Ethylene Glycol

Crop Production

Identification of Petitioned Substance

Chemical Name:
Ethylene Glycol

Other Names:
1,2-dihydroxyethane
1,2-Ethanediol
monoethylene glycol
2-hydroxyethanol
ethylene alcohol
ethylene dihydrate

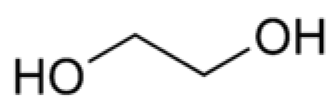
Trade Names:

CAS Number:
107-21-1

Other Codes:
European Inventory of Existing Commercial Chemical Substances (EINECS) No. 203-473-3
National Institute for Occupational Safety and Health/Registry of Toxic Effects of Chemical Substances – KW2975000
Hazardous Substance Data Bank – 5012
National Cancer Institute – C00920

Characterization of Petitioned Substance

Composition of the Substance:



Ethylene Glycol Chemical Structure

Ethylene glycol is used as a de-icer and anti-icer (antifreeze). It is a deactivator for all pesticides used before the crop emerges from the soil and in herbicides before or after the crop emerges. Also, it is a component in hydraulic brake fluid and inks, and is used as a solvent. The molecular formula for ethylene glycol is $C_2H_6O_2$ and the molecular weight is 62.7.

Properties of the Substance:

Product Chemistry	
Physical State	Viscous liquid
Color	Colorless
Odor	Odorless
Melting Point	– 13 degrees Centigrade
Boiling Point	198 degrees Centigrade
Specific Gravity	1.11
Water Solubility	Soluble in water
Vapor Pressure	0.06 mm Hg at 20 degrees Centigrade
Vapor Density	2.14
Flashpoint	127 degrees Centigrade
Explosive Limits	3.20 – 15.30%

Specific Uses of the Substance:

Ethylene glycol has been used in a wide variety of industrial applications because of its unique chemical and physical properties. Approximately 35% of all ethylene glycol is used to make solid state resins, 26% is used in antifreeze, 24% is used to make polyester fibers, 4% is used to make polyester films, 3% is used in chip resin exports, and 8% is used in surface coatings, polyester and alkyd resins, chemical intermediates, and other miscellaneous industrial applications (CMR, 2004).

Ethylene glycol plays an essential role in the transportation industry, where it is used as an ingredient in hydraulic brake fluids, as the major component in automotive antifreeze/coolant, and as a component of de-icing fluids for aircraft, runways, and taxiways (Forkner et al., 2004; Lewis, 2001; O'Neil et al., 2001; and Rebsdat and Mayer, 2005). Another important industrial use for ethylene glycol is as an intermediate in the synthesis of esters, ethers, and resinous products, particularly polyester fibers and resins (O'Neil et al., 2001; and Rowe and Wolf, 1982). As a solvent, ethylene glycol is used in the paint and plastic industries; the formulation of printers' inks, stamp pad inks, and inks for ball point pens; and as a softening agent in cellophane (O'Neil et al., 2001). Ethylene glycol has also been used as a stabilizer for soy bean foam used in fire extinguishers and in the manufacture of explosives, plasticizers, elastomers, and synthetic waxes (Lewis, 2001 and O'Neil et al., 2001). Earlier, Browning (1965) noted small amounts of ethylene glycol have been used in pharmaceutical preparations (components of skin lotions and powders and as a substitute for glycerin).

Approved Legal Uses of the Substance:

An inert ingredient is defined by the U.S. Environmental Protection Agency as any ingredient in a pesticide product that is not intended to affect a target pest. EPA has reassessed ethylene glycol under 40 CFR 180.920 when used as an inert ingredient "Antifreeze, deactivator for all pesticides used before crop emerges from soil and in herbicides before or after crop emerges." The Agency concluded in the reassessment that, based on the available information, when used in accordance with good agricultural practice, ethylene glycol could "be considered reassessed as safe under section 408(q) of the FFDCA." The conclusion from the tolerance exemption reassessment of ethylene glycol under 40 CFR 180.920 also applies to its tolerance exemption under 40 CFR 180.1040, and the exemption is to be maintained. The use pattern of ethylene glycol under 40 CFR 180.1040 significantly limits its exposure potential and does not impact in any significant way the exposure potential of ethylene glycol under 40 CFR 180.920, and therefore, the risk conclusions under 40 CFR 180.920 remain unchanged. Ethylene glycol can be found on page four of the 72 page list of inert ingredients last updated by EPA on January 27, 2009. –see: http://www.epa.gov/opprd001/inerts/inert_nonfooduse.pdf and http://www.epa.gov/opprd001/inerts/ethyleneglycol.pdf.

Under the Federal Insecticide, Fungicide, and Rodenticide Act, ethylene glycol is exempt from tolerances for residues when used in foliar applications to peanut plants (U.S. EPA, 2007a)

The U. S. Food and Drug Administration approved ethylene glycol for use only as components of adhesives used in articles to package, transport, or hold food (21 CFR 175.105).

Ethylene glycol is not listed in 21 CFR Part 184 by the U.S. Food and Drug Administration (FDA) as a direct food substance affirmed as generally recognized as safe (GRAS). It is not listed in 21 CFR Part 186 as an indirect food substance affirmed as GRAS. Nor is it listed among the more than 3000 substances that comprise an FDA inventory known as "Everything Added to Food in the United States" (EAFUS). The EAFUS list of substances contains ingredients added directly to food that FDA has either approved as food additives or listed or affirmed as GRAS.

Action of the Substance:

Ethylene glycol dissolves in water and is miscible in alcohol and acetone, has the capability to hold large amounts of heat before boiling, and lowers the freezing point of water (Lewis, 2001; O'Neil et al., 2001; and Rebsdat and Mayer, 2005). In addition, ethylene glycol is hygroscopic (has the ability to absorb twice its weight in water), is suitable for use as an industrial humectant (drying agent), and possesses excellent solvent properties (Forkner et al., 2004; Lewis, 2001; and O'Neil et al., 2001).

Status

U.S. Environmental Protection Agency:

Ethylene glycol is permitted as an inert ingredient for use in non-food use pesticide products by the U.S. Environmental Protection Agency (40 CFR 180.920) – see: http://www.epa.gov/opprd001/inerts/inert_nonfooduse.pdf

An inert ingredient is defined by the U.S. Environmental Protection Agency as any ingredient in a pesticide product that is not intended to affect a target pest. EPA announced its policy on toxic inert ingredients in pesticide products in the Federal Register of April 22, 1987 (52 FR 13305). Through its policy, EPA encourages the use of the least toxic inert ingredients available and requires the development of data necessary to determine the conditions of safe use of products that contain toxic inert ingredients. In developing this policy, EPA categorized inert ingredients into the following four lists according to toxicity:

List 1--Inerts of toxicological concern.
List 2--Potentially toxic inerts, with high priority for testing.
List 3--Inerts of unknown toxicity.
List 4--Inerts of minimal concern.

In the Federal Register of November 22, 1989 (58 FR 48314), EPA issued a notice announcing some modifications to the previously published Lists 1 and 2. In that notice, EPA also noted that List 4 was being divided into two parts. The original List 4 became List 4A, representing minimal risk inert ingredients. List 4B was created to represent inert ingredients for which EPA has sufficient information to conclude that their current use patterns in pesticide products will not adversely affect public health and the environment.

Ethylene glycol (CAS Registry No. 107-21-1) was on the U.S. Environmental Protection Agency's List 3 – Inerts of Unknown Toxicity. List 3 is now obsolete, and because EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to ethylene glycol when used as an inert ingredient in pesticide formulations, the List Classification for ethylene glycol was changed from List **3** to List 4B in 2006. http://www.epa.gov/opprd001/inerts/ethyleneglycol.pdf.

Under the Federal Insecticide, Fungicide, and Rodenticide Act, ethylene glycol is exempt from tolerances for residues when used in foliar applications to peanut plants (U.S. EPA, 2007a)

U.S. Environmental Protection Agency (2007b) has designated ethylene glycol as a hazardous air pollutant under the Clean Air Act. Ethylene glycol is on the list of chemicals appearing in "Toxic Chemicals Subject to Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986" and it has been assigned a reportable quantity limit of 5,000 pounds (U.S. EPA, 2007c). The reportable quantity limit represents the amount of a designated hazardous substance which, when released to the environment, must be reported to the appropriate authority.

U.S. Food and Drug Administration:

The U.S. Food and Drug Administration approved ethylene glycol for use only as components of adhesives used in articles to package, transport, or hold food (21 CFR 175.105).

Consumer Product Safety Commission:

Ethylene glycol (or mixtures containing 10% or more by weight of ethylene glycol) is designated as a hazardous substance under Section 3(b) of the Federal Hazardous Substances Act and requires special labeling (Consumer Product Safety Commission, 2007). The Commission identifies the major factors that it considers when evaluating liquid-filled children's products that contain hazardous chemicals, and informs the public of its experience with exposure to these hazardous chemicals to children. To reduce the risk of exposure to hazardous chemicals, such as mercury, ethylene glycol, diethylene glycol, methanol, ethylene chloride, petroleum distillates, toluene, xylene, and related chemicals, the Commission requests manufacturers to eliminate the use of such chemicals in children's products. The Commission also recommends that, before purchasing products for resale, importers, distributors, and retailers obtain assurances from manufacturers that liquid-filled children's products do not contain hazardous liquid chemicals.
See: http://edocket.access.gpo.gov/cfr_2009/janqtr/pdf/16cfr1500.231.pdf.

International:

Ethylene glycol is not listed as a carcinogen by the International Agency for Research on Cancer.

Ethylene glycol is not allowed for use in organic crop production by either the European Union (European Union, 2008) or Codex Alimentarius (Codex Alimentarius, 2008).

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

Evaluation Question #1: Is the petitioned substance formulated or manufactured by a chemical process? (From 7 U.S.C. § 6502 (21).)

Ethylene glycol is manufactured by a method introduced in 1937, where ethylene oxide is formed from ethylene by direct oxidation. Ethylene oxide is then hydrolyzed to ethylene glycol (Brown et al., 1980 and Forkner et al., 2004). Ethylene oxide reacts with water to produce ethylene glycol according to the chemical equation $C_2H_4O + H_2O \rightarrow HOCH_2CH_2OH$. This reaction can be catalyzed by either acids or bases, or can occur at neutral pH under elevated temperatures. This soon became the primary method for the production of ethylene glycol and is currently the only method used in the United States (Brown et al., 1980; Forkner et al., 2004; and Rebsdat and Mayer, 2005).

Ethylene oxide is converted to ethylene glycol through un-catalyzed neutral hydrolysis (pH 6 – 10) in the presence of a large excess of water at high temperatures and pressures (Forkner et al., 2004 and Rebsdat and Mayer, 2005). Selectivity of ethylene glycol is 89 – 91% in this process. The primary byproduct is di-ethylene glycol with higher glycols such as tri-ethylene and tetra-ethylene glycols formed in smaller amounts. This product mixture is fed through a series of evaporators to remove the water and then through vacuum distillation for separation and refinement of the individual glycols.

<u>Evaluation Question #2:</u> Is the petitioned substance formulated or manufactured by a process that chemically changes the substance extracted from naturally occurring plant, animal, or mineral sources? (From 7 U.S.C. § 6502 (21).)

There are no naturally occurring plant, animal, or mineral sources of ethylene glycol. The chemically synthesized ethylene glycol is the only form that is available for use.

<u>Evaluation Question #3:</u> Is the petitioned substance created by naturally occurring biological processes? (From 7 U.S.C. § 6502 (21).)

Ethylene glycol may be released to soil via natural processes associated with the metabolism of ethylene by plants (Blomstrom and Beyer, 1980). In vegetation of all types, most phases of plant development are affected by the metabolic process which produces ethylene glycol as a by-product. This biological process however, cannot produce enough ethylene glycol for the numerous uses it has commercially.

<u>Evaluation Question #4:</u> Is there environmental contamination during the petitioned substance's manufacture, use, misuse, or disposal? (From 7 U.S.C. § 6518 (m) (3).)

In air, estimated releases of 2.9 million pounds of ethylene glycol to the atmosphere from 1,487 domestic manufacturing and processing facilities in 2005, accounted for about 29% of the estimated total environmental releases from facilities required to report to the Toxics Release Inventory (TRI05, 2007). During the application of de-icing solutions to aircraft, an estimated 49 – 80% of de-icing solutions containing ethylene glycol are released on airport runways. The remainder is retained on the aircraft or is immediately dispersed to the air (Sills and Blakeslee, 1992).

In water, estimated releases of 0.54 million pounds of ethylene glycol to surface water from 1,487 domestic manufacturing and processing facilities in 2005, accounted for about 6% of the estimated total environmental releases from facilities required to report to the Toxics Release Inventory (TRI05, 2007). Ethylene glycol is released to surface waters in waste water from production and processing facilities, from spills, in runoff (i.e., through the use of ethylene glycol as de-icing fluids), and in the disposal of used antifreeze. The U.S. EPA (2000) estimated that 21 million gallons of aircraft de-icing fluid (including both ethylene and propylene glycol-based fluids) are discharged to surface waters per year in the United States with an additional 2 million gallons discharged to publically owned treatment works. Ethylene glycol that is released onto the ground when used in aircraft de-icing fluid may contaminate nearby groundwater (Corsi et al., 2001). Groundwater samples collected from a perched water table at the Ottawa Airport in Canada contained 415 mg/L of ethylene glycol (Sills and Blakeslee, 1992).

In soils, estimated releases of 1.7 million pounds of ethylene glycol to soils from 1,487 domestic manufacturing and processing facilities in 2005, accounted for about 17% of the estimated total environmental releases from facilities required to report to the Toxics Release Inventory (TRI05, 2007). An additional 1.9 million pounds, constituting about 19% of the total environmental emissions, were released via underground injection (TRI05, 2007). The major sources of ethylene glycol release to soil are from the disposal of used antifreeze fluids and de-icing fluids containing this compound (U.S. EPA, 1979 and 1987 and Ware, 1988). Ethylene glycol may also be released to soil via natural processes associated with the metabolism of ethylene by plants (Blomstrom and Beyer, 1980).

The above information was taken from the Agency for Toxic Substances & Disease Registry (ATSDR), Toxicological Profile for Ethylene Glycol. See- http://www.atsdr.cdc.gov/toxprofiles/tp96.html#bookmark09.

U.S. EPA TRI Program

The United States (U.S.) Environmental Protection Agency (EPA) Toxics Release Inventory (TRI) program collects information on the disposal or other releases and other waste management activities for over 650 chemicals from industrial sources in all 50 states and the U.S. territories.

The information has been collected annually since 1987. For 2005, the latest year for which data are available, disposal or other releases of TRI chemicals totaled almost 4.34 billion pounds from almost 23,500 U.S. facilities submitting over 89,300 chemical forms.

Evaluation Question #5: Is the petitioned substance harmful to the environment? (From 7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i).)

Ethylene glycol has a low vapor pressure and dissolves in water. If released to the atmosphere (i.e., as vapors generated at elevated temperatures), ethylene glycol should exist almost entirely in the vapor phase (Eisenreich et al., 1981). The high solubility of ethylene glycol in water ensures that at least partial removal of the compound will occur by wet deposition. Ethylene glycol released to surface water likely will not partition to the atmosphere via volatilization (Thomas, 1990). Ethylene glycol is not expected to adsorb to sediment or soil particles and it is expected to have a very high mobility in soil and could leach into groundwater (Swann et al., 1983).

Ethylene glycol undergoes rapid photochemical oxidation by reacting with hydroxyl free radicals with a half-life of 1.4 days (Atkinson, 1989 and U.S. EPA, 1993). It is degraded in both water (Battersby and Wilson, 1989; Bieszkiewicz et al., 1979; Bridie et al., 1979; Caskey and Taber, 1981; Dwyer and Tiedje, 1983; and Evans and David, 1974) and soil (Klecka et al., 1993; McGahey and Bouwer, 1992; and Revitt and Worrall, 2003) primarily by biodegradation. Based on the available data, ethylene glycol is biodegraded under both aerobic and anaerobic conditions from within a day to a few weeks.

The lethal concentrations (LC_{50}) of ethylene glycol in rainbow trout, bluegill/sunfish, and gold fish were 41,000 mg/L at 96 hours, 27,500 – 41,000 mg/L at 96 hours, and 27,500 – 41,000 mg/L at 96 hours, respectively. For the water flea, *Phytobacterium phosphoreum,* the LC_{50} was 46,300 mg/L at 48 hours.

The following is quoted directly from the Concise International Chemical Assessment Document (CICAD) on the environmental aspects of ethylene glycol:

"Ethylene glycol released to the atmosphere will be degraded by reaction with hydroxyl radicals; the half-life for the compound in this reaction has been estimated at between 0.3 and 3.5 days.

No hydrolysis of ethylene glycol is expected in surface waters.

The compound has little or no capacity to bind to particulates and will be mobile in soil.

The low octanol/water partition coefficient and measured bioconcentration factors in a few organisms indicate low capacity for bioaccumulation.

Ethylene glycol is readily biodegradable in standard tests using sewage sludge. Many studies show biodegradation under both aerobic and anaerobic conditions. Some studies suggest a lag phase before degradation, but many do not. Degradation occurs in both adapted and unadapted sludges. Rapid degradation has been reported in surface waters (less in salt water than in fresh water), groundwater, and soil inocula. Several strains of microorganisms capable of utilizing ethylene glycol as a carbon source have been identified."

This CICAD on the environmental aspects of ethylene glycol was prepared by the Institute of Terrestrial Ecology, United Kingdom, based on the report *Environmental hazard assessment: Ethylene glycol* (Nielsen et al., 1993). The report on ethylene glycol prepared by the German Chemical Society Advisory Committee on Existing Chemicals of Environmental Relevance (BUA, 1991) was also used as a source document. In addition to these documents, a search of recent literature was conducted up to 1998. This CICAD was approved as an international assessment at a meeting of the Final Review Board, held in Washington, DC, USA, on 8-11 December 1998. The CICAD report on ethylene glycol can be viewed at: http://www.inchem.org/documents/cicads/cicads/cicad_22.htm.

Evaluation Question #6: Is there potential for the petitioned substance to cause chemical interaction with other substances used in organic crop or livestock production? (From 7 U.S.C. § 6518 (m) (1).)

According to Material Safety Data Sheet (MSDS) for ethylene glycol from Malinckrodt Baker, Inc., ethylene glycol is incompatible with strong oxidizing agents. It reacts violently with chlorosulfonic acid, oleum, sulfuric acid, and perchloric acid. At room temperature it will cause ignition with chromium trioxide, potassium permanganate and sodium peroxide; causes ignition at 212° F (100° C) with ammonium dichromate, silver chlorate, sodium chloride, and uranyl nitrate. Of the specific chemicals listed as being incompatible with ethylene glycol, none appear on the National Organic Program's *National List of Allowed and Prohibited Substances*.

Three incompatibles appear in the *OMRI Generic Materials List* (2009), sodium chloride, sulfuric acid, and potassium permanganate. The Organic Materials Review Institute (OMRI) is a national nonprofit organization that reviews products to determine their suitability for producing, processing, and handling organic food and fiber under the USDA National Organic Program Rule.

Sodium chloride (salt) is allowed with restrictions for use as a pest lure, repellent, or as part of a trap, or as a disease control. It may be used for other pesticidal purposes only if the requirements of 205.206(e) or met. For livestock, sodium chloride may be used as a source of sodium and chlorine, and in processing and handling, it is allowed but must not contain materials such as prohibited flowing agents or whiteners.

Sulfuric acid is allowed with restrictions and may be used as both an adjuvant or inert ingredient in combination with active pesticidal substances that are permitted as pesticides in organic production. It may also be used to adjust the pH of liquid fish products. It is considered to be permitted as a sanitizer or cleaner provided measures are taken to prevent contact of the organically produced products or ingredients with the substance used.

Potassium permanganate is allowed with restrictions and may be used for disinfecting livestock facilities or for food contact surfaces, provided measures are taken to prevent contact of the organic livestock, organically produced products, or organic ingredients with the substance used. It may be used in packaging material provided there is no direct contact with organic processed products.

Sodium chloride and sulfuric acid are used in organic crop production as would be ethylene glycol if added to the National List. However, the probability of ethylene glycol reacting with either is unknown when all substances are used as intended and according to the directions of the manufacturers.

Evaluation Question #7: Are there adverse biological or chemical interactions in the agro-ecosystem by using the petitioned substance? (From 7 U.S.C. § 6518 (m) (5).)

U.S. Environmental Protection Agency (2007b) has designated ethylene glycol as a hazardous air pollutant under the Clean Air Act. Ethylene glycol (or mixtures containing 10% or more by weight of ethylene glycol) is designated as a hazardous substance under Section 3(b) of the Federal Hazardous Substances Act and requires special labeling (Consumer Product Safety Commission, 2007). It has the ability to persist in the environment for a few weeks before it biodegrades and it could potentially interact with other chemicals and organic substances. However, the LC_{50} in fish is quite high and the reportable quantity limit of 5,000 pounds when it is released to the environment would tend to support the contention that ethylene glycol may not have adverse effects on the agro-ecosystem when used as intended.

Evaluation Question #8: Are there detrimental physiological effects on soil, organisms, crops, or livestock by using the petitioned substance? (From 7 U.S.C. § 6518 (m) (5).)

The rate of biodegradation of ethylene glycol in simulated subsurface soils is dependent on substrate concentrations, soil types, and ambient soil temperature. Greater than 95% removal was consistently accomplished in <5 and 7 days at ethylene concentrations of 100 and 1,000 ppm, respectively; however, substrate concentrations of 10,000 ppm showed negligible loss of ethylene glycol. The rate of degradation was higher in soils with high organic matter. A doubling in the degradation rate was observed with a 10°C increase in soil temperature. McGahey and Bouwer, (1992) concluded that microorganisms naturally occurring in soils and groundwater are effective in biodegrading ethylene glycol with a half-life ranging from 0.2 to 0.9 days. Therefore, it seems that soils and microorganisms are not detrimentally affected by ethylene glycol, except at very high concentrations.

Concise International Chemical Assessment Documents (CICADs) are the latest in a family of publications from the International Programme on Chemical Safety (IPCS) -- a cooperative programme of the World Health Organization (WHO), the International Labour Organisation (ILO), and the United Nations Environment Programme (UNEP). CICADs join the Environmental Health Criteria documents (EHCs) as authoritative documents on the risk assessment of chemicals.

The following is directly quoted from the Concise International Chemical Assesment Document 22, *Ethylene Glycol: Environmental Aspects.*

> "Terrestrial organisms are much less likely to be exposed to ethylene glycol and generally show low sensitivity to the compound. Concentrations above 100 000 mg/litre were needed to produce toxic effects on yeasts and fungi from soil. Very high concentrations and soaking of seeds produced inhibition of germination in some experiments; these are not considered of environmental significance. A no-observed-effect level (NOEL) for orally dosed ducks at 1221 mg/kg body weight and reported lethal doses for poultry at around 8000 mg/kg body weight indicate low toxicity to birds."

No information was found on the effect of ethylene glycol on crops. Domestic cats have a voracious appetite for ethylene glycol and often experience kidney failure when they have access to antifreeze containing this compound (Lewis, 1998). This is likely due to the sweet taste of ethylene glycol and other domestic and farm animals may react in a similar manner. Therefore, animals should not have access to ethylene glycol containing compounds and any spills should be cleaned-up immediately.

<u>Evaluation Question #9:</u> Is there a toxic or other adverse action of the petitioned substance or its breakdown products? (From 7 U.S.C. § 6518 (m) (2).)

The National Institute for Occupational Safety and Health/Registry of Toxic Effects of Chemical Substances has the following toxicological data for ethylene glycol:

Ocular Exposure:

Draize test, rabbit, eye: 500 mg/24 hours –mild
Draize test, rabbit, eye: 100 mg/one hour – mild
Draize test, rabbit, eye: 1,440 mg/six hours - moderate

Lethal Dose (LD_{50}):

Oral, mouse: LD_{50} = 5,500mg/kg
Oral, rat: LD_{50} = 4,700mg/kg
Skin, rabbit: LD_{50} = 9,530 uL/kg

Ethylene glycol is more acutely toxic for humans than for laboratory animals by ingestion. The single oral lethal dose for humans has been estimated at 1.4 mL/kg or about 100 mL for an adult.

Carcinogenicity:

Ethylene glycol is not listed as a carcinogen by the American Conference of Governmental Industrial Hygienists, International Agency for Research on Cancer, the National Toxicology Program, or California Proposition 65.

Data on the epidemiological, reproductive, neurotoxic, and mutagenic effects of ethylene glycol are not available. An expert panel convened by the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction concluded that developmental and reproductive risks stemming from exposure to the chemicals propylene glycol and ethylene glycol are negligible.

In case of the ingestion of ethylene glycol, it is sequentially metabolized to glycoaldehyde, glycolic acid, glyoxylic acid, oxalic acid, and finally to calcium oxalate. Adverse renal effects occur 24 – 72 hours after the ingestion of large amounts of ethylene glycol and are characterized by the presence of calcium oxalate monohydrate crystals in the renal tubules and urine. Characteristic histo-pathological changes include renal tubular focal degeneration, atrophy, and interstitial inflammation. Renal damage, if untreated, can lead to renal failure. With therapy, normal or near-normal renal function can be restored (Agency for Toxic Substances and Disease Registry, 2007).

<u>Evaluation Question #10:</u> Is there undesirable persistence or concentration of the petitioned substance or its breakdown products in the environment? (From 7 U.S.C. § 6518 (m) (2).)

A primary tool used to determine the environmental fate of chemicals is the determination of the octanol/water partition coefficient which is the ratio of the chemical concentration in octanol divided by the concentration in water. The octanol/water partition coefficient has been shown to correlate well with bioconcentration factors in aquatic organisms and adsorption to soil or sediment. An octanol-water partition coefficient of <3 is considered low. Ethylene glycol dissolves in water. In soils, ethylene glycol is expected to have a very high mobility, especially in moist soil, therefore, it could leach into ground water (Swann et al., 1983). Its low octanol/water partition coefficient value of -1.36 suggests that bio-concentration and bio-magnification of ethylene glycol are not likely to occur (Agency for Toxic Substances and Disease Registry, 2007). Based on the available data, ethylene glycol is biodegraded under both aerobic and anaerobic conditions from within a day to a few weeks, depending on on substrate concentrations, soil types, and ambient soil temperature.

It appears that ethylene glycol degrades more rapidly at higher ambient temperatures than at low ambient temperatures (Evans and David, 1974). Dwyer and Tiedje (1983) proposed that the methanogenic degradation pathway for ethylene glycol proceeds through the formation of ethanol, followed by acetate. Both ethanol and acetate would be readily metabolized and utilized as energy sources by microorganisms.

<u>Evaluation Question #11:</u> Is there any harmful effect on human health by using the petitioned substance? (From 7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i) and), 7 U.S.C. § 6518 (m) (4).)

Some of the potential health effects of ethylene glycol are:

Eye: May cause moderate eye irritation.

Skin: Low hazard for usual industrial handling. A single prolonged skin exposure is not likely to result in the material being absorbed in harmful amounts.

Ingestion: The lethal dose in adult humans for ethylene glycol is about 100 mL (1/3 cup). Swallowing may cause nausea, vomiting, or diarrhea. Excessive exposure may cause central nervous system effects, cardio-pulmonary effects (metabolic acidosis), and kidney failure.

Inhalation: If ethylene glycol is heated or misted in work areas that are poorly ventilated, vapor/mist may accumulate and cause respiratory irritation and symptoms such as headache and nausea. Ethylene glycol has a very low vapor pressure at room temperature, so inhalation exposures are not expected unless the material is heated or misted.

Chronic exposure: Ethylene glycol may cause kidney failure. Repeated excessive exposure to ethylene glycol may cause irritation of the upper respiratory tract. In humans, effects have been reported on the central nervous system, including nystagmus (involuntary, rapid, rhythmic movement of the eyeball).

<u>Evaluation Question #12:</u> Is there a wholly natural product that could be substituted for the petitioned substance? (From 7 U.S.C. § 6517 (c) (1) (A) (ii).)

There are two solvents on the Organic Materials Review Institute's Generic Materials List (2007) that possibly could be used in the place of ethylene glycol. Ethyl alcohol and isopropyl alcohol are listed on the Organic Material Review Institute's Generic Materials List (2007) that may be substituted for ethylene glycol when used as an inert ingredient. Both alcohols are permitted as inert ingredients for use in non-food use pesticide products by the U.S. Environmental Protection Agency (40 CFR 180.920), and can be found on pages 42 and 44 of the 72 page list of inert ingredients last updated by EPA on January 27, 2009.

If ethylene glycol is used in fungicide formulations, there are natural fungicides available for use by both homeowners and professionals to combat plant diseases (Beckerman, 2008). The active ingredients in these compounds include sulfur, lime-sulfur, copper, horticultural oil, neem oil, and bicarbonates.

<u>Evaluation Question #13:</u> Are there other already allowed substances that could be substituted for the petitioned substance? (From 7 U.S.C. § 6517 (m) (6).)

Ethylene glycol is a solvent that is used to disperse active compounds to control plant pests and diseases and is defined by the U.S. Environmental Protection Agency as an inert ingredient in non-food use pesticide products. It could also used as a solvent in herbicides. As alternatives, organic crop producers could use synthetic substances that are already allowed in organic crop production to control plant pests listed in 7 CFR 205.601. They include: ammonium carbonate; boric acid; copper sulfate; elemental sulfur; lime sulfur; oils – horticultural – narrow range oils as dormant, suffocating, and summer oils; insecticidal soaps; sticky traps/barriers; and sucrose octanoate esters. Also, these synthetic substances could possibly be used with phermones to control insects and pests. Some of these substances have conditions or restriction for use and depending on the crop of interest and the pest/insect of concern, some decision would have to be made about which one may be the most appropriate for use.

In the case of weed control, organic crop producers could use soap-based herbicides and mulches as prescribed in 7 CFR 205.601. Again, the crop of interest and the weed of concern would affect which method of control would be most applicable.

For plant diseases, the following synthetic substances can be used: coppers – fixed – copper hydroxide; copper oxide, copper oxy-chloride; copper products exempt from a U.S. Environmental Protection Agency tolerance; copper sulfate; hydrated lime; hydrogen peroxide; lime sulfur; oils – horticultural - narrow range oils – dormant, suffocating, and summer oils; peracetic acid; potassium bicarbonate; elemental sulfur; streptomycin; and tetracycline. The synthetic copper compounds allowed for use in organic crop production must be used in such a manner as to minimize the copper accumulation in soils. Other allowed synthetic substances such as peracetic acid, streptomycin (used in apples and pears only); and tetracycline are for fire blight control only. Therefore, depending on the infected crop and the plant disease of concern, these allowed substances may or may not be of benefit and some decision would be needed as to which one is the most appropriate for use. In all cases (pest/insect control; plant disease control; and weed control), the conditions for using materials on the National List of Synthetic Substances must be documented in the organic farming system plan.

<u>Evaluation Question #14:</u> Are there alternative practices that would make the use of the petitioned substance unnecessary? (From 7 U.S.C. § 6517 (m) (6).)

As found in 7 CFR 205.205, organic crop producers must implement a crop rotation including but not limited to sod, cover crops, green manure crops, and catch crops that provides for pest management in annual and perennial crops. In addition, cultural practices that remove habitat for pest organisms and the selection of plant species and varieties that are resistant to prevalent pests are important alternative practices. Pest infestations may also be controlled by the augmentation or introduction of predators and parasites of the pest, development of habitat for natural enemies of the pests, and the use of non-synthetic controls such as lures, traps, and repellants. When these practices prove insufficient to prevent or control pests, a biological or botanical substance or a substance on the National List of Synthetic Substances allowed for use in organic crop production (7 CFR 205.601) may be applied to prevent, suppress, or control pests. Also, these substances could possibly be used in conjunction with phermones to control insects and pests (see information in the response to Question 13).

In the case of weeds, sanitation measures to remove weed seeds and cultural practices that enhance crop health, including the selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent weeds. Weeds may also be controlled through: 1) mulching with fully biodegradable materials; 2) mowing; 3) livestock grazing; 4) hand weeding and mechanical cultivation; 5) flame, heat, or electrical means; or 6) plastic or other synthetic mulches provided they are removed from the field at the end of the growing or harvest season. When these practices prove insufficient to prevent or control weeds, soap-based herbicides or mulches on the National List of Synthetic Substances allowed for use in organic crop production (7 CFR 205.601) may be applied to prevent, suppress, or control weeds (see information in the response to Question 13).

In the case of plant diseases, sanitation measures to remove disease vectors and cultural practices that enhance crop health, including the selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent diseases. Plant diseases may also be controlled through management practices which suppress the spread of disease organisms and the application of non-synthetic biological, botanical, or mineral inputs. When these practices prove insufficient to prevent or control plant diseases, a substance on the National List of Synthetic Substances allowed for use in organic crop production (7 CFR 205.601) may be applied to prevent, suppress, or control plant diseases (see information in the response to Question 13).

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