

July 2000

EGBE:

A WORLD OF SOLUTIONS 2000

This information is brought to you by the member companies of the American Chemistry Council Ethylene Glycol Ethers Panel: The Dow Chemical Company, Eastman Chemical Company, Equistar Chemicals, L.P., Shell Chemical Company, and Union Carbide Corporation. For more information, call your supplier representative, or Dr. Susan Lewis, Manager, Ethylene Glycol Ethers Panel (703/741-5635 or by e-mail Susan_Lewis@americanchemistry.com).

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Ethylene glycol butyl ether (EGBE) is a key ingredient in hundreds of products ranging from industrial and consumer cleaning solutions to water- and solvent-based paints and coatings. EGBE's popularity stems from several special performance characteristics that also provide economic value. EGBE has been tested extensively to assess health and environmental safety.

This brochure presents information about EGBE uses and health and environmental testing collected by the American Chemistry Council Ethylene Glycol Ethers (EGE) Panel. Further information is available from manufacturers through their product labels, Material Safety Data Sheets (MSDS), and other product safety literature, which should be consulted prior to use.

WIDESPREAD USE

Approximately 650 million pounds (300 million kilotonnes) of EGBE are produced each year in the United States and Europe. EGBE is sold commercially under a variety of names. EGBE is also referred to by its chemical names: ethylene glycol monobutyl ether, butyl glycol ether (BGE), or 2-butoxyethanol.

MAKING THINGS WORK

EGBE has been used for more than half a century. Today it is used extensively in both water- and solvent-based coatings and industrial and consumer cleaners.^{25 a} Cleaners made with EGBE can remove oils, fats, waxes, greases and baked-on or ground-in residues from floors, walls, glass, metal parts, and equipment. Paints and coatings that use EGBE range from lacquers, varnishes and enamels to water-based coatings and inks.

When added to cleaners, EGBE helps lift soil and keeps it suspended until it can be rinsed or wiped away. Because EGBE's chemical structure includes an ether and an alcohol, it can attack water-insoluble oils and greases and water-soluble stains. EGBE thus offers manufacturers a variety of cleaning capabilities, from heavy-duty industrial jobs to milder janitorial and household uses.

Because EGBE is compatible with both petroleum solvents and water, it is found in a wide-range of coatings – from automotive and packaging coatings to wood furniture finishes. It is used widely in water-based industrial paints and coatings.

In household products, EGBE uses include glass and tile cleaners, waxes, rust removers and metal polishes. The same properties that allow EGBE to dissolve and hold soils and stains in suspension make the compound an effective ingredient in water-based protective paints and coatings. EGBE also acts to dissolve or suspend pigments and resins until the coating is applied to surfaces. Once the coating is applied, EGBE is designed to evaporate, leaving a uniform, dry finish.

PHYSICAL CHARACTERISTICS

CHEMICAL NAME Ethylene Glycol Monobutyl Ether
CAS NUMBER 111-76-2
MOLECULAR FORMULA C₆H₁₄O₂
APPEARANCE Colorless, liquid
BOILING POINT 171°C(340°F) at 760 mmHg
STRUCTURE C₄H₉-O-CH₂-CH₂-OH
SOLUBILITY Miscible in both water and organic solvents

^a. References listed on last page.

EXTENSIVE TESTING FOR HEALTH EFFECTS

EGBE has been used for decades in consumer and industrial applications. A U.S. National Toxicology Program review²¹ noted: “The human experience in the use of 2-butoxyethanol (EGBE) has been remarkably free of serious complications.” The only confirmed adverse human health effects have occurred in a few reported cases of unsuccessful intentional ingestion suicide attempts. One epidemiology study² reported an association between birth defects and presumed maternal workplace exposures to EGBE and other glycol ethers. An American Chemistry Council-sponsored review of the study by independent scientists¹⁸ found these results lack convincing biological plausibility for two reasons. First, EGBE has been tested in animals and found not to be teratogenic. Second, the associations could have been the result of methodological problems. The independent review also found that few subjects appeared to have exposure to glycol ethers that could be confirmed.

EGBE exposure in laboratory animals has been found to reduce body weight gain and food consumption and to cause red blood cell breakage (hemolysis).^{1, 5, 7, 8, 17, 20, 23, 28, 31} These effects in animals, however, were found to disappear shortly after exposures were terminated. Animal studies have also demonstrated that EGBE does not cause adverse reproductive or birth effects, unless exposures are so high that they cause significant maternal toxicity, according to the U.S. National Institute for Occupational Safety and Health (NIOSH) and the World Health Organization (WHO).^{7, 8, 13, 14, 19, 20, 22, 24, 27, 31} As the WHO³¹ explained, EGBE “did not cause adverse reproductive or developmental effects in either sex [of rats] at less than toxic doses.”

The most sensitive effect of EGBE exposure noted in laboratory animals has been hemolysis due to EGBE’s major metabolite, butoxyacetic acid (BAA). Therefore, many scientific studies have investigated the effects of EGBE and BAA on red blood cells. One of the most significant findings has been the comparative resistance of human red blood cells to the hemolytic effects seen in rats. Dr. Burhan I. Ghanayem of the National Institute of Environmental Health Sciences (NIEHS) has concluded from his extensive studies that: “Humans of both sexes are comparatively insensitive to the erythrocyte swelling and hemolysis...by BAA.”^{9, 10, 11}

These findings have been confirmed in studies conducted for the American Chemistry Council’s EGE Panel by Dr. Mark M. Udden of the Baylor College of Medicine in Houston.^{29, 30} “Unlike the red blood cells of rats, which have been shown to be particularly sensitive, human blood cells are much less susceptible to hemolysis caused by BAA,” according to Udden. Dr. Udden’s research also found that even among potentially sensitive individuals there was a resistance of human red blood cells to the hemolytic effects of BAA: “Although BAA is a potent cause of hemolysis in rats, red blood cells in humans – including the elderly and patients with two disorders which are marked by chronic hemolysis – were not susceptible to BAA-induced hemolysis or loss of deformability.”

Physiologically-based pharmacokinetic (PBPK) models have been developed to show how EGBE and its metabolite BAA are absorbed, distributed and eliminated from the body.^{3, 4, 15} These models take into account known differences between the anatomy and metabolism of rats and humans. The PBPK models demonstrate that blood concentrations high enough to cause hemolysis in humans could not occur when EGBE is used as directed.

Various governmental health organizations have developed benchmarks to assess the safety of EGBE use. The 1997 WHO review³¹ determined, based upon a detailed description of the toxicity information, that 13.3 mg/m³ (2.5 ppm) for 24 hours/day throughout a lifetime was a “tolerable” (*i.e.*, without appreciable risk) concentration for humans. EPA’s 1999 peer-reviewed assessment³² similarly found the EGBE database adequate to establish exposure levels for all individuals “including sensitive subgroups” that “are likely to be without appreciable risk of deleterious [non-carcinogenic] effects during a lifetime.” EPA noted that its conclusions encompass all individuals, including children, because, the Agency’s experts found, adults are “more sensitive than neonates, infants, and children.” These EPA-established exposure levels (lifetime exposures of 0.5 mg/kg/day for ingestion or 13 mg/m³ (2.5 ppm) for inhalation) exceed reasonably foreseeable exposures that consumers would experience during normal use of products containing EGBE or living near facilities where EGBE was manufactured or used.

In the most recent research on EGBE, animals in an NTP study were exposed to up to 125 ppm (rats) and 250 ppm (mice) in air for their lifetimes. NTP reported²¹ in 1998 that these studies found “some” evidence of cancer in mice and “equivocal” evidence in rats. The Panel is conducting research to assess the statements of their expert consultants that the tumor increases in the NTP studies are unlikely to be relevant to human risk.¹⁶ EPA’s 1999 assessment of the NTP results³² found the slight increases in tumors of “uncertain relevance” to humans because “EGBE is generally negative in genotoxic tests” and of “the lack of human data to support the findings in rodents.” The tumor increases appear to be secondary to irritation or hemolytic effects that would not occur in humans when

EGBE is used as directed and in accordance with manufacturer recommendations and good hygiene practice. Using its 1996 (draft) cancer guidelines, EPA concluded that the human carcinogenic potential of EGBE “cannot be determined.”³² The IRIS review also noted that if EPA’s old 1986 guidelines were used, the NTP results would place EGBE in the Group C “possible” human carcinogen category. Substances are placed in Group C without consideration of relevance to the assessment of risk to man of the site, incidence, or type of tumor species used, or the method of exposure in the animal study.

RECOGNIZING THE DIFFERENCES: EGBE, EGME & EGEE

The distinctive toxicological characteristics of the more than twenty different commercial ethylene glycol ethers are frequently not appreciated. Hazard communication efforts that fail to distinguish among the ethylene glycol ethers may unnecessarily raise concern about structurally similar chemicals that, in fact, are much different in terms of toxicity. Such confusion stems from studies that revealed significant adverse reproductive effects and birth defects in laboratory animals exposed to ethylene glycol methyl ether (EGME) and ethylene glycol ethyl ether (EGEE) and their acetates (EGMEA and EGEEA) and a few other glycol ethers. Animal studies have found that EGBE does not show the same pattern of toxicity as these other glycol ethers.^{7, 8, 13, 14, 19, 20, 22, 23, 24, 27, 31} EPA’s 1999 EGBE assessment³² concluded that the safe exposure levels it established were adequate to address any potential reproductive or developmental effects as “EGBE is not significantly toxic to the reproductive organs (male or female) of parents, nor to the developing fetuses of laboratory animals.” Recognizing these differences, the American Chemistry Council’s EGE Panel member companies have for many years recommended that EGME and EGEE and their acetates not be used in consumer products. These U.S. manufacturers have voluntarily adopted warnings intended to limit sales to certain industrial applications.

KNOWING OCCUPATIONAL EXPOSURE LIMITS

Advisory/regulatory groups have established occupational exposure limits for EGBE and cautioned against skin contact.

EXPOSURE LIMITS - Current Values for EGBE

American Conference of Governmental Industrial Hygienists (ACGIH TLV, USA)	20ppm	97 mg/m ³
Permissible Exposure Limit (OSHA - PEL, USA)	50ppm	242 mg/m ³
Indicative Limit Value (ILV - EU)	20ppm	97 mg/m ³
Maximale Arbeitsplatz-Konzentration (MAK- Germany)	20ppm	97 mg/m ³
Occupational Exposure Standard (OES - UK)	25ppm	121 mg/m ³

EGBE air concentrations measured in a number of workplaces and other use areas show levels are typically well below these occupational hygiene limits.³¹

EGBE IN THE ENVIRONMENT

EGBE’s characteristics when released to land, water or air have also been studied, as have potential effects on the environment.²⁶

EGBE moves to water because of its high solubility, low volatility and minimal tendency to bind to soil or sediment. In water, it will typically degrade rapidly -- its half-life is less than two weeks. Studies using a variety of protocols have found EGBE meets the U.S. EPA definition of “readily” biodegradable in both aerobic surface waters and under typical waste treatment plant conditions. In the air, EGBE has a half-life of less than two days.

EGBE has been found to cause toxicity in fish and other organisms only at the high concentrations that allow it to be classified in U.S. EPA’s “practically non-toxic” category.²⁶ Tests with algae, yeast, protozoa, bacteria and fungi also show that EGBE will not cause adverse effects except at concentrations well above any that have been found in the environment. The 1997 WHO review found any potential risk to aquatic organisms to be “low” and EGBE concentrations in air to be of “no environmental significance.”³¹

REVISING REGULATIONS

Despite these extensive health and environmental studies, EGBE has been categorized in the United States within a broad range of hazardous chemicals. When Congress listed 190 chemicals and categories in the 1990 Clean Air Act Amendments (CAAA) as Hazardous Air Pollutants (HAPs), it included the category of all “ethylene glycol ethers.” At that time, EPA had not specifically looked at the information available on EGBE. The listing thus ignored the substantial toxicological differences among the diverse chemicals that make up the category of ethylene glycol ethers. The listing also preceded many of the EGBE studies discussed above. In 1998, after reviewing the toxicity studies on several commercial ethylene glycol ethers, the EPA Air Office found EGBE to be among the members of the category not of special concern (63 Fed. Reg. 71376, Dec. 28, 1998).

EPA is directed under the CAAA to delist HAPs if there are “adequate data on the health and environmental effects of the substance to determine that emissions, ambient concentrations, bioaccumulation or deposition of the substance may not be anticipated to cause any adverse effects to human health or adverse environmental effects.” The Panel has filed a petition asking EPA to delist EGBE. The petition has been found complete (64 Fed. Reg. 42125, Aug. 3, 1999). If EGBE is delisted, U.S. facilities that manufacture, process and use the substance will not be subject to Maximum Achievable Control Technology (MACT) requirements under the CAAA for this compound.

In 1994, based on additional toxicological information, the United Nations (UN) Committee of Experts deleted EGBE from its list of substances requiring special toxicity labeling. As a result, EGBE (UN2369) was not included in the Ninth Revised Edition of the UN Recommendations. The U.S. Department of Transportation (as the U.S. representative to the UN Committee) has revised its Hazardous Materials Table to reflect the new classification by deleting EGBE.

CONCLUSIONS

EGBE is one of the most versatile chemicals in the marketplace today for a wide variety of uses. Human experience and animal studies have shown that it is unlikely to cause adverse health effects when used as directed and in accordance with product safety information and good hygiene practices. EGBE studies also show it is unlikely to cause adverse environmental impacts because it is not persistent, does not bioaccumulate, and has low toxicity to aquatic organisms.

Research continues so that industry, government and academic scientists can increase our knowledge about EGBE.

As with all chemicals, EGBE should be used with care and in accordance with governmental regulations. EGBE and products containing EGBE are not intended to be ingested. Airborne concentrations of EGBE should be maintained below permissible exposure limits. Consistent with governmental standards, skin contact with EGBE before it is diluted in commercial formulations should be avoided.

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This information was collected by the member companies of the American Chemistry Council Ethylene Glycol Ethers Panel.

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For the most current information on regulatory classification, use and handling of EGBE, consult your supplier's Material Safety Data sheets (MSDS) and other product literature.

**Background Scientific
Literature on EGBE**

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<p>A summary of the American Chemistry Council EGE Panel-sponsored research on ethylene glycol ethers is available from the American Chemistry Council EGE Panel.</p>
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