federal register

[OPTS-42066; FRL-2810-8]

Isopropyl Biphenyl/Diisopropyl Biphenyl 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 EPA consider requiring chemical fate, health effects and ecological effects testing of isopropyl biphenyl (CAS No. 25640-78-2) and diisopropyl biphenyl (CAS No. 69009-90-1) under section 4(a) of the Toxic Substances Control Act (TSCA). EPA is not at this time initiating rulemaking under section 4(a) to require chemical fate, health effects or ecological effects testing of isopropyl biphenyl or diisopropyl biphenyl. EPA believes that there is no significant release of isopropyl biphenyl or diisopropyl biphenyl to the aquatic environment. Based on the limited exposure to these chemicals during manufacture, production, and use, isopropyl biphenyl and diisopropyl biphenyl are not expected to cause substantial or significant human exposure or present an unreasonable risk of injury to human health or the environment.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M Street SW., Washington D.C. 20460, Toll free: (800-424-9065), In Washington,

D.C.: (554-1404), Outside the USA: (Operator-202-554-1404).

PLEMENTARY INFORMATION: EPA is ot initiating rulemaking at this time under section 4(a) of TSCA to require health effects testing, ecological effects testing or chemical fate testing of isopropyl biphenyl or diisopropyl biphenyl 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.*) establishes 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 Isopropyl Biphenyl (IPBP) (CAS No. 25640-78-2) and Diisopropyl Biphenyl (DPBP) (CAS No. 69009-90-1) for priority testing consideration in its Fourteenth Report, published in the **Federal Register** on May 29, 1984 (49 FR 22389) (Ref. 1). this notice constitutes EPA's response to the ITC's designation of IPBP and DPBP.

The ITC recommended that IPBP and DPBP be tested for chronic health effects, with emphasis on neurotoxic and kidney effects; ecological effects, cluding acute and chronic toxicity to h, aquatic invertebrates and algae and oconcentration: and chemical fate, to include water solubility, octanol/water partition coefficient, persistence and soil mobility.

The ITC based its health effects testing recommendation on the potential for dermal exposure through the use of IPBP and DPBP in carbonless copy paper, and potential human exposure from the consumption of contaminated fish, and potential drinking water contamination from landfill leachate. Studies referencing adverse health effects in office workers when they were exposed to carbonless copy paper, adverse effects in laboratory animals and a lack of chronic toxicity data were offered as rationale for the ITC recommendations for chronic toxicity testing with emphasis on neurotoxic and kidney effects.

The ecological effects testing recommendation from the ITC was based on the detection of IPBP in the aquatic environment and on a study which suggests that IPBP is toxic to fish at concentrations less than 1.0 mg/L. Inconsistencies in this study with respect to solubility limits and a lack of ata on the effects of IPBP and DPBP on uatic invertebrates, algae, and oconcentration potential served as additional rationale for the recommended ecological effects testing.

The ITC recommended chemical fate testing to determine the potential for transport and persistence of IPBP and DPBP within the aquatic environment.

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 insufficient 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 making a section 4(a)(1)(A)(i) finding in which both exposure and toxicity information are considered to make the 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 sections 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 concerning IPBP and DPBP, 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 under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); and published and unpublished data available to the Agency, including information submitted under the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716).

III. Review of Available Data

A. Exposure and Release

1. *Background.* Two companies currently manufacture IPBP and DPBP: they are Sybron Chemical Company, Wellford, South Carolina (Refs. 2 and 3) and Koch Chemical Company, Corpus Christi, Texas (Ref. 2). Commercial IPBP is a mixture of isomers of IPBP and varying amounts of DPBP isomers. DPBP is a by-product of IPBP and is not isolated for sale as a separate commercial product (Refs. 4 and 5). Hereafter in this notice the commercial IPBP products containing DPBP as a byproduct will be referred to as IPBP/DPBP. Because DPBP is not separated from the commercially produced IPBP, EPA has focused its testing assessment on IPBP/DPBP rather than on the individual homologues IPBP and DPBP or their various isomers. Koch Chemical Company produces IPBP/DPBP under the tradename Sure Sol ®-250, a mixture containing a minimum of 94 percent IPBP (Ref. 6). Sybron Chemical Company produces three different grades of commercial IPBP/DPBP under the tradenames PG, MPG, and CG (Ref. 4). PG and MPG contain approximately 75 percent IPBP; CG contains, at a minimum, 94 percent IPBP. Combined production by these two firms is

between 2 and 8 million pounds annually (Ref. 7).

The principal uses of IPBP/DPBP are as a dielectric fluid in high-power capacitors and as a solvent for use in carbonless copy paper. Westinghouse Corporation uses Koch Chemical Company's Sure Sol ®-250 in its capacitor-impregnating fluid which it calls Wemcol ™ (Ref. 6). Mead Corporation, the sole user of IPBP/DPBP as a dye solvent for carbonless copy paper, purchases the chemical in tank trucks and dilutes it 15 percent with deodorized kerosene for viscosity control. Colorless dyes are then dissolved in the solution, which is then microencapsulated in modified polyurethane cells. The cells are then mixed with wax in a wiped-film evaporator that drives off water. The hot melt wax product contains 20 to 25 percent capsules and 70 to 75 percent wax. The final product is a wax-flake material which is placed in plastic bags and boxed for shipment. The wax flake material is applied to the paper by common paper coating processes (Ref. 8).

2. *Occupational exposure.* IPBP/DPBP is produced within a closed system. Sybron Chemical Company reported that approximately six to eight workers are exposed to IPBP/DPBP each day, 5 days per week (Ref. 9). The final product is packaged and shipped in tank wagons or drums. Koch Chemical Company (Ref. 10) reported that approximately 20 workers are involved in the manufacture of Sure Sol ®-250. The product is manufactured periodically throughout the year. While in production status the material is produced 24 hours per day, 7 days per week, in four shifts. However, Sure Sol ®-250 was produced for only 2 to 3 months in 1983 (Ref. 11).

During the processing of IPBP/DPBP for use as a dielectric fluid, 18–24 workers may be exposed (Refs. 12 through 14). The IPBP/DPBP is unloaded, stored, and placed in the capacitors within a closed system.

An estimated six operators (Ref. 8) are exposed to IPBP/DPBP during the wax-flake processing procedure required for its use on carbonless copy paper. Exposure to workers during the coating, slitting, collating, and packaging of carbonless copy paper is minimal because it is economically advantageous for the manufacturers to maintain the integrity of the carbonless copy paper and not release the mixture contained within the polyurethane cells.

3. *General population exposure.* Exposure to IPBP/DPBP through its use and disposal as a dielectric fluid is discussed in Unit II.A.4.C.

Exposure to IPBP/DPBP through its use in carbonless copy paper is estimated to be minimal. The amount of IPBP/DPBP contained on one side of an 8½ x 11 inch sheet of carbonless copy paper is roughly estimated based on the following: Mead recommends applying 1.2 to 1.8 pounds (lbs.) wax per ream of paper (Ref. 15). Thus, the average application is 1.5 lb. wax per 20 lb. ream of 500 (17x22 inch) sheets. One pound of wax contains 25 percent capsules; a capsule consists of microencapsulated cells containing about 13 percent dye and 85 percent solvent. The dye solvent is 85 percent commercial IPBP/DPBP and 15 percent kerosene. On this basis, the amount of IPBP/DPBP per side of an 8½ x 11 inch sheet of carbonless copy paper is estimated to be 31.5 milligrams of IPBP/DPBP per side of an 8½ x 11 inch sheet of the carbonless copy paper. The use of carbonless copy paper causes the polyurethane capsules to break; the chemicals evolve slowly and tend to stick with the paper and dusts (Ref. 21). Therefore, based on the estimated concentration of IPBP/DPBP per sheet of paper and the fact that the IPBP/DPBP is encapsulated on the back portion of the paper, dermal exposure is estimated to be limited.

4. *Environmental Release.* Release may occur through the production, processing, use and disposal of IPBP/DPBP.

a. *Production.* Koch Chemical Corporation (Ref. 11) manufacturing wastes containing IPBP/DPBP are limited to rinsewaters produced when the manufacturing process tanks are switched from Sure Sol®-250 to a different product. The rinsewater is combined with all aqueous wastes generated in the plant. The aqueous wastewater is treated in an on-site system which treats 1 million gallons per day via primary and secondary processes. Primary treatment consists of oil/water separation. Oils are recycled to a cooking unit, sludges are landfarmed, and the effluent is treated in an activated sludge system. The effluent from the activated sludge system is discharged to Corpus Christi Bay under permits from both the EPA and the Texas Department of Water.

Sludges produced during primary treatment are treated on an on-site landfarm. The sludges originate from the primary treatment processes as well as other sources. The landfarm is equipped with monitoring wells and is treated as a hazardous waste area.

Sybron Chemical Company (Ref. 9) reported that their scrubber effluent is treated in an on-site biological system which treats 35,000 gallons per day via secondary processes. Their facility consists of a series of aerated lagoons with holding times of 60 to 90 days. The waste water is pumped from these lagoons through a trickling filter and placed in aerated lagoons. Sybron's effluent is discharged into a stream under permits from the state of South Carolina (Ref. 16).

Material safety data sheets for both manufacturers recommend that, in the event of a spill, the material be absorbed in solid medium and subsequently incinerated or buried in a landfill (Refs. 17 and 4).

b. *Processing.* During the processing of IPBP/DPBP for use as a dielectric fluid in capacitors, the IPBP/DPBP is unloaded, stored and placed into the capacitors within a closed system. Releases are expected to be minimal and are limited to accidental spills. In case of spills, the area is cleaned with absorbents which are placed into drums or barrels and disposed of in landfills (Refs. 14, 13 and 12).

In the manufacture of hot melt wax for carbonless copy paper at Mead Corporation, the process of incorporating the raw IPBP/DPBP into the polyurethane cells is conducted within a closed system (Ref. 18), thereby allowing for minimal release.

Release of IPBP/DPBP to the environment from paper mills that handle recycled carbonless copy paper appears to be limited. The American Paper Institute (Ref. 19) reported that 290 of 304 reporting paper mills are believed to qualify as secondary fiber mills (Table 1). However, only a limited number of these facilities accept carbonless copy paper. Only 85 of the 290 mills are listed as direct dischargers. Of these 85 (Table 2), 52 employ some form of secondary treatment, 15 had primary treatment, 7 had no external treatment, and 11 were unknown with respect to treatment. For those mills reported as sending their waste to Publicly Owned Waste Treatment Facilities (POTWs) it was determined through the 1982 Needs Survey (Ref. 20) that of the 15,425 POTWs listed in the United States 52 percent employ secondary treatment, 16.3 percent employ advanced secondary treatment and 1.4 percent employ tertiary treatment. Therefore, 69.7 percent of all POTWs employ secondary treatment at a minimum. If 155 recycling mills are listed as indirect dischargers, and 69.7 percent of the POTWs in the U.S. have secondary treatment at a minimum, then 108 of the indirect dischargers and 52 of the direct dischargers employ some form of secondary treatment, with 48 mills being self-contained (no effluent discharge).

TABLE 1.—METHOD OF DISCHARGE AMONG MILLS USING WASTEPAPER AS THE PRINCIPAL FIBER SOURCE

	Total mills	Direct disch.	Indirect disch.	Self-contained	Irrigation	Unknown
Deink Fine and Tissue	20	13	5	2		
Deink Newsprint	6	2	3			1
Deink Market Pulp	5	1	3			1
Wastepaper-Tissue	24	11	4	8		1
Wastepaper-Board	163	51	90	18	1	3
Wastepaper-Molded Products	20	2	13	2		3
Wastepaper-Construction Prod.	66	5	37	18	1	5
Totals	[1] 304	85	155	48	2	14

[1] Only 290 mills qualify as secondary fibermills. (Ref. (19))

TABLE 2.—CONTROL TECHNOLOGY EMPLOYED BY DIRECT DISCHARGE SECONDARY FIBER MILLS

	Unknown	No external treatment	Primary treatment only	Secondary treatment		Unspecified or other configuration
				Activated sludge	Aerated stabilization basin	
Deink Fine and Tissue		1	1	8	3	
Deink Newsprint				1	1	
Deink Market Pulp						[1] 1
Wastepaper-Tissue	2	2	4	1	2	
Wastepaper-Board	9	3	8	6	21	4
Wastepaper-Molded Products			1		1	
Wastepaper-Construction Prod.		1	1			3
Totals	11	7	15	16	28	8

[1] System expected to come online in early 1985. (Ref. (19))

c. *Use and Disposal.* The use of IPBP products, carbonless copy paper and electric fluid, do not result in a significant release of IPBP/DPBP to the environment. The use of carbonless copy paper causes the polyurethane capsules to break, the chemicals are released slowly and tend to stick with the paper and dusts (Ref. 21). Accidental leakage from electrical capacitors damaged during use or ruptured upon failure are potential sources of IPBP release to the environment. Because IPBP is more flammable than are PCBs, capacitor manufacturers have taken precautions to protect against rupture (Ref. 22).

Disposal of carbonless copy paper is via recycling facilities or sanitary landfills. At present, the disposal of capacitors is extremely limited. IPBP/DPBP is used as a dielectric fluid in capacitors as a replacement for PCBs. The switch did not occur until the late 1970's. The average life span of a large high voltage capacitor is 20 years, the average life of a small appliance capacitor is 15 years (Ref. 22). Therefore, most of the capacitors produced with IPBP as the dielectric fluid are still in service. At present, waste disposal firms would treat IPBP/DPBP capacitors as they do transformers containing PCBs. Liquids would be incinerated, and solids would be placed in secure landfills (Ref. 23).

The placement of IPBP/DPBP-containing products in sanitary or secure landfills would result in IPBP/DPBP partitioning to soil and sediment where it would biodegrade. Based on this biodegradation potential, groundwater contamination through landfill leachates is extremely unlikely (see Unit II.B.).

B. Chemical Fate

IPBP has a low vapor pressure, a high boiling point, a low estimated water solubility and a high octanol/water partition coefficient (Table 3). DPBP has a low vapor pressure, a high boiling point, a low estimated water solubility, and a high octanol/water partition coefficient (Table 3).

TABLE 3.—PHYSICAL AND CHEMICAL PROPERTIES

Data	IPBP	DPBP
Vapor pressure	5.73×10^{-3} mm Hg at 25 °C (est) [a].	6.85×10^{-4} mm Hg at 25 °C (est).[a]
Boiling point	o—IPBP 270 °C [b], p—IPBP 291 °C[c]	4,4' DPBP 335 °C.[d]
Water solubility	0.10 mg/l [a]	4.3×10^{-4} mg/l (est).[c]
Octanol/water	Log P=5.5 [a]	Log P=7.3. [a]

[a] (Ref. 24).
[b] (Ref. 25).
[c] (Ref. 26).
[d] (Ref. 27).

These properties indicate that, under equilibrium conditions, IPBP and DPBP will tend to partition to the soil and sediment where they will bind strongly to the organic matter present. The low water solubility and the low vapor pressure and high boiling point of IPBP and DPBP will tend to retard their entry into the water and air, respectively.

Addison *et al.* (Ref. 28) modeled the equilibrium distribution of IPBP in the environment using the environmental partitioning model developed by Mackay (Ref. 29) and Mackay and Paterson (Ref. 30). The model coverts physical property data to fugacity capacities and then uses these capacities to calculate the partitioning behavior of a chemical in the air, water soil, sediment, suspended aquatic matter, and aquatic biota. The model does not consider any dynamic factors such as rate of degradation of the compound in any compartment. The Mackay model predicts that IPBP will partition primarily to soil and sediment.

The soil adsorption coefficient (Koc) of IPBP was calculated by the method of Kenage and Goring (Ref. 31) to be 23,500. Compounds having a Koc value greater than 1,000 are expected to be tightly bound to organic matter in soil and are considered immobile (Ref. 32). The lower vapor pressure and higher estimated log P of DPBP relative to IPBP indicate that it will partition even more strongly to the soil and sediment than IPBP.

Studies have shown IPBP to be biodegradable. In one river die-away study (Ref. 33) IPBP was added to two sets of Delaware River water samples: one contained only the indigenous river microflora, and the other received an additional inoculum prepared from soil. The IPBP was biodegraded 80 percent within 48 hours, with the biodegradation rate being slightly higher for the sample enriched with the soil inoculum. Biodegradation tests performed with sewer sludge have shown that 60 percent of IPBP biodegrades in 24 hours and 100 percent in less than 1 week (Ref. 34).

Based on the physical and chemical properties of IPBP/DPBP, and the modeling study by Mackay, IPBP/DPBP is expected to partition primarily to soil and sediment where it will rapidly biodegrade. The results of the river die-away study show that the fraction of IPBP/DPBP that is discharged to water is also expected to rapidly biodegrade. Releases to the environment from the production and processing of IPBP/DPBP are expected to be minimal. Secondary waste treatment facilities will be sufficient to reduce the concentrations of IPBP/DPBP discharged to receiving waters to negligible levels. Because closed systems are employed and because of the low vapor pressure of IPBP/DPBP, EPA expects that atmospheric releases and occupational exposures will be minimal.

c. Environmental Effects

1. *Acute toxicity.* The aquatic toxicity for Wemcol®, a commercial dielectric fluid containing approximately 98 percent IPBP and approximately 1 percent DPBP, was studied in fish by Ozburn *et al.* (Ref. 35). In a 96-hour flow-through assay with flagfish (*Jordanella floridae*) the LC_{50} in adults was >0.75 mg/L. The LC_{50} in fry was 0.28 mg/L. Ozburn also studied the reproductive effects. It was determined that the thresholds for spawning impairment, hatching impairment, and fry survival were >0.42 mg/L, >0.47 mg/L, and 0.43 mg/L, respectively. The bioconcentration in flagfish for Wemcol® was 2,896 at 3.5 µg/L for 28 days and 10,790 at 2.41 µg/L, with half-life depuration periods of 2.88 and 1.61 days, respectively.

2. *Environmental concentrations.* The Wisconsin Department of Natural Resources (Ref. 36) in surveying their lakes and stream fishes tentatively detected IPBP in four of their survey sites and DPBP in two of their sites. Upon review of the study it was noted that gas chromatographic/mass spectral (GC/MS) interpretation techniques were the mode of analysis. IPBP was tentatively detected in three of the four sites. Detection at the fourth site was at the detection limit of the instrument. DPBP was tentatively detected at one site and at the other site at the detection limit of the instrument. No quantitative levels for the respective compounds were given. Peterman in his master's thesis (Ref. 37) tentatively detected IPBP and DPBP in fish from the Fox River in Wisconsin, downstream from a recycling paper mill. However, according to Peterman (Ref. 38) recent fish monitoring studies of the Fox River downstream of the paper mill by the State of Wisconsin have not detected any IPBP/DPBP.

D. Health Effects

1. *Acute Toxicity.* IPBP/DPBP has a low acute toxicity with a reported LD_{50} in a 14-day oral rat study of 4.7 g/kg (Refs. 39 and 40). IPBP/DPBP was not judged to be an eye irritant (Refs. 41 and 42) as normal eye appearance was rated in rabbits 72 hours after a 24-hour dosing period. An acute dermal toxicity was determined in rabbits (Ref. 43) with an LD_{50} >6,000 mg/kg of body weight. Dermal irritation was present but transient, with the skin returning to normal within 5 days. IPBP/DPBP was judged (Refs. 6, 44, and 45) to be a mild to moderate irritant on intact and abraded skin.

Several acute inhalation studies have been reported for IPDP/DPBP. A 1977 study submitted by Mead Corporation exposed a group of 10 rats to an aerosol concentration of 1.67 mg/L (exceeded concentration level) for 1 hour (Ref. 46). No adverse effects were observed. The LC_{50} was determined to be >1.67 mg/L. A 1975 study for Sun Oil (Ref. 47) exposed 10 rats to a reported atmospheric concentration of 20.8 mg/L for 1 hour at 18–20 °C. No deaths occurred. Grooming and slight depression were observed during and immediately following exposure. Animals returned to normal within 1 hour following termination of exposure. Necropsy revealed no gross anomalies. A 1974 study by Scientific Associates (Ref. 48) conducted for the Mead Corporation, exposed 10 albino rats to an ambient chamber concentration of approximately 4 mg/L at a flow rate of 7 liters per minute. The animals were exposed for a period of 1 hour plus an 8-minute equilibration period; a 14-day observation period followed. All animals survived the initial exposure period. Two mortalities were noted in the latter part of the observation period. The authors noted that at this concentration (4 mg/L) they were unable to observe the animals due to the heaviness of the mist. This corroborates the pathology findings for the remaining animals of moderate to severe lung congestion. It was noted that all other tissues were not remarkable. A 1959 (Haley *et al.*) study exposed 12 rats to 15.85 g/m³, (15.85 mg/L) for 1 hour (Ref. 44). They reported 12 out of 12 animals died by the third day. When exposed to 3.87 g/m³ (3.87 mg/L) for 1 hour 5 out of 8 animals died by day 14. At 0.99 g/m³ for 1 hour no deaths occurred at day 14. This study does suggest a higher toxicity than indicated by the previous data, however, although not cited, it is thought that the data were obtained at temperatures higher than 20 °C as the authors noted that they ran hot-air controls. The elevated temperatures could have altered some of the exposure patterns used in this study. The Sun Oil Study (Ref. 47) appears inconsistent with the other studies with respect to the extreme level of the reported exposure concentration (20.8 mg/L) and the lack of any deaths. It appears that the exposure concentration for this study may have been reported incorrectly.

2. *Metabolism.* IPBP was studied for its potential use as an anti-inflammatory agent (Refs. 49 and 50). These characterization studies by Sullivan *et al.*, conducted in accordance with standard toxicology guidelines (Ref. 51) and submitted to the Food and Drug Administration, showed that two distinct metabolic pathways were involved in the biotransformation of IPBP in laboratory animals and in man. In the rat, the metabolite atrolactic (AA) acid must be hydroxylated to be excreted, which in turn produces methyl glycolic acid (MGA). When MGA accumulates, it precipitates in the kidney tubules producing nephrotoxicity in the rat. The dog, unlike the rat, is capable of directly eliminating the atroloactic acid; therefore, no development of nephrotoxicity occurs. In the monkey, the failure to detect the atrolactic acid metabolite indicated that the monkey was also capable of elminating the metabolite, resulting in no development of nephrotoxicity. Human studies showed the subjects did not require conversion of the metabolite to atrolactic acid for elimination, therefore no nephrotoxicity would result.

The Agency believes that, based on the results of the metabolism study showing nephrotoxicity to be species-sensitive for the rat, further chronic testing for nephrotoxicity is unnecessary.

Oral and gastrointestinal absorption is nearly complete (Ref. 49). Tulp *et al.* (Ref. 52) studied the retention of Wemcol® in the abdominal fat of rats using a single oral 12.5 mg dose. After one week, no IPBP could be detected. Sullivan *et al.* (Ref. 49) also studied tissue distribution and retention in the rat using a single 25 mg/kg oral dose of 4-iso(14C) propyl biphenyl. After 48 hours, 88 percent was excreted in the urine and feces, with the remaining 12 percent retained in the carcass. The elimination results of 48 hours after a single intraperitoneal dose were similar. IPBP was retained principally in the liver, where metabolism takes place. The remaining IPBP was sequestered in fat from which it was released slowly into the blood stream for metabolism by the liver and ultimate renal elimination. Thus, 48 hours after a single oral or intreperitoneal dose of IPBP, over 80 percent of the IPBP has been eliminated.

3. *Genotoxicity.* No evidence of mutagenic activity was found for IPBP when it was tested directly or in the presence of rat liver enzyme preparations. The indicator strains used were *Salmonella typhimurium*, *Saccharomyces cerevisiae* and *Escherichia coli* (Refs. 53 through 55).

4. *Human Dermal Irritation.* Repeated insult human patch testing was performed on a total of 687 panelists

using varyious IPBP containing products. The results indicated no evidence of delayed contact hypersensitivity or primary skin irritation (Ref. 56).

5. *Epidemological.* The papers referenced by the ITC with respect to IPBP/DPBP as the cause of health complaints to office workers did not upon review support any inference that these chemicals were the cause of the complaints. Kleinman and Horstman (Ref. 57) did not address the chemical composition of the carbonless copy paper used in their epidemological study; instead they refer the reader to another paper. This paper, Gockel *et al.* (Red. 58) is entitled "Formaldehyde Emissions from Carbonless Copy Paper Forms". This paper does not state that IPBP/DPBP was specifically identified or that IPBP/DPBP was inferentially indicated as being present in the carbonless copy paper being used by the office workers. Additionally, the paper does not state that IPBP/DPBP was, in some other manner, the etiological agent of the complaints by the officer workers.

The paper by Levy and Hanoa (Ref. 59), when translated and reviewed, was found to be taken from a newsletter distributed to physicians in Norway. The paper stated that there were some health complaints from office workers who used a particular lot of carbonless copy paper. The author states that the paper was sent to Sweden for analysis and that it did contain " . . . monoisopropyl biphenyl and other impurities . . ." No quantification or identification was given for the monoisopropyl biphenyl or the impurities. The paper further states that when the specific lot of paper was replaced, the complaints disappeared. The paper does not state if the new lot of carbonless copy paper contained monoisopropyl biphenyi. A study by Jeansson *et al.* (Ref. 60), in cooperation with the National Swedish Board of Occupational Safety and Health, investigated health complaints related to carbonless copy paper. The 1983 study was conducted in three principal areas: the effects of chemicals found in carbonless copy paper on skin and mucous membranes were evaluated with the aid of toxicological literature; patients referred to the Department of Occupational Dermatology at the Caroline Hospital due to medical troubles, in conjunction with carbonless copy paper handling, were examined and tested; and at the Department of Occupational Medicine at the Soder Hospital different brands of paper and handling environments were studied and weighed against health complaints. The report concluded ". . . that no specific relation between the chemicals in the market-leading carbonless copying papers and symptoms has been established and that reported symptoms are unspecific and rapidly disappearing." The market-leading brands of carbonless copy paper did contain IPBP/DPBP.

III. Decision Not to Initiate Rulemaking

EPA has decided that testing of IPBP/DPBP under sections 4(a)(1)(A) of 4(a)(1)(B) of TSCA is not warranted at this time because the potential for an unreasonable risk of injury to health or the environment is extremely limited and because there is no evidence of significant or substantial exposure to humans or substantial release to the environment. The IPBP/DPBP are produced and processed within a closed system. The Agency believes that because of the low vapor pressures of IPBP and DPBD, releases to the workplace resulting in occupational exposure will be minimal. The physical and chemical properties of IPBP and DPBP, in conjunction with the data submitted on biodegradation, show that the secondary waste treatment facilities at the production and paper recycling plants will reduce effluent concentrations to negligible levels. Disposal of IPBP/DPBP containing substances in secure or sanitary landfills will allow for microbial degradation with little or no transport of the chemicals due to their high soil adsorption coefficients.

EPA is unable to make the finding that IPBP/DPBP may present an unreasonable risk of health effects, at this time. The data now available to the Agency do not suggest any unreasonable risk of adverse health effects. The ITC's concern for nephrotoxicity can be dismissed on the basis of comparative metabolism studies which showed that atrolactic acid, which is responsible for nephrotoxicity in the rat, is not formed in humans or other primates. Epidemiological studies referencing adverse health effects, including neurotoxic effects, in office workers exposed to carbonless copy paper did not directly infer that IPBP/DPBP was the cause of health complaints, although this was the basis of the ITC's concern for neurotoxicity.

EPA's review of available information concerning IPBP/DPBP has revealed no basis for requiring testing for health effects, ecological effects or chemical fate.

IV. References

(1) USEPA. Fourteenth Report of the Interagency Testing Committee to the Administrator; Receipt of Report and Request for Comments Regarding Priority List of Chemicals. Federal Register, May 29, 1984, (49 FR 22389).

(2) SRI. Stanford Research Institute International. 1983 Directory of Chemical Producers, United States of America. Menlo Park, CA: SRI, pp. 345, 672. 1983.

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V. Public Record

The EPA has established a public record of this testing decision (docket number OPTS-12066). This record includes:

(1) **Federal Register** Notice designating Isopropyl Biphenyl/Diisopropyl Biphenyl to the priority list and comments received in response thereto.

(2) Contractor reports.

(3) Communications consisting of letters, contact reports of telephone conversations, and meeting summaries.

(4) Confidential Business Information submissions by Sybron Chemical Company, Koch Chemical Company, Mead Corporation. While part of the public record, these submissions are not available for public review.

The record, containing the basic information considered by the Agency in developing its decision, is available for inspection in the OPTS Reading Room from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in Rm. E-107, 401 M St., SW., Washington, D.C. 20460. The Agency will supplement this record periodically with additional relevant information received. (Sec. 4, 90 Stat. 2006; (15 U.S.C. 2603)).

Dated: April 24, 1985.

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