AR201-13460

American Chemistry Council *Good Chemistry Makes It Possible*

December 21, 2001

Via Certified Mail and e-mail

Christine Todd Whitman, Administrator
U.S. Environmental Protection Agency (EPA)
P.O. Box 1473
Merrifield, VA 22116

**Re: Brominated Flame Retardant Industry Panel (BFRIP),
HPV Chemical Challenge Program Submission,
Test Plans and Data for Cyclododecane, 1,2,5,6,9,10-hexabromo- (CAS No. 319-455-6) and Phenol, 4,4-isopropylidenebisO2,6-dibromo-(sic) (CAS No. 79-94-7)**

Dear Administrator Whitman:

The BFRIP of the American Chemistry Council is pleased to submit the attached data assessment for Cyclododecane, 1,2,5,6,9,10-hexabromo- (CAS No. 319-455-6) and Phenol, 4,4-isopropylidenebisO2,6-dibromo-(sic) (CAS No. 79-94-7) to EPA's HPV Chemical Challenge Program (Program). This submission fulfills BFRIP's commitment to the Program for the year 2001. Data for two additional chemicals will be submitted in time to meet our commitment for 2003. BFRIP member companies are Albemarle Corp., Great Lakes Chemical Corp. and Ameribrom, Inc., a subsidiary of Bromine Compounds Ltd.

In addition to the test plans and data summaries for (CAS No. 319-455-6) and (CAS No. 79-94-7), please also find a set of robust summaries contained in EPA's HPV format document for both of these chemicals.

This subemission is also being sent electronically to the following e-mail addresses:

Oppt.ncic@epa.gov
Chem.rtk@epa.gov

In preparing this test plan, the Panel has given careful consideration to the principles contained in the letter EPA sent to all Program participants on October 14, 1999. As requested by EPA in that letter, the Panel has sought to maximize the use of scientifically appropriate categories of related chemicals and of structure activity relationships.

MF-53600

If you require additional information, please contact the BFRIP's technical contact, Wendy K. Sherman at (703) 741-5639 or wendy_sherman@americanchemistry.com.

Sincerely yours,

Courtney M. Price
Vice President, CHEMSTAR

Attachments

cc: C. Auer, EPA/OPPT
B. Leczynski, EPA/OPPT
BFRIP Members
Steve Russell, ACC (without attachments)

AR201-13460A

HPV

DATA SUMMARY AND TEST PLAN

FOR

PHENOL, 4,4'-ISOPROPYLIDENBIS[2,6-DIBROMO-

(TETRABROMOBISPHENOL A, TBBPA)

CAS No. 79-94-7

Prepared by

American Chemistry Council
Brominated Flame Retardant Industry Panel (BFRIP)
1300 Wilson Blvd
Arlington,VA

December 20, 2001

1.0 INTRODUCTION

The Brominated Flame Retardant Industry Panel (BFRIP) was formed in the 1980s to address issues related to the brominated flame retardants that its members manufacture in common, conduct research, and interact with regulatory agencies and other interested parties. Its members, who are global manufacturers of brominated flame retardants, are Albemarle Corporation, Ameribrom Inc. (a subsidiary of Dead Sea Bromine Group), and Great Lakes Chemical Corporation. Akzo-Nobel is an associate member. BFRIP, organized under the American Chemistry Council, volunteered under the U.S. EPA's High Production Volume (HPV) program to prepare the Data Summary/Test Plan and Robust Summaries for phenol, 4,4'-isopropylidenbis{2,6-dibromo. This compound (CAS No. 79-94-7) is also known as tetrabromobisphenol A or TBBPA. As discussed below, TBBPA is a data-rich chemical, including valid guideline studies or other information for all SIDS endpoints. For that reason, no additional tests are proposed for purposes of this program.

2.0 TBBPA STRUCTURE AND PROPERTIES

TBBPA, a solid at room temperature, is a brominated phenolic molecule with a molecular weight of 543.87 (Figure 1). The composition of the commercial product is typically 98% TBBPA with the remainder composed of other brominated bisphenol A compounds. Its measured vapor pressure and log octanol/water partition coefficient are $<1.19 \times 10^{-5}$ Pa *(Lezotte, F. and Nixon, W. Project Number 439C-128. 2001. Wildlife International, Ltd, Easton, MD)* and 5.903 *(MacGregor, J. and Nixon, W. Project Number: 439C-129. 2001. Wildlife International, Ltd. Easton, MD)*, respectively. TBBPA's melting point is 181°C *(Albemarle Corporation, 2001)*, and its water solubility has been described as 0.001002 mg/L *(estimated, EPIWIN V3.04)*; <0.5 ug/L *(Albemarle Corporation 2000)*; ≤0.8 ug/L *(Brekelman, 2000)*.

TBBPA has been analyzed for the presence of 15 2,3,7,8-substituted polybrominated-p-dibenzodioxins and dibenzofurans. None of the analytes were present at or above the quantitation limits established by the U.S. Environmental Protection Agency *(Ranken et al., Bul. Soc. Chim. Belg., 103/5-6, 1994)*.

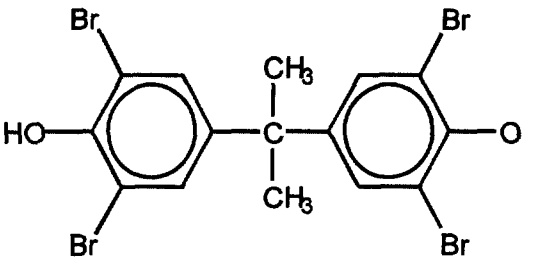

Figure 1. Tetrabromobisphenol A (TBBPA)

3.0 TBBPA APPLICATIONS

TBBPA is used as a reactive flame retardant in epoxy resin printed circuit boards and as an additive flame retardant in acrylonitrile-butadiene-styrene (ABS) resins for electronic enclosures. In the epoxy resin circuit boards, TBBPA covalently reacts with the epoxy resin backbone and ceases to exist as a chemical entity. TBBPA is the predominant flame retardant used in printed circuit boards worldwide. The reasons for TBBPA's dominance is that it is highly effective as a flame retardant and needs only low load levels, highly cost effective, compatible with the circuit board's other components, able to maintain the board's physical properties, qualified for use, and has health and safety data supporting its use. TBBPA is also used as the starting material for the production of TBBPA-derived flame retardants.

4.0 TBBPA TOXICOLOGY DATA SUMMARY

4.1 Environmental Fate (BFRIP)

TBBPA's measured and predicted environmental fate parameters are provided in Table 1.

TBBPA is predicted to partition to soil and sediment if released to the environment. Based on a release of 1,000 kg/hr to air, water and soil, the predicted partitioning is: air – 0.0000004%, water - 1.13%, soil - 44.9%, and sediment - 53.9% *(Level III Fugacity Model, EPIWIN V3.04, Syracuse Research Corporation).* The majority would be reacted in sediment and soil (83.9%) with only 16.1% of the total undergoing advection. TBBPA is expected to be essentially immobile in soil, where it can undergo degradation. Actual test data shows TBBPA's half-life in a 64-day aerobic and anaerobic soil studies to be approximately 50 days and in a 56-sediment/water degradation study, 48 to 84 days *(Fackler 1989).*

TBBPA is not expected to volatilize from water based on its air-water partition coefficient and its river and lake volatilization half lives, and is expected to partition to biomass *(EPIWIN V3.04, Syracuse Research Corporation).*

While not expected to undergo biodegradation during sewage treatment, TBBPA is expected to be removed from the effluent during passage through a wastewater treatment plant. Removal is estimated to be via sludge adsorption (93.14%) with only minimal biodegradation (0.78%). A total removal of 93.9% is predicted *(STP Fugacity Model, EPIWIN V3.04, Syracuse Research Corporation).*

4.1.1 Photodegradation

TBBPA may undergo abiotic degradation. TBBPA's calculated half-life in water by UV radiation was 10.2 days in spring, 6.6 days in summer, 25.9 days in autumn, and 80.7 days in winter. The half-life of TBBPA adsorbed onto silica gel and exposed to UV radiation was 0.12 days. *(reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995).*

Photolysis of TBBPA in the presence of UV light and hydroxyl radicals has also been reported; TBBPA was reported to totally degrade within 5-6 days with an estimated 33 hour half-life *(Eriksson and Jakobsson, 1998, Organohalogen Compounds, Vol 23, 419-422).*

Table 1. Environmental Fate Parameters for TBBPA.

Parameter	Estimation Program or Test Result	Result
Photodegradation	WHO EHC #172, 1992	Has potential to undergo photodegradation; However, not likely to be a significant route of environmental degradation due to low vapor pressure
Hydrolysis	-	Not likely to be a significant route of environmental degradation due to low water solubility
Distribution	Estimated (EPI win, V.3.04)	Level III Fugacity Model predicts at 1000 kg/Hr emissions to air, water and soil: Air 0.0000004 %, Water 1.3%, Soil 45%, Sediment 54%
Atmospheric Oxidation	Estimated (EPI win, V.3.04)	Overall OH Rate Constant = 2.9 x 10-12 cm3/molecule-sec Half-Life = 3.6 Days (12-hr day; 1.56 x 10+6 OH/cm3) Half-Life = 43.4 Hrs
Henry's Law Constant	Estimated (EPI win, V.3.04)	2.31 x 10-13 atm-m3/mole at 25 °C 9.43 X 10-12 unitless at 25 ° C
Soil Koc	Estimated (EPI win, V.3.04)	5.6 x 10+6
Octanol-Water Partition Coefficient	Estimated (EPI win, V.3.04)	1.6 x 10+7
Air-Water Partition coefficient	Estimated (EPI win, V.3.04)	9.4 x 10-12
Biomass to Water Partition Coefficient	Estimated (EPI win, V.3.04)	3.1 x 10+6
Volatization from Water	Estimated (EPI win, V.3.04)	Half life: 6.7 x 10+5 years (River);7.3 x 10+6 years (Lake)
Sewage Treatment Plant Fugacity Model	Estimated (EPI win, V.3.04)	Total Removal: 94%, Total Biodegradation: 0.78%, Primary Sludge: 59.8%, Waste Sludge: 33.3%, Final Water Effluent: 6%
Level III Fugacity Model	Estimated (EPI win, V.3.04)	At Emissions to Air, Water, Soil and Sediment of 1,000, 1,000, 1,000 and 0 kg/hr, respectively: Fugacity (atm): Air 4.3 x 10-17, Water 4.5 x 10-20, Soil 1.5 x 10-21, Sediment 8 x 10–20 Reaction (kg/hr): Air 0.0007, Water 48, Soil 1.9 x10+3, Sediment 570 Advection (kg/hr): Air 0.0009, Water 247, Soil 0, Sediment 237 Reaction (%): Air 2.5 x 10-5, Water 2, Soil 63, Sediment 19 Advection (%): Air 3 x 10-5, Water 8, Soil 0, Sediment 8
Biodegradation	CITI-Japan, 1992	Not readily biodegradable
	Fackler P., 1989	Aerobic Soil (64 D): Degradable, Half-life ~50 D
	Fackler P., 1989	Anaerobic Soil (64 D): Degradable, Half-life ~50 D
	Fackler P., 1989	Sediment/Water (56 D): Degradable, Half-life 67 D

4.1.2 Water Stability (Hydrolysis)

A hydrolysis study has not been conducted on TBBPA, and the EPIWIN software is unable to make a prediction for this chemical structure. However, if it occurs, hydrolysis is unlikely to be a significant route of environmental degradation for TBBPA due to its low water solubility.

4.1.3 Biodegradation

TBBPA is not "readily" biodegradable by sewage sludge, but can be degraded in soil and sediment. TBBPA's half-life in a 64-day aerobic and anaerobic soil studies was approximately 50 days. TBBPA's half-life in a 56-sediment/water degradation study was 48 to 84 days.

While not expected to be biodegraded in a wastewater treatment plant, 93.92% removal is predicted. Removal is estimated to be mainly by sludge adsorption (93.14%) with only minimal biodegradation (0.78%).

4.1.3.1 64-Day Aerobic Soil Degradation (BFRIP)

The biodegradability of ^{14}C-TBBPA was tested under aerobic conditions in three soil types, i.e., Massachusetts sandy loam, a California clay loam, and Arkansas silty loam. The three soil types contained: sand (83%)-silt (13%)-clay (4%), sand (16%)-silt (58%)-clay (26%), and sand (43%)-silt (24%)-clay (33%), respectively. Thin layer chromatography (TLC) showed biodegradation of TBBPA in all soil types. Less than or equal to 6% of the applied radioactive TBBPA was recovered in the volatile traps, indicating partial degradation to C02. Results of the TLC analysis indicated variable degradation rates of TBBPA which were dependent on soil type. After 64 days, the amount of TBBPA remaining in the soils ranged from 36 to 82%, with the highest level in sandy loam soil and the lowest in the silty loam soil. Degradation products (2 or 3 depending on soil type) were not specifically identified, but the dimethyl and diethyl derivatives of TBBPA were ruled out based on TLC characteristics of authentic standards. *(Fackler 1989, SLS Report 88-11-2848; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.)*

4.1.3.2 64-Day Anaerobic Soil Degradation (BFRIP)

The biodegradability of TBBPA was tested under anaerobic conditions in three soil types; Massachusetts sandy loam (MSL), Arkansas silty loam (ASL), and California clay loam (CCL). The three soil types contained: sand (83%)-silt (13%)-clay (4%), sand (16%)-silt (58%)-clay (26%), and sand (43%)-silt (24%)-clay (33%), respectively. Thin layer chromatography showed biodegradation of TBBPA in all soil types. Less than 0.5% of the radiolabel was recovered in the volatile traps, indicating little degradation to C02. The recovered radioactivity in all traps was almost exclusively C02. Results of the TLC

analysis indicated variable degradation rates that were dependent on the soil type. After 64 days, the amount of TBBPA remaining in the soils were MSL: 43.7-57.4%, ASL: 53.4-65%, and CCL: 89.5-90.6%. Radioactivity recovered from the water ranged from 0.5 to 2.5%. Degradation products (2 or 3 depending on soil type) were not specifically identified, but the dimethyl and diethyl derivatives of TBBPA were ruled out based on TLC characteristics of authentic standards. *(Fackler 1989, SLS Report 88-11-2849; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.)*

4.1.3.3 56-Day Sediment/Water Microbial Degradation (BFRIP)

The biodegradability of ^{14}C-TBBPA was tested under aerobic conditions in a sediment/water microbial test system using natural river sediment and water. The test conditions were pH 5.5, field moisture capacity 15.9%, temperature 24-26 degrees C, and the composition of the soil (6.8% carbon) was 925 sand, 6% silt, and 2% clay. TBBPA biodegraded at all tested concentrations (0.01, 0.1 and 1 mg/L). Half-lives calculated for TBBPA in the sediment/water microbial test systems ranged between 48 days at 0.01 ug/L concentration and 84 days at the 1 mg/L concentration with apparent correlations between half-life and TBBPA concentration and half-life and microbial population. The half-life in sterile soil was extrapolated to be 1300 days, indicating that the degradation observed in the active test systems was due to microbial degradation rather than physical processes. Less than 8% of the applied radioactive carbon from TBBPA was recovered in the volatile traps indicating partial degradation to C02. Filtered water contained less than 5% of the applied radioactivity. The amount of radioactivity observed to be remaining in the sediment at test termination, 44.7, 64.2, and 60.8% in the 0.01, 0.1 and 1 mg radioactive TBBPA/L treatments, respectively, was comparable to the amounts reported in the aerobic degradation study in soil. Half-lives calculated for TBBPA in the sediment/water microbial test systems ranged between 48 and 84 days, with an apparent correlation between half-life and concentration of TBBPA and half-life and microbial population. *(Fackler 1989, SLS Report 89-8-3070; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.)*

4.1.3.4 Sequential Anaerobic Aerobic Microbial Degradation

The degradation of TBBPA was evaluated in a sequential anaerobic-aerobic system. TBBPA was incubated with a slurry of anaerobic sediment from a wet ephemeral desert stream bed contaminated with chemical industry waste. Anaerobic incubation resulted in an 80% decreased in the original TBBPA concentration. One metabolite was produced and identified as bisphenol A (BPA). BPA persisted in the anaerobic slurry but was degraded aerobically by gram negative bacteria present in the contaminated soil. Thus, sequential anaerobic-aerobic degradation of TBBPA was observed *(Ronen et al., Appl. Environ. Microbioll, 66(6), 2372-2377, 2000).*

4.1.3.5 14-Day Activated Sludge Biodegradation

TBBPA was tested in Japan's activated sludge biodegradation test. No biodegradation was observed over the 14-day study *(Data of Existing Chemicals Based on the CSCL Japan, CITI, 1992, Tokyo).*

4.1.4 Transport (Fugacity) (BFRIP)

If released in equal amounts to air, water and soil, TBBPA was predicted to partition to soil and sediment. Based on a release of 1,000 kg/hr to air, water and soil, the predicted partitioning would be: air – 0.0000004%, water - 1.13%, soil - 44.9%, and sediment - 53.9%. The majority would be reacted in sediment and soil (83.9%) with only 16.1% of the total undergoing advection *(Level III Fugacity Model, EPIWIN modeling software, V3.04, Syracuse Research Corporation).*

4.2 Ecotoxicology Data

All LC50 and EC50 values derived from acute tests in fish, daphnia, freshwater alga, and marine alga were greater than TBBPA's estimated and measured water solubility.

TBBPA's water solubility was estimated to be 0.001 mg/L using Syracuse Research Corporation's modeling software *(EPIWIN V3.04).* It's estimated octanol water partition coefficient is 7.20 using the same software. TBBPA's measured water solubility is $\leq$ 0.08 mg/L *(Brekelman, 2000).*

4.2.2 Acute Toxicity to Fish (BFRIP)

The 96-hour LC50 values for bluegill sunfish *(Calmbacher 1978)*, rainbow trout *(Calmbacher 1978)* and fathead minnow *(Surprenant 1988; SLS Report #88-10-2834)* were 0.51, 0.40 and 0.54 mg/L, respectively. The LC50 in killifish was determined to be 8.2 mg/L at 48 hours. These acute studies were reported in the Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.

4.2.3 Acute Toxicity to Aquatic Invertebrates (BFRIP, Other)

The 48-hour LC50 for *Daphnia magna* was 0.96 mg/L *(Morrissey 1978).* The 96 hour EC50 for the Eastern oyster was 0.098 mg/L *(Surprenant, 1989, Report #89-1-2898).* The 96 hour EC50 in <1, 5, or 10 day old Mysid shrimp was 0.86, 1.1, and 1.2 mg/L, respectively *(Goodman et al., Bull. Environn. contam. Toxicol. (1988) 41:746-753).* These acute studies were reported in the Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.

4.2.4 Acute Toxicity to Aquatic Plants (BFRIP, Other)

The growth of freshwater green algae, *Selenastum capricornutum*, was not affected by 5.6 mg/L, the highest level tested *(Giddings 1988, Report No 88-10-2828; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995).*

The growth of marine unicellular alga, *Skeletonema costatum*, *Thalassiosira pseudonana*, and *Chlorella* sp. was investigated following TBBPA exposure. The 96 hr EC50 for *Clorella* was > 1.5 mg/L, the highest dose tested. The 72 hr EC50 for *S. costatum* ranged from 0.09-1.14 mg/L. The 72 hr EC50 for *T. pseudonana* ranged from 0.13-1.0 mg/L. All EC50's were higher than TBBPA's water solubility. *(Walsh et al., Ecotoxicology and Environmental Safety 14, 215-222 (1987); reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995)*

4.2.5 Prolonged Exposure Data

Prolonged exposure to TBBPA was not toxic at the limit of its water solubility to fish early life stages, the water flea *D. magna*, or the sediment midge *C. tentans*.

4.2.5.1 Fish Early Life Stage (BFRIP)

In an early life stage test, fathead minnow embryos and larvae were continuously exposed for 35 days to TBBPA concentrations 0, 0.024, 0.04, 0.084, 0.16 or 0.31 mg/L. Survival of embryos to doses less than 0.31 mg/L was unaffected; survival at 0.31 mg/L was less than controls. Growth was not affected at any dose level. The Maximum Acceptable Toxicant Concentration (MATC), the range encompassing the highest test concentration that had no significant effect and the lowest concentration that had a significant effect, was 0.22 mg/L for fathead minnow embryos and larvae exposed continuously for 35 days. The MATC in this fish early life stage test was greater than TBBPA's estimated and measured water solubility *(Surprenant, D., 1989, Study No. 89-2-2937; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995).*

4.2.5.2 Daphnia Life Cycle (BFRIP)

In a chronic study on an aquatic invertebrate specie, *Daphnia magna* were continuously exposed (flow-through) for 21 days to mean measured concentrations of 0.056, 0.1, 0.19, 0.30, 0.98 mg ^{14}C-TBBPA/L. Nominal concentrations were 0.31, 0.25, 0.5, 1.0, 2.0 mg/L. After 21 days, daphnia survival ranged from 95-100% in all treatment groups and was statistically comparable to control survival. Organism growth, e.g. individual body length, in the all treatment groups was also comparable to the control means and was not affected by treatment at any dose level. Reproduction at the highest dose level (0.98 mg/L measured or 2 mg/L nominal) was approximately one-third of that in the control groups and was statistically significantly different from controls. Reproduction at all other dose levels was statistically comparable to controls. The maximum acceptable toxicant concentration (MATC) for reproduction was > 0.3 and < 0.98 mg/L (measured concentration) or > 1 and < 2 mg/L (nominal concentration). The MATC for survival and growth was $\geq$ 0.98 mg/L (measured) or $\geq$ 2 mg/L (nominal). Survival and growth were not affected by chronic exposure of Daphnia to TBBPA. Reproduction in Daphnia was not affected by doses < 0.98 or 2 mg/L, measured or nominal, respectively. The MATC for chronic exposure of Daphnia to TBBPA was > 0.98 or 2 mg/L, measured or

nominal, respectively. All of these doses are greater than TBBPA's estimated or measured water solubility. *(Surprenant, D., 1989, Study No. 89-01-2925; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995)*

4.2.5.3 Sediment Organism Toxicity (BFRIP)

The subchronic effects of the sediment-bound form of TBBPA to a representative benthic invertebrate species, the midge *Chironomus tentans*, were determined. The study consisted of a series of three 14-day (partial life cycle) tests. Each test was conducted with sediment containing different organic carbon levels: high (6.8% organic carbon), mid (2.7%) or low (0.25%) organic carbon content. The sediments were physically characterized as having a high sand content, 2-8% silt, and were slightly acidic (pH 5.4-5.5). The sediment concentration of TBBPA ranged between 13 and 200 mg/kg (nominal).

The test systems achieved and maintained equilibrium between sediment and water for the duration of the tests. The highest mean interstitial water concentrations of TBBPA were measured in the nominal 200 mg/kg treatments where midges were continuously exposed to interstitial water concentrations of 0.046 mg/L (HOC), 0.045 mg/L (MOC) and 0.039 mg/L (LOC) TBBPA.

Sediment/interstitial water partitioning coefficients (Kd) were 7,349; 5,378 and 5,816, in the HOC, MOC, and LOC groups, respectively, at the highest dose tested. These Kd values indicate TBBPA preferentially partitions to sediment rather than water.

Midge survival and growth in all TBBPA-treated sediments was statistically comparable to control organisms. The no effect sediment concentrations were 228 to 341 mg TBBPA/kg sediment, corresponding to 0.039 to 0.046 mg TBBPA/L interstitial water. The NOEC in interstitial water was greater that TBBPA's estimated water solubility. The NOECs in both sediment and interstitial water were independent of the total organic carbon content of the sediments. *(Breteler, R., 1989, Study No. 90-08-3067A; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.)*

4.2.5.4 Amphibian Thyroid Hormone System

The potential for TBBPA to adversely affect the amphibian thyroid hormone system was investigated using the tadpole (*Xenopus*) tail regression assay. Tadpoles were microinjected with TBBPA at developmental stage 58 (hind limbs emerged; forelimbs formed, but not emerged) at doses up to 60 ug/tadpole. Tail resorption was not affected by TBBPA. Positive controls showed delayed tail resorption. *(Balch and Metcalfe, Proceedings of the 3rd Annual Workshop on BFRs in the Environment, August 2001, Burlington, Ontario).*

4.2.6 Bioconcentration Studies

Several biococentration studies have been performed. Bioconcentration studies in fish produced bioconcentration factors (BCF) ranging from 20 to 1200. The half-life in fish was < 1 day, and plateau levels were reached in appr. 4 days. During depuration, TBBPA and its metabolites were eliminated within 3-7 days.

TBBPA's bioconcentration factor in oysters was 720 and its depuration half-life was 3- 5 days. TBBPA's BCF in sediment midges was $\lesssim$ 1000, except when tested in low (<1%) organic carbon sediments.

4.2.6.1 Carp Bioconcentraton

The bioconcentration of TBBPA was evaluated in Japanese carp following an 8 week exposure period at concentrations of 8 or 80 ug/L. The BCF was 30~341 at 80 ug/L and 52~485 at 8 ug/L. The LC50 in killifish was determined to be 8.2 mg/L at 48 hours. *(Data of Existing Chemicals Based on the CSCL Japan, CITI, 1992, Tokyo; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995)*

4.2.6.2 Fathead Minnow Bioconcentration (^{14}C-TBBPA) (BFRIP)

Fathead minnows were exposed to 4.7 ug/L ^{14}C-TBBPA (flow through conditions) for a 24-day exposure period followed by a 6-day depuration period. ^{14}C-activity remained below the limit of radiometric detection in water during depuration. The concentration of ^{14}C-activity in fish tissue reached a steady-state level on day 4 of exposure. The mean steady-state concentration on a whole body basis was 5,800 ug/Kg or a BCF of 1200 (mean equilibrium tissue concentration = 5800 ug/kg; mean water concentration = 4.7 ug/L). This BCF value was based on ^{14}C-residues and therefore represents the sum total of parent compound, any retained metabolites and assimilated carbon. The BCF of the parent compound (TBBPA) may be lower.

Rapid elimination of the radiolabel was observed. The whole-body half-life in the fish was < 1 day. 98% of the ^{14}C-activity was eliminated by 6 days of depuration; elimination of 95% occurred between day 1 and 4 of depuration. ^{14}C-TBBPA residues did not persist in fish tissue. *(Fackler, P., 1989, SLS No. 89-3-2952; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.)*

The results of this study indicated ready uptake in continuously exposed fathead minnows with steady-state reached within 4 days. Extending the period of continuous exposure up to 24 days did not increase the levels in fish. During depuration, the fathead minnows rapidly and nearly completely eliminated the ^{14}C-residue. The whole body half- life was < 24 hours and by day 6 of the elimination period only 2% of the ^{14}C-residue remained in the exposed fish. Therefore, these residues should not persist once the fish are no longer continuously exposed. Intermittent exposures should not result in any significant TBBPA tissue residues because of the short half-life (<24 hours) of TBBPA and its metabolites.

4.2.6.3 Blue Gill Sunfish Bioconcentration (^{14}C-TBBPA)

Blue gill sunfish were exposed to ^{14}C-TBBPA for 28 days to 0.0098 mg/L (flow-through) followed by a 14-day withdrawal period. The bioconcentration factor (BCF) in edible tissue was 20 and 170 in visceral tissue. These BCF values were based on 14C-residues and therefore represent the sum total of parent compound, any retained metabolites and assimilated carbon. Plateau levels were reached within 3-7 days. The whole body half-life was < 24 hours. The radiocarbon dissipation to <0.01 mg/kg in fish tissue occurred within 3-7 days of the beginning of the withdrawal phase. TBBPA did not show accumulation potential in this test. *(Nye, D., 1978, Project 780241; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995)*

4.2.6.4 Bioconcentration in Eastern Oysters (^{14}C-TBBPA) (BFRIP)

Eastern oysters were exposed to nominal concentration of 1 ug/L of 14C-TBBPA for 20 D followed by a 14-day depuration period. The concentration of 14C-residues in the aquaria water remained constant throughout the 20-day exposure period. During depuration 14C-residues in the water remained $\leqq$ 0.34 ug/L, the limit of radiometric detection. 14C-residues reached steady-state in oyster tissues by day 5. The mean steady-state bioconcentration factor was 720. The depuration half-life was between 3-5 days *(Fackler, P. 1989, SLS Number 89-1-2918; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995).*

4.2.6.5 Chironmid (BFRIP)

The subchronic effects of TBBPA on the survival and growth of the sediment midge, Chironomus tentans, were evaluated in a 14 day continuous exposure via treated sediments under flow-through conditions. As a part of the study, bioconcentration factors were calculated (ratio of the body concentration and interstitial water). In the high (>4%) organic carbon sediment, the BCF ranged from 240-520. In the mid (1.5-3%) organic carbon sediment, the BCF ranged from 490-1100. In the low (<1%) organic carbon sediment, the BCF ranged from 650 to 3200. TBBPA accumulated substantially less in high organic than in low organic sediment, indicating that bioavailability was significantly affected by the total organic carbon content in the sediment. In the high and mid organic carbon sediments, TBBPA's BCF was $\lessapprox$ 1,000. Only in the low (<1%) organic carbon sediment at the highest dose tested, 200 mg/kg sediment, was the BCF > 1,500 *(Breteler, R., 1989, SLS No. 89-08-3067; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995).*

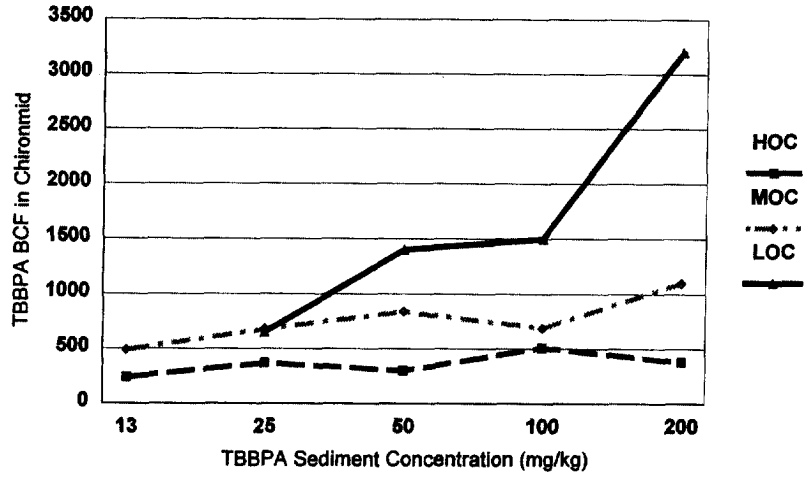

Figure 2. TBBPA BCF in *Chronomus tetans* following a 14-day sediment exposure.

4.3 Mammalian Toxicology Data

TBBPA produced minimal effects in mammals when tested in acute and subchronic studies. TBBPA was not acutely toxic or irritating to the skin or eye. TBBPA did not induce chloracne on skin exposure and did not induce skin sensitization in guinea pigs. Testing in human volunteers showed no evidence of irritation or induction of skin sensitization. TBBPA was negative in the Ames Salmonella mutagenicity test and in the *in vitro* chromosome aberration test. Pharmacokinetic studies demonstrate TBBPA has a short half-life and is readily metabolized and excreted, as would be expected of a chemical possessing two hydroxyl groups suitable for metabolic conjugation.

4.3.1 Acute Toxicity Data

The oral LD50 in the rat is >5,000 mg/kg and the dermal LD50 in rabbits is > 2,000 mg/kg. TBBPA was also not acutely toxic by inhalation; the inhalation LC50 in rats is >2550 mg/m^3 for a 2 hour exposure. TBBPA is not irritating to the skin or eye. These acute studies were reported in the Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.

4.3.2 Repeated Dose Toxicology

4.3.2.1 14-Day Rat Inhalation

In a 14-day inhalation study, no systemic toxicity was observed in rats treated with up to 18 mg/L. Rats were exposed to an atmosphere of 0, 2, 6 or 18 mg micronized TBBPA/L air (0, 2000, 6000, or 18,000 mg/m3) for 4 h daily, 5 days/week for 2 weeks. Mortality, body weight gain, food consumption, hematological, biochemical or urinary parameters were not affected by treatment. No gross or microscopic lesions were detected in any

dose level. *(Goldenthal et al. 1975; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995)*

4.3.2.2 21 Day Rat Dermal

In a 21-day dermal study, no systemic toxicity was observed in rabbits treated with 0, 100, 500, or 2,500 mg TBBPA/kg body weight for 6 hours/day, 5 days/week for 3 weeks. No mortality or overt signs of toxicity were observed. Body weight gain, hematological parameters, urinalysis, organ weights, and gross and microscopic examinations did not reveal any compound-related changes. *(Goldenthal et al., 1979; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995)*

4.3.2.3 28-Day Rat Oral

In a 28-day oral study, no toxicity was observed in rats treated with up to 1,000 ppm TBBPA in the diet. Rats were fed at dietary dose levels of 0, 1, 10, 100 or 1000 ppm TBBPA for 28 days after which one group was sacrificed and the remaining rats placed on untreated diets for 2, 6 or 12 weeks. No effects on general appearance, behavior, body weight, food consumption or mortality were observed. No compound related gross or microscopic lesions or variations in organ weights were observed at any dose level. Liver and adipose bromine levels were similar in rats of the control and high dose groups sacrificed at the end of the 28 day treatment period. *(Goldenthal and Geil, 1972; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995)*

4.3.2.4 90-Day Rat Oral

In a 90-day oral study, no toxicity was found in rats treated with up to 100 mg/kg in the feed. Rats were fed a diet supplying 0, 0.3, 3, 30 or 100 mg TBBPA/kg body weight for 90 days. No toxicological effects were detected at any dose level for appearance, demeanor, body weight gain, food consumption, hematology, clinical chemistry values, urinalysis, organ weights, and gross and microscopic examinations. The total bromine content in liver, kidney, skeletal muscle, fat and serum of rats in the 3 mg/kg dose group did not differ from that of the controls. (The 3 mg/kg group was the only group tested for total bromine content.) *(Quast et al. 1975; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995).*

4.3.2.5 90-Day Rat Oral

In another 90-day study, a no adverse effect level of 4,900 mg/kg diet (~700 mg/kg body weight) was determined in mice *(Tobe et al., 1986; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995).*

4.3.3 Genetic Toxicity – Mutation

4.3.3.1 Ames Salmonella

TBBPA has been tested in multiple Ames assays. All results were negative for mutagenicity *(reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995).*

4.3.3.2 Intragenic recombination

The Sp5 and SPD8 cell lines were developed by the paper's authors. The clones used in this study exhibit spontaneous partial duplication of the hprt gene, resulting in a non-functional hgprt protein. These mutants revert spontaneously to a functional hprt gene phenotype by recombination with a frequency of 1×10^5 reversions/cell generation. This reversion frequency is said to increase by exposure to chemical or physical agents. Treatment with the test substance was for 24 hr.

In the SPD8 cells, TBBPA concentrations of 0, 5, 10, 20, 30, and 40 ug/ml resulted in a reversion frequency of 1.0, 1.1, 1.4, 1.3, 1.3, and 1.0, respectively. Cytoxicity was not observed at the doses tested. In the Sp5 cells, TBBPA concentrations of 0, 10, 20, 40, 70 ug/ml resulted in a reversion frequency of 1.0, 0.8, 0.8, 1.0 and 0.7, respectively. Cytotoxicity was observed at 70 ug/ml. None of these reversion frequencies were statistically different from the control (Student's t test, $p<0.05$). Thus, TBBPA had no effect in either the SPD8 or Sp5 recombination assay *(Helleday et al. Brominated flame retardants induce intragenic recombination in mammalian cells. Mutation Research 439 (1999) 137-147).*

4.3.4 Genetic Toxicity – Chromosome Aberration (BFRIP)

TBBPA was tested in the *in vitro* mammalian chromosome aberration test using human peripheral lymphocytes (HPBL) in both the absence and presence of an Arochlor-induced S9 activation system. Dose levels in the definitive assay in absence of exogenous metabolic activation (4 hr treatment, 20 hr harvest) were 6.25, 25, 100 ug/ml, and for a 20 hr treatment, 20 hr harvest were 6.25, 25, 75 ug/ml. In the presence of metabolic activation (4 hr treatment, 20 hr harvest), test article concentrations were 3.125, 12.5, 50 ug/ml.

The test article was soluble in treatment medium at all concentrations tested. Toxicity (mitotic inhibition) was appr. 54 and 59% at the highest dose level evaluated for chromosome aberrations, 100 ug/ml and 75 ug/ml in the non-activated 4 hr and 20 hr exposure groups, respectively. Toxicity (mitotic inhibition) was 58% at the highest dose level evaluated for chromosome aberrations, 50 ug/ml, in the S9 activated study.

No statistically significant increases in structural and numerical chromosome aberrations were observed in the non-activated or the S9 activated 4 hr exposure groups relative to the solvent control group, regardless of dose level ($p>0.05$, Fisher's exact test). In the absence of a positive response in the non-activated 4 hr exposure group, the non-activated 20 hr continuous exposure group was evaluated for structural and numerical chromosome

aberrations. No statistically significant increases in structural and numerical chromosome aberrations were observed in the non-activated 20 hr continuous exposure group relative to the solvent control group, regardless of dose level ($p>0.05$, Fisher's exact test). The positive controls performed as expected.

TBBPA was negative for the induction of structural and numerical chromosome aberrations in the in vitro chromosome aberration test using human peripheral lymphocytes *(Gudi, R. and Brown, C. In vitro chromosome aberration test. Test Article: Tetrabromobisphenol A (TBBPA). Study Number: AA47PV.341.BTL. 2001. BioReliance, Rockville, MD).*

4.3.5 Developmental Toxicity Data

Several studies have evaluated the potential of TBBPA to induce developmental effects. None were observed.

4.3.5.1 Rat Oral Prenatal Developmental Toxicity (BFRIP)

TBBPA is not a developmental toxicant (not teratogenic) in rats. TBBPA was administered by gavage at dose levels of 0, 100, 300, or 1,000 mg/kg body weight on gestation days 0-19 to pregnant rats. No signs of toxicity were observed at any dose level. No effect of treatment was evident from gestational parameters (body weight, body weight gain, or food consumption), uterine implantation data, liver weights or necropsy findings. No effect of treatment was evident from fetal body weights, fetal sex distribution, or from fetal external, visceral, or skeletal examinations *(Schroeder, R. An oral prenatal developmental toxicity study with tetrabromobisphenol A in rats. Study No. 474-005. 2001. MPI Research, Mattawan, MI.).*

4.3.5.2 Rat Oral Developmental Toxicity

TBBPA was administered by gavage at dose levels of 0, 30, 100, 300, 1,000, 3,000, or 10,000 mg/kg body weight on gestation days 6-15 to pregnant rats. No signs of toxicity were observed in rats receiving doses of 3,000 mg/kg or less. No differences in the mean numbers of viable or nonviable fetuses, resorption, implantations, or corpora lutea were detected between treated and control rats *(Goldenthal et al., 1978; reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995).*

4.3.5.3 Rat Oral Developmental Toxicity

Female rat were treated with TBBPA at doses of 0, 280, 830, or 2,500 mg/kg body weight from day 0-19 of gestation. Birth rate was not impaired by treatment. No toxic effects were observed on the embryo or fetus. No skeletal or visceral abnormalities were detected. Postnatal development (21 days post-birth) was not impaired *(Noda, et al. 1985. Annual Report, Osaka City Institute of Public Health and Environmental Sciences).*

4.3.6 Reproductive Toxicity Data

Several developmental toxicity studies on TBBPA are available, one of which was recently completed under current guidelines and Good Laboratory Practices using the TBBPA in commercial production and use at a top dose of 1,000 mg/kg/d. All studies are negative for developmental toxicity.

Several repeated dose studies, in more than one mammalian species, are also available and none show evidence of an effect on the reproductive tract.

According to the SIDS Manual, when teratology and 90 day studies show no effects on the reproductive system then the requirement for the reproductive endpoint are met.

4.3.7 Other

In the rat, TBBPA was readily absorbed, metabolized and eliminated within 72 hours after oral dosing. Recovery of ^{14}C-activity in the conventional and bile-cannulated rat administered a single oral dose of ^{14}C-TBBPA was 92 and 98.5% of the dose, respectively, by 72 hours post-dosing. Owing to the extensive elimination, total tissue retention at 72 hours was limited. In the conventional rat, 2% of the dose was retained in the tissues, but <1% in the cannulated rat at 72 hours. Essentially no deposition of TBBPA was detected in adipose tissue, heart, spleen, testis or thymus (<0.0005% of dose). The primary route of elimination was the feces; only negligible amounts were detected in urine. Glucuronic acid and sulphate ester conjugates were detected in bile; however the parent molecule was the predominant form found in species due to deconjugation by intestinal bacteria *(Haak et al., Xenobiotica, 2000, 30,9,881-890; Larsen, G. et al, Organohalogen Compounds, 31, 413-416, 199).*

Earlier work concluded that in rats, after oral dosing, approximately 95 percent of the administered material was found in the feces and less than 1.1 percent in the urine within 72 hours. Blood and tissue levels were extremely low at all time points measured. The half-life in the blood was about 20 hours; the maximum half life in any tissue was less than 3 days. Because of the short half-life, the small amounts of TBBPA absorbed would have relatively little persistence or accumulation in mammalian systems. *(Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995)*

5 TBBPA TEST PLAN

A complete set of SIDS-level data currently exists on TBBPA (Table 3), and the results are described in the attached robust summaries. Therefore, no testing is planned under this program.

Table 3. TBBPA HPV Test Plan.

Study Type	Data Available	Data Acceptable	Estimation	Testing Required
Physical/Chemical				
Melting Point	Y	Y	-	N
Boiling Point	N	-	-	N
Vapor Pressure	Y	Y	-	N
Water Solubility	Y	Y	-	N
Environmental Fate				
Photodegradation	Y	-	Y	N
Stability in Water	N	-	Y	N
Biodegradation	Y	Y	-	N
Transport (Fugacity)	N	-	Y	N
Ecotoxicity				
Acute Toxicity to Fish	Y	Y	-	N
Acute Toxicity to Aquatic Invertebrates	Y	Y	-	N
Toxicity to Aquatic Plants	Y	Y	-	N
Toxicology Data				
Acute Toxicity	Y	Y	-	N
Repeated Dose Toxicity	Y	Y	-	N
Genetic Toxicity – Mutation	Y	Y	-	N
Genetic Toxicity – Chromosome Aberration	Y	Y	-	N
Developmental Toxicity	Y	Y	-	N
Reproductive Toxicity	Y	Y	-	N

Sponsor	Albemarle Corporation	Create Date:	2/6/01
CAS Number	Phenol 4 4'-isopropylidenebis[2 6-dibromo-		
Consortium	CMA Brominated Flame Retardant Industry Panel (BFRIP)		

Select an End Point: TO - Genetic toxicity in vitro

End Points with check contain data.

Physical/Chemical Properties

- ✓ Melting Point
- Boiling Point
- ✓ Partition Coefficient
- ✓ Vapor Pressure
- ✓ Water Solubility

Environmental Fate

- ✓ Photodegradation
- Stability in Water
- ✓ Biodegradation
- ✓ Transport

Ecotoxicity

- ✓ Acute Toxicity to Fish
- ✓ Toxicity to Aquatic Plant
- ✓ Acute Toxocity to Aquatic Invertebrates

Health

- ✓ Acute Toxicity
- Genetic Toxicity in Vivo
- ✓ Repeat Dose Toxicity
- ✓ Genetic Toxicity in Vitro
- Reproductive Toxicity
- ✓ Developmental Tox/Teratogenicity

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Melting Point

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01	
CAS Number	79947	Phenol 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1	
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y	

Revision Date:
12/11/01

Test Substance

Remarks: The commercial TBBPA product supplied by Albemarle Corporation.

Chemical Category

Method

>> Method/Guideline followed

Not specified.

>> GLP: Unknown

>> Year study performed: 2000

Remarks for Method

Results

>> Precision: =

>> Melting Point Value: 181

>> Upper Value: 0

>> Unit: °C

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Melting Point

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

>> Decomposition No

>> Sublimation No

Results Remark

Conclusions

TBBPA's melting point is 181 degrees C.

Data Quality

Reliability

Data Reliability Remarks

Reference

>> Remarks Albemarle Corporation Technical Data Sheet. Available on-line at http:\\www.albemarle.com.

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Melting Point

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

General

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Partition Coefficient

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Revision Date:
12/11/01

Test Substance

Remarks

The test article was a composite of the commercial TBBPA products produced by Albemarle Corp., Dead Sea Bromine Group, and Great Lakes Chemical Corp. Its composition was TBBPA 98.91%, o,p'-TBBPA 0.05%, 2,4,6-tribromophenol <0.01%, tribromobisphenol A 1.04%.

Chemical Category

Method

>> Method/Guideline followed

OPPTS 830.7560 Generator Column Method

>> GLP Yes

>> Year study performed 2001

Remarks for Method

A single generator column was prepared. The column was packed with Chromosorb W HP support and loaded with a nominal 1.0% (w/w) solution of the test substance in octanol. Dilutions of the final test substance solution in octanol were anlayzed to determine the concentration of the test substance in octanol. The column temperature was maintained at 25 +/- 0.05 degrees C and reagent water satruated with octanol was pumped through it at approximately 1.0 mL per minute to elute the test substance. Samples of the eluate were collected and analyzed via HPLC/MS (single quadrupole MS detector operated in the negative, selective ion mode) to determine the concentration of the substance in the aqueous solute fraction. Chromatographic separations were achieved using a Keystone Betaqsil C-18 column.

Results

>> Precision =

>> Value of Log Pow 5.903

>> Upper Value 0

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Partition Coefficient

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

>> Temperature 25 degrees C

Results Remark

The octanol/water partition coefficient (Kow) of TBBPA was determined to 8.024 x 10E5 at 25 +/- 0.05 degrees C using the generator column method. The log Kow was calculated to be 5.903.

Conclusions

The octanol/water partition coefficient (Kow) of TBBPA was determined to 8.024 x 10E5 at 25 +/- 0.05 degrees C using the generator column method. The log Kow was calculated to be 5.903.

Data Quality

Reliability High

Data Reliability Remarks

This study was performed according to current guidelines by a laboratory with considerable expertise.

Reference

>> Remarks

MacGregor, J. and Noxon, W. Determination of the n-Octanol/water partition coeficient of tetrabromobisphenol A. Project Number: 439C-129. 2001. Wildlife International, Ltd. Easton, MD.

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Partition Coefficient

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

General

This study was sponsored by the ACC Brominated Flame Retardant Industry Panel.

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Partition Coefficient

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	75947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	2
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Revision Date:
12/11/01

Test Substance

Remarks: 14C-TBBPA (phenyl -UL-carbon 14), Synthesized by Midwest Research Institute, Kansas City, MO. Radiochemical purity > 98%. Specific activity 9.32 mCi/mM.

Chemical Category

Method

>> Method/Guideline followed

Other, Predates OECD and EPA Guidelines

>> GLP Unknown

>> Year study performed 1978

Remarks for Method

14C-TBBPA, n-octanol, and distilled water were added to a centrifuge tube. The tube was centrifuged at 3000 rpm for 15 minutes. Duplicate samples of the organic and aquesous phases were analyzed by liquid scintillation.

The method followed that of Leo, Hansch and Elkins (1971).

Results

>> Precision =

>> Value of Log Pow 4.54

>> Upper Value 0

>> Temperature Ambient

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Partition Coefficient

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	2
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Results Remark

The average partition coefficient of TBBPA was 34,644 (log Kow = 4.54).

Conclusions

The average partition coefficient of TBBPA was 34,644 (log Kow = 4.54).

Data Quality

Reliability Reasonable.

Data Reliability Remarks

This study is old and is not performed according to current guideline. Nonetheless, it does provide an indication of TBBPA's partition coefficient.

Reference

>> Remarks

Velsicol Chemical Company. Partition Coefcient of Several Flame Retardants and Industrial Chemicals. Testing facilitiy: Velsicol Chemical Company. Project No. 484058, Report #3. 1979.

General

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Partition Coefficient

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	2
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Sponsored by Velsicol Company

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Water Solubility

Sponsor ID	100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	N

Revision Date: 12/11/01

Test Substance

Remarks: The tests article was a composite of the commercial TBBPA products produced by Albemarle Corp, Dead Sea Bromine Group, and Great Lakes Chemical Corp.

Chemical Category

Method

>> Method/Guideline followed

OECD Method 105 (Column Elution)

>> GLP: Yes

>> Year study performed: 2000

Remarks for Method

Two columns, filled with test substance coated on an inert carrier material, were eluted with double distilled water at different flow rates. The test was performed at 21.5 +/- 1 degree C. At each flow rate, the concentration of TBBPA in the eluate was determined via HPLC at different time intervals.

Results

>> Precision: <=

>> Water Solubility Value: 0

>> Upper Value: 0

EPA High Production Volume (HPV) Track

Physical-Chemical End Point: Water Solubility

Sponsor ID	100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	N

>> Unit mg/L

>> Temperature 21.5

>> Solubility Category Insoluble

>> pH Value 0 **>> pKa Value** 0

Results Remark

At a flow rate of 23-24 ml/hr, the mean concentration was 0.82, 0.0666, 0.81, and 0.07 mg/L in the two columns. At a flow rate of 10-12 ml/hr, the mean concentration was 0.058, 0.053, 0.069, 0.056 mg/L in the two columns. At a flow rate of 5-6 ml/hr the mean concentration was 0.046 and 0.048 in the two columns.

The mean concentrations were flow dependent. The higest eluate concentrations analyzed were detected in samples taken at the high flow rates (22-24 mg/L). No explanation for the decrease in water solubility found at the lower flow rate was given. Therefore, an upper value for TBBPA's water solubility was reported <= 0.08 ml.

The pH of the water fraction collected for determination of flow rate varied from 7.6-8.1.

The pKa of TBBPA has not been determined.

Conclusions

TBBPA's water solubility was reported as <= 0.08 mg/L.

Data Quality

Reliability

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Water Solubility

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01	
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1	
Consortia ID	101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	N	

Data Reliability Remarks

Reference

>> Remarks

Brekelmans, J. 2000. Determination of the water solubility of tetrabromobisphenol A. Project No. 292804. NOTOX B.V., Hetogenbosch, the Netherlands.

General

Study sponsored by Bromine Science & Environmental Forum.

TBBPA's water solubility was estimated to be 0.001 mg/L using Syracuse Research Corporation's modeling software (EPIwin V3.04).

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Water Solubility

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	2
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	N

Revision Date: 12/11/01

Test Substance

Remarks: 14C-TBBPA (phenyl-UL-carbon 14), 9.32 mCi/mM. Synthesized by Pathfinder Labs, St. Louis, MO. Radiochemical purity > 98%

Chemical Category

Method

>> Method/Guideline followed

Predates OECD and EPA Guidelines

>> GLP: Unknown

>> Year study performed: 1978

Remarks for Method

14C-TBBPA was diluted with reference standard to achieve a suitable specific activity, and placed in a centrifuge tube (a total of 6 tubes were prepared). The solvent was evaporated to dryness, and 20 ml of distilled water added. The tubes were place in a water bath (35 degrees C) and shaken overnight. Next, the tubes were centrifuged (12,000G) for 1 hr at 15 (2 tubes), 25 (2 tubes) or 35 (2 tubes) degrees C. Solutions were anlayzed in duplicate by liquid scintillation.

Results

>> Precision: range

>> Water Solubility Value: 1

>> Upper Value: 4

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Water Solubility

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	2
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	N

>> Unit ppm

>> Temperature 15, 25, 35

>> Solubility Category Slightly soluble

>> pH Value 0

>> pKa Value 0

Results Remark

14C-TBBPA's water solubility at 15, 25 and 35 degees C was determined to be 0.72, 4.16, and 1.77 ppm, respectively.

The pH at which this study was conducted was not reported. The pKa of TBBPA has not been determined.

Conclusions

14C-TBBPA was found to be slightly soluble (0.7 - 4 ppm) in water.

Data Quality

Reliability Unknown.

Data Reliability Remarks

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Water Solubility

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	2
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	N

Reference

>> Remarks

Velsicol Chemical Company. Water solubility of several flame retardants and industrial chemicals. Testing facility: Velsicol Chemical Company. Project 428048, Report #1. 1978.

General

TBBPA's water solubility was estimated to be 0.001 mg/L using Syracuse Research Corporation's modeling software (EPIwin V3.04).

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Vapor Pressure

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Revision Date:
12/11/01

Test Substance

Remarks: The test article was a composite of the commercial TBBPA products produced by Albemarle Corp., Dead Sea Bromine Group, and Great Lakes Chemical Corp. Its composition was TBBPA 98.91%, o,p'-TBBPA 0.05%, 2,4,6-tribromophenol <0.01%, tribromobisphenol A 1.04%.

Chemical Category

Method

>> Method/Guideline followed

OECD Method 104, US EPA OPPTS 830.7950

>> GLP Yes

>> Year study performed 2001

Remarks for Method

The spinning rotor guage (SRG) system was used to determine vapor pressure. The SRG measured the rotational frequency of a stainless steel ball that was magnetically suspended within a vacuum chamber. In the presence of a sample, the deceleration rate of ball rotation was proportional to the vapor pressure of the sample. Initially, the background pressure and out-gassing rate of an empty sample chamber were determined a minimum of two times in the absence of sample. The vapor pressures of a reference material and the test material were then sequentially determined at 20 +/- 1.0 degrees C by measuring the pressure increase over backgound with the respective material loaded in the test chamber.

Results

>> Precision <

>> Vapor Pressure Value 0.00001

>> Upper Value 0

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Vapor Pressure

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

>> Unit Pascals

>> Temperature 20 degrees c

>> Decomposition No

Results Remark The vapor pressure of TBBPA was determined to be < 1.19 x 10E-5 Pa at 20 degrees C using the spinning rotor gauge method.

Conclusions

The vapor pressure of TBBPA was determined to be < 1.19 x 10E-5 Pa at 20 degrees C using the spinning rotor gauge method.

Data Quality

Reliability High

Data Reliability Remarks

This study was performed by a laboratory with considerable expertise using current guidelines. The spinning rotor guage was validated by the US National Institute of Standards and Technology.

Reference

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Vapor Pressure

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

>> Remarks

Lezotte, F. and Nixon, W. Determination of the vapor pressure of tetrabromobisphenol A using the spinning rotor gauge method. Project Number 439C-128. 2001. Wildlife International, Ltd, Easton, MD.

General

This study was sponsored by the ACC Brominated Flame Retardant Industry Panel.

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point: Biodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79[illegible]7	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Revision Date: 12/10/01

Test Substance

Remarks

14C-Tetrabromobisphenol A (TBBPA) (specific activity 12.9 mCi/mmol). Synthesized by Chemsyn Science Laotratories, Lenexa, KS.

TBBPA, 99.06% purity, obtained from Great Lakes Chemical Corp.

14C-O,O' dimethyl-TBBPA; 14C-O,O' diethyl-TBBPA (presumed metabolites). Synthesized by Chemsyn Science Laotratories, Lenexa, KS.

Chemical Category

Method

>> Method/Guideline followed

Not specified.

>> Test Type

aerobic

>> GLP Yes

>> Year study performed 1989

>> Contact Time 64

>> Inoculum

Those present in the natural soils.

Remarks for Method

This study investigated the biodegradability of TBBPA in 3 different soil types under aerobic conditions. The three soil types were sandy loam, clay loam, and silty loam. Twelve test systems, four replicates for each soil type, were used. Each test system consisted of a 250 ml glass Erlenmeyer flask to which a 50 ml round bottom glass tube was fused. The study was conducted in the dark. About 50 mg (dry wt) of soil were added to each flask, and 100 uL of the test solution was added to each. After mixing, the flasks were sealed and incubated at 21.5 +/- 1 degree centigrade. Evolved gas was collected on a hydroxide trapping solution. On days 1,2,4,8,16,32 and 64 the KOH solution was collected and alliquots quantitated.

At test termination, the soil was combusted and the radioactive CO2 trapped and counted via liquid scintillation.

Prior to soil extraction, duplicate aliquots of each soil were analyzed for moisture

determination. Two replicates from each soil type were extracted by Soxhlet extraction for at least 16 hrs. Thin layer chromatography was used in an attempt to identify metabolites. A mass balance was performed.

Results

>> Precision range

>> Degradation Value 18

>> Upper value 64

>> Time Frame 64

>> Time Units Days

>> Breakdown products Yes

Results Remarks

The major portion of the applied radioactivity was recovered in the soil. No radioactivity was detected in the volatile plugs after Soxhlet extraction. The maximum radioactivity recovered in the CO2 trap was 5.5% in the clay loam soil.

After 64 days, the amount of TBBPA remaining in the soil was 74.3-81.9%, 35.9-40.1% and 41.1-43.2% for the sandy loam, silty loam, and clay loam, respectively. In all soil replicates, 2 biodegradation products were detected that resembled each other in TLC mobility characteristics, but not that of the dimethyl or diethyl derivatives of TBBPA. In addition, a third unknown degradation product was detected in one replicate of the silty loam soil.

A radiochemical mass balance showed appr. 80% recovery for the sandy and clay loams, and 60% for the silty loam. The lower recovery for the silty loam is probably due to inhomogeneity in the distribution of the radioactivity.

Efficiency of extraction varied for each soil type. Recovered radioactivity after the Soxhlet extraction were 52.4 - 56.1%, 45.5 - 48.6%, and 10.1 - 18.6% for the sandy loam, the silty loam, and the clay loam, respectively.

Conclusions

TBBPA was susceptible to biodegradation in soils under aerobic conditions with an estimated half-life of appr. 50 days. Twenty to 60% (depending on the soily type) of the initial TBBPA concentration was degraded. Some 14C-CO2 was detected, indicating TBBPA was able to undergo complete mineralization. Two major metabolites were detected. These metabolites were not the O,O-dimethyl and O,O-diethyl derivatives of TBBPA, but their exact identity was not determined.

Data Quality

Reliability High

Data Reliability Remarks

Study performed under a TSCA test rule.

Reference

>> Remarks

Fackler, P. Determination of the biodegradabilty of tetrabromobisphenol A in soil under aerobic conditions. SLS Report: 88-11-2848. 1989. Springborn Life Sciences, Inc. Wareham, Mass.

Reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.

General

This study was sponsored by the Brominated Flame Retardant Industry Panel.

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point: Biodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	2
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Revision Date: 12/10/01

Test Substance

Remarks

14C-Tetrabromobisphenol A (TBBPA) (specific activity 12.9 mCi/mmol). Synthesized by Chemsyn Science Laboratories, Lenexa, KS.

TBBPA, 99.06% purity, obtained from Great Lakes Chemical Corp.

14C-O,O' dimethyl-TBBPA; 14C-O,O' diethyl-TBBPA (presumed metabolites). Synthesized by Chemsyn Science Laboratories, Lenexa, KS.

Chemical Category

Method

>> Method/Guideline followed

Not specified.

>> Test Type

anaerobic

>> GLP Yes

>> Year study performed 1989

>> Contact Time 64

>> Inoculum

Those organisms naturally present in soils.

Remarks for Method

This study investigated the biodegradability of TBBPA in 3 different soil types under anaerobic conditions. The three soil types were sandy loam, clay loam, and silty loam. Twelve test systems, four replicates for each soil type, were used. Each test system consisted of a 250 ml glass Erlenmeyer flask to which a 50 ml round bottom glass tube was fused. The study was conducted in the dark. About 50 mg (dry wt) of soil were added to each flask, and 100 uL of the test solution was added to each. After mixing, the soil was covered with water, purged with nitrogen and the flasks were sealed and incubated at 21.4 +/- 1 degree centigrade. Each flask was purged with nitrogen daily to maintain anaerobic conditions and to capture evolved methane and CO2 or other volatile products.

Evolved gas was collected on a hydroxide trapping solution. On days 1,2,4,8,16,32 and 64 the KOH solution was collected and alliquots quantitated.

At test termination, the soil was combusted and the radioactive CO2 trapped and counted via liquid scintillation.

Prior to soil extraction, duplicate aliquots of each soil were analyzed for moisture determination. Two replicates from each soil type were extracted by Soxhlet extraction for at least 16 hrs. Thin layer chromatography was used in an attempt to identify metabolites. A mass balance was performed.

Results

>> Precision range

>> Degradation Value 9

>> Upper value 56

>> Time Frame 64

>> Time Units Days

>> Breakdown products Yes

Results Remarks

The major portion of the applied radioactivity was recovered in the soil. Minimal radioactivity was recovered in the volatile traps. The recovered radioactivity in the traps was almost exclusively CO2 and the maximum radioactivity recovered in the CO2 trap was 0.35% in the silty loam soil.

Minimal radioactivity was recovered in the water (maximum of 2.5% in the silty loam).

After 64 days, the amount of TBBPA remaining in the soil was 43.7 - 57.0%, 53.4 to 65.0% and 89.5 to 90.6% in the sandy loam, silty loam, and clay loam, respectively. Three major degradation products were detected in the sandy loam and which did not resemble the dimethyl

or diethyl presumed metabolites. In the other 2 soil types, 2 of these same unknown metabolites were observed.

A radiochemical mass balance showed recovery ranged from 82-117%.

Efficiency of extraction varied for each soil type. Recovered radioactivity after the Soxhlet extraction were 87.5 and 104.7% (mean) for the sandy and clay loam, respectively. In the silty loam soil, 48.3% was recovered.

Conclusions

TBBPA was susceptible to biodegradation in soils under anaerobic conditions with an estimated half-life of approximately 50 days. 14C-CO2 production was negligible. Two or 3 degradation products, depending on soil type, were detected. Although these degradation products were not definitively identified, the O,O-dimethyl and O,O-diethyl derivatives of TBBPA were ruled out.

Data Quality

Reliability High

Data Reliability Remarks

This test was performed under a TSCA test rule.

Reference

>> Remarks

Fackler, P. Determination of the biodegradabilty of tetrabromobisphenol A in soil under anaerobic conditions. SLS Report: 88-11-2849. 1989. Springborn Life Sciences, Inc. Wareham, Mass.

Reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.

General

This study was sponsored by the Brominated Flame Retardant Industry Panel.

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point: Biodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	3
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Revision Date: 12/11/01

Test Substance

Remarks: 14C-TBBPA (UL-14C), specific activity of 9.32 mCi/mole. Radiopurity of 96.0%. Synthesized by Midwest Research Institute, Kansas City, Missouri.

Chemical Category

Method

>> Method/Guideline followed

OECD Guideline 209

>> Test Type

aerobic

>> GLP Yes

>> Year study performed 1989

>> Contact Time 56

>> Inoculum

Those organisms naturally present in sediment.

Remarks for Method

Each test system was an Erlenmeyer flask connected to a series of traps for evolved gases. The flasks were maintained in the dark and held at 25 +/- 2 degrees C in a water bath. Ninety three flask, three replicates for each concentration (10, 100 and 1000 ug/L) and sampling interval (days 0, 4, 7, 10, 14, 21, 28, 42 and 56) were established at test inititation. Additionally, triplicate sterile control vessles were established with addition of HgCl2 for sampling at alternate intervals. Sediment (obtained from a small spring-fed brook in Mass), appr. 40 ml corresponding to appr. 20 g dry wt, was added to each flask followed by 135 ml river water. The hydroxide trapping solution, was added to each 14C-C02 trap. The vessles were then dosed by delivering 10 ul of each stock solution into the aqueous phases of respective flasks. After stirring, the flasks were sealed and kept at a temperature of 25 +/- 2 degrees C. On a daily basis, oxygen was bubbled through each flask for at least 5 minutes in order to maintain aerobic conditions and a viable microbial population.

On days 0, 14, 28, 42 and 56 dissolved oxygen, pH and temperature were measured in each test vessel remaining in the study at those respective sampling intervals. At each interval, the

aqueous phase, the KOH solution (CO2 trap), and the volatile traps were anlayzed for total 14C content via liquid scintilation. Also, the sediment from the sacrificed flasks was mixed, triplicate portions combusted, and the 14C-CO2 trapped and counted via liquid scintillography. In addition, the sediment was extracted (Soxhlet for 16 hrs) and analyzed by liquid scintillography. HPLC was performed to determine the percent TBBPA comprising the extractable residues. A mass balance was performed. Finally, bacterial plate counts were measured for the test termination replicates (d 56).

Results

>> Precision range

>> Degradation Value 36

>> Upper value 55

>> Time Frame 56

>> Time Units Days

>> Breakdown products Yes

Results Remarks

The biodegradability of TBBPA was tested under aerobic conditions in a sediment/water microbial test system using natural river sediment and water. Results from a 56 day aerobic test regime showed biodegradation of TBBPA occurred in all tested concentrations, 10, 100 and 1000 ug/L, determined by high performance liquid chromatography employing radiometric detection. Half-lives calculated for TBBPA in the sediment/water microbial test systems were 48 d (10 ug/L), 69 d (100 ug/L) and 84 d (1000 ug/L), with an apparent correlation between half-life and concentration of TBBPA, and half-life and microbial population. The different half-lives observed were suspected to be due to the different microbial populations present at the respective concentrations.

Only a limited amount, less than 8% of the applied radioactivity, was recovered in the CO2 traps, suggesting partial biodegradation to products unidentified. TBBPA and its biodegradation products were recovered from the sediment and particulate phase of the test system. Filtered water contained less than 5% of the applied radioactivity. The amounts of TBBPA remaining at test termination, 44.7%, 64.2% and 60.8% in the 10, 100 and 1000 ug/L treatements, respectively, were comparable to the amounts present in the previous aerobic soil study conducted in this laboratory. The aerobic soil study showed that degradation of TBBPA was dependent upon soil type and that 20 - 60% of the dose had degraded at the end of the study, day 64.

The temperature in the water baths ranged from 24-26 degrees C. The pH of the individual test vessles ranged from 5.2 to 6.6 (mean = 5.7). The dissolved O2 content ranged from 3.8 to > 20 mg/L and was no lower than 6.4 mg/L after test initiation. The microbial plate counts indicated all flasks had viable microbial populations, and that the observed degradation of TBBPA correlated well with microbial populations. Some inhibition was observed at the 100 and 1000 ug/L concentrations and may have contributed to the decreased degradation observed for these higher concentrations. Extrapolation of the sterile control data indicated the half-life would be 1300 days, clearly demonstrating that the degradation observed in the active test systems was due to microbial degradation rather than physical processes.

Conclusions

TBBPA was susceptible to biodegradation in a sediment/water system under aerobic conditions with an estimated half-life of appr. 48 to 84 days (depending on concentration and microbial population).

Results from a 56 day aerobic test regime showed biodegradation of TBBPA occurred in all tested concentrations, 10, 100 and 1000 ug/L, determined by high performance liquid chromatography employing radiometric detection. Half-lives calculated for TBBPA in the sediment/water microbial test systems ranged between 48 and 84 days, with an apparent correlation between half-life and concentration of TBBPA and half-life and microbial population. Only a limited amount, less than 8% of the applied radioactivity, was recovered in the CO2 traps, suggesting partial mineralization.

TBBPA and its biodegradation products were recovered from the sediment and particulate phase of the test system. Filtered water contained less than 5% of the applied radioactivity. The amounts of TBBPA remaining at test termination, 44.7%, 64.2% and 60.8% in the 10, 100 and 1000 ug/L treatments, respectively, was comparable to the results of the previous aerobic soil study conducted in this laboratory.

Data Quality

Reliability High

Data Reliability Remarks

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	3
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

This study was performed under a TSCA test rule.

Reference

>> Remarks

Fackler, P. Tetrabromobisphenol A - Determination of hte Biodegradability in a Sediment/Soil Microbial System. 1989. SLI Report: 89-8-3070. Springborn Laboratories, Inc., Wareham, Mass.

Reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.

General

Study sponsored by the Brominated Flame Retardant Industry Panel.

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point: Biodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Revision Date: 12/11/01

Test Substance

Remarks: TBBPA

Chemical Category

Method

>> Method/Guideline followed

Japan's MITI/MHW Guideline, corresponds to OECD 301C or 302C

>> Test Type

aerobic

>> GLP Unknown

>> Year study performed 1992

>> Contact Time 14

>> Inoculum

activated sludge collected from domestic and industrial sewage plants and river basins in Japan

Remarks for Method

Test performed in accordance with the "Biodegradation test of chemical substance by microorganisms etc." stipulated in the Order Prescribing the Items of the Test Relating to the New Chemical Substance (1974, Order of the Prime Minister, the Minister of Health and Welfare, the Minister of International Trade and Industry No. 1).

100 mg/L TBBPA
30 mg/L sludge
Temperature 25 +/- 1 degrees C.
Reference substance - aniline
Duration - 14 days.

Results

>> Precision =

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point: Biodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	4
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

>> Degradation Value 0

>> Upper value 0

>> Time Frame 14

>> Time Units Days

>> Breakdown products No

Results Remarks

The positive control, aniline, performed as expected.

Conclusions

TBBPA was not "readily biodegradable" in this 14 day aerobic sludge test. This test presents only minimal conditions for biodegradation.

Data Quality

Reliability High

Data Reliability Remarks

Y

This study was performed by the Japanese government testing laboratory.

Reference

Biodegradation and Bioaccumulation Data of Existing Chemicals Based on the CSCL Japan. Edited by the Chemicals Inspection & Testing Institute, Japan. 1992. I

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point: Transport between Environmental Compartments (Fugacity)

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Revision Date: 12/19/01

Test Substance

Remarks: Tetrabromobisphenol A (TBBPA)

Chemical Category

Method

>> Method/Guideline followed

Developed by D. Mackay and co-workers

>> Test Type: Level III fugacity model

>> Year study performed: 2001

Remarks for Method

Model Used: Level III Fugacity Model (Full- Output), EPIWIN V3.04

Input Parameters: chemical structure only; model default parameters accepted; model based on emissions of 1000 kg/Hr each to air, water and soil

Results

>> Media

Air: 4.34 x 10-7%; Water: 1.13%; Soil: 44.9%; Sediment: 53.9%

>> Distribution Concentration

Not provided by model.

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point: Transport between Environmental Compartments (Fugacity)

Sponsor ID	100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Results Remark

Estimated by model:
Soil Koc: 6.5 x 10+6
Vapor Pressure: 0.000135 mm Hg
Liquid VP: 0.00838 mm Hg (super-cooled)
Melting Pt: 206 deg C
Log Kow: 7.2
Henry's LC: 2.31 x 10-13 atm-m3/mole

Conclusions

If released at equal rates to air, water, and soil, TBBPA is predicted to partition primarily to sediment (appr. 54%) and soil (appr. 45%). Only trace amounts would partition to water (1%) and air (4 x 10-7%). Approximately 84% would be reacted with only 16% advected.

The model was also run 7 times using all permutations of air, water and soil emission rates as either 0 or 1000 kg/hr. The results were as follows. If released solely to air, the model predicted TBBPA would partition appr. 80% to soil and 20% to sediment; total reacted = 96%. If released soley to water, TBBPA would partition 98% to sediment and 2% to water; total reacted = 56%. If released solely to soil, TBBPA would partition to soil (99.9%); total reacted = 100%. If released at equal rates to both air and water, TBBPA would partition 73% to sediment and 24% to soil; total reacted = 76%. If released at equal rates to both air and soil, TBBPA would partition 88% to soil and 12% to sediment; total reacted = 98%. If released at equal rates to both water and soil, TBBPA would partition 70% to sediment, 28% to soil, and 3% to water; total reacted = 78%.

Based on the above, TBBPA is not expected to move from water, soil or sediment to air. Furthermore, TBBPA is not expected to move from soil to water.

Data Quality

Reliability High

Data Reliability Remarks

Reference

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point: Transport between Environmental Compartments (Fugacity)

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

>> Remarks

Level III Fugacity Model, EPIWIN V3.04, Syracuse Research Corporation, Syracuse, NY.

General

EPA High Production Volume (HPV) Track

Ecotoxicity End Point :
Toxicity to Aquatic Plants

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Revision Date: 2/8/01

Test Substance

Remarks The test article was a combination of the non-labeled commercial TBBPA product and 14C-TBBPA (12.9 mCi/mmole, tested as 100% active ingredient). The non-labeled product was a composite sample made from the commercial products supplied by Ethyl Corporation, Bromine Compunds Ltd, and Great Lakes Chemical Corp.

Chemical Category

Method

>> Method/Guideline followed

EPA TSCA Guideline 797.1050 (US EPA, 1985) as amended on 20 May 1987 (US EPA, 1987)

>> Test Type

static

>> GLP Yes

>> Year study performed 1988

>> Species

Freshwater green algae

>> End Point Reduction in cell density.

>> Analytical monitoring 14C-activity

>> Exposure period 96 hrs

>> Statistical Method See Results.

Remarks for Method

96-Hr duration. 20-24 degress C, constant illumination (4800 lux), shaking at 100 rpm. Test organism: Selenastrum capricornutum obtained from Carolina Biological Supply Company, Burlington, NC; 5 day old inoculum. Test media: Marine Biological Laboratory medium prepared with distilled deionized water.

Results

EPA High Production Volume (HPV) Track

Ecotoxicity End Point :
Toxicity to Aquatic Plants

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

>> Nominal concentration 0, 0.6, 1.2, 2.4, 4.8, 9.6 mg/L

>> Measured concentration 0, 0.34, 0.76, 1.5, 3.0, 5.6 mg/L

>> Precision >

>> Endpoint Type EC50-CD

>> Endpoint Value 6 **>> Unit used** mg/L

>> Concentration Type Measured **>> Endpoint Time** 96

>> NOEC Precision >= **>> NOEC** 6 **>> Unit used** mg/L

>> NOEC Concentration Type Measured

>> NOEC Effect(s) assesse No effects observed

>> LOEC Precision > **>> LOEC** 6 **>> Unit used** mg/L

>> LOEC Concentration Type Measured

>> LOEC Effect(s) assesse No effects observed.

>> Response of Control Group (was it satisfactory? Yes

>> Statistical results

See results.

Results Remark

Measured test concentrations ranged from 0.34 to 5.7 mg TBBPA/L (based on mean of 0 and 96 hr radiometric analysis). Mean measured concentrations averaged 61% of nominal. Measured concentrations at 96 hrs were nearly identical to those measured at 0 hrs.

To confirm the results obtained by radioassay, the nominal 9.6 mg/L test solution at 0 and 96 hr were analyzed for TBBPA via HPLC. TBBPA concentrations averaged 0.55 mg/L at 96 hrs, much less than the concentrations measured in the same test solutions by radioassay (5.1 and 6.1 mg/L, respectively). The test laboaratory accounted for this discrepancy with the rationale that fine

particles of undissolved TBBPA would not have passed through the HPLC column, and thus not measured. Further, based on these results the test laboratory stated " we believe the true aqueous solubility of TBBPA is appr. 0.5 mg/L." All TBBPA concentrations tested, therefore, were at or above the solubility limit, and concentrations measured in the filtered samples by radioassay probably represented a considerable amount of undissolved test material.

Cell densities were determined at 24, 48, 72 and 96 hrs. Algae growth was not inhibited in any of the test concentrations of TBBPA compared to controls. Mean cell densities in cultures exposed to TBBPA ranged from 121-151% of the mean cell densities of controls at 96 hrs.

pH: 7.0-9.6. Temperature: 22-24 degrees C. Conductivity (umhos/cm): 210-240.

Conclusions

Growth of S. capricornutm was not reduced by 96 hrs of exposure to TBBPA concentrations well above the limits of aqueous solubility.

Data Quality

Reliability High

Data Reliability Remarks

Test performed under a TSCA test rule.

Reference

>> Remarks

Giddings, J. Toxicity of tetrabromobisphenol A to the freshwater green alga Selenastrum capricornutum. Report No. 88-10-2828. 1988. Springborn Life Sciences, Inc. Wareham, Mass.

General

Study sponsored by the Brominated Flame Retardant Industry Panel.

All LC50 and EC50 values derived from acute tests in aquatic species are greater than TBBPA's estimated and measured water solubility. The 96 hour LC50 values for bluegill sunfish, rainbow trout and fathead minnow are 0.51, 0.40 and 0.54 mg/L, respectively. The 48 hour LC50 for Daphnia magna is 0.96 mg/L. The 96 hour EC50 for the Eastern oyster was 0.098 mg/L. The growth of freshwater green alga was not affected by 5.6 mg/L, the highest level tested. The 96 hour EC50 in

EPA High Production Volume (HPV) Track

Ecotoxicity End Point :
Toxicity to Aquatic Plants

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

<1, 5, or 10 day old Mysid shrimp was 0.86, 1.1, and 1.2 mg/L, respectively. (as reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995)

EPA High Production Volume (HPV) Track

Ecotoxicity End Point :
Toxicity to Aquatic Plants

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	2
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	N

Revision Date: 12/14/01

Test Substance

Remarks TBBPA obtained from Great Lakes Chemical Corporation

Chemical Category

Method

>> Method/Guideline followed

similar to Walsh and Alexander (1980) except carried out for 72 or 96 hr

>> Test Type

static

>> GLP Unknown

>> Year study performed 1987

>> Species

Skeletonema costatum, Thalassiosira pseudonana, Chlorella sp.

>> End Point population growth as indicated by cell numbers

>> Analytical monitoring GC

>> Exposure period 72 hr:S. costatum, T. pseudonana; 96 hr:Chlorella

>> Statistical Method see results

Remarks for Method

Population density was estimated by cell counts on a hemacytomer. Each test was replicated. The test article was added to the growth flasks by adding 0.05 test article in nanograde acetone to 51 ml grouwth media with algae.

Growth media were prepared from seawater collected from an inshore site on the Gulf of Mexico and from 5 commercial sea salt formulations. Toxicity was expressed as the EC50 based upon cell numbers after incubation for 72 or 96 hr. The EC50s were derived by straight line graphical interpolation without calculation of confidence intervals.

The highest test concentration was determined by adding the test compound solution slowly to the growth medium and observing the highes concentration at which crystals did not form.

Results

>> Nominal concentration

>> Measured concentration

>> Precision

>> Endpoint Type

>> Endpoint Value 0 **>> Unit used**

>> Concentration Type **>> Endpoint Time** 0

>> NOEC Precision **>> NOEC** 0 **>> Unit used**

>> NOEC Concentration Type

>> NOEC Effect(s) assesse

>> LOEC Precision **>> LOEC** 0 **>> Unit used**

>> LOEC Concentration Type

>> LOEC Effect(s) assesse

>> Response of Control Group (was it satisfactory?

>> Statistical results

see results

Results Remark

The 96 hr EC50 in Chlorella sp. was > 1.5 mg/L TBBPA, the highest dose tested.

The 72 hr EC50 in S. costatum ranged from 0.09 to 0.89 mg/L in the six different growth media. The 72 hr EC50 in T. pseudonana ranged from 0.13-1.0 mg/L in the six different grwoth media.

Response of each alga species to the test article varied with growth media. Growth of the alga was similar in the various media.

The pH and PO4 concentration varied with the growth media and range from 7.6-8.2 and 13.8-21.4, respectively.

Conclusions

The authors concluded "Toxicity of compounds in algal tests is apparently the result of interactions between algae, grouwth medium, toxicant, and solvent." The EC50 concentrations were greater than TBBPA's water solubility.

The effect of pH seemed clear with TBBPA: the sensitivity of all algae was greatest in the 2 media with the lowest pH (7.6). TBBPA would be driven toward the unionized form at lower pH.

Data Quality

Reliability High

Data Reliability Remarks

Study performed in EPA's Gulf Breeze Laboratory.

Reference

>> Remarks

Walsh et al. 1987. Responses of marien unicellular algae to brominated organic compounds in six growth media. Ecotoxicology and Environmental Safety 14, 215-222.

General

All LC50 and EC50 values derived from acute tests in aquatic species are greater than TBBPA's estimated and measured water solubility. The 96 hour LC50 values for bluegill sunfish, rainbow trout and fathead minnow are 0.51, 0.40 and 0.54 mg/L, respectively. The 48 hour LC50 for Daphnia magna is 0.96 mg/L. The 96 hour EC50 for the Eastern oyster was 0.098 mg/L. The growth of freshwater green alga was not affected by 5.6 mg/L, the highest level tested. The 96 hour EC50 in <1, 5, or 10 day old Mysid shrimp was 0.86, 1.1, and 1.2 mg/L, respectively. (as reported in

Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995)

EPA High Production Volume (HPV) Track

Ecotoxicity End Point:
Acute Toxicity to Aquatic Invertebrates

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Revision Date: 12/10/01

Test Substance

Remarks: A tetrabromobisphenol A (TBBPA) commercial product (FMBP4A).

Chemical Category

Method

>> Method/Guideline followed

Pre-dates OECD and EPA Guidelines

>> Test Type

static

>> GLP Unknown

>> Year study performed 1975

>> Species

Daphnia magna

>> Analytical monitoring No.

>> Exposure period 48 hrs

>> Statistical Method Spearman-Karber Estimator

Remarks for Method

Daphnia magna were obtained from a laboratory stock culture which was originally obtained from the National Water Quality Laboratory, Duluth, MN. Stock cultures were maintained at 19-21 degrees C in 350 L stainless steel tanks. Twenty hours prior to the starting the bioassay, appr. 15 adults with full brood chambers were isolated into soft lake water. The following morning the newly released instars (< 20 hrs old) were removed and distributed to the test beakers. Test temperature was maintained at 17 +/- 1 degree C.

Results

The bioassay was conducted at five concentrations of TBBPA: 0.32, 0.56, 1.0, 1.8 and 3.2

mg/L plus a control and a solvent (acetone) control. Four replicates were run. Five organisms were introduced into each test beaker. Mortality was recorded every 24 hrs.

Dilution water: lake water. pH=7.32. Total hardness = 64 mg/L as CaCO3. Total alkalinity of 32 mg/L as CaCO3. Specific conductance of 130 umhos/cm.

>> Nominal concentration 0, 0.32, 0.56, 1.0, 1.8, 3.2 mg/L

>> Measured concentration Not measured.

>> Precision =

>> Endpoint Type LC50

>> Endpoint Value 1 **>> Unit used** mg/L

>> Concentration Type Nominal **>> Endpoint Time** 48

>> Statistical results

see results.

Results Remark

The 48 hr LC50 of TBBPA to D. Magna was 0.96 mg/L (based on nominal concentration). The 95% confidence interval was 0.81 - 1.13 mg/L. The no effect concentration was 0.32 mg/L. These concentrations are greater than TBBPA's water solubility.

Conclusions

The 48 hr LC50 of TBBPA to D. Magna was 0.96 mg/L (based on nominal concentration).

Data Quality **Reliability** Reasonable.

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Data Reliability Remarks

Reference

>> Remarks

Velsicol Chemcial Company. The acute toxicity of FMBP4-A to the water flea Daphnia magna Straus. Testing facitlity: Union Carbide Corp. Environmental Services, Tarrytown Technical Center, Tarrytown, NY. Study No.: UCES 11506-03-52. 1978.

General

Study sponsored by Velsicol Chemical Corporation.

All LC50 and EC50 values derived from acute tests in aquatic species are greater than TBBPA's estimated and measured water solubility. The 96 hour LC50 values for bluegill sunfish, rainbow trout and fathead minnow are 0.51, 0.40 and 0.54 mg/L, respectively. The 48 hour LC50 for Daphnia magna is 0.96 mg/L. The 96 hour EC50 for the Eastern oyster was 0.098 mg/L. The growth of freshwater green alga was not affected by 5.6 mg/L, the highest level tested. The 96 hour EC50 in <1, 5, or 10 day old Mysid shrimp was 0.86, 1.1, and 1.2 mg/L, respectively. (as reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995)

EPA High Production Volume (HPV) Track

Ecotoxicity End Point:
Acute Toxicity to Aquatic Invertebrates

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	3
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Revision Date: 12/18/01

Test Substance

Remarks: TBBPA obtained from Great Lakes Chemical Corporation.

Chemical Category

Method

>> Method/Guideline followed

Not stated

>> Test Type

flow-through

>> GLP Unknown

>> Year study performed 1988

>> Species

Mysid shrimp

>> Analytical monitoring GC/ECD

>> Exposure period 96 hrs

>> Statistical Method see results

Remarks for Method

Results

Mysids of three ages (n=20/treatment) were exposed during a flow-through 96-hr acute test. The age of the mysids wree <=1, 5 and 10 days old at initiation. Test article concentations were 535, 445 or 84 ug/L (nominal). Seawater for the test was pumped from Santa Rosa Sound, FL, filtered and diluted to a nominal 20% using freshwater from a chlorinated municipal supply. Temperature was 21 =/- 1 degree C. Mysids were fed live Artemia nauplii twice daily during the test. The photoperiod was 14L:10D. A mixture of triethylene glycol and acetone was used a carrier solvent. Test article concentration was determined twice during the test (GC-ECD). Detection limit = 1 ug/L. Mortality data analyzed by the moving average method,

the binomial test or the probit method.

Mean Salinity test water = 20.6%. pH = 7.96-8.16. Dissolved O2 mean = 6.9.

>> Nominal concentration 0, 84, 445, 535, 1150 ug/L

>> Measured concentration x

>> Precision =

>> Endpoint Type LC50

>> Endpoint Value 1 **>> Unit used** mg/L

>> Concentration Type Measured **>> Endpoint Time** 96

>> Statistical results

see results

Results Remark

The mysid age groups selected for testing encompassed the entire juvenile stage of M. Bahia. At the end of the 96 hr test, those <= 1 day old at test initiation were appr. 5 d old, the initial 5 d olds were 9 d old, and the initial 10 d olds were 14 d old adults. Survival of the mysides in the control treatments were >= 94%.

The 95 hr LC50 values for the initial <= 1, 5, and 10 d old Mysids were 860, 1100 and 1200 ug/L, respectively. The 95% confidence interval for the 1 day old encompassed the LC50 values for the 5 and 10 d olds. Only 5% of the 5 d old mysids and 45% of the 10 d olds died during exposure to 1150 ug/L, the highest concentration tested. Solubility problems were encounted in concentations higher thatn those reported so further testing to obtain more definitive LC50 values for the 5 nd 10 day old age groups was not conducted.

Conclusions

The 95 hr LC50 values for the initial <= 1, 5, and 10 d old Mysids were 860, 1100 and 1200 ug/L, respectively. The 95% confidence interval for the 1 day old encompassed the LC50 values for the 5 and 10 d olds.

Data Quality

Reliability High

Data Reliability Remarks

Study performed in EPA's Gulf Breeze Laboratory.

Reference

>> Remarks

Goodman et al. 1988. Acute toxicity of malathion, tetrabromobisphenol A and tributyltin chloride to mysids (Mysidopsis bahia) of three ages. Bull. Environ. Contam. Toxicol. 41:746-753.

General

All LC50 and EC50 values derived from acute tests in aquatic species are greater than TBBPA's estimated and measured water solubility. The 96 hour LC50 values for bluegill sunfish, rainbow trout and fathead minnow are 0.51, 0.40 and 0.54 mg/L, respectively. The 48 hour LC50 for Daphnia magna is 0.96 mg/L. The 96 hour EC50 for the Eastern oyster was 0.098 mg/L. The growth of freshwater green alga was not affected by 5.6 mg/L, the highest level tested. The 96 hour EC50 in <1, 5, or 10 day old Mysid shrimp was 0.86, 1.1, and 1.2 mg/L, respectively. (as reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995)

EPA High Production Volume (HPV) Track

Ecotoxicity End Point:
Acute Toxicity to Aquatic Invertebrates

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Revision Date: 12/9/01

Test Substance

Remarks: 14C-TBBPA, specific activity of 12.2 mCi/mole; obtained from Chemsyn Science Laboratories.

Non-labelled composite of commercial TBBPA products produced by Great Lakes Chemical Corporatin, Ethyl Corporation, and Bromine Compounds, Ltd.

Chemical Category

Method

>> Method/Guideline followed

EPA Environmental Effects Guidelines, Fed. Reg. 1985, and the EPA/OTS guidelines.

>> Test Type

flow-through

>> GLP Yes

>> Year study performed 1989

>> Species

Crassostrea virginica

>> Analytical monitoring Yes

>> Exposure period 96 hrs

>> Statistical Method See Results

Remarks for Method

Results

Eastern oysters were exposed to concentrations of TBBPA for 96 hrs and shell deposition was observed. The EC50 is defined as that concentration resulting in a 50% reduction in shell deposition. Forty organisms were exposed in duplicate test aquaria (20 per aquaria) in a flow-through system to five concentations of TBBPA, a dilution (seawater) water control and a solvent (acetone) control. Each replicate was radiometrically analyzed for 14C-TBBPA on days 0, 1, 4. The TBBPA concentration in the highest dose level was also confirmed using HPLC at test initiation and termination. Nominal test concentrations were 0, 19, 32, 54, 90 and 150 ug AI/L. Measured concentrations were 0, 18, 32, 51, 87 and 150 ug/L. Confirmation of the high

dose by HPLC: 110 ug/L.

>> Nominal concentration 0, 19, 32, 54, 90 and 150 ug AI/L.

>> Measured concentration 0, 18, 32, 51, 87 and 150 ug/L.

>> Precision =

>> Endpoint Type EC50

>> Endpoint Value 98 **>> Unit used** micrograms/L

>> Concentration Type Measured **>> Endpoint Time** 96

>> Statistical results

See results

Results Remark

Results of this study are based on mean measured concentrations determined by radiometric analyses. Reduction in shell deposoition was 60% among oysters exposed to the highest test concentration (150 ug/L). Shell growth was reduced by 47 ot 33% in the remaining test concentrations (87-18 ug/L) and showed a concentration-effect relationship. Based on these data the 96-hr EC50 for TBBPA in eastern oysters was calculated to be 98 ug/L. The no observed effect concentration (NOEC) was < 18 ug/L, the lowest measured concentration of TBBPA tested. An estimated NOEC of 2.6 ug/L was calculated from the observed dose-response curve.

Conclusions

Based on these data the 96-hr EC50 for TBBPA in eastern oysters was calculated to be 98 ug/L.

Data Quality

Reliability High

EPA High Production Volume (HPV) Track

Ecotoxicity End Point:
Acute Toxicity to Aquatic Invertebrates

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	4
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Data Reliability Remarks

Study performed under a TSCA test rule.

Reference

>> Remarks

Surprenant D. 1988. Acute toxicity of tetrabromobisphenol A to eastern oysters (Crassostrea virginica) under flow-through conditions. SLS Report #89-1-2898. Springborn Life Sciences, Wareham, Mass.

Reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.

General

Sponsored by the Brominated Flame Retardant Industry Panel

All LC50 and EC50 values derived from acute tests in aquatic species are greater than TBBPA's estimated and measured water solubility. The 96 hour LC50 values for bluegill sunfish, rainbow trout and fathead minnow are 0.51, 0.40 and 0.54 mg/L, respectively. The 48 hour LC50 for Daphnia magna is 0.96 mg/L. The 96 hour EC50 for the Eastern oyster was 0.098 mg/L. The growth of freshwater green alga was not affected by 5.6 mg/L, the highest level tested. The 96 hour EC50 in <1, 5, or 10 day old Mysid shrimp was 0.86, 1.1, and 1.2 mg/L, respectively. (as reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995)

EPA High Production Volume (HPV) Track

Toxicity End Point:
Acute Toxicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Revision Date:
12/9/01

Test Substance

Remarks: The test article was the commercial tetrabromobisphenol A (TBBPA) product known as Saytech RB-100 produced by Ethyl Corporation.

Chemical Category

Method

>> Method/Guideline followed

Not specified

>> GLP: Yes

>> Year study performed: 1981

>> Species

rat

>> Strain: Sprague-Dawley

>> Sex: Both

>> Number of males per dose: 5

>> Number of females per dose: 5

>> Vehicle: methylcellulose (15 ml/kg)

>> Route of Administration

Oral

Remarks for Method

EPA High Production Volume (HPV) Track

Toxicity End Point:
Acute Toxicity

Sponsor ID	[redacted]	Albemarle Corporation	Create Date	[redacted]	
CAS Number	[redacted]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1	
Consortia ID	[redacted]	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed	Y	

TBBPA was administered orally by gavage in methylcellulose to 5 males and 5 female Sprague Dawley rats in a single dose of 5,000 mg/kg body weight and observed for 14 days.
The rats weighed 180-280 g at initiation, and were obtained from Charles River Breeding Laboratories, Wilmington, Massachusetts. The rats were observed immediately after dosing and at 2, 4 and 24-hrs after dosing, and daily for 14 days. The rats were then sacrificed by CO2 inhalation.

Results

>> Precision >

>>Acute Lethal Value 5000

>> Unit mg/kg-bw

>> Deaths per Dose

No rats died on test.

Results Remark

None of the rats died during the 14 day study. No clinical signs of toxicity were observed over the 14 day study. No gross lesions attributable to the test article were observed on necropsy.

Conclusions

The oral LD50 of TBBPA in rats was > 5,000 mg/kg-bw.

Data Quality

Reliability High

Data Reliability Remarks

EPA High Production Volume (HPV) Track

Toxicity End Point:
Acute Toxicity

Sponsor ID	[redacted]	Albemarle Corporation	Create Date	[redacted]	
CAS Number	[redacted]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1	
Consortia ID	[redacted]	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y	

This study was performed according to guidelines (EPA and GLP) current at the time of study performance by a laboratory with considerable expertise.

Reference

>> Remarks

Mallory, V. Acute Oral Toxicity Study in Rats (14 Day). PH 402-ET-001-81. Tetrabromo Bisphenol-A. Lot #R6/FD2. 1981.

General

This study was sponsored by Ethyl Corporation, Baton Rouge, LA.

The results of this test are consistent with earlier tests. Tests performed in 1958, 1966, 1967 in Holtzman, Dublin and Wistar rats, respectively, produced acute oral LD50 values of > 50 mg/kg, > or = 10,000 mg/kg, and >50,000 mg/kg, respectively. A 1978 test in mice reported an oral LD50 of > 10,000 mg/kg. (as reported in the 1995 Environmental Health Criteria Document #173, World Health Organization, Geneva)

EPA High Production Volume (HPV) Track

Toxicity End Point:
Acute Toxicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01	
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	2	
Consortia ID	1101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y	

Revision Date:
12/9/01

Test Substance

Remarks
The test article was the commercial tetrabromobisphenol A (TBBPA) product known as Saytech RB-100 produced by Ethyl Corporation.

Chemical Category

Method

>> Method/Guideline followed
EPA OPPTS Method

>> GLP Yes

>> Year study performed 1981

>> Species
rabbit

>> Strain New Zealand white

>> Sex Both

>> Number of males per dose 5

>> Number of females per dose 5

>> Vehicle None

>> Route of Administration
Dermal

Remarks for Method

EPA High Production Volume (HPV) Track

Toxicity End Point:
Acute Toxicity

Sponsor ID	[illegible]	Albemarle Corporation		Create Date	[illegible]
CAS Number	[illegible]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-		Study Number	[illegible]
Consortia ID	[illegible]	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed	Y

TBBPA was applied at 2000 mg/kg-bw to 10 rabbits (5 males, 5 females). The test article was administered directly on the skin which was abraded within 2 hrs prior to application. Twenty-four hrs prior to testing the trunk of the animals was shaved so that no less than 10% of the dorsal body surface area was available for application of the test article. Immediately prior to dosing, the skin was abraded by making 4 epidermal incisions with a clean needle throught the stratum corneum, but not deep enough to distrub the derma or to produce bleeding. The test article was apllied directly onto the exposed skin taking care to spread the substance evenly over the entire abraded area. Gauze followed with a rubber dam was wrapped around the application site, and the test article was held in contact with the skin for 24 hrs after which the wrapping was removed and the site washed.

Observations were recorded at 2 and 4 hrs after the 24 hr exposure period, and twice daily thereafter for 14 days. All rabbits were sacrificed by intravenous sodium pentobarbital on day 14 and a gross necropsy performed.

Results

>> Precision >

>>Acute Lethal Value 2000

>> Unit mg/kg-bw

>> Deaths per Dose

None

Results Remark

All animals survived through the 14 day observation period. Slight erythema and edema were observed in 1 of 10 rabbits on day 1. No other signs were visible during the 14 day study. No visible lesions were detected on gross necropsy.

Conclusions

The dermal L50 of TBBPA in rabbits was > 2000 mg/kg-bw.

EPA High Production Volume (HPV) Track

Toxicity End Point:
Acute Toxicity

Sponsor ID	[illegible]	Albemarle Corporation	Create Date	[illegible]	
CAS Number	[illegible]	Phenol, 4,4'-isopropylidenebis[2 6-dibromo-	Study Number	2	
Consortia ID	[illegible]	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed.	Y	

Data Quality

Reliability High

Data Reliability Remarks

This study was performed according to guidelines (EPA and GLP) current at the time of study performance by a laboratory with considerable expertise.

Reference

>> Remarks

Mallory, V. Acute Dermal Toxicity Study in Rabbits (14 Day). PH 422-ET-001-81. Tetrabromo Bisphenol-A. Lot #R6/FD2. 1981.

General

This study was sponsored by Ethyl Corporation, Baton Rouge, LA.

The results of this study are consistent with earlier studies conducted in female albino rabbits which reported a dermal LD50 values of >10,000 mg/kg-bw (1966) and >200 mg/kg-bw (1958) (highest dose tested). (as reported in the 1995 Environmental Health Criteria Document #173, World Health Organization, Geneva)

EPA High Production Volume (HPV) Track

Toxicity End Point:
Acute Toxicity

Sponsor ID	100021	Albemarle Corporation	Create Date	7/6/01	
CAS Number	5947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	3	
Consortia ID	100012	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y	

Revision Date:
12/10/01

Test Substance

Remarks TBBPA.

Chemical Category

Method

>> Method/Guideline followed

Predates EPA and OECD Guidelines.

>> GLP Unknown

>> Year study performed 1966

>> Species

rat

>> Strain Dublin

>> Sex M

>> Number of males per dose 10

>> Number of females per dose 0

>> Vehicle None

>> Route of Administration

Inhalation

Remarks for Method

EPA High Production Volume (HPV) Track

Toxicity End Point:
Acute Toxicity

Sponsor ID	[redacted]	Albemarle Corporation		Create Date	[redacted]
CAS Number	[redacted]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-		Study Number	[redacted]
Consortia ID	[redacted]	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed:	Y

A single concentration of 1,267 ppm was administerd to rats in a glass exposure chamber. Test material was introduced into the test chamber by bubbling air through molten test material, maintained at 180-185 degrees C, and into the chamber at 10 L/min for 1 hr. The nominal concentration was calculated from the ratio of the weight of the material vaporized to the total volume of air bubbled through the material during the entire exposure period. Rats were weighed prior to testing and the end of the two week post-exposure. After the 14 day observation period, all rats were sacrificed.

Results

>> Precision >

>>Acute Lethal Value 1267

>> Unit ppm(air)

>> Deaths per Dose

No mortality occurred.

Results Remark

There was no mortality and body weight gain was not affected.

Conclusions

The 1 hr inhalation LC50 of TBBPA in rats was >1267 ppm.

Data Quality

Reliability Reasonable.

Data Reliability Remarks

EPA High Production Volume (HPV) Track

Toxicity End Point:
Acute Toxicity

Sponsor ID	[illegible]	Albemarle Corporation	Create Date	[illegible]
CAS Number	[illegible]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	
Consortia ID	[illegible]	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed	Y

Reference

>> Remarks

Michigan Chemical Co., St. Louis, MI. Acute toxicity and irritation studies on tetrabromobisphenol A. Testing Facility: Hill Top Research, Inc., Miamiville, OH. Study No.: Q-38D. 1966.

General

Sponsored by Michigan Chemical Co.

The results of this study are consistent with other studies conducted (1967) in male and female Wistar rats, NMDI mice and guinea pigs. Five males and 5 females of each species were exposed to 50 mg TBBPA /L (aerosol) for 8 hrs in a stainless steel inhalation chamber. Animals were observed for 48 hrs and sacrificed. No mortality and no signs of toxicity occurred, and the 8 hr LC50 was reported as > 50 mg/L. (reported in World Health Organization EHC # 172, 1995, Geneva).

These results are also consistent with a 1958 study in female albino rabbits (n=10) which reported an inhalation LC50 value of > 200 mg/kg-bw.

EPA High Production Volume (HPV) Track

Toxicity End Point:
Acute Toxicity

Sponsor ID	[redacted]	Albemarle Corporation	Create Date	2/6/01
CAS Number	[redacted]	Phenol 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	[redacted]
Consortia ID	[redacted]	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Revision Date:
12/14/01

Test Substance

Remarks TBBPA

Chemical Category

Method

>> Method/Guideline followed

Pre-dates OECD and EPA Guideline

>> GLP Unknown

>> Year study performed 1967

>> Species

rats, mice, guinea pig

>> Strain Wistar rats, NMDI mice

>> Sex Both

>> Number of males per dose 5

>> Number of females per dose 5

>> Vehicle none

>> Route of Administration

Inhalation

Remarks for Method

Groups of rats, mice and guinea pigs (n=30) wree exposed for 8 hours to a concentration of 50 mg/L in a stainless steel inhalation chamber. An aerosol was produced by an aerosol apparatus, and administered into the chamber under continuous air flow throughtouthe 8 hr expsoure period. Animals were maintained for an additional 48 hrs and then sacrificed.

Results

>> Precision >

>>Acute Lethal Value 50

>> Unit mg/L air

>> Deaths per Dose

None

Results Remark

No adverse findings were detected at necropsy, and no signs of toxicity were observed throughout the study.

Conclusions

The 8 hr inhalation LC50 of TBBPA in three species was > 50 mg/L air.

Data Quality

Reliability High

Data Reliability Remarks

Sponsor ID	[redacted]	Albemarle Corporation	Create Date	[redacted]	
CAS Number	[redacted]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1	
Consortia ID	[redacted]	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed.	Y	

Reference

>> Remarks

Great Lakes Chemical Corp. Acute inhalaiton toxicity study of tetrabomobisphenol A to rats. Testing Facility: international Bio Research, Inc., St. Louis, MO. 1967.

General

Sponsored by Great Lakes Chemical Corporation

Sponsor	[illegible]	Albemarle Corporation	Create Date: 2/6/01
CAS Number	[illegible]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	
Consortium	[illegible]	CMA Brominated Flame Retardant Industry Panel (BFRIP)	

Select an End Point: TO - Developmental toxicity/teratogenicity

[illegible]

Physical/Chemical Properties

- ✔ **Melting Point**
- **Boiling Point**
- ✔ **Partition Coefficient**
- ✔ **Vapor Pressure**
- ✔ **Water Solubility**

Environmental Fate

- ✔ **Photodegradation**
- **Stability in Water**
- ✔ **Biodegradation**
- ✔ **Transport**

Ecotoxicity

- ✔ **Acute Toxicity to Fish**
- ✔ **Toxicity to Aquatic Plant**
- ✔ **Acute Toxocity to Aquatic Invertebrates**

Health

- ✔ **Acute Toxicity**
- **Genetic Toxicity in Vivo**
- ✔ **Repeat Dose Toxicity**
- ✔ **Genetic Toxicity in Vitro**
- **Reproductive Toxicity**
- ✔ **Developmental Tox/Teratogenicity**

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	[redacted]	Albemarle Corporation		Create Date	2/6/01
CAS Number	[redacted]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-		Study Number	1
Consortia ID	[redacted]	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed:	Y

Revision Date: 12/13/01

Test Substance

Remarks: The test article was described as tetrabromobisphenol A, a white powder.

Chemical Category

Method

>> Method/Guideline followed

Pre-dates OECD and EPA test guidelines

>> GLP: Unknown

>> Year study performed: 1972

>> Species

rat

>> Strain | **Mammal strai:** Charles River CD

>> Sex: Both

>> Number of males per dose: 25 | **>> Number of females per dose:** 25

>> Route of Administration: Oral, in the diet

>> Exposure Period: 28

>> Frequency of treatment: daily

>>Doses: 0, 1, 10, 100 or 1000 ppm in the diet

>> Control Group: Yes

>> Post observation period: yes - 2, 6, 12 weeks

>> Statistical Method: Not described.

Remarks for Method

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	110021	Albemarle Corporation		Create Date	2/6/01
CAS Number	79947	Phenol 4,4' isopropylidenebis[2,6-dibromo-		Study Number	1
Consortia ID	110012	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed:	Y

Groups of 25 female and 25 male Charles River CD rats (males 260-341 g, femals 183-232 g) were fed TBBPA in the diet at 0, 1, 10, 100 or 1000 ppm for 28 days. After 4 weeks, 5 rats/sex per group were sacrificed and the remaining rats placed on control diets for 2, 6 or 12 weeks.

Animals were housed individually with food and water available ad libitum and observed daily. Body weights were determined once/wk. Mean food consumption was measured weekly. At the 28 day sacrifce and at the 3 recovery sacrifices, organ weights were measured and tissues collected for microscopic exam. Bromine levels were measured in liver and adipose of the control and high dose animals (5M/5F) at 28 days.

Organs weighed were spleen, liver, adrenals, kidneys, testes, ovaries, heart, thyroid/parathryroid, brain and pituitary. Histopathology of the liver, kidneys and thyroids were performed on all animals at 28 days.

Hematology, clinical chemistry, urinalysis were not performed.

Results

>> NOAEL Precision >=

>> NOAEL dose 1000 **>> Unit** ppm in feed

>> NOAEL Effec None.

>> LOAEL Precision >

>> LOAEL dose 1000 **>> Unit** ppm in feed

>> LOAEL Effect None.

>> Actual dose received by dose level by sex

appr. 0, 1, 10, 100 or 1000 mg/kg bw

>> Toxic response

None.

>> Statistical results

See results.

Results Remark

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	[redacted]	Albemarle Corporation	Create Date	[redacted]	
CAS Number	[redacted]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	[redacted]	
Consortia ID	[redacted]	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y	

In a 28-day oral study, no toxicity was observed in rats treated with up to 1,000 ppm TBBPA in the diet. Rat were fed at dietary dose levels of 0, 1, 10, 100 or 1000 ppm TBBPA for 28 days after which one group was sacrificed and the remaining rats placed on untreated diets for 2, 6 or 12 weeks. No effects on general appearance, behavior, body weight, food consumption or mortality were observed. No compound related gross or microscopic lesions or variations in organ weights were observed at any dose level. Liver and adipose bromine levels were comparable in rats of the control and high dose groups sacrificed at the end of the 28 day treatment period.

Conclusions

The no effect level in this 28 day study was > 1000 ppm TBBPA in the diet. Further, the bromine content of liver and adipose tissue in the control and high dose animals after 28 days of treatment were comparable.

Data Quality

Reliability Reasonable.

Data Reliability Remarks

This study is old and not conducted according to current guidelines. However, it demonstrates TBBPA's lack of toxicity, and the comparable bromine content in tissues of the control and high dose groups is consistent with TBBPA's rapid metabolism and elimination (Haak et al., Xenobiotica, 2000, 30,9,881-890).

Reference

>> Remarks

Goldenthal and Geil, 1972. Tetrabromobisphenol A. Twenty-eight day toxicity studye in ratws. Study NO. 274-010. International Research and Development Corporation, Mattawan, MI.

Reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995)

General

This study was sponsored by Great Lakes Chemical Corporation.

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	[redacted]	Albemarle Corporation		Create Date	[redacted]
CAS Number	[redacted]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-		Study Number	2
Consortia ID	[redacted]	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed:	Y

Revision Date: 12/13/01

Test Substance

Remarks: The test article was described as tetrabromobisphenol A.

Chemical Category

Method

>> Method/Guideline followed

Pre-dates OECD and EPA guidelines

>> GLP: Unknown

>> Year study performed: 1975

>> Species

rat

>> Strain | **Mammal strai:** Sprague-Dawley

>> Sex: Both

>> Number of males per dose: 5

>> Number of females per dose: 5

>> Route of Administration: Oral, in the diet

>> Exposure Period: 90

>> Frequency of treatment: daily

>>Doses: 0, 0.3, 3, 30, 100 mg/kg bwt

>> Control Group: Yes

>> Post observation period: None

>> Statistical Method: ANOVA, Dunnett's test

Remarks for Method

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	[redacted]	Albemarle Corporation		Create Date	[redacted]
CAS Number	[redacted]	Phenol 4,4'-isopropylidenebis[2,6-dibromo-		Study Number	[redacted]
Consortia ID	[redacted]	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed:	Y

TBBPA was administered to male and female rats in their diet for 90 days. The concentrations of TBBPA in the diet were adjusted so that rats were administered 0, 0.3, 3, 30 or 100 mg/kg-bw/d. The parameters evaluated included: appearance, demeanor, body weights, food consumption, routine hematology measurements, clinical chemistry determinations (serum urea nitrogen, alkaline phosphatase activity and serum glutamic pyruvic transaminase activity), routine urinalyses, organ weights, organ-to-body weight ratios, and gross and microscopic pathological examination of tissues.

Organs weighed: brain, heart, liver, kidney, testes.

Histopathology in control and high dose: heart, liver, kidney, thyroid, trachea, parathyroid, lung, adrenal, spleen, pancreas, stomach, small intestine (3 levels) large intestin, gonads, uterus, urinary bladder, accessory sex glands, skeletal muscle, spinal cord, brain, eye, pituitary gland, thymus, aorta, peripheral nerve, mesenteric and mediastinal lymph nodes.

The total bromine content in liver, kidney, skeletal muscle, fat and serum of rats in the control and 3 mg/kg dose group was determined at the end of the 90 day treatment period.

Results

>> NOAEL Precision >

>> NOAEL dose 100 **>> Unit** mg/kg-bw

>> NOAEL Effec None.

>> LOAEL Precision >

>> LOAEL dose 100 **>> Unit** mg/kg-bw

>> LOAEL Effect None.

>> Actual dose received by dose level by sex

0, 0.3, 3, 30 or 100 mg/kg-bw/d

>> Toxic response

None.

>> Statistical results

See results

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	[redacted]	Albemarle Corporation		Create Date	[redacted]
CAS Number	[redacted]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-		Study Number	[redacted]
Consortia ID	[redacted]	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed:	Y

Results Remark

In a 90-day oral study, no toxicity was found in rats treated with up to 100 mg/kg bwt in the feed. No toxicological effects were detected at any dose level for appearance, demeanor, body weight gain, food consumption, hematology, clinical chemistry values, urinalysis, organ weights, and gross and microscopic examinations. The total bromine content in liver, kidney, skeletal muscle, fat and serum of rats in the 3 mg/kg dose group did not differ from that of the controls. (The 3 mg/kg group was the only group tested for total bromine content.)

Conclusions

The NOEL in this 90 day oral toxicity study of TBBPA in the rat was greater than 100 mg/kg-bw/day, the highest dose tested. The total bromine content in liver, kidney, skeletal muscle, fat and serum of rats in the control and 3 mg/kg dose group were comparable.

Data Quality

Reliability High

Data Reliability Remarks

This study is old and not conducted according to current guidelines. Nonetheless, the study was well conducted, and demonstrates TBBPA's lack of toxicity. Further, the comparable bromine content in tissues of the control and 3 mg/kg-bwt group is consistent with the 1972 28 day study (Goldenthal and Geil, 1972) and TBBPA's rapid metabolism and elimination (Haak et al., Xenobiotica, 2000, 30,9,881-890).

Reference

>> Remarks

Quast, J and Humiston, C. 1975. Results of a 90-day toxicological study in rats given tetrabormobisphenol A in the diet. Toxicology Research Laboratory, The Dow Chemical Company, Midland, MI.

Reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995)

General

This study was sponsored by Dow Chemical Company.

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	[illegible]	Albemarle Corporation		Create Date	2/6/01
CAS Number	[illegible]	Phenol 4,4'-isopropylidenebis[2,6-dibromo-		Study Number	[illegible]
Consortia ID	[illegible]	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed:	Y

Revision Date: 12/13/01

Test Substance

Remarks: Tetrabromobisphenol A

Chemical Category

Method

>> Method/Guideline followed

Not specified

>> GLP: Unknown

>> Year study performed: 1986

>> Species

mice

>> Strain | **Mammal strai:** B6C3F1

>> Sex: Both

>> Number of males per dose: 10

>> Number of females per dose: 10

>> Route of Administration: Oral, in the diet

>> Exposure Period: 90

>> Frequency of treatment: daily

>>Doses: 0, 500, 4,900, 15,600 or 50,000 ppm in the diet

>> Control Group: Yes

>> Post observation period: no

>> Statistical Method: not specified

Remarks for Method

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	[redacted]	Albemarle Corporation		Create Date	[redacted]
CAS Number	[redacted]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-		Study Number	[redacted]
Consortia ID	[redacted]	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed:	Y

Mice (10/sex/group) were fed TBBPA in the diet at 0, 500, 4900, 15600 or 50000 ppm in the diet for 90 days.

Results

>> NOAEL Precision =

>> NOAEL dose 4900 **>> Unit** ppm in feed

>> NOAEL Effec None.

>> LOAEL Precision =

>> LOAEL dose 15600 **>> Unit** ppm in feed

>> LOAEL Effect Decreased body weight gain, red blood cells, hemoglobin, hematocrit, serum triglycerides and total serum protein.

>> Actual dose received by dose level by sex

Not available.

>> Toxic response

see results

>> Statistical results

not described

Results Remark

All animals in the highest dose died during the study, possibly because of malnutrition and anemia. No deaths occured at the lower doses. Body weight gains were decreased at the 15,600 ppm dose level, although food consumption was not. Red blood cells, hemoglobin, hematocrit, serum triglycerides and total serum protein were decreased at the 15,600 ppm dose level. Organ weights were not affected, except for an increase in spleen weight at 15,600 ppm. Histopathological changes were not observed.

Conclusions

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	[redacted]	Albemarle Corporation		Create Date	[redacted]
CAS Number	[redacted]	Phenol, 4 4'-isopropylidenebis[2,6-dibromo-		Study Number	[redacted]
Consortia ID	[redacted]	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed	Y

The no adverse effect level in this 90 day mouse study was 4,900 ppm in the diet.

Data Quality

Reliability Reasonable

Data Reliability Remarks

The lack of toxicity observed in mice in this 90-day study at dose of 4900 ppm (diet) and less is consistent with the lack of toxicity observed repeated dose studies in rats and rabbits.

Reference

>> Remarks

Tobe et al. 1986. Subchronic toxicity study of tetrabromobispheno-A: report to the Ministry of Health and Welfare (in Japanese).

Reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.

General

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	[redacted]	Albemarle Corporation		Create Date	[redacted]
CAS Number	[redacted]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-		Study Number	[redacted]
Consortia ID	[redacted]	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed	Y

Revision Date: 12/13/01

Test Substance

Remarks: micronized Tetrabromobisphenol A

Chemical Category

Method

>> Method/Guideline followed

Pre-dates OECD and EPA guidelines

>> GLP Unknown

>> Year study performed 1975

>> Species

rat

>> Strain **Mammal strai** Charles River CD

>> Sex Both

>> Number of males per dose 5 **>> Number of females per dose** 5

>> Route of Administration Inhalation

>> Exposure Period 14

>> Frequency of treatment 5 d/wk; 4 hr/d

>>Doses 0, 2, 6 and 18 mg/L (0, 2000, 6,000, 18,000 mg/m3)

>> Control Group Yes

>> Post observation period no

>> Statistical Method not specified

Remarks for Method

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/6/01	
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1	
Consortia ID	1101072	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y	

Rats were exposed to micronized TBBPA via whole body inhalation exposures at concentrations of 0, 2, 6, or 18 mg/L for 4 hr/d, 5 d/wk for a total of 10 exposures. Air flow and introduction of test material was dynamic and controlled by a Wright dust feeder and regulated by a flow meter. Animals were observed during each exposure, and daily for 2 weeks for general toxicity, appearance, behavior, and mortality. Body weights and food consumption were recorded weekly. At the end of the study, routine hematology, serum chemistry (BUN, glucose, SAP, SGOT, SGPT) and urinalysis was performed. Organs weighed at sacrifice were spleen, liver, adrenals, kidneys, testes, ovaries, heart, thyroid/parathyroid, and brain. Absolute and relative organ weights were determined. A gross necropsy was performed on all animals. Histopathology was performed on tissues from the control, 6 and 18 mg/L groups. Treatment groups were statistically compared to the control group by sex.

Results

>> NOAEL Precision =

>> NOAEL dose 2 **>> Unit** mg/l air

>> NOAEL Effec none

>> LOAEL Precision =

>> LOAEL dose 6 **>> Unit** mg/l air

>> LOAEL Effect salivation, lacrimation, nasal discharge

>> Actual dose received by dose level by sex

0, 2000, 6000, 18,000 mg/m3 micronized TBBPA

>> Toxic response

see results

>> Statistical results

see results

Results Remark

No effect of treatment was found on mortality, morbundity, body weight, hematology, serum chemistries, urinalysis, gross necropsy or microscopic exams.

Excessive salivation, red or clear nasal discharge and lacrimation were observed in animals at the 6 or 18 mg/L doses. Liver weights, in the absence of a dose response, were decreased in the females of all exposure concentrations compared to the control females (control = 14.45 g; 2 mg/L = 12.48 g; 6 mg/L = 12.53 g; 18 mg/L = 12.5 g).

Conclusions

The no effect level for this 14 d inhalation study of micronized TBBPA in rats was 6 mg/L (2,000 mg/m3). Effects seen at higher doses were limited to salivation, lacrimation and nasal discharge.

Data Quality

Reliability Reasonable

Data Reliability Remarks

Reference

>> Remarks

Goldenthal et al. 1975. 14-Day inhalation toxicity study in rats. Study No. 274-021. International Reasearch and Development Corporation.

Reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.

General

Sponsored by Great Lakes Chemical Corporation.

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	[illegible]	Albemarle Corporation	Create Date	[illegible]	
CAS Number	[illegible]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	[illegible]	
Consortia ID	[illegible]	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y	

Revision Date: 12/13/01

Test Substance

Remarks: Tetrabromobisphenol A

Chemical Category

Method

>> Method/Guideline followed

Pre-dates OECD and EPA Guidelines

>> GLP: Unknown

>> Year study performed: 1979

>> Species

rabbit

>> Strain | **Mammal strai:** New Zealand white

>> Sex: Both

>> Number of males per dose: 4 | **>> Number of females per dose:** 4

>> Route of Administration: Dermal

>> Exposure Period: 21

>> Frequency of treatment: 6 hr/d; 5 d/wk

>>Doses: 0, 100, 500 or 2500 mg/kg-bw

>> Control Group: Yes

>> Post observation period: none

>> Statistical Method: Bartlett's test, Dunnett's

Remarks for Method

TBBPA was applied dermally as a paste in saline to the clipped backs of rabbits for 6 hr/d for 5 d/wk for 3 weeks for a total of 15 applications. Sites were non-occluded. Half of the rabbits per dose had abraded test sites, the others were non-abraded. Animals were restrained with the use of a collar during the 6 hr exposure period, after which the collars were removed and the test sites wiped clean. Test sites were scored for irritation at the end of each exposure period.

Body weights were measured weekly. Hematology, biochemistry and urinalysis measurements were determined pre-trest and at 3 weeks. Gross necropsies were performed on all rabbits at sacrifice. Histopathology was performed on control and high dose. Statistical anlayses were perfomed. Organs weighed were spleen, liver, adrenals, kidneys, testes, ovaries, heart, thyroid/parathyroid and brain.

Results

>> NOAEL Precision =

>> NOAEL dose 2500 **>> Unit** mg/kg-bw

>> NOAEL Effec Very slight erythema at site of application.

>> LOAEL Precision >

>> LOAEL dose 2500 **>> Unit** mg/kg-bw

>> LOAEL Effect none

>> Actual dose received by dose level by sex

as above

>> Toxic response

see results

>> Statistical results

see results

Results Remark

Sponsor ID	[illegible]	Albemarle Corporation	Create Date	[illegible]	
CAS Number	[illegible]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	[illegible]	
Consortia ID	[illegible]	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed	Y	

No difference between treated and control in: mortality, moribundity, appearance, body weight, organ weight, hematology, biochemistry, urinalysis, gross necropsy or microscopic comparisons. Very slight erythema was detected in the high dose group thoughout the study.

Conclusions

The no adverse effect level in this 21-day dermal repeated dose study in rabbits was 2500 mg/kg-bw.

Data Quality

Reliability Reasonable.

Data Reliability Remarks

Reference

>> Remarks

Goldenthal et al., 1979. Three week dermal toxicity study in rabbits. Study No. 163-549. International Research and Development Corporation.

Reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.

General

Sponsored by Velsicol Corporation.

EPA High Production Volume (HPV) Track

Toxicity End point:
Toxicity in Vitro (Gene Mutations)

Sponsor ID	[redacted]	Albemarle Corporation		Create Date	[redacted]
CAS Number	[redacted]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-		Study Number	[redacted]
Consortia ID	[redacted]	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed:	Y

Revision Date: 12/9/01

Test Substance

Remarks: The test article was the commercial tetrabromobisphenol A (TBBPA) product known as Saytech RB-100 produced by Ethyl Corporation.

Chemical Category

Method

>> Method/Guideline followed

EPA/OECD Guideline No. Not specified.

>> Test Type

Ames test

>> System of Testing: Bacterial

>> GLP: Unknown

>> Year study performed: 1981

>> Species

Salmonella typhimurium

>> Metabolic Activation

S-9 from induced (A1254) male Sprague Dawley rats

>> Concentration

0.005, 0.015, 0.05, 0.15, and 0.5 mg/plate

>> Statistical Method: Not specified.

Remarks for Method

The test article was tested with and without metabolic activation in S. Typhimurium strains TA1535, TA1537, TA1538, TA98, adn TA100 in the standard Ames assay. Positive controls were sodium azide, 9-aminoacridine, 2-nitrofluorene, and 2-aminoanthracene.

EPA High Production Volume (HPV) Track

Toxicity End point:
Toxicity in Vitro (Gene Mutations)

Sponsor ID	[illegible]	Albemarle Corporation	Create Date	[illegible]/01
CAS Number	[illegible]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	1
Consortia ID	[illegible]	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y

Results

>> Result Negative

>> Cytotoxic Concentration

No toxicity observed.

>> Genotoxic Effects Unconfirmed

>> Statistical results

No statistically significant differences between treatment and negative control.

Results Remark

With and without metabolic activation, all concentrations of the test article failed to induce an average number of revertants/plate three times greater than that found in the solvent controls. The positive controls performed as expected. The sterility controls were all negative for bacterial contamination.

Conclusions

TBBPA was negative in the Ames test both with and without metabolic activation.

Data Quality

Reliability High

Data Reliability Remarks

This study was performed according to standard practices by a laboratory with considerable expertise.

Reference

EPA High Production Volume (HPV) Track

Toxicity End point:
Toxicity In Vitro (Gene Mutations)

Sponsor ID	[illegible]	Albemarle Corporation		Create Date	[illegible]
CAS Number	[illegible]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-		Study Number	1
Consortia ID	[illegible]	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed:	Y

>> Remarks

Curren, R. Activity of T1685 in the Salmonella/microsomal assay for bacterial mutagenicity. Microbiological Associates, Bethesda, MD. 1981.

General

Study sponsored by Ethyl Corporation, Baton Rouge, LA.

The results of this study are consistent with earlier Ames tests performed on TBBPA. A 1977 study in the 5 standard strains plus Saccharomyces cerevisiae strain D4, with and without metabolic activation, at doses of 0.1 to 500 ug/plate was also negative (Study sponsored by Velsicol Corporation). A 1976 study also was negative (study sponsored by Great Lakes Chemical Corp). The results of this study are also consistent with those of Mortelmans et al. (Environmental Mutagens, 1986, 8(Suppl 7):1-119). TBBPA was tested in S. Typhimurium TA100, TA1535, TA1537 and TA98 in concentrations of 0, 100, 333, 1000, 3333 and 10,000 ug/plate with and without S9 mix of Arochlor 1254-treated male Sprague-Dawley rats and male Syrian hamsters. TBBPA was dissolved in DMSO. TBBPA was negative for mutagenic activity. (Reported in Environmental Health Criteria Document # 172, World Health Organization, Geneva, 1995.)

EPA High Production Volume (HPV) Track

Toxicity End point:
Toxicity In Vitro (Gene Mutations)

Sponsor ID	[redacted]	Albemarle Corporation		Create Date	[redacted]
CAS Number	[redacted]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-		Study Number	[redacted]
Consortia ID	[redacted]	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed:	Y

Revision Date:
12/11/01

Test Substance

Remarks The test article was a composite of the commercial TBBPA products produced by Albemarle Corp., Dead Sea Bromine Group, and Great Lakes Chemical Corp. The purity was 98.91%.

Chemical Category

Method

>> Method/Guideline followed

Evans, H.J. 1976. In: A Hollaender (Ed.), Chemical Mutagens, Vol 4. Plenum Press, NY.

>> Test Type

Cytogenetic assay

>> System of Testing Non-bacterial

>> GLP Yes

>> Year study performed 2001

>> Species

Primary cultures - human lymphocytes

>> Metabolic Activation

Arochlor-induced S9

>> Concentration

See Results.

>> Statistical Method See Results.

Remarks for Method

TBBPA was tested in the in vitro mammalian chromosome aberration test using human peripheral lymphocytes (HPBL) in both the absence and presence of an Arochlor-induced S9 activation system. A preliminary toxicity test was performed to establish the dose range in the cytogenetic test. The chromosome aberration assay was used to evaluate the clastogenic potential of the test article.

Definitive assay in absence of exogenous metabolic activation: 4 hr treatment, 20 hr harvest.

Test article concentrations: 6.25, 25, 100 ug/ml.

Definitive assay in absence of exogenous metaoblic activation: 20 hr treatment, 20 hr harvest.
Test article concentrations: 6.25, 25, 75 ug/ml.

Definitive assay in presence of exogenous metaoblic activation: 4 hr treatment, 20 hr harvest.
Test article concentrations: 3.125, 12.5, 50 ug/ml.

Results

>> Result Negative

>> Cytotoxic Concentration

See Results.

>> Genotoxic Effects Unconfirmed

>> Statistical results

See Results.

Results Remark

The test article was soluble in treatment medium at all concentrations tested. Toxicity (mitotic inhibition) was appr. 54 and 59% at the highest dose level evaluated for chromosome aberrations, 100 ug/ml and 75 ug/ml in the non-activated 4 hr and 20 hr exposure groups, respectively. Toxicity (mitotic inhibition) was 58% at the highest dose level evaluated for chromosome aberrations, 50 ug/ml, in the S9 activated study.

No statistically significant increases in structural and numerical chromosome aberrations were observed in the non-activated or the S9 activated 4 hr exposure groups relative to the solvent control gorup, regardless of dose level ($p>0.05$, Fisher's exact test). In the absence of a positive response in the non-activated 4 hr exposure group, the non-activated 20 hr continuous exposure gorup was evaluated for structural and numerical chromosome aberrations. No statistically significant increases in structural and numerical chromosome aberrations were observed in the non-activated 20 hr continuous exposure group relative to the solvent control group, regardless of dose level ($p>0.05$, Fisher's exact test). The positive controls performed as expected.

Conclusions

EPA High Production Volume (HPV) Track

Sponsor ID	[illegible]	Albemarle Corporation	Create Date	[illegible]
CAS Number	[illegible]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	[illegible]
Consortia ID	[illegible]	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed	Y

TBBPA was negative for the induction of structural and numerical chromosome aberrations in the in vitro chromosome aberration test using human peripheral lymphocytes.

Data Quality

Reliability High

Data Reliability Remarks

This study was perfomed according to current guidelines by a laboratory with considerable expertise.

Reference

>> Remarks

Gudi, R. and Brown, C. In vitro chromosome aberration test. Test Article: Tetrabromobisphenol A (TBBPA). Study Number: AA47PV.341.BTL. 2001. BioReliance, Rockville, MD.

General

This study was sponsored by the ACC Brominated Flame Retardant Industry Panel.

EPA High Production Volume (HPV) Track

Toxicity End point:
Toxicity in Vitro (Gene Mutations)

Sponsor ID	[illegible]	Albemarle Corporation	Create Date	[illegible]	
CAS Number	[illegible]	Phenol 4,4'-isopropylidenebis[2,6-dibromo-	Study Number	[illegible]	
Consortia ID	[illegible]	CMA Brominated Flame Retardant Industry Panel (BFRIP)	Completed:	Y	

Revision Date: 12/11/01

Test Substance

Remarks: TBBPA, obtained from Aldrich Chemical (Stockholm, Sweden)

Chemical Category

Method

>> Method/Guideline followed

Other, Test and cell line developed by the paper's authors

>> Test Type

Intragenic recombination

>> System of Testing: Non-bacterial

>> GLP: No

>> Year study performed: 1999

>> Species

Mammalian cells in culture (Sp5 and SPD8 duplication cell lines)

>> Metabolic Activation

None

>> Concentration

0, 5, 10, 20, 30, 40 ug/ml

>> Statistical Method: Student's t test

Remarks for Method

The Sp5 and SPD8 cell lines were developed by the publication's authors. The clones used in this study exhibit a spontaneous partial duplication of the hprt gene, resulting in an non-functional HGPRT protein. These mutants revert spontaneously to a functional hprt gene phenotype by recombination with a frequency of appr. 1 x 10E5 reversions/cell generation. This reversion frequency is said to increase by exposure to chemical or physical agents.

Treatment with the test substance were perfomed for 24 hr at 37 degrees C.

EPA High Production Volume (HPV) Track

Toxicity End point:
Toxicity In Vitro (Gene Mutations)

Sponsor ID	[illegible]	Albemarle Corporation		Create Date	[illegible]
CAS Number	[illegible]	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-		Study Number	[illegible]
Consortia ID	101012	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed:	Y

Results

>> Result Negative

>> Cytotoxic Concentration

See results.

>> Genotoxic Effects Unconfirmed

>> Statistical results

See results.

Results Remark

SPD8 cells: TBBPA concentrations of 0, 5, 10, 20, 30, and 40 ug/ml resulted in the following reversion frequency 1.0, 1.1, 1.4, 1.3, 1.3, and 1.0, respectively. Cytoxicity was not observed at the doses tested.

Sp5 cells: TBBPA concentrations of 0, 10, 20, 40, 70 ug/ml resulted in the following reversion frequency 1.0, 0.8, 0.8, 1.0 and 0.7. Cytotoxicity was observed at 70 ug/ml.

None of these reversion frequencies were statistically different from the control ($p<0.05$).

Conclusions

TBBPA had no effect in either the SPD8 or Sp5 recombination assay.

Data Quality

Reliability Unknown.

Data Reliability Remarks

This is a non-standard genotoxicity test. The validation of the test system, reliability, reproducibility and predictive ability of this test is unknown. This test was included in this record for the sake of completeness.

Reference

EPA High Production Volume (HPV) Track

Toxicity End point:
Toxicity In Vitro (Gene Mutations)

Sponsor ID	100031	Albemarle Corporation		Create Date	2/6/01
CAS Number	79947	Phenol, 4,4'-isopropylidenebis[2,6-dibromo-		Study Number	3
Consortia ID	110102	CMA Brominated Flame Retardant Industry Panel (BFRIP)		Completed:	Y

>> Remarks

Helleday, T., Tuominen, K., Bergman, A., Jenssen, D. Brominated flame retardants induce intragenic recombination in mammalian cells. Mutation Research 439 (1999) 137-147.

General