[OPTS 91007; FRL #2978-1]

Toxic and Hazardous Substances Control; 2-Methoxyethanol, 2-Ethoxyethanol and Their Acetates; Referral for Additional Action

AGENCY: Environmental Protection Agency (EPA).

ACTION: Section 9 Report to the Occupational Safety and Health Administration (OSHA).

SUMMARY: This notice describes EPA's intended action with respect to the manufacture and use of 2-methoxyethanol, 2-ethoxyethanol and their acetates (2-ME, 2-EE, 2-MEA, 2-EEA, respectively). These four chemicals are part of a class of chemicals known as glycol ethers. Their respective Chemical Abstract Service Registry Numbers are 109-86-4, 101-80-5, 110-49-6, and 111-15-9. EPA has reasonable basis to conclude that the risk of injury to worker health from exposure to these glycol ether during their manufacture and during processing and use is unreasonable and this risk may be prevented or reduced to a sufficient extent by action taken by OSHA under the Occupational Safety and Health Act (OSHAct). Accordingly, EPA is using this Federal Register notice as a report to OSHA under section 9(a) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2608(a), and OSHA consequently is required to respond to EPA within 180 days of the publication of this notice in the Federal Register.

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SUPPLEMENTARY INFORMATION:

I. Background

2-Methoxyethanol, 2-methoxyethanol acetate, 2-ethoxyethanol, and 2-ethoxyethanol acetate (2-ME, 2-MEA, 2-EE, 2-EEA, respectively) are chemicals produced at a rate of approximately 320 million pounds per year. They are used as solvents to produce such industrial products as paints and coatings, cleaners, inks and adhesives. Other industrial uses are as jet fuel additives, chemical intermediates, in printed circuit board and semiconductor manufacture, and pharmaceutical synthesis. They are also used in paints, coatings, cleaners, inks, lacquer thinners, and photographic developers. Half of the annual production of 2-ME is used as a deicing additive for military jet fuel. As intermediates, 2-EE and 2-ME are used to manufacture the ether acetates (2-EEA and 2-MEA) and certain plasticizers. Approximately 569,000 workers may be exposed to these glycol ethers. Over 146,000 workers are exposed to either 2-ME or 2-MEA and 206,000 workers to either 2-EE or 2-EEA at levels that EPA believes present an unreasonable risk from possible developmental or reproductive effects.

In an Advance Notice of Proposed Rulemaking (ANPR) published in the Federal Register of January 24, 1984 (49 FR 2921), EPA determined, based on animal studies, that adverse reproductive and developmental effects are associated with these glycol ethers at concentrations to which humans may be exposed. EPA also announced its intent to start a regulatory investigation under the authority of TSCA to reduce exposure to these glycol ethers. In order to assist EPA in its regulatory investigation, the Agency sought comments and available data on (1) the extent and nature of exposure; (2) substitutes for these glycol ethers; (3) the economic impact of alternative means of regulating these glycol ethers; (4) ways to control exposure; and (5) the toxicity of these glycol ethers.

Twenty organizations responded to the ANPR. Most manufacturers and users of these glycol ethers felt that regulation is unnecessary and that a ban would be harmful (circuit board manufacturers said that a ban would be disastrous), and that at any rate, because exposure is primarily to workers the problem is OSHA's. The manufacturers of potential substitutes see no technical impediment to using their solvents in place of the subject glycol ethers except for some electronic applications. The Environmental Defense Fund (EDF), the only non-industrial respondent, felt that the glycol ethers should either be restricted or banned.

Also on January 24, 1984, EPA sent its "Preregulatory Assessment of 2-Methoxyethanol, 2-Ethoxyethanol and Their Acetates" to scientists in business, academia, labor unions, and public interest groups asking for their comments on the Agency's preliminary assessment of glycol ethers' risk.

Many comments on the analysis of the data were received. The reviewers found the assessment generally credible, although there was considerable comment on the Agency's use of quantitative methods. The Agency has revised its assessment to reflect the comments received.

Following the issuance of the ANPR, the Agency continued its regulatory investigation by conducting further assessments of exposure to glycol ethers, risk control methods and costs, and the availability of substitutes for these glycol ethers. EPA considered various regulatory options, including prohibiting the use of the glycol ethers in some or all uses and imposing various forms of exposure controls in the workplace.

As a result of the information submitted in response to the ANPR and other information developed by EPA, the Agency has determined that a workplace standard of the same type as the current OSHA standard (permissible exposure limits, possibly combined with engineering controls, work practices and personal protective equipment) can reduce risk to a sufficient extent for workplace settings where these glycol ethers are either used, manufactured, formulated or processed. OSHA has authority to promulgate and enforce this type of standard; therefore, EPA, pursuant to section 9(a) of TSCA, is submitting to OSHA a report on the risks of occupational uses of these glycol ethers.

EPA's investigation of risks to consumers has led the Agency to conclude the current information will not support an unreasonable risk finding for consumer use. EPA will continue to consult with the Consumer Product Safety Commission pursuant to section 9(d) of TSCA to resolve outstanding issues, particularly the presence of these glycol ethers in consumer products.

II. Authority

TSCA provides EPA with broad authority to assess and regulate chemical substances in the environment, in the workplace, and in commercial products. Under section 6(a) of TSCA, EPA is authorized to impose regulatory controls if the Agency finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance presents or will present an unreasonable risk of injury to human health or the environment.

To determine whether a risk is unreasonable, EPA balances the probability that harm will occur from the chemical substance under consideration against the social and economic costs of placing restrictions on the chemical. Specifically, as stated in section 6(c) of TSCA, this conclusion incorporates consideration of:

1. The effects of the chemical substance on health or the environment.

2. The magnitude of human or environmental exposure to the chemical substance.

3. The benefits of the chemical substance for various uses.

4. The availability of substitutes for such uses.

5. The reasonably ascertainable economic consequences of regulation, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

The Agency realizes that no single mathematical formula can be used to evaluate unreasonable risk, since the amount and nature of the information will differ in each case. Instead, EPA applies a case-by-case approach, weighing quantitative information with qualitative factors, and applying generlly accepted principles of responsible public health administration and prudent public policy.

If the EPA Administrator makes an unreasonable risk finding, one or more of several regulatory measures may be applied to the extent necessary to protect adequately against the risk. Those measures include: prohibiting or limiting the manufacture, processing or distribution in commerce; labeling; recordkeeping and testing; prohibiting or otherwise regulating any manner or method of commercial use or disposal; requiring the revision of quality control procedures; and a requirement that chemical manufacturers notify the public of unreasonable risk associated with a chemical. The EPA Administrator is required by TSCA to apply the least burdensome requirement(s) to protect adequately against such risk.

Under section 9(a)(1) of TSCA, the Administrator is required to submit a report to another Federal agency when two determinations are made. The first determination is that the Administrator has a reasonable basis to conclude that a chemical substance or mixture presents or will present an unreasonable risk of injury to health or the environment. The second determination is that the unreasonable risk may be prevented or reduced to a sufficient extent by action taken by another Federal agency under a Federal law not administered by EPA. Section 9(a)(1) *provides that where the Administrator* makes these two determinations, EPA must provide an opportunity to the other Federal agency to assess the risk described in the report, to interpret its own statutory authorities, and to initiate an action under the Federal laws that it administers.

Accordingly, section 9(a)(1) requires a report requesting the other agency (1) to determine if the risk may be prevented or reduced to a sufficient extent by action taken under its authority, and (2) if so, to issue an order declaring whether or not the activities described in the report present the risk described in the report.

Under section 9(a)(2), EPA is prohibited from taking any action under section 6 or 7 with respect to the risk reported to another Federal agency pending a response to the report from the other Federal agency. There would be no similar restriction on EPA for any risks associated with a chemical substance or mixture that is not within the section 9(a)(1) determinations and therefore not part of the report submitted by EPA to the other Federal agency.

The second agency may take one of three possible actions set out below. The Administrator may not take any action under section 6 or 7 with respect to such risk if the other agency either:

a. Issues an "order" within the EPA deadline, stating that the activities EPA described do not present the "unreasonable risk" EPA has attributed to them; or

b. "Initiates" within 90 days of its response to EPA action to "protect against" the risk identified by EPA.

c. Takes no action within 90 days of its response to EPA to "protect against" the risk identified by EPA.

On the other hand, EPA may take further action if the other agency either:

a. Determines that its law does not authorize action to prevent or reduce the unreasonable risk to a sufficient extent; or

b. Explicitly defers to EPA despite the existence of adequate authority on its part (unless its own statutory authority precludes such action), presumably on the ground that action by EPA is preferable on practical or public policy grounds; or

c. Does nothing, in which case EPA, once the deadline has expired, remains free to act as before.

III. Findings Under Section 9(a)

In this unit, EPA discusses the findings used to support its decision to refer glycol ether risks to OSHA for action. Units III.A and B discuss the *factors used to assess the potential risks* to workers exposed to the glycol ethers. Unit III.C is a summary of the effect of these glycol ethers on the environment. Units III.D and E are a summary of the benefits of the continued use of the glycol ethers and the potential consequences of regulatory action. Units III.F and G present the conclusions with respect to the unreasonable risk determination and the determination that the risk from these glycol ethers can be reduced to a sufficient extent by OSHA.

A. The Effects of the Chemical Substance on Health

2-Methoxyethanol, 2-ethoxyethanol, and 2-ethoxyethanol acetate have been shown to produce adverse reproductive and developmental effects in a number of animal species at levels of exposure well below current OSHA standards. These adverse effects include effects on adult male testicular tissue, effects on the embryo or fetus, and effects on the pregnant female. 2-Methoxyethanol acetate has been shown to produce adverse testicular effects at relatively high doses. The fact that the great number of studies that have been conducted by many investigators in many countries, in several animal species, are in agreement in terms of the nature of the developmental and reproductive effects that these glycol ethers cause, gives EPA confidence in its conclusion that current exposure to these chemicals may pose a significant hazard to humans.

Additionally, data derived from laboratory animals demonstrate that exposure to 2-ME may result in a variety of toxic hematologic effects, including hemolysis, bone-marrow depression, and immunosuppression. *Adverse hematologic effects have* been seen in humans, although attributing the cause to 2-ME is made somewhat uncertain because the exposure involved other chemicals in addition to 2-ME. Some hematologic effects seen in animals from exposure to 2-ME have resulted from exposures at concentrations lower than those that produced developmental and reproductive effects. EPA's assessment of the hematologic effects of 2-ME are contained in the unpublished report "Review of Hematologic Effect of 2-Methoxyethanol" (Ref. 42).

1. *Animal studies.* EPA relied primarily on a number of studies of various animal species in its analysis of the toxicity of these glycol ethers (Refs. 10, 17 through 22, 34 through 40, 44 through 46, 61, 69, 70, and 72 through 74). These data from these studies upon *which EPA relied are summarized and* analyzed in detail in "Reproductive and Developmental Effects Assessment of 2-Methoxyethanol and 2-Ethoxyethanol" (Ref. 56). This report summarizes these studies and other studies that EPA relied upon to support its conclusions.

The data show that 2-ME is developmentally toxic in laboratory animals following exposure via inhalation. In rabbits, the most sensitive species tested to date, the minimally toxic embryo/fetal dose (embryo/fetal death or resorptions) is 10 parts per

million (ppm). The no observed effect level (NEOL) is 3 ppm. 2-ME is also maternally toxic in rabbits at 50 ppm (the highest dose level tested), and in rats at 3 ppm (the lowest dose level tested). Other fetal effects, such as skeletal and soft tissue abnormalities, occur at higher doest (50 ppm and above) in rabbits and rats. The expected toxicant in 2-ME activity is methoxyacetic acid, which is the major metabolite of 2-ME.

2-ME causes testicular atrophy in rats with deceased testicular weight following exposure via inhalation. The NOEL for reduced fertility is 100 ppm. 2-ME also produced testicular damage in the rabbit via inhalation at 100 ppm and orally in the rat at 100 mg/kg. The NEOLs for these effects were 30 ppm and 50 mg/kg, respectively. Significantly, 2-ME caused its effects (in the rat) after only two oral exposures at the lowest observed effect level (NEOL). At higher doses (250 mg/kg), a single exposure resulted in testicular damage. The data suggest that 2-ME may have a primary effect on the testis. 2-ME exposure also reduces fertility in the male rats at high doses.

Available data also show that 2-EE is developmentally toxic in laboratory animals. The NEOL for these effects is 50 ppm in both the rabbit and the rat following exposure via inhalation. Fetal effects occur at the highest dose tested in each species (175 ppm in the rabbit, 250 ppm in the rat). 2-EE is maternally toxic in rats at 250 ppm. Complete maternal data in rabbits are not available at present. 2-EE is also developmentally toxic following dermal exposure. Doses totaling 1.0 ml/day caused resorptions and visceral and skeletal abnormalities in rats. These effects were noted in the presence of maternal toxicity; they nevertheless indicate that dermal exposure to 2-EE presents a health hazard. Lastly, 2-EE caused behavioral and neurochemical changes in rat offspring at 100 ppm.

2-EE has been shown to cause testicular damage in the rat at oral doses of 500 mg/kg and higher, with 250 mg/kg being the NEOL. 2-EE was testicularly toxic in the rabbit via inhalation at concentrations of 400 ppm, although other toxic effects also occurred at this level.

Available developmental toxicity data on 2-EEA, 2-ME and methoxyacetic acid, as well as metabolism data on 2-ME, indicate that 2-MEA and 2-EEA are expected to show similar profiles of developmental and reproductive toxicity as 2-ME and 2-EE, since all four chemicals are metabolized to an alkoxyacetic acid. Such an acid, methoxyacetic acid, has shown to cause both reproductive and developmental effects similar to the parent compound.

EPA has considered what exposure times are necessary to cause developmental effects from exposure to these glycol ethers. The available data indicate the developmental effects can be caused by short term exposures to 2-ME and 2-EE. The shortest exposure tested for 2-ME, single oral doses, has been shown to cause developmental and testicular effects. The Agency is unable, however, to estimate the level of inhalation exposure that would result in adverse effects over a short term (defined as less than 8 hours).

All of these substances are believed to be rapidly absorbed through the skin into the blood, thus causing the same effects as oral doses. Measurements made on excised pieces of human skin show extremely rapid absorption of these glycol ethers. The rates observed are 1.6 to 2.8 milligrams per square centimeter per hour (mg/cm²/hr) for 2-ME, 0.8 mg/cm²/hr for 2-EE, and 0.8 mg/cm²/hr for 2-EEA (Ref.14).

2. *Human studies.* EPA is not aware of any studies of the toxicity of these glycol ethers to humans that have examined developmental or reproductive effects.

B. Human Exposure and Risk

1. *Exposure sources*—a. *Manufacture.* Workers involved in manufacturing these glycol ethers are potentially exposed at several places in the manufacturing plant. The highest potential exposure occurs at packaging and drum filling locations, while all other locations are typically well controlled (closed systems, ventilated, etc.). Inhalation exposure at manufacturing plants ranges from 0.1 to 4.2 ppm. At a typical plant, EPA estimates 30 workers would be involved in these operations for less than 8 hours per day on a daily basis. There is also a high potential for dermal contact whenever container filling is not done automatically. However, most container filling is done automatically, ventilation is normally used, and protective equipment is normally worn (Ref. 60).

b. *Processing.* Glycol ethers are formulated in products under a much wider variety of conditions than those found in manufacturing plants. (Formulation of glycol ethers into products after their manufacture is considered "processing" under sec. 3 of TSCA.) In most cases, products are formulated under tightly controlled conditions (closed system, ventilation) where exposures are very low (non-detectable to less than 5 ppm.) However, some small quantity formulations of paints or other coatings are processed in open vessels where mean exposures can range up to 10 ppm. The potential for dermal contact in those situations can be quite high. In a typical plant, 20 workers are involved for less than 8 hours per day on a daily basis. Most establishments attempt to control exposures through the use of ventilation and personal protective equipment.

c. *Uses.* During the use of most glycol ether-containing products, the object is to evaporate the glycol ethers and other solvents from the coating, ink or cleaned surface. This evaporation results in a high potential for both dermal and inhalation exposure to glycol ethers.

i. *Trade users.* There are many products that may contain these substances used in a variety of trades. Prominent among these are inks used in printing, paints, varnishes, stains, lacquers, paint removers, and cleaning solvents used by woodworkers, painters, furniture finishers, and metal workers, and auto paints used in body shops. The inhalation exposures are known from observations made by NIOSH and OSHA to be at the level of 0 to 50 ppm for an 8-hour time-weighted average (TWA) (approximately 3 ppm average).

A typical case is the application of finishing or refinishing coatings on automobiles. Inhalation exposure levels may range from non-detectable to as high as 85 ppm. There is also a high potential for dermal contact. Workers are typically coating automobiles for 4 hours per day, 3 to 5 days a week. Most large shops control exposure through the use of ventilated spray booths and protective equipment. Small shops may not have this apparatus; frequently it is not well used or maintained (Ref. 47A).

ii. *Industrial users.* Industrial users are manufacturing establishments that apply glycol ether-containing paints and other coatings to products such as automobiles, appliances and furniture of use glycol ether-containing cleaners to clean a variety of machinery and work surfaces. This group also includes semi-conductor manufacturers who coat silicon wafers with photoresists. Most establishments attempt to control exposures through spray booths, exhaust hoods, general ventilation and personal protective equipment. Where glycol ether-containing cleaning products are used, the potential for dermal contact can be high.

iii. *Consumer Uses.* These glycol ethers are known to have been widely used in consumer products. However, because of wholesale switching to substitute solvents by EPA has not been able to identify manufacturers who currently use these glycol ethers in their

consumer products. Consequently, consumer exposure is irrelevant to the unreasonable risk finding contained in this report.

2. *Exposure analysis framework.* This picture of different causes and patterns of exposure among different people is the basis for dividing the exposed population into three major populations at risk. One population is the manufacturing, formulating and processing workers. Their exposure is characterized by processes where the release of glycol ether solvents is controlled and engineering and other controls are widely available. The second population at risk are the workers in major industries who use products containing the solvents. Their exposure is characterized by dissipative use of the solvents under conditions where exposure is prevented or reducted through engineering controls, special work practices and protective equipment. The third population at risk are what EPA is calling the trade workers using these products. Their exposure is characterized by dissipative use of the products under conditions where there frequently is little or no active removal of the vapors. The only limitations on their exposure are the relatively small amount of solvent used and the shorter and less consistent use of the glycol ether-containing products.

3. *Exposure levels.* Data on the exposure levels for men and women in trade uses, industrial uses, and glycol ethers manufacturing, formulating and processing are shown in the table "Populations at Risk" contained in this unit. The exposure data show that in most large industries the majority of exposures are relatively low (exposures below 0.03 ppm for 2-ME and below 1 ppm for 2-EE). What EPA has defined as trade uses, however, account for most of the highest exposure category (exposures above 3 ppm for 2-ME and 10 ppm for 3-EE).

Some trades that are likely to use these glycol ethers are not counted in the Agency's estimates either because EPA is not familiar with their use, or because EPA cannot estimate the number of people in the trade.

The exposure data in the table "Populations at Risk" are based solely on inhalation exposure to these glycol ethers, but dermal absorption will, in many cases, be a major contribution to the total exposure, and it can easily exceed the dose absorbed by inhalation.

4. *Risk analysis*—a. *Risk summary.* Based upon the results of animal studies, EPA has concluded that exposure at levels equal to current OSHA standards from the use of products containing these substances may cause both developmental toxicity effects and testicular damage in humans. In all cases 2-EE and its acetate are less potent in causing these effects than 2-ME and its acetate. EPA's evaluation of the safety of these substances shows that there is only a small or no margin of safety for many of their uses.

b. *Risk analysis methodology.* In its risk assessment (Ref. 78), EPA relies primarily on the analytical methodology of identifying the margin of safety, that is, the difference between worker exposure levels and the concentration levels at which no adverse, statistically significant effects were observed in test animals, i.e., the NOEL. This margin, which is equal to or some fraction of the NOEL, is a tool commonly used in evaluating the significance of human toxic exposures. To assure chemical safety, it has been standard Federal and state agency practice to establish a margin of 100 to allow for the possible greater sensitivity and variability of humans over the experimental animals. Exposures below this level have often been considered reasonably safe and above this level as possible hazardous. The Agency has analyzed the specific data on these glycol ethers and believes that a margin of safety of 100 is necessary to be reasonably confident of no human effects. The Agency's approach is consistent with its proposed guidelines for the health assessment of suspect developmental toxicants published in the Federal Register of November 23, 1984 (49 FR 46324). (This margin, combined with the economic impacts of achieving it, and other factors, is considered in making the finding of unreasonable risk discussed in Unit III.F below.)

In order to facilitate its analysis of the effectiveness of various control options, EPA divided the exposed populations according to ranges of margins of safety that applied to each group. Specifically, exposed worker populations were divided between trade users, industrial users, and workers in glycol ether manufacturing, formulating, and processing facilities. These groups were then subdivided between men and women (assuming 80 percent men and 20 percent women (Ref. 67) according to exposure levels that were (1) over one-tenth the NOEL for male or female effects respectively, (2) between one-tenth and one one-hundredth the male or female NOEL, (3) below one one-hundredth the male or female NOEL.

c. *Risk levels.* As the following table entitled "Populations at Risk" indicates, between 206,000 and 350,000 workers are exposed to levels of these glycol ethers that represent a margin of safety of less than 100. (The upper range assumes that none of the workers exposed to 2-EE and 2-EEA are also exposed to 2-ME and 2-MEA; the lower range assumes that all of the workers exposed to 2-EE and 2-EEA are also exposed to 2-ME and 2-MEA.) Approximately 90 percent of these higher risk workers are in the trade group.

TABLE—POPULATIONS AT RISK FROM 2-EE AND 2-ME

	Total [1]		Trade uses		Industrial		Manufacturing formulation, and processing	
	2-ME	2-EE	2-ME	2-EE	2-ME	2-EE	2-ME	2-EE
Number of Men at Risk, by use, Assuming Men Comprise 80 Percent of Exposed Population								
Margin of Safety less than 10	2,808				2,520		288	
Margin of Safety between 10 and 100	113,065	154,380	112,977	139,126	88	14,157		1,097
Margin of Safety greater than 100	194,466	297,772	62,907	111,976	129,928	162,173	1,730	23,622
Number of Women at Risk,[2] by use, Assuming Women Comprise 20 Percent of Exposed Population								
Margin of Safety less than 10	26,966	14,639	26,244	14,539	652		72	
Margin of Safety between 10 and 100	30	37,074		20,143		15,244	30	1,687
Margin of Safety greater than 100	48,587	61,325	15,701	27,994	32,482	26,838	403	4,493

[1] 2-ME and 2-EE are not additive because data includes people exposed to both chemicals. Data for 2-EE includes 2-EEA; data for 2-ME includes 2-MEA.
[2] For women, risk occurs during pregnancy.

Up to 46,000 workers are exposed to levels that represent a margin of safety of less than 10. Dermal exposures are not accounted for since EPA has no data for these exposures.

d. *Uncertainties.* Some of the sources of uncertainty in estimating the risks of testicular toxicity can be quantitatively estimated because both the biological site of action and the range of human

variability have been tentatively identified.

The biologic site of action of both 2-ME and 2-EE on the testis appear to be the primary germ cells. An extensive review by Meistrich (Ref. 32) suggests that it may be possible to estimate the reduction in the fertility of a human population exposed to 2-ME. He calculates that, at exposures between 1 and 5 ppm, the incidence of human infertility will increase from 15 percent of all couples to 18 percent of all couples.

The testicular effects of 2-EE can be considered to be similar to those of 2-ME but occur at approximately threefold higher exposure levels. The NOEL for all testicular effects is 100 ppm. This NOEL implies that exposures above 1 ppm would be considered by EPA to present a risk of testicular effects or that, by the Meistrich approach, infertility of couples will increase 1 percent from exposures between 5 and 25 ppm of 2-EE.

Because of a lack of data, dermal exposure has not been accounted for in determinating the risks. To the extent that there is significant dermal exposure and that exposure is not controlled, the risks are underestimated and some populations may actually be exposed to considerably higher levels than the Agency has determined based on inhalation data alone. A comparison of the risks from dermal and inhalation exposure can provide a perspective on the amount the risks may be underestimated. Fifteen minutes of absorption to a hand that is wet with 100 percent 2-ME will result in absorption of between 260 and 455 of 2-ME. This is the equivalent of exposure from inhalation to between 87 and 117 ppm of 2-ME for 15 minutes. Another comparision is that exposure to 1 ppm of 2-ME for 15 minutes (an exposure with a margin of safety of less than 10) is equivalent to immersion of less than 1 square inch of skin for 15 minutes.

Clearly, when no protection is used, dermal absorption can easily exceed inhalation exposure. This has especially important implications for controlling trade exposures where the nature of the product, and its hazards, may not be known and suitable protective clothing may not be readily available. It implies that there is a risk from all uses where there may be skin contact.

Additionally, while EPA has not established a safe or acceptable level of exposure to 2-ME with respect to hematologic effects, EPA believes that there is some risk to humans of incurring these effects through uncontrolled exposure to 2-ME.

e. *Conclusion.* The populations at a significant risk of reproductive and developmental effects are all men and women of childbearing age who on jobs that may use products containing 2-ME, 2-EE and their acetates. (These populations total as many as 350,000 in numbers.) The risk is especially high were there are no industrial ventilation controls or special protective equipment used.

EPA concludes that almost all trade users will have a significant risk of health effects from using these products.

C. The Effect of the Chemical Substance on the Environment

2-Ethoxyethanol and 2-methoxyethanol appear to be of only moderate to low concern regarding their toxicity of microorganisms and aquatic organisms (Refs. 50 and 51). EPA's PRL-1 reports (Refs. 54 and 55) also indicate that both 2-EE and 2-ME are biodegradable, with little or no tendency to bioaccumulate. More limited information on the effects of 2-EEA and 2-MEA on the environment are contained in the unpublished EPA reports "Chemical Hazard Information Profile Draft Report, 2-Methoxyethanol Acetate" and "Chemical Hazard Information Profile Draft Report, 2-Ethoxyethanol Acetate" (Refs. 52 and 53). Those reports indicate that 2-EEA was moderately biodegradable, whereas 2-MEA was slightly to moderately biodegradable.

D. Benefits of Glycol Ethers

1. *Background.* These glycol ethers have been used in commerce for over 50 years. Glycol ethers, as a family, are unique chemicals because they contain both the alcohol (—OH) and ether (—O—) moiety in the same molecule. This combination makes the glycol ethers useful in formulations containing organic and inorganic materials. Glycol ethers are useful solvents for a host of commonly used resins in the paint and coatings industry. In addition, they have relatively slow evaporation rates, which are desirable in terms of film formation.

2. *Uses.* Total domestic consumption of these glycol ethers is approximately 320 million pounds (Ref. 80). Domestic consumption of the glycol ethers can be divided into industrial uses that include chemical intermediates, industrial coatings, industrial solvents, and jet fuel additives and trade uses that include coatings and solvents used in trade industries.

a. *Industrial uses.* Chemical intermediates constitute the largest single application of glycol ethers, accounting for 36 percent of total domestic consumption. However, all but one-eighth of chemical intermediate use is directly associated with the production of glycol ether acetates. Production of 153 million pounds of 2-EEA requires 107 million pounds of 2-EE, and production of 1 million pounds of 2-MEA requires 0.7 million pounds of 2-ME. The one-eighth of glycol ethers used in chemical intermediate applications other than acetate production is nearly all accounted for by the 2-ME used in the production of the plasticizer di-methoxyethyl phthalate and the solvent ethylene glycol dimethyl ether.

Industrial coating formulations are the largest end-use category, accounting for 27 percent of domestic usage. Glycol ethers, primarily 2-EE and its acetate, are formulated into a wide array of industrial coatings. Protective finishes for cars, trucks, heavy equipment, and sheet sheet are among the largest uses of glycol ether-containing coatings. Original equipment manufacturers value glycol ethers for the smooth, glossy, durable finish they impart in both low temperature cure coatings and high temperature baked enamels. Formulators value glycol ethers for their compatibility with a variety of resins, their effectiveness in coupling resin polymers with colorants and additives, and their miscibility with both other solvents and water.

Industrial solvents represent the second largest end-use of glycol ethers, comprising 15 percent of domestic consumption. Electric circuit board manufacture, semiconductor manufacture, and textile dyeing are among the many industrial solvent applications. Electric circuit board manufacture is the largest single use in this category, accounting for consumption of 15 million pounds of glycol ethers. In this application, 2-ME serves as the carrier solvent for the catalyst in epoxy resins applied to a reinforcement material (e.g., fiberglass) during circuit board manufacture.

All four glycol ethers are used as solvents in cleaners in metal fabrication, manufacture of electrical and mechanical machinery, and miscellaneous applications. Glycol ethers are combined with other solvents and cleaners, or applied undiluted in cleaning applications. In some instances, the glycol ethers may be applied manually.

Jet fuel additives constitute the fourth largest domestic end-use of glycol ethers, accounting for 10 percent, or 33 million pounds, of total consumption. One part 2-ME is added to 1,000 parts jet fuel to prevent the fuel from freezing in jets without fuel heaters, and to act as

an antimicrobial agent in order to prevent clogging of fuel lines. Military uses dominate this market. Small private planes, such as Lear jets and Cessnas, represent a small part of the total. These additives are not employed in most commercial aircraft, which have in-line heaters.

b. *Trade uses.* Three trade industries—commercial printing, auto refinishing, and maintenance painting—together represent the third largest domestic end-use of glycol ethers. (All trade uses might constitute a larger end-user group than industrial solvents.) Altogether they account for 13 percent of domestic consumption. Glycol ether usage in printing inks has been declining in recent years to the extent that in 1982 this application was estimated to account for only 9 percent of trade industry consumption of glycol ethers. Three million pounds are used in rotogravure, flexographic, letterpress, and other printing processes. In addition, approximately 2 million pounds of 2-EE and 2-EEA are used as cleaning solvents in the printing industry.

Auto refinishing and maintenance paint formulations are functionally similar to industrial coatings, and are formulated by the same companies. Their distinguishing characteristic is that they are applied in non-industrial settings. Maintenance painters apply glycol ether-containing coatings to bridges, buildings, houses, ships, and highways.

3. *Substitutes*—a. *Summary.* In most cases, there are not one-for-one replacements for these glycol ethers. Blends of solvents would have to be used in order to achieve the cost/performance properties of these glycol ethers. The most likely substitutes would be blends of solvents that contain either the higher homologs of the ethylene oxide derived chemicals (e.g., ethylene glycol propyl ether, ethylene glycol butyl ether), or chemicals based on propylene oxide (e.g., propylene glycol methyl ether and propylene glycol methyl ether acetate). Other blend components would be aromatics, ketones, and esters. Much reformulation has been done in the area of paints and coatings. The biggest substitution problems would be in electronic applications 2-ME and industrial finishes containing 2-EEA. Coating manufacturers and users are concerned about the long-term impact of substitution on performance properties such as weathering and durability. In applications such as circuit board manufacture, solvency power of the substitute is the key consideration. Substitutes are available for most of the trade uses of these glycol ethers.

b. *Substitutes in glycol ether formulating and processing-intermediates.* With respect to intermediate use (other than glycol ether acetate manufacture), since glycol ethers become consumed in the manufacture of another chemical, substitution does not involve replacement of the glycol ether by the intermediate manufacturer but rather replacement of the chemical product itself at the point of end-use. For example, another plasticizer would need to be employed instead of di-methoxyethyl phthalate during vinyl plastics production.

i. *Industrial coatings.* Within industrial coatings, 2-EEA represents 80 percent of glycol ethers usage (among the four glycol ethers). Thus, to a large extent, replacement of these glycol ethers in coatings would mean substitution for 2-EEA, to a much lesser extent (17 percent) substitution for 2-EE, and to a minimal extent (3 percent) substitution for 2-ME.

The glycol ethers (and other solvents) are employed in three steps of the coating formulation process—resin production, pigment dispersion, and final mixing. During resin production, the glycol ethers act as chain transfer agents and therefore affect the characteristics of the polymer formed—its molecular weight average and distribution, extent of cross linking, and number of side branches. Since the polymer properties directly affect the formulated coating' rheology (flow properties), application properties, and durability, replacement of glycol ethers in this application is relatively difficult.

The second area of glycol ethers' use in coatings formulations is for pigment dispersion. Pigment dispersion solvents directly affect the stability, hue, and tinting strengths of the pigment. In addition, they affect the stability and application properties of the formulated coating. Replacement of glycol ethers as pigment dispersion solvents is considered to be less difficult than their replacement in resin production (Ref. 77).

The final glycol ether use in coatings formulation is as a let-down solvent during the mixing of the resin and pigment to produce the formulated paint. Glycol ethers in this application contribute to the overall solvent properties and the effectiveness of the coating application process. Use as a let-down solvent is considered to be the easiest use in which to replace these glycol ethers. Although comparable formulations can to some extent be reformulated as a group, each formulation ultimately requires individual attention and testing. Because coating formulations of each company are considered trade secrets, there is little direct sharing between companies of reformulation knowledge and experience. Some progress has been made in identifying potential substitutes for glycol ethers in coating formulations. Much of the work to date is described in the EPA report titled "Glycol Ethers and Acetates: Uses and Substitutes" (Ref. 77). Additional information is provided in responses to the glycol ethers ANPR. Industry representatives indicate that substitution will be accomplished on a case-by-case basis, and in most instances will involve a mixture of solvents.

ii. *Industrial solvents.* The substitution candidates identified above have successfully replaced the glycol ethers in many of the industrial solvent applications. In other applications, however, feasible replacements for these glycol ethers have not yet been identified.

iii. *Electronics applications.* Glycol ethers perform a critical role in circuit board manufacture, and in other electronic applications. In the predominant method of circuit board manufacture, 2-ME retains the epoxy resin catalyst (usually dicyandiamide) used to cure epoxy resins in solution throughout the production process. Circuit board manufacturers claim that they have attempted to identify a substitute for 2-ME but have not been successful. One manufacturer indicates that propylene glycol methyl ether (PGME) has been used as a substitute solvent in some circuit board manufacture, occasionally in conjunction with a co-solvent such as dimethyl formamide.

Glycol ethers are employed in a number of other electronic applications. The American Electronics Association had indicated that approximately 175 products used in the electronics industry contain one or more of these glycol ethers. Individual companies have indicated their use of all four glycol ethers in semiconductor manufacture, with 2-EEA used in the greatest quantity.

2-EEA is used in photoresist solutions applied to silicon wafers during the manufacture of semiconductors. The photoresist is applied to the wafer, then selectively hardened into circuitry images through exposure to ultraviolet light that shines through diagrams contained in film. 2-EEA acts as a solvent for the film-forming materials in the photoresist. 2-EEA affects the ability

to construct rigidly defined chip construction parameters such as the angles of "walls" within the circuitry design. Although some efforts have been made to replace 2-EEA in this application, these efforts have not been successful to date. Thus, the banning of 2-EEA could have a serious impact on semiconductor manufacture.

iv. *Printing ink manufacture.* Printing industry representatives indicate that glycol ethers are used in flexographic, letterpress, gravure, screening, and labeling inks and for press cleanup. In recent years, ink companies have reformulated away from glycol ethers. Potential substitutes in ink applications include PGME, blends of PGME and dipropylene glycol methyl ether and propylene glycol methylene ether acetate.

c. *Substitutes for industrial use.* Industrial uses of glycol ethers include the use of industrial coatings and industrial solvents containing glycol ethers. The use of substitute products will occur when the manufacturers of these products have successfully reformulated them.

d. *Trade product substitutes.* There are currently substitute products for most trade uses of these glycol ethers.

e. *Toxicity of substitutes.* With respect to the toxicity of substitutes, the Agency has examined the toxicity of the most likely substitutes for these glycol ethers in industrial, trade and consumer products (ethylene glycol butyl ether and its acetate, diethylene gylcol monomethyl ether and its acetate, propylene glycol methyl ether and its acetate, dipropylene glycol methyl ether and its acetate, and ethylene glycol propylether. The analysis shows that all have considerably lower toxicity (higher NOELS) than these glycol ethers. Developmental and reproductive effects either can be demonstrated only at much higher exposure to these substitutes or have not been demonstrated at all. The Agency is aware that there may be some hematologic risks from the use of these substitutes. EPA believes, however, that any risks from the substitutes are less than those presented by 2-ME, 2-EE, or their acetates and that use of substitutes will reduce overall risks to humans (Ref. 88).

E. The Reasonably Ascertainable Consequences of Potential Regulation

This unit describes the regulatory measures that could be used to control exposure to workers. As discussed below, EPA has concluded that some control methods are both technologically and economically feasible and could provide a reasonable margin of safety for manufacture, processing, and use of these glycol ethers.

1. *Control measures.* The Agency has examined a variety of control measures to determine their technical and economic feasibility and their effectiveness in reducing or eliminating exposure to these glycol ethers. Generally, the options can be grouped in the following categories:

a. A ban on some or all manufacture and use.

b. Workplace exposure limits for some or all manufacture and use.

c. Product concentration limits.

i. *Ban on Manufacture and Use.* EPA evaluated a full phase-out of manufacture and use of these glycol ethers. However, based on responses to the ANPR, EPA believes that certain manufacturers are manufacturing and using, and can continue to manufacture and use, these chemicals in a manner that provides adequate protection to worker health. In view of this assessment, the full ban option does not appear necessary to protect against risk. In particular, some industries, especially the electronics industry, may have severe problems in obtaining feasible substitutes.

ii. *Workplace Exposure Limits.* The control of employee exposure to dangerous materials is a standard part of most industrial production procedures. In addition, OSHA controls the industry concentrations of these glycol ethers in the plant atmosphere through permissible exposure limits (PELs) at less than the following 8-hour time weighted average (TWA) levels:

2-ME: 25 ppm
2-MEA: 25 ppm
2-EE: 200 ppm
2-EEA: 100 ppm

OSHA also requires that every precaution be taken to avoid skin contact. OSHA established the above control levels based on hematologic and neurologic effects, not the developmental and reproductive effects.

A lower TWA limit of 5 ppm recently has been recommended for all four glycol ethers by the American Conference of Governmental Industrial Hygienists, based on developmental and reproductive effects.

EPA evaluated current industrial control practices for glycol ethers, and identified additional control measures that could reduce exposures to a sufficient extent (Ref. 60). EPA identified possible control requirements for nine representative industrial facilities. In all facilities except for ink application, cleaning solvent use, and photographic applications, EPA found that exposure during industrial use of glycol ethers already has been controlled to 5 ppm or below. EPA evaluated a tenth facility, an electric circuit board manufacturer, at which glycol ether exposures in the 5 to 10 ppm range were reported.

Glycol ether usage at trade facilities is relatively small; their process operations are less well controlled; and such facilities may have a smaller financial base to recover fixed compliance costs than the industrial facilities. For these reasons, trade facilities might find it difficult to implement control equipment measures to achieve reduced levels of glycol ethers exposure. However, product substitution is an alternative in such settings.

iii. *Product concentration limits.* Product concentration limits were considered by EPA not to be a viable option because these glycol ethers generally are not useful except at concentrations (typically 10 to 100 percent) that can produce very significant exposures in all uncontrolled settings. In addition, specifying an allowable concentration level would be ineffective because the degree of exposure is considerably affected by factors other than concentration, such as air exchange rates, temperature, humidity, and mode of use.

2. *Cost of controls.*—a. *complete ban.* The direct costs of a general ban (excepting exports and jet fuel use) on all manufacture and use of these glycol ethers was estimated by calculating the direct costs of replacing these glycol ethers with substitutes. The potential costs are of two types, (1) reformulation efforts by product formulators and, (2) changes in formulator raw material costs. Total reformulation costs for a general ban would be about $300 million. The annual cost would be about $65 million if they were amortized over 10 years (the period that the coating and ink industries experience a nearly complete product turnover). EPA estimates that the annual increase in raw materials to be incurred under a general ban would be about $23 million.

b. *Trade ban.* The total annualized cost of banning just the trade uses of these glycol ethers would be about $22 million, of which $17 million would be reformulation costs and $5 million would be increased raw material costs.

c. *Lower permissible exposure limits for workplace manufacturing, processing or use.* EPA also evaluated the cost of imposing lower permissible exposure limits than those OSHA now requires for all workplace settings where glycol ethers exposus may occur. Each industrial user faced with these limits can either install and utilize

engineering controls and personal protective equipment or switch to a product that does not contain these glycol ethers.

If *all* workplaces—industrial and trade—installed engineering controls and used personal protective equipment, then capital costs for the control levels evaluated are between $44.2 million and $88.0 million; operating costs are high—$1.24 to $1.25 billion.

However, an option for any firm facing the exposure limits that provide an adequate margin of safety would be to substitute away from the glycol ethers. EPA concluded, based on its analysis of the cost of lower exposure limits versus substitution, that many firms may opt for subsitution. In two industrial sectors, electric circuit board manufacture and semiconductor fabrication, firms would be more likely to incur the costs of controlling exposures rather than replace the gylcol ethers. Consequently, the annualized costs of revised PELs for all workers would be $83 million (assuming the move by many firms to substitutes).

Reduced usage of these glycol ethers will vary among the three control options. A ban on all uses, except exports and jet fuel manufacture and use, would lead to a 280 million pound reduction in consumption and remove roughly 569,000 persons from any risk; a limited ban on trade use would lead to 45 million pound reduction and remove roughly 316,000 persons from any risk; and setting new exposure limits would reduce cosumption by 231 million pounds and reduce the risk to roughly 350,000 persons, based on a level that has margin of safety greater than 100. The relative reduction in the use of 2-ME represents the major difference between the general ban and reduced exposure limits. Under a new exposure limit EPA estimated a 19 percent reduction in the use of 2-ME, while a general ban would result in a 55 percent reduction of 2-ME. (Note that total persons removed from risk data cannot be obtained from the "Populations at Risk" table which presents data according to 2-EE/2-EEA and 2-ME/2-MEA exposures. These data are not additive because of double counting; see ref. 80.)

F. Unreasonable Risk From 2-Methoxyethanol, 2-Ethoxyethanol, and Their Acetates

1. *Industrial (manufacturing, processing and use).* EPA believes that the exposure levels associated with certain manufacture, processing, distribution in commerce, and use of these glycol ethers or mixtures containing these glycol ethers present an unreasonale risk to human health. Approximately 200,000 industrial workers are exposed to these glycol ethers, and as many as 4,000 of those workers are exposed to concentration levels that afford little or no margin of safety from incurring effects similar to those observed in test animals. A larger number—32,000 to 36,000—are exposed to concentration levels that EPA believes do not afford a sufficient margin of safety. EPA has also concluded that reasonable methods such as reduced workplace PELs, controlled work practices and protective equipment could be used to control exposure. The cost of instituting new PELs, for example, for all industrial workers is approximately $61 million annually.

2. *Trade uses.* As many as 43,000 trade workers are exposed to concentration levels that afford little or no margin of safety from incurring effects similar to those observed in test animals. Between 159,000 and 272,000 are exposed to concentrations levels that EPA believes do not afford a sufficient margin of safety.

Because of the high costs of engineering controls, work practices, and personal protetive equipment, occupational control standards that would substantially reduce trade worker risk from glycol ether exposure may result in trade users complying by substituting other products. The cost of complete substitution would be about $22 million annually.

To put this in perspective, a typical glycol ethers-containing paint costing $35 per gallon might increase 8¢ to 9¢ per gallon as the result of switching to a substitute. Reduced PELs, assuming compliance using engineering controls and personal protective equipment, on the other hand, might result in an increase of many dollars per gallon. Cessation of trade use also would eliminate 97 percent of the exposure to 2-ME at levels greater than 0.1 ppm (the limit of detection associated with the exposure data) and 68 percent of the exposure to 2-EE at levels greater than 0.5 ppm.

EPA believes that the estimated cost of substitution in trade uses is reasonable in view of the potential fetal lives saved and the sterility and other health effects avoided. EPA believes that there are effective substitutes for most if not all trade uses of these glycol ethers.

G. Prevention of Unreasonable Risk by OSHA

Based on the entire record developed during EPA's regulatory investigation, the Agency has determined that a reasonable basis exists to conclude that the current conditions of manufacture and use of glycol ethers present an unreasonable risk of injury to human health, and that the risk to workers can be prevented or reduced to a sufficient extent by actions taken under the Occupational Safety and Health Act (OSHA. Therefore, pursuant to section 9(a) of TSCA, the Agency is issuing this report. A response from OSHA to the Administrator of EPA is requested within 180 days of publication of this report in the Federal Register.

IV. Report Record

EPA has established a record for this proceeding (docket control number OPTS-91007). A public version of the record, without any confidential business information, is available to the public in the Toxic Substances Public Information Office, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. The Agency also maintains a record of confidential information that is not a part of the public record. The Public Information Office is located in Rm. E-107, 401 M St., SW., Washington, DC 20460.

The record includes information considered by EPA in developing this report. EPA will supplement the record with additional information as it is received. The record now includes the following categories of information:

1. The Federal Register notices.
2. Support documents.
3. Reports.
4. Memoranda and letters.
5. Documents identified in Unit V, "References".

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