201-14618

Don Lederer
Product Steward
Solutia Inc
575 Maryville Centre Drive
St. Louis, Missouri 63141

P.O. Box 66760
St. Louis, Missouri 63166-6760
Tel 314-674-1113
Fax 314-674-8808
dalede@Solutia.com

July 24, 2003

Ms. Marianne L. Horinko
Acting Administrator
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116

Attn: Chemical Right-to-Know Program

Re: HPV Challenge Program, AR-201

Phosphoric acid, Dibutyl phenyl ester (DBPP)
CAS Number 2528-36-1

Solutia, Inc., Company Registration Number is pleased to submit the attached Test Plan and Robust Summaries for Phosphoric acid, Dibutyl phenyl ester (DBPP; CAS Number 2528-36-1) as a part of our commitment to the EPA High Production Volume Challenge Program, AR-201.

The attached files are:

1. This cover letter in MS Word 2000
2. Test Plan in MS Word 2000
3. Robust Summaries (IUCLID format) in MS Word 2000

The complete matrix of SIDS data elements, including physical/chemical properties and results of biological and toxicology studies, indicate that no additional testing is required.

Please contact me at 314-674-1113 if there are any questions relating to this submission.

Regards,

Donald A. Lederer
Product Stewardship Manager

HIGH PRODUCTION VOLUME (HPV)

CHEMICALS CHALLENGE PROGRAM

TEST PLAN

For

Phosphoric acid, Dibutyl phenyl ester (DBPP)

CAS NO. 2528-36-1

Prepared by:

Solutia Inc. Registration No.

575 Maryville Centre Drive,
St. Louis, Missouri 63141

July 25, 2003

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EXECUTIVE SUMMARY

Solutia Inc. voluntarily submits the following screening information data and Test Plan covering the chemical, Phosphoric acid, dibutyl phenyl ester, also known as Dibutyl Phenyl Phosphate or DBPP (CAS No. 2528-36-1), for review under the Environmental Protection Agency's High Production Volume (HPV) Chemicals Challenge Program.

A substantial amount of data exists to evaluate the potential hazards associated with DBPP. Use of key studies or estimation models, available from data already developed, provide adequate support to characterize the Endpoints in the HPV Chemicals Challenge Program without the need for additional, unnecessary testing.

TABLE OF CONTENTS

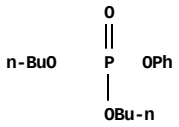
TEST PLAN FOR DIBUTYL PHENYL PHOSPHATE (DBPP)

I. INTRODUCTION AND IDENTIFICATION OF CHEMICAL

Under EPA's High Production Volume (HPV) Chemicals Challenge Program, Solutia Inc. has committed to voluntarily compile basic screening data on Dibutyl Phenyl Phosphate, also known as DBPP. The data included in this Test Plan provide physicochemical properties, environmental fate, and human and environmental effects of DBPP, as defined by the Organization for Economic Cooperation and Development (OECD). The information provided comes from existing data developed on behalf of Solutia Inc. or found in the published scientific literature and fulfills Solutia's obligation to the HPV Challenge Program.

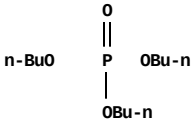
A. Structure and Nomenclature

Commerical DBPP is manufactured as what is called in the industry a "phosphate ester base stock". As such, it is actually a mixture of 3 organophosphate (OP) ester components in an approximate ratio of 70% Dibutylphenyl Phosphate (DBPP): 15% Tributyl Phosphate (TBP): 15% Butylphenyl Diphenyl Phosphate (BDPP). Following is a structural characterization of DBPP and associated esters, including their nomenclature. For the remainder of this dossier, we will refer to DBPP, recognizing we are designating the 70:15:15 OP ester mixture.

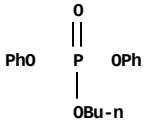


Phosphoric acid, dibutyl phenyl ester
CAS No. 2528-36-1
Synonyms: Dibutyl Phenyl Phosphate, DBPP

Additional components of commercial grade dibutylphenyl phosphate (DBPP) include:



Phosphoric acid, tributyl ester
CAS No. 126-73-8
Synonyms: TBP, tributyl phosphate



Phosphoric acid, butyl diphenyl ester
CAS No. 2752-95-6
Synonyms: butyl diphenyl phosphate, BDPP

B. Manufacturing & Use

Commercial DBPP is manufactured by a single US producer, Solutia Inc. at a single manufacturing site. The manufactured product is a phosphate ester base stock, and as such consists of the three organophosphate ester components as described in the Structure and Nomenclature section of this Test Plan. This composition is a consequence of the reaction chemistry and is not altered during manufacture. The majority of the data presented in this Test Plan has the commercial mixture as the test article.

Commercial DBPP is blended as a component with other ingredients into certain SKYDROL ® brand fire resistant Hydraulic Fluids. This blending is conducted at a single manufacturing site in a closed operation.

A TLV of 3.5 mg/m3 (8-hr TWA) has been established for DBPP (ACGIH, 2002). In addition, a second component of commercial DBPP, Tributyl Phosphate (TBP), has an established TLV of 2.2 mg/m3 (8-hr TWA)(ACGIH, 2002). These values have been established to protect against possible ocular, dermal or respiratory tract irritation. Only a few employees are involved in the manufacture and blending of commercial DBPP. There is minimal potential for skin or airborne exposure due to the closed nature of the manufacturing and blending processes. Eye and skin protection are routinely worn, and respiratory protective equipment is available should airborne exposure limits be exceeded.

SKYDROL Hydraulic Fluids are approved for use in essentially all of the world's commercial aircraft and in many types of military and general aviation aircraft. These hydraulic fluids are used in closed systems within an aircraft, thus potential for exposure to commercial DBPP by passengers is minimal. The potential for occasional, inadvertent ocular, dermal or inhalation exposure during aircraft maintenance activities has been minimized by use of good industrial hygiene practices by aircraft mechanics. Customer's employees are routinely provided with Solutia's information on the effectiveness of various types of protective equipment.

II. TEST PLAN RATIONALE

The information obtained and included to support this Test Plan has come from either 1) internal studies conducted by/or for Solutia Inc. (or its predecessor Monsanto Co.), 2) has been extracted from the scientific literature either as primary references or as found in well-accepted, peer-reviewed reference books, or 3) were estimated using environmental models accepted by the US EPA (1999b) for such purposes. This assessment includes information on physicochemical properties, environmental fate, and human and environmental effects associated with DBPP. The data used to support this program include those Endpoints identified by the US EPA (1998); key

studies have been identified for each data Endpoint and summarized in Robust Summary form and included in Section VI. of this Dossier.

All studies were reviewed and assessed for reliability according to standards specified by Klimisch *et al* (1997), as recommended by the US EPA (1999a). The following criteria were used for codification:

> 1. Reliable without Restriction - Includes studies which comply with US EPA and/or OECD-accepted testing guidelines, which were conducted using Good Laboratory Practices (GLPs) and for which test parameters are complete and well documented,
>
> 2. Reliable with Restrictions – Includes studies which were conducted according to national/international testing guidance and are well documented. May include studies conducted prior to establishment of testing standards or GLPs but meet the test parameters and data documentation of subsequent guidance; also includes studies with test parameters which are well documented and scientifically valid but vary slightly from current testing guidance. Also included were physical-chemical property data obtained from reference handbooks as well as environmental endpoint values obtained from an accepted method of estimation (i.e. EPIWIN).
>
> 3.Not Reliable – Includes studies in which there are interferences in either the study design or results that provide scientific uncertainty or where documentation is insufficient.

Those studies receiving a Klimisch rating of 1 or 2 are considered adequate to support data assessment needs in this Dossier.

III. TEST PLAN SUMMARY AND CONCLUSIONS

Conclusion: All HPV Endpoints have been satisfied with data from studies that were either well documented, used OECD guideline methods and conducted in accord with GLPs, or were estimated from acceptable estimation modeling programs. Hence, no further testing for any of the HPV Endpoints is deemed necessary, as summarized in Table 1.

In summary:
Physical-chemical property values (Melting Point, Boiling Point, Vapor Pressure, Partition Coefficient and Water Solubility) were obtained from reputable reference books, utilized accepted estimation models or are measured values which have come from acceptable studies. Thus, these values were classified as "2-Reliable with restrictions".

Environmental Fate values for Photodegradation, and Transport (Fugacity) were obtained using a computer estimation –modeling program (EPIWIN, 2002) recommended by EPA; as such, they were designated "2-Reliable with restrictions". The EPIWIN program was unable to estimate Stability in Water (Hydrolysis). Based on the lack of functional groups suggestive of the potential for hydrolysis to occur and the stability of DBPP as a test substance in dynamically conducted aquatic toxicity testing, it is accepted that DBPP does not hydrolyze in an acidic or near neutral aqueous environment. From data available, aqueous hydrolysis of DBPP can increasingly occur as alkalinity increases, a property observed with other alkyl, aryl phosphates. Thus, no additional testing is needed for further confirmation. Biodegradation testing (SCAS test) of DBPP was conducted. That study was well-documented and was conducted using methodology that proceeded, but is considered consistent with, methodology recommended in OECD test guideline 302. It, thus, has been designated as "2-Reliable with restrictions".

Ecotoxicity – An acute fish study conducted for 14 consecutive days of treatment, and thus extending OECD guidelines for Acute Toxicity to Fish (OECD 203) has been used to fulfill the Acute Fish Toxicity Endpoint. As this study was conducted according to methods which are even more rigorous than OECD guidelines for this endpoint, and as the study itself is well documented, it has been designated "1-Reliable without restrictions". Acute Plant Toxicity and the Acute Invertebrate Toxicity studies, consistent with OECD test guidance, have been designated "2-Reliable with restrictions". Additionally, chronic aquatic studies with r. trout and daphnia (both considered "1-Reliable without restriction") further support these HPV Endpoints such that no additional testing with DBPP is warranted.

Mammalian Toxicity Endpoints (Acute Toxicity, Repeated Dose Toxicity, Ames and Chromosomal Aberration Testing, and Reproductive Toxicity) have all been filled with tests that either conformed directly with OECD test guidance or followed test designs similar to OECD guidance.

The Acute Toxicity Endpoint is supported by an oral rat toxicity study which was conducted preceding codification of OECD and GLP guidance but was well documented and followed methodology consistent with later guidance; it is considered "2- Reliable with restrictions".

The Repeated Dose Toxicity Endpoint has been met with a 90-Day Subchronic rat study (similar to OECD guideline 408) conducted in accordance with GLPs. It has been codified as "1- Reliable without restrictions".

An Ames test, limited by conduct of a single rather than double trial, has been used to fulfill this HPV Endpoint. This study is considered "2-Reliable with restrictions". In support of that study and its results, we also provide a summary of a similar Ames test, conducted under the auspices of the US NTP, as Supplemental information. An *in vivo* Chromosomal Aberration assay has been used to support its respective

Endpoint. Following a study design equivalent to OECD guideline # 475, it has been classified as "1- Reliable without restriction".

The Reproductive Toxicity HPV Endpoint has been filled using a Two-Generation Rat Reproduction study which followed OECD test guideline #416 and is considered "1- Reliable without restriction".

Following is a tabular summary of the Test Plan developed for DBPP.

Table 1. Test Plan Matrix for Dibutyl Phenyl Phosphate (DBPP)

	Info. Avail.	OECD	GLP	Other Study	Estimat. Method	Accept-Able ?	Testing Recomm.
PHYSICAL CHEMICAL							
Melting Point	Y	N	N	N	Y	Y	N
Boiling Point	Y	N	N	N	-	Y	N
Vapor Pressure	Y	N	N	N	-	Y	N
Partition Coefficient	Y	N	N	N	-	Y	N
Water Solubility	Y	N	N	N	-	Y	N
ENVIRONMENTAL FATE ENDPOINTS							
Photodegradation	Y	N	N	N	Y	Y	N
Stability in Water	Y	N	N	N	-	Y	N
Biodegradation	Y	N	N	Y	-	Y	N
Transport between Environmental Compartments (Fugacity)	Y	N	N	N	Y	Y	N
ECOTOXICITY							
Acute Toxicity to Fish	Y	Y	Y	Y	-	Y	N
Acute Toxicity to Aquatic Invertebrates	Y	N	Y	Y	-	Y	N
Toxicity to Aquatic Plants	Y	N	N	N	-	Y	N
MAMMALIAN TOXICITY							
Acute Toxicity	Y	N	N	N	-	Y	N
Repeated Dose Toxicity	Y	Y	Y	Y	-	Y	N
Genetic Toxicity – Mutation (Ames)	Y	N	N	Y	-	Y	N
Genetic Toxicity – Chromosomal	Y	Y	Y	N	-	Y	N

Chromosomal Aberrations							
Developmental Toxicity	-	-	-	-	-	-	-
Reproductive Toxicity	Y	Y	Y	N	-	Y	N

Y = Yes; N = No; - = Not applicable

IV. DATA SET SUMMARY AND EVALUATION

The key studies used in this assessment to fulfill the HPV requirements have been placed in an Endpoint-specific matrix, and further discussed below. Robust Summaries for each study referenced can be found in Section VI of this Dossier.

A. Chemical/Physical Properties

Table 2. Selected Chemical/Physical Properties of DBPP

Chemical	Boiling Pt. (^{o}C.)	Melting Pt.(^{o} C.)	Vapor Pressure (hPa @ 25 ^{o}C)	Water Solubility (mg/L)	Partition Coefficient (Log Kow)
DBPP CAS No. 2528-36-1	131-132	87.5	0.00933	96 @ 25 ^{o}C.	4.27

All HPV Endpoints for Physical-Chemical Properties have been completed with reliable information, either taken from reputable textbook-references (Table 2), or use of an EPA-endorsed estimation model or from studies conducted specifically to derive this information. The supporting studies, which have been designated as "2-Reliable with restrictions", are included in the Robust Summary section of this Dossier.

In summary, these data indicate that DBPP is a liquid at room temperature and has a low vapor pressure. It has a moderate octanol:water partition coefficient and moderate solubility in water.

Conclusion – Adequate reference values are available to provide needed information on the Physical-Chemical Properties associated with DBPP. Therefore, no additional data development is needed for these HPV Endpoints.

B. Environmental Fate and Biodegradation

Both a Semi-Continuous Activated Sludge (SCAS) test and a River Die-Away test have been conducted with DBPP. While conducted prior to inception of standardized international guidelines for **Biodegradability** testing and GLPs, these studies followed similar standards for conduct subsequently codified into OECD guideline 302 and GLP documentation. They are considered "2-Reliable with restrictions". Both studies have been summarized in the Robust Summary section of this Dossier. The SCAS study has been selected to fulfill this HPV Endpoint and is cited in Table 3 below.

No/little information could be located regarding Photodegradation, Stability in Water (Hydrolysis) and Transport (Fugacity) for DBPP following an extensive literature search. Thus, we have incorporated the use of the estimation models found in EPIWIN (2002) for determination of these HPV Endpoints which have been designated "2-Reliable with restrictions". Estimated **Photodegradation** Rate and **Fugacity** values are cited with the Robust Summaries and also are included in Table 3; thus, these HPV Endpoints are considered complete and each judged as "2-Reliable with restrictions". Limited data is available on Stability of DBPP in Water and the EPIWIN (2002) program is not capable of estimating a hydrolysis value for DBPP. Data available support the conclusion that aqueous hydrolysis of DBPP becomes increasingly important with increasing alkalinity, a characteristic well recognized for other industrial organophosphate chemicals (Mayer, et. al., 1981).

Table 3. Environmental Fate and Biodegradation Parameters for Dibutyl Phenyl Phosphate (DBPP)

Chemical	Biodegradation Rate	Stability in Water (T ½ days @ 25 deg.)	Fugacity (%)	Photodegrad. Rate (T ½)
DBPP CAS No. 2528-36-1	95 %	>100 (pH 5) 57 (pH 7) 10 (pH 9)	Air – 1.21 Water – 40.2 Soil – 55.8 Sediment – 2.8	4.57 hrs-EPIWIN.

The Environmental Fate and Biodegradability of DBPP can be summarized as follows.

If released to the atmosphere, DBPP is expected to rapidly react by photochemically induced hydroxyl radicals, as it has an estimated photodegradation half-life of 4.5 hrs (Table 3 - Photodegradation). Fugacity modeling indicates that DBPP would be expected to precipitate into water and subsequently partition into the soil compartment (Table 3 – Fugacity). In aqueous solution, DBPP is expected to rapidly biodegrade under aerobic conditions primarily due to microbial activity. As with other industrial alkyl, aryl phosphates, it is resistant to hydrolysis in neutral or acid waters (Table 3). Upon further partitioning into the soil compartment (Table 3- Fugacity) DBPP could undergo rapid degradation, especially in a moist, basic soil environment. Like other phosphate esters, DBPP would strongly adsorb to soil particles and much would become soil-bound; thus,

leaching is not an issue. Rapid biodegradation would be the predominant fate process once in the soil compartment. Significant volatilization from soil or water to air is not expected, based on its Vapor Pressure (Table 2). Due to DBPP's modest water solubility and high binding capacity to soil particulate matter, the potential for persistence or bioaccumulation is judged as minimal.

Conclusion – Adequate studies are available to provide needed information for the HPV Designated Environmental Properties associated with DBPP. No further testing is planned.

C. Aquatic Toxicity

Sufficient information is available to characterize the acute toxicity of DBPP to algae, invertebrates and fish. An acute fish study, following OECD test guidance has been conducted on R. trout and is considered "1-Reliable without restriction". A Robust Summary has been prepared for this study and it has been cited in Table 4. Well conducted studies summarizing the effects of DBPP in *D. magna* and Selenastrum algae have been used to fulfill the Acute Invertebrate and Algal Toxicity Endpoints. While not conducted specifically to meet OECD guidelines, both studies used methodology recommended by the US EPA Committee of Methods for Toxicity Testing with Aquatic Organisms (EPA, 1975). These recommendations are consistent with OECD guidelines; the Daphnia study was conducted under GLPs. Hence, these studies have been designated as "2- Reliable with restrictions", selected for development of Robust Summaries, and are cited in Table 4. Two additional aquatic toxicity studies, an Early Life Stage study in R. trout and a Chronic Daphnia study, are included in the Robust Summary section of this dossier, as each study provides additional Supplemental information. Both acute aquatic studies (fish and daphnia) reported LC50/EC50 values in the 2.0 ppm range. Results of these chronic studies are consistent with the level of acute toxicity reported and further support use of the acute studies for HPV purposes.

Table 4. Aquatic toxicity parameters for Dibutyl Phenyl Phosphate (DBPP)

Chemical	Fish LC 50 (mg/L)	Invertebrate EC50 (mg/L)	Algae EC50 (mg/L)
DBPP CAS No. 2528-36-1	2.7 (R. trout)	2.3 (D. magna)	5.4 (Selenastum)

Conclusion – An adequate study is available to meet each of the three Acute Aquatic Toxicity Endpoints for DBPP. No additional testing is necessary for this completed HPV Endpoint category.

D. Mammalian Toxicity Endpoints

A summary of toxicity data used to fulfill the HPV Endpoints for Mammalian Toxicity is found in Table 5. Each report citation has been further summarized in the Robust Summary section of this Dossier.

Table 5. Mammalian Toxicity of Dibutyl Phenyl Phosphate (DBPP)

Chemical	Acute Oral LD50 (rat)	Repeat Dose Toxicity	Ames Test	Chromosomal Aberrations	Reproductive Toxicity
DBPP CAS No. 2528-36-1	2,620 mg/kg	(91-day Rat oral) NOEL = 5 mg/kg/d	Non-mutagenic TA 1535, 1537, 1538, 98, 100 with and w/out S9	(in vivo rat bone marrow) Non-mutagenic	(2-Gen. rat) NOEL = 5 mg/kg/d

1.0 Acute Toxicity

Results of an acute oral toxicity study with DBPP fulfills the HPV Acute Toxicity Endpoint. While conducted prior to OECD Test Guidelines and GLP guidance, its study design is generally consistent with present testing guidance and provides sufficiently reliable, documented information to be classified as "2- Reliable with restrictions".

Thus, DBPP is considered to be slightly toxic after administration by acute oral dosing.

Conclusion – A study of sufficient quality is available to assess the Acute hazard associated with DBPP. Therefore, no additional data development is needed for the Acute Toxicity HPV Endpoint.

2.0 Repeated Dose Toxicity

DBPP has been adequately tested in a subchronic rodent study to define its Repeated Dose toxicity. This study is cited in Table 5 and summarizes a 91-day subchronic rat study by the oral route. This study was conducted using a study design according to OECD Test Guideline 408, and conducted under GLP auspices. Hence, it is considered "1- Reliable without restriction". In all cases, no evidence of an effect on the male or female reproductive organs (including testes) was observed. Urinary bladder and liver proved to be microscopically derived target tissues. The Urinary bladder effects seen are considered related to the Tributyl Phosphate (TBP), in as much as the pathological lesions reported in this study have been seen with TBP (Cascieri et al. 1985; Laham et al, 1985); TBP accounts for approximately 15 % of commercial DBPP. Statistically significant, but generally slight, inhibition of cholinesterase appeared to be of a subclinical nature, as no classical signs of cholinesterase inhibition were observed in rats

from this study; similarly, no classical signs of cholinesterase inhibition were observed in other repeated dose studies (2-Gen. reproductive toxicity study, reported later) or in the acute oral toxicity study previously described. No gross, organ weight/ratio (testes only) or microscopic effects were observed in the ovaries or testes/epididymides or in central/peripheral nerves at any dose level in this study.

Conclusion - The Repeated Dose HPV Endpoint for DBPP has been fulfilled with a well-conducted and documented 91-Day Subchronic study in rats deemed "1-Reliable without restriction". No further testing is needed for completion of information related to the Repeat Dose HPV Endpoint.

3.0 Mutagenicity and Chromosomal Aberrations

3.1 Ames/Point Mutation Testing

When tested in the standard Ames assay for point mutations, DBPP elicited no mutagenic response in any of the *S. Typhimurium* tester strains employed, either with or without inclusion of metabolic activation (Table 5). This study has been classified as "2-Reliable with restrictions" due to its use of fewer replications than recommended in OECD study guide # 471. However, an additional Ames assay (Zeiger et al, 1985), conducted on behalf of the NCI/NTP program, validates the lack of mutagenicity seen in the Ames test with DBPP. The Zeiger et al study is also summarized in the Robust Summary section of this Dossier and referenced in Table 5.

Thus, it is concluded that adequate testing of sufficient quality has been performed on DBPP to evaluate the Ames Test (Point Mutation) HPV requirement; no further testing is needed for this Endpoint.

3.2 - Chromosomal Aberrations

DBPP has been tested *in vivo* for induction of Chromosomal Aberrations in rat bone marrow cells. This study followed OECD Guideline # 475 and was conducted following GLPs. Thus this study is considered as "1-Reliable without restriction". No mutagenic activity was observed with DBPP.

The HPV Chromosomal Aberration Endpoint for testing of DBPP has, thus, been fulfilled with an adequately conducted and documented *in vivo* study; thus, no further testing is needed.

4.0 Reproductive Toxicity

Of direct relevance to completion of the Reproductive Toxicity Endpoint for this HPV assessment with DBPP, is identification of a well documented 2-Generation rat reproduction toxicity study conducted according to OECD Guideline 416. This study has been assessed as "1- Reliable without restriction". It has been summarized in the Robust Summary section of this Dossier and is included in Table 5.

No evidence of morphological effects of either male or female reproductive organs was observed following subchronic DBPP testing (Table 5), nor was there any increase in organ weights or weight ratios of testes/epididymides after subchronic, repeated dose testing.

I**n conclusion, the Reproductive Toxicity HPV Endpoint has been fulfilled using a well documented and conducted 2-Generation reproductive study which has been assessed as "1- Reliable without restriction". Thus, the data requirements for this HPV Endpoint have been met and no further testing is required.**

V. REFERENCES

ACGIH. 2002. American Conference of Governmental Industrial Hygienists. TLV®s and BEI®s Based on the *Documentation of the Threshold Limit Value & Biological Exposure Indices,* Cincinnati, Ohio.

Casieri, T, Ballester, EJ, Seaman, RF, McConnell, JW, Thackara, JW and Fletcher, MJ. 1985. Subchronic toxicity study with tributyl phosphate in rats. Toxicologist 5:97.

EPIWIN. 2002. Version 3.10, Syracuse Research Corporation, Syracuse, New York.

Klimisch, H.-J., Andreae, M. and Tillman, U. 1997. A systemic approach for evaluating the quality of experimental toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Laham, S, Long, G and Broxup, B. 1985. Induction of urinary bladder hyperplasia in Sprague-Dawley rats orally administered tri-n-butyl phosphate. Arch. Environ. Health 40:301-306.

Mayer, FL, WJ Adams, MT Finley, PR Michael, PM Mehrle and VW Saeger. 1981. In: *Aquatic Toxicology and Hazard Assessment*, ASTM STP 737, DR Branson and KL Dickson, Eds. American Society for Testing and Materials, Philadelphia, 103-137 pp.

US EPA. 1975. Committee of Methods for Toxicity Testing with Aquatic Organisms. Methods of acute toxicity tests with fish, macroinverterates and amphibians. US EPA Ecol. Res. Ser. 660/3-75009.

US EPA, 1998. Guidance for meeting the SIDS requirements (The SIDS Guide). Guidance for the HPV Challenge Program (11/31/98).

US EPA, 1999a. Determining the adequacy of existing data. Guidance for the HPV Challenge Program (2/10/99).

US EPA, 1999b. The use of structure-activity relationships (SAR) in the High Production Volume Chemicals Challenge Program. OPPT, EPA.

Zeiger, E, Anderson, B, Haworth, S, Lawlor, T and K Mortelmans. 1988. *Salmonella* Mutagenicity Tests: IV. Results from the testing of 300 chemicals. Environ. Mol. Mutagen. 11 (12):1-158.

VI ROBUST STUDY SUMMARIES -

A IUCLID Data Set for DBPP is Appended

I U C L I D

Data Set

Existing Chemical	:	ID: 2528-36-1
CAS No.	:	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
Revision date	:	
Date of last update	:	17.07.2003
Number of pages	:	29
Chapter (profile)	:	Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4
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

1.7.1 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

2.1 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 = Co/Cw where Co and Cw 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 (4)

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in	:	Water
Value	:	= 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.

Replicate extractions and analyses were conducted.

Result : 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

3.1.1 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 cm3/(molecule*sec). Based on 1.5E6 OH molecules/cm3 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 (5)

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 resistent to hydrolysis in neutral or acid conditions, but does hydrolyze under more basic conditions.

pH	Hydrolysis T 1/2 (days) at 25 deg. C
5	> 100
7	57
9	10

Report Limited to methods and summary data. However, sufficient information is available to understand properites of DBPP, which are consistent with other alkyl, aryl phosphates.

Flag	:	Critical study for SIDS endpoint

23.06.2003 (6)

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

06.06.2003 (7)

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

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 ± 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 : (2) valid with restrictions
Flag : Critical study for SIDS endpoint
17.07.2003 (4)

Type : aerobic
Inoculum : other: natural river water
Concentration : 1 mg/l related to Test substance
related to
Contact time : 28 day(s)
Degradation : - (±) % after
Result :
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).

dual-flame ionization detection (GC-FID/FID).

Result : 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 CaCO3; and total alkalinity, 360 mg/L. Water quality was measured five times during the test (temperature, DO, pH, NH3). 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 (8)

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

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 ± 1°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 mortalites 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 : no data
Method : 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 ± 1°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 (11)

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 ± 1°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 CaCO3; and total alkalinity, 368 mg/L. Water quality was measured periodically during the test (temperature, DO, pH, NH3). Test water was maintained at 10 ± 1 °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 (13)

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 -

Analytical monitoring	:	yes
Method	:	other: "Protocol for Conducting Chronic Toxicity Tests with the Water Flea (Daphnia magna)."
Year	:	1980
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	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. 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 (<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. 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). 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 22 ± 1°C, 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. 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.
Remark	:	Supplemental HPV study as a fully acceptable acute study has already been reviewed for this endpoint.
Result	:	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.
Reliability	:	(1) valid without restriction

06.06.2003 (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

Type	:	LD50
Value	:	2620 - mg/kg bw
Species	:	rat
Strain	:	Sprague-Dawley
Sex	:	male/female
Number of animals	:	22
Vehicle	:	
Doses	:	2250, 2500, 2750 and 3000 mg/kg
Method	:	other
Year	:	1959
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	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).
Result	:	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 congenstion of the lungs were observed.
Reliability	:	(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.
Flag	:	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

Type	:	Sub-chronic
Species	:	rat
Sex	:	male/female
Strain	:	Sprague-Dawley
Route of admin.	:	oral feed
Exposure period	:	91 days
Frequency of treatm.	:	daily
Post exposure period	:	none
Doses	:	0, 5, 50 and 250 mg/kg/d
Control group	:	yes
NOAEL	:	>= 5 - mg/kg bw
LOAEL	:	= 50 - mg/kg bw
Method	:	OECD Guide-line 408 "Subchronic Oral Toxicity - Rodent: 90-day Study"
Year	:	1986
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4

Method : 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 controled. 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.

Result : 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 thyphimurium 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

Method	:	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 etal 1983 (NTP). The preincubation assay was performed usig 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.
Remark	:	Supplemental study confirming lack of mutagenic response of DBPP in Salmonella test.
Result	:	No mutagenic response observed at any test strain, with or without metabolic activation.
Test substance	:	Commercial grade DBPP.
Reliability	:	(2) valid with restrictions

17.07.2003 (17)

5.6 GENETIC TOXICITY 'IN VIVO'

Type	:	Cytogenetic assay
Species	:	rat
Sex	:	male/female
Strain	:	Fischer 344
Route of admin.	:	i.p.
Exposure period	:	Single IP doses followed by sacrifices after 6, 12 and 24 hr
Doses	:	0, 40, 200 and 400 mg/kg (males) and 0, 60, 300 and 600 mg/kg (females)
Result	:	negative
Method	:	OECD Guide-line 475 "Genetic Toxicology: In vivo Mammalian Bone Marrow Cytogenetic Test - Chromosomal Analysis"
Year	:	1986
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	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 Bartletts test + ANOVA. If significance was determined then Dunnett's test was applied. $p<0.05$.
Result	:	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	:	premating (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 controled. 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

gross examination. After weaning of F1a pups. all low and mid dose F0 parental males and female were sacrified 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 Nenenyi -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. $P<0.05$

Result : 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 premating 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.

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

Reliability : (1) valid without restriction
Flag : Critical study for SIDS endpoint
17.07.2003 (19)

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

23.05.2003

5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

5.11 ADDITIONAL REMARKS

6.1 ANALYTICAL METHODS

6.2 DETECTION AND IDENTIFICATION

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

(1) MPBPWIN. Version 1.40. EPIWIN (Estimation Program Interface for Windows). Version 3.05. Syracuse Research Corporation. Syracuse, NY. (EPIWIN, 2000)

(2) ACGIH. 1986. American Conference of Governmental Industrial Hygienists in Documentation of TLVs and BEIs. 5th edition. Cincinnati, Ohio. p. 176.

(3) Occupational Safety and Health Administration (OSHA). 2002. Occupational Safety and Health Guideline for Dibutyl Phenyl Phosphate. U.S. Department of Labor. http://www.osha-slc.gov/SLTC/healthguidelines/dibutylphenylphosphate/recognition.html (accessed 10/31/2002).

(4) Saeger, V.W., O. Hicks, R.G. Kaley, P.R. Michael, J.P. Mieure, and E.S. Tucker. 1979. Environmental fate of selected phosphate esters. Environ. Sci. Technol. 13:840.

(5) AOPWIN. Version 1.90. Atmospheric Oxidation. EPWIN (Estimation Program Interface for Windows). Version 3.05. Syracuse Research Corporation. Syracuse, NY. (EPIWIN, 2000)

(6) Monsanto Co. internal memo. 1978. PRM. Phosphate Ester Hydrolysis. EPA OTS90519459 (ID No. 40-7842792).

(7) Level III Fugacity Model. EPIWIN (Estimation Program Interface for Windows). Version 3.05. Syracuse Research Corporation. Syracuse, NY. (EPIWIN, 2000)

(8) Solutia Study no. AB-79-325. 1979. Dynamic Toxicity of DBPP (AB-79-1384336-3) to Rainbow Trout (Salmo gairdneri).

(9) USEPA EcoSAR model (v. 0.99f).

(10) ABC Laboratories, Inc. 1978. Acute Toxicity of DBPP (AB-78-1384336-1a) to Daphnia magna. Solutia Study No. AB19790149. Report #22307B.

(11) USEPA. ECOSAR model (v. 0.99g). EPIWIN. Version 3.10.

(12) EG&G Bionomics. 1978. Toxicity of Dibutylphenyl Phosphate (BN-78-1384336-2) to the Freshwater Alga, Selenastrum capricornutum. Report #BP-78-12-198. Solutia Study No. BN19790148

(13) ABC Laboratories, Inc. 1980. Early Life Stage Toxicity of DBPP to Rainbow Trout (Salmo gairdneri) in a Flow-Through System. Report to Monsanto Chemical Company (AB-80-516), September 4, 1980.

(14) EG&G Bionomics. 1980. The Chronic Toxicity of Dibutylphenyl Phosphate to the Water Flea (Daphnia magna). Report #BW-80-4-651. Solutia Study No. BN19800300.

(15) Solutia Study no. Y-56-29. Toxicological Investigation of DiButyl Phenyl Phosphate.

(16) Solutia Study no. HL-84-348; Subchronic Toxicity Study in Rats: Dibutylphenyl Phosphate (DBPP) [also published as Healy, CE, RS Nair, JK Lemen, FR Johannsen. 1991. Fundam. Appl. Toxicol. 16:117-127].

(17) Zeiger, E, B Anderson, S Haworth, T Lawlor, K Mortelmans. 1988. Salmonella Mutagenicity Tests: IV. Results from the testing of 300 chemicals. Environ. Mol. Mutagen. 11 (supplement 12): 1-158.

(18) Solutia Study no. SR-84-416; An Assessment of the Mutagenic Potential of Dibutylphenyl Phosphate in the Acute In Vivo Rat Bone Marrow Cytogenetics Assay.

(19) Solutia Study No. HL-84-349. Two Generation Reproduction Study in Rats. Dibutylphenyl Phosphate.[also published in Healy, CE, RS Nair, NK Lemen, FR Johannsen. 1991. Subchronic and Reproductive Studies with Dibutyl Phenyl Phosphate in Sprague-Dawley Rats. Fundam. Appl. Toxicol. 16: 117-127].

10.1 END POINT SUMMARY

10.2 HAZARD SUMMARY

10.3 RISK ASSESSMENT