

pouring facilities and one bar billet grinder will at least equal the amount currently required to be spent on the two bar billet grinders. The company's proposal has been reviewed by EPA's technical staff and they have determined that the bottom pouring facilities will improve the efficiency and productivity of the Lorain Plant. The company has indicated that the date originally established for initiation of operation of the bar billet grinders—May 30, 1984—can be met for the bottom-pouring portion of the project.

This notice represents the Agency's formal determination that the modernization project at the Lorain, Ohio plant, as amended by the requested substitution, meets the requirements of the Steel Industry Compliance Extension Act, and is equivalent to the project originally specified in the consent decree. 42 U.S.C. 7413(e)(1)(B) and (e)(2).

Finding

This notice amends an earlier finding published in the Federal Register on January 6, 1983 (48 FR 730), by striking that portion of Finding Number 2 beginning with the subtitle "Lorain Works" and continuing through the words "quality bar shipments" and substituting therefore the following:

Lorain Works \$9.86 Mn

Initiation of operation: May 30, 1984.

Installation of facilities to permit bottom-pouring of steel ingots at the Lorain BOP Shop and one additional high-capacity fixed head bar billet grinder at the Billet Conditioning Facility. The project includes a new building, billet handling equipment and air quality control equipment consisting of a bag house to collect emissions from the billet grinder. The facilities will provide the necessary capability for quality bar shipments.

Consent

I hereby give notice that I have consented to the entry of an amendment to the Lorain Works consent decree allowing a substitution of modernization projects as described above.

Dated: November 3, 1983.

William D. Ruckelshaus,
Administrator.

[FR Doc. 83-30721 Filed 11-14-83; 8:45 am]
BILLING CODE 6560-50-M

[OPTS-42042; TSH-FRL 2452-8]

4-(1,1,3,3-Tetramethylbutyl)phenol; 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's) recommendation that 4-(1,1,3,3-tetramethylbutyl)phenol (TMBP) be tested for health and environmental effects under section 4(a) of the Toxic Substances Control Act (TSCA). Subsequent to the ITC's recommendation, the manufacturers proposed specific aquatic toxicity testing for the chemical and presented to EPA information regarding production, use, toxicity and exposure of TMBP. The Agency also received additional health effects data through the TSCA section 8(d) Health and Safety Data Reporting requirement. EPA believes that the available health effects information and the proposed aquatic toxicity testing program will provide sufficient information to reasonably predict the effects of TMBP. Consequently, the Agency is not initiating rulemaking at this time to require testing of TMBP under TSCA section 4(a). EPA seeks comments on its conclusions and on the adequacy of the proposed industry testing program.

DATE: Comments should be submitted on or before December 30, 1983.

ADDRESSES: Written comments should bear the document control number [OPTS-42042] and should be submitted in triplicate to: TSCA Public Information Office (TS-799), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St. SW., Washington, D.C. 20460.

The administrative record supporting this action is available for public inspection in Rm. E-107 at the above address from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Pesticides and Toxic Substances, Room E-543, Environmental Protection Agency, 401 M St. SW., Washington, D.C. 20460, Toll Free: (800-424-9065). In Washington, DC.: (554-1404). Outside the USA: (Operator 202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 4(a) of the Toxic Substances Control Act (TSCA) (Pub. L. 94-469, 90

Stat. 2006 *et seq.*; 15 U.S.C. 2601 *et seq.*) authorizes the EPA to promulgate regulations requiring testing of chemical substances and mixtures in order to develop data relevant to assessing the risks that such chemicals may present to health and the environment. Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend to the EPA a list of chemicals to be considered for promulgation of testing rules under section 4(a) of the Act.

On November 3, 1982, the ITC placed 4-(1,1,3,3-tetramethylbutyl)phenol (TMBP) on its priority testing list in its Eleventh Report to the EPA Administrator which was published in the Federal Register on December 3, 1982 (47 FR 54624). The ITC recommended that TMBP be considered for short-term health effects testing, including mutagenicity, and for environmental effects testing including acute and chronic toxicity to fish and aquatic invertebrates, toxicity to plants, bioconcentration, and chemical fate.

The ITC recommended TMBP for testing, in part, because of a large estimated annual production volume, multiple consumer uses, expected releases and subsequent environmental exposure, expected resistance to biodegradation, and detection in surface water and workplace atmosphere. The health effects recommendations were also based on an observed leukodermal action of TMBP, which the ITC believed indicated a profound effect on the biochemical and physiological processes in the dermal cells of several species. It recommended that short-term health effects tests, including mutagenicity, be used to provide a means to investigate the toxicological mechanisms of TMBP. No data were found to exist for subchronic, chronic, mutagenic, teratogenic, reproductive effects or pharmacokinetics testing of TMBP. The ITC believed that information resulting from short-term testing could be used in determining the need for further health effect studies.

Environmental effects testing of TMBP was recommended because of a potential risk to the aquatic environment as indicated by: (1) Its introduction to the aquatic environment from uses of TMBP-containing products; (2) its detection in wastewater entering a freshwater river system at levels exceeding a known LC₅₀; and (3) its expected persistence, bioconcentration and transport through the food chain due to a relatively high estimated octanol/water partition coefficient. No data were found on the long-term effects of TMBP on either aquatic plants or animals; nor were data on the

physiological, behavioral, or ecosystem effects of TMBP. Chemical fate testing was also recommended to better characterize the transport, transformation, and persistence of TMBP in the aquatic environment.

This notice provides EPA's response to the ITC's designation of TMBP for testing consideration.

II. Exposure

TMBP is a synthetic compound commercially available in the form of waxy, non-dusting white to light tan flakes or as a pale yellow liquid in the molten state, both of which have a phenolic odor (Ref. 1). Solid TMBP is stable at room temperature (calculated vapor pressure of 0.962×10^{-3} mm Hg at 25°C), soluble in many organic solvents (Ref. 2) and has a low solubility in water [(0.017 g/l at 25°C (Ref. 3) and 0.10 g/l at 25°C (Ref. 4)]. The compound is susceptible to oxidation by molecular oxygen, singlet oxygen, or hydroxyl radicals (Ref. 2). TMBP is not expected to hydrolyze and should not react with dilute aqueous acids, but it may form water-soluble salts with strong bases. The melting point for this compound is 84°C, the calculated volatilization half-life is 473 h, and the log P octanol/water value is 3.7 (Ref. 5). The empirical formula for TMBP is $C_{14}H_{12}O$ and its molecular weight is 206.

TMBP is used predominantly as a chemical intermediate. TMBP's two main commercial applications are (1) TMBP-resins formed by a condensation reaction of TMBP with aldehydes and (2) nonionic TMBP-surfactants formed by polycondensation of ethylene oxide with the base TMBP molecule. A minor application involves sulfonation, yielding bisphenol mono- and disulfides.

TMBP resins are used as tackifiers, as extenders in adhesives, in varnishes and marine paints, and as binders in printing inks. TMBP resins are a member of the phenolformaldehyde resin class. These resins are classified as either resoles or novolaces depending upon their chemical composition and properties.

TMBP resoles are used in the rubber industry where the methylol groups provide cross-linking, which is desirable in the butyl rubber curing process for tire manufacture. They are also used in the curing system for neoprene contact adhesives. TMBP novolaces are normally used in combination with certain modified pine tars as general and specific purpose tackifiers. These tackifiers may find use in synthetic rubber and blends used in products such as tires and rubber belts. TMBP release from the chemical matrix existing in this use appears to be minimized.

In coatings, TMBP resins are blended with drying oils to make varnishes which are resistant to alkalis, water, and sea water, and possess good color stabilization properties. In printing inks, TMBP resoles are used as binders for offset and gravure inks, which are used for the printing of magazines and catalogues.

Nonionic TMBP-surfactants, or TMBP-ethoxylates, are used as detergents, wetting agents, and as emulsifiers for aromatic solvents and pesticides. As detergents, TMBP-ethoxylates are used predominately in industrial and institutional cleaners and to a lesser extent in consumer products. Other uses for TMBP ethoxylates are in textile scouring, oil emulsifiers, and in acrylic polymer emulsions (Refs. 6, 7, and 8).

No data on production trends exists for TMBP but production is known to be substantial (Ref. 6). For instance, production in 1977 was reported to be between 12 and 70 million pounds (Ref. 9) and estimated by industry and the ITC to be 45-55 million pounds in 1978 (Ref. 10). Current (1982) annual production levels are reported to be about 40 million pounds (Ref. 11). Specific end use consumption patterns and market growth rates are not available for this chemical in the literature. However, the Agency believes that demand for TMBP is stable and that substantial market growth is unlikely.

TMBP is produced commercially by a closed system reaction of phenol and diisobutylene at elevated temperatures in the presence of an acid, such as sulfuric acid, or a Lewis acid catalyst (Ref. 11). The main reaction product is a mixture of the ortho and para-isomers which are subsequently separated by distillation (Ref. 12 and 13). Import and export data have not been published for TMBP since 1975 when 30,000 pounds were imported. More recent import volumes are thought to be small as well (Ref. 14).

TMBP-formaldehyde resins are manufactured in closed systems and tightly controlled areas because of the presence of formaldehyde. TMBP is also used as a captive intermediate in the manufacture of TMBP-surfactants. Again, manufacturing operations and equipment are closed to the atmosphere due to the explosibility and known toxicity of phenols, formaldehyde, and ethylene oxide (Ref. 11).

More than 90 percent of the TMBP manufactured is used or processed on-site. When TMBP is shipped outside the production facility, it is shipped in the form of flakes in 50 pound bags or in bulk as molten TMBP in insulated rail tankcars and tanktrucks (Ref. 1).

During the manufacturing process, TMBP is transferred as a molten material in closed systems. The transfer of molten TMBP occurs by automated pumping to storage tanks and, as needed, to the closed kettles or mixing tanks for use as a reactant in manufacturing TMBP-products. When TMBP-flakes are produced, molten TMBP is transferred to an enclosed water-cooled drum flaker which is maintained under negative pressure to minimize dusting. The flakes then enter a controlled dispensing system from which the flakes are packaged. These packaging stations are vented, usually by exhaust snorkels. Worker in these areas are also provided protective equipment, including masks, respirators and complete outerwear clothing for their use (Ref. 11).

The manner in which TMBP is produced and handled leads the Agency to believe the potential for worker exposure and the number of workers exposed to be quite small. From the TSCA section 8(a) Preliminary Assessment Information submitted by the TMBP manufacturers, a total of fewer than 200 employees work in positions where exposure to TMBP may occur. This information also shows that none of the manufacturers is producing the chemical every workday of the year. Potentials for worker exposures to TMBP at the manufacturing facilities will occur intermittently and only as a result of accidental (i.e., spills, etc.) or incidental (i.e., sampling, maintenance, etc.) exposure. No information is available from the National Occupational Hazard Survey on potential exposures to TMBP.

In those areas of the TMBP production in domestic operations which are not self-contained, the potential for exposure to TMBP is more likely. Such operations include filter changing, catalyst bed changing, bulk loading or unloading, reactor sampling, and TMBP flaking and bagging. These activities are shown to generally involve only 1 or 2 workers, are carried out only a few times during the year, and involve only brief periods of potential exposure (Ref. 11).

At least 95-98 percent of all TMBP used in the United States is chemically altered before reaching the consumer market. Except for low residual levels of unreacted TMBP present in surfactants, the remaining 2-5 percent is believed to be physically encapsulated. EPA's concern for exposure to low levels of unreacted TMBP in surfactants had been addressed through several studies of typical TMBP-ethoxylated surfactants containing residual amounts of TMBP

(Refs. 15, 16, 17, 18, 19, 20, and 21). The results of these studies showed that TMBP-containing surfactants produced no significant toxic effects in a 2-year chronic study nor in several subchronic studies, produced no reproductive effects, and caused no genetic damage.

TMBP has been identified in a chemical plant's effluent at 5 ppm and in the Delaware River (Refs. 22 and 23). It was present in water samples taken from the Delaware during the winter months at 1-2 ppb, and in summer samples at approximately 0.2 ppb. The highest concentrations were found around Philadelphia, Pa. The same authors (Ref. 23) traced industrial organic chemicals from their sources into the Delaware River, through various treatment facilities, and into one of Philadelphia's finished drinking water facilities. Various octylphenols, but predominantly TMBP, were identified in the intake water supply of the drinking water treatment plant at 0.4 ppb and in finished drinking water at approximately 0.01 ppb. The Agency concludes, however, that there is no reason to believe these levels of exposure pose a risk to human health given the health effects information described below.

The Agency is aware of two manufacturers which have plant effluents that are expected to enter brackish and salt water habitats. Both plants are located in Texas on the Gulf coast, and are described as having elaborate on-site waste treatment plants. One of these manufacturers found TMBP at 2-34 ppb in its effluent during a 1983 manufacturing period. This range corresponds to a daily discharge of 0.06 to 1.0 pounds of TMBP (Ref. 11). A recent analysis from the other manufacturing plant found 20 ppb TMBP in the effluent. This is equivalent to a yearly discharge of 2,766 pounds of TMBP and a daily discharge of 0.008 pounds of TMBP (Ref. 11)—a negligible amount.

No information was available on the environmental releases of TMBP following land disposal of manufacturing or processing wastes or following the ultimate disposal of industrial or consumer products.

III. Health and Environmental Effects

A. Human Health. No data were available on the absorption, tissue distribution, and metabolism of this compound in any species. Limited information was available on the urinary excretion of TMBP in humans. TMBP was found to be excreted in the urine of workers employed in a Japanese factory manufacturing the chemical. A range of 1.8 to 4.8 $\mu\text{g}/\text{ml}$ was reported

for packers during their work shift; off duty, a range of 0.8 to 3.1 $\mu\text{g}/\text{ml}$ was reported. Inhalation and dermal absorption were suggested as possible routes of entry into the body (Ref. 24). The study authors made no attempt to determine the nature (free or conjugated form) of the excretory product(s).

TMBP was shown to have no effect on conjugation reactions (sulfation and glucuronidation) that occur in rat liver (Ref. 25). *In vitro* studies showed that 4.6×10^{-3} M TMBP medium for 80 minutes inhibited cresolase activity associated with the enzyme tyrosinase obtained from potato rinds (Ref. 26). TMBP inhibited enzyme activity to 61 percent of the control value.

The acute oral toxicity (LD_{50}) of TMBP was approximately 3,210 mg/kg for mice and 4,600 mg/kg for rats (Ref. 27). The authors reported that TMBP caused drowsiness, decreased motor activity of the animals, and death in 2-3 days. The pathological changes observed at death included liver dystrophy, bronchopneumonia, spleen hemorrhages, and changes in brain and kidney blood vessels. In 1972, Marhold (as reported in Ref. 28) reported an oral LD_{50} of 2,160 mg/kg for rats. The dermal LD_{50} (lowest concentration at which death of any animals was observed) for the mouse was 5,280 mg/kg. Testing by one manufacturer reported a dermal LD_{50} of 2 ml/kg (1,880 mg/kg) for rabbits (Ref. 29).

TMBP was considered to be a moderate toxicant (Refs. 25 and 27) and severe skin and eye irritant to rabbits (Ref. 29). Prolonged contact of the compound with the skin produced local burns, irritation, inflammation, edema, and eschar (scab.). Also, the compound quickly produced severe eye irritation, inflammation, suppuration, and persistent turbidity of the cornea in rabbits (Refs. 27 and 29). At 500 mg/24 hour, TMBP caused moderate skin irritation, and at 50 mg/24 hour, it produced severe eye irritation in rabbits (Ref. 28).

TMBP caused depigmentation of the skin and hair in black mice. This effect was noticed as early as 9 weeks from the time the animals received 0.103 mg per animal of either the crude or refined compound daily for 7 months, subcutaneously (Ref. 26). In a parallel set of experiments in mice, these same investigators administered, by gavage, 0.24 mg of TMBP 3 times per week per animal for 6 months. Less pronounced depigmentation was observed in mice dosed orally.

In the first study, depigmentation was seen on the body surface of mice where the compound was injected, indicating a systemic action. No other toxic

parameter was studied in these mice. However, another study (Ref. 30) cited some unpublished data from the Hara Nakajima study, where small quantities of a mixture of 0.5 g TMBP, 5 ml propylene glycol, and 50 g polyethylene glycol were applied to the skin of rabbits daily for 20 weeks. This treatment produced capillaritis, consisting of perivascular cellular infiltration and formation of thrombi.

A few cases of skin depigmentation were observed among the product packers in a Japanese factory producing TMBP along with *p*-tert-butylphenol and *p*-tert-amyphenol (Ref. 24). The workers who developed depigmentation also had high levels of urinary metabolites of these compounds in comparison to plant operators and engineers who had no such symptoms. In another Japanese factory producing TMBP and *p*-tert-butylphenol, 51 cases of leucoderma were reported among workers engaged in the synthetic process during a period of 5 years (Ref. 26). The biopsy of patients' skin revealed the depletion of melanin granules in the epidermis, the presence of vacuolated and edematous cells of capillary walls in cutis, and an increase in perivascular histiocytes. All these histological findings suggest a characteristic capillaritis. Because these workers were exposed to several alkylphenols, including TMBP, it is difficult to ascertain which of these compounds was the causative agent. Several cases of occupational vitiligo were also reported in Japanese workers exposed to resins and detergents containing the compound (Ref. 26). There are no known reports of human health effects specifically attributed to TMBP.

In a subchronic toxicity study (Ref. 31), which was submitted to EPA pursuant to TSCA section 8(d), the authors reported that rats receiving 30, 300, or 3,000 ppm TMBP in their diets for 3 months did not experience any discernible treatment-related effect on the liver or kidney at doses up to 3,000 ppm. Doses of 300 ppm did not influence the thyroid gland, but upon administration of 30 ppm TMBP for 1 month, the thyroxin content in female animals was increased, though slightly. Dosages of 3,000 ppm resulted in clearly higher mean thyroxin concentrations in female animals during the test. The histopathological analysis of the other organs of the animals in the control and the highest dosage group of this study also did not provide an indication for specific organ-damaging effects of TMBP. After receiving 300 ppm, the increase in body weight was slightly reduced, primarily in males (<0

percent). Furthermore, some significant reductions in organ weights for male and female animals receiving the 300 ppm dose, as compared to the control animals, point to an impairment in growth. For rats receiving 3,000 ppm, the weight gain and organ growth was clearly delayed.

In another study (Ref. 20), test rats were maintained for 2 years on diets containing up to 1.4 percent tert-octylphenoxy-polyethoxy ethanol, which is one of several typical surfactants shown to contain residual TMBP levels of 50-300 ppm (Ref. 11). Results of this study showed no effect on survival, growth, organ to body weight ratios for liver, kidney, spleen, heart and testes, and no histological abnormalities. The Agency believes the results of this study, in combination with those of the TMBP subchronic study, are sufficient to reasonably predict the human health risk associated with known exposures to TMBP and, therefore, no subchronic or chronic effects testing is being required at this time.

Little information was in the available literature on tests of TMBP for oncogenicity in any species. However, one study, a two-stage (initiation-promotion) carcinogenic bioassay, showed that TMBP failed to promote carcinomas after tumor initiation by the known carcinogen dimethylbenzanthracene, but TMBP produced papillomas in 11 percent of the 18 surviving test animals (Ref. 32). To initiate tumor formation, these investigators applied 75 µg (25 µl of a 0.3 percent solution in benzene) of dimethylbenzanthracene to the shaved test area on the back of each of 40 female Sutter mice aged 2-3 months. After 1 week, 20 of the animals each received 25 µl of 22 percent TMBP in benzene on the test area twice weekly for 12 weeks. The remaining animals received benzene during this period. TMBP alone, without tumor initiation, was not tested. However, concurrent control groups in other experiments, as reported in this study, showed an incidence of papillomas among surviving mice similar to the TMBP treated mice (i.e., 3 of 22 for 13 percent, 1 of 15 for 7 percent, and 2 of 16 for 13 percent). These control mice were initiated with 5 percent DMBA, but not treated with a solution of TMBP. The Agency concludes that these findings do not indicate an oncogenic potential for TMBP.

No information was found on the testing of TMBP for teratogenic, reproductive effects or neurotoxic effects. Information on the effects of

related compounds on these parameters also is lacking. However, information does not suggest that TMBP may present an unreasonable risk of these effects to human health and, therefore, no further testing is found to be necessary at this time.

A mutagenicity study of *S. typhimurium* histidine auxotrophs using TMBP doses up to 12,500 µg per plate was also submitted to EPA pursuant to TSCA section 3(d) (Ref. 33). In this study, the authors reported that dosages ranging up to 8 µg per plate exhibited no bacteriotoxic effect and the total number of microorganisms per plate remained unchanged. A growth-inhibiting effect could not be established. However, with increased dosages (greater than 8 µg per plate), TMBP exhibited strong bacteriotoxicity both with and without the microsomal S-9 fraction. At 2,500 µg per plate, TMBP precipitated out of the medium, so results at or greater than this concentration are inconclusive. The authors concluded from their study that TMBP exhibited no mutagenic effect, nor was there a dose-dependent doubling or a significant increase in the number of mutants when compared to the negative control. The positive controls employing endoxan, tryptoflavin, and 2-aminoanthrazine were clearly mutagenic. Since TMBP appears to have low toxicity and is negative in this mutagenicity study, the Agency believes there is no basis suggesting that TMBP may present an unreasonable mutagenic risk to humans and therefore no further testing is found to be necessary at this time.

No epidemiological studies were in the available literature specifically concerned with the exposure to TMBP.

B. Environmental. TMBP is toxic to a species of marine shrimp. The static 96-hour LC₅₀ value of the compound tested on shrimp (*Crangon septemspinosa*) was 1.1 mg/l. The lethal threshold for the shrimp was determined to be 1.0 mg/l (Ref. 5). Based on a series of alkylphenols testing on this shrimp and the juvenile Atlantic salmon (*Salmo salar*) fish, these investigators suggested that phenols and alkyl substituents ranging from 6 to 12 carbon atoms are highly toxic to aquatic fauna. Tertiary alkyl substituents appeared to impart less toxicity than did primary or secondary substituents. However, TMBP itself was not tested in fish. The Agency has concluded that further acute and perhaps chronic testing with aquatic organisms is necessary.

The bioconcentration factor was not experimentally determined for the compound, but four closely related

parasubstituted phenols (sec butyl-, hexyl-, nonyl- and dodecylphenol) were tested in 4-day uptake and excretion studies with juvenile Atlantic salmon (*Salmo salar*). Based on the data from these studies and using the log P value for TMBP, McLeese *et al.* developed an equation to predict the bioconcentration factor for TMBP (Ref. 5). A bioconcentration factor of 331 for fish was calculated; this is described as a moderate bioconcentration factor (Ref. 5). Of course, life stage, fat content, and metabolic factors may result in a range of bioconcentration values for various species under actual experimental conditions. However, EPA believes that the estimated bioconcentration factor is sufficient to reasonably predict the bioconcentration potential of TMBP, and that there is no basis for requiring such a determination at this time.

TMBP inhibited spore germination (sporostatic action) and its outgrowth in the bacterium *Bacillus megaterium*. At concentrations of 3.2 and 10.0 µg/ml of the nutrient medium, the compound caused 50 percent inhibition of spore germination for 2 and 24 hours, respectively. Approximately 99 percent sporostasis was caused at concentrations of 32 and 100 µg/ml (ppm) for periods of 2 and 24 hours, respectively. At 100 µg/ml, TMBP prevented any outgrowth of bacterial spores for 24 hours (Ref. 4). The sporostatic effect was reversible; washing away the compound restored the ability to germinate in the nutrient broth. It was suggested by the authors that this compound blocks the inherent triggering process of the bacterial spores to germinate.

No information was found on the effects of TMBP on terrestrial plants.

IV. Negotiated Testing Program

The Octylphenol Program Panel (the Panel) and the Agency began discussions in February, 1983, regarding testing needs for TMBP. The panel consisted of a representative of each of the major domestic TMBP manufacturers and is organized under the auspices of the Chemical Manufacturers Association. Subsequent to the initial discussions, the Panel submitted protocols (Ref. 34) for an initial minimum set of aquatic toxicity tests. These test protocols included flow-through acute toxicity testing for four freshwater species: *Daphnia magna*, *Lepomis microchirus* (bluegill sunfish), *Salmo gairdneri* (rainbow trout), and *Scenedesmus obliquus* (a green alga).

The protocols for these studies have been reviewed by EPA and are believed

to be a reasonable approach to characterizing the aquatic toxicity of TMBP. The Agency also believes that these studies on freshwater plants and animals could be used to reasonably determine the need to test TMBP's toxicity on marine plants and animals in the future should significant releases of TMBP to the marine environment occur. The Agency and the Panel agree that results for these acute toxicity studies for TMBP will be utilized in determining the need to initiate chronic toxicity studies. The basis for requiring chronic toxicity testing, and to which the Octylphenol Program Panel agreed, will depend on EPA's interpretation of the dose-response curve for each study, the observational recordings of the test organism's activities during dosing in each study, and the 96-hour LC_{50} determined in each aquatic toxicity study. EPA believes that 96-hour LC_{50} 's below 1ppm are of special concern and would most likely trigger chronic toxicity testing. LC_{50} 's greater than 1 ppm, however, may require a more in-depth analysis of the data. If the Agency finds that chronic effects testing is needed in one or all of the acute toxicity test species, the Panel will initiate testing in accordance with EPA's aquatic testing guidelines.

The documentation supporting this agreement and the testing protocols are available for examination in the public record for this proceeding. Testing will be initiated within 3 months after EPA announces final acceptance of the test program. The Panel anticipated having final reports available for Agency review on the acute tests within 4 months after initiation of testing. Representatives of the Panel will then be prepared to meet with EPA to discuss the significance of the test results and the need for further aquatic testing. The Panel will file periodic reports with EPA to keep the Agency informed of the status of the testing program.

The Octylphenol Program Panel has furnished EPA with the name and address of the laboratory that would conduct these tests. The Panel has stated that it will adhere to the Good Laboratory Practice Standards (GLP's) issued by the U.S. Food and Drug Administration, as published in the Federal Register of December 22, 1978 [43 FR 69369]. The Panel also has agreed to laboratory audits/inspections in accordance with the authority and procedures outlined in TSCA section 11 at the request of authorized representatives of the EPA. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are

being met, that reports accurately reflect the underlying raw data and interpretations and evaluations thereof, and that the studies are being conducted according to Good Laboratory Practices.

The Panel has further committed that all raw data, documentation, records, protocols, specimens, and reports generated as a result of each study will be retained for at least 10 years from the date of publication of the acceptance of a negotiated testing agreement. In addition, correspondence and other documents relating to the interpretation and evaluation of data shall also be retained.

The Agency plans to issue in the Federal Register a notice of the receipt of all test data submitted by industry under this test program. Subject to TSCA section 14, the notice will provide information similar to that described in TSCA section 4(d). Except as otherwise provided in TSCA section 14, any data submitted will be made available by EPA for examination by any person.

Should industry fail to conduct the testing according to the specified protocols or fail to follow Good Laboratory Practices, such actions may invalidate the tests. In such cases, a data gap may still exist, and the Agency may decide to promulgate a test rule or otherwise require further testing.

V. Decision Not To Initiate Rulemaking

When combined with existing data on TMBP, TMBP-based surfactants and other alkyl phenols, EPA believes the industry's proposed testing program will provide adequate basis to evaluate the effects of concern to the ITC. Therefore, EPA is not initiating rulemaking under section 4(a) of TSCA to require testing of TMBP at this time. EPA's specific responses to the ITC's recommendations are set forth below.

A. Health Effects

1. *Short-term tests.* Under the TSCA section 8(d) reporting rule for health and safety data, the Agency has received studies on TMBP which addresses the health effects testing recommendation of the ITC i.e., short-term tests including mutagenicity. Although the Agency believes that an Ames test alone normally does not provide sufficient data to adequately characterize the mutagenic potential of a chemical, EPA cannot conclude from the available information that there is reason to believe TMBP is mutagenic. Therefore, because EPA does not find that there is substantial exposure to TMBP and because there is no basis to believe TMBP may present an unreasonable risk of mutagenicity, EPA is not requiring further mutagenicity testing of TMBP.

2. *Subchronic effects.* Although not specifically recommended by the ITC, EPA believed that a well-conducted subchronic test would provide information on leucoderma which was noted in the ITC report, and other chronic toxic effects which might occur as a result of repeated occupational exposure to TMBP. EPA received a subchronic study (Ref. 31) from Mobay Chemical Corporation in response to the section 8(d) rule. This study, as noted in Unit III above, showed that TMBP exhibited low toxicity over a 90-day exposure period. EPA believes that there is no basis to believe that TMBP may present an unreasonable risk of any significant toxic effect and, therefore, no further testing is required.

B. Environmental Effects

EPA believes that the results of the environmental effects testing negotiated with the Octylphenol Program Panel are likely to provide sufficient data to reasonably predict the acute toxicity of TMBP to aquatic plants and animals, and serve as a basis for determining the need for continued aquatic toxicity testing of this chemical. Furthermore, the Agency and the Panel agree that any additional testing should not be initiated until EPA has had a chance to fully evaluate data from the testing being proposed and discuss with the Panel any additional testing needs.

Little information was available on the transport properties of TMBP. However, TMBP is expected to exhibit the properties of a lipophilic phenol: it has an experimentally determined log P (octanol/water) value of 3.7 (Ref. 5), and both its water solubility and its vapor pressure are low. Thus, the chemical would likely bind to organic materials in soils and potentially bioconcentrate in fat tissues of aquatic and terrestrial animals.

No information was available on the volatility of TMBP from water. Because experimentally derived data were not available on the vapor pressure of TMBP at 20°-25°C, a half-life for evaporation from water cannot be estimated; but, due to the low calculated vapor pressure, the compound would not be expected to evaporate rapidly. No detectable amount of the pure compound was reported to volatilize into the air (Ref. 1). No data were found in the available literature on the soil adsorption of TMBP, but the soil organic matter/water partition coefficient of the compound was calculated based on the log P value of 3.7. From these calculations, the compound may be expected to bind to soils when in the environment (Ref. 35).

The Agency can reasonably predict the chemical fate, including biodegradation, of TMBP. The ITC cited environmental concentration of 5 ppm for TMBP (Ref. 23). It recommended chemical fate testing based on its inability to predict the fate of TMBP at this high concentration. However, this concentration was reported for wastewater not a river. The actual river concentration, i.e., 1-2 ppb, of TMBP was 2,500-5,000 times lower than that reported by the ITC. The Agency believes that TMBP may be susceptible to biodegradation and other chemical fate processes based on a demonstration that there was a 50 percent reduction in total octylphenol concentrations i.e., from 400 to 200 ppm, between wastewater treatment influent and effluent levels (Ref. 23). Therefore, the Agency believes that chemical fate testing of TMBP should not be required at this time.

VI. References

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VII. Public Record

The EPA has established a public record for this testing decision [Docket Number OPTS-42042]. This record includes:

(1) Federal Register notice containing the designation of TMBP to the priority list and all comments on TMBP received in response to that notice.

(2) Communications with industry.

(3) Letters.

(4) Contact reports of telephone conversations.

(5) Meeting summaries of agency industry and agency-public meetings.

(6) Testing proposal.

(7) Published and unpublished data.

This record contains the basic information considered by the Agency in developing the decision given in this publication. The Agency will supplement this record periodically with additional relevant information received.

(Sec. 4, 90 Stat. 2003 (15 U.S.C. 2061))

Dated: November 3, 1983.
 William D. Ruckelshaus,
Administrator.
 [FR Doc. 83-30720 Filed 11-14-83; 8:45 am]
 BILLING CODE 6560-50-M

DEPARTMENT OF ENERGY

Office of Hearings and Appeals

Objections to Proposed Remedial Orders Filed; Period of September 26 Through October 14, 1983

During the period of September 26 through October 14, 1983, the notices of objection to proposed remedial orders listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Any person who wishes to participate in the proceeding the Department of Energy will conduct concerning the proposed remedial orders described in the Appendix to this Notice must file a request to participate pursuant to 10 CFR 205.194 within 20 days after publication of this Notice. The Office of Hearings and Appeals will then determine those persons who may participate on an active basis in the proceeding and will prepare an official service list, which it will mail to all persons who filed requests to participate. Persons may also be placed on the official service list as non-participants for good cause shown.

All requests to participate in these proceedings should be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20585.

George B. Breznay,
Director, Office of Hearings and Appeals.
 November 7, 1983.

Pester Corporation, Des Moines, Iowa, HRO-0195, Motor Gasoline

On October 11, 1983, Pester Corporation, 303 Keosauqua Way, P.O. Box 10006, Des Moines, Iowa, filed a Notice of Objection to a Proposed Remedial Order which the DOE Kansas City (Missouri) Office of Enforcement issued to the firm on August 30, 1983. In the PRO, the Kansas City Office of Enforcement found that during the period January 1, 1977, through January 31, 1980, Pester Corporation charged prices in excess of maximum lawful selling prices in its sales of motor gasoline. According to the PRO, the Pester Corporation violation resulted in \$1,483,074 of overcharges.

Southwestern Gulf Petroleum Co., Houston, Texas, HRO-0194, Crude Oil

On October 11, 1983, Southwestern Gulf Petroleum Co., 13101 Northwest Freeway, Suite 320, Houston, Texas 77040, and the Attorney General for the State of Texas, P.O. Box 12548, Capital Station, Austin, Texas 78711, filed Notices of Objection to a Proposed Remedial Order which the DOE Houston, Texas Office of Enforcement issued

to the firm on September 1, 1983. In the PRO the Houston, Texas Office found that during April to December 1980, Southwestern Gulf Petroleum violated 10 CFR 212.183, 212.186, 210.82 and 205.202 in its sales of crude oil. According to the PRO the Southwestern Gulf Petroleum Company's violation resulted in \$12,878,118.76 of overcharges.

[FR Doc. 83-30781 Filed 11-14-83; 8:45 am]
 BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[WH-FRI-2469-6]

National Drinking Water Advisory Council; Open Meeting

Under Section 10(a)(2) of Pub. L. 92-423, "The Federal Advisory Committee Act," notice is hereby given that a meeting of the National Drinking Water Advisory Council established under the Safe Drinking Water Act, as amended (42 U.S.C. §300f *et seq.*), will be held at 9:00 a.m. on December 1, 1983, and at 8:30 a.m. on December 2, 1983; at the Langford Resort Hotel, Treetop Room, 300 East New England Avenue, Winter Park, Florida 32789. Council subcommittees will be meeting at the Hotel on November 30, 1983.

The purpose of the meeting will be to review the Advance Notice of Proposed Rulemaking on the revised regulations, a review of the Council's position on the fluoride standard in view of a second report from the Surgeon General (if received), and EPA updates on the reauthorization of the Safe Drinking Water Act, development of a ground water policy, and Federal implementation of the Underground Injection Control program in twenty-three States.

This meeting will be open to the public. The Council encourages the hearing of public statements and will allocate a portion of its meeting time for public participation. Oral statements will be limited to 5 minutes. It is preferred that there be one presenter for each statement. Any outside parties interested in presenting an oral statement should petition the Council by telephone at (202) 382-5533. The petition should include the topic of the proposed statement, the petitioner's telephone number, and should be received by the Council before November 23, 1983.

Any person who wishes to file a written statement can do so before or after a Council meeting. Accepted written statements will be recognized at the Council meeting and will be part of the permanent meeting record.

Any member of the public wishing to attend the Council meeting, present an oral statement, or submit a written

statement, should contact Ms. Charlene Shaw, Executive Assistant, National Drinking Water Advisory Council, Office of Drinking Water (WH-550), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460.

The telephone number is: Area Code 202/382-5533.

Dated: November 4, 1983.

Rebecca W. Hanmer,
Acting Assistant Administrator for Water.

[FR Doc. 83-30723 Filed 11-14-83; 8:45 am]
 BILLING CODE 6560-50-M

[SAB-FRL-2469-5]

Science Advisory Board; Closed Meeting

Under Pub. L. 92-463, notice is hereby given that a meeting of an ad-hoc Subcommittee on the Science Advisory Board will be held in Denver, Colorado on December 1, 1983 to determine the recipients of the Agency's 1983 Scientific and Technological Achievement Cash Awards. These awards are established to give honor and recognition to EPA employees who have made outstanding contributions in the advancement of science and technology through their research and development activities, and who have published their results in peer reviewed journals.

Pursuant to section 10(d) of the U.S.C. Appendix 1 and 5 U.S.C. 522(c), I hereby determine that this meeting is concerned with information exempt from disclosure, and that the public interest requires that this meeting be closed.

In selecting the recipients for the awards, and in determining the actual cash amount of each award, the Agency requires full and frank advice from the Science Advisory Board. This advice will involve professional judgments on those employees whose published research results are deserving of a cash award as well as those that are not. In addition, the Board will advise on the amount of money to be allocated for each award. Discussions of such a personal nature, where disclosure would constitute an unwarranted invasion of personal privacy, are exempted under Section 10(d) of Title 5, U.S. Code, Appendix 1. In accordance with the provisions of the Federal Advisory Committee Act, minutes of the meeting will be kept for Agency and Congressional review.

The Science Advisory Board shall be responsible for maintaining records of the meeting, and for providing an annual report setting forth a summary of the meeting consistent with the policy of U.S.C. Appendix 1, section 10(d).