

[OPTS-42064; FRL-2809-6]

1,2-Dibromo-4-(1,2-Dibromoethyl)Cyclohexane; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice is EPA's response to the Interagency Testing Committee's (ITC) designation of 1,2-dibromo-4-(1,2-dibromoethyl)cyclohexane (tetrabromoethylcyclohexane or TBEC).

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CAS No. 3322-93-8) for priority consideration for health effects, chemical fate, and ecological effects testing. EPA is not initiating rulemaking at this time under section 4(a) of the Toxic Substance Control Act (TSCA) to require any testing of TBEC because EPA's analysis of data obtained under TSCA indicates that few people are exposed to TBEC and then at very low levels, that little if any TBEC is released to the environment, and that existing data do not suggest potential adverse effects from exposure to TBEC given the low exposures that are expected.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: EPA is not initiating rulemaking at this time under section 4(a) of TSCA to require health effects, chemical fate, or ecological effects testing of TBEC as designated by the ITC in its Fourteenth Report.

I. Background

Section 4(e) of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) established the ITC to recommend to EPA a list of chemicals to receive priority consideration for testing under section 4(a) of TSCA.

The ITC designated TBEC for priority consideration in its Fourteenth Report published in the Federal Register of May 29, 1984 (49 FR 22389). This notice constitutes EPA's response to the ITC's designation of TBEC.

The ITC recommended the following health effects tests for TBEC: (1) Toxicokinetics; (2) subchronic studies including sperm morphology and vaginal cytology examination; and (3) chronic toxicity studies, including oncogenicity if it is determined that there is substantial exposure to the compound. The ITC's rationale for health effects testing was that TBEC is structurally related to ethylene dibromide (EDB), a known carcinogen that has been shown to produce reproductive abnormalities in several species. The ITC also expected releases from production and use to result in human exposure.

The ITC recommended the following chemical fate tests for TBEC: (1) Water solubility; (2) octanol-water partition coefficient; (3) soil mobility; and (4) persistence. The ITC's rationale for chemical fate testing was that releases

from production and use are likely to result in environmental exposure, including releases to the aquatic environment.

The ITC recommended the following ecological effects tests for TBEC: (1) Acute and chronic toxicity to fish, aquatic invertebrates, and algae; and (2) bioconcentration. The ITC's rationale for ecological effects testing of TBEC was that releases to the aquatic environment from production and use of TBEC are likely. Although no data were found, the ITC stated that TBEC may be highly toxic to aquatic organisms and may bioconcentrate substantially. A similar compound, 1,2-dichloro-4-(1,2-dichloroethyl)cyclohexane, adversely affected trout and bluegills after 1 hour of exposure at 5 parts per million (ppm).

Under section 4(a)(1) of TSCA, the Administrator shall by rule require testing of a chemical substance to develop appropriate test data if the Agency finds that:

(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment.

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture.

(ii) there are sufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

EPA uses a weight-of-evidence approach in which both exposure and toxicity information are considered in making a section 4(a)(1)(A)(i) finding that the chemical may present an unreasonable risk. For the section 4(a)(1)(B)(i) finding, EPA considers only production, exposure, and release information to determine whether there is substantial production, and significant or substantial exposure, or substantial release. Thus, while EPA can require testing for an effect under section

4(a)(1)(A) only if there is a suspicion of a hazard, under section 4(a)(1)(B) EPA can require testing whether or not there are data suggesting adverse effects if the relevant production and exposure or release criteria are met.

For the findings under both section 4(a)(1)(A)(ii) and 4(a)(1)(B)(ii), EPA examines toxicity and fate studies to determine whether existing information is adequate to reasonably determine or predict the effects of human exposure to, or environmental release of, the chemical. In making the third finding, that testing is necessary, EPA considers whether ongoing testing will satisfy the information needs for the chemical and whether testing which the Agency might require would be capable of developing the necessary information. EPA's process for determining when these findings can be made is described in detail in EPA's first and second proposed test rules as published in the Federal Register of July 18, 1980 (45 FR 48528) and June 5, 1981 (46 FR 30300). The section 4(a)(1)(A) finding is discussed in 45 FR 48528, and the section 4(a)(1)(B) finding is discussed in 46 FR 30300.

In evaluating the ITC's testing recommendations for TBEC, EPA considered all available relevant information including the following: Information presented in the ITC's report recommending testing consideration: production volume, use, exposure, and release information reported by manufacturers of TBEC under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); and published and unpublished data available to the Agency.

II. Review of Available Data

A. Human Exposure and Environmental Release

One company currently manufactures TBEC, Ethyl/Saytech in Sayreville, NJ, a subsidiary of Ethyl Corporation. Production was about 800,000 pounds in 1982 by Chemtronics, Inc. under contract to Saytex Corporation (an Ethyl Corporation Company) (Refs. 1 and 2). Ethyl Corporation has submitted to EPA production volumes for 1979, 1980, 1981, and 1983 and a projected production volume for 1984 as confidential business information (Ref. 3).

Ethyl/Saytech reports that TBEC is produced in a batch operation involving closed reaction vessels, then dried and packaged in an open operation (Ref. 4). The number of workers potentially exposed to TBEC per shift is small—three during production operations and

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one in the baghouse where packaging occurs (Refs. 4 and 5). Exposure to TBEC is unlikely to occur during the wet phase of its production, since the types of closed equipment used for handling liquids normally preclude operator contact. A higher potential for dermal and inhalation exposure to TBEC exists when the compound is handled as a solid (drying and packaging) rather than as a liquid. To minimize worker exposure during packaging, employees are required to wear disposable coveralls, shoe covers, dust caps, cotton gloves, and dust masks. The packaging is done in a separate room within the manufacturing facility, thereby reducing the chance of exposure for workers in other parts of the plant (Ref. 4). At ambient temperatures, the maximum airborne concentration of TBEC vapor that can be attained is approximately 0.04 ppm on the basis of an estimated vapor pressure of TBEC at 20°C of 2.83×10^{-3} torr (Ref. 6). Neither the Occupational Safety and Health Administration (OSHA) nor the American Conference of Governmental Industrial Hygienists (ACGIH) has established a standard for TBEC.

TBEC is used non-consumptively, primarily as an additive type flame retardant in expandable polystyrene (EPS) beads, from which polystyrene bead boards are made. These bead boards are used for thermal insulation in housing. TBEC is also used as an additive type flame retardant in extruded polystyrene foam and as a flame retardant in an adhesive in fabric/vinyl lamination (Ref. 5). None of the companies that process TBEC for any of its applications are manufacturers of the chemical.

During its addition to EPS beads, virtually no human exposure to TBEC is likely to occur, since this process takes place in a closed vessel (Refs. 7 and 8). Routine contact would be limited to a small number of people involved in loading TBEC into process vessels. Ethyl/Saytech recommends that protective clothing including gloves be worn when handling TBEC.

The production of EPS bead board from EPS beads impregnated with 1 percent TBEC requires little direct operator involvement, and hence poses little potential for dermal exposure to TBEC. Routine contact would be limited to loading the EPS beads into the pre-expander feed hopper. Although TBEC vapors could conceivably be released during various processing steps (most notably, pre-expansion), the maximum ambient concentration of TBEC vapor would be limited by its saturated vapor pressure at the ambient air temperature

(estimated to be 0.04 ppm at 20°C) (Ref. 6). Occupational and consumer exposure to TBEC from its use in polystyrene bead board would be extremely low because TBEC impregnated in polystyrene would have little tendency to migrate from the plastic. The low tendency of a flame retardant to migrate from plastics is not an incidental property; it is considered a desirable trait, and one criterion by which a flame retardant is chosen (Ref. 9).

In other processes, such as the extrusion of polystyrene foam, little exposure to TBEC is expected since release of TBEC vapor at very high temperatures would only occur within the extruder; the temperature of the plastic would drop immediately upon extrusion. Little exposure to TBEC is expected to result from its adhesive use, since application of the adhesive would be an automated process (Ref. 10).

From information on production and use of TBEC, EPA concludes that little if any TBEC is released to the environment during its manufacture, processing, distribution in commerce, use or disposal. Ethyl/Saytech reports that it uses baghouse collectors with a rated efficiency of 99 percent to control release of TBEC dust to the atmosphere (Ref. 4). The sole aqueous waste stream associated with the production of TBEC is sent to a holding tank and then distilled. After solvent recovery, still bottoms are sent to a licensed waste dump site (Refs. 11 and 12). All other production wastes are disposed of in a licensed landfill (Ref. 4).

When EPS beads are suspended in water prior to the addition of TBEC, aqueous wastes may result. However, even if water were used on a once-through basis at a rate of 1 lb water/lb polystyrene, the maximum annual release of dissolved TBEC nationwide due to this process would be 60 lb, assuming 60 million pounds of TBEC-treated EPS bead to be produced annually (Ref. 13) and assuming a water solubility of 1 ppm (Ref. 14) for TBEC. In addition, on the basis of estimated soil-adsorption coefficients for TBEC of 1,230 and 11,900 (Refs. 15 and 16), any TBEC entering a municipal sewage treatment plant should be adsorbed onto the sludge. It is unlikely that any aqueous wastes containing TBEC would be generated in the production of extruded polystyrene foam, adhesives, or bead board containing TBEC.

The disposal of bead board impregnated with TBEC does not raise EPA concerns for a number of reasons. First, bead board contains a relatively low concentration of TBEC (1 percent w/w). Secondly, the polymer matrix is

impregnated with TBEC, and therefore release to the environment is expected to be very slow. Finally, as discussed in Unit II.C of this notice, TBEC will strongly adsorb to the organic matter in soil.

B. Health Effects

1. *Toxicokinetics.* Cannon Laboratories (Ref. 17) reported on the pattern of excretion and the tissue distribution of ¹⁴C-TBEC in rats. Five rats (age and sex not specified) were given daily oral doses of ¹⁴C-TBEC for 14 days, equivalent to a total of 1.13 mg/kg. Two of the five rats were housed in metabolic cages. The other three animals were sacrificed 7, 14, and 30 days after their last dose of ¹⁴C-TBEC to determine the tissue distribution of the radiolabel.

Excreta data for the two rats maintained in metabolic cages are as follows. Of the label introduced as ¹⁴C-TBEC, between 55 and 66 percent was recovered in the urine; 23 to 28 percent was recovered in the feces. The nature of the substance(s) containing the ¹⁴C-label in these samples was not specified. The data also show that 0.28 percent of the ¹⁴C was recovered as ¹⁴CO₂, and 0.22 percent as other (unspecified) ¹⁴C-labeled volatiles.

The tissue sample concentrations of ¹⁴C detected on study day 15 were: liver (2.03-2.40 ppm) > kidney (1.85-2.01 ppm) > fat (0.363-0.427 ppm) > brain (0.207-0.297 ppm) > leg muscle (0.086-0.98 ppm). Thirty days after the last dose of ¹⁴C-TBEC, the concentrations of ¹⁴C in tissue samples were reduced > 77 percent: kidney (0.230 ppm) > liver (0.153) > brain (0.055 ppm) > fat (0.032 ppm) > leg muscle (0.019 ppm).

These data indicate that what TBEC is absorbed is fairly readily excreted.

2. *Acute Toxicity.* In a 14-day acute oral toxicity study in ten Sprague-Dawley rats (5 males and 5 females) an LD50 of 3,220 mg/kg has been reported (Ref. 18).

In a 14-day acute dermal study in rabbits (5 males and 5 females) (Ref. 19), none of the animals died during the 14-day postexposure observation period. Slight to moderate erythema was observed in 5 of the 10 rabbits at 2 and 4 hours after the removal of the TBEC sample. No visible lesions were observed in any of the animals at necropsy. Based on these observations, a dermal LD50 of > 5g/kg for TBEC in rabbits was reported.

The results of a primary skin irritation test in six albino rabbits (sex, age and weight not specified) have been reported (Ref. 20). TBEC (0.5 g per area) was applied to two sites, one intact and one

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abraded, on each rabbit. The exposed sites were observed at 24 and 72 hours after the removal of TBEC for signs of irritation. Both the 24- and 72-hour observations were negative. In this study, TBEC (0.5 g per site) was not an irritant to either intact or abraded skin in rabbits.

The results of an eye irritation study in six rabbits (age, sex, and weight not specified) have been reported (Ref. 21). TBEC (0.1 g) was instilled into one eye of each animal; the untreated eye of the animal served as the control. Reactions to the treatment were recorded at 24, 48, and 72 hours. An "initial reaction quite severe" was noted for one animal without further details. All other observations were negative.

These data indicate that TBEC does not exhibit a high degree of acute toxicity.

3. *Mutagenicity.* TBEC did not exhibit mutagenic activity in: (1) *Salmonella typhimurium*, strains TA98, TA100, TA1535 or TA1537 (Ref. 22); (2) *Salmonella typhimurium*, strains TA98, TA100, TA1535, TA1538 or *Saccharomyces cerevisiae-D4 (gene conversion assay)* (Ref. 23); or *Salmonella typhimurium*, strains TA98, TA100, TA1535, TA1537 and TA1538 (Ref. 24).

Chromosomal aberration and sister chromatid exchange studies on TBEC in Chinese hamster ovary cells are planned by NTP (Ref. 25).

4. *Subchronic Toxicity.* Cannon Laboratories (Ref. 26) conducted a 90-day feeding study with TBEC in rats. Sprague-Dawley rats (15 males and 15 females per dose level) were fed TBEC (0, 0.01, 0.10, and 1.0 percent [Groups I-IV, respectively]), mixed in NIH-07 rat mash for 90 days. Doses for groups I-IV, respectively, were approximately 0, 4, 40, and 400 mg/kg/day. The rats were given the control diet (0 percent TBEC) for 12 days before initiation of the study, and from day 91 to autopsy, which was on study day 133 or 138. The active feeding portion of the study was discontinued at day 90.

On day 90, three male and three female rats from each group were sacrificed. All tissues and organs were examined for any gross abnormalities. The liver, both kidneys, thyroid and heart were weighed and the relative organ weights calculated. The remaining animals were sacrificed on day 133 or 138, and their tissues and organs examined for gross abnormalities.

Tissue samples were obtained from all rats sacrificed on day 90, 133, or 138 in the 0 and 1.0 percent TBEC groups and from those in the 0.01 and 0.10 percent TBEC groups that appeared abnormal at autopsy. The following

tissues were fixed, stained with hematoxylin and eosin, and examined using a light microscope: adrenals; bone marrow; brain; esophagus; heart; intestine (large or small not specified); kidney; liver; lung; oral mucosa; prostate; salivary glands; spleen; stomach; testes or ovaries; thyroid; urinary bladder; uterus; gross lesions; and tissue masses.

The mean body weights of the 1.0 percent TBEC-treated group were significantly lower than those of the other three groups during weeks 1-19. Mean food consumption values of the rats that received the test material at the 1.0 percent level were lower than the other 3 groups for week 1 and higher than the other 3 groups for weeks 8 and 14 in males, while in females the mean food consumption values were lower than the other 3 groups for week 1 and higher than the other 3 groups for weeks 3, 4, 14, and 15.

In the animals sacrificed on day 90, statistically significant difference (p values not given) were detected in males treated with 1.0 percent TBEC. The 1.0 percent TBEC group mean body weight (416.3 g) was significantly less than that of the control group (522.7 g) and the relative liver weight was significantly greater (5.4 percent) than that of the control group (4.5 percent). In females treated with 1.0 percent TBEC, the mean absolute heart weight was significantly less (0.94 g) than that of the control group (1.17 g), and the relative liver (4.7 percent), kidney (1.08 percent) and thyroid (0.0097 percent) weights were significantly greater than those of the control group (4.0, 0.86, and 0.0068 percent, respectively).

For male rats treated with 1.0 percent TBEC and sacrificed on study day 133 or 138, the mean absolute weights of the thyroid (0.028 g) and heart (1.56 g) and the mean absolute body weight (471 g) were significantly less than those of the control group (0.033, 1.80, and 549.4 g, respectively). No significant difference was found in the relative organ weights between this group and the control group.

For female rats treated with 1.0 percent TBEC and sacrificed on study day 133 or 138, the mean absolute body weight (288.1 g) was significantly less than that of the control animals (319.2 g) and the relative kidney (0.99 percent) and thyroid (0.0095 percent) weights were significantly less than those of the controls (0.86 and 0.0078 percent, respectively).

Histopathologic evaluation found bronchopneumonia, colloid storage in thyroid, lipid depletion in adrenals, dilated tubules in kidneys, or subcutaneous adenocarcinoma.

respectively, in 19, 7, 45, 6, and 2 percent (1 animal) of the TBEC-exposed animals examined and 14, 30, 4, 68, and 0 percent of the control group. As noted previously, histopathologic examination was performed on all animals in the control and 1.0 percent dose groups and on only those animals from the 0.01 and 0.1 percent dose group judged abnormal in the gross necropsy. The subcutaneous adenocarcinoma occurred in one animal in the 0.01 percent group. It is most likely a spontaneous tumor of a type that has a very high background level (75 to 95 percent) at one year of age in the Sprague-Dawley rat. In addition, there were sporadic incidences (2-4 percent) of chronic bronchitis, hemorrhagic lungs, chronic renal disease, and hydronephritis of the kidney in the test groups. Cannon (Ref. 28) reported that "no marked differences in the rate of various histopathologic anomalies" were apparent among the 0.01, 0.10, and 1.0 percent TBEC-fed groups. No adverse effects were reported on histopathological examination of the reproductive organs.

While this study is not definitive, the unremarkable effects reported in this study do not support a requirement for additional health effects testing under section 4(a)(1)(A) of TSCA.

C. Chemical Fate

1. *Water Solubility and Octanol/Water Partition Coefficient.* A water solubility of 1.0 mg/L (1 ppm) (Ref. 14) and a log of the octanol/water partition coefficient (log P) of 4.96 for TBEC (Ref. 27) have been estimated. These estimated properties indicate that under equilibrium conditions, TBEC will partition primarily into the soil/sediment compartment.

2. *Soil mobility.* The adsorption properties of TBEC to soil have not been reported in the available literature. However, using equations developed by Kenaga (Ref. 14) and Kenaga and Goring (Ref. 15) a value for the adsorption coefficient (K_{oc}) can be estimated from either the log P or water solubility values. EPA has calculated K_{oc} values of 11,900 and 1,230 from a calculated log P of 4.96 and an estimated water solubility value of 1.0 mg/L, respectively. These estimates of K_{oc} indicate that TBEC will adsorb strongly to organic matter in soil and sediment and therefore can be considered relatively immobile in these media (Ref. 14).

3. *Persistence.* EPA is not aware of any information on the environmental persistence of TBEC in the available literature. However, as discussed in Unit II.A of this notice, little if any TBEC is expected to be released to the

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environment as a result of its manufacture, distribution in commerce, processing, use, or disposal.

D. Environmental Effects

1. *Acute Toxicity.* EPA is not aware of any information on environmental effects of TBEC in the available literature. However, a report was found on the acute effects of the corresponding chlorinated compound, 1,2-dichloro-4-(1,2-dichloroethyl)cyclohexane (DDC), mentioned by the ITC, and 1,2-dibromocyclohexane (DBC) in the larval sea lamprey *Petromyzon marinus*, the rainbow trout *Salmo gairdnerii*, and bluegill sunfish *Lepomis macrochirus* (Ref. 28). In a static, 24-hour screening test conducted with 5.0 ppm DDC, two specimens of each species were exposed. The test chemical had no effect on the lampreys but caused unspecified "illness" to both fish species in about 1 hour; no deaths were observed. In contrast, 5.0 ppm DBC produced no effect on sea lamprey and rainbow trout. No testing of DBC was performed with the bluegill fish.

The purpose of this study was to screen as many chemicals as possible for selective toxicity to the lamprey but not to the fish. The experiments utilized only two specimens of each species, and only one concentration of DDC and DBC was tested. No replicates were done. Details on the methodology used for each of the 4,348 chemicals tested were not reported, and "illness" was not defined. Because of the above deficiencies, a definitive conclusion on the toxicity of DDC and DBC cannot be made. However, the data suggest that neither DDC nor DBC was toxic to the sea lamprey larva, but that DDC was toxic to both fish species at 5 ppm. Nonetheless, as discussed in Unit IIA of this notice, little if any TBEC is expected to be released to the environment as a result of its manufacture, distribution in commerce, processing, use, or disposal.

2. *Bioconcentration.* No data were found in the available literature on the bioconcentration of TBEC in food chains and ecosystems. Using the equation ($\log BCF = 0.85 \log P - 0.70$) developed by Veith (Ref. 29), the bioconcentration factor (BCF) for TBEC estimated from its log P value is 3,280. This estimate indicates that TBEC may bioconcentrate to a significant degree (Ref. 29). However, as discussed in Unit IIA of this notice, little if any TBEC is expected to be released to the environment as a result of its manufacture, distribution in commerce, processing, use, or disposal.

III. Decision Not To Initiate Rulemaking

EPA has decided not to initiate rulemaking at this time to require health

effects, chemical fate or ecological effects testing of TBEC. The ITC recommended health effects testing for TBEC because it believed that TBEC was structurally related to EDB and releases from production and use were expected to result in human exposure. Although there are only limited health effects data on TBEC (Unit IIB), they suggest that TBEC is not as toxic as EDB.

Oral LD₅₀s for EDB of 0.117 and 0.248 g/kg have been reported in female and male rats, respectively (Ref. 30). A dermal LD₅₀ for EDB of 0.300 g/kg in the rabbit has been reported (Ref. 31). Rowe et al. (Ref. 30) reported increased weight of kidneys, lungs, and liver and decreased weight of testes and spleen in a 13-week subchronic inhalation study with EDB in rats. Exposures were 7 hours per day, 5 days per week at 50 ppm. (This corresponds to an oral dose of 57 mg/kg/day assuming 100 percent absorption). Exposure to 25 ppm EDB for 30.5 weeks (7 hours per day, 5 days per week) showed no adverse effects.

The Occupational Safety and Health Administration (OSHA) in support of its proposal to lower the permissible exposure limit (PEL) for EDB to 0.1 ppm (Ref. 32) has summarized the health effects data on EDB. Reproductive effects of EDB in several animal species have been clearly established, specifically in early stages of sperm development. A series of male reproductive studies was carried out in bulls (Refs. 33 through 41). Reproductive impairment, as measured by decreased sperm density and motility and sperm abnormalities, was found after two weeks of exposure to 2 or 4 mg/kg EDB in the diet.

The mutagenic effects of EDB have been reviewed in detail by NIOSH (Ref. 39), Ramong (Ref. 40), IARC (Ref. 41), and EPA (Ref. 42). Mutagenic effects have been detected in a variety of *in vitro* and *in vivo* systems including *Salmonella typhimurium* (Refs. 32 through 48).

On the basis of the scientific evidence presented in its proposal to lower the PEL of EDB to 0.1 ppm (Ref. 32) OSHA stated that it "believes that EDB is a potent animal carcinogen. EDB produces tumors at the site of direct contact and at sites remote from the site of administration" (Ref. 32).

OSHA stated in its proposal (Ref. 32) that it "believes that the total risk to the health of employees exposed to EDB is the result of the compounded risks from carcinogenicity, mutagenicity, spermatotoxicity, teratogenicity, and damage to the kidneys, liver, spleen, respiratory tract, central nervous system, circulatory system, skin and

eyes. Therefore, the totality of the adverse health effects associated with exposure to EDB warrant the reduction in the PEL to 0.10 parts per million."

Even if TBEC were as toxic as EDB, a compound with far broader human exposure, expected exposure levels to TBEC are already below the proposed OSHA 8-hour time-weighted average (TWA) permissible exposure limit (PEL) for EDB of 0.10 ppm (Ref. 32). Because few people are exposed to TBEC and at expected exposure levels below 0.10 ppm and because consumer exposure to TBEC is expected to be negligible, EPA concludes that health effects testing for TBEC is not warranted.

The ITC recommended chemical fate and ecotoxicity testing of TBEC because it believed that the production and uses of TBEC made environmental exposure likely, including releases to the aquatic environment. However, EPA concludes that, on the basis of information presented in Unit IIA of this notice, there is neither sufficient environmental release to support TSCA section 4(a)(1)(A) or 4(a)(1)(B) findings for chemical fate and ecological effects testing of TBEC nor existing ecotoxicity data to support a TSCA section 4(a)(1)(A) finding that TBEC may present an unreasonable risk to the environment.

IV. Public Record

EPA has established a public record for this decision not to test under Section 4 of TSCA (docket number OPTS-42064). The record includes the following information:

A. Supporting Documentation

- (1) Federal Register notice containing the ITC Report designating 1,2-dibromo-4-(1,2-dibromoethyl) cyclohexane to the Priority List.
- (2) Communications consisting of:
 - (a) Written public and intra-agency or interagency memoranda and comments.
 - (b) Summaries of telephone conversations.
 - (c) Summaries of meetings.
- (3) Reports—published and unpublished factual materials, including contractors' reports.

B. References

- (1) Memorandum from George E. Parris, Dynamac Corporation, Rockville, MD to TSCA Interagency Testing Committee, Production and use of 1,2-dibromo-4-(1,2-dibromoethyl)-cyclohexane, PIR-327, November 10, 1982.
- (2) USEPA. Fourteenth report of the ITC to the Administrator, receipt of report and request for comments, 49 FR 22389, May 29, 1984.

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- (3) Ethyl Corporation, Baton Rouge, LA. Letter submitted to Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC. Information needs for 1,2-dibromo-4-(1,2-dibromoethyl)-cyclohexane. Confidential Business Information, August 17, 1984.
- (4) Dynamac Corporation, Rockville, MD. Letter from W. W. Perry to Martin Grief, Environmental Protection Agency, Washington, DC, with information addendum A on IR-327, 1,2-dibromo-4-(1,2-dibromoethyl)-cyclohexane attached, January 27, 1984.
- (5) Ethyl Corporation, Baton Rouge, LA. Answers to questions submitted by Tina Rosenthal, Dynamac Corporation, Rockville, MD, August 17, 1984.
- (6) Dynamac Corporation, Rockville, MD. TBEC exposure calculations, August 7, 1984.
- (7) Schwarz, R. A. (inventor), Cosden Technology, Inc. (assignee). Foamable polymeric styrene particles. U.S. Patent 4,389,495.
- (8) Innes, James, Ethyl Corporation, Baton Rouge, LA. Personal communication with John Harris, Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, DC, August 24, 1984.
- (9) Modern Plastics, Plastiscopie: better bromides, safer foams pace FR advances 61(5):214, 1984.
- (10) Innes, James, Ethyl Corporation, Baton Rouge, LA. Personal communication with John Harris, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC, August 27, 1984.
- (11) Makfinsky, Laverne, Ethyl/Saytech Sayreville, NJ. Personal communication with John Harris, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC, August 24, 1984.
- (12) Dynamac Corporation, Rockville, MD. Letter from Ann Engelkemeir to Laverne Makfinsky, Ethyl/Saytech, Sayreville, NJ, September 13, 1984.
- (13) Engelkemeir, Ann, Dynamac Corporation, Rockville, MD. "Calculations: Theoretical Maximum Loss of TBEC Dissolved in Wastewater From Evaporation of TBEC into Beds via Aqueous Suspension." September 27, 1984.
- (14) Dynamac Corporation, Rockville, MD. "Estimation of Water Solubility of TBEC at 25°C." October 5, 1984.
- (15) Kenaga, E. E. "Predicted Bioconcentration and Soil Sorption Coefficients of Pesticides and Other Chemicals." *Ecotoxicol. Environ. Saf.* 4:26-38, 1980.
- (16) Kenaga, E. E. and C. A. I. Goring. "Relationship Between Water Solubility, Soil Sorption, Octanol/Water Partitioning, and Concentration of Chemicals in Biota." *ASTM Spec. Tech. Publ. STP 702/78-115*, 1982.
- (17) Cannon Laboratories, Inc. "Excretion and Tissue Distribution of ¹⁴C-RW-4-178A Administered Orally to Rats." Laboratory No. 8E-0182. Submitted to Cities Service Corporation, Tulsa, OK, July 17, 1978. Submitted to Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC by Ethyl Corporation, Baton Rouge, LA, August 17, 1984.
- (18) Pharmakon Research International, Inc. "Acute Oral Toxicity Study in Rats (4 Days)." PH 402-EI-004-31, Saytech BCL-462, Lot No. 14-1487E, October 15, 1981. Submitted to: Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC, by Ethyl Corporation, Baton Rouge, LA, August 17, 1984.
- (19) Pharmakon Research International, Inc. "Acute Dermal Toxicity Test in Rabbits." PH 422-005-81, Saytech BCL-462, Lot No. 14-1487E, October 13, 1981. Submitted to: Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC, by Ethyl Corporation, Baton Rouge, LA, August 17, 1984.
- (20) WARF Institute, Inc. "Primary Skin Irritation BCL-462 GR-2-23A." WARF No. 0102052, Madison, WI, October 28, 1970. Submitted to: Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC, by Ethyl Corporation, Baton Rouge, LA, August 17, 1984.
- (21) WARF Institute, Inc. "Eye Irritation BCL-462 GR-2-23A." WARF No. 0102052, Madison, WI, October 28, 1970. Submitted to: Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC, by Ethyl Corporation, Baton Rouge, LA, August 17, 1984.
- (22) Weisburger, E. K. TSCA Interagency Testing Committee, Memorandum to D. Canter, National Toxicology Program, NIH, November 8, 1983.
- (23) Litton Bionetics, Inc. "Mutagenicity Evaluation of RW 4144-1." Final report, LBI Project No. 20838. Submitted to: Cities Service Company, Tulsa, OK, October, 1977. Submitted to: Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC, by Ethyl Corporation, Baton Rouge, LA, August 17, 1984.
- (24) Cannon Laboratories, Inc. "Evaluation of the Mutagenic Potential of 1062-482-SB in the Ames Salmonella/Microsome Plate Test." Laboratory No. 9E-8321, October 22, 1979. Submitted to: Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC, by Ethyl Corporation, Baton Rouge, LA, August 17, 1984.
- (25) Jordan, F. NTP (National Toxicology Program), Results Report, Results and Status Information on All NTP Chemicals Produced from NTP Chemtrack System, November 1, 1984.
- (26) Cannon Laboratories, Inc. "Brewery-Bay Feeding Study in Rats Evaluating Cities Service Compound RW-4-178A." Laboratory No. 8E-0182. Submitted to: Cities Service Company, Tulsa, OK, September 13, 1978. Submitted to: Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC, by Ethyl Corporation, Baton Rouge, LA, August 17, 1984.
- (27) Dynamac Corporation, Rockville, MD. "Estimation of Log Octanol/Water Partition Coefficient for TBEC." October 5, 1984.
- (28) Applegate, V. C., J. H. Howell, A. E. Hall, and M. A. Smith. "Toxicity of 4,348 Chemicals to Larvae of Lampreys and Fishes, Fish and Wildlife Service, U.S. Department of Interior, Washington, DC. Special scientific report Fisheries No. 207, March 1957.
- (29) Veith, G.D., D.L. DeFoe and V.V. Bergstedt. "Measuring and Estimating the Bioconcentration Factor of Chemicals in Fish." *J. Fish. Res. Board Can.* 36:1049-1048, 1979.
- (30) Rowe, V.K., H.C. Spencer, D.E. McCollister, and E.M. Adams. "Toxicity of Ethylene Dibromide Determined on Experimental Animals." *Arch. Ind. Hyg. Occ. Med.* 6:158-71.
- (31) NIOSH. Ethane, 1,2-dibromo. Registry of Toxic Effects of Chemical Substances: 1981-2, Vol. II, NIOSH Pub. #83-107, Cincinnati, Ohio, 222, 1983.
- (32) OSHA. Occupational exposure to ethylene dibromide: notice of proposed rulemaking, 48 FR 45958, October 7, 1983.
- (33) Amir, D. and R. Volcani. "Effect of dietary ethylene dibromide on bull semen." *Nature* 200:99-100, 1965.
- (34) Amir, D. and R. Volcani. "The effect of dietary ethylene dibromide on the testes of bulls." *Fertility and Sterility* 12:144, 1967.
- (35) Amir, D. "The sites of the spermidic action of ethylene dibromide in bulls." *J. Reprod. Fert.* 35:519-25, Exhibit 4-22, 1973.
- (36) Amir, D. "Individual and age differences in the spermidic effect of ethylene dibromide in bulls." *J. Reprod. Fert.* 44:561-65, 1975.
- (37) Amir, D. and U. Lavon. "Changes in total nitrogen, lipoproteins and amino acids in epididymal and ejaculated spermatozoa of bulls treated orally with ethylene dibromide." *J. Reprod. Fert.* 27:73, 1978.
- (38) Amir, D., C. Esauult, J.N. and M. Courrot. "DNA and protein changes in the spermatozoa of bulls treated orally with ethylene dibromide." *J. Reprod. Fert.* 51:453, 1977.
- (39) National Institution for Occupational Safety and Health. Criteria for a recommended standard * * * Occupational exposure to ethylene dibromide. DHEW (NIOSH) Publication No. 77-221, Exhibit 4-4, 1977.
- (40) Rannug, U. "Genotoxic effects of 1,2-dibromoethane and 1,2-dichloroethane." *Mutat. Res.* 79(3):289-295, 1980.
- (41) IARC. Ethylene Dibromide. In: IARC monographs on the evaluation of the carcinogenic risk of chemicals to man: some fumigants, the herbicides 2,4-D and 2,5-T chlorinated dibenzodioxins and miscellaneous industrial chemicals, Vol. 15, *World Health Organization, Lyon, France*, 196-200, 1977.
- (42) USEPA. Ethylene Dibromide. Rebuttable Presumption Against Registration Position Document 4, Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, DC, September 27, 1983.
- (43) Ames BN. "The detection of chemical mutagens with enteric bacteria." In Hollaender, A. (ed): *Chemical Mutagens: Principles and Methods for Their Detection*. New York, Plenum, Vol. 1, pp. 267-82, 1975.
- (44) Buselmaier, W., G. Rohrborn, and P. Propping. "Pesticide mutagenicity investigations by the host mediated assay and the dominant lethal test on mice." *Biol. Zentralbl.* 91: 311-23 (Ger), 1972.
- (45) Buselmaier, W., G. Rohrborn, and P. Propping. "Comparative investigations on the mutagenicity of pesticides in mammalian test systems." *Mutat. Res.* 27:25-26, 1973.

(46) Brem, H., A.B. Stein, and H.S. Rosenkranz. "The mutagenicity and DNA-modifying effect of haloalkanes." *Cancer Res.* 34:2576-79, 1974.

(47) McCann, J., E. Choi, E. Yamasaki, and B.N. Ames. "Detection of carcinogens as mutagens in the Salmonella/microsome test: assay of 300 chemicals." *Proc. Nat. Acad. Sci.* (Washington, D.C.) 72:5135-5139, 1975.

This record includes basic information considered by the Agency in developing this notice, and is available from 8 a.m. to 4 p.m. Monday through Friday except legal holidays, in the OPTS Reading Room, Rm. E-107, 401 M St., SW., Washington, D.C. 20460. The Agency will supplement the record periodically with additional relevant information received.

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