

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

**FOR FURTHER INFORMATION CONTACT:** Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Room E-542, 401 M Street SW., Washington, D.C. 20460, Toll Free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the U.S.A.: (Operator 202-554-1404).

**SUPPLEMENTARY INFORMATION:** The Interagency Testing Committee (ITC) in its Thirteenth Report to the Administrator, published in the Federal Register of December 14, 1983 (48 FR 55674), designated that DGBA be given priority consideration for health effects testing.

#### I. Background

Section 4(e) of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) established the ITC to designate to EPA a list of chemicals to receive priority consideration for testing under section 4(a) of TSCA. EPA is required to respond within 12 months of the date of designation, either by initiating rulemaking under section 4(a) or publishing in the Federal Register reasons for not doing so.

The ITC designated DGBA for priority testing consideration in its Thirteenth Report. The specific designation was alkyloxyethylene acetates and included two chemical substances, DGBA and ethylene bis(oxyethylene) diacetate. The ITC recommended that both chemicals be tested for toxicokinetics, subchronic toxicity, and reproductive effects. The Agency is responding to the ethylene bis(oxyethylene) diacetate designation in a separate notice.

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,

#### 40 CFR Part 799

[OPTS-42062; TSH-FRL 2690-3]

#### 2-(2-Butoxyethoxy) Ethyl Acetate; Response to the Interagency Testing Committee

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

**ACTION:** Advance Notice of Proposed Rulemaking (ANPR).

**SUMMARY:** On November 8, 1983, The Interagency Testing Committee (ITC) designated 2-(2-Butoxyethoxy)ethyl acetate, CAS No. 124-17-4, also known as diethylene glycol butyl ether acetate (DGBA), for priority testing consideration for reproductive effects, subchronic toxicity, and toxicokinetic studies. EPA is issuing this ANPR under section 4(a) of the Toxic Substances Control Act (TSCA) to (1) inform the public that EPA is expanding the scope of this rulemaking to include diethylene glycol butyl ether (DGBE), CAS No. 112-34-5; (2) define the testing EPA is considering proposing for both chemicals; and (3) seek public comment on EPA's plan to propose a test rule for these chemicals. This action constitutes EPA's response to the ITC for DGBA.

**DATE:** Written comments should be submitted on or before January 18, 1985.

**ADDRESS:** Written comments should bear the document control number [OPTS-42062] and should be submitted in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Room E-108, 401 M Street SW., Washington, D.C. 20460.

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, EPA can require testing under section 4(a)(1)(B) 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 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 DGBA, 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).

## II. Response of EPA to the ITC

EPA has reviewed the ITC's report, the data upon which its testing recommendations were based, and information obtained from EPA's own information-gathering activities. The Agency has previously indicated that although it would generally initiate rulemaking for testing through publication of a proposed rule, it may in certain instances such as chemical categories and certain complex chemicals initiate action through publication of an advance notice of proposed rulemaking, as it is doing in this case. There are a number of reasons why the Agency has chosen to initiate rulemaking for DGBA and DGBE by issuing this ANPR.

First, rather than just responding to the ITC designation of DGBA alone, EPA is expanding this rulemaking proceeding by including a second chemical substance (DGBE). Addition of DGBE to this rulemaking has resulted from the Agency's review of information concerning both chemical substances, which are members of a larger chemical category—the glycol ethers. This review has led the Agency to conclude that both DGBA and DGBE are likely to have similar toxicological effects. Both DGBA and DGBE have similar acute and subchronic toxicity and both chemical substances affect the renal system in rats (see Unit III. E below). In addition, the acetate esters of other glycol ethers (methyl and ethyl ethylene glycols) have been shown to produce effects identical to their corresponding ethers (Ref. 7). Moreover, the ITC's concern for DGBA's potential to cause reproductive effects, which was based on an analogy to the effects of certain glycol ethers, also applies to DGBE (See Unit III. F). Finally, DGBE is believed to have similar or greater consumer and occupational exposures than DGBA (see Unit III. D). Thus, the Agency believes that DGBE and DGBA (which is the acetate ester of DGBE) should both be included in this TSCA section 4(a) rulemaking proceeding.

Second, expansion of this rulemaking to include DGBE has raised difficult scientific and policy issues that the Agency believes necessitate early public comment through this ANPR. For example, based upon information on structural analogs, DGBA is believed to rapidly metabolize to DGBE. If this is the case, it may be necessary to require

testing of only DGBE because toxicological data on DGBE may allow EPA to predict the risks of human exposure posed by both DGBA and DGBE (see Unit V). The submission of early public comment on this issue will assist the Agency in ensuring that any proposal which the Agency issues will provide for only that testing which is necessary to reasonably determine or predict the health effects of DGBA and DGBE.

Finally, the manufacturers and/or importers of DGBE (who were notified of the Agency's concern in April 1984 (Ref. 16), recently submitted a number of studies on the toxic effects of DGBE. The Agency is still reviewing these studies and, because they were submitted only recently, EPA could not make a final assessment of whether the studies are adequate to evaluate the toxicological effects of DGBE and possibly DGBA prior to its statutory deadline for issuing this response to the ITC designation of DGBA. Issuance of this ANPR both initiates the section 4(a) rulemaking process and provides the public with an early opportunity to comment on the issue of whether these studies will provide sufficient data to reasonably determine or predict the health effects of concern not only for DGBE but also for the ITC-designated chemical substance DGBA.

## III. General Information

### A. Chemical Description

DGBE and DGBA are colorless, relatively nonpolar liquids with faint, sweet odors. A summary of the physical properties of DGBE and DGBA is presented in the table below. The chemicals are excellent solvents and cosolvents for high molecular weight resins (Ref. 10).

PHYSICAL PROPERTIES OF DGBE AND DGBA<sup>1</sup>

Property	DGBE	DGBA
Density (g per ml)	0.948	0.961
Molecular weight (g per mole)	162.3	204.3
Freezing point (°C)	-68.0	-32
Boiling point (°C)	230.4	246.6
Vapor pressure at 25°C (mm Hg)	0.043	<0.01
Flash point open cup (°C)	200.6	240.

<sup>1</sup> (Ref. 8).

### B. Manufacturing

DGBE is manufactured by reacting n-butyl alcohol with ethylene oxide. DGBA is manufactured by reacting DGBE with acetic anhydride. Both chemicals are produced in enclosed processes with all waste streams recycled. DGBE is produced or imported by eight companies (Ref. 19). Production of DGBE in 1981 and 1982 was 50 and 48

million pounds, respectively (Ref. 11). DGBA is produced by only one company, Tennessee Eastman at Kingsport, Tennessee. Current production is confidential, but is in the range of 1 to 10 million pounds per year (Ref. 2).

#### C. Use

DGBE and DGBA are found in a number of industrial and consumer products. DGBE and DGBA are used in inks and industrial coatings as solvents and carriers. Unlike the lower molecular weight glycol ethers which rapidly evaporate, DGBE and DGBA serve to slow the rate of evaporation (Ref. 10). Inks and coatings containing DGBE and DGBA are usually oven dried (Refs. 2 and 20). DGBE and DGBA are also used as coalescing agents in consumer latex paint at concentrations of 0.5 to 3 percent by weight (Refs. 5, 12, and 21). Coalescing agents are compounds added to latex paints to act as plasticizers for the latex polymer. Plasticizers soften the colloidal latex particles and allow them to merge and form a uniform film upon drying. Coalescing agents slowly volatilize from paint over several days following application (Ref. 12). DGBE and DGBA also serve as solvents in the manufacture of microelectronics (Ref. 3).

DGBE is also used as a diluent in brake fluids, and as a component of cutting oils (Ref. 10), and in a number of consumer and industrial products including metal cleaners, paint removers, stamp pad inks, floor cleaners and floor wax strippers, floor finishes, spray cleaners, and penetrating oils (Ref. 6).

#### D. Potential Exposure

EPA believes at the present time that the largest exposures to DGBE and DGBA will occur from their use as coalescing agents in latex paints and as solvents in consumer products. Exposures during manufacture and processing are believed to be low. Actual chemical production occurs only a few weeks per year and in enclosed processes. They are used in low concentrations in various products and their low vapor pressure minimizes their potential for inhalation exposure in other uses (Refs. 2, 5 and 6).

A study of coalescing agents indicates that DGBE and DGBA will be slowly released from latex wall paint to the air over several days following application (Ref. 12). While DGBA and DGBE have low vapor pressures, releases of the glycol ethers from the large surface areas of painted walls are estimated to result in concentrations of 1 to 5 parts per million (ppm) in consumers' homes. Consumers exposed to these levels are

estimated to receive doses of 1 to 10 milligrams per kilogram per day (mg/kg/day). While consumers would be exposed to these levels for only a few days per year, painters would be exposed each workday (Ref. 9).

The estimated dosage from dermal exposure to DGBE and DGBA in latex paint is believed to be much less than that by inhalation. While painters and consumers received significant dermal exposure to latex paints, dermal contact with DGBE and DGBA in the paints is expected to be minimal. Both compounds are reported to partition into the latex polymer particles from the solvent portion of latex paints; as a result, they would be relatively unavailable for dermal absorption (Ref. 12).

DGBE is also used in a wide variety of commercial and consumer products. Some commercial products have considerable dermal exposure, such as cutting fluids and brake fluids. Consumer products containing DGBE such as cleaners, waxes, and penetrating oils also have potential for dermal exposure. Levels of DGBE in commercial products is not known, but DGBE is present in consumer products at levels up to 10 percent (Ref. 6).

#### E. Health Effects

Little toxicological information has been found on DGBE and DGBA. DGBE and DGBA have relatively low acute toxicities with the rat oral median lethal doses (LD<sub>50</sub>s) greater than 5,000 milligrams per kilogram (mg/kg). At doses slightly less than the LD<sub>50</sub>, DGBE has been reported to cause narcosis (Ref. 8). In rabbits, dermal LD<sub>50</sub>s differ from oral LD<sub>50</sub>s by a factor of only two, indicating that both chemicals are absorbed through the skin (Refs. 1 and 15). The chemicals are relatively nonirritating to the skin and eye (Refs. 1 and 8). The limited subchronic data indicate that in rats, oral doses of 500 to 1,000 mg/kg/day of either chemical affect the renal system, causing degeneration of the kidney tubules (Refs. 1 and 4). DGBA has also been reported to cause hematuria (Ref. 1).

DGBE and DGBA are also suspected of causing reproductive and other effects based upon analogy to other glycol ethers, and to ethylene glycol butyl ether (EGBE) in particular. EGBE has been reported to cause teratogenic and fetotoxic effects, renal toxicity, hematuria, and hemolysis (erythrocyte fragility) (Ref. 13).

Erythrocyte fragility has been reported as the lowest observed effect for EGBE with an inhalation no-observed-effect concentration of 32 ppm (Ref. 14). No information has been found

on the mutagenicity and oncogenicity of DGBA and DGBE.

EPA has no information on the environmental effects of DGBE and DGBA. The ITC had no concerns over DGBA's environmental effects due to its predicted rapid degradation in the environment. Based upon its own analysis, the Agency agrees with the ITC that DGBA will rapidly degrade (Ref. 18). The Agency also believes that DGBE will degrade in a similar manner to DGBA (Ref. 17).

#### IV. Tentative EPA Decision

##### A. Preliminary Finding

At this time, EPA believes that DGBE and DGBA may meet the criteria for a finding under section 4(a)(1)(B)(i) of TSCA. This belief is based upon the potential for substantial human exposure presented in Unit III, D above. EPA also believes that DGBA and DGBE may meet the criteria for a finding under section 4(a)(1)(A)(i) for hematological effects. EGBE, a close analog to DGBA and DGBE, is reported to have a no-observed-effect level for hematological effects close to the levels estimated for exposures from latex paint (Ref. 14). The Agency believes that the available data may be inadequate to reasonably determine or predict the health effects of these chemicals and that testing is necessary to develop such data.

##### B. Testing Under Consideration

In order to assess the potential hazards of DGBE and DGBA, EPA is considering proposing testing DGBE and DGBA for the following effects: Subchronic toxicity (including neurotoxic and behavioral toxicity and renal and hematological effects), developmental effects, reproductive toxicity, mutagenicity and carcinogenicity. The subchronic toxicity testing is being considered on the basis of the lack of no-observed-effect levels for the reported renal effects. Testing for developmental, hematological, and reproductive effects is based upon analogy to the effects of other glycol ethers. Neurotoxic effects testing is based upon the narcosis reported for DGBE (See Unit V, 4 below). Evidence of mutagenicity and carcinogenicity have not been reported nor is EPA aware of any evidence of these effects in other glycol ethers. However, because of the specific emphasis TSCA places upon carcinogenicity and mutagenicity, the Agency is proposing mutagenicity testing with oncogenicity testing if the mutagenicity testing is positive.

At the present time, EPA is considering requiring the following test

program for both compounds. A 90-day subchronic oral study would be performed with a complete histopathology of reproductive organs including: ovaries, testes, uterus, cervix and vagina, epididymides, seminal vesicles, and prostate and pituitary glands. Effects observed in these organs would trigger a requirement for full reproductive effects testing. Neurotoxicity and behavioral toxicity testing would also be performed on the test animals. As part of the 90-day subchronic study, a satellite group is proposed to evaluate hematological effects. Hematological testing would consist of serial sacrifices with blood counts, measurements of blood chemistry, and bone marrow studies over the first 2 weeks of dosing. This schedule is being considered because of the transitory blood effects reported for EGBE (Ref. 13). Developmental effects testing by the oral route would be required as would a tiered mutagenicity test sequence. Positive findings in certain mutagenicity tests would lead to further mutagenicity testing and, in some cases, to carcinogenicity testing. EPA is also considering requiring comparative pharmacokinetics for the inhalation and oral routes of exposure to allow an evaluation of the effect of the route of exposure upon the effects of DGBA and DGBE.

#### V. Issues for Comments

1. EPA requests comments on the testing program set forth in this advance notice for DGBE and DGBA.
2. EPA is considering testing of only DGBE if DGBA can be shown to rapidly metabolize to DGBE. Is such an approach appropriate for these two substances? If so, what testing is necessary to demonstrate that this metabolism occurs and to permit the use of DGBE test data in assessing the risks of exposure to DGBA?
3. EPA is considering proposing testing for toxic effects by oral administration of doses while the major route of exposure for DGBE and DGBA will be inhalation and to a lesser extent dermal contact. EPA recognizes the toxicological problems in extrapolation of dose response data from one route of exposure to another. However, the Agency believes that the low vapor pressures of DGBE and DGBA may prevent inhalation dosing of the animals at levels sufficient to reliably evaluate the chemicals' toxic effects. EPA requests comments and information on the effect of the route of administration on the toxicology of these chemicals.
4. EPA is considering requiring neurotoxicity testing for DGBA and DGBE. Neurotoxicity testing is being

considered because of the report that DGBE caused narcosis when administered at doses near the acute LD<sub>50</sub>, and also because another glycol ether, ethylene glycol methyl ether, has been reported to cause neuropathy in workers (Ref. 6). However, DGBE and DGBA have not been reported to cause neurotoxic effects when tested at lower doses for longer periods of time (Refs. 1 and 4). Further, ethylene glycol ethyl and butyl ethers, which are structurally closer to DGBE and DGBA than ethylene glycol methyl ether, do not cause neuropathy. EPA recognizes that consumer and commercial exposures from latex paints result in doses several orders of magnitude below the levels of DGBE reported to cause narcosis, but in the absence of test data, the Agency is reluctant to conclude that the substances are unlikely to present unreasonable risks of neurotoxicity. EPA is therefore requesting comments on the need for neurotoxicity testing.

#### VI. Development of Rulemaking

After reviewing the ITC report and other available information, EPA believes that there is sufficient reason to proceed with the development of a test rule for DGBE and DGBA. A bibliography of all published and unpublished studies received by the Agency is available for review as part of the public record (see Unit VII below). In publishing this ANPR, EPA wishes to receive comments on the testing being considered and the basis for requiring that testing.

The Agency will analyze all comments, production and use patterns, available data, and other relevant issues raised on comments on this ANPR.

#### VII. Public Record

EPA has established a public record for this ANPR, docket number [OPTS-42062]. The record includes the following information:

##### A. Supporting Documentation

- (1) Federal Register notice containing the designation of DGBA to the priority list (48 FR 55874) and all comments on DGBA received in response to that notice.
- (2) Communications (public).
  - (a) Letters.
  - (b) Contact reports of telephone conversations.
  - (c) Meeting summaries.
  - (3) Published and unpublished data.
  - (4) Technical support document.

##### B. References

- (1) Draize, J.A., E. Alvarez, M.F. Whitesell, G. Woodard, E.C. Hagen, A.A. Nelson. "Toxicological investigations of compounds

proposed for use as insect repellents. A. Local and systemic effects following topical skin application. B. Acute oral toxicity. C. Pathological examination." *Journal of Pharmacological and Experimental Therapeutics* 93: 26-39. 1948.

(2) Eastman Kodak Company, Eastman Chemicals Division, Kingsport, TN 37662. Letter from D.W. Kreh to TSCA Public Information Office, U.S. Environmental Protection Agency, Washington, D.C. 20460. January 1984.

(3) Engelhard Industries, Engelhard Industries Specialty Chemicals Division, 1 West Central Ave. East Newark, NJ 07029. Letter from W.J. Stimpfel, March 1984.

(4) Kesten H.D., M.G. Mulinos, L. Pomerantz. "Pathologic effects of certain glycols and related compounds." *Archives of Pathology* 27: 447-465. 1939.

(5) NIOSH, National Institute for Occupational Safety and Health, Cincinnati, OH. Computer print-out: NIOSH Trade-name Ingredient Data Base—National Occupational Hazard Survey. Retrieved Nov. 15, 1983.

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(8) Patty's Industrial Hygiene and Toxicology, 1982, 3rd rev. ed., Vol. 2 C, New York: Wiley-Interscience pp. 3909-4052, 1982.

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(11) SRI, Stanford Research Institute International, Glycol Ethers. *In* Chemical Economics Handbook, Menlo Park, CA. p.663.5022H, Online update April 1984, 1984.

(12) Sullivan D.A. "Water and solvent evaporation from latex and latex paint films." *Journal of Paint Technology* 47(610): 60-67. 1975

(13) Tyler T.R., G. Milliciously, D.E. Dodd, I.M. Pritts, K.A. France, L.C. Fisher. "A teratologic evaluation of ethylene glycol monobutyl ether in Fisher 344 rats and New Zealand White rabbits following inhalation exposure." Bushy Run Research Center, R.D. 4, Mellon Rd. Export, PA 15632, 1983.

(14) Tyler T.R. "Acute and subchronic toxicity of ethylene glycol monobutyl ether." Union Carbide Corporation, Corporate Applied Toxicology, P.O. Box 8361, South Charleston, WV 25303, 1983.

(15) Union Carbide Corp. Toxicology studies data sheet: butyl carbitol. Union Carbide Corp., Corporate Applied Toxicology, P.O. Box 8361, South Charleston, WV 1966.

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(17) USEPA. (May 1). Behavior/distribution of diethylene glycol butyl ether in the environment. Intraagency memorandum from R. Kinerson to P. Price, Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, DC 20460. 1948.

(18) USEPA. (November 20) U.S. Environmental Protection Agency. ENPART analysis of DCBA, TGD, and oleylamine. Interagency memorandum to Test Rules Development Branch, Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, DC 20460. 1984.

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

#### List of Subjects in 40 CFR Part 799

Testing, Environmental protection.  
Hazardous material, Chemicals.

(Sec. 4, Pub. L. 94-469, 90 Stat. 2003; 15 U.S.C. 2601)

Dated: November 8, 1984.

William D. Ruckelshaus,

Administrator.

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