.45	0.32
	Combined compounding and conversion	1.99	0.58	0.41
Photographic film	Compounding	0.88	0.72	0.18
	Conversion	0.63	0.63	0.13
	Combined compounding and conversion	1.49	1.23	0.31
Rubber	Compounding	0.88	0.72	0.18
	Conversion	0.63	0.52	0.13
	Combined compounding and conversion	1.49	1.23	0.31

Table 3.12 continued.

Scenario		PEC_{local}		
		Marine water - emission episode (μg/l)	Marine water - annual average (μg/l)	Marine sediment (mg/kg wet wt.)
Polyurethane	Compounding	0.88	0.02	0.18
	Conversion	0.63	0.63	0.13
	Combined compounding and conversion	1.49	1.23	0.31
Textiles/fabric coating	Compounding	0.26	0.02	0.05
	Conversion	3.1	0.02	0.64
	Combined compounding and conversion	3.34	2.75	0.69
Pigment dispersions	Production of dispersions	0.88	0.72	0.18
Paints	Formulation	7.9	6.5	1.64
	Application	0.05	0.02	0.01
Adhesives		negligible	negligible	negligible

Notes: a) Calculation uses average dilution in the receiving water. If minimum dilution at the site was used, the PEC would be a factor of 1.88 times higher. Similarly if maximum dilution at the site was used, the PEC would be a factor of 6.67 times lower.

Measured levels in water and sediment

Boethling and Cooper (1985) reported that 2-ethylhexyl diphenyl phosphate was not detected (detection limit 10 μg/l) in water samples collected near to an aryl phosphate production site and a large user of hydraulic fluids in the USA in the late 1970s.

Boethling and Cooper (1985) reported the results of an early 1980s survey of the levels of 2-ethylhexyl diphenyl phosphate in surface water in the United States. The substance was not found (detection limit of the method was 0.1 μg/l) in four samples from Saginaw River (industrialised area), four samples from Baltimore Harbour (industrialised area), three samples from Detroit River (industrialised area), four samples from Delaware River (industrialised area near to aryl phosphate manufacturer), seven samples from Kanawha River (industrialised area near to aryl phosphate manufacturer) and four samples from Eastern Lake Superior (remote area).

Boethling and Cooper (1985) reported the results of an early 1980s survey of the levels of 2-ethylhexyl diphenyl phosphate in sediment in the United States. The substance was not found (detection limit of the method was 0.03-0.2 mg/kg) in four samples from Saginaw River (industrialised area), three samples from Baltimore Harbour (industrialised area), two samples from Detroit River (industrialised area), two samples from Delaware River (industrialised area near to aryl phosphate manufacturer), six samples from Kanawha River (industrialised area near to aryl phosphate manufacturer) and two samples from Eastern Lake Superior (remote area).

Comparison of measured levels with predicted levels

Limited monitoring data show that 2-ethylhexyl diphenyl phosphate has generally not been detected in surface water and sediment in North America. However, it is not clear if these data refer to samples collected near to the plastics industry (the major user of

the substance) and the detection limit of the method used is sometimes above the concentrations predicted. Therefore it is not possible to compare these data directly with the predicted levels, especially in a European context. Predicted concentrations are used in the risk characterisation here.

3.3.2 Terrestrial compartment

Calculation of PECs

PECs for the soil compartment were estimated using EUSES 2.0.3 and are summarised in Table 3.13.

Estimated regional concentrations for the soil compartment are summarised below.

$PEC_{regional}$ = 3.04×10^{-4} mg/kg wet weight for agricultural soil
= 1.81×10^{-3} μg/l for pore water of agricultural soil
= 2.88×10^{-4} mg/kg wet weight for natural soil
= 0.02 mg/kg wet weight for industrial soil

Table 3.13 Summary of predicted local concentrations for the terrestrial compartment

Scenario		**PEC_{local}**		
		Agricultural soil – 30 day average (mg/kg wet weight)	**Agricultural soil – 180 day average (mg/kg wet weight)**	**Groundwater under agricultural soil (μg/l)**
Production of 2-ethylhexyl diphenyl phosphate		negligible[a]	negligible [a]	negligible[a]
PVC – 1	Compounding	0.23	0.2	1.16
	Conversion	2.83	2.39	14.2
	Combined compounding and conversion	3.06	2.58	15.4
PVC – 2	Compounding	0.23	0.2	1.17
	Conversion	0.83	0.7	4.17
	Combined compounding and conversion	1.06	0.9	5.34
PVC – 3	Compounding	0.17	0.15	0.86
	Conversion	0.61	0.52	3.08
	Combined compounding and conversion	0.78	0.66	3.95

Table 3.13 continued.

Scenario		PEC_{local}		
		Agricultural soil – 30 day average (mg/kg wet wt.)	**Agricultural soil – 180 day average (mg/kg wet wt.)**	**Groundwater under agricultural soil (μg/l)**
PVC – 4	Compounding	0.12	0.10	0.6
	Conversion	0.09	0.07	0.43
	Combined compounding and conversion	0.20	0.17	1.03
PVC – 5	Compounding	0.12	0.10	0.6
	Conversion	0.09	0.07	0.43
	Combined compounding and conversion	0.20	0.17	1.03
PVC – 6	Compounding	0.12	0.10	0.6
	Conversion	0.43	0.36	2.14
	Combined compounding and conversion	0.54	0.46	2.74
PVC – 7	Compounding	0.12	0.10	0.6
	Conversion	0.42	0.36	2.14
	Combined compounding and conversion	0.54	0.46	2.74
Photographic film	Compounding	0.24	0.20	1.2
	Conversion	0.17	0.14	0.86
	Combined compounding and conversion	0.41	0.35	2.06
Rubber	Compounding	0.24	0.20	1.2
	Conversion	0.17	0.14	0.86
	Combined compounding and conversion	0.41	0.35	2.06
Polyurethane	Compounding	0.24	0.20	1.2
	Conversion	0.17	0.14	0.86
	Combined compounding and conversion	0.41	0.35	2.06
Textiles/fabric coating	Compounding	0.07	0.06	0.34
	Conversion	0.85	0.72	4.28
	Combined compounding and conversion	0.92	0.78	4.62
Pigment dispersions	Production of dispersions	0.24	0.20	1.2
Paints	Formulation	2.17	1.84	10.9
	Application	0.01	9.46×10^{-3}	0.06
Adhesives		negligible	negligible	negligible

Notes: a) Sewage sludge from the production sites is not applied to land.

Boethling and Cooper (1985) reported that 2-ethylhexyl diphenyl phosphate was not detected (detection limit 0.1 mg/l) in soil samples collected near to an aryl phosphate production site and a large user of hydraulic fluids in the United States.

There are insufficient measured data to make a comparison with predicted levels. Predicted levels are used in the risk characterisation here.

3.3.3 Air compartment

Calculation of PECs

Concentrations of 2-ethylhexyl diphenyl phosphate in air were estimated using EUSES 2.0.3. The PECs calculated are summarised in Table 3.14.

The predicted regional concentration in air is 5.42×10^{-7} mg/m^3.

Table 3.14 Summary of predicted local concentrations for the air compartment

Scenario		PEC_{local}
		Annual average concentration in air (mg/m^3)
Production of 2-ethylhexyl diphenyl phosphate		5.42×10^{-7}
PVC – 1	Compounding	1.17×10^{-6}
	Conversion	4.76×10^{-4}
	Combined compounding and conversion	4.76×10^{-4}
PVC – 2	Compounding	2.84×10^{-5}
	Conversion	1.4×10^{-4}
	Combined compounding and conversion	1.68×10^{-4}
PVC – 3	Compounding	2.11×10^{-5}
	Conversion	1.03×10^{-4}
	Combined compounding and conversion	1.24×10^{-4}
PVC – 4	Compounding	1.48×10^{-5}
	Conversion	1.48×10^{-5}
	Combined compounding and conversion	2.91×10^{-5}
PVC – 5	Compounding	5.9×10^{-7}
	Conversion	1.79×10^{-5}
	Combined compounding and conversion	2.91×10^{-5}
PVC – 6	Compounding	7.21×10^{-6}
	Conversion	3.39×10^{-5}
	Combined compounding and conversion	4.11×10^{-5}
PVC – 7	Compounding	5.49×10^{-6}
	Conversion	2.53×10^{-5}
	Combined compounding and conversion	3.02×10^{-5}
Photographic film	Compounding	2.91×10^{-5}
	Conversion	3.53×10^{-5}
	Combined compounding and conversion	5.77×10^{-5}
Rubber	Compounding	2.91×10^{-5}
	Conversion	2.91×10^{-5}
	Combined compounding and conversion	5.77×10^{-5}
Polyurethane	Compounding	6.37×10^{-7}
	Conversion	3.53×10^{-5}
	Combined compounding and conversion	5.77×10^{-5}

Table 3.14 continued.

Scenario		PEC_{local}
		Annual average concentration in air (mg/m^3)
Textiles/fabric coating	Compounding	5.34×10^{-7}
	Conversion	1.02×10^{-6}
	Combined compounding and conversion	1.43×10^{-4}
Pigment dispersions	Production of dispersions	2.91×10^{-5}
Paints	Formulation	1.22×10^{-4}
	Application	5.42×10^{-7}
Adhesives		negligible

Boethling and Cooper (1985) reported that 2-ethylhexyl diphenyl phosphate was not detected (detection limit 2 $\mu g/m^3$) in air samples collected near to an aryl phosphate production site and a large user of hydraulic fluids in the United States.

Limited measured data indicate that the concentration of 2-ethylhexyl diphenyl phosphate in air is low. The predicted concentration for a production site is below the detection limit of the method used to determine actual levels near the production site. There appear to be no measured levels taken close to PVC, rubber or other polymer sites. Predicted concentrations are, therefore, used in the risk characterisation here.

3.3.4 Non-compartment specific exposure relevant for the food chain

Predicted concentrations in biota and food

Predicted concentrations of 2-ethylhexyl diphenyl phosphate in fish and earthworms are shown in Table 3.15. The predicted concentrations in prey species for marine food chains are also included. Predicted concentrations in human intake media are shown in Table 3.16. The concentrations were calculated using EUSES 2.0.3.

Measured levels in biota and food

Gilbert *et al.* (1986) carried out a survey of the levels of total trialkyl and triaryl phosphates, including 2-ethylhexyl diphenyl phosphate, in composite total diet samples (spanning 15 commodity food types) representing an average adult diet for eight regions of the United Kingdom. The mean total dietary intake of total organic phosphates was estimated to be 0.072-0.105 mg/day. In general the highest concentration of total phosphate esters (total triaryl and trialkyl) was in offal and nuts (these food groups have only a low relative importance in diet). No 2-ethylhexyl diphenyl phosphate was found in any of the samples analysed.

Daft (1982) reported finding 2-ethylhexyl diphenyl phosphate in the fats/oils composite of the US market basket survey food categories. In particular, a margarine sample was found to contain 20 ppm (20 mg/kg). The substance was also found to be present in plastic bread bags at up to 400 ppm (400 mg/kg) but was not found in the bread itself (<0.5 ppm (<0.5 mg/kg)). The report also indicated that some phosphate esters

(including triphenyl phosphate and 2-ethylhexyl diphenyl phosphate) are common contaminants in organic solvents used in the analysis.

Total diet studies carried out in the USA between April 1982 and April 1984 indicated that the mean total daily intake of 2-ethylhexyl diphenyl phosphate was 132 ng/kg bodyweight in infants, 602 ng/kg body weight for toddlers, 200 to 208 ng/kg body weight for 14-16 year olds and 110 to 217 ng/kg bodyweight for adults (Gunderson 1988).

Comparison of measured levels with predicted levels

The available measured data indicate that 2-ethylhexyl diphenyl phosphate is present in some items of food. It is not possible, however, to compare these data directly with most of the local scenarios considered in this assessment. Therefore, the predicted concentrations are used in the risk characterisation.

The predicted regional daily human intake is around 0.52 µg/kg bodyweight day, which is similar to, but slightly higher than the upper end of the total daily intake from food alone determined in US dietary intake study (around 0.22 µg/kg bodyweight/day, Gunderson 1988). However, a similar dietary intake study carried out in the United Kingdom found no 2-ethylhexyl diphenyl phosphate to be present in food (Gilbert *et al.* 1986).

Table 3.15 Summary of predicted local concentrations for secondary poisoning

Scenario		Predicted concentration			
		Fish (mg/kg)	**Earthworms (mg/kg)**	**Marine fish (mg/kg)**	**Marine top predators (mg/kg)**
Production of 2-ethylhexyl diphenyl phosphate		n/a[a] 0.17	0.01[b] 0.01[b]	6.65 n/a[c]	1.34 n/a[c]
PVC – 1	Compounding	0.77	3.38	0.34	0.08
	Conversion	7.63	41.4	3.95	0.80
	Combined compounding and conversion	8.24	44.7	4.27	0.87
PVC – 2	Compounding	0.77	3.39	0.34	0.08
	Conversion	2.35	12.1	1.17	0.25
	Combined compounding and conversion	2.96	15.5	1.49	0.31
PVC – 3	Compounding	0.61	2.51	0.25	0.06
	Conversion	1.78	8.96	0.87	0.19
	Combined compounding and conversion	2.23	11.5	1.1	0.23
PVC – 4	Compounding	0.48	1.75	0.18	0.05
	Conversion	0.39	1.25	0.13	0.04
	Combined compounding and conversion	0.7	2.99	0.3	0.07

Table 3.15 continued.

Scenario		Predicted concentration			
		Fish (mg/kg)	Earthworms (mg/kg)	Marine fish (mg/kg)	Marine top predators (mg/kg)
PVC – 5	Compounding	0.16	1.75	0.01	0.01
	Conversion	0.43	1.25	0.16	0.04
	Combined compounding and conversion	0.7	2.99	0.3	0.07
PVC – 6	Compounding	0.31	1.75	0.09	0.03
	Conversion	0.69	6.23	0.29	0.07
	Combined compounding and conversion	0.83	7.96	0.37	0.09
PVC – 7	Compounding	0.27	1.75	0.07	0.03
	Conversion	0.55	6.22	0.22	0.06
	Combined compounding and conversion	0.66	7.95	0.28	0.07
Photo-graphic film	Compounding	0.79	3.49	0.35	0.08
	Conversion	0.71	2.5	0.3	0.07
	Combined compounding and conversion	1.24	5.97	0.58	0.13
Rubber	Compounding	0.79	3.49	0.35	0.08
	Conversion	0.61	2.5	0.25	0.06
	Combined compounding and conversion	1.24	5.97	0.58	0.13
Poly-urethane	Compounding	0.16	3.48	0.02	0.01
	Conversion	0.71	2.5	0.3	0.07
	Combined compounding and conversion	1.24	5.97	0.58	0.13
Textiles/ fabric coating	Compounding	0.16	1.0	0.01	0.01
	Conversion	0.17	12.4	0.02	0.02
	Combined compounding and conversion	2.59	13.4	1.29	0.27
Pigment dispersion	Production of dispersions	0.79	3.49	0.35	0.08
Paints	Formulation	5.91	31.8	3.04	0.62
	Application	0.16	0.17	0.01	0.01
Adhesives		negligible	negligible	negligible	negligible

Notes: a) Calculation uses average dilution in the receiving water. If minimum dilution at the site was used, the PEC would be a factor of 1.88 times higher. Similarly if maximum dilution at the site was used, the PEC would be approximately a factor of 6.67 times lower. This production site does not discharge to the freshwater environment.
b) Sewage sludge from the production sites is not applied to land.
c) Not applicable, this production site does not discharge to the marine environment.

Table 3.16 Summary of predicted local concentrations in food for human consumption

Scenario		Concentration							
		Fish (mg/kg)	Root crops (mg/kg)	Leaf crops (mg/kg)	Drinking water (mg/l)	Meat (mg/kg)	Milk (mg/kg)	Air (mg/m^3)	Total daily human intake (mg/kg bw/day)
Production of 2-ethylhexyl diphenyl phosphate		7.38[a]	6.8×10^{-3}	8.0×10^{-4}	2.0×10^{-3}	2.2×10^{-3}	6.9×10^{-4}	0	0.01
		0.17	6.8×10^{-3}	8.0×10^{-4}	4.7×10^{-5}	7.6×10^{-4}	2.4×10^{-4}	0	3.4×10^{-4}
PVC – 1	Compounding	1.38	4.62	1.9×10^{-3}	1.2×10^{-3}	3.0×10^{-3}	9.4×10^{-4}	6.3×10^{-7}	0.03
	Conversion	15.1	56.5	0.70	0.01	0.66	0.21	4.8×10^{-4}	0.35
	Combined compounding and conversion	16.3	61.1	0.70	0.02	0.66	0.21	4.8×10^{-4}	0.38
PVC – 2	Compounding	1.38	4.62	0.04	1.2×10^{-3}	0.04	0.01	2.8×10^{-5}	0.03
	Conversion	4.54	16.6	0.21	4.2×10^{-3}	0.19	0.06	1.4×10^{-4}	0.10
	Combined compounding and conversion	5.76	21.2	0.25	5.3×10^{-3}	0.23	0.07	1.7×10^{-4}	0.13
PVC – 3	Compounding	1.07	3.43	0.03	8.6×10^{-4}	0.03	9.3×10^{-3}	2.1×10^{-5}	0.02
	Conversion	3.39	12.2	0.15	3.1×10^{-3}	0.14	0.05	1.0×10^{-4}	0.08
	Combined compounding and conversion	4.3	15.7	0.18	4.0×10^{-3}	0.17	0.05	1.2×10^{-4}	0.10
PVC – 4	Compounding	0.79	2.38	0.02	6.0×10^{-4}	0.02	6.5×10^{-3}	1.4×10^{-5}	0.01
	Conversion	0.61	1.7	0.02	4.3×10^{-4}	0.02	6.5×10^{-3}	1.4×10^{-5}	0.01
	Combined compounding and conversion	1.24	4.08	0.04	1.0×10^{-3}	0.04	0.01	2.9×10^{-5}	0.03

Table 3.16 continued.

Scenario		Concentration							
		Fish (mg/kg)	Root crops (mg/kg)	Leaf crops (mg/kg)	Drinking water (mg/l)	Meat (mg/kg)	Milk (mg/kg)	Air (mg/m^3)	Total daily human intake (mg/kg bw/day)
PVC – 5	Compounding	0.16	2.38	9.6×10^{-4}	6.0×10^{-4}	1.5×10^{-3}	4.8×10^{-4}	4.8×10^{-8}	0.01
	Conversion	0.71	1.71	0.03	4.3×10^{-4}	0.02	7.8×10^{-3}	1.7×10^{-5}	0.01
	Combined compounding and conversion	1.24	4.08	0.04	1.0×10^{-3}	0.04	0.01	2.9×10^{-5}	0.03
PVC – 6	Compounding	0.45	2.38	0.01	6.0×10^{-4}	0.01	3.3×10^{-3}	6.7×10^{-6}	0.01
	Conversion	1.21	8.5	0.05	2.1×10^{-3}	0.05	0.02	3.3×10^{-5}	0.05
	Combined compounding and conversion	1.5	10.9	0.06	2.7×10^{-3}	0.06	0.02	4.1×10^{-5}	0.06
PVC – 7	Compounding	0.38	2.38	8.2×10^{-3}	6.0×10^{-4}	8.1×10^{-3}	2.6×10^{-3}	5.0×10^{-6}	0.01
	Conversion	0.94	8.49	0.04	2.1×10^{-3}	0.04	0.01	2.5×10^{-5}	0.05
	Combined compounding and conversion	1.16	10.9	0.04	2.7×10^{-3}	0.04	0.01	3.0×10^{-5}	0.06
Photo-graphic film	Compounding	1.42	4.76	0.04	1.2×10^{-3}	0.04	0.01	2.9×10^{-5}	0.03
	Conversion	1.25	3.4	0.05	8.6×10^{-4}	0.05	0.02	3.5×10^{-5}	0.02
	Combined compounding and conversion	2.32	8.16	0.09	2.1×10^{-3}	0.08	0.03	5.7×10^{-5}	0.05

Table 3.16 continued.

Scenario		Concentration							
		Fish (mg/kg)	Root crops (mg/kg)	Leaf crops (mg/kg)	Drinking water (mg/l)	Meat (mg/kg)	Milk (mg/kg)	Air (mg/m^3)	Total daily human intake (mg/kg bw/day)
Rubber	Compounding	1.42	4.76	0.04	1.2×10^{-3}	0.04	0.01	2.9×10^{-5}	0.03
	Conversion	1.06	3.4	0.04	8.6×10^{-4}	0.04	0.01	2.9×10^{-5}	0.02
	Combined compounding and conversion	2.32	8.16	0.09	2.1×10^{-3}	0.08	0.03	5.7×10^{-5}	0.05
Poly-urethane	Compounding	0.17	4.75	1.1×10^{-3}	1.2×10^{-3}	2.3×10^{-3}	7.3×10^{-4}	9.5×10^{-8}	0.03
	Conversion	1.25	3.4	0.05	8.6×10^{-4}	0.05	0.02	3.5×10^{-5}	0.02
	Combined compounding and conversion	2.32	8.16	0.09	2.1×10^{-3}	0.08	0.03	5.7×10^{-5}	0.05
Textiles/ fabric coating	Compounding	0.16	1.36	8.5×10^{-4}	3.4×10^{-4}	1.2×10^{-3}	3.6×10^{-4}	6.1×10^{-10}	7.8×10^{-3}
	Conversion	0.18	17	2.1×10^{-3}	4.3×10^{-3}	6.6×10^{-3}	2.1×10^{-3}	4.8×10^{-7}	0.09
	Combined compounding and conversion	5.01	18.3	0.21	4.6×10^{-3}	0.20	0.06	1.4×10^{-4}	0.11
Pigment dispersion	Production of dispersions	1.42	4.76	0.04	1.2×10^{-3}	0.04	0.01	2.9×10^{-5}	0.03
Paints	Formulation	11.7	43.4	0.18	0.01	0.18	0.06	1.2×10^{-4}	0.26
	Application	0.16	0.22	8.1×10^{-4}	5.6×10^{-5}	8.0×10^{-4}	2.5×10^{-4}	9.8×10^{-11}	1.5×10^{-3}
Adhesives			neg.	neg.	neg.	neg.	neg.	neg.	neg.
Regional sources		0.16	7.2×10^{-3}	8.0×10^{-4}	4.3×10^{-5}	7.6×10^{-4}	2.4×10^{-4}	5.4×10^{-7}	3.2×10^{-4}

Notes: a) Calculation uses average dilution in the receiving water. If minimum dilution at the site was used, the concentration would be a factor of 1.88 times higher. Similarly if maximum dilution at the site was used, the concentration would be approximately a factor of 6.67 times lower.

4 Effects assessment: Hazard identification and dose (concentration) – response (effect) assessment

4.1 Aquatic compartment

The following sections review the available toxicity data for 2-ethylhexyl diphenyl phosphate with aquatic organisms. Where possible, a validity marking is given for each study (this appears in the summary tables within each section). The following validity markings have been used:

1 **Valid without restriction.** The test is carried out to internationally recognised protocols (or equivalent protocols) and all or most of the important experimental details are available.

2 **Use with care.** The test is carried out to internationally recognised protocols (or equivalent protocols) but some important experimental details are missing, or the method used, or endpoint studied, in the test means that interpretation of the results is not straightforward.

3 **Not valid.** There is a clear deficiency in the test that means the results cannot be considered valid.

4 **Not assignable.** Insufficient detail is available on the method used to allow a decision to be made on the validity of the study.

In terms of the risk assessment, toxicity data assigned a validity marking of one or two are considered to be of acceptable quality when deriving the predicted no-effect concentration (PNEC).

Several of the tests are unpublished studies carried out by industry. It has not been possible to validate all of these tests within the scope of this report and these are assigned a validity marking of four unless it is clear that some aspects of the test invalidate the results (for these a validity marking of three is given). The studies given a validity marking of four have also been considered along with the studies assigned a validity marking of one or two when deriving the PNEC.

One important property when considering the aquatic toxicity data is water solubility. The water solubility of 2-ethylhexyl diphenyl phosphate is in the range 0.051-1.9 mg/l, and a value of 0.051 mg/l is used in the assessment. Several studies have been carried out at concentrations greater than this water solubility and, although this in itself does not necessarily invalidate the test (for example, co-solvents or solubility aids could have been used in the test to aid dispersion of the substance in the test media), this does introduce some uncertainty over the concentration to which the organisms were actually exposed in the test. In cases where it is clear that undissolved test substance was present in the test media, the tests have been marked as invalid.

A further complication arises in the interpretation of the test results, as some products containing significant amounts of triphenyl phosphate have been tested. This substance itself has been shown to be very toxic to aquatic organisms (see the risk

evaluation report for triphenyl phosphate in this series) but it is impossible to establish if the effects seen in the tests with the commercial 2-ethylhexyl diphenyl phosphate products were due to the 2-ethylhexyl diphenyl phosphate component, the triphenyl phosphate component or both.

4.1.1 Toxicity to fish

Short-term studies

The short-term toxicity of 2-ethylhexyl diphenyl phosphate to freshwater fish is summarised in Table 4.1.

Ferro (2002) give 96-hour LC_{50} values for a 2-ethylhexyl diphenyl phosphate from unpublished studies of 32 mg/l with bluegill sunfish (*Lepomis macrochirus*), 15 mg/l with rainbow trout (*Oncorhynchus mykiss*) and 14 mg/l with fathead minnows (*Pimephales promelas*). Similar 96-hour LC_{50} values of 10-100 mg/l for *Lepomis macrochirus*, 15 mg/l and 1-10 mg/l for *Oncorhynchus mykiss* and 14 mg/l for *Pimephales promelas* are also reported from unpublished studies in IUCLID (2000a). These results are all higher than the water solubility of the test substance.

A fish 96-hour LC_{50} and a 14-day LC_{50} of 0.55 and 0.27 mg/l respectively can be estimated for 2-ethylhexyl diphenyl phosphate from the log K_{ow} value of 5.73 using the USEPA ECOSAR (version 0.99h) software.

Using the methods given in the TGD, a 96-hour LC_{50} of 0.16 mg/l can be estimated using the equation for polar narcosis (recommended for esters) and a log K_{ow} of 5.73.

No short-term toxicity data are available for to the substance in marine fish.

Long-term studies

The long-term toxicity of 2-ethylhexyl diphenyl phosphate to freshwater fish is summarised in Table 4.2.

IUCLID (2000a) reports the results of an unpublished 71-day fish early life stage test with 2-ethylhexyl diphenyl phosphate with rainbow trout (*Oncorhynchus mykiss*). The test was carried out using a flow-through system and the most sensitive endpoint determined was survival. The no observable effect concentration (NOEC) and lowest observable effect concentration (LOEC) for survival were determined to be 0.021 and 0.058 mg/l respectively based on measured concentrations. No adverse effects were noted on hatchability or growth (as determined by both weight and length).

The US Environmental Protection Agency (USEPA) ECOSAR program (v0.99h) predicts a long-term no effect concentration of 0.017 mg/l.

There are no long-term toxicity data for the substance marine fish.

Table 4.1 Short-term toxicity of 2-ethylhexyl diphenyl phosphate to freshwater fish

Species	Test guideline	Number of animals/ treatment	Age/ size	Cosolvent	Concs tested	N or M	Test conditions						End-point	Control resp.	Effect conc.	Ref.	Val.
							Media	Temp.	Hard.	pH	Static/ flow	D.O.					
Lepomis macrochirus													Mortality		96h-LC_{50} = 32 mg/l	Ferro 2002	4
				Acetone		N							Mortality		96h-LC_{50} = 10-100 mg/l	IUCLID 2000a	4
Oncorhynchus mykiss													Mortality		96h-LC_{50} = 15 mg/l	Ferro 2002	4
	OECD 203			Acetone		N							Mortality		96h-LC_{50} = 15 mg/l	IUCLID 2000a	4
				Acetone		N							Mortality		96h-LC_{50} = 1-10 mg/l	IUCLID 2000a	4
Pimephales promelas													Mortality		96h-LC_{50} = 14 mg/l	Ferro 2002	4
	OECD 203					N							Mortality		96h-LC_{50} = 14 mg/l	IUCLID 2000a	4

Notes: N = Nominal concentration.
M = Measured concentration.
Temp. = Temperature.
Hard. = Water hardness (given as mg $CaCO_3$/l).
D.O. = Dissolved oxygen (given as mg O_2/l or per cent saturation).
Val. = Validity rating (see Section 4.1): 1) Valid without restriction; 2) Use with care; 3) Not valid; 4) Not assignable.

Table 4.2 Long-term toxicity of 2-ethylhexyl diphenyl phosphate to freshwater fish

Species	Test guideline	Number of animals/ treatment	Age/ size	Co-solvent	Concs tested	N or M	Test conditions						End-point	Control resp.	Effect conc.	Ref.	Val.
							Media	Temp.	Hard.	pH	Static/ flow	D.O.					
Oncorhynchus mykiss	ASTM 1980		Eggs and fry			M					Flow		Survival		71d-NOEC = 0.021 71d-LOEC = 0.058 mg/l-	IUCLID 2000a	4
													Hatch.		71d-NOEC >0.058 mg/l	IUCLID 2000a	4
													Growth		71d-NOEC >0.058 mg/l	IUCLID 2000a	4

Notes: N = Nominal concentration.
M_f = Measured concentration.
Temp. = Temperature.
Hard. = Water hardness (given as mg $CaCO_3$/l).
D.O. = Dissolved oxygen (given as mg O_2/l or per cent saturation).
Val. = Validity rating (see Section 4.1): 1) Valid without restriction; 2) Use with care; 3) Not valid; 4) Not assignable.

4.1.2 Toxicity to aquatic invertebrates

Short-term studies

The short-term toxicity of 2-ethylhexyl diphenyl phosphate to freshwater aquatic invertebrates is summarised in Table 4.3.

Ziegenfuss *et al.* (1986) determined the acute toxicity of 2-ethylhexyl diphenyl phosphate (purity not given) to both the daphnid *Daphnia magna* and the midge *Chironomus tentans.* The test method was based on ASTM (1980). The 48-hour LC_{50} values determined were 0.15 mg/l for *D. magna* and 0.79 mg/l for *C. tentans.*

A similar, possibly the same, 48-hour EC_{50} of 0.15 mg/l has been determined for 2-ethylhexyl diphenyl phosphate (purity not given) with *Daphnia magna* using the ASTM E729 method (Adams and Heidolph 1985).

E G and G Bionomics (1979) also determined a 48-hour EC_{50} of 0.15 mg/l for 2-ethylhexyl diphenyl phosphate with *Daphnia magna* (this may be the same result as reported by Ziegenfuss *et al.* (1986) and Adams and Heidolph (1985)). The purity of the test substance was not given and the test was carried out using a static system with nominal concentrations. The test report indicates that *Daphnia* were found to be trapped on the surface in the 0.036 mg/l exposure group, but no trapped *Daphnia* were noted at higher or lower exposure concentrations. The presence of trapped *Daphnia* on the surface could be an indication of physical rather than toxicological effects of the test substance (such as that caused by undissolved test substance adhering to the exposed *Daphnia*) but as the effect was seen only at one concentration, this is unlikely to have affected the results of the test.

Similar 48-hour EC_{50}s of 0.15 mg/l are also reported in IUCLID (2000a) from two unpublished studies (these are most probably the same studies as Adams and Heidolph (1985) and E G and G Bionomics (1979)) but it is indicated that the substance tested is no longer representative of current production. Other unpublished data reported in IUCLID (2000a) include a 24-hour EC_{50} of 28 mg/l for *Daphnia magna*, 48-hour EC_{50}s of 0.79 mg/l and 0.5 mg/l with midge *Chironomus tentans* and a 96-hour EC_{50} of 0.5 mg/l with midge *Paratanytarsus parthenogenetica.*

Ferro (2002) gives a 48-hour EC_{50} for *Daphnia magna* of 28 mg/l for a commercial 2-ethylhexyl diphenyl phosphate from an unpublished study. This result is well above the reported water solubility of the test substance.

Bayer (2002) quotes a 48-hour EC_o of 6.3 mg/l and a 48-hour EC_{50} above100 mg/l for another commercial 2-ethylhexyl diphenyl phosphate, again from an unpublished study. These results are again above the water solubility of the substance.

Boethling and Cooper (1985) reported a 48-hour EC_{50} of 0.5-0.8 mg/l for *Chironomus plumosas*. No further details are available.

Using the methods given in the TGD, a 48-hour EC_{50} of 0.36 mg/l can be estimated for *Daphnia magna* using the equation for polar narcosis (recommended for esters) and a log K_{ow} of 5.73. This is in good agreement with the majority of experimental data. The USEPA ECOSAR program (v0.99h) predicts a value of 0.12 mg/l for the same endpoint.

There are no short-term toxicity data for the substance with marine invertebrates.

Table 4.3 Short-term toxicity of 2-ethylhexyl diphenyl phosphate to freshwater invertebrates

Species	Test guide-line	Number of animals/ treatment	Age/ size	Co-solvent	Concs. tested	N or M	Test conditions						End-point	Cont. resp.	Effect conc.	Ref.	Val.
							Media	Temp.	Hard.	pH	Static/ flow	D.O.					
Chironomus plumosas															48h-EC_{50} = 0.5-0.8 mg/l	Boethling and Cooper 1985	4
Chironomus tentans	ASTM 1980		2nd instar (10-14 day)				Well water				Static		Immobil. mortality		48h-LC_{50} = 0.79 mg/l	Ziegen-fuss *et al*. 1986	2
	ASTM 1980	10 replicates of one animal in 40 ml per treatment				N	Well water	22°C					Immobil. mortality		48h-EC_{50} = 0.79 mg/l	IUCLID 2000a	4
	USEPA 1975					N							Immobil. mortality		48h-EC_{50} = 0.5 mg/l	IUCLID 2000a	4
Daphnia magna	ASTM 1980		<24 h				Well water				Static		Immobil. mortality		48h-LC_{50} = 0.15 mg/l	Ziegen-fuss *et al.* 1986	2
	ASTM E729		<24 h	Dimethyl formamide or acetone at up to 1.0 ml/l		N		20-23°C	120-250	7.0-8.5	Static	6.0-9.3 mg/l	Immobil. mortality		24h-EC_{50} = 0.60 mg/l 48h-LC_{50} = 0.15 mg/l	Adams and Heidolph 1985	2
													Immobil. mortality		48h-EC_{50} = 28 mg/l	Ferro 2002	4
	OECD 202					N							Immobil. mortality		48h-EC_{50} = 0.15 mg/l	IUCLID 2000a	4

Table 4.3 continued.

Species	Test guide-line	Number of animals/ treatment	Age/ size	Co-solvent	Concs. tested	N or M	Test conditions						End-point	Cont. resp.	Effect conc.	Ref.	Val.
							Media	Temp.	Hard.	pH	Static/ flow	D.O.					
Daphnia magna (continued)	USEPA 1975	15 per treatment	<24 h	Dimethyl formamide (conc. not given)	0.013, 0.022, 0.036, 0.060, 0.10, 0.17 and 0.28 mg/l plus control and solvent control.	N	Recon well water	22°C	175 mg/l	8.1	Static		Immobil. mortality	0% Mortality	48h-EC_{50} = 0.15 mg/l	E G and G Bionomics 1979	2
													Immobil. mortality		48h-EC_{50} >100 mg/l	Bayer 2002	4
													Immobil. mortality		24h-EC_{50} = 28 mg/l	IUCLID 2002a	4
Parata-nytarsus parthen-ogenetica	USEPA 1975			Dimethyl formamide		N							Immobil. mortality		96h-EC_{50} = 0.5 mg/l	IUCLID 2000a	4

Notes: N = Nominal concentration.
M = Measured concentration.
Hard. = Water hardness (as mg $CaCO_3$/l).
Temp. = Temperature.
D.O. = Dissolved oxygen (given as mg O_2/l or per cent saturation).
Val. = Validity rating (see Section 4.1): 1) Valid without restriction; 2) Use with care; 3) Not valid; 4) Not assignable.

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Long-term studies

The long-term toxicity of 2-ethylhexyl diphenyl phosphate to freshwater invertebrates is summarised in Table 4.4.

Adams and Heidolph (1985) carried out a standard 21-day reproduction study with *Daphnia magna* using a commercial 2-ethylhexyl diphenyl phosphate product (purity unknown). The test was carried out using a flow-through system and the exposure concentrations were verified by measurement. The 21-day NOEC was determined to be 18 µg/l based on reproduction and 43 µg/l based on survival.

The Adams and Heidolph (1985) result is probably the same test as carried out by E G and G Bionomics (1979). This test was a 21-day *Daphnia magna* reproduction study using a flow-through system. The nominal concentrations used were 9.4, 19, 38, 75 and 150 µg/l. The corresponding mean measured concentrations (based on two replicate samples collected at weekly intervals) were 6.0, 12, 18, 43 and 75 µg/l. All animals exposed to a mean measured concentration of 75 µg/l died during the first seven days of the study, but survival in all other treatment groups at the end of the 21-day test period was similar to that in the control and solvent control group (survival in the solvent control group was found to be statistically significantly lower ($p=0.05$) than in the control group on day seven; however, survival in the solvent control and control group was comparable at all other time points). Therefore, the NOEC for survival was determined to be 43 µg/l. The average cumulative number of offspring per female in the 43 µg/l treatment group was found to be statistically significantly reduced compared with the control group at all time points and was statistically significantly reduced compared with the solvent control group on days 12 to 21. The average cumulative number of offspring per female in the 18 µg/l treatment group was significantly reduced compared with the control groups on days 11, 12 and 13, but not at other time periods. This was not thought to represent a treatment related effect at this level as the number of offspring produced in the solvent control group was also significantly less than produced in the control group on days 9 and 11 (the response in the two control groups was similar at all other time points). The 21-day NOEC for reproduction was therefore 18 µg/l.

IUCLID (2000a) reports the results of a further, unpublished, 21-day reproduction study with *Daphnia magna*. The NOEC determined in this study was reported to be 0.18 mg/l. However, this may be a typing error as IUCLID (2000a) also indicates that the maximum threshold concentration in this study was between 0.018 and 0.043 mg/l, which is similar to the value reported above by Adams and Heidolph (1985) and E G and G Bionomics (1979) (it may even be the same result).

There are no long-term toxicity data for the substance with marine invertebrates.

4.1.3 Toxicity to algae

The toxicity of 2-ethylhexyl diphenyl phosphate to fresh water algae is summarised in Table 4.5.

Table 4.4 Long-term toxicity of 2-ethylhexyl diphenyl phosphate to freshwater invertebrates

Species	Test guide-line	Number of animals/ treatment	Age/ size	Co-solvent	Concs. tested	N or M	Test conditions						End-point	Cont. resp.	Effect conc.	Ref.	Val.
							Media	Temp.	Hard.	pH	Static/ flow	D.O.					
Daphnia magna	USEPA, 1976	20 per replicate, four replicates per treatment	<24 h	Acetone or dimethyl formamide at up to 0.1 ml/l	Five concentrations plus control and solvent control	M		21-23°C	160-180 mg/l	8.0-8.5	Flow	7.5-8.0 mg/l	Sur-vival and repro.		7d-EC_{50} = 0.053 mg/l 14d-EC_{50} = 0.053 mg/l 21d-EC_{50} = 0.047 mg/l	Adams and Heidolph 1985.	2
													Sur-vival		21d-NOEC = 0.043 mg/l		
													Repro.		21d-NOEC = 0.018 mg/l		

Table 4.4 continued

Species	Test guide-line	Number of animals/ treatment	Age/ size	Co-solvent	Concs. tested	N or M	Test conditions						End-point	Cont. resp.	Effect conc.	Ref.	Val.
							Media	Temp.	Hard.	pH	Static/ flow	D.O.					
Daphnia magna	USEPA 1975	20 per replicate, four replicates per treatment	<24 h	Dimethyl formamide at up to 57 µl/l	Five concentrations plus control and solvent control. The nominal concentrations were 9.4, 19, 38, 75 and 150 µg/l. The respective mean measured concentrations. were 6.0, 12, 18, 43 and 75 µg/l.	M	Recon .well water	23°C	166-170	8.0-8.4	Flow	7.5-7.8	Survival	89% survival in control; 80% survival in solvent control	21d-NOEC = 0.043 mg/l	E G and G Bionomics 1979	2
													Repro.	Average cumul. young/ female was ~95 in control group and ~85 in solvent control group (read from graph)	21d-NOEC = 0.018 mg/l		

Notes: N = Nominal concentration.
M = Measured concentration.
Temp. = Temperature.
Hard. = Water hardness (given as mg $CaCO_3$/l).
D.O. = Dissolved oxygen (given as mg O_2/l or per cent saturation).
Val. = Validity rating (see Section 4.1): 1) Valid without restriction; 2) Use with care; 3) Not valid; 4) Not assignable.

Table 4.5 Toxicity of 2-ethylhexyl diphenyl phosphate to freshwater algae

Species	Test guideline	Initial inoculum conc.	Cosolvent	Concs. tested	N or M	Test conditions				Endpoint	Control response	Effect conc.	Ref.	Val.
						Media	Temp.	Hard.	pH					
Selenastrum carpricornutum	OECD 201	1×10^4 cells/ml			N	Algal assay media	24°C			*In vivo* chlorophyll		72h-EC_{50} = 0.2 mg/l	IUCLD 2000a	4

Notes: N = Nominal concentration.
M = Measured concentration.
Temp. = Temperature.
Hard. = Water hardness (given as mg $CaCO_3$/l).
Val. = Validity rating (see Section 4.1): 1) Valid without restriction; 2) Use with care; 3) Not valid; 4) Not assignable.

IUCLID (2000a) reports the results from an unpublished study on the toxicity of 2-ethylhexyl diphenyl phosphate to *Selenastrum capricornutum*[6]. The 72-hour EC_{50} was determined to be 0.2 mg/l based on *in vivo* chlorophyll formation. IUCLID (2000a) indicates that the substance tested is not representative of the currently produced substance but gives no further details on what was actually tested.

The USEPA ECOSAR program (v0.99h) predicts a 96-hour EC_{50} value of 0.051 mg/l and a long-term no effect concentration of 0.042 mg/l for green algae.

There are no toxicity data for 2-ethylhexyl diphenyl phosphate with marine algae.

4.1.4 Toxicity to microorganisms

Bayer (2002) and IUCLID (2000a) report that the IC_{50} for respiration inhibition in activated sludge was above 10,000 mg/l for a commercial 2-ethylhexyl diphenyl phosphate based on unpublished results in an OECD 209 test.

4.1.5 Toxicity to sediment organisms

No data have been located.

4.1.6 Predicted no effect concentration (PNEC) for the aquatic compartment

Surface water

Acute toxicity data are available for fish (lowest LC_{50} = 1-10 mg/l), invertebrates (lowest EC_{50} = 0.15 mg/l for *Daphnia magna*) and algae (lowest EC_{50} = 0.2 mg/l for a non-standard endpoint and a substance that may have a different composition to the current production material). Given that the water solubility of the test substance is reported to be 0.051-1.9 mg/l, the results are difficult to interpret in terms of whether the substance is acutely toxic at concentrations below its solubility limit.

Long-term toxicity data are available for fish and *Daphnia.* The 71-day NOEC for *Oncorhynchus mykiss* was 0.021 mg/l determined in an early life stage test investigation hatchability, survival and growth. The 21-day NOEC for *Daphnia magna* is similar at 0.018 mg/l. No reliable NOEC is available for algae.

Annex B discusses the available data for algae for the trialkyl/aryl and triaryl phosphate esters as a whole. This shows that algae are unlikely to be more sensitive to 2-ethylhexyl diphenyl phosphate than *Daphnia magna*. The predicted no effect value from the ECOSAR program is higher than the *Daphnia* value.

Therefore, it is proposed that an assessment factor of 10 is applied to the *Daphnia magna* NOEC to give a $PNEC_{water}$ of 1.8 μg/l.

There are no data available on marine species. A PNEC of 0.18 μg/l can be calculated using the freshwater data as above with an assessment factor of 100.

[6] *Selenastum capricornutum* is now known as *Pseudokirchneriella subcapitata.*

Microorganisms

An IC_{50} of above10,000 mg/l has been determined for 2-ethylhexyl diphenyl phosphate in an activated sludge respiration inhibition test. According to the TGD, an assessment factor of 100 is appropriate for this type of test result, and so the $PNEC_{microorganisms}$ is estimated to be above 100 mg/l. Although the water solubility of the test substance was exceeded in this test, the actual solubility in pure water may not be relevant to the exposure of microorganisms during waste water treatment.

Sediment

No sediment toxicity data are available for 2-ethylhexyl diphenyl phosphate. In the absence of data, the equilibrium partitioning method is used to estimate the PNEC.

$$PNEC_{sed} = \frac{K_{susp-water}}{RHO_{susp}} \times PNEC_{water} \times 1000$$

where $K_{susp\text{-}water}$ = suspended sediment-water partition coefficient = 238 m^3/m^3 (see Section 3.1.2).

RHO_{susp} = bulk density of suspended sediment = 1,150 kg/m^3.

Using a $PNEC_{water}$ of 1.8 μg/l, the $PNEC_{sed}$ is estimated to be 0.373 mg/kg wet weight.

As the log K_{ow} of this substance is above five, according to the TGD the resulting PEC/PNEC ratios should be increased by a factor of 10 when using this PNEC to take into account the possibility of direct ingestion of sediment-bound substance.

For the marine assessment, the marine water PNEC is used in the same way to derive a PNEC of 0.037 mg/kg wet weight. An additional factor of 10 is applied to the PEC/PNEC ratios in this case as well.

4.2 Terrestrial compartment

No terrestrial toxicity data are available suitable for use in determining a PNEC for 2-ethylhexyl diphenyl phosphate. In the absence of data, the equilibrium partitioning method can be used to estimate the PNEC.

$$PNEC_{soil} = \frac{K_{soil-water}}{RHO_{soil}} \times PNEC_{water} \times 1000$$

where $K_{soil\text{-}water}$ = soil-water partition coefficient = 285 m^3/m^3 (see Section 3.1.2).

RHO_{soil} = bulk density of wet soil = 1,700 kg/m^3.

Using a $PNEC_{water}$ of 1.8 μg/l, the $PNEC_{soil}$ is estimated as 0.302 mg/kg wet weight.

As the log K_{ow} of this substance is above five, according to the TGD the resulting PEC/PNEC ratios should be increased by a factor of 10 when using this PNEC to take into account the possibility of direct ingestion of sediment-bound substance.

4.3 Atmosphere

No information is available on the toxicity of 2-ethylhexyl diphenyl phosphate to plants and other organisms exposed via air. The very low vapour pressure of the substance means that volatilisation to the atmosphere is likely to be limited and the resulting concentrations are likely to be very low. Thus, the possibility of 2-ethylhexyl diphenyl phosphate contributing to atmospheric effects such as global warming and acid rain is likely to be very small. In addition, as the substance does not contain halogen atoms it will not contribute to ozone depletion.

4.4 Mammalian toxicity

4.4.1 Toxicokinetics, metabolism and distribution

There are no available *in vivo* or *in vitro* data on the absorption, distribution or elimination of 2-ethylhexyl diphenyl phosphate in mammals, including humans.

4.4.2 Acute toxicity

Oral

An acute oral lethality study in the rat conducted by Monsanto plc is briefly described in IUCLID (2000a). Rats of unspecified strain and number were administered undiluted 2-ethylhexyl diphenyl phosphate by gavage. No further details, such as study date, were reported but it is stated that the study was not Good Laboratory Practice (GLP) compliant. The LD_{50} was reported to be greater than 15,800 mg/kg bodyweight (Monsanto 1971b, cited in IUCLID 2000a).

In another oral lethality study in rats (Kehoe 1949, cited in USEPA 2004), four male and female rats (weighing 140-300 g) per group (strain and number of groups not reported) received a single dose of 2-ethylhexyl diphenyl phosphate. Pharmacotoxic (not defined) observations were made for 15 days post-dosing but not reported. The oral LD_{50} was reported to be greater than 24,000 mg/kg.

An oral lethality study with rabbits is mentioned in IUCLID (2000a), but the only information provided is that it was reported in 1953 and was not GLP compliant. The LD_{50} was greater than 24,000 mg/kg bodyweight.

Inhalation

An acute inhalation study in rats was performed by Monsanto (1971a, cited in IUCLID 2000a). The strain and number of rats are not reported but the study was conducted in 1983 to EPA/TSCA methods and was stated to be GLP compliant. The test material was heated to 125°C at the beginning of the 4-hour inhalation period. The LD_{50} was reported to be greater than 4.8 mg/l. This is assumed to be the highest concentration tested.

An earlier (1973) inhalation study in rats exposed for 6 hours gave an LD_{50} of greater than 3 mg/l. In this study, the test material was heated to 325°F (Monsanto 1970, cited in IUCLID 2000a). No further study details were reported.

Dermal

In a study not conducted to GLP or to any stated guidelines, rabbits of an unspecified strain were dermally exposed to undiluted test material. The LD_{50} was reported to be greater than 7,940 mg/kg bodyweight but no further information was provided (Monsanto 1971b, cited in IUCLID 2000a).

In another study, reported by Johannsen *et al.* (1977), undiluted test material was applied to the intact, clipped dorsal skin of New Zealand albino male and female rabbits under occluded conditions. After 24 hours, the test material was removed by washing and the animals were then held for a 14-day observation period, after which they were killed and subject to a gross pathological examination. The LD_{50} was reported to be greater than 7.9 g/kg.

It is unclear, given that both the reports relate to work undertaken by Monsanto plc and report very similar LD_{50} values, whether these data represent the same experiment.

Other routes

In an early study (Treon *et al.* 1953) that was poorly reported in IUCLID (2000a), rabbits received intravenous doses of 2-ethylhexyl diphenyl phosphate. The lethality, expressed as an LC_{50}, was given as between 218 and 272 mg/kg bodyweight. In the references of the IUCLID file, it is noted that the test substance was administered as a suspension (5 ml of material plus 10 ml olive oil plus 90 ml of 0.9 per cent saline plus 1 g lecithin).

Neurotoxicity

There are no data on the acute neurotoxicity of 2-ethylhexyl diphenyl phosphate.

Summary of acute toxicity

No information is available from human studies.

Of the few available studies, only one acute inhalation study in rats has been conducted to GLP and test guidelines. However, limited information on a few other studies using the dermal or oral route is available. It is, however, uncertain if some of data reported in the IUCLID relates to the same experiments as were reported in a paper by Johannsen *et al.* (1977). Despite this uncertainty, it seems likely that the LD_{50} by the oral route in the rat is greater than 15,800 mg/kg bodyweight, while that for the dermal route in rabbits is greater than 7,940 mg/kg bodyweight. The inhalation LD_{50} in rats is reported as 4.8 mg/l. The oral and dermal values are above the limit doses (2,000 mg/kg in oral and dermal routes) applied in modern studies, which indicate a generally low level of toxicity. For inhalation exposure, a GLP-compliant study gave a 4-hour LD_{50} in rats greater than 4.8 mg/l, which would suggest it may be appropriate to consider classification of the material.

4.4.3 Irritation

Information is available for humans and for experimental animals.

Skin

Human

Two studies are reported which appear to be Human Repeated Insult Patch Tests (HRIPT). There are a number of methodological variations that can be applied to the basic test design (such as Draize test, Shelanski-Shelanski test, Voss-Griffith test and modified Draize test) which allow for the detection of sensitisation, but can also inform on primary irritation potential.

In the first of the non-GLP compliant studies reported in IUCLID (2000a), the Shelanski patch test method was used in 200 subjects (sex of volunteers not presented), and 30 subjects presented with cumulative irritation. Of these, 18 were judged erythema score 1 (barely perceptible) and 12 were erythema score 2 (clear erythema). According to the remarks in the IUCLID, when applying the EU criteria to these results, no classification is required for sensitisation (Monsanto 1968).

In the second study presented in the USEPA HPV test plan (USEPA 2004), which was described as a “skin irritation, repeated insult patch test”, male and female subjects received multiple applications of the undiluted test material under non-occlusive dressing followed by challenge. No further details are reported but it is concluded that the material was neither a primary irritant nor sensitiser (Industrial Biology Research and Testing Laboratory 1959).

Animal

A single study of skin irritation (Monsanto 1971b) appears in both IUCLID (2000a) and the USEPA HPV test plan (USEPA 2004). In this GLP non-compliant study, three rabbits (strain and sex not reported) were given dermal applications of the test material (amount not reported). The reaction was reported as slightly irritating; no further details were reported in either document. As the same reference code is used in both documents, these are assumed to be reports of the same experiment.

Eye

In a study stated as being conducted to a Draize design by Monsanto (1971b, cited in IUCLID 2000a), test material was applied undiluted to the eyes of three rabbits of unspecified strain. No detailed methodology or results were reported but it was noted that slight irritation of the eye was found. This same study is also reported in the USEPA HPV test plan.

Summary of irritation

Two poorly reported studies from secondary sources are available on the irritancy of 2-ethylhexyl diphenyl phosphate to human skin. One of the studies suggests very slight irritation but the information provided is too limited to draw a confident conclusion.

A single study in three rabbits reported in both secondary sources indicates a slight potential for irritation, and a further study of irritant effects to the eye in three rabbits also reports slight irritation. Given the reports that only slight irritation was observed for both skin and eye, it is considered that the irritant potential of 2-ethylhexyl diphenyl phosphate may be low.

4.4.4 Corrosivity

Although of limited quality, the studies available that assessed skin or eye irritation suggest 2-ethylhexyl diphenyl phosphate has only limited irritancy potential and, therefore, it is considered unlikely that 2-ethylhexyl diphenyl phosphate possesses corrosive properties.

4.4.5 Sensitisation

Human

The available studies are summarised under Section 4.4.3. The substance does not cause skin sensitisation based on these results.

Animal

No experimental animal data is available for evaluation.

Summary of Sensitisation

The two human studies of skin sensitisation reported in the available secondary sources present only limited information. Exploration of the primary sources may provide more informative study descriptions. However, the information that is available does not suggest that 2-ethylhexyl diphenyl phosphate has sensitising potential.

4.4.6 Repeated-dose toxicity

Animal data

There are no data on repeated inhalation exposure to 2-ethylhexyl diphenyl phosphate.

In a 12-day repeat-dose study, male and female rats weighing between 152 and 369 grams (strain unspecified), with group size of 12 per dose level, received undiluted test material (described as Lot-2014)) by oral gavage at 5 or 10 g/kg bw/day, for 12 consecutive days. Pharmacotoxic observations (details of examinations not provided) were made through day 17 (not clear from description in USEPA HPV test plan if the 17 days is from the beginning or end of dosing). It is reported that one animal in each test group did not survive till the end of the dosing period (no reasons reported). Pharmacotoxic signs included soft stools, hair loss and skin irritation around anogenital area which was reversible following cessation of dosing. It is also reported that dose-related weight losses of up to 24 per cent were reported (no further details given in the USEPA HPV test plan) and that weight gain occurred in 21/22 animals following cessation of dosing. No mention is made of a control group.

In a 90-day GLP-compliant sub-chronic oral feed study, male and female Sprague-Dawley rats (numbers not stated) were fed diets containing 0.001, 0.005, 0.010, 0.025 and 0.625 per cent test material (equivalent to 0.6, 3, 6, 15, and 375 mg/kg bodyweight). The test material was a 1:1 mixture of Monsanto's Santicizer 141 and Bayer's Disflamoll DPO; the purity of each sample was 92.7 per cent and 92.5 per cent

2-ethylhexyl diphenyl phosphate, respectively. The concentrations of the main impurities in Santicizer 141 and Disflamoll DPO were, respectively, 3.8 per cent and 2.1 per cent triphenyl phosphate, and 3.5 per cent and 5.2 per cent bis-2-ethylhexyl phenyl phosphate. Details of the study methodology were not provided, although it is apparent from the summarised results that examinations undertaken (at undefined time points) included measurement of bodyweight, food consumption and blood chemistry and urinalysis, as well as organ weight analysis and pathological examination of at least the liver. No effects on any of these indicators were seen in the 0.6, 3, and 6 mg/kg treated groups but there were some liver enzyme increases (not specified) in the males, but not the females, at 15 mg/kg bodyweight. The lowest observed adverse effect level (LOAEL) in males was 15 mg/kg bodyweight and the NOAEL in females was 15 mg/kg bodyweight. Overall, the no observed adverse effect level (NOAEL) was given as 6 mg/kg bodyweight, based on the liver enzyme changes. In the 375 mg/kg bodyweight treated groups, there were decreases in body weight and water intake, In the blood parameters, there were decreases in haemoglobin and haematocrit (HCT), increases in protein and gamma-GT and increases in the white cell counts and urea in females only. There was an increase in liver weight, liver enzymes and liver pathology (further details not reported). Adrenal gland weight was increased in females alone but kidney weight was elevated in both sexes. At the end of a 28-day recovery period, there remained a decrease in body weight and increases in white blood cells and gamma-GT in the blood (Monsanto 1992b, cited in IUCLID 2000a).

In a second 90-day GLP-compliant sub-chronic oral feed study (Monsanto 1992a, cited in IUCLID 2000a), male and female Sprague-Dawley rats (numbers not stated) were fed diets containing 0, 0.2, 0.4, and 0.8 per cent test material (stated to be equivalent to 0, 120, 240 and 480 mg/kg bw/day). The test material was a 1:1 mixture of Monsanto's Santicizer 141 and Bayer's Disflamoll DPO; the purity of the samples was 92.7 per cent and 92.5 per cent 2-ethylhexyl diphenyl phosphate respectively. The concentrations of the main impurities in Santicizer 141 and Disflamoll DPO were, respectively, 3.8 per cent and 2.1 per cent triphenyl phosphate and 3.5 per cent and 5.2 per cent bis-2-ethylhexyl phenyl phosphate. The authors used a conversion factor of 600 to go from per cent w/w in diet to mg/kg bodyweight of test substance per day. Details of the study methodology were not provided although it is apparent from the summarised results that examinations undertaken (at undefined time points) included measurement of bodyweight, food consumption and blood chemistry and urinalysis, as well as organ weight analysis and pathological examination of at least the liver. Effects were seen on blood and liver parameters at all tested concentrations, and no NOAEL was derived from this study. In the 0.2 per cent group, there were increases in blood protein and albumin, and a decrease in mean corpuscular volume (of red cells) (MCV) in males, increases in liver weights and accompanying hypertrophy of centrilobular liver cells. In the 0.4 per cent treated rats, there was a body weight decrease in female rats and in the blood, increases in protein and albumin in both sexes and decreases in MCV and HCT (this latter in females only). There were increases in liver weights in both sexes and hypertrophy of centrilobular liver cells in males only. There was an increase in adrenal gland weight in females and accompanying vacuolation of adrenal cortical cells. In the 0.8 per cent treated groups, there was a body weight decrease in females and in the blood parameters, increases in protein and albumin, decreases in MCV and a decrease in the HCT in females. Liver weight was increased in both sexes along with increased adrenal gland weights in females, with hepatic pathology noted in males. In the 0.8 per cent treated groups, body weight was decreased in both sexes. In the blood parameters, protein and albumin, MCV, HCT and haemoglobin all increased. Liver and adrenal gland weights and pathology (not described) were increased in both sexes. Kidney weights were increased in the males alone.

In a third 90-day sub-chronic oral feed study reported in the USEPA HPV test plan (BIBRA 1990), approximately four-week old male and female Sprague-Dawley rats (ten males and ten females per group) were fed diets containing 0, 0.2, 0.4 and 0.8 per cent

2-ethylhexyl diphenyl phosphate (as Santicizer 141) and then sacrificed. Observations were made on survival, appearance and behaviour and pharmacologic effects, body weight (twice weekly), food and water consumption, urinalysis (at 42 and 90 days), haematology, and clinical chemistry at necropsy, gross necropsy, organ weights (nine organs), histopathological analysis of 33 tissues (plus all lesions) in high-dose and control animals, as well as of liver, adrenal and ovary tissue from low-and mid-dose animals. The reported results show that all animals survived the study and that no adverse behavioural effects were noted in treated animals. Bodyweight gains in the high- and mid-dose group were suppressed, with statistical significance in the high dose only; the reporting of weight gain reduction is unclear in the summary reporting. Food and water consumption was reduced in the high-dose group in females, the latter leading to dehydration. There was a dose-related reduction in HCT and haemoglobin and clinical chemistry changes were indicated to suggest effects on liver, kidney testes and ovaries (no further details reported). There was also a dose-related increase in liver weight accompanied by enzyme induction and histopathological changes. Treated animals showed a dose-related increase in adrenal weights accompanied by increases in vacuolated cortical cells in the mid- and high-dose animals. There were increases in kidney, testes and brain weights but no histopathological findings in these organs. The high-dose females showed hyperplasia of the interstitial gland cells in the ovaries. No NOAEL was established in this study but at the lowest concentration tested of 0.2 per cent (dietary 2-ethylhexyl diphenyl phosphate), which was estimated to be equivalent to less than approximately 160 mg/kg/day for males and 174 mg/kg/day for females, there were increases in weight in the adrenal glands, kidney, testis and brain but with no histopathological findings.

In an early 24-month oral feeding study in rats (strain not specified), groups of 20 males and 20 females were fed diets containing 0. 0.625, 0.125, 1.0 or 5.0 per cent 2-ethylhexyl diphenyl phosphate (purity unspecified). The test material was dissolved in alcohol and distributed over a single layer of pellets and the alcohol evaporated to dryness. It was reported that the diet containing one per cent 2-ethylhexyl diphenyl phosphate had a bitter taste (it is presumed that this was reported by a technician and that the observation might also be applicable to the five per cent treatment). There are few results reported in the IUCLID, other than that there were no effects at 0.0625 and 0.125 per cent, reduced growth in the one per cent group, and treatment-related deaths, and food consumption and growth decreases in the five per cent group. The NOAEL was reported to be 0.125 per cent 2-ethylhexyl diphenyl phosphate in the diet (Treon *et al.* 1953, cited in IUCLID 2000a).

In a 26-month oral study in dogs, two litters of dogs were used. Each litter contained three dogs; one dog was assigned as a control and the other two were treated. Dogs in two treatment group received capsules containing 0.5 or 1.0 ml/kg 2-ethylhexyl diphenyl phosphate (purity unspecified) six days a week. However, the poor level of reporting is such that it is unclear what the actual period of treatment was. No effects are reported for the 0.5 ml/kg treated dogs but body weight reduction was reported for the 1.0 ml/kg treated animals (Treon *et al.* 1953).

Neurotoxicity

In a study designed to evaluate delayed neurotoxicity and dose-response relationships, Johannsen *et al*. (1977) reported that adult hens (strain unspecified) were given 2-ethylhexyl diphenyl phosphate (the 2-ethylhexyl diphenyl phosphate was prepared from “essentially pure and /or high quality alkyl alcohols”) at 10 g/kg in undiluted dose or a corn oil solution twice daily by oral gavage, for three days. A further three day dosing period to the same regimen was conducted from study day 21, to give a total received dose of 120 g/kg. Hens were observed for signs of neurotoxicity and subject to histopathological examination (in particular brain, sciatic nerve and spinal cord); no treatment-related effects were reported in any of the hens treated with 2-ethylhexyl

diphenyl phosphate. Although it appears that no positive control was included in the study design, evidence of neurotoxicity was reported in this paper for a number of other aryl phosphates tested, suggesting that the test method was capable of detecting neurotoxic agents. The authors concluded that 2-ethylhexyl diphenyl phosphate was not neurotoxic under their test conditions. The IUCLID (2000a) also contains a poorly reported synopsis of this study from Monsanto (1972).

Human data

No human data are available.

Summary and discussion of repeated- dose toxicity

There is a 12-day oral (gavage) study in which rats received either 5 or 10 g/kg for 12 consecutive days, although it is unclear what the subsequent recovery period was. Only general observations were made in the summary report in the USEPA HPV test plan and it is considered uninformative in establishing a toxicity profile for this substance. Similarly, the summary of the 26-month oral (capsule) study in six dogs given in the IUCLID is considered too limited for useful evaluation.

Two GLP-compliant 90-day oral (feeding) studies are described in IUCLID (2000a). Both used a mixture of two commercial products containing a high proportion (greater than 92 per cent) of 2-ethylhexyl diphenyl phosphate and with measured concentrations of other identified alkyl phosphates. The results of both studies were consistent with each other in that effects on blood and liver enzyme and liver and adrenal pathology were similar. The study in which rats were fed diets containing 0.001, 0.005, 0.010, 0.025 and 0.625 per cent test material (equivalent to 0.6, 3, 6, 15, and 375 mg/kg bodyweight) was more informative as a NOAEL at 6 mg/kg bodyweight was identified. In the second study, using diets containing 0, 0.2, 0.4, and 0.8 per cent test material (stated as equivalent to 0, 120, 240 and 480 mg/kg bw/day), no NOAEL was identified, although the dose-related effects were similar to those seen in the first study.

A third 90-day feeding study in rats was described in the USEPA HPV test plan. This also used a commercial product (Santicizer 141) of 2-ethylhexyl diphenyl phosphate and also at concentrations in the feed of 0.2, 0.4 and 0.8 per cent 2-ethylhexyl diphenyl phosphate. Again, the changes seen in the blood, liver enzymes and pathological changes in the liver and adrenals were dose related and similar to those seen in the other two 90-day studies. In addition, this study reported weight increases in the kidney, brain and testes and some hyperplasia of the interstitial gland cells in the ovaries in the females receiving the 0.8 per cent test material (high dose). A NOAEL was not identified in this study and it was thus reported to be less than 0.2 per cent 2-ethylhexyl diphenyl phosphate in the diet.

An early (1953) 24-month study in which groups of 20 male and 20 female rats were provided with diets containing 0. 0.625, 0.125, 1.0 and 5.0 per cent 2-ethylhexyl diphenyl phosphate was poorly reported although the NOAEL was reported to be 0.125 per cent 2-ethylhexyl diphenyl phosphate in the diet. This is equivalent to 75 mg/kg bodyweight (using the 600 conversion factor of percentage in diet to mg/kg) but as no biochemical or pathological parameters appear to have been reported in this study, this NOAEL is considered unreliable.

In a study by Johannsen *et al*. (1977) on adult hens (strain unspecified) given a total dose of 120 g/kg over a 21-day period, no treatment-related effects were reported in any of the hens treated with 2-ethylhexyl diphenyl phosphate. Although it appears that

no positive control was included in the study design, evidence of neurotoxicity was reported in this paper for a number of other aryl phosphates tested suggesting that the test method was capable of detecting neurotoxic agents; in addition, the hen is a well-established model for the detection of delayed neuropathy. Given these results and that no indications of neuropathy were reported in any of the repeat-dose rodent studies, it is likely that any neurotoxic potential of 2-ethylhexyl diphenyl phosphate is very low.

4.4.7 Mutagenicity

Studies in vitro

Genetic mutations

Two *in vitro* studies reported in the IUCLID investigate the potential of 2-ethylhexyl diphenyl phosphate to induce gene mutations, and two others are reported in the USEPA HPV test plan. It is probable but not certain that the “Ames” test reported in the IUCLID is, at least in part, the same experiment as reported in the USEPA HPV but this cannot be confirmed due to the very limited reporting in these secondary sources.

In an Ames test using *Salmonella typhimurium*, cells were exposed to an unspecified test material at an unstated concentration, in the presence or absence of metabolic activation (Monsanto 1978a). The result was reported to be negative, though methods and results are not given in detail. The study was not conducted to GLP, and no details are presented as to any replicate design or the inclusion of any positive controls.

In the USEPA HPV test plan, a microbiological cell mutation assay is described (Litton Bionetics, Inc. 1978a) in which S. *typhimurium* tester strains TA-1535, TA-1537, TA-1538, TA-98, TA-100 and *Saccharomyces cerivisiae* were tested using five concentrations (not specified) of 2-ethylhexyl diphenyl phosphate in the form of a commercial product (Santicizer 141). A solvent and six positive control compounds (unspecified) were included in this plate incorporation assay. The study was performed with and without metabolic activation (Arachlor-induced rat liver microsomes S-9). The results were all negative and although not GLP, the study conduct and quality was reported to use data quality review, SOPS and maintained study records. The year of the study (1978) is the same as that above and the general study outline appears very similar to that reported in the IUCLID.

In a mouse lymphoma assay, using tester strain L5178Y TK, the test compound (unspecified) was administered, with and without metabolic activation, at concentrations of 0.063 to 0.5 µl/ml. The study was not GLP compliant, and the results were reported to be negative (Monsanto 1978b).

In a Fischer mouse lymphoma assay using the L5178Y cell line described in the USEPA HPV test plan report, a commercial 2-ethylhexyl diphenyl phosphate (Santicizer 141) was tested at five concentrations (not specified), together with the solvent (DMSO) and positive controls (EMS and DMN), in duplicate cultures (Litton Bionetics, Inc., 1978b). The study was conducted with and without metabolic activation (Arachlor-induced rat liver microsomes S-9), using the plate incorporation assay. The results were all negative and although not GLP, the study conduct and quality was reported to use data quality review, SOPS and maintained study records. Again, it is possible that this is the same mouse lymphoma assay that was partially reported in the IUCLID (2000a).

Chromosomal effects

No *in vitro* studies into clastogenicity were reported.

Studies in vivo

An *in vivo* cytogenetic study (an *in vivo* bone marrow chromosome in rats) is described in both IUCLID 2000a (as Monsanto 1983) and the USEPA HPV test plan report (Hazleton Laboratories America 1983), and the following description is based on information extracted from both these secondary sources.

A single dose of a commercial 2-ethylhexyl diphenyl phosphate (Santicizer 141) in corn oil was given by oral gavage to four groups of 24 male and 24 female Sprague-Dawley rats, approximately 50 days old, at doses of 1,500, 5,000 and 15,000 mg/kg. Similar-sized groups received corn oil (vehicle control) or cyclophosphamide (positive control). Six males and six females from each group were sacrificed at 6, 12, 24 and 48 hours post-dosing. Observations were made of survival, general appearance, toxic and pharmacologic effects. The study endpoint was structural and numerical aberrations in bone marrow chromosomes, and this was achieved by examination of metaphase spreads. It is reported that test animals lost weight in a dose-related manner following dosing and that four mid-dose animals died during the study. There were no statistically-significant differences in chromosome structural defects or number between treated and control animals. Since there was no evidence of mitotic delay after analysis of the mitotic index, the slides from the 48-hour time point were not analysed. The study was GLP compliant, and conforms to EPA/TSCA guidelines.

Summary of mutagenicity

Tests for gene mutation in *S. typhimurium*, and mammalian and yeast cells did not reveal any evidence of mutagenicity. The robustness of these studies could not, be verified due to the poor level of reporting in the IUCLID (2000a); however, further information is reported in the USEPA HPV test plan report.

Assuming the studies reported in the different secondary sources represent the same experiments, 2-ethylhexyl diphenyl phosphate can be considered not to be mutagenic in the presence or absence of metabolic activation, under the test conditions.

The *in vivo* bone marrow chromosome study in rats seems to be well conducted and reported and provides reliable evidence for a negative finding under the test conditions.

4.4.8 Carcinogenicity

There are no data available on the carcinogenicity of 2-ethylhexyl diphenyl phosphate. However, the negative *in vitro* and *in vivo* studies reported in Section 4.4.7 indicating a low genotoxic potential and the absence of proliferative lesions in the repeat-dose toxicity studies suggest that any potential for carcinogenicity would be also be low.

4.4.9 Toxicity to reproduction

Fertility and reproductive performance

A GLP-compliant one-generation reproduction in rats (BIBRA 1992) is reported in both IUCLID (2000a) and the USEPA HPV test plan USEPA (2004). The following description draws from both secondary sources.

Groups of 16 male and 32 female Sprague-Dawley rats, approximately 7 to 8 weeks old, received diets containing 0.2, 0.4 or 0.8 per cent of one commercial 2-ethylhexyl diphenyl phosphate (Santicizer 141) according to the USEPA HPV test plan but a 1:1 mixture of two commercial products according to the IUCLID (2000a). This latter report notes that the concentrations of the main impurities in both products were 3.8 and 2.1 per cent triphenyl phosphate and 3.5 and 5.2 per cent bis-2-ethylhexyl phenyl phthalate, which raises issues on the accuracy of reporting of the study. Male rats were treated for 70 days prior to mating and female rats 21 days prior to mating. Observations were made on survival, general appearance, behaviour, toxic and pharmacologic effects, body weight, food and water consumption, gross necropsy, and organ weights (eight organs). Histopathological analysis (ten tissues plus lesions) was undertaken in high-dose and control animals. Pregnancy rate, gestational parameters, litter parameters, pup sex, survival and weight gain were recorded. In the study results reported, it was noted that a male and a female rat did not survive the study but the deaths were not considered treatment-related. No adverse clinical or behavioural effects were noted in test animals but there was a reduction in body weight gain in the high-dose group and in males in the mid-dose group. Food and water consumption was reduced in the high-dose females. Mating indices and reproductive performance were unaffected by treatment. F1 pup body weight gain was reduced in the mid- and high-dose groups; 21-day survival was reduced in the high-dose pup group. A dose-related increase in relative and absolute liver and adrenal weight was seen in each sex of the parental and F1 generation. Where liver and adrenal pathology was seen, it was described as centrilobular necrosis and vacuolation of cortex cells respectively. The reproductive parental and F1 NOAEL was determined to be 0.2 per cent 2-ethylhexyl diphenyl phosphate in the diet: this is equivalent to approximately 144 mg/kg/day.

Developmental toxicity

Two developmental studies conducted to EPA TSCA guidelines and GLP are described in IUCLID (2000a).

In the first (Monsanto 1979), groups of five mated female rats (Sprague-Dawley according to IUCLID (2000a), but COBS CD according to Robinson *et al.* (1986)) received daily doses of 2-ethylhexyl diphenyl phosphate (Santicizer 141) by oral gavage at doses of 250, 500, 1,000 and 5,000 mg/kg bw/day from day 6 to 15 of gestation. Necropsy and uterine examinations were performed on day 20 of gestation. No foetal examinations were conducted. There were reductions in body weight at all dose levels and the maternal NOAEL was determined to be less than 250 mg/kg bw. No further details were reported in the IUCLID (2000a) but further information on this study is reported in Robinson *et al*. (1986). It appears that this investigation was a preliminary range-finding study to select doses for a fuller teratogenicity study described in Monsanto (1980, cited in IUCLID 2000a) and Robinson *et al*. (1986) (see below). The authors report that rats given 2-ethylhexyl diphenyl phosphate had slight reductions in body weight gains at 1,000 mg/kg/day, moderate reductions at 2,500 mg/kg/day and severe reductions at 5,000 mg/kg/day. All rats survived until scheduled sacrifice and post-implantation loss was increased in the 5,000 mg/kg/day group.

In the second study (Monsanto 1980, cited in IUCLID (2000a) and Robinson *et al*. (1986)), groups of five mated female Sprague-Dawley rats received daily doses of Santicizer 141 (93 per cent 2-ethylhexyl diphenyl phosphate, with 3.1 per cent triphenyl phosphate, and 3.0 per cent di(2-ethylhexyl)phenyl phosphate) at doses of 300, 1,000 and 3,000 mg/kg bw/day from day 6 to 15 of gestation. At 3,000 mg/kg/day, maternal toxicity was anticipated based on the preliminary study, and this was indeed the case. Maternal toxicity was also elicited to a lesser extent in the 1,000 mg/kg/day group. The total number of foetuses and litters with malformations was increased in the groups receiving 1,000 or 3,000 mg/kg/day 2-ethylhexyl diphenyl phosphate. Skeletal variations which were increased in the treated groups included rib changes and reduced ossification. The authors propose that these variations could relate to the maternal toxicity clearly evident at 3,000 mg/kg, and also noted that the values were well within historical control ranges and that concurrent control values were generally somewhat lower than the historical means. Importantly, neither the malformations nor variations achieved statistical significance and the authors concluded that the malformations and variations found in groups treated with 2-ethylhexyl diphenyl phosphate (Santicizer 141) were not treatment-related because most occurred only once, lacked any dose-response pattern and occurred at incidences that generally fell within the historical control range for this strain of rat at their laboratory. The maternal NOAEL cited in the IUCLID is 1,000 mg/kg/day, and the NOAEL for teratogenicity (developmental effects) was considered to be greater than 3,000 mg/kg/day.

Summary of toxicity to reproduction

One study on fertility and reproductive performance and two studies that address developmental effects are available for evaluation of effects on reproduction. On the basis of the available information, it would seem that, in a reliable fertility study, the parental and F1 NOAEL was estimated to be 144 mg/kg/day of 2-ethylhexyl diphenyl phosphate. In the developmental studies, no clearly treatment-related developmental effects were seen at doses of up to 3,000 mg/kg bw/day of 2-ethylhexyl diphenyl phosphate. The NOAEL was thus considered to be greater than 3,000 mg/kg bw/day.

4.4.10 NOAEL and Margins of Safety (MOS) for assessment of human exposure via the environment

There are no studies available on carcinogenicity but the available negative information on *in vitro* and *in vivo* mutagenicity and chromosome effects does not suggest that 2-ethylhexyl diphenyl phosphate is likely to possess a carcinogenic potential to exposed humans. The studies available on fertility and reproductive performance and the information on potential teratogenicity suggest that there were no adverse developmental effects at up to 3,000 mg/kg bw/day. Although somewhat limited, the studies do not suggest that 2-ethylhexyl diphenyl phosphate has neurotoxic potential.

A number of 90-day repeat dose studies in the rat were suitable for consideration in this assessment. The effects seen in these studies were generally consistent and of these, that which was able to demonstrate a clear NOAEL was considered to be the most informative and reliable. In this study (Monsanto report 1992b, cited in IUCLID 2000a), a NOAEL for liver enzyme perturbations of 6 mg/kg bodyweight was identified. The substance is of low systemic toxicity and there do not appear to be any other special toxicological concerns.

A margin of safety of at least 200-fold is considered to be sufficient to protect against effects on humans through the environment. This is made up of uncertainty factors for

interspecies variation (10), intraspecies variation (10) and extrapolation from sub-chronic to chronic (2).

A number of possible areas for clarification in the mammalian toxicity data base are listed in Appendix 1.

4.4.11 PNEC for secondary poisoning

A NOAEL of 6 mg/kg bw/day has been established for liver enzyme changes based on a 90-day dietary exposure study in rats (NOEC = 0.1 per cent diet, 100 mg/kg).

The TGD recommends an assessment factor of 90 for extrapolation of a 90-day mammalian toxicity test.

Based on this value, a $PNEC_{oral}$ of 100/90 = 1.1 mg/kg can be calculated.

No avian toxicology data appropriate for calculation of a $PNEC_{oral}$ were identified for 2-ethylhexyl diphenyl phosphate.

4.5 Hazard classification

4.5.1 Classification for human health

2-Ethylhexyl diphenyl phosphate is not currently classified with respect to human health on Annex 1 of Directive 67/548/EEC. The following provisional labelling is applied by manufacturers for human health effects:

Xi: R36/38 Irritating to eyes and skin.

According to the criteria of the European Union (EU), 2-ethylhexyl diphenyl phosphate does not need to be classified on the basis of its acute toxicity, skin or eye irritancy or sensitizing ability nor its potential corrosivity to the skin or eye.

The inhalation LD_{50} in rats is reported as greater than 4.8 mg/l and as this LD_{50} is between 2 and 20 mg/l, there may be a need – on the basis of the limited information currently available - to adopt a classification of ‘R20: Harmful by inhalation’. The substance does not need to be classified for effects on fertility, reproductive performance and developmental toxicity. There are no data to address effects via or during lactation.

2-Ethylhexyl diphenyl phosphate does not need to be classified as a mutagen and, although there are no carcinogenicity studies available for evaluation, in the light of the negative mutagenicity results, there seems no reason to consider a carcinogenicity classification.

4.5.2 Classification for the environment

2-Ethylhexyl diphenyl phosphate is not currently classified as dangerous for the environment.

Given that the water solubility of the test substance is reported to be 0.051 to 1.9 mg/l, the acute toxicity results are difficult to interpret in terms of whether the substance is acutely toxic at concentrations below its solubility limit. However, based on a BCF

around 934 l/kg and an acute EC_{50} for *Daphnia magna* of 0.15 mg/l, the following classification would appear to be appropriate:

N: Dangerous for the environment.

R50/53: Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.

4.6 PBT assessment

The criteria for persistence (P and vP), bioaccumulation potential (B and vB) and toxicity (T) included in the TGD are shown in Table 4.6.

Table 4.6 Criteria for identification of PBT and vPvB substances

Criterion	PBT criteria	vPvB criteria
P	Half-life above 60 days in marine water or above 40 days in freshwater* or half-life above180 days in marine sediment or above 120 days in freshwater sediment*	Half-life above 60 days in marine water or freshwater or above 180 days in marine or freshwater sediment
B	BCF above 2,000	BCF above 5,000
T	Chronic NOEC below 0.01 mg/l or classification for certain human health end points, or endocrine disrupting effects	Not applicable

Notes: * For the purpose of marine environment risk assessment, half-life data in freshwater and freshwater sediment can be overruled by data obtained under marine conditions.

Persistence: 2-ethylhexyl diphenyl phosphate is readily biodegradable (Section 3.1.1). Hence the substance does not meet the P criterion.

Bioconcentration: a value of 934 is selected from the available data in Section 0. Hence the substance does not meet the B criterion.

Toxicity: the lowest NOEC value from the available tests is 0.018 mg/l. The substance does not meet the T criterion.

The overall conclusion is that the substance does not meet any of the PBT criteria.

5 Risk characterisation

This section identifies the potential risks that 2-ethylhexyl diphenyl phosphate might pose for the freshwater and marine aquatic compartments, terrestrial compartment, air compartment and predatory organisms through secondary poisoning. The risk characterisation is performed by comparing the PECs with the PNECs to derive a risk characterisation ratio (RCR). An RCR of less than one implies that any risk resulting from that level of exposure is acceptable. An RCR above one implies a potential risk, and all such values are highlighted in bold in the following tables. Annex C considers the effect of a faster hydrolysis rate on the overall conclusions.

As discussed in Section 3.1.2, the adsorption potential of the substance (represented by the K_{oc}) is estimated, and this has a significant influence on its predicted partitioning behaviour in the environment. There is some evidence for triphenyl phosphate (see the risk evaluation report of that substance in this series) that the prediction method might underestimate the K_{oc} for this type of substance. A sensitivity analysis has been performed in Annex D, and this shows that a higher K_{oc} value would affect the conclusions, but not necessarily in a straightforward (or especially significant) way. Further testing for sediment sorption coefficient is suggested for triphenyl phosphate, and this could indicate a need for further studies with this substance.

5.1 Aquatic compartment

5.1.1 Surface water

The PNEC for surface water was estimated as 1.8 μg/l. The resulting PEC/PNEC ratios are summarised in Table 5.1.

Table 5.1 Summary of risk characterisation ratios for surface water

Scenario		PEC (μg/l)	Risk characterisation ratio
Production of 2-ethylhexyl diphenyl phosphate		0.19	0.11
PVC – 1	Compounding	1.76	0.98
	Conversion	19.6	**10.9**
	Combined compounding and conversion	21.2	**11.8**
PVC – 2	Compounding	1.76	0.98
	Conversion	5.87	**3.26**
	Combined compounding and conversion	7.46	**4.15**
PVC – 3	Compounding	1.35	0.75
	Conversion	4.38	**2.44**
	Combined compounding and conversion	5.56	**3.09**
PVC – 4	Compounding	0.99	0.55
	Conversion	0.76	0.42
	Combined compounding and conversion	1.58	0.88

Table 5.1 continued.

Scenario		PEC (μg/l)	Risk characterisation ratio
PVC – 5	Compounding	0.99	0.55
	Conversion	0.76	0.42
	Combined compounding and conversion	1.58	0.88
PVC – 6	Compounding	0.99	0.55
	Conversion	3.1	**1.72**
	Combined compounding and conversion	3.92	**2.18**
PVC – 7	Compounding	0.99	0.55
	Conversion	3.1	**1.72**
	Combined compounding and conversion	3.92	**2.18**
Photographic film	Compounding	1.81	**1.01**
	Conversion	1.34	0.75
	Combined compounding and conversion	2.98	**1.66**
Rubber	Compounding	1.81	**1.01**
	Conversion	1.34	0.75
	Combined compounding and conversion	2.98	**1.66**
Polyurethane	Compounding	1.81	**1.01**
	Conversion	1.34	0.75
	Combined compounding and conversion	2.98	**1.66**
Textiles/fabric coating	Compounding	0.64	0.36
	Conversion	6.02	**3.35**
	Combined compounding and conversion	6.49	**3.61**
Pigment dispersions	Production of dispersions	1.81	**1.01**
Paints	Formulation	15.1	**8.41**
	Application	0.25	0.14
Adhesives		negligible	negligible
Regional sources		0.17	0.10

The PEC/PNEC ratios are greater than one for the use of 2-ethylhexyl diphenyl phosphate in some PVC applications, polyurethane, photographic film, textiles/fabric coating and rubber. Risks are identified for the formulation of paint and the production of pigment dispersions. Further information is needed on process emissions to refine the PECs for these scenarios. Information from three users of the substance in different use areas indicates the possibility of release to waste water, but with no information on the possible levels. Many of the ratios are not very far above one, and so revision of the exposure assessment may remove the concern.

The sensitivity analysis in Annex C suggests that a faster hydrolysis rate than assumed in this assessment would only have a small impact on surface water concentrations.

The PNEC is derived using an assessment factor of 10 and is not likely to be revised through further testing.

The risk from production and regional sources appears to be low.

5.1.2 Waste water treatment

The PNEC for waste water treatment processes is estimated at above 100 mg/l. The PEC/PNEC ratios were calculated and found to be less than 0.01 for all uses of 2-ethylhexyl diphenyl phosphate.

Based on the risk characterisation ratios, the risk to waste water treatment plants from production and use of 2-ethylhexyl diphenyl phosphate is low. The PEC/PNEC ratios are not shown here.

5.1.3 Sediment

The PNEC for sediment was estimated as 0.373 mg/kg wet weight. The resulting PEC/PNEC ratios, increased by a factor of 10 to take into account the possibility of direct ingestion of sediment-bound substance, are summarised in Table 5.2.

Table 5.2 Summary of risk characterisation ratios for sediment

Scenario		PEC (mg/kg wet wt.)	Risk characterisation ratio
Production of 2-ethylhexyl diphenyl phosphate		0.04	**1.06**
PVC – 1	Compounding	0.37	**9.79**
	Conversion	4.07	**109**
	Combined compounding and conversion	4.4	**118**
PVC – 2	Compounding	0.37	**9.79**
	Conversion	1.22	**32.6**
	Combined compounding and conversion	1.55	**41.5**
PVC – 3	Compounding	0.28	**7.51**
	Conversion	0.91	**24.4**
	Combined compounding and conversion	1.15	**30.9**
PVC – 4	Compounding	0.21	**5.5**
	Conversion	0.16	**4.2**
	Combined compounding and conversion	0.33	**8.75**
PVC – 5	Compounding	0.21	**5.5**
	Conversion	0.16	**4.2**
	Combined compounding and conversion	0.33	**8.75**
PVC – 6	Compounding	0.21	**5.5**
	Conversion	0.64	**17.2**
	Combined compounding and conversion	0.81	**21.8**
PVC – 7	Compounding	0.21	**5.5**
	Conversion	0.64	**17.2**
	Combined compounding and conversion	0.81	**21.8**
Photographic film	Compounding	0.38	**10.1**
	Conversion	0.28	**7.45**
	Combined compounding and conversion	0.62	**16.6**

Table 5.2 continued.

Scenario		PEC (mg/kg wet wt.)	Risk characterisation ratio
Rubber	Compounding	0.38	**10.1**
	Conversion	0.28	**7.45**
	Combined compounding and conversion	0.62	**16.6**
Polyurethane	Compounding	0.38	**10.1**
	Conversion	0.28	**7.45**
	Combined compounding and conversion	0.62	**16.6**
Textiles/fabric coating	Compounding	0.13	**3.55**
	Conversion	1.25	**33.5**
	Combined compounding and conversion	1.35	**36.1**
Pigment dispersions	Production of dispersions	0.38	**10.1**
Paints	Formulation	3.14	**84.1**
	Application	0.05	**1.37**
Adhesives		negligible	negligible
Regional sources		0.04	0.99

The ratios are greater than one for all scenarios considered with the exception of the regional scenario. The further information noted for the surface water compartment would also refine the sediment assessment. However, the extra factor of 10 used for sediment means that the emission estimates would have to be reduced significantly to remove all of the concerns. The majority of the scenarios would still show a risk without the extra factor of 10.

The sensitivity analysis in Annex C suggests that a faster hydrolysis rate than assumed in this assessment could have an effect on the local and regional sediment PECs. It may therefore be possible to refine the PECs by carrying out further testing[7] to investigate the actual degradation (mineralization) half-life in sediment under relevant environmental conditions.

The PNEC for sediment is based on the equilibrium partitioning approach. As noted above, the PNEC on which this is based is not likely to be revised. Toxicity data for sediment organisms would allow a PNEC to be derived directly, and remove the need for the additional factor. It is likely that three long-term tests on sediment organisms would be required.

5.2 Terrestrial compartment

The PNEC for soil is estimated as 0.302 mg/kg wet weight. The resulting risk characterisation ratios, increased by a factor of 10 to take into account the possibility of direct ingestion of soil-bound substance, are summarised in Table 5.3.

The PEC/PNEC ratios are greater than one for all local scenarios except for production sites, adhesives and paint application. The further information on exposures identified for the aquatic compartment would also have an influence on the risk ratios here.

Table 5.3 Summary of risk characterisation ratios for the terrestrial compartment

Scenario		PEC (mg/kg wet wt.)	Risk characterisation ratio
Production of 2-ethylhexyl diphenyl phosphate		negligible[a]	negligible
PVC – 1	Compounding	0.23	**7.65**
	Conversion	2.83	**93.6**
	Combined compounding and conversion	3.06	**101**
PVC – 2	Compounding	0.23	**7.66**
	Conversion	0.83	**27.4**
	Combined compounding and conversion	1.06	**35.1**
PVC – 3	Compounding	0.17	**5.68**
	Conversion	0.61	**20.3**
	Combined compounding and conversion	0.78	**25.9**
PVC – 4	Compounding	0.12	**3.95**
	Conversion	0.09	**2.82**
	Combined compounding and conversion	0.20	**6.76**
PVC – 5	Compounding	0.12	**3.94**
	Conversion	0.09	**2.82**
	Combined compounding and conversion	0.20	**6.76**
PVC – 6	Compounding	0.12	**3.94**
	Conversion	0.43	**14.1**
	Combined compounding and conversion	0.54	**18**
PVC – 7	Compounding	0.12	**3.94**
	Conversion	0.42	**14.1**
	Combined compounding and conversion	0.54	**18**
Photographic film	Compounding	0.24	**7.88**
	Conversion	0.17	**5.64**
	Combined compounding and conversion	0.41	**13.5**
Rubber	Compounding	0.24	**7.88**
	Conversion	0.17	**5.63**
	Combined compounding and conversion	0.41	**13.5**
Polyurethane	Compounding	0.24	**7.87**
	Conversion	0.17	**5.64**
	Combined compounding and conversion	0.41	**13.5**
Textiles/fabric coating	Compounding	0.07	**2.26**
	Conversion	0.85	**28.1**
	Combined compounding and conversion	0.92	**30.4**

[7] The half-life determined in such a test would be the result of degradation by both biodegradation and hydrolysis to biodegradable substances.

Table 5.3 continued.

Scenario		PEC (mg/kg wet wt.)	Risk characterisation ratio
Pigment dispersion	Production of dispersions	0.24	**7.88**
Paints	Formulation	2.17	**71.9**
	Application	0.01	0.37
Adhesives		negligible	negligible
Regional sources	Agricultural soil	3.04×10^{-4}	0.01
	Industrial soil	0.02	0.66
	Natural soil	2.88×10^{-4}	<0.01

Notes: a) Sewage sludge from the production sites is not applied to land.

However, the extra factor of 10 used for soil means that the emission estimates would have to be reduced greatly to remove all of the concerns. Many of the scenarios would still give a risk without the extra factor of ten.

Like sediment, the sensitivity analysis in Annex C suggests that a faster hydrolysis rate than assumed in this assessment could have an effect on the local and regional soil PECs. It may therefore be possible to refine the PECs by carrying out further testing to investigate the actual degradation (mineralization) half-life in soil under relevant environmental conditions.

The PNEC for soil is based on the equilibrium partitioning approach. As noted above, the aquatic PNEC on which this is based is not likely to be revised. Toxicity data for terrestrial organisms would allow a PNEC to be derived directly, and remove the need for the additional factor. As for sediment, it is likely that three long-term tests would be required.

The risk to soil from production sites and at the regional level appears to be low.

5.3 Atmosphere

No information is available on the toxicity of 2-ethylhexyl diphenyl phosphate to plants and other organisms exposed via air. The very low vapour pressure of the substance means that volatilisation to the atmosphere is likely to be limited and the resulting concentrations are likely to be very low (the predicted concentrations are all $<6\times10^{-4}$ mg/m^3). This means that the possibility of 2-ethylhexyl diphenyl phosphate contributing to atmospheric effects such as global warming and acid rain is likely to be very small. In addition, as the substance does not contain halogen atoms, it will not contribute to ozone depletion.

5.4 Secondary poisoning

A PNEC for secondary poisoning of 1.1 mg/kg food was derived for 2-ethylhexyl diphenyl phosphate. The resulting risk characterisation ratios are shown in Table 5.4.

Table 5.4 Summary of risk characterisation ratios for secondary poisoning

Scenario		Fish food chain		Earthworm food chain	
		PEC (mg/kg)	Risk characterisation ratio	PEC (mg/kg)	Risk characterisation ratio
Production of 2-ethylhexyl diphenyl phosphate		0.17	0.15	0.01[a]	<0.01
PVC – 1	Compounding	0.77	0.69	3.38	**3.05**
	Conversion	7.63	**6.87**	41.4	**37.2**
	Combined compounding and conversion	8.24	**7.42**	44.7	**40.3**
PVC – 2	Compounding	0.77	0.69	3.39	**3.05**
	Conversion	2.35	**2.11**	12.1	**10.9**
	Combined compounding and conversion	2.96	**2.66**	15.5	**13.9**
PVC – 3	Compounding	0.61	0.55	2.51	**2.26**
	Conversion	1.78	**1.6**	8.96	**8.06**
	Combined compounding and conversion	2.23	**2.01**	11.5	**10.3**
PVC – 4	Compounding	0.48	0.43	1.75	**1.57**
	Conversion	0.39	0.35	1.25	**1.13**
	Combined compounding and conversion	0.70	0.63	2.99	**2.69**
PVC – 5	Compounding	0.16	0.15	1.75	**1.57**
	Conversion	0.43	0.39	1.25	**1.13**
	Combined compounding and conversion	0.70	0.63	2.99	**2.69**
PVC – 6	Compounding	0.31	0.28	1.75	**1.57**
	Conversion	0.69	0.62	6.23	**5.61**
	Combined compounding and conversion	0.83	0.75	7.96	**7.16**
PVC – 7	Compounding	0.27	0.24	1.75	**1.57**
	Conversion	0.55	0.50	6.22	**5.6**
	Combined compounding and conversion	0.66	0.59	7.95	**7.16**
Photo-graphic film	Compounding	0.79	0.71	3.49	**3.14**
	Conversion	0.71	0.64	2.5	**2.25**
	Combined compounding and conversion	1.24	**1.11**	5.97	**5.38**
Rubber	Compounding	0.79	0.71	3.49	**3.14**
	Conversion	0.61	0.55	2.5	**2.25**
	Combined compounding and conversion	1.24	**1.11**	5.97	**5.38**

Table 5.4 continued.

Scenario		Fish food chain		Earthworm food chain	
		PEC (mg/kg)	Risk characterisation ratio	PEC (mg/kg)	Risk characterisation ratio
Poly-urethane	Compounding	0.16	0.15	3.48	**3.14**
	Conversion	0.71	0.64	2.5	**2.25**
	Combined compounding and conversion	1.24	**1.11**	5.97	**5.38**
Textiles/ fabric coating	Compounding	0.16	0.15	1.0	0.90
	Conversion	0.17	0.15	12.4	**11.2**
	Combined compounding and conversion	2.59	**2.33**	13.4	**12.1**
Pigment dispersion	Production of dispersion	0.79	0.71	3.49	**3.14**
Paints	Formulation	5.91	**5.32**	31.8	**28.6**
	Application	0.16	0.15	0.17	0.15
Adhesives		neg.	neg.	neg.	neg.

Notes: a) Sewage sludge from the production sites is not applied to land.

The PEC/PNEC ratios are above one for the fish food chain for the use of 2-ethylhexyl diphenyl phosphate in some PVC applications, rubber, photographic film, polyurethane, textiles and the formulation of paints. PEC/PNEC ratios are above one for the earthworm food chain for all uses apart from the compounding step for textiles/fabric coating and the application of paints. The further information on exposures identified for the aquatic compartment would also have an influence on the risk ratios here. Some of the ratios are above ten, and so the emission estimates would need to be significantly lower to remove the risks.

The PNEC is based on unspecified perturbations of liver enzymes (although there are indications of other liver changes). The consequence of such effects at the population level is unknown, and so a more detailed assessment of the toxicity profile could be performed to assess the implications if other endpoints were considered. In addition, the estimated earthworm BCF value is of uncertain validity, so this could be refined with a test if necessary.

5.5 Risks to human health following environmental exposure

A NOAEL of 6 mg/kg bw/day in rats was identified in Section 4.4.10 as the most appropriate value for use in this assessment. A margin of safety of 200 is considered necessary to provide sufficient reassurance against effects on human health with this result. The estimated human exposures via the environment were calculated in Section 3.3.4 and are included in Table 5.5 together with the resulting margins of exposure.

Table 5.5 Margin of exposure between daily human doses and the NOAEL (6 mg/kg bw/day)

Scenario		Total daily human intake (mg/kg bw/day)	Margin of exposure
Production of 2-ethylhexyl diphenyl phosphate		0.01 3.4×10^{-4}	600 17,650
PVC – 1	Compounding Conversion Combined compounding and conversion	0.03 0.35 0.38	200 **17** **16**
PVC – 2	Compounding Conversion Combined compounding and conversion	0.03 0.10 0.13	300 **60** **46**
PVC – 3	Compounding Conversion Combined compounding and conversion	0.02 0.08 0.10	300 **75** **60**
PVC – 4	Compounding Conversion Combined compounding and conversion	0.01 0.01 0.03	600 600 200
PVC – 5	Compounding Conversion Combined compounding and conversion	0.01 0.01 0.03	600 600 200
PVC – 6	Compounding Conversion Combined compounding and conversion	0.01 0.05 0.06	600 **120** **100**
PVC – 7	Compounding Conversion Combined compounding and conversion	0.01 0.05 0.06	600 **120** **100**
Photographic film	Compounding Conversion Combined compounding and conversion	0.03 0.02 0.05	200 300 **120**
Rubber	Compounding Conversion Combined compounding and conversion	0.03 0.02 0.05	200 300 **120**
Polyurethane	Compounding Conversion Combined compounding and conversion	0.03 0.02 0.05	200 300 **120**
Textiles/fabric coating	Compounding Conversion Combined compounding and conversion	7.8×10^{-3} 0.09 0.11	770 **67** **55**
Pigment dispersion	Production of dispersions	0.03	200

Table 5.5 continued.

Scenario		Total daily human intake (mg/kg bw/day)	Margin of exposure
Paints	Formulation	0.26	**23**
	Application	1.5×10^{-3}	4,000
Adhesives		negligible	not relevant
Regional sources		3.2×10^{-4}	18,750

Possible risks are indicated for: five of the PVC scenarios, relating to the conversion step (either alone or with compounding); photographic film, rubber and polyurethane (for combined compounding and conversion); textiles and fabric coating (conversion and conversion with compounding) and for paint formulation.

The assessment could be refined by improving the estimates for total daily human dose. This could involve:

- better release information and/or monitoring data at locations close to sources of release;
- measurements of the uptake of 2-ethylhexyl diphenyl phosphate in plants to replace the current estimated values. The root crop contribution to the total dose is greater than 70 per cent in all of the scenarios showing a risk.

In addition, a more in-depth consideration of the effects of concern could be performed.

5.6 Marine risk assessment

Although a PEC/PNEC approach can be applied to the marine environment, there are additional concerns which may not be adequately addressed using the above methods. Chief among these is the possibility of hazardous substances accumulating in parts of the marine environment. The effects of such accumulation are unpredictable in the long term, and once such accumulation has occurred it may be difficult to reverse. The properties which lead to substances behaving in this way also lead to greater uncertainty in estimating exposures and/or effect concentrations, and so make a quantitative risk assessment more difficult. In order to identify substances which are likely to behave in this way, criteria have been developed relating to the persistence, accumulation and toxicity of the substance. The first part of the marine assessment is therefore a comparison of the properties of the substance with these criteria. This is presented in Section 4.6.

PEC values for the marine assessment are presented in Sections 3.3.1 and 3.3.4. These were calculated using EUSES. PNECs for marine aquatic species are included in Section 4.1.6. The PNEC for secondary poisoning for the marine environment is the same as that for the freshwater fish and terrestrial food chains (Section 4.4.11). The resulting PEC/PNEC ratios are in Table 5.6.

Table 5.6 Summary of risk characterisation ratios for the marine compartment

Scenario		PEC/PNEC ratio			
		Local marine compartment	**Local marine sediment compartment**	**Fish-eating birds and mammals**	**Top predators**
Production of 2-ethylhexyl diphenyl phosphate[a]		**156**	**1,560**	**5.98**	**1.21**
PVC – 1	Compounding	**4.74**	**47.4**	0.3	0.07
	Conversion	**57.1**	**571**	**3.56**	0.72
	Combined compounding and conversion	**61.7**	**617**	**3.84**	0.78
PVC – 2	Compounding	**4.74**	**47.4**	0.3	0.07
	Conversion	**16.8**	**168**	**1.05**	0.22
	Combined compounding and conversion	**21.4**	**214**	**1.34**	0.28
PVC – 3	Compounding	**3.54**	**35.4**	0.23	0.06
	Conversion	**12.4**	**124**	0.78	0.17
	Combined compounding and conversion	**15.9**	**159**	0.99	0.21
PVC – 4	Compounding	**2.48**	**24.8**	0.16	0.04
	Conversion	**1.8**	**18**	0.12	0.03
	Combined compounding and conversion	**4.19**	**41.9**	0.27	0.06
PVC – 5	Compounding	**2.48**	**24.8**	0.01	0.01
	Conversion	**1.8**	**18**	0.14	0.04
	Combined compounding and conversion	**4.19**	**41.9**	0.27	0.06
PVC – 6	Compounding	**2.48**	**24.8**	0.08	0.03
	Conversion	**8.66**	**86.6**	0.26	0.06
	Combined compounding and conversion	**11**	**110**	0.33	0.08
PVC – 7	Compounding	**2.48**	**24.8**	0.06	0.02
	Conversion	**8.64**	**86.4**	0.2	0.05
	Combined compounding and conversion	**11**	**110**	0.25	0.06
Photo-graphic film	Compounding	**4.88**	**48.8**	0.31	0.07
	Conversion	**3.51**	**35.1**	0.27	0.06
	Combined compounding and conversion	**8.3**	**83**	0.52	0.12
Rubber	Compounding	**4.88**	**48.8**	0.31	0.07
	Conversion	**3.51**	**35.1**	0.23	0.06
	Combined compounding and conversion	**8.3**	**83**	0.52	0.12

Table 5.6 continued.

Scenario		PEC/PNEC ratio			
		Local marine compartment	**Local marine sediment compartment**	**Fish-eating birds and mammals**	**Top predators**
Poly-urethane	Compounding	**4.88**	**48.8**	0.01	0.01
	Conversion	**3.51**	**35.1**	0.27	0.06
	Combined compounding and conversion	**8.3**	**83**	0.52	0.12
Textiles/ fabric coating	Compounding	**1.45**	**14.5**	0.01	0.01
	Conversion	**17.2**	**172**	0.02	0.01
	Combined compounding and conversion	**18.6**	**186**	**1.16**	0.24
Pigment dispersion	Production of dispersions	**4.88**	**48.8**	0.31	0.07
Paints	Formulation	**43.9**	**439**	**2.74**	0.56
	Application	0.30	**3.04**	0.01	0.01
Adhesives		negligible	negligible	negligible	negligible

Notes: a) Calculation uses average dilution in receiving water. If minimum dilution at the site was used, the PEC/PNEC would be a factor of 1.88 times higher. Similarly if the maximum dilution at the site was used the PEC/PNEC would be 6.67 times lower.

Risks are indicated for all scenarios for marine waters and marine sediments, with the exception of adhesives and regional sources. Further information on emissions from these processes indicated for the freshwater environment would also help to refine these results. More specifically for the marine assessment, information on whether any of these processes can be considered not to discharge to the marine environment, or if they only do so after effluent treatment (the calculations above assume a direct discharge to the marine environment without waste water treatment) would be useful.

Further toxicity testing with freshwater organisms is not indicated for the freshwater assessment. However, testing on sediment organisms is suggested, and this would have implications for the marine sediment risks. There is also the possibility of testing on marine species, which would allow the assessment factor to be reduced.

The size of the PEC/PNEC ratios suggests that no one part of the further information requirements would be sufficient on its own to reduce the ratios to below one.

Risks are indicated for a small number of uses for effects through marine food chains on marine predators. Similar conclusions to those for the freshwater and terrestrial secondary poisoning assessments are applicable here. The ratios are generally lower than those for the freshwater food chain, and there may be more possibility of removing at least some of the risks through improved emission estimates alone.

6 Conclusions

2-Ethylhexyl diphenyl phosphate can enter the environment from its production and use, and from the use of articles made from materials containing it. Based on the available information, potential risks are identified for all of the life cycle steps for one or more of the protection goals. The overall conclusions are summarised in Table 6.1 in a simplified form. In particular, the different steps within the use of each material have been combined here, and risks are indicated for PVC provided at least one of the different uses shows a risk for the specific protection goal. Section 5 should be consulted for the detailed results.

Table 6.1 Summarised potential environmental risks identified for 2-ethylhexyl diphenyl phosphate

Life cycle stage	Surface water	Sediment	WWTP	Air	Soil	Aquatic food chain	Terrestrial food chain	Marine water	Marine sediment
Production	-	✸	-	-	-	-	-	✸	✸
PVC	✸[a]	✸[b]	-	-	✸[b]	✸[c]	✸[b]	✸	✸
Photographic film	✸	✸	-	-	✸	✸	✸	✸	✸
Rubber	✸	✸	-	-	✸	✸	✸	✸	✸
Polyurethane	✸	✸	-	-	✸	✸	✸	✸	✸
Textile/fabric coating	✸	✸	-	-	✸	✸	✸	✸	✸
Pigment dispersions	✸	✸	-	-	✸	-	✸	✸	✸
Paints	✸	✸	-	-	✸	✸	✸	✸	✸
Adhesives	-	-	-	-	-	-	-	-	-
Regional	-	-	-	-	-	-	-	-	-

Notes: a) Risks for five PVC uses.
b) Risks for all PVC uses.
c) Risks for three PVC uses.

There are also potential risks for humans exposed via the environment for the majority of the life cycle stages, and risks for marine food chain exposure for production, two PVC uses, textile coating and paint formulation.

There are very limited monitoring data available for 2-ethylhexyl diphenyl phosphate and these cannot be related to specific current activities.

The potential risks that have been identified could be reassessed following additional work, in particular:

- Collation of further site and industry-specific information on releases of 2-ethylhexyl diphenyl phosphate from use in the different types of materials indicated. This work could include:
    - Improved description of practices at sites using 2-ethylhexyl diphenyl phosphate, to determine the realism of the emission estimates, ideally through surveys of representative sites.
    - Targeted monitoring to confirm or replace the calculated PEC values (especially in water, sediments and WWTP sludge).
    - Information on the fate of sludges from sites using the substance.

    - Surveys to locate user sites, especially in relation to marine discharges.
- Long-term sediment and soil organism testing.
- Studies on the fate of the substance in WWTP (municipal and industrial).
- Studies on uptake of 2-ethylhexyl diphenyl phosphate into plants from soil.
- Further testing to investigate the actual degradation (mineralization) half-life in sediment and soil under relevant environmental conditions.
- Clarification of some aspects of the mammalian toxicity data (see Appendix 1).

The secondary poisoning PNEC is based on unspecified perturbations of liver enzymes (although there are indications of other liver changes). The consequence of such effects at the population level is unknown, and so a more detailed assessment of the toxicity profile could be performed to assess the implications if other endpoints were considered. The earthworm BCF value could also be refined with a test if necessary.

Possible risks to sediment organisms and marine organisms are identified for production. This conclusion could be refined through the testing indicated above, but it is more appropriate for the local control authority to consider this conclusion[8].

There may be opportunities to read across information and test results from this substance to the other aryl phosphates assessed in this group (and vice versa). Therefore the additional work indicated above should be considered in relation to that proposed for other members of the group. The overview document should be consulted for more information on this.

[8] More recent data for the UK site suggest that current emissions are lower than assumed for this report. In addition, a biological WWTP is being installed, which should have a significant effect on emissions when it becomes operational later in 2009. Further details are provided in the confidential appendix.

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8 Glossary of terms

Term	Description
Biochemical oxygen demand (BOD)	A measure of degradation potential.
Bioconcentration factor (BCF)	A measure of chemical uptake, being the ratio between the concentration in an organism and the concentration in an environmental compartment (usually water).
CAS number (no.)	An identifying code number assigned to chemicals by the Chemical Abstract Services. The CAS number is a generally recognised identification reference for a chemical; a substance can have more than one such number.
Inherently biodegradable	Some potential for environmental degradation to carbon dioxide and water, and so on, as measured by laboratory screening tests involving micro-organisms.
Lowest observed effect concentration (LOEC)	The lowest concentration in a toxicity test that gives rise to adverse effects (relative to a control).
Median effective concentration (EC_{50})	The concentration in a toxicity test at which a particular effect is observed in half of the organisms exposed for a specified time.
Median lethal loading (LL_{50})	The loading of substance in a water-accommodated fraction that leads to death in half of the organisms exposed for a specified time.
Median lethal concentration/dose (LC/D_{50})	The concentration in a toxicity test that can be expected to cause death in half of the organisms exposed for a specified time.
No observed effect concentration (NOEC)	The highest concentration in a toxicity test that does not give rise to adverse effects (relative to a control).
Octanol-water partition coefficient (K_{ow})	This parameter gives an indication of the partitioning behaviour of a substance between water and lipid-containing materials such as cell membranes or organic matter in soils and sediments.
Readily biodegradable	Rapid environmental degradation to carbon dioxide and water, and so on, as measured by laboratory screening tests involving micro-organisms.

9 Abbreviations

Acronym	Description
ASTM	American Society for Testing and Materials
B	Bioaccumulative
BCF	Bioconcentration factor
BMF	Biomagnification factor
BOD	Biochemical oxygen demand
bw	Bodyweight
CAS	Chemical Abstract Services
CMR	Carcinogenic, mutagenic and toxic to reproduction
DEHP	Di(2-ethylhexyl)phthalate
DIN	Deutsche Industrie Norm (German norm)
DSC	Differential scanning calorimetry
EC	European Communities
EC_{50}	Median effect concentration
EC_x	As EC_{50}, but for x% effect; x usually being 0, 10, or 100
ECB	European Chemicals Bureau
EEC	European Economic Communities
EHDP	2-Ethylhexyl diphenyl phosphate
EINECS	European Inventory of Existing Commercial Chemical Substances – this lists all chemical substances that were supplied to the market prior to 18 September 1981
EPA	Environmental Protection Agency (USA)
ESD	Emission Scenario Document
ESR	The Existing Substances Regulation – Council Regulation (EEC) 793/93 on the evaluation and control of the risks of 'existing' substances.
EU	European Union
EUSES	European Union System for the Evaluation of Substances (software tool in support of the TGD on risk assessment)
HPLC	High performance liquid chromatography
HPTLC	High performance thin layer chromatography
HPV	High Production Volume (supply above 1,000 tonnes per year)
IUCLID	International Uniform Chemical Information Database: contains non-validated tonnage, use pattern, property and hazard information for chemicals, submitted by industry under the Existing Substances Regulation (ESR)
K_{oc}	Organic carbon normalised distribution coefficient
K_{ow}	Octanol-water partition coefficient

Kp	Solids-water partition coefficient
L(E)C_{50}	Median lethal (effect) concentration
LD_{50}	Median lethal dose
LL_{50}	Median lethal loading
LO(A)EL	Lowest observed (adverse) effect level
LOEC	Lowest observed effect concentration
log K_{ow}	Log of the octanol-water partition coefficient (K_{ow})
NO(A)EL	No observed (adverse) effect level
NOEC	No observed effect concentration
n.t.p.	Normal temperature and pressure
OECD	Organisation for Economic Co-operation and Development
P	Persistent
PBT	Persistent, bioaccumulative and toxic
PEC	Predicted environmental concentration
pH	Logarithm (to the base 10) of the hydrogen ion concentration [H+]
pK_a	Logarithm (to the base 10) of the acid dissociation constant
PNEC	Predicted no effect concentration
ppm	Parts per million
SCAS	Semi-continuous activated sludge unit
TGA	Thermogravimetric analysis
TGD	Technical Guidance Document
TLC	Thin layer chromatography
TSCA	Toxic Substances Control Act (USA)
USEPA	Environmental Protection Agency, USA
vB	Very bioaccumulative
vP	Very persistent
vPvB	Very persistent and very bioaccumulative
w/w	Weight per weight ratio
wt	Weight
wwt	Wet weight
WWTP	Waste water treatment plant

10 Data collection and peer review process

This report has been produced using publicly available data gathered and assessed by the contractor for the Environment Agency. Additional information has been submitted voluntarily by member companies of the Phosphate Ester Flame Retardant Consortium (PEFRC, http://www.pefrcnet.org/), and the Environment Agency would like to thank them for their co-operation.

The Environment Agency has been keen to ensure that the data used in this report are as complete and accurate as possible. Original reports and literature articles for key studies were retrieved and assessed for reliability wherever possible (it is clearly indicated where this was not the case).

The main scientific literature search was performed in 2002, with some further limited searching to consider specific issues up to 2007.

Drafts of this report have been circulated to key stakeholders in UK and European Industry for comment on several occasions, as well as members of the UK and European chemical regulatory community in July 2007. The Advisory Committee on Hazardous Substances has also provided helpful comments as part of its own deliberations on this substance group (their last review was in September 2007).

In addition, certain technical aspects of the report were peer-reviewed by an independent expert group set up by the Environment Agency for this purpose in April 2007. The experts were:

- Dr Kay Fox (independent consultant);
- Dr Tamara Galloway (University of Plymouth).

Their comments have not been published but are available on request. All comments received have been addressed in the final report where appropriate.

The Institute for Environment and Health wrote the human health effects assessment, and this was peer-reviewed by colleagues at the Health and Safety Executive and Health Protection Agency.

Appendix 1 Points for clarification on mammalian toxicity data

The following points summarise uncertainties in the mammalian dataset (Section 4.4), and may lead to revision of the assessment risks for humans exposed via the environment, and of the classification, if addressed.

- Information on the exact specification/composition of the materials tested in the studies reported in the secondary sources would be useful, including the nature and amount of any impurities where a commercial product was used.
- For many of the acute experimental studies, only limited information has been provided in the summaries. It would be helpful if further details such as number of animals used, doses tested and the incidence of any reported adverse effects in the primary study reports were provided.
- Further information on the acute rat inhalation studies reporting an LC_{50} greater than 4.8 mg/l would be useful to decide if classification for this endpoint is required, as this value falls within the range 2-20 mg/l per four hours requiring an R20 classification for vapours.
- In a number of instances (such as Johannsen *et al*., 1977 and Monsanto 1971b, cited in IUCLID 2000a, and studies mentioned in the USEPA HPV test plan), reports of study findings drawn from multiple secondary sources show similarities. This raises questions as to whether the reports relate to the same experiment or not.
- With regard to the reports in secondary sources of a slight irritancy potential for this chemical, it would be advisable to examine in more detail the doses, irritation scores and time scale over which effects were observed (see Monsanto 1971b, cited in IUCLID 2000a), since consideration of the primary data source may permit a confident conclusion to be reached as to the chemical's potential to cause dermal or ocular irritancy.
- Similarly, the primary sources of Monsanto (1968) and a second study (dated 1979) described in the USEPA HPV test plan, should be examined to provide more informative study descriptions to improve the confidence of the data on which sensitising potential is assessed.
- In the 12-day repeat-dose study in rats (Kehoe (1949), cited in the USEPA HPV test plan), it is not clear if the reported effect on bodyweight relates to absolute weight or to weight change; also not clear are the period under consideration for this assessment, whether the weight changes seen were dose-related and statistically significant, and was there any period of withdrawal of treatment (recovery phase) and, if so, of what duration.
- Within Section 4.4.6 on repeat-dose toxicity in animals, more details from the original study reports are needed. This is particularly crucial for the 90-day rat oral feeding study (Monsanto report BB 92-9898) where information should be provided on weight gain changes in relation to control groups and to clarify whether or not the controls received the vehicle alone.
- The 24-month rat study is poorly reported in the secondary source. Given its potential importance, further details would be useful if available. The same is also true for the reporting in the secondary source used of a non-GLP compliant 26 month oral study in dogs.

- Some of the summaries reviewed for Section 4.4.7 on mutagenicity state that positive controls were tested but that all results were negative. This aspect requires some further clarification, where information is available in the primary test reports.
- It would be helpful to confirm if the two Ames-type studies on *S. typhimurium* and the two mouse lymphoma assays reported in the USEPA HPV test plan and the IUCLID represent the same set of experiments (Litton Bionetics 1978a and 1978b; Monsanto report BO-78 0080; Monsanto report 78-0085). In addition any information on positive control findings would be of value.
- For the study reported as BIBRA Report 804 (7)/2/92 in the IUCLID and US EPA HPV test plan, the information given on the nature of the test material employed appears contradictory.
- The NOAEL for parental toxicity in the fertility and the reproductive toxicity studies was much higher (144 mg/kg/day) than found in the 90-day studies (6 mg/kg/day and LOAEL at 15 mg/kg/day). This may be due to the more thorough investigation of repeat-dose toxicity endpoints in the 90-day studies compared to the reproductive studies. Further views on this would be useful.

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