

# I U C L I D

## Data Set

**Existing Chemical** : ID: 2528-36-1  
**CASNo.** : 2528-36-1  
**Common name** : Dibutyl Phenyl Phosphate  
**TSCA Name** : Phosphoric acid, dibutyl phenyl ester  
**Synonym** : DBPP

**Producer related part**  
**Company** : Solutia Inc.  
**Creation date** : 17.03.2003

**Substance related part**  
**Company** : Solutia Inc.  
**Creation date** : 17.03.2003

**Status** :  
**Memo** :

**Printing date** : 17.07.2003  
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**Flags (profile)** : Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE),  
Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

## 1.0.1 APPLICANT AND COMPANY INFORMATION

## 1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

## 1.0.3 IDENTITY OF RECIPIENTS

## 1.0.4 DETAILS ON CATEGORY/TEMPLATE

## 1.1.0 SUBSTANCE IDENTIFICATION

**Remark** : Commerical Grade Dibutyl Phenyl Phosphate (DBPP) is a mixture of organophosate esters in the approximate ratio of 70% DBPP, 15% Tributyl Phosphate (TBP)[CAS no. 126-73-8], and Butyl Diphenyl Phosphate (BDPP)[CAS no. 2752-95-6].

23.06.2003

## 1.1.1 GENERAL SUBSTANCE INFORMATION

## 1.1.2 SPECTRA

## 1.2 SYNONYMS AND TRADENAMES

## 1.3 IMPURITIES

## 1.4 ADDITIVES

## 1.5 TOTAL QUANTITY

## 1.6.1 LABELLING

## 1.6.2 CLASSIFICATION

## 1.6.3 PACKAGING

## 1.7 USE PATTERN

# 1. General Information

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1.7.1 DETAILED USE PATTERN

1.7.2 METHODS OF MANUFACTURE

1.8 REGULATORY MEASURES

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.8.2 ACCEPTABLE RESIDUES LEVELS

1.8.3 WATER POLLUTION

1.8.4 MAJOR ACCIDENT HAZARDS

1.8.5 AIR POLLUTION

1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES

1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS

1.9.2 COMPONENTS

1.10 SOURCE OF EXPOSURE

1.11 ADDITIONAL REMARKS

1.12 LAST LITERATURE SEARCH

1.13 REVIEWS

## 2. Physico-Chemical Data

Id 2528-36-1  
Date 17.07.2003

### 2.1 MELTING POINT

Value : = 87.5 - °C  
Sublimation :  
Method : other: calculated (MPBPWIN v1.40)  
Year :  
GLP : no  
Test substance : other TS

Source : EPIWIN (2000).  
Test substance : Dibutylphenyl phosphate [CAS No. 2528-36-1]  
Reliability : (2) valid with restrictions  
Flag : Critical study for SIDS endpoint  
28.05.2003 (1)

### 2.2 BOILING POINT

Value : = 131 - 132 °C at  
Decomposition :  
Method : other: not reported  
Year : 1986  
GLP : no data  
Test substance : other TS

Remark : Reported as 267.8-269.6 deg. F @ 760 mm Hg.  
Test substance : Dibutylphenyl phosphate [CAS No. 2528-36-1]  
Reliability : (2) valid with restrictions  
Flag : Critical study for SIDS endpoint  
10.07.2003 (2)

### 2.3 DENSITY

#### 2.3.1 GRANULOMETRY

### 2.4 VAPOUR PRESSURE

Value : = .00933 - hPa at 25 °C  
Decomposition :  
Method : other (measured): not reported  
Year :  
GLP : no data  
Test substance : other TS

Remark : Reported as 0.007 mm Hg @ 25 deg. C (77 deg. F).  
Source : OSHA. 2002  
Test substance : Dibutylphenyl phosphate [CAS No. 2528-36-1]  
Reliability : (2) valid with restrictions  
Flag : Critical study for SIDS endpoint  
28.05.2003 (3)

## 2.5 PARTITION COEFFICIENT

**Partition coefficient** : octanol-water  
**Log pow** : = 4.27 - at 25 °C  
**pH value** : -  
**Method** : other (measured): direct partition experiments  
**Year** : 1979  
**GLP** : no data  
**Test substance** : as prescribed by 1.1 - 1.4

**Method** : Partition coefficients were determined via direct partition experiments. At least two concentrations of the test substance, ranging from 100 ppm to 1% (10,000 ppm) were prepared in 100 ml of n-octanol. The n-octanol test solutions were combined with 500 ml purified water in a 1-l glass bottle at room temperature (ca. 25 deg. C) and shaken for 48 hours. Shaken mixtures were allowed to separate for 1 week in the dark. Concentrations of the test substance in each phase were determined by gas chromatography with dual flame-ionization detectors (GC -FID/FID). The partition coefficient (P) was calculated using the following equation:

$$P = C_o/C_w$$

where  $C_o$  and  $C_w$  are the concentrations of the test substance in n-octanol and water, respectively.

**Result** : The nominal test substance concentration in octanol was used in calculations as only a negligible amount of the compound partitioned into the water phase.

The partition coefficient (P) of dibutylphenyl phosphate was reported as 18,800 (log P = 4.27).

**Test substance** : Dibutylphenyl phosphate [CAS No. 2528-36-1]  
**Reliability** : (2) valid with restrictions  
**Flag** : Critical study for SIDS endpoint  
 06.06.2003

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## 2.6.1 SOLUBILITY IN DIFFERENT MEDIA

**Solubility in Value** : Water  
 : = 96 - mg/l at 25 °C  
**pH value** : -  
**concentration** : at °C  
**Temperature effects** :  
**Examine different pol.** :  
**pKa** : at 25 °C  
**Description** : slightly soluble (0.1-100 mg/L)  
**Stable** :  
**Deg. product** :  
**Method** : other: as reported in study  
**Year** : 1979  
**GLP** : no data  
**Test substance** : as prescribed by 1.1 - 1.4

**Method** : Water solubility was determined using a single saturated aqueous solution of the test substance. 25 ml of the test substance was combined with 500 ml purified water in a 1-l glass bottle at room temperature (ca. 25 deg. C) and shaken for 48 hours. The shaken mixture was allowed to separate for 1 week in the dark and then centrifuged (@ 20000g) for 1 hour. The concentration of the test substance in the aqueous phase was determined by gas chromatography with dual flame-ionization detectors (GC -FID/FID). Replicate extractions and analyses were conducted.

## 2. Physico-Chemical Data

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**Result** : Replicate extractions and analyses were conducted.  
: The authors reported that the results for the replicate analyses of the aqueous solution had mean relative average deviation of 13%. The water solubility of dibutylphenyl phosphate was reported as 96 ppm (total for all components of the commercial mixture).  
**Test substance** : Dibutylphenyl phosphate [CAS No. 2528-36-1]  
**Reliability** : (2) valid with restrictions  
**Flag** : Critical study for SIDS endpoint  
06.06.2003 (4)

### 2.6.2 SURFACE TENSION

### 2.7 FLASH POINT

### 2.8 AUTO FLAMMABILITY

### 2.9 FLAMMABILITY

### 2.10 EXPLOSIVE PROPERTIES

### 2.11 OXIDIZING PROPERTIES

### 2.12 DISSOCIATION CONSTANT

### 2.13 VISCOSITY

### 2.14 ADDITIONAL REMARKS

### 3. Environmental Fate and Pathways

Id 2528-36-1  
Date 17.07.2003

#### 3.1.1 PHOTODEGRADATION

Type : other  
Light source :  
Light spectrum : - nm  
Relative intensity : - based on intensity of sunlight  
Deg. product :  
Method : other (calculated): AOPWIN v1.90  
Year :  
GLP : no  
Test substance : other TS

Remark : Vapor phase dibutylphenyl phosphate is susceptible to reaction with photochemically produced hydroxyl (OH) radicals. The 2nd order rate constant for reaction with hydroxyl radicals was calculated as  $56.174E-12$   $cm^3/(molecule*sec)$ . Based on  $1.5E6$  OH molecules/ $cm^3$  and assuming 12 hours of sunlight per day, the estimated photo-oxidation half-life is 4.57 hours.

Source : EPIWIN  
Test substance : Dibutylphenyl phosphate [CAS No. 2528-36-1]  
Reliability : (2) valid with restrictions  
Flag : Critical study for SIDS endpoint  
28.05.2003

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#### 3.1.2 STABILITY IN WATER

Deg. product :  
Method : other  
Year : 1978  
GLP : no  
Test substance : as prescribed by 1.1 - 1.4

Method : Buffered aqueous solutions held at pH of 5, 7 and 9 were spiked with approx. 0.5 ppm test material and held at 25 deg. C. Photolysis was prevented by keeping the solutions in the dark and biodegradation prevented by autoclaving the solutions and glassware prior to spiking. Concentrations of the parent materials were monitored over a 42-day period by withdrawal and analysis of aliquots of hexane-extracted solutions. Analysis was performed using GC with nitrogen/phosphorus detector. Hexane rinses of the walls of test flask were analyzed after 42 days to measure potential absorbance.

Remark : The test substance (Dibutylphenyl phosphate) is considered resistant to hydrolysis in neutral or acid conditions, but does hydrolyze under more basic conditions.

pH	Hydrolysis T 1/2 (days) at 25 deg. C
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5	> 100
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7	57
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9	10
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Report Limited to methods and summary data. However, sufficient information is available to understand properties of DBPP, which are consistent with other alkyl, aryl phosphates.

Flag : Critical study for SIDS endpoint  
23.06.2003

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#### 3.1.3 STABILITY IN SOIL

#### 3.2.1 MONITORING DATA

#### 3.2.2 FIELD STUDIES

#### 3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type : fugacity model level III  
Media : other  
Air : 1.21 % (Fugacity Model Level I)  
Water : 40.2 % (Fugacity Model Level I)  
Soil : 55.8 % (Fugacity Model Level I)  
Biota : % (Fugacity Model Level II/III)  
Soil : 2.79 % (Fugacity Model Level II/III)  
Method : other  
Year : 2003

Remark : Air: half-life = 4.57 hr, emissions = 1000 kg/hr  
Water: half-life = 208 hr, emissions = 1000 kg/hr  
Soil: half-life = 208 hr, emissions = 1000 kg/hr  
Sediment: half-life = 832 hr, emissions = 0 kg/hr

Persistence Time: 179 hr

Physical properties of dibutylphenyl phosphate used as the model input parameters were water solubility of 96 mg/L, vapor pressure of 7E-3 mm Hg, log Kow of 4.27, and melting point of 87.5°C. All property values were taken from this IUCLID dossier.

Test substance : Dibutylphenyl phosphate [CAS No. 2528-36-1]  
Reliability : (2) valid with restrictions  
Flag : Critical study for SIDS endpoint  
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#### 3.3.2 DISTRIBUTION

#### 3.4 MODE OF DEGRADATION IN ACTUAL USE

#### 3.5 BIODEGRADATION

Type : aerobic  
Inoculum : activated sludge, domestic  
Contact time :  
Degradation : 95 - (±) % after 24 hour(s)  
Result :  
Deg. product : not measured  
Method : other: Semi-Continuous Activated Sludge (SCAS)  
Year : 1979  
GLP : no  
Test substance : as prescribed by 1.1 - 1.4

### 3. Environmental Fate and Pathways

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Date 17.07.2003

**Method** : A SCAS test was conducted using the Soap and Detergent Association semi-continuous procedure with modified feed (JAOCS, 1965, 42:986 and JAOCS, 1969, 46:432). The test substance was tested at two feeding rates: 3 mg/l per 24-hour cycle for 4 weeks and 13 mg/l per 24-hour cycle for 21 weeks.

The tests were conducted in magnetically-stirred, 1.5-l glass vessels. Primary degradation measurements were conducted on a one-cycle/week basis. During the chosen cycle, 50-ml samples of the mixed liquor were collected immediately after feeding and at the end of the cycle. Each sample was repeatedly extracted with aliquots of hexane (3 x 25 ml), the extracts were combined and concentrated, and the test substance concentration was determined by gas chromatography with dual-flame ionization detection (GC -FID/FID). Off-gases from each sample vessel during a complete 24-h cycle were passed through a series of three hexane scrubbers in order to check for volatilization of the test substance. The hexane was analyzed for the presence of the test substance.

Analytical recovery experiments were conducted by analyzing mixed liquor samples, spiked with known amounts of the test substance, by the method described previously. Average recoveries obtained were  $80 \pm 11\%$ .

**Result** : No significant volatilization of the test substance was observed (i.e., <0.5% loss).

Results (percent biodegradation) of the activated sludge primary biodegradation test of dibutyl phenyl phosphate:

3 mg/l feed level, 24-h cycle, 4 week duration: >95%

13 mg/l feed level, 24-h cycle, 21 week duration: 52 +/- 11%

**Reliability Flag** : (2) valid with restrictions  
17.07.2003 : Critical study for SIDS endpoint

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**Type** : aerobic  
**Inoculum** : other: natural river water  
**Concentration** : 1 mg/l related to Test substance related to  
**Contact time** : 28 day(s)  
**Degradation Result** : - ( $\pm$ ) % after  
**Deg. product** : not measured  
**Method** : other: River Die-Away Test (RDA)  
**Year** : 1979  
**GLP** : no  
**Test substance** : as prescribed by 1.1 - 1.4

**Method** : River water was obtained from the Mississippi River near St. Louis, Missouri, USA. Settled water (200 ml) was added to 16-oz narrow-mouth screw-cap bottles. Heat-sterilized water controls (with test substance) were prepared similarly to ensure that any decrease in test substance concentration was due to biodegradation and not some other process. The test substance, prepared as 50 ug test substance/ul of ethanol, was added to each bottle in 4 microliter volumes. Bottles were sealed with foil-lined caps and stored at room temperature in the dark. A set of positive controls (linear alkylbenzenesulfonate [LAS] in river water) was prepared similarly and used to verify the biological activity of the test medium.

Chemical analyses of the active and control samples were conducted periodically by sacrificing a bottle containing the test substance or a control. The sample was repeatedly extracted with aliquots of hexane (3 x 25 ml), the extracts were combined and concentrated, and the test substance concentration was determined by gas chromatography with dual-flame ionization detection (GC-FID/FID).

### 3. Environmental Fate and Pathways

Id 2528-36-1  
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**Result** : dual-flame ionization detection (GC-FID/FID).  
: The study demonstrated that dibutylphenyl phosphate was primarily degraded at a moderate to rapid rate. No residual ester remained at the end of the test period. Based on the biodegradation die-away curves presented, complete degradation was observed by day 7. Sterile-water controls demonstrated no significant evidence of non-biological degradation or loss of the test substance.

Approximate percent degradation of the test substance (estimated from reported die-away curve):  
Day 0: 0%  
Day 2: ~5% deg.  
Day 4: ~70% deg.  
Day 7: ~100% deg.

**Reliability** : (2) valid with restrictions  
Study supplied as supplemental study for this endpoint.

06.06.2003 (4)

#### 3.6 BOD5, COD OR BOD5/COD RATIO

#### 3.7 BIOACCUMULATION

#### 3.8 ADDITIONAL REMARKS

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Type** : flow through  
**Species** : Salmo gairdneri (Fish, estuary, fresh water)  
**Exposure period** : 14 day(s)  
**Unit** : mg/l  
**LC50** : = 2.7 -  
**EC50 (14-day)** : = 1.2 -  
**Limit test** :  
**Analytical monitoring** : yes  
**Method** : other: EPA 660/3-75-009  
**Year** : 1979  
**GLP** : yes  
**Test substance** : as prescribed by 1.1 - 1.4

**Method** : Rainbow trout were obtained from a fish hatchery and held in culture tanks for two weeks, under a 16 hours light/8 hours dark cycle. Fish were fed commercial fish food until 48 hours before the test. Fish had a mean weight and length of 1.21 g and 40.1 mm, respectively.

A flow through test using a Brungs proportional diluter was conducted. Test was performed in 30-liter tanks with 30 fish per tank. Test solutions were replaced as necessary to maintain concentration over the 14-day test period. A 16-hr light cycle was employed. Test dilution water characteristics at the start of testing were DO, 9.3 mg/L; pH, 7.7; total hardness, 240 mg/L as CaCO<sub>3</sub>; and total alkalinity, 360 mg/L. Water quality was measured five times during the test (temperature, DO, pH, NH<sub>3</sub>). Test water was maintained at 12 ± 1°C. Five concentrations (0.20, 0.37, 0.69, 1.3, 3.0 mg/L) and an acetone solvent control were tested. LC50 and CI were calculated according to method of Litchfield and Wilcoxon.

Test concentrations were measured during the test using gas chromatography with flame ionization detection (GC-FID). Test concentrations were maintained at 99% nominal throughout the test. Across all test vessels, DO varied between 60 to 100% saturation and ammonia remained below the toxic limit.

**Result** : Fish lost equilibrium at test concentrations lower than those with observed mortality. A 14-d EC50 (95% confidence interval) for loss of equilibrium of 1.2 (0.96-1.5) mg/L was reported. Growth appeared to be reduced at 0.86 mg/L, but not 0.38 mg/L.

Toxicity (LC50) values (+ confidence interval):

24-h LC50 = 5.7 (4.4-7.4) mg/L  
 96-h LC50 = 2.7 (2.4-3.1) mg/L  
 6-d LC50 = 2.7 (2.4-3.1) mg/L  
 12-d LC50 = 2.6 (2.3-3.0) mg/L  
 14-d LC50 = 2.4 (2.0-2.8) mg/L

**Reliability** : (1) valid without restriction  
**Flag** : Critical study for SIDS endpoint  
 25.06.2003

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**Type** : other: estimated  
**Species** : other: fish  
**Exposure period** : 96 hour(s)  
**Unit** : mg/l  
**LC50** : = 1.5 -  
**Method** : other: calculated (EcoSAR)  
**Year** :  
**GLP** : no

## 4. Ecotoxicity

Id 2528-36-1  
Date 17.07.2003

**Test substance** : other TS

**Remark** : An acute fish 96-h LC50 was calculated using ECOSAR, from the USEPA. The SAR for esters (phosphate) was used. The structure was determined from the CAS RN, as stored in the accompanying database of SMILES notations within ECOSAR.

**Test substance** : Dibutylphenyl phosphate [CAS No. 2528-36-1]  
**Reliability** : (2) valid with restrictions  
28.05.2003 (9)

### 4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

**Type** : static  
**Species** : Daphnia magna (Crustacea)  
**Exposure period** : 48 hour(s)  
**Unit** : mg/l  
**NOEC** : = 1 -  
**EC50** : = 2.3 -  
**Method** : other: EPA 660/3-75-009  
**Year** : 1975  
**GLP** : yes  
**Test substance** : as prescribed by 1.1 - 1.4

**Method** : Groups of ten D. magna Straus (<24-h old) were tested at  $19 \pm 1^\circ\text{C}$ , in a series of six test concentrations. Test concentrations were 1.0, 1.8, 3.2, 5.6, 10.0, and 32 mg/L, plus clean water and solvent (0.5 mL/L dimethyl formamide [DMF]) controls. Tests were conducted in well water from St. Peters, Missouri. Photoperiod was 18 hr. Test concentrations were not measured. Daphnids were not fed.

Tests were conducted in 250-mL beakers containing 200 mL of solution. Dissolved oxygen was monitored to ensure the concentration did not fall below 2 mg/L before the end of the test. Water quality was measured, according to SOPs, for the following parameters: dissolved oxygen (8.6 mg/L), pH (7.8), alkalinity (360 mg/L), hardness (240 mg/L) and temperature. No significant changes were observed in any parameter over the course of the test. No control mortalities were observed. The estimated EC50 and 95% confidence limits were determined using probit analysis.

**Result** : 24-h EC50 (95% CL) = 5.0 (3.8-6.6) mg/L  
48-h EC50 (95% CL) = 2.3 (1.9-2.7) mg/L  
NOEC = 1.0 mg/L

**Reliability** : (2) valid with restrictions  
**Flag** : Critical study for SIDS endpoint  
06.06.2003 (10)

**Type** : other  
**Species** : Daphnia magna (Crustacea)  
**Exposure period** : 48 hour(s)  
**Unit** : mg/l  
**EC50** : = 1.955 -  
**Method** : other: EcoSAR  
**Year** : 2003  
**GLP** : no  
**Test substance** : other TS

**Method** : Calculated according to ECOSAR, from the US EPA. The SAR for esters was used. The structure was determined from the CAS RN 2528-36-1 as stored in the accompanying database of SMILES notations within ECOSAR. A measure log Kow of 4.27 was used.

**Remark** : Supplemental information provided, as both an acute and a chronic

daphnia study have been performed on this chemical and fully support this HPV endpoint.

**Test substance** : Dibutyl Phenyl Phosphate [CAS 2528-36-1].

**Reliability** : (2) valid with restrictions

23.06.2003 (11)

## 4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

**Species** : Selenastrum capricornutum (Algae)

**Endpoint** : other: yield

**Exposure period** : 96 hour(s)

**Unit** : mg/l

**Limit test** :

**Analytical monitoring Method** : no data  
: other: USEPA "Algal Assay Procedure: Bottle Test." National Eutrophication Research Program, Pacific Northwest Water Laboratory, Corvallis, OR. 82p.

**Year** : 1971

**GLP** : no data

**Test substance** : as prescribed by 1.1 - 1.4

**Method** : Cultures were incubated at  $24 \pm 1^\circ\text{C}$ , under 4000 lux illumination for the entire study period. Triplicate culture flasks were employed for each of the test concentrations and controls used. Acetone was used as a cosolvent (0.05 mL per test flask). Chlorophyll-a was measured using a Turner Model 111 fluorometer. Cell counts were made using a hemacytometer and a Zeiss Standard 14 compound microscope. Specifics of the culture medium were not provided. Results were analyzed using probit analysis and regression analysis. The pH was maintained between 7.0-7.7 during the test.

**Result** : Based on Chlorophyll-a data:  
24-h EC50 = >10 mg/L  
48-h EC50 = <10 mg/L  
72-h EC50 (95% CI) = 5.9 (0.3-11.4) mg/L  
96-h LC50 (95% CI) = 5.4 (3.3-8.6) mg/L

Based on cell counts data:  
96-h LC50 (95% CI) = 6.0 (4.2-8.5) mg/L

**Reliability** : (2) valid with restrictions

**Flag** : Critical study for SIDS endpoint

06.06.2003 (12)

**Species** : other algae: Green Algae

**Endpoint** :

**Exposure period** : 96 hour(s)

**Unit** : mg/l

**EC50** : .22 -

**Method** : other: EcoSAR calculation

**Year** : 2003

**GLP** : no

**Test substance** : other TS

**Method** : Calculations made according to EcoSAR from the USEPA. The SAR for esters was used. The structure was determined from the CAS RN 2528-36-1 as stored in the accompanying database of SMILES notations within EcoSAR. A measured log Kow of 4.27 was used.

**Remark** : Supplemental information as an acute algae study fulfills this HPV endpoint.

**Test substance** : Dibutyl Phenyl Phosphate [CAS 2528-36-1].

**Reliability** : (2) valid with restrictions

23.06.2003

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**4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA****4.5.1 CHRONIC TOXICITY TO FISH**

**Species** : Salmo gairdneri (Fish, estuary, fresh water)  
**Endpoint** : other: survival, growth, and behavior  
**Exposure period** : 60 day(s)  
**Unit** : mg/l  
**NOEC** : > .11 -  
**Analytical monitoring** : yes  
**Method** : other: ASTM "Standard Practice for Conducting Toxicity Tests on the Early Life Stages of Fishes"; Draft No. 2. ASTM Committee E-35.21. 52p.  
**Year** : 1979  
**GLP** : yes  
**Test substance** : as prescribed by 1.1 - 1.4

**Method** : Rainbow trout eggs were obtained from a fish hatchery and held in culture tanks at  $10 \pm 1^\circ\text{C}$ , with a 16-hour photoperiod, for 48 hours before testing.

A flowthrough test using a two-liter Brungs proportional diluter was conducted. Test solutions were replaced at a rate of 5.5 times daily. Test dilution water characteristics at the start of testing were DO, 9.3 mg/L; pH, 8.2; total hardness, 255 mg/L as  $\text{CaCO}_3$ ; and total alkalinity, 368 mg/L. Water quality was measured periodically during the test (temperature, DO, pH,  $\text{NH}_3$ ). Test water was maintained at  $10 \pm 1^\circ\text{C}$ .

Five nominal (+ mean measured) test concentrations [0.006 (0.0065), 0.012 (0.015), 0.025 (0.023), 0.050 (0.056), and 0.100 (0.110) mg/l] and an acetone solvent control were used. Test concentrations were measured using gas chromatography with flame ionization detection (GC-FID). Across all test vessels, DO varied between 47 to 100% saturation and ammonia remained below the toxic limit.

Fifty eggs were put into each of two incubator cups per duplicate aquaria (200 eggs per test concentration). Egg mortality and hatching success were recorded daily. Surviving fry were placed into growth chambers (four groups of 20 fry each), fed, and allowed to grow.

**Remark** : Supplemental information for HPV endpoint as fully acceptable acute study has been reported.

**Result** : No effects on hatching mortality or success, as compared to controls, were observed for any test concentration. No effects on fry survival, behavior, or morphological abnormalities were observed. No dose-related effects on growth were observed. The overall NOEC for this study is greater than the highest mean measured test substance concentration (i.e., >0.110 mg/L).

**Reliability** : (1) valid without restriction

06.06.2003

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**4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES**

**Species** : Daphnia magna (Crustacea)  
**Endpoint** : other: reproduction and growth  
**Exposure period** : 21 day(s)  
**Unit** : mg/l  
**NOEC** : = .092 -  
**LOEC** : = .25 -

<b>Analytical monitoring</b>	:	yes	
<b>Method</b>	:	other: "Protocol for Conducting Chronic Toxicity Tests with the Water Flea (Daphnia magna)."	
<b>Year</b>	:	1980	
<b>GLP</b>	:	yes	
<b>Test substance</b>	:	as prescribed by 1.1 - 1.4	
<b>Method</b>	:	<p>A 200-mL proportional diluter system was used to deliver test concentrations. Test vessels were 1.75-L glass jars, modified to allow water to flow through. Nitex mesh retained the daphnids during the test.</p> <p>DO and temperature were measured in the test systems daily. Total hardness, alkalinity, specific conductance, and pH were measured weekly. Both solvent and clean water controls were used. Daphnids (&lt;24-h old) were used to start the test. Survival and production of offspring were counted daily from day 7 to day 21. Lengths were recorded daily using a stereo microscope fitted with an ocular micrometer. Daphnids were fed commercial fish food and unicellular green algae.</p> <p>Nominal test concentrations were 0.012, 0.025, 0.05, 0.10, and 0.20 mg/L. Dimethyl formamide (DMF) was the cosolvent. Test concentrations were verified using a gas chromatograph with a nitrogen/phosphorus detector (GC-NPD).</p> <p>Measured test concentrations were 111% of nominal during the test. During the test, DO ranged from 8.6-9.0 mg/L, temperature was maintained at <math>22 \pm 1^\circ\text{C}</math>, total hardness ranged from 171-176 mg/L, total alkalinity ranged from 122-126 mg/L, specific conductivity was maintained at 440 mg/L, and pH ranged from 7.8-8.3.</p> <p>LC50 calculations used an internal computer program which calculated values based on either (in order of preference, depending on data points considered): moving ave. angle analysis, probit analysis or binomial probability. Other parameters measured used ANOVA and Dunnetts test. P=0.05 in all cases.</p>	
<b>Remark</b>	:	Supplemental HPV study as a fully acceptable acute study has already been reviewed for this endpoint.	
<b>Result</b>	:	Statistically significant differences, as compared to controls, were noted for survival, number of gravid females, length, and young produced at 0.25 mg/L, but not at 0.092 mg/L. The 21-day NOEC was 0.092 mg/L and the LOEC was 0.25 mg/L.	
<b>Reliability</b> 06.06.2003	:	(1) valid without restriction	(14)

**4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS****4.6.2 TOXICITY TO TERRESTRIAL PLANTS****4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS****4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES****4.7 BIOLOGICAL EFFECTS MONITORING**

### 4.8 BIOTRANSFORMATION AND KINETICS

### 4.9 ADDITIONAL REMARKS

**5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION****5.1.1 ACUTE ORAL TOXICITY**

<b>Type</b>	:	LD50
<b>Value</b>	:	2620 - mg/kg bw
<b>Species</b>	:	rat
<b>Strain</b>	:	Sprague-Dawley
<b>Sex</b>	:	male/female
<b>Number of animals</b>	:	22
<b>Vehicle</b>	:	
<b>Doses</b>	:	2250, 2500, 2750 and 3000 mg/kg
<b>Method</b>	:	other
<b>Year</b>	:	1959
<b>GLP</b>	:	no
<b>Test substance</b>	:	as prescribed by 1.1 - 1.4
<b>Method</b>	:	In an initial Minimum Lethal Dose (MLD) study using 2 rats per test group, the MLD was identified as being between 2200-2600 mg/kg. For full LD50 study, 4 groups of young adult SD rats of mixed sex (either 5 or 6 per group) were administered test material, undiluted, by gavage and held for 14 days. Daily observations were made for clinical signs. At death or study termination all animals underwent necropsy. Food and water were given ad libitum. Body weights were recorded. LD50 presumably determined by method of deBeer (1949).
<b>Result</b>	:	OLD50 = 2620 mg/kg. CI not reported. No. of deaths/survivors observed at dosages of : 2250 mg/kg (0/5), 2500 mg/kg (1/6), 2750 mg/kg (5/6) and 3000 mg/kg (5/5). Deaths occurred between 12-48 hr postdosing, with most occurring during 24-48 hr after dosing. Only generalized clinical signs of toxicity were observed: gradual weakness and lethargy, moderate diarrhea and coma prior to death. At autopsy, hyperemia of the liver and congestion of the lungs were observed.
<b>Reliability</b>	:	(2) valid with restrictions Study design generally consistent with OECD guidance although conducted prior to codification. Sufficient data to ascertain the acute toxicity of DBPP, with added reliability of initial MLD preliminary study.
<b>Flag</b>	:	Critical study for SIDS endpoint
17.07.2003		

(15)

**5.1.2 ACUTE INHALATION TOXICITY****5.1.3 ACUTE DERMAL TOXICITY****5.1.4 ACUTE TOXICITY, OTHER ROUTES****5.2.1 SKIN IRRITATION****5.2.2 EYE IRRITATION**

## 5.3 SENSITIZATION

## 5.4 REPEATED DOSE TOXICITY

<b>Type</b>	: Sub-chronic
<b>Species</b>	: rat
<b>Sex</b>	: male/female
<b>Strain</b>	: Sprague-Dawley
<b>Route of admin.</b>	: oral feed
<b>Exposure period</b>	: 91 days
<b>Frequency of treatm.</b>	: daily
<b>Post exposure period</b>	: none
<b>Doses</b>	: 0, 5, 50 and 250 mg/kg/d
<b>Control group</b>	: yes
<b>NOAEL</b>	: $\geq 5$ - mg/kg bw
<b>LOAEL</b>	: = 50 - mg/kg bw
<b>Method</b>	: OECD Guide-line 408 "Subchronic Oral Toxicity - Rodent: 90-day Study"
<b>Year</b>	: 1986
<b>GLP</b>	: yes
<b>Test substance</b>	: as prescribed by 1.1 - 1.4
<b>Method</b>	: Groups of 15 male and 15 female SD rats (43 days old) were administered a diet admixed directly with test material for 91 days. Levels of test material were verified during weekly diet analysis. All rats were examined for morbidity and mortality twice daily. Body weights and food consumption were measured weekly, as were detailed signs of toxicity. Humidity, temperature and lighting were controlled. Clinical pathology for the following indices were measured for all rats during study week 5 and 13: Hematology - HCT, HGB, RBC, WBC, Platelets, erythrocyte morphology and differ. leukocytes; Serum Chemistry - Ca, In. Phos, CL, Na, K, GLU, ALT, AST, BUN, Albumin, globulin, T. Prot., Creat., T. Bili and T. Chol. Plasma and RBC cholinesterase (CHE) were measured for all rats at study week 6 and term. Brain CHE was determined for all rats at term. An ophthalmoscopic examination was given to all rats prior to study start and at study term. At the end of the study, all rats were given a necropsy and organ weights and body:organ weight ratios recorded for: brain, kidney, liver, testes with epididymides. Histopathological examinations of a full set of tissues and organs, including ovaries and testes, were given to all rats on study. Statistical analysis of body weights, food consumption, growth rates, clinical pathology, organ weights and ratios were performed using Leven's Test for homogeneity and ANOVA followed by Terpstra-Jonckheere test and Dunnett's test for group-wise comparison. A RIBIT analysis for trend was used to evaluate both the urinary bladder and liver changes. $p = <0.05$ was used throughout.
<b>Result</b>	: Diet analysis verified mixing efficiency and dosage administered. No adverse clinical signs of toxicity, including no signs characteristic of cholinesterase inhibition, were observed throughout the study. Following are the significant study findings:  250 mg/kg/d - statistically significantly depressed body weights and growth rates in both males and females; statistically lower food consumption in both males and females; statistically lower RBC, HCT, HGB, and RBC morphology changes in both males and females at 13-week interval; T. Chol. was decreased significantly in males at weeks 5 and 13; Plasma and RBC CHE were statistically lower in both males and females at study weeks 6 and term. Brain CHE was depressed significantly only in females; groups of male rats exhibited increased absolute and relative liver weights at term, while only relative liver weight increases were seen for females; reduced hepatocytic vacuolation and fatty accumulations were seen in livers of both male and female rats; epithelial hyperplasia and submucosal

livers of both male and female rats; epithelial hyperplasia and submucosal inflammation were observed in urinary bladders of male and female rats.

50 mg/kg/d - Statistically decreased body weight and food consumption seen in males only. Plasma CHE was depressed at term for females only. Urinary bladder histopathology as mentioned above, although to a lesser extent, seen in males and, equivocally, in females. Reduced liver hepatocyte vacuolation seen only in males.

5 mg/kg/d - NOEL

**Reliability** : (1) valid without restriction  
**Flag** : Critical study for SIDS endpoint  
 17.07.2003

(16)

### 5.5 GENETIC TOXICITY 'IN VITRO'

**Type** : Ames test  
**System of testing** : Salmonella typhimurium strains TA 1535, 1537, 1538, 98, 100 and S. cerevisiae D4 yeast  
**Test concentration** : 0, 0.001, 0.01, 0.1, 1.0, and 5.0 ul  
**Cycotoxic concentr.** : 5.0 ul  
**Metabolic activation** : with and without  
**Result** : negative  
**Method** : other  
**Year** : 1977  
**GLP** : no  
**Test substance** : as prescribed by 1.1 - 1.4

**Method** : Study design generally consistent with OECD guidelines 471 and 480 although fewer replications were conducted. Methodology employed the plate overlay technique. DMSO (dimethyl sulfoxide) was the solvent. Approximately 10E8 cells from overnight culture of each indicator strain were placed in a tube containing 2 ml molten agar supplemented with biotin and histidine. Test material of doses specified were added and the mixture poured over agar plates. An activation system was added for each tester strain and dose level, and used Arochlor 1254 induced rat liver supernatant. Plates were incubated for 48 hr @ 37 deg.C and then scored for histidine revertant colonies. A single test of unspecified no. plates was used. A positive response was considered when an increase in colonies of 2X vs solvent control was observed in 3 or more test concentrations. Appropriate positive, solvent and negative controls were used. Each provided an acceptable, expected response.

**Result** : No mutagenic response was observed in any of the tester strains, with or without metabolic activation.

**Reliability** : (2) valid with restrictions  
 Reliability of results enhanced by use of Supplemental data below which supports the lack of mutagenic activity of DBPP in Salmonella.

**Flag** : Critical study for SIDS endpoint  
 06.06.2003

**Type** : Ames test  
**System of testing** : Salmonella typhimurium tester strains TA 1535, TA 100, TA 98, TA 97  
**Test concentration** : 0, 1, 3.3, 10, 33, 66, 76, 100, 200 ug/plate  
**Cycotoxic concentr.** : 200 ug/plate with S9 and 66 ug/plate without S9  
**Metabolic activation** : with and without  
**Result** : negative  
**Method** : other  
**Year** : 1988  
**GLP** : no data  
**Test substance** : as prescribed by 1.1 - 1.4

<b>Method</b>	: S. typhimurium strains TA97, TA98, TA1535, TA1537 and TA100 were obtained from Dr. Bruce Ames (UC-Berkeley) and cultures grown overnight with shaking at 37 deg. C in Oxoid No. 2 broth and analyzed for phenotype prior to use in mutagenicity testing. S-9 fractions of Arochlor 1254-treated male SD rats and male Syrian hamster liver were prepared as described by Haworth et al 1983 (NTP). The preincubation assay was performed using 0.05 ml test chemical, 0.10 ml Salmonella culture, and S-9 or buffer (0.5 ml), incubated in capped tube for 20 min. Top agar was added and contents of tubes mixed and poured onto the surface of petri dishes containing V-B medium. Histidine-independent colonies arising on the plates were counted following 48 hr incubation @ 37 deg C. Three plates per dose level were used in two independently conducted trials. S-9 fractions used for each tester strain were made up of either 10% or 30% solutions of hamster liver and rat liver homogenates derived from Arochlor 1254-treated animals. Concurrent solvent (DSMO) and positive controls were run. Positive response was judged based on reproducible dose-related increase in colonies vs solvent control in replicate trials.
<b>Remark</b>	: Supplemental study confirming lack of mutagenic response of DBPP in Salmonella test.
<b>Result</b>	: No mutagenic response observed at any test strain, with or without metabolic activation.
<b>Test substance</b>	: Commercial grade DBPP.
<b>Reliability</b>	: (2) valid with restrictions
17.07.2003	

(17)

## 5.6 GENETIC TOXICITY 'IN VIVO'

<b>Type</b>	: Cytogenetic assay
<b>Species</b>	: rat
<b>Sex</b>	: male/female
<b>Strain</b>	: Fischer 344
<b>Route of admin.</b>	: i.p.
<b>Exposure period</b>	: Single IP doses followed by sacrifices after 6, 12 and 24 hr
<b>Doses</b>	: 0, 40, 200 and 400 mg/kg (males) and 0, 60, 300 and 600 mg/kg (females)
<b>Result</b>	: negative
<b>Method</b>	: OECD Guide-line 475 "Genetic Toxicology: In vivo Mammalian Bone Marrow Cytogenetic Test - Chromosomal Analysis"
<b>Year</b>	: 1986
<b>GLP</b>	: yes
<b>Test substance</b>	: as prescribed by 1.1 - 1.4
<b>Method</b>	: Groups of 6 male and 6 female F344 rats per group were administered test material in corn oil via ip injection at doses of 0, 40, 200 and 400 mg/kg (males) and 0, 60, 300 and 600 mg/kg for females. Dosages were selected on the basis of a preliminary study showing deaths in females at 1250 mg/kg and at 625 mg/kg in males. Cholcicine dissolved in RBSS was administered to each rat 2-3 hr prior to sacrifice. After 6, 12 and 24 hr postdosing, femoral bone marrow cells were processed, slides prepared from cell suspensions and stained. Slides from 5 animals per group per each time point were assessed. Evaluations for mitotic index occurred using at least 1000 cells/animal; 60 cells/animal were evaluated for chromosomal aberrations. The number of chromosomal aberrations/cell, frequency of aberrant cells and the mean mitotic index were evaluated statistically using Bartlett's test + ANOVA. If significance was determined then Dunnett's test was applied. p<0.05.
<b>Result</b>	: No significant differences in the percentage of chromosomal aberrant cells or frequency of aberrations/cell were observed between treated and control animals of either sex. A significant difference in the mitotic index was observed between the negative control females (2.10+/-0.76) vs DBPP-

treated groups (3.30+/-0.35 and 3.0+/-0.61 for the 600 and 400 mg/kg groups respectively) only at the 24-h interval. One 400 mg/kg male rat exhibited marked ataxia, while 4 females dosed at 600 mg/kg IP also exhibited ataxia.

**Reliability** : (1) valid without restriction  
**Flag** : Critical study for SIDS endpoint  
 06.06.2003 (18)

## 5.7 CARCINOGENICITY

### 5.8.1 TOXICITY TO FERTILITY

**Type** : Two generation study  
**Species** : rat  
**Sex** : male/female  
**Strain** : Sprague-Dawley  
**Route of admin.** : oral feed  
**Exposure period** : pre mating (M/F), growth (M/F), mating (M/F), gestation (F) and lactation (F)  
**Frequency of treatm.** : daily  
**Premating exposure period**  
     **Male** :  
     **Female** :  
**Duration of test** :  
**No. of generation studies** : 2  
**Doses** : 0, 5, 50 and 250 mg/kg/d  
**Control group** : yes  
**NOAEL parental** : >= 5 -  
**NOAEL F1 offspring** : >= 5 -  
**NOAEL F2 offspring** : >= 5 -  
**Result** : Mating and fertility indices were comparable among parental animals of both generations  
**Method** : OECD Guide-line 416 "Two-generation Reproduction Toxicity Study"  
**Year** : 1987  
**GLP** : yes  
**Test substance** : as prescribed by 1.1 - 1.4

**Method** : SD rats, 45 d old and consisting of 30 male and 30 female rats per dose group, for both the F0 or F1 parental generation, were fed diets admixed with DBPP at dosages of 0, 5, 50 and 250 mg/kg/d through two generations. During the second breeding of the first generation (F1b) control and high dose parents were selected for cross fostering of some of the litters to assess the potential route of toxicity to offspring seen in the F1a generation. Rats selected for the F1 parental generation came from F1a litters. Test diets were available throughout growth, mating, gestation (F) and lactation (F). The F0/F1 parental generations were examined daily for morbidity and mortality and for detailed clinical observations weekly. Individual body weights were recorded weekly through gestation and on days 0, 7, 14 and 21 postpartum (for females). Food consumption was measured weekly except during the mating phase or during gestation/lactation (females). Food and water were given ad libitum and humidity, temperature and lighting were controlled. Mating was carried out on a 1:1 M:F basis for up to 10 consecutive days, followed by another 10-day interval if needed. The following indices were recorded on test days 0, 4, 7, 14, and 21 after birth: number of live and dead pups/sex/litter, pup weights, clinical observations of offspring, and external abnormalities. F1a and F2 generation litters were weaned on day 21 of lactation and parental animals selected; F1a pups were weaned also on d21 and subjected to gross examination. After weaning of F1a pups, all low and mid dose F0

**Result**

gross examination. After weaning of F1a pups. all low and mid dose F0 parental males and female were sacrificed and subjected to necropsy. All control and high dose animals were retained until the F1b pups were weaned. F1a parental generation handled as per F0. The urinary bladder was examined microscopically for all groups while the following organs/tissues were examined from high dose and control animals: vagina, uterus, ovaries, testes, epididymides, seminal vesicles, prostate, urinary bladder and all unusual lesions. Parental body weights and food consumption values were statistically analyzed using Levene's test and ANOVA, followed by Dunnett's test, the Kruskal, Wallis H-test, then the Nemenyi-Kruskal Wallis or Terpstra-Jonckhelle trend test. Fetal fertility and offspring were measured using Fishers Exact test, while pup bodyweight was analyzed using Kevene, ANOVA, Dunnet's and Student's t.  $P < 0.05$

: Mating and fertility indices were comparable among all parental animals, treated and control, of both generations. Following were effects noted:

250 mg/kg/d:

Parental - Lower body weights and food consumption was observed in F0 and F1 male and female parental generation, beginning midway through the 10-week pre-mating growth phase and continuing to the end of the study (in the case of females, this included gestation and lactation). Mean maternal body weights were lower during gestation of the F1b generation. F0 and F1 males and females exhibited hyperplasia of the transitional epithelium of the urinary bladder. No microscopic findings related to treatment were observed in the reproductive organs.

Offspring - Offspring Viability Index (# pups alive on day 4 vs # pups born x 100) was decreased for F1a pups (but not for F1b or F2 generations). Mean pup body weights were also reduced for F1a pups. A reduction in the number of F1a and F2 generation pups alive at weaning (day 21)- Weaning Index- was also observed. The negative trend for F1a offspring surviving on days 4 and 21 and F2 offspring on day 21 was statistically significant.

Cross-fostering resulted in no differences in Viability Index between groups and thus no definitive conclusion.

50 mg/kg/d:

Parental - Lower mean body weights seen in F1 females throughout most of study. F0 males exhibited urinary bladder hyperplasia.

Offspring - Offspring Viability Index and Weaning Index decreased for F1a pups, but not for F1b or F2.

**Reliability****Flag**

17.07.2003

5 mg/kg/d: NOEL for all generations, both parental and offspring

: (1) valid without restriction

: Critical study for SIDS endpoint

(19)

**5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY****5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES**

23.05.2003

## 5. Toxicity

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### 5.9 SPECIFIC INVESTIGATIONS

### 5.10 EXPOSURE EXPERIENCE

### 5.11 ADDITIONAL REMARKS

**6.1 ANALYTICAL METHODS**

**6.2 DETECTION AND IDENTIFICATION**

## 7. Eff. Against Target Org. and Intended Uses

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7.1 FUNCTION

7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

7.3 ORGANISMS TO BE PROTECTED

7.4 USER

7.5 RESISTANCE

**8.1 METHODS HANDLING AND STORING**

**8.2 FIRE GUIDANCE**

**8.3 EMERGENCY MEASURES**

**8.4 POSSIB. OF RENDERING SUBST. HARMLESS**

**8.5 WASTE MANAGEMENT**

**8.6 SIDE-EFFECTS DETECTION**

**8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER**

**8.8 REACTIVITY TOWARDS CONTAINER MATERIAL**

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# 10. Summary and Evaluation

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10.1 END POINT SUMMARY

10.2 HAZARD SUMMARY

10.3 RISK ASSESSMENT