

Sponsor	1100021	Albemarle Corporation	Create Date:	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-		
Consortium				

Select an End Point: **EN - Biodegradation**

End Points with check contain data.

Physical/Chemical Properties <input checked="" type="checkbox"/> Melting Point <input checked="" type="checkbox"/> Boiling Point <input checked="" type="checkbox"/> Partition Coefficient <input checked="" type="checkbox"/> Vapor Pressure <input checked="" type="checkbox"/> Water Solubility	Ecotoxicity <input checked="" type="checkbox"/> Acute Toxicity to Fish Toxicity to Aquatic Plant Acute Toxicity to Aquatic Invertebrates
Environmental Fate <input checked="" type="checkbox"/> Photodegradation <input checked="" type="checkbox"/> Stability in Water <input checked="" type="checkbox"/> Biodegradation <input checked="" type="checkbox"/> Transport	Health <input checked="" type="checkbox"/> Acute Toxicity Genetic Toxicity in Vivo <input checked="" type="checkbox"/> Repeat Dose Toxicity <input checked="" type="checkbox"/> Genetic Toxicity in Vitro Reproductive Toxicity <input checked="" type="checkbox"/> Developmental Tox/Teratogenicity

Add/Edit Selected End Point	View Selected End Point	Print Robust Summaries for Selected End Point	Print Screen	Previous Screen	Main Menu
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EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Water Solubility

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	N

Revision Date

2/5/2004

Test Substance

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-

Chemical Category

Method

>> Method/Guideline followed

Estimation

>> GLP No

>> Year study performed 2003

Remarks for Metho

The water solubility was estimated from the Kow using WSKOW module of EPIWIN suite. Only the chemical structure was entered into the software program.

Results

>> Precision =

>> Water Solubility Value 0

>> Upper Value 0

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Water Solubility

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthallimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	N

>> Unit mg/L

>> Temperature 25 degrees C

>> Solubility Category Insoluble

>> pH Value 0

>> pKa Value 0

Results Remark

pH and pKa values not applicable - water solubility estimated, not measured.

Conclusions

The water solubility was estimated to be 3.029×10^{-9} mg/L.

Data Quality

Reliability

Data Reliability Remarks

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Water Solubility

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthallimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	N

Reference

>> Remarks

All estimations were performed using EPI Win Suite, V.304, Syracuse Research Corporaiton, North Syracuse, New York.

General

Sponsor: Albemarle Corporation, Baton Rouge, LA

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Vapor Pressure

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Revision Date

2/5/2004

Test Substance

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-

Chemical Category

Method

>> Method/Guideline followed

Estimation

>> GLP No

>> Year study performed 2003

Remarks for Metho

Results

>> Precision

=

>> Vapor Pressure Value

2.54E-22

>> Upper Value

0

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Vapor Pressure

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis(tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

>> Unit mm Hg

>> Temperature 25 degrees C

>> Decompositio No

Results Remark

Conclusions

The vapor pressure was estimated to be 2.54×10^{-22} mm Hg.

Data Quality

Reliability

Data Reliability Remarks

Reference

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Vapor Pressure

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

>> Remarks

All estimations were performed using EPI Win Suite, V.304, Syracuse Research Corporaiton, North Syracuse, New York.

General

Sponsor: Albemarle Corporation, Baton Rouge, LA

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Partition Coefficient

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Revision Date

2/5/2004

Test Substance

Remark Phthalimide, N,N'-ethylenebis[tetrabromo-

Chemical Category

Method

>> Method/Guideline followed

Estimation

>> GLP No

>> Year study performed 2003

Remarks for Metho

The octanol/water partition coefficient was estimated using the KOWWIN module of the EPIWIN suite. Only the chemical structure was entered into the software program.

Results

>> Precision =

>> Value of Log Pow 9.7966

>> Upper Value 0

>> Temperature 25 degrees C

2/11/2004

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Partition Coefficient

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Results Remark

Conclusions

The Log Kow was estimated to be 9.7966.

Data Quality

Reliability

Data Reliability Remarks

Reference

>> Remarks

All estimations were performed using EPI Win Suite, V.304, Syracuse Research Corporaiton, North Syracuse, New York.

General

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Partition Coefficient

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthallimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Sponsor - Albemarle Corporation, Baton Rouge, LA

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Melting Point

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis(tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Revision Date

2/5/2004

Test Substance

Remark

Phthalimide, N,N'-ethylenebis(tetrabromo-

Chemical Category

Method

>> Method/Guideline followed

Estimation

>> GLP No

>> Year study performed 2003

Remarks for Metho

The melting point was estimated using the MPBWIN module of EPI WIN. Only the chemical structure was entered into the software program.

Results

>> Precision =

>> Melting Point Value 350

>> Upper Value 0

>> Unit °C

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Melting Point

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis(tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

>> Decompositio No

>> Sublimation No

Results Remark

Conclusions

The melting point was estimated to be 350 degrees C.

Data Quality

Reliability

Data Reliability Remarks

Reference

>> Remarks

All estimations were performed using EPI Win Suite, V.304, Syracuse Research Corporaiton, North Syracuse, New York.

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Melting Point

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

General

Sponsor: Albemarle Corporation, Baton Rouge, LA

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Boiling Point

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Test Substance

Revision Date

2/5/2004

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-

Chemical Category

Method

>> Method/Guideline followed

Estimation

>> GLP No

>> Year study performed 2003

Results

Remarks for Metho

The boiling point was estimated using the MPBPWIN module of EPI WIN suite. Only the chemical structure was entered into the software program.

>> Precision

=

>> Boiling Point Value

887

>> Upper Value

0

>> Unit

°C

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Boiling Point

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

>> Pressur

760

>> Pressure Uni

mm Hg

>> Decompositio

No

Results Remark

Conclusions

The boiling point was estimated to be 886.97 degrees C.

Data Quality

Reliability

Data Reliability Remarks

EPA High Production Volume (HPV) Track

Physical-Chemical End Point:
Boiling Point

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis(tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Reference

>> Remarks

All estimations were performed using EPI Win Suite, V.304, Syracuse Research Corporaiton, North Syracuse, New York.

General

Sponsor: Albemarle Corporation

EPA High Production Volume (HPV) Track

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

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Revision Date

2/5/2004

Test Substance

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-

Chemical Category

Method

>> Method/Guideline followed

Estimation

>> Test Type

Level III fugacity model

>> Year study performed

2003

Remarks for Metho

Transport was estimated using the Level III Fugacity Model included in EPIWIN Suite, v3.04. Only the chemical structure was entered into the software program. The model assumed emissions of 1000 kg/hr to each of air, water and soil, and 0 emissions to sediment.

Results

>> Media

Air (0.0106%), Water (1.09%), Soil (41.8%), Sediment (57.1%)

>> Distribution Concentratio

Fugacity (atm): Air 3.82e-25; Water 9.6e-32; Soil 1.6e-32; Sediment 1.7e-31

Reaction (kg/hr): Air 0.211; Waer 4.06; Soil 899; Sediment 53.2

Advection (kg/hr): Air 0.0198; Waer 21.1; Soil 0; Sediment 22.1

Reaction (%): Air 0.0211; Water 0.406; Soil 89.9; Sediment 5.32

EPA High Production Volume (HPV) Track

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

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis(tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Advection (%): Air 0.00198; Water 2.11; Soil 0; Sediment 2.21

Results Remark

Henry's Law Constant: 3.64×10^{-21} atm-m³/mole
Vapor Press 4.15×10^{-19} mm Hg
Liquid VP: 6.77×10^{-16} mm Hg (super-cooled)
Melting Pt: 350 deg C
Log Kow: 9.8
Soil Kow: 2.59×10^9 (calc by model)

Conclusions

The substance is expected to partition to sediment and soil in the environment where it will be essentially immobile. Only minimal amounts are expected to partition to water or air.

Data Quality

Reliability

Data Reliability Remarks

Reference

>> Remarks

All estimations were performed using EPI Win Suite, V.304, Syracuse Research Corporation, North Syracuse, New York.

General

EPA High Production Volume (HPV) Track

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

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Sponsor: Albemarle Corporation, Baton Rouge, LA

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Stability in Water

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	N

Revision Date

2/5/2004

Test Substance

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-

Chemical Category

Method

>> Method/Guideline followed

Estimation

>> Test Type HYDROWIN v1.67

>> GLP No

>> Year study performed 2003

Remarks for Method

The potential for hydrolysis was estimated using the HYDROWIN module of EPIWIN suite. Only the chemical structure was entered into the software program.

Results

>> Nominal concentration Not applicable

>> Measured concentration Not applicable

>> Precision >

>> Hydrolysis Result 12

>> Upper Value 0

>> Unit Months

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Stability in Water

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis(tetrabromo-	Study Number	1
Consortia ID			Completed:	N

>> pHVal 0

>> Temperature 25 degrees C

>> Breakdown product No

Results Remarks

HYDROWIN could not calculate a half life. It reported that the hydrolysis rate was expected to be extremely slow or $t_{1/2} > 1$ year. The estimation was based on the amide function.

The pH was not specified by the model; hence, the entry of zero in that field.

Conclusions

Based on these results and the substance's estimated negligible water solubility and minimal partitioning to water, hydrolysis is not expected to be a significant route of environmental degradation.

Data Quality

Reliability

Data Reliability Remarks

Reference

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Stability in Water

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthallimide, N,N'-ethylenebis(tetrabromo-	Study Number	1
Consortia ID			Completed:	N

>> Remarks

All estimations were performed using EPI Win Suite, V.304, Syracuse Research Corporaiton, North Syracuse, New York.

General

Sponsor: Albemarle Corporation, Baton Rouge, LA

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Photodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	N

Revision Date

2/5/2004

Test Substance

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-

Chemical Category

Method

>> Method/Guideline followed

Estimation

>> Light Source

Sunlight

>> Light Source Spectrum in nm

1

>> Relative Intensity

Not applicable

>> Absorption Spectrum of Substanc

Not applicable

>> GLP

No

>> Year study performed

2003

Remarks for Method

The potential for reaction with atmospheric hydroxyl radicals was estimated using the AOP module of EPI WIN suite. Only the chemical structure was entered into the program.

Results

>> Concentration Value

0

>> Unit

>> Temperature

>> Direct Photolysis Precisio

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Photodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	N

>> Direct Photolysi

>> Direct Photolysis Upper valu

>> Direct Photolysis Uni

>> Indirect Photolysis Precisio

>> Indirect Photolysi

>> Indirect Photolysis Upper value

>> Indirect Photolysis Uni

>> Sensitizer

>> Sensitizer Concentration

>> Sensitizer Unit

>> Rate Constan

>> Breakdown product

Results Remark

The overall OH rate constant was calculated to be 39.4691 E-12 cm³/molecule-sec. The half-life was estimated to be 0.271 days or 3.252 hours based on a 12-hr day and 1.5E6 OH/cm³.

Conclusions

The substance is not expected to be persistent in air.

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Photodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	N

Data Quality

Reliability

Data Reliability Remarks

Reference

>> Remarks

All estimations were performed using EPI Win Suite, V.304, Syracuse Research Corporaiton, North Syracuse, New York.

General

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Biodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	N

Revision Date

2/5/2004

Test Substance

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-

Chemical Category

Method

>> Method/Guideline followed

Estimation

>> Test Type

BIOWIN, EPIWIN suite, v3.04

>> GLP

No

>> Year study performed

2003

>> Contact Time

0

>> Inoculum

Remarks for Method

The potential for biodegradation was estimated using the BIOWIN module of EPIWIN suite. Only the chemical structure was entered into the program.

Results

>> Precision

>> Degradation Value

0

2/11/2004

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Biodegradation

Sponsor ID	<input type="text" value="1100021"/>	Albemarle Corporation	Create Date	<input type="text" value="2/5/2004"/>
CAS Number	<input type="text" value="32588764"/>	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	<input type="text" value="1"/>
Consortia ID	<input type="text"/>		Completed:	<input type="text" value="N"/>

>> Upper value

>> Time Frame

>> Time Units

>> Breakdown product

Results Remark

Conclusions

BIOWIN predicted that the substance "does not biodegrade fast" using either the linear or non-linear model. The program predicted the substance would be "recalcitrant" with respect to an ultimate or primary biodegradation timeframe.

Data Quality

Reliability

Data Reliability Remarks

Reference

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Biodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	N

>> Remarks

All estimations were performed using EPI Win Suite, V.304, Syracuse Research Corporaiton, North Syracuse, New York.

General

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Biodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	2
Consortia ID			Completed:	Y

Revision Date

2/5/2004

Test Substance

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-; 99%+ purity

Chemical Category

Method

>> Method/Guideline followed

MITI Guideline, in accordance with Law No. 117, 1973, Japan.

>> Test Type

Ready biodegradation

>> GLP Unknown

>> Year study performed 1981

>> Contact Time 14

>> Inoculum

Standard activated sludge, NOS

Remarks for Method

Innoculum = Standard activated sludge, 30 ppm (w/v), collected in Japan
Concentration of test chemical = 100 ppm (w/v)
Temperature of incubation = 25 +/- 1
Negative controls = basal culture only; water + test substance
Positive control = basal culture + aniline
Automated closed-system oxygen consumption measuring apparatus (BOD-meter)
UV-VIS spectrophotomer, 200-350 nm scan range, measured wave length 254 nm, 10 mm quartz cell.

Results

>> Precision

=

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Biodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	2
Consortia ID			Completed:	Y

>> Degradation Value 0

>> Upper value 0

>> Time Frame 28

>> Time Units Days

>> Breakdown product No

Results Remark

% degradation of test substance by BOD or UV after 28 days = 0.
% degradation of aniline after 7 days = 67%.

Conclusions

The test substance was not readily biodegradable under the conditions of this test.

Data Quality

Reliability Good

Data Reliability Remarks

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Biodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	2
Consortia ID			Completed:	Y

Reference

>> Remarks

The Biodegradability Test of S-502. November 5, 1981. Chemical Biotesting Center. Chemicals Inspectoin & Testing Institute, Japan. Tokyo.

General

EPA High Production Volume (HPV) Track

Ecotoxicity End Point:
Acute Toxicity to Fish

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Test Substance

Revision Date

2/5/2004

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-; 99%+ purity

Chemical Category

Method

>> Method/Guideline followed

MITI; In accordance with Law No. 117. 1973. Japan

>> Test Type

Acute toxicity, 48 hour exposure

>> GLP Unknown

>> Year study performed 1982

>> Species

Orange-red Killifish (*Oryzias latipes*)

>> Analytical monitoring No

>> Exposure period 48 hours

>> Statistical Method Not provided

Remarks for Method

This study was performed as a preliminary test to the bioconcentration test in carp.

Adult killifish, avg body wt = 0.32 g.

Preparation of test media - Auxiliary agent: HCO-40 (polyoxyethylene hydrogenated castor oil), Crystallized sugar. Test compound (1.0 g) and crystallized sugar (10 g) were ground together. HCO-40 (20 g) added and mixed thoroughly. Ion exchanged water was added to 1 liter.

Test temperature = 25 deg C.

EPA High Production Volume (HPV) Track

Ecotoxicity End Point:
Acute Toxicity to Fish

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Results

>> Nominal concentration 500 ppm (w/v)

>> Measured concentration Not done.

>> Precision >

>> Endpoint Type LC50

>> Endpoint Value 500 >> Unit used ppm

>> Concentration Type Nominal >> Endpoint Time 48

>> Statistical result

Not provided

Results Remark

Conclusions

The 48 hr LC50 in orange-red killifish was > 500 ppm, the highest dose tested.

Data Quality

Reliability

Data Reliability Remarks

EPA High Production Volume (HPV) Track

Ecotoxicity End Point:
Acute Toxicity to Fish

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

This study was performed by an experienced laboratory as a part of a fish bioconcentration study.

Reference

>> Remarks

The Bioaccumulation of Compound S-503 by Carp. Chemical Biotesting Center. Chemicals Inspection & Testing Institute, Japan. Tokyo.

General

Sponsor: Columbian Carbon Japan, Ltd.

EPA High Production Volume (HPV) Track

Ecotoxicity End Point:
Acute Toxicity to Fish

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	3
Consortia ID			Completed:	N

Revision Date

2/6/2004

Test Substance

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-

Chemical Category

Method

>> Method/Guideline followed

Estimation

>> Test Type

LC50, 96 hour

>> GLP

No

>> Year study performed

2003

>> Species

Not specified

>> Analytical monitoring

Not applicable

>> Exposure period

96 hours

>> Statistical Method

Not applicable

Remarks for Method

The ECOSAR module of EPIWIN, v3.04, was used to estimate the 96 hour LC50 value in fish. The module selected the class "imides" for the estimation. Only the chemical structure was entered into the program.

Results

EPA High Production Volume (HPV) Track

Ecotoxicity End Point:
Acute Toxicity to Fish

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	3
Consortia ID			Completed:	N

>> Nominal concentration Not applicable

>> Measured concentration Not applicable

>> Precision =

>> Endpoint Type LC50

>> Endpoint Value 0 >> Unit used mg/L

>> Concentration Type Nominal >> Endpoint Time 96

>> Statistical result

Not applicable.

Results Remark

ECOSAR estimated the 96 hr LC50 in fish to be 0.000612 mg/L and indicated that the chemical may not be soluble enough to measure this predicted effect. Further, the predicted Kow was greater than the program's cut off of 5.0 for fish and daphnid acute toxicity.

Conclusions

The substance is not expected to be acutely toxic to fish at its limit of water solubility.

Data Quality

Reliability

Data Reliability Remarks

EPA High Production Volume (HPV) Track

Ecotoxicity End Point:
Acute Toxicity to Fish

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis(tetrabromo-	Study Number	3
Consortia ID			Completed:	N

Reference

>> Remarks

All estimations were performed using EPI Win Suite, V.304, Syracuse Research Corporaiton, North Syracuse, New York.

General

Sponsor: Albemarle Corporation

View of End Points for a Data Set

Sponsor	1100021	Albemarle Corporation	CreateDate:	2/5/2004
CAS No	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-		
Consortia				

Physical/Chemical Properties

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

Environmental Fate

- ☐ Photodegradation
- ☐ Stability in Water
- ☐ Transport
- ☐ Biodegradation

Ecotoxicity

- ☐ Acute Toxicity to Fish
- ☐ Toxicity to Aquatic Plants
- ☐ Acute Toxicity to Aquatic Invertebrates

Health

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

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Photodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	N

Revision Date

2/5/2004

Test Substance

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-

Chemical Category

Method

>> Method/Guideline followed

Estimation

>> Light Source

Sunlight

>> Light Source Spectrum in nm

1

>> Relative Intensity

Not applicable

>> Absorption Spectrum of Substanc

Not applicable

>> GLP

No

>> Year study performed

2003

Remarks for Method

The potential for reaction with atmospheric hydroxyl radicals was estimated using the AOP module of EPI WIN suite. Only the chemical structure was entered into the program.

Results

>> Concentration Value

0

>> Unit

>> Temperature

>> Direct Photolysis Precisio

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Photodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	N

>> Direct Photolysi

>> Direct Photolysis Upper valu

>> Direct Photolysis Uni

>> Indirect Photolysis Precisio

>> Indirect Photolysi

>> Indirect Photolysis Upper value

>> Indirect Photolysis Uni

>> Sensitizer

>> Sensitizer Concentration

>> Sensitizer Unit

>> Rate Constan

>> Breakdown product

Results Remark

The overall OH rate constant was calculated to be 39.4691 E-12 cm³/molecule-sec. The half-life was estimated to be 0.271 days or 3.252 hours based on a 12-hr day and 1.5E6 OH/cm³.

Conclusions

The substance is not expected to be persistent in air.

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Photodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	N

Data Quality

Reliability

Data Reliability Remarks

Reference

>> Remarks

All estimations were performed using EPI Win Suite, V.304, Syracuse Research Corporaiton, North Syracuse, New York.

General

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Biodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	N

Revision Date

2/5/2004

Test Substance

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-

Chemical Category

Method

>> Method/Guideline followed

Estimation

>> Test Type

BIOWIN, EPIWIN suite, v3.04

>> GLP

No

>> Year study performed

2003

>> Contact Time

0

>> Inoculum

Remarks for Method

The potential for biodegradation was estimated using the BIOWIN module of EPIWIN suite. Only the chemical structure was entered into the program.

Results

>> Precision

>> Degradation Value

0

2/11/2004

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Biodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	N

>> Upper value

>> Time Frame

>> Time Units

>> Breakdown product

Results Remark

Conclusions

BIOWIN predicted that the substance "does not biodegrade fast" using either the linear or non-linear model. The program predicted the substance would be "recalcitrant" with respect to an ultimate or primary biodegradation timeframe.

Data Quality

Reliability

Data Reliability Remarks

Reference

EPA High Production Volume (HPV) Track

Environmental Fate and Pathway End Point:
Biodegradation

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	N

>> Remarks

All estimations were performed using EPI Win Suite, V.304, Syracuse Research Corporaiton, North Syracuse, New York.

General

EPA High Production Volume (HPV) Track

Toxicity End Point:
Acute Toxicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Revision Date

2/6/2004

Test Substance

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-

Chemical Category

Method

>> Method/Guideline followed

Other

>> GLP Unknown

>> Year study performed 1976

>> Species

rat

>> Strain Sherman-Wistar

>> Sex Both

>> Number of males per dose

5

>> Number of females per dose

5

>> Vehicle Corn oil

>> Route of Administratio

Oral, by gavage

Remarks for Metho

EPA High Production Volume (HPV) Track

Toxicity End Point:
Acute Toxicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis(tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Rats wighted between 200 and 300 gm. Deprived of food, but not water, for 24 hours prior to dosing. The test article was administered as a 33% w/v suspension in corn oil at a single dose of 7.5 g/kg. The animals were observed daily for 14 days.

Results

>> Precision >

>>Acute Lethal Value 7500

>> Unit mg/kg-bw

>> Deaths per Dos

No animals died on-test.

Results Remark

Conclusions

The oral LD50 in the rat was > 7500 mg/kg, the highest dose tested.

Data Quality

Reliability

Data Reliability Remarks

EPA High Production Volume (HPV) Track

Toxicity End Point:
Acute Toxicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Reference

>> Remarks

K. Gabriel. Acute Oral Toxicity - Rats. Cities Service Company - LTW-31-1. Biosearch, Inc. Philadelphia, PA. January 1976.

General

Sponsored by Cities Service Company, Canbury, NJ.

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Revision Date

2/6/2004

Test Substance

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-; Tested as the commercial product BT-93

Chemical Category

Method

>> Method/Guideline followed

Other

>> GLP Unknown

>> Year study performed 1976

>> Species

rat

>> Strain Mammal strai Sprague-Dawley

>> Sex M

>> Number of males per dose 10

>> Number of females per dose 0

>> Route of Administratio Diet

>> Exposure Period 28

>> Frequency of treatment Daily

>>Dose 0.01, 0.1, and 1% in the diet

>> Control Group Yes

>> Post observation perio None

>> Statistical Method T-test: body wt, feed consumption, organ wt

Remarks for Metho

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthallimide, N,N'-ethylenebis(tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

See results.

Results

>> NOAEL Preciso

>> NOAEL dos >> Unit

>> NOAEL Effec

No adverse effects noticed at the highest dose tested, 1% in the diet.

>> LOAEL Precision

>> LOAEL dos >> Unit

>> LOAEL Effec

None noted. LOAEL > highest dose tested.

>> Actual dose received by dose level by sex

Not available.

>> Toxic response

None observed.

>> Statistical result

See results.

Results Remark

The test article was fed to Sprague Dawley male rats (n=10/group) at 0, 0.01, 0.1 and 1% of the diet for 28 days. No mortality occurred during the study. No clinical signs of toxicity were observed. Mean body weights, body weight gains, food consumption and organ weights were not affected by treatment. Organs weighed at necropsy were liver, heart, spleen, kidney, and testes. Hematology and serum chemistry parameters were not affected by treatment. No gross or microscopic lesions attributable to test article were detected at necropsy or on light microscopy. The 28-day NOEL was 1% of the diet. This is estimated to be ~ 1,000 mg/kg/d using the assumption of consumption of 25 g diet per 250 g rat per day. This study was performed prior to the adoption of Good Laboratory Practices or EPA/OECD guidelines. (Report Cities Service Company, CITEX BT-93. Rat - 28-Day Feeding Study -

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Study Code T-626. 1976. Warf Institute, Inc. Madison, WS)

Conclusions

The NOEL was 1% of the diet, the highest dose tested. This is approximately equal to 1000 mg/kg/day.

Data Quality

Reliability

Data Reliability Remarks

This study is old and does not conform to present-day guidelines. However, the lack of adverse effects is consistent with a lack of toxicity observed in this species in a modern developmental toxicity study at a comparable dose. Thus, the results are considered credible.

Reference

>> Remarks

Report Cities Service Company, CITEX BT-93. Rat – 28-Day Feeding Study – Study Code T-626. 1976. Warf Institute, Inc. Madison, WS

General

Sponsor - Cities Service Company.

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	2
Consortia ID			Completed:	Y

Revision Date

2/6/2004

Test Substance

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-; Tested as the commercial product BT-93

Chemical Category

Method

>> Method/Guideline followed

Other

>> GLP Unknown

>> Year study performed 1978

>> Species

rat

>> Strain Mammal strai Sprague-Dawley

>> Sex Both

>> Number of males per dose 15 >> Number of females per dose 15

>> Route of Administratio Oral, in the diet

>> Exposure Period 90

>> Frequency of treatment Daily

>>Dose 0.01, 0.1, and 1.0% of the diet

>> Control Group Yes

>> Post observation perio 42 days

>> Statistical Method Analysis of Variance

Remarks for Metho

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	2
Consortia ID			Completed:	Y

Rats were acclimated for 12 days prior to study initiation. All rats were housed individually in wire cages. The test diets were mixed prior to initiation of the study and weekly thereafter. Food was replenished weekly. After 90 days, all animals were placed on the control diet for 46 days.

Animals were observed twice daily during the work week and once daily on week ends. Body weights were recorded initially and weekly thereafter. Food consumption was recorded for one week prior to initiation and weekly thereafter. Blood was drawn from the orbital sinus for hematology and serum chemistry exams on days 0 (all rats), 45 (10/sex/dose), and 92 (10/sex/dose). Hamatology exams consisted of hemoglobin, hematocrit, differential, leukocytes, and erythrocytes. Serum chemistries included protein, glutamic pyruvic transaminase, alkaline phosphatase, BUN, glucose. Urine was collected on days 0 (all animals), 45 (10/sex/dose) and 90 (10/sex/dose) for analysis. The urinalysis included color, turbidity, pH and occult blood. On day 92, 3/sex/dose were randomly selected and sacrificed by CO2 exposure. A complete necropsy was performed. The liver, kidneys, heart, and thyroids were weighed and the relative organ weights calculated. The following were fixed in formalin: adrenals, bone marrow, brain, esophagus, heart, intestine, kidney, liver, lung, oral mucosa, tissue mass, prostate, salivary gland, spleen stomach, testes or ovaries, tongue, thyroid, urinary bladder, uterus, gross lesions. All tissues from the 90-day and recovery sacrifices were examined microscopically from animals in the control and high dose group. The tissues were stained with hematoxylin and eosin.

Body weights, food consumption, hematology and organ weights were compared using Analysis of Variance. $P \leq 0.5$ or 0.1 .

Results

>> NOAEL Preciso

>=

>> NOAEL dos

1000

>> Unit

mg/kg-bw

>> NOAEL Effec

No adverse effects were detected.

>> LOAEL Precision

>=

>> LOAEL dos

1000

>> Unit

mg/kg-bw

>> LOAEL Effec

No adverse effects were detected.

>> Actual dose received by dose level by sex

Not available

>> Toxic response

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis(tetrabromo-	Study Number	2
Consortia ID			Completed:	Y

No toxicity was observed.

>> Statistical result

See results.

Results Remark

EBTBP was administered to four groups of Sprague Dawley rats (n=15/sex/group) at 0, 0.01, 0.1 and 1.0% of the diet for 90 days followed by 46 days during which the rats were fed control diet. No changes in hematology or serum chemistry values related to treatment were detected on study days 0, 45, 92. No effect of treatment was found on urinalysis (d 0, 45 and 90). The mean relative and absolute organ weights of the liver, kidney, heart, and thyroids from the control and 1.0% groups were statistically comparable. Several animals died on test from non-test article related causes (most deaths were related to collection of blood for hematology and serum chemistry evaluations). Gross necropsy from animals dieing on test and sacrificed on days 92, 134, 135 and 136 revealed no test article-related gross lesions. No test article related lesions were detected on histopathology. The 90-day NOEL was 1% of the diet. This is estimated to be ~ 1,000 mg/kg/d using the assumption of consumption of 25 g diet per 250 g rat per day. This study was performed prior to the adoption of Good Laboratory Practices or EPA/OECD guidelines. (Report: 90-Day Feeding Study in Rats Evaluating Cities Service Compound RW-4-178B. Laboratory Number: 8E-0183. September 19, 1978. Cannon Laboratories, Inc. Reading, PA)

Conclusions

The NOEL was 1% in diet for 90-days. This is approximately equivalent to 1000 mg/kg/day.

Data Quality

Reliability

Data Reliability Remarks

This study is old and does not conform to current guidelines. Nonetheless, the results are considered valid. The results are consistent with a lack of effects seen in a rat 28 day study performed in separate laboratory and with the lack of toxicity observed in a modern rat developmental study performed in a third laboratory. All three studies were performed at a comparable dose.

Reference

EPA High Production Volume (HPV) Track

Toxicity End Point:
Repeated Dose Toxicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	2
Consortia ID			Completed:	Y

>> Remarks

Report: 90-Day Feeding Study in Rats Evaluating Cities Service Compound RW-4-178B.
Laboratory Number: 8E-0183. September 19, 1978. Cannon Laboratories, Inc. Reading, PA.

General

Sponsor: Cities Services Company, Norman, OK.

EPA High Production Volume (HPV) Track

Toxicity End Point:
Developmental Toxicity/Teratogenicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	

Revision Date

2/6/2004

Test Substance

Remark Phthalimide, N,N'-ethylenebis[tetrabromo-; tested as the commercial product Saytech BT-93

Chemical Category

Method >> Method/Guideline followed

EPA OPPTS Method 870.3700

>> GLP Yes

>> Year study performed 1988

>> Species

rat

>> Strain Mammal strai Sprague-Dawley

>> Sex F

>> Number of males per dose 0 >> Number of females per dose 25

>> Route of Administratio Oral by gavage in corn oil

>> Days of Gestation 6-15

>> Frequency of treatment Once daily

>> Doses 100, 500, 1000 mg/kg/day

>> Control Group Yes Concurrent controls

>> Statistical Method

All analyses were 2-tailed for a significance level of 5% unless otherwise specified. The treated groups were compared to the control group or by an individual group by group comparison depending on the test. Continued under Remarks for Method.

Remarks for Metho

EPA High Production Volume (HPV) Track

Toxicity End Point:
Developmental Toxicity/Teratogenicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	

The test article was administered to four groups of 25 mated female Sprague Dawley rats by gavage in corn oil at doses of 0, 100, 500 or 1000 mg/kg/d on gestation days 6-15. The animals were observed daily for clinical signs of toxicity. Body weights were measured on gestation days 0, 6, 9, 12, 16, and 20. Food consumption was measured daily. All females were sacrificed on gestation day 20 and subjected to a cesarean section. Fetuses were individually weighed, sexed, and examined for external, visceral and skeletal abnormalities.

ANOVA followed by Dunnett's test was used to analyze maternal and fetal data including body weight, food consumption, number of viable fetuses, implantation sites, and corpora lutea. A one-tailed Mann-Whitney was the test used for analyses of number of postimplantation loss, dead fetuses, and resorptions. Fetal sex ratios were analyzed using the Chi square test. A one-tailed Fisher's exact test was used for the number of fetuses and litters with variations and malformations.

Results

>> Maternal Precision/NOAEL >=

>> Maternal NOAEL dos 1000

>> Unit used mg/kg-bw

>> Maternal NOAEL effect No adverse effects

>> Maternal Precision/LOAEL >

>> Maternal LOAEL dose 1000

>> Unit used mg/kg-bw

>> Maternal LOAEL effect No adverse effects

>> Developmental Precision/NOAE >=

>> Developmental NOAEL dos 1000

>> Unit used mg/kg-bw

>> Developmental NOAEL effect No adverse effects

>> Developmental Precision/NOAE >

>> Developmental LOAEL dose 1000

>> Unit used mg/kg-bw

>> Developmental LOAEL effect No adverse effects

>> Actual dose

1000 mg/kg/day

>> Maternal data with dose level (with NOAEL value).

Survival was 100% in the control and treated groups. There were no abortions or premature deliveries. The pregnancy rate was 100% in all groups. No treatment-induced clinical signs were observed.

>> Fetal data with dose level (with NOAEL value).

EPA High Production Volume (HPV) Track

Toxicity End Point:
Developmental Toxicity/Teratogenicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	

Mean numbers of corpora lutea, gravid uterine weight, implantation sites, viable fetuses, late resorptions, fetal sex ratios and mean fetal weights comparable in control and treated groups.

>> Statistical result

No indication of maternal toxicity or teratological effects.

Results Remark

No maternal mortality or clinical signs of toxicity were observed during the study. No treatment-related differences were noted among the groups with respect to maternal body weights, food consumption, necropsy or caesarean section data. No treatment-induced fetal malformations or developmental variations were detected.

Conclusions

The maternal and fetal NOEL \geq 1,000 mg/kg/d.

Data Quality

Reliability

High

Data Reliability Remarks

This study was performed at an experienced laboratory using modern guidelines.

Reference

>> Remarks

D. E. Rodwell. Teratology Study in Rats with BT-93. Final Report. SLS Study No. 3196.4. 1988. Springborn Life Sciences, Inc. Spencerville, OH

General

Sponsor - Ethyl Corporation, Baton Rouge, LA

EPA High Production Volume (HPV) Track

Toxicity End Point:
Developmental Toxicity/Teratogenicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	2
Consortia ID			Completed:	

Revision Date

2/6/2004

Test Substance

Remark Phthalimide, N,N'-ethylenebis[tetrabromo-; tested as the commercial Saytech BT-93 product

Chemical Category

Method >> Method/Guideline followed

EPA OPPTS Method 870.3700

>> GLP Yes

>> Year study performed 1988

>> Species

rabbit

>> Strain Mammal strain New Zealand white

>> Sex F

>> Number of males per dose

0

>> Number of females per dose

20

>> Route of Administration

Oral by gavage in carboxymethyl cellulose

>> Days of Gestation

7-19

>> Frequency of treatment

Once daily

>> Doses 1000

>> Control Group Yes

Concurrent controls

>> Statistical Method

All analyses were 2-tailed for a significance level of 5% unless otherwise specified. The treated groups were compared to the control group or by an individual group by group comparison depending on the test. Continued under Remarks for Method.

Remarks for Method

EPA High Production Volume (HPV) Track

Toxicity End Point:
Developmental Toxicity/Teratogenicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	2
Consortia ID			Completed:	

EBTBP was administered to two groups of 20 mated female New Zealand White rabbits each by gavage in methyl cellulose at dose of 0 or 1,000 mg/kg/d on gestation days 7-19. The animals were observed daily for clinical signs of toxicity. Body weights were measured on gestation days 0, 7, 10, 13, 19, 24 and 29. Food consumption was measured daily. All females were sacrificed on gestation day 29 and subjected to a cesarean section. Fetuses were individually weighed sexed and examined for external, visceral and skeletal abnormalities.

ANOVA followed by Dunnett's test was used to analyze maternal and fetal data including body weight, food consumption, number of viable fetuses, implantation sites, and corpora lutea. A one-tailed Mann-Whitney was the test used for analyses of number of postimplantation loss, dead fetuses, and resorptions. Fetal sex ratios were analyzed using the Chi square test. A one-tailed Fisher's exact test was used for the number of fetal variations and malformations utilizing the dam (litter) as the experimental unit.

This study was conducted according to US TSCA Guidelines and Good Laboratory Practices.

Results

>> Maternal Precision/NOAEL >=

>> Maternal NOAEL dose 1000

>> Unit used mg/kg-bw

>> Maternal NOAEL effect No adverse effects

>> Maternal Precision/LOAEL >

>> Maternal LOAEL dose 1000

>> Unit used mg/kg-bw

>> Maternal LOAEL effect No adverse effects

>> Developmental Precision/NOAEL >=

>> Developmental NOAEL dose 1000

>> Unit used mg/kg-bw

>> Developmental NOAEL effect No adverse effects

>> Developmental Precision/NOAEL >

>> Developmental LOAEL dose 1000

>> Unit used mg/kg-bw

>> Developmental LOAEL effect No adverse effects

>> Actual dose

1000 mg/kg/day

>> Maternal data with dose level (with NOAEL value).

Survival was 100% in the control and treated groups. There were no abortions or premature deliveries. The pregnancy rate was 90% in the control and 95% in the high dose group.

EPA High Production Volume (HPV) Track

Toxicity End Point:
Developmental Toxicity/Teratogenicity

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis(tetrabromo-	Study Number	2
Consortia ID			Completed:	

>> Fetal data with dose level (with NOAEL value).

Intrauterine survival and fetal weights were not adversely affected by treatment. The incidence and type of developmental malformations and variations were not indicative of a teratological effect.

>> Statistical result

No adverse effects were noted.

Results Remark

No maternal mortality, abortions or clinical signs of toxicity were observed during the study. Maternal body weights, weight gain, food consumption, necropsy observations and cesarean section data were generally comparable among the groups. No treatment-related malformations or developmental variations were observed. The maternal and fetal NOEL was 1,000 mg/kg/d. This study was conducted according to US TSCA Guidelines and Good Laboratory Practices. (D. E. Rodwell. Teratology Study in Rabbits with BT-93. Final Report. SLS Study No. 3196.5. 1988. Springborn Life Sciences, Inc. Spencerville, OH).

Conclusions

The NOEL for maternal toxicity, embryo/fetal toxicity or fetal teratogenicity was 1000 mg/kg/day, the highest dose tested.

Data Quality

Reliability

High

Data Reliability Remarks

This study was performed at an experienced laboratory using modern guidelines.

Reference

>> Remarks

D. E. Rodwell. Teratology Study in Rabbits with BT-93. Final Report. SLS Study No. 3196.5. 1988. Springborn Life Sciences, Inc. Spencerville, OH

General

Sponsored by Ethyl Corporation, Baton Rouge, LA.

EPA High Production Volume (HPV) Track

Toxicity End point:
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Revision Date

2/6/2004

Test Substance

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-

Chemical Category

Method

>> Method/Guideline followed

MITI, the Industrial Safety and Health Law, 1979 (a modification of the Ames tet)

>> Test Type

Ames test

>> System of Testin

Bacterial

>> GLP

Unknown

>> Year study performed

1982

>> Species

Salmonella typhimurium, E. Coli WP2 uvrA

>> Metabolic Activation

Rat Liver microsomes (S-9)

>> Concentration

10, 50, 100, 500, 1000, 5000 ug/plate

>> Statistical Method

Not specified in English translation

Remarks for Metho

Salmonella strains TA1535, TA1537, TA1538, TA98 and TA100 and E. Coli, WP2 uvrA were used in this modification of the Ames assay. All strains were tested with and without metabolic activation. Both solvent and positive controls were used. The solvent was DMSO. The positive controls were 2-(2-furyl)-3-(5-nitro-2-furyl)acrylamide, N-ethyl-N'-nitro-N-nitrosoguanidine, 9-Aminoacridine, 2-Nitrofluorene, and 2-Aminoanthracene.

EPA High Production Volume (HPV) Track

Toxicity End point:
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

Results

>> Result Negative

>> Cytotoxic Concentratio

Not cytotoxic

>> Genotoxic Effect Unconfirmed

>> Statistical result

Not provided

Results Remark

No mutagenic activity was detected in the 5 Salmonella strains or in the E.coli strain. The positive controls responded as expected.

Conclusions

The test article was not mutagenic.

Data Quality

Reliability Good

Data Reliability Remarks

Reference

EPA High Production Volume (HPV) Track

Toxicity End point:
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	1
Consortia ID			Completed:	Y

>> Remarks

Maruyama K. Mutagenicity Evaluation of Ethylene-1,2-bis(3,4,5,6-tetrabromophthalimide) in the Ames Salmonella/Microsome Assay. February 18, 1982. Chemicals Inspection & Testing Institute, Japan. Induced Mutation Division.

General

EPA High Production Volume (HPV) Track

Toxicity End point:
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	2
Consortia ID			Completed:	Y

Test Substance

Revision Date

2/6/2004

Remark

Phthalimide, N,N'-ethylenebis[tetrabromo-

Chemical Category

Method

>> Method/Guideline followed

Other

>> Test Type

Ames test

>> System of Testin

Bacterial

>> GLP

Unknown

>> Year study performed

1978

>> Species

saccharomyces cerevisiae, Salmonella typhimurium

>> Metabolic Activation

Male Sprague Dawley rats, induced with Arochlor 1254, Hepatic S-9

>> Concentration

1, 10, 50, 100, 500, 1000 ug/plate

>> Statistical Method

Not specified

Remarks for Metho

Salmonella strains TA1535, 1537, 1538, 98 and 100 and Sacchromyces D4 were utilized, and tested both with and without metabolic activation. Solvent and negative controls were included. The solvent was DMSO. Five different positive controls were utilized. Each strain was tested in duplicate.

EPA High Production Volume (HPV) Track

Toxicity End point:
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	2
Consortia ID			Completed:	Y

Results

>> Result Negative

>> Cytotoxic Concentratio

Cytotoxicity not observed.

>> Genotoxic Effect Unconfirmed

>> Statistical result

Not provided,

Results Remark

No mutagenic activity was associated with the test article. The positive controls performed appropriately.

Conclusions

The test substance was not mutagenic under the conditions of this test.

Data Quality

Reliability

Data Reliability Remarks

Reference

EPA High Production Volume (HPV) Track

Toxicity End point:
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100021	Albemarle Corporation	Create Date	2/5/2004
CAS Number	32588764	Phthalimide, N,N'-ethylenebis[tetrabromo-	Study Number	2
Consortia ID			Completed:	Y

>> Remarks

Parke G and Charles S. Mutagenicity Evaluation of RW-4-178B in the Ames Salmonella/Microsome Plate Test. Cannon Laboratories, Inc. Reading, PA.

General

Sponsor = Cities Service Company, Tulsa, OK.