

201-15086A

TEST PLAN FOR 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo-  
(CAS NO. 632-79-1)

OVERVIEW

Great Lakes Chemical Corporation and Albemarle Corporation agree to sponsor 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo- (CAS NO. 632-79-1) under the Environmental Protection Agency's (EPA) High Production Volume (HPV) Chemical Challenge Program. The companies hereby submit a test plan for this substance. It is the intent of the sponsoring companies to use existing data combined with new studies specified in the test plan to fulfill the Screening Information Set (SIDS) endpoints for environmental fate, ecotoxicity and human health effects.

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## TEST PLAN

### CHEM 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo-

CAS #  
632-79-1

Study Type	Data Available	Data Acceptable	Testing Required
<b>Physical/Chemical Properties</b>			
Melting Point	Y	Y	N
Boiling Point <sup>A</sup>	Y	Y	N
Vapor Pressure <sup>A</sup>	Y	Y	N
Partition Coefficient	Y	N	Y
Water Solubility <sup>A</sup>	Y	N	Y
<b>Environmental Fate</b>			
Photodegradation	Y	Y	N
Stability in Water	N	N	N
Biodegradation	Y	Y	N
Fugacity <sup>A</sup>	Y	Y	N
<b>Ecotoxicity</b>			
Acute Toxicity to Fish	Y	Y	N
Acute Toxicity to Aquatic Invert.	Y	Y	N
Toxicity to Aquatic Plants	N	N	N
<b>Human Health Effects Toxicity</b>			
Acute Toxicity	Y	Y	N
General Toxicity (repeated dose)	Y	Y	N
<i>In vitro</i> Genetic Toxicity (Mutagenicity)	Y	Y	N
<i>In vitro</i> Genetic Toxicity (Chromosomal aberration)	N	N	Y
Reproductive Toxicity	N	N	N
Developmental Toxicity	Y	Y	N

<sup>A</sup>Modeled using EPIWIN v3.11

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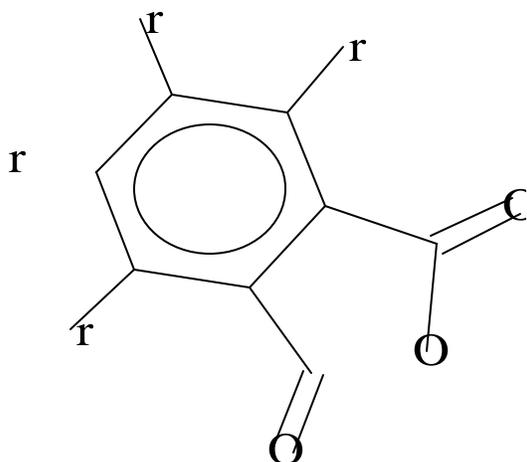
## 1. Introduction

Great Lakes Chemical Corporation and Albemarle Corporation submit this test plan for 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo- (CAS NO. 632-79-1) for hazard review under the Environmental Protection Agency High Production Volume Chemical Program. The technical contact for this chemical is:

Richard Henrich  
Great Lakes Chemical Corporation  
West Lafayette, IN 47906  
Phone (765) 497-6114

## 2. Designation of Test Substance

The test substance presented in this test plan is 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo-. (CAS NO. 632-79-1), hereafter referred to as 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO-. The chemical structure is as follows:



This chemical is also known as: Tetrabromophthalic anhydride.

The chemical is sold under the trade names **Great Lakes PHT4** and **Saytex®RB49**.

### 2.1 Applications

1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- is primarily used as a flame retardant in the production of unsaturated polyester resins. Its derivatives are also used as flame retardants in rigid polyurethane polyols, wire coatings, and wool.

### 3. Criteria for Determining Adequacy of Data

All available studies were reviewed and assessed for adequacy according to the standards of Klimisch et al. (1997). Studies receiving a Klimisch rating of 1 or 2 were considered to be adequate.

### 4. Discussion of Available Test Information

#### 4.1 Chemical and Physical Properties

The results of chemical/physical property testing are shown in Table 1.

Table 1. Chemical/physical properties of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO-.

Endpoint	Value
Molecular Weight	463.70
Melting point (° C)	279.5 - 280.5
Boiling point (° C) <sup>A</sup>	394.08
Vapor pressure (mmHg at 25° C) <sup>A</sup>	$2.03 \times 10^{-8}$
Partition coefficient (Log Pow or Kow)	1.98 measured 5.63 modeled <sup>A</sup>
Water solubility (mg/l at 20 ° C) <sup>A</sup>	0.01903

<sup>A</sup>Modeled using EPIWIN v3.11

#### 4.1.1 Melting Point

The melting point of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- 279.5- 280.5 ° C was determined by Weast and Astle, (1979).

#### 4.1.2 Boiling Point

A boiling point of 394.08 °C was estimated by EPIWIN v3.11.

#### 4.1.3 Vapor Pressure

The vapor pressure of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO-  $2.03 \times 10^{-8}$  mmHg was estimated by EPIWIN v3.11.

#### 4.1.4 Octanol/Water Partition Coefficient

The octanol/water partition coefficient of log Pow 1.98 was determined for 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- by Yu (1978). A value of 5.63 was obtained using EPIWIN v3.11. Because of the large discrepancy represented here, this parameter will be reevaluated as indicated in the test plan.

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#### 4.1.5 Water Solubility

A water solubility study for 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- was conducted, but is considered invalid due to the experimental method employed. In this study the solubility of the material was 241 ppm at 25 °C. An estimated value of 0.01903 mg/L was obtained using EPIWIN v3.11, which may be closer to the actual solubility of the material. This parameter will be evaluated in an OPPTS guideline study as part of the test plan for this material.

#### 4.1.6 Summary/Test Plan for Physical Properties

The physical properties of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- have been assessed in the aforementioned studies and using EPIWIN v3.11. However, due to the large discrepancies, the partition coefficient and the water solubility will be reevaluated as part of the test plan for 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO-.

#### 4.2 Environmental Fate/Pathways

Results of environmental fate modeling and studies are summarized in Table 2.

Table 2. Environmental fate parameters for 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO-.

Endpoint	Value
Photolysis (Atmospheric T <sub>1/2</sub> )	5 hr
Indirect Photolysis (OH sensitizer) (Hydroxyl Radical Rate Constant) <sup>A</sup> (Atmospheric T <sub>1/2</sub> ) <sup>A</sup>	0.0244 10 <sup>-12</sup> cm <sup>3</sup> /molecule-sec 438.552 days
Stability in Water	Not determined
Biodegradation	Not readily biodegraded
Henry's Law Constant <sup>A</sup>	6.508 x 10 <sup>-7</sup> atm/m <sup>3</sup>
Log K <sub>oc</sub> <sup>A</sup>	1.917
Environmental transport (Fugacity Level III mass percentages) <sup>A</sup>	Air = 0.179 Water = 3.53 Soil = 55.5 Sediment = 40.8

<sup>A</sup> Estimated using EPIWIN v3.11

##### 4.2.1 Photodegradation

A hydroxyl radical-induced photodegradation rate constant of ca. 0.0244 10<sup>-12</sup> cm<sup>3</sup>/molecule-sec has been estimated using EPIWIN (v3.11). The same program estimates a half-life of 438.552 days for photodegradation. However, in a photodegradation study conducted by Yu (1978), 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- was rapidly hydrolyzed, ½ life 5 hr., to

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tetrabromophthalic acid; and the later compound was then gradually and extensively photodegraded. Despite such a large discrepancy, further delineation of this parameter is not necessary for this screening level assessment since this material is not expected to partition to air.

#### **4.2.2 Stability in Water**

The stability of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- in water has not been experimentally determined and EPIWIN was not able to make an estimation of the stability of this substance in water. However, since a very minimal amount of this substance is expected to partition to the water column, this parameter will not be evaluated as part of this screening level assessment.

#### **4.2.3 Fugacity**

Level III fugacity modeling has been conducted on 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- using EPIWIN v3.11. The results indicate that the test substance will partition preferentially to soil, and sediment, 64 and 34%, respectively. A calculated Henry's Law Constant of  $6.508 \times 10^{-7} \text{ atm}\cdot\text{m}^3/\text{mol}$  suggests that the test substance will not rapidly volatilize from water. Volatilization from soil or sediment is also strictly limited. A water soil partition constant (Koc) of 1.917 has been estimated using EPIWIN.

#### **4.3.4 Biodegradation**

Butz (1979) conducted a 28-day biodegradation study (no guideline was mentioned), in this study, 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- was rapidly hydrolyzed to 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- acid, the material became bound to soil within 28 days, the soil-bound radiocarbon was identified as 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- acid (94%) and 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- (4.0%). This indicates that 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- is probably persistent in soil. EPIWIN v3.11 Level III Fugacity Model has predicted that 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- is expected to be found predominantly in soil and sediment and its persistence estimate is based on its transformation in these media. The overall persistence takes into account both a chemical's media-specific half-life as well as its rate of transport into and out of that compartment. The overall persistence for 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- is 1000 days using the default emission scenario of the level III multimedia model.

#### **4.3.5 Bioaccumulation**

Nye (1978) conducted a bioaccumulation study of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- in the Bluegill sunfish. In this study, 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- was not accumulated at any time during the treatment phase. Concentrations of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- in edible and visceral tissue were  $<0.01$  ppm, which was the limit of detection for this material in this assay. Also, a pharmacokinetic study was conducted in rats with 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- (Diaz, 1978). The chemical was rapidly distributed in the body and rate of elimination in urine was proportional to the concentration in blood. In this study, the

half-life of the material was < 7.0 hours in all tissues examined, steady state was achieved in this study within 2 days of continuous feeding. Based on the results of these two studies, 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- is not expected to bioaccumulate or biomagnify in the food chain.

#### **4.3.6 Summary/Test Plan for Environmental Fate Parameters**

1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- is not expected to biodegrade rapidly and is expected to partition primarily to soil and sediment. The stability of this material in water was not assessed and it was not possible to make an estimation using EPIWIN. However, testing of this parameter seems unnecessary due to the very low percentage that is expected to partition to the water column (2%).

### **4.3 Ecotoxicity**

#### **4.3.1 Acute Toxicity to Fish**

There are 96-hour acute toxicity studies of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- available in two species of fish, *Salmo gairdneri* and *Lepomis macrochirus* (Calmbacher, 1978). In these studies the LC50 was determined to be > 10 mg/L for both species, indicating that 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- is not toxic to fish when exposed acutely.

#### **4.3.2 Acute Toxicity to Aquatic Invertebrates**

A 48-hour toxicity study in *Daphnia magna* revealed an LC50 > 5.6 mg/L, which was the highest achievable concentration in the test medium (Morrissey, 1978). Few details of the experimental methods and conditions were provided in this paper, nevertheless, this study indicates that one would not expect 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- to be toxic to aquatic invertebrates.

#### **4.3.3 Acute Toxicity to Aquatic Plants**

No data are available.

#### **4.3.4 Summary/Test Plan for Ecotoxicity**

Acute toxicity studies for 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- in fish and daphnids were considered valid (with restrictions), and thus are adequate for the purposes of this screening level assessment. No data are available on the toxicity of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- to aquatic plants. However, as the water solubility of this compound is very low and it is not expected to partition to the water column, further testing of this material will not be conducted at this time. Once more definitive information is available on the solubility then, this issue may need to be revisited.

## **4.4 Human Health Data**

### **4.4.1 Acute Mammalian Toxicity**

There are three oral LD50 studies of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- available in rats and one in the mouse. In rats, the oral LD50s observed were > 50 mg/kg bw (Wolven, 1958), > 3200 mg/kg bw (Diaz, 1978), and > 10000 mg/kg bw (Doyle, 1964). In the mouse, an LD50 of > 10000 mg/kg bw was determined by Dean (1978). These studies were all determined to be valid with restrictions, due to the fact that they were not conducted according to GLP standards. Nevertheless, these data do indicate that 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- is not expected to be toxic by the oral route of administration. This information is adequate for this screening level assessment. Acute dermal toxicity studies are available in the rabbit (Doyle, 1964 and Wolven, 1958). In these two studies the dermal LD50 was reported to be > 10000 and > 200 mg/kg bw, respectively. These studies indicate that 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- is non-toxic by the dermal route of exposure.

### **4.4.2 Repeated Dose Mammalian Toxicity**

Rats exposed to 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- powder at concentrations of 2 or 8 mg/L, 4 hr/day, 5 days/week for three weeks exhibited decreased liver weights, body weights and food consumption as well as respiratory effects (congestion and increased lung weights, inflammatory lesions) typical of exposures to dusts (Wazeter, 1975). A NOEC was not identified in this study. In a dermal repeated dose study, rabbits were exposed to 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- at doses of 50, 500, or 5000 mg/kg/day (Wazeter, 1975). A NOAEL of 50 mg/kg day was observed in this study based on slight irritation of the application sites.

### **4.4.3 Genetic Toxicity**

#### **4.4.3.1 Mutagenicity**

The mutagenic potential of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- was examined in a study by Brusick (1976). This was a bacterial gene mutation assay with 5 strains of Salmonella and Saccharomyces (D4), with and without metabolic activation. In this study the material was negative in all assays.

#### **4.4.3.2 Chromosomal aberration**

No studies which evaluated the potential of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- to produce chromosomal aberrations are available.

### **4.4.4 Reproductive Toxicity**

Results of the developmental toxicity study (see Section 4.4.5 below) indicate no effect of up to 3000 mg/kg/day test material during organogenesis on the number of resorptions, implantations, corpora lutea or viable or nonviable fetuses. Also, in the 21-day inhalation study, and in the 28-

day dermal study, no effects were observed on the reproductive organs evaluated in these studies. Together, this information indicates that 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- is not a reproductive toxicant.

#### **4.4.5 Developmental Toxicity**

Data from a pilot study in rats show that 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- is not a developmental toxicant at doses up to 3000 mg/kg/day (Goldenthal 1978). This dose was not maternally toxic and no compound related effects were observed as indicated by the number of viable or nonviable fetuses, resorptions, implantations, and corpora lutea for females receiving dosages of 3000 mg/kg/day or less. At 10000 mg/kg/day or more, four out of five dams were dead by gestation day 14. While not conclusive, this pilot study suggests that 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- is not expected to produce teratological effects at the current limit dose required under OPPTS Guidelines, which is now 1000 mg/kg/day bw.

#### **4.5 Additional Data**

##### **4.5.1 Skin and Eye Irritation**

An adequate study shows that 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- is not irritating to rabbit skin (Wazeter, 1974). The primary dermal irritation score in this study was 0.2. When undiluted 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- was instilled into rabbit eyes (100 mg), the substance produced irritation (Wazeter, 1974). However, this could have been mechanical irritation. In an undocumented literature reference, the material is characterized as not irritating to eyes of rabbits (Mallory et al., 1986).

##### **4.5.2 Sensitization**

1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- has been characterized as a sensitizer in guinea pigs (Wazeter, 1975). In this study intradermal injections of the test compound (0.1%) were made 3x/week for a total of 10 sensitizing doses. Two weeks following the administration of the tenth dose, a challenge dose, at a volume of 0.05 mL was injected. All eight guinea pigs responded to the challenge dose, four exhibited an average flare response, the remaining four exhibited a response that was 158 to 186% of the response obtained during the sensitizing period.

##### **4.5.3 Summary/Test plan for mammalian toxicity**

Valid data are available to represent the acute and repeated dose general toxicity of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO-. One bacterial mutagenicity study is available, but potential of the compound to produce chromosomal aberrations has not been evaluated. One developmental pilot study does exist on this material, which indicates that it is not expected to be teratogenic. Although multi-generation reproductive studies are not available for this material, it is not expected to be a reproductive toxicant based on the data from the developmental study, which also evaluated the number of resorptions, implantations, and corpora lutea. Furthermore, two repeated dose studies in which reproductive organs were evaluated for effects, demonstrated no effects that would indicate any reproductive potential of 1,3-

ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO-. This material will be further evaluated as part of this screening assessment, an in vitro chromosomal aberration study will be conducted.

## 5. Summary

The physical properties of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- have been assessed and the partition coefficient and the water solubility of this compound will be further evaluated due to discrepancies between measured data and the predictions made by EPIWIN v3.11.

With regard to the environmental fate of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO-, it is not expected to biodegrade rapidly and is expected to partition primarily to soil and sediment. The stability of this material in water was not assessed and it was not possible to make an estimation using EPIWIN. However further evaluation of the hydrolytic potential of this compound is not necessary due to the low potential for 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- to partition to water. The ecotoxicity profile of this material has been evaluated to a limited extent in that acute toxicity studies for 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- in fish and daphnids were considered valid, and thus are adequate for the purposes of this screening level assessment. No data are available on the toxicity of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO- to aquatic plants. However, due to the low water solubility of this chemical, based on the EPIWIN v3.11 prediction, this study will not be conducted at this time. Once a more definitive value on water solubility is available, aquatic toxicity may need to be reconsidered.

The human health effects of this compound have been assessed in animal models. Valid data are available to represent the acute and repeated dose general toxicity of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO-. One bacterial mutagenicity study is available, but potential of the compound to produce chromosomal aberrations has not been evaluated. As part of this screening assessment, an in vitro chromosomal aberration study will be conducted. One developmental pilot study does exist on this material, which indicates that it is not expected to be teratogenic. Although multi-generation reproductive studies are not available for this material, it is not expected to be a reproductive toxicant based on the data from the developmental study, which also evaluated the number of resorptions, implantations, and corpora lutea. Furthermore, two repeated dose studies in which reproductive organs were evaluated for effects, demonstrated no effects that would indicate any reproductive potential of 1,3-ISOBENZOFURANDIONE, 4,5,6,7-TETRABROMO-. Therefore, further evaluation of this material in mammals is not necessary at this time as it would likely only confirm the low toxicity of this compound while causing the redundant death of many animals.

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