

1 OPTS-42067; TSH-FRL 2569-41

### 2-Phenoxyethanol; Response to the Interagency Testing Committee

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of Decision Not to Initiate Rulemaking.

**SUMMARY:** The Twelfth Report of the Interagency Testing Committee (ITC) designated the chemical 2-phenoxyethanol (2-PE) for priority consideration of health effects testing. After publication of the ITC report, the domestic producers of 2-phenoxyethanol formed an *ad hoc* group and began a program for testing the chemical. The Agency has concluded that the data being generated from this program, combined with the existing data, will enable EPA to reasonably determine or predict the potential health effects of 2-PE which were of concern to the ITC. Therefore, at this time, EPA is not initiating rulemaking under section 4(a) of the Toxic Substances Control Act (TSCA). This notice constitutes the Agency's response to the ITC's designation of 2-PE, as mandated by section 4(e) of TSCA.

**FOR FURTHER INFORMATION CONTACT:** Edward A Klein, Director, TSCA Assistance Office (TS-798), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., S.W., Washington, D.C. 20460, Toll Free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator 202-554-1404).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 4(a) of the Toxic Substances Control Act (TSCA) (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*)

authorizes EPA to promulgate regulations which require manufacturers and processors to test chemical substances and mixtures. Data developed through these test programs are used by EPA to determine the risks that these chemicals may present to human health and the environment. Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the Act. The ITC may designate, at any one time, up to 50 of the chemical entries on its list for priority consideration by EPA. EPA is required to respond within 12 months of the date of designation, either by initiating rulemaking under TSCA section 4(a) or publishing in the Federal Register reasons for not doing so.

On May 11, 1983, the Administrator of EPA received the Twelfth Report of the ITC which designated 2-phenoxyethanol (2-PE) for priority testing consideration (Ref. 25). Testing was recommended for teratogenicity, short-term genotoxicity, reproductive, and subchronic effects. The rationale developed by the ITC was based on: (1) Consumer and worker exposure from the use of 2-PE in consumer products and industrial solvents, (2) the structural similarity of 2-PE to the alkyl glycol ethers (i.e., 2-methoxyethanol and 2-ethoxyethanol) that have demonstrated teratogenic, reproductive, and mutagenic effects in various test systems, and (3) lack of data on chronic effects.

After publication of the ITC Report, the producers of 2-PE submitted market information, exposure estimates, and health effects data to EPA and formed an *ad hoc* group to address the ITC's concerns (Refs. 6 through 10, 12, and 19). They also submitted to EPA a testing program designed to develop data to characterize the potential health effects of 2-PE for which there are not adequate data. Most of the data citing production levels and consumption patterns were claimed to be confidential business information (CBI). Nonconfidential summaries of this information have been prepared and are included in the public record. EPA has considered these data and additional data reported by manufacturers under TSCA sections 8(a) and 8(d) in conjunction with other information in making its decision on 2-PE.

##### II. Assessment of Exposure and Health Effects

###### A. Production, Use, and Exposure

2-Phenoxyethanol (CAS No. 122-99-6) or 2-PE, is a viscous, colorless liquid with a slight roselike odor. It is an

aromatic glycol ether with a high boiling point (245°C at 760 mm Hg), high solubility in organic solvents, moderate solubility in water (2ml/100ml) and low volatility (Refs. 3, 4, and 13). The maximum attainable saturation concentration of 2-PE vapor is 40 ppm by weight (Ref. 6).

2-PE is commercially manufactured by catalytically reacting phenol with ethylene oxide using a batch process (Ref. 14). Total annual production has been estimated to be about five million pounds (Ref. 14).

Over 90 percent of the annual production of 2-PE is used as a coalescing agent in latex paints where a high boiling point, solvency for latex polymers, low affinity for water and slow volatility characteristics are desired (Refs. 4, 6, 14, and 20). 2-PE is added at its minimum level for coalescence; i.e., about 0.8 percent by weight, to prevent adverse effects on paint stability and performance (Refs. 4 and 6). Smaller quantities of 2-PE are used as a solvent in paint removers and inks, as a dye carrier, and as an intermediate; 5-10 percent is used as a cosmetic preservative (antimicrobial) and/or fragrance (Refs. 6 and 10).

The ITC expressed concern for the potential widespread occupational and consumer exposure to 2-PE. Data from the National Occupational Hazard Survey (NOHS) conducted by the National Institute for Occupational Safety and Health estimated that 9,560 workers are potentially exposed to 2-PE (Ref. 17). Machine operators, sewers and stitchers, and pressmen and printers accounted for the bulk of the exposures.

Data supplied by the manufacturers and estimates based on studies by NIOSH and the Occupational Safety and Health Administration (OSHA) indicate generally low exposure levels during 2-PE production and processing (Refs. 7, 16, 17, 21, and 24). While no recommended threshold limit values (TLV's) exist for 2-PE, indirect control is expected during the production process which requires closed process equipment, spot ventilation, gloves and goggles to comply with the OSHA limits on phenol (5 ppm) and ethylene oxide (50 ppm; 1 ppm proposed) (Refs. 22 and 24). In a survey conducted by Dow Chemical Company of employee exposure to 2-PE as DOWANOL® EPh, 8-hour time-weighted averages (TWA) ranged from 0.02 ppm (lower limit of detection) to 0.9 ppm. (Ref. 7). Results of area sampling and personal breathing zone sampling of one CBI-classified operation found air concentrations of 2-PE ranging from 0.5 to 14.5 ppm.

When NIOSH estimated the concentration of 2-PE in the breathing zone of workers in the operations, the mean 8-hour TWA concentration of total paint mist did not exceed  $5 \text{ mg/m}^3$  when OSHA requirements were met (Refs. 16 and 20). Based on this figure of  $5 \text{ mg/m}^3$ , spray painting with a latex paint containing 1 percent 2-PE by weight of paint solids would produce an estimated airborne concentration of  $50 \text{ } \mu\text{g/m}^3$  (9.0 ppb) 2-PE within the employee's breathing zone. This represents less than 0.025 percent of the maximum air saturation (i.e., 40 ppm) for 2-PE (Ref. 2).

Consumer exposure to 2-PE may result from its use in latex paints, paint removers, and inks (Ref. 6). In its major use as a coalescing aid, 2-PE is added at the rate of 6-7 pounds per 100 gallons of paint or about 0.6 percent by weight. The coalescing aid functions as a potential solvent or plasticizer for the latex polymer to allow the polymer particles to coalesce more readily. Thus, 2-PE is partially dissolved in the polymer and would be released very slowly and incompletely from the finished paint film. Its release would depend on its rate of migration from the polymer and its volatility. Release of 2-PE is expected to occur during its application and also during the subsequent drying and curing of the paint. Worst case exposure estimates modeling release of 2-PE were submitted to EPA from the 2-PE *ad hoc* producers group (Ref. 6). Both dermal absorption and inhalation potential were considered. When using latex paints containing 2-PE, it was estimated that dermal absorption of the paint would result in a daily maximum dose of 3.9 mg/kg. This is based on an average daily use of 4 gallons of paint containing 0.6 percent weight/volume 2-PE per gallon (or 30 g 2-PE per gallon); a 70-kg person getting 1 percent of the paint on 23 percent of exposed skin; and 100 percent absorption. The 2-PE *ad hoc* producers group did not estimate the concentration of 2-PE in air over a paint film but stated that the partial pressure would be extremely low suggesting insignificant inhalation exposures (Ref. 5). The low vapor pressure (.03 mm Hg), low evaporation rate, and low saturation concentration of 2-PE (40 ppm) support this conclusion.

In an independent effort for EPA, Dynamac Corporation determined that the maximum total dose of inhaled 2-PE absorbed by a 70-kg male over one week would be 1.9 mg/kg (Ref. 2). This is based on an adult male painting his 9 x 12 x 8 foot room in two hours with a roller brush, using 1 gallon of latex paint

containing 0.7 percent 2-PE. The exposure model used by Dynamac was based on actual evaporation data generated from a latex paint containing a coalescent with properties similar to 2-PE. Thus, there is a potential for widespread human exposure to 2-PE in latex paints. However, as shown, the levels of exposure are expected to be low.

Estimates of exposure to 2-PE from other minor TSCA uses, i.e., paint removers, inks, and dye applications suggest that these exposures do not result in substantial exposure (Ref. 6). The small fraction of 2-PE production that goes into these uses and the small amount of 2-PE used in typical product formulations further limits the exposure potential (Refs. 6 and 7). While there is no estimate of the number of people exposed to 2-PE from these and other consumer uses, the potential for widespread human exposure through the use of products containing 2-PE, albeit at low levels, does exist.

#### B. Health Effects Data

2-PE is moderately toxic by the dermal and oral routes; it causes mild irritation to the eyes and skin. Based on acute dermal  $\text{LD}_{50}$  values of 2.0-13.0 g/kg in laboratory animals, it is not likely to be acutely toxic through this route of exposure (Refs. 5, 12, 18, and 23). The acute oral  $\text{LD}_{50}$  values in rodents range from 1.2 to 2.3 gm/kg of body weight (Refs. 1, 12, 18, and 23); oral doses of greater than 3 g/kg caused 100 percent lethality in rats (Ref. 7). Ocular irritation was reported to be mild in dilutions of up to 5 percent 2-PE (Refs. 2, 12, and 18); however, severe eye irritation was seen in rabbits when undiluted chemical was used (Ref. 5).

When tested in the *Salmonella typhimurium*/mammalian microsomal assay (Ames) at doses up to 5 mg/plate both with and without metabolic activation, 2-PE gave no signs of toxicity or mutagenicity in any of the tester strains (Ref. 18). Negative results were also obtained in the mouse micronucleus test when 2-PE was tested at 300, 600, and 1,200 mg/kg (Ref. 18). It was concluded from these results that 2-PE failed to show any evidence of mutagenic potential.

Adequate data exist to characterize the subchronic oral toxicity of 2-PE. An oral 13-week study was performed with Phenoxetol® (99 percent pure 2-PE) in 15 CD rats/sex at doses of 0, 80, 400, and 2,000 mg/kg/day (Ref. 18). The no-observed-effect level reported in the study was 80 mg/kg. Increases in thyroid, hematological and renal abnormalities were seen at the highest dose levels, the male animals being the

most sensitive to the effects of the chemical. In the 2,000 mg/kg group the relative organ weights of the liver, kidneys, and thyroid were significantly increased in both sexes. These changes were accompanied by histopathological changes in the kidney and thyroid. While cellular necrosis in the liver was not reported, significant increases in blood chemistries indicated that either cellular injury and/or significant adaptive processes occurred. Kidney pathology, expressed as prominent groups of distended tubules and chronic inflammatory cell infiltration, was seen in both sexes. Similar kidney effects also occurred in a dose related manner in some male animals exposed to 400 mg/kg 2-PE. The only effect seen in any of the reproductive organs was an increased incidence (4 of 15 high dose compared to 1 of 15 controls) of minimal to moderate tubular atrophy of the testes in male animals at 2,000 mg/kg. No statistically significant changes in either the relative weights or the absolute weights of the uterus, ovary or testes were seen at any dose; minimal histopathological changes were observed in the tissues examined. There are no data available to determine whether the thyroid, hematological, renal, or testicular abnormalities detected in the oral subchronic study at the highest dose would also be observed after dermal application of 2-PE, an expected route of exposure in humans.

Available data suggest little basis for concern for reproductive toxicity associated with exposure to 2-PE. Nagano et al. (Ref. 15) found that testicular atrophy, assessed in terms of testicular weight and histopathology, was not significant when oral doses of 2-PE were given to male mice at doses of 500, 1,000, or 2,000 mg/kg for 5 weeks. In the 2,000 mg/kg dose group, there was 100 percent mortality. Although testicular atrophy was observed in one of five animals at 1,000 mg/kg, concern is mitigated by the fact that this dose is one-half the oral  $\text{LD}_{100}$  dose, an as such is expected to be similar to the  $\text{LD}_{50}$  in rodents. Thus, the changes observed are of questionable toxicological significance (Refs. 1, 12, 18, and 23). Additionally, as cited above from the oral subchronic study (Ref. 18), no statistically significant effects occurred in any reproductive organ at doses as high as 2,000 mg/kg in male or female rats.

Because the ITC recommended that 2-PE be considered for reproductive and teratogenic effects testing based on the structural similarity of 2-PE to the alkyl glycol ethers, EPA considered the available data on these compounds

when assessing the testing needs of 2-PE. Salient points in this regard are the existence of the existing data reviewed in alkyl glycol ethers (2-ME) and 2-ethoxyethanol and their acetate esters that testicular damage and fetotoxic effects occur at previously presumed no-effect levels. While the blood, liver, kidney, central nervous system, and reproductive effects of these chemicals have been well recognized, these recent studies demonstrate specific reproductive effects at exposure levels much lower than those at which other toxic effects are seen. The reproductive effects seen in male animals are expressed as marked testicular atrophy, histologic changes, and accompanying infertility. The histological effect seen was degeneration of the germinal epithelium of the testes. It was observed that the histopathological changes gave a more accurate picture of testicular toxicity than did other observations, such as reduced fertility. Similar testicular effects have been observed in dermal, oral, and inhalation studies in mice, rats, and rabbits; rabbits have been the most sensitive species tested to date (Ref. 11). It can reasonably be assumed, in light of these data on the alkyl glycol ethers, that if 2-PE were a similar reproductive hazard, the subacute study in mice and/or the subchronic studies in rats would have detected it.

The alkyl glycol ethers cited above also induced fetotoxic effects (fetal deaths or malformations) in rats, mice or rabbits after inhalation or dermal exposure (Ref. 11). The Agency, however, could find no data to assess the potential of 2-PE to cause these effects.

### III. Ongoing and Planned Testing

The *ad hoc* group of 2-PE producers has initiated a testing program designed to characterize the potential health effects of 2-PE for which there are not adequate data, thereby addressing the concerns identified by the ITC and the Agency. Because of the diversity and resulting market sensitivity of the various production/end-use patterns of the chemical (intermediate, paint products, non-TSCA cosmetic uses) the producers group initiated a two-phase testing program as follows.

In order to assess the teratogenic potential of 2-PE, the producers group initiated a dermal teratology study in rabbits. The low volatility of this chemical precludes a study by the inhalation route. The New Zealand white rabbit was chosen as the test

species based on historical use within the testing lab, the acceptability of methods to apply the test chemical by the dermal route, and the known sensitivity of this species to the fetotoxicity of other glycol ethers. The dose levels chosen were based on the results of a probe study done to determine maximum-tolerated dose levels. The protocols for these studies have been reviewed by EPA scientists and are acceptable. They are also available for examination in the public record of this proceeding.

Further, upon completion of the teratology study, the *ad hoc* group of producers has agreed to meet with EPA scientists to discuss the interpretation of the test results. The members of the *ad hoc* group of 2-PE producers believed that the potential teratogenicity of the chemical would play a major role in their individual decisions to continue producing and marketing 2-PE. Therefore, when the results of this study are available in December of 1984, the producers will be able to evaluate the appropriateness of the known uses and applications of 2-PE in light of the new test data and existing data. After evaluation of the teratology data EPA will review the need to develop additional data in this area, which could include metabolic and pharmacokinetic studies and/or additional teratology testing in another species.

Also, if the results of the teratology study are clearly negative, the industry group will conduct a dermal subchronic study and mutagenicity studies. A dermal subchronic study will be done using male and female rabbits to assess 2-PE's potential to cause toxic effects of the type seen in the oral gavage study, and to clarify the doses at which 2-PE causes toxic effects after repeated exposure to intact skin. Special attention will be given to the reproductive organs; complete histopathological examinations will be carried out to insure that 2-PE does not induce testicular changes in rabbits of the types seen with some alkyl glycol ethers.

To characterize further the mutagenic potential of 2-PE, the *ad hoc* group of producers will perform a test for gene mutation in mammalian cells in culture and an *in vitro* cytogenetics assay. The proposed mutagenicity tests would complement the existing *Salmonella typhimurium*/mammalian microsome assay and the mouse micronucleus assay, and complete the first tier base set tests EPA normally requires in a test rule. The combined results of these tests should provide the type of screening data the ITC recommended obtaining for 2-PE. Following a review of the results

from these tests by industry and EPA personnel, a determination will be made if further studies are necessary. Pending further evaluation, a chronic bioassay and/or additional mutagenicity testing may also need to be considered. If EPA cannot come to an agreement with the industry group to do the additional testing, a test rule may be promulgated under section 4(a) of TSCA.

The *ad hoc* group of 2-PE producers has agreed to perform the testing according to a prescribed schedule. The rabbit dermal teratology probe study began in April, 1984. Thus the full teratology study should begin in June, 1984. Preliminary data from the teratology study is expected to be delivered to the Agency by September, 1984. The final report should be completed by December, 1984.

Protocols for the dermal subchronic study and the mutagenicity studies will be submitted for Agency review prior to initiation of testing. If industry does not make a good faith effort to adhere to the proposed schedule, the Agency will consider initiating the rulemaking process. It can reasonably be anticipated that, presuming the individual producers will continue to market 2-PE, the subchronic and mutagenicity study should begin within 60 days after completion of the final report on the teratology study. Final results should be in the Agency's hands by middle or late 1985.

The Agency has concluded that the proposed testing plan is sufficient to provide the initial information necessary to assess the potential health hazards of 2-PE which the ITC identified in their report. Also, because testing is already underway the industry-sponsored program will permit EPA to evaluate the potential effects of 2-PE more readily than if the Agency initiated rulemaking.

The *ad hoc* group has informed EPA that the tests being conducted will be done by the Toxicology Research Laboratory, Health and Environmental Sciences USA, Dow Chemical Co., Midland, Michigan. The *ad hoc* group has agreed to adhere to the TSCA Good Laboratory Practice Standards issued by the EPA as published in the Federal Register of November 29, 1983 (48 FR 53922). This agreement includes the inspection of testing facilities. The *ad hoc* group also understands that the Agency plans to publish quarterly in the Federal Register a notice of the receipt of any test data submitted under this testing 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 comment. The Agency believes that the data submitted in support of the test in which the Agency will require testing.

#### IV. Decision Not To Initiate Rulemaking

EPA believes that the testing program already initiated by the *ad hoc* group of producers of 2-PE, coupled with the existing data, will provide sufficient data to reasonably determine or predict the potential teratogenic, mutagenic, reproductive, and subchronic effects of 2-PE which were of concern to the ITC. Hence, the Agency is not initiating rulemaking under section 4(a) of TSCA to require testing of 2-PE at this time.

The Agency reached this decision after a careful evaluation of the existing data and a review of the structural analogy developed by the ITC comparing 2-PE to the short-chain alkyl glycol ethers 2-methoxyethanol and 2-ethoxyethanol and their acetates. Existing data show that the presence of both an aromatic and aliphatic moiety in the 2-PE molecule results in a compound which exhibits a high boiling point, high organic solubility, and low water solubility. In contrast, most aliphatic glycol ethers have comparatively low boiling points, high aqueous solubilities, and can be expected to have very different end-uses and biological endpoints, as indicated in Unit II, and in recent review by Leaf (Ref. 13) and Hardin (Ref. 11).

EPA believes that the two-phase testing program proposed by the *ad hoc* producers group, together with the existing data, will provide the type of data needed to evaluate the potential health effects of 2-PE and resolve any lingering doubts about a structure-activity relationship of 2-PE to the alkyl glycol ethers. As noted in Unit III, the dermal teratology study in rabbits, considered by the ITC and EPA to be the most critical issue, will initiate the program. Because of the known sensitivity of the rabbit to the fetotoxic effects of other glycol ethers, the acceptability of methods for dermal testing in rabbits, and the knowledge that 2-PE is absorbed through the skin, EPA believes that a negative finding in the rabbit teratology study on 2-PE would be sufficient in this case to remove concern for teratology.

Also, as noted in Unit III, negative results in the teratology study would trigger a dermal subchronic study to characterize 2-PE's potential to cause toxic effects by dermal absorption and to screen for potential testicular effects

in rabbits. EPA could find no data to support the finding that 2-PE is a potential reproductive hazard either of the degree or type of that seen with the alkyl glycol ethers 2-ME, 2-EE, or their acetates. As noted in Unit III, few indications of testicular changes were seen in two rodent species exposed orally to 2-PE. However, since the types of testicular effects seen with these compounds can be identified by histopathological techniques, specific attention will be given to the reproductive organs, to insure that 2-PE does not induce these changes in a nonrodent species.

Finally, 2-PE will be tested for its ability to induce gene mutation in cells in culture and chromosomal aberrations in an *in vitro* assay. 2-PE has been tested and found negative in both an *in vitro* gene mutation assay (Ames test) and an *in vivo* chromosomal aberration assay (micronucleus test). EPA believes, at this time, that the combined results of these base set tests should provide sufficient data to reasonably predict the mutagenic potential of 2-PE.

The Agency has concluded, at this time, that the data being generated from this program will be sufficient to determine or reasonably predict the health effects of concern to the ITC. Thus, the Agency currently believes that testing is not necessary. When data are available upon completion of the testing planned by the *ad hoc* producers group, a complete assessment of further testing needs for 2-PE will be made. For these reasons, EPA has decided not to initiate rulemaking under section 4(a) of TSCA to require testing of 2-PE at this time.

#### V. References

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- (2) Capitol Systems Group, Inc. and Dynamac Corp. Final Technical Support Document: 2-Phenoxyethanol. Washington, D.C. Office of Pesticides and Toxic Substances. U.S. Environmental Protection Agency. EPA 88-01-8530. 1983.
- (3) Dow Chemical U.S.A. Technical data: Organic chemicals/developmental products. DOWANOL® EPh in the textile industry. Oxides and Intermediates, TS & D Laboratory, Organic Chemicals Department, 1710 Building, Midland, MI 48640. (n.d.).
- (4) Dow Chemical Company. Technical data: Organic chemicals/oxides and intermediates. DOWANOL® EPh ethylene glycol phenyl ether. Organic Chemicals Department, 9008 Building, Midland, MI 48640. 1981.
- (5) Dow Chemical Company. Health and Environmental Sciences, Chemicals and Plastics Regulations, 1803 Building, Midland, MI 48640. Information on 2-phenoxyethanol. Letter from Carlos M. Bowman to Martin

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(12) Hill Top Research, Inc. Acute oral and acute dermal toxicity, and acute eye irritation potential of sample 2219-88. Hill Top Report No. 80-478-21. Cincinnati, OH: Emery Industries, Inc. 1980.

(13) Leaf D. A. "Glycol Ethers and Acetates: Uses and Substitutes". Draft Report. Economics and Technology Division, Office of Pesticides and Toxic Substances, Environmental Protection Agency, Washington, DC 20460. 1983.

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(21) OSHA. Occupational Safety and Health Administration. U.S. Department of Labor. Spray finishing operations. (29 CFR 1910.94). 1981.

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#### VI. Public Record

The EPA has established a public record of this testing decision (docket number OPTS-42057). This record includes:

(1) *Federal Register* notice designating 2-PE to the priority list and comments received thereon.

(2) Communications before industry testing proposal consisting of letters, contact reports of telephone conversations, meeting summaries.

(3) Testing proposals and protocols.

(4) Published and unpublished data, including the references cited above.

(5) Nonconfidential summaries of market data.

The record, containing the basic information considered by the Agency in developing the decision, is available for inspection from 8:00 a.m. to 4:00 p.m. Monday through Friday, except legal holidays, in Rm. E-107, 401 M St., SW., Washington, DC 20460. The Agency will supplement this record periodically with additional relevant information received. (Sec. 4, 90 Stat. 2003; 15 U.S.C. 2601).

Dated: May 14, 1984.

William D. Ruckelshaus,  
*Administrator.*

[FR Doc. 84-13565 Filed 5-18-84; 8:45 am]

BILLING CODE 6560-50-M