Supporting Documents for Initial Risk-Based Prioritization of High Production Volume Chemicals

Chemical/Category: **CAS No. 110-71-4, Ethane, 1,2-dimethoxy- (also known as 1,2-Dimethoxyethane, or Monoglyme)**

Contents:

QUALITATIVE SCREENING-LEVEL RISK CHARACTERIZATION FOR 1, 2-Dimethoxyethane (CAS No. 110-71-4) (Monoglyme)

1. Background

The High Production Volume (HPV) Challenge Program[1] is a voluntary initiative aimed at developing and making publicly available screening-level health and environmental effects information on chemicals manufactured in or imported into the United States (U.S.) in quantities greater than one million pounds per year. In the Challenge Program, producers and importers of HPV chemicals voluntarily sponsor chemicals; sponsorship entails the identification and initial assessment of the adequacy of existing toxicity data/information, conducting new testing if adequate data do not exist, and making both new and existing data and information available to the public. Each complete data submission contains data on 18 internationally agreed to "SIDS" (Screening Information Data Set[Error! Bookmark not defined.,2]) endpoints that are screening-level indicators of potential hazards (toxicity) for humans or the environment and environmental fate.

The Environmental Protection Agency's Office of Pollution Prevention and Toxics (OPPT) is evaluating the data submitted in the HPV Challenge Program on approximately 1,400 sponsored chemicals. Data submitted to the Organisation for Economic Co-operation and Development (OECD) HPV Programme are also being evaluated. OPPT developed a screening-level hazard characterization that consists of an objective evaluation, conducted according to established EPA guidance**Error! Bookmark not defined.**,[3], of the quality and completeness of the data set provided and is based primarily on hazard data provided by sponsors. The characterization does not draw conclusions regarding the completeness of all data generated with respect to a specific chemical substance or mixture. The OECD SIDS documents (SIDS Initial Assessment Profile; SIAP and SIDS Initial Assessment Report; SIAR) provide similar information. Under both the HPV Challenge and OECD HPV Programs, chemicals that have similar chemical structures, properties and biological activities may be grouped together and their data shared across the resulting category. Evaluation of chemical category formation and data extrapolation(s) among category members is performed in accord with established U.S. EPA[1] and OECD[4] guidance.

In 2006 and 2007, EPA received data on uses of and reasonably likely exposures to chemicals on the Toxic Substances Control Act (TSCA) Inventory of existing chemicals, submitted in accordance with the requirements of the Inventory Update Reporting (IUR) rule[5]. Information is collected every five years under IUR, promulgated under the authority of section 8(a) of TSCA. The most recent reports pertain to chemicals manufactured in (including imported into) the U.S. during calendar year 2005 in quantities of 25,000 pounds or more at a single site. Information is reported on the identity of the chemical manufactured or imported and the quantity, physical form, and number of persons reasonably likely to be exposed during manufacture of the chemical. For chemicals manufactured or imported in quantities of 300,000 pounds or more at a single site during calendar year 2005, additional information was reported on the industrial processing and uses of the chemical, the number of industrial processing sites and of employees reasonably likely to be exposed to the chemical at these sites, the consumer and commercial uses of the chemical and an indication whether the chemical is used in products intended for use by children under 14 years of age.

For these qualitative screening-level risk characterization documents, EPA has reviewed the IUR data to evaluate exposure potential. In addition, exposure information that may have become available through prior Agency actions has been considered, as appropriate. The resulting exposure information has been combined with the screening-level hazard characterizations to develop this qualitative screening-level risk characterization[6,7]. These screening-level risk characterizations are technical documents intended to support subsequent decisions and actions by OPPT.

---

[1] U.S. EPA. High Production Volume (HPV) Challenge Program; http://www.epa.gov/chemrtk/index.htm.
[2] U.S. EPA. HPV Challenge Program – Information Sources; http://www.epa.gov/chemrtk/pubs/general/guidocs.htm.
[3] U.S. EPA. Risk Assessment Guidelines; http://cfpub.epa.gov/ncea/raf/rafguid.cfm.
[4] OECD. Guidance Document on the Development and Use of Chemical Categories; http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html.
[5] U.S. EPA – Basic IUR Information: http://www.epa.gov/opptintr/iur/pubs/guidance/basic-information.htm
[6] U.S. EPA Guidelines for Exposure Assessment; http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=15263
[7] U.S. EPA. Risk Characterization Program; http://www.epa.gov/osa/spc/2riskchr.htm.

Accordingly, the document is not written with the goal of informing the general public. The purpose of the qualitative screening level risk characterizations is two-fold: to support initial risk-based decisions to prioritize chemicals and inform risk management options and to identify data needs for individual chemicals or chemical categories.

2. Supporting Chemical Justification

The sponsor submitted data for additional chemicals to support characterization of some hazard endpoints for the HPV chemical 1,2-dimethoxyethane, or monoglyme. The supporting chemicals are 1,3-dioxolane (CAS No. 646-06-0) for the aquatic toxicity endpoints and 2-methoxyethanol (CAS No. 109-86-4) for the human health toxicity endpoints. EPA accepted the use of 1,3-dioxalane as a supporting chemical for aquatic toxicity because it is similar to monoglyme in terms of chemical class (neutral organic/diether) and it has a similar octanol-water partition coefficient. For the human health endpoints, 2-methoxyethanol is a major metabolite of monoglyme in mammals. Thus, EPA agrees that these chemicals are appropriate analogs for monoglyme.

3. Physical-Chemical Properties and Environmental Fate

This report was prepared using the best available data from a number of sources, but draws no conclusions regarding whether additional relevant data may exist. Monoglyme is a liquid at room temperature. It has high water solubility and high vapor pressure. It is highly mobile in soil, does not bioaccumulate, and does not hydrolyze under environmental pHs. Biodegradation is expected to be slow. In the atmosphere, it is expected to photodegrade within slightly over one day. Based on these findings, monoglyme is expected to be moderately persistent (P2) and the bioaccumulation potential for monoglyme is ranked low (B1) based on its estimated bioconcentration factor (BCF) of 3.

4. Hazard Characterization

Aquatic Organism Toxicity. The potential aquatic toxicity of monoglyme was assessed using data from the analog 1, 3-dioxolane (CAS No. 646-06-0). The evaluation of available aquatic toxicity data on the analog suggests that the potential acute hazard for fish, aquatic invertebrates and aquatic plants is low.

Human Health Toxicity. The acute toxicity of monoglyme is low via oral, dermal and inhalation routes of exposure. The potential toxicity from repeated exposure to monoglyme was assessed using a major metabolite, 2-methoxyethanol (CAS No. 109-86-4). In laboratory animals, repeated exposure to 2-methoxyethanol results in testicular degeneration and adverse effects on the process of blood cell formation. The thymus and adrenal gland are also potential targets of toxicity. The metabolism of monoglyme to 2-methoxy acetic acid, which interferes with sperm production, can lead to adverse effects on reproduction. Developmental toxicity studies with monoglyme in laboratory animals indicate adverse effects on fetal body weight, skeletal structure and survival. Several genetic toxicity studies with monoglyme are available. Monoglyme was positive for causing gene mutations in bacteria. In mammalian cells, monoglyme did not show a potential to induce gene mutations, but did induce sister chromatid exchanges (SCE) and chromosomal aberrations. The potential health hazard of monoglyme is high based on the results of the repeated-dose (effects on blood, thymus, adrenal gland, and testicular degeneration) and developmental (increased fetal death and skeletal effects and decreased fetal body weight) toxicity studies at relatively low doses. Available data also suggest that monoglyme has the potential to be genotoxic.

5. Exposure Characterization

This exposure characterization was completed using available 2006 Inventory Update Rule (IUR) submissions. Data and information that are claimed Confidential Business Information (CBI) by the submitter were reviewed and considered by EPA in preparing this assessment but are not disclosed in this summary.

In addition, the following sources were reviewed to identify exposure and use information: the HPV Challenge Submissions, OECD SIDS Data, the Toxics Release Inventory (TRI), OSHA PEL documentation, various databases and public sources.

1, 2-Dimethoxyethane was manufactured and/or imported in the United States in amounts ranging from 1,000,000 to 10,000,000 pounds in 2005. The HPV submission indicates that the chemical is used primarily as an industrial solvent, process aid and as a component of lithium batteries and industrial coatings.

Exposure to Workers
The National Occupational Exposure Survey (NOES), conducted between 1981 and 1983 estimated a total of 3319 workers potentially exposed to this chemical (NIOSH, 2007b). Based on IUR reporting, the maximum total number of workers likely to be exposed to this chemical during manufacturing and industrial processing and use is less than 100. There may be additional potentially exposed workers that are not included in this estimate since not all production volume has been accounted for, and there is at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions. This chemical has a vapor pressure of 48 torr at 20°C. OPPT has established 0.001 torr as a value above which worker exposures to vapors should be estimated for chemical assessments. Therefore, this chemical's vapor pressure could result in significant worker exposures to vapors if workers are close to the liquid. This chemical does not have an OSHA Permissible Exposure Limit.

The IUR-based ranking for worker exposure is high.

Exposures to General Population and the Environment
The chemical is not on the Toxics Release Inventory. Based on use information, EPA assumes for the purpose of this risk prioritization that there is potential for exposures to the general population and the environment. The IUR-based ranking for general population and the environment is high due to the assumption that there will be exposure to this chemical.

Exposure to Commercial Workers and Consumers
Non-CBI IUR information indicates potential exposure to monoglyme for commercial workers and consumers. Based on its vapor pressure as cited above, there could be significant worker exposures to vapors if workers are near products containing this chemical. Information provided also suggests that monoglyme will be used in consumer products. The IUR-based ranking for commercial workers and consumers is high due to the assumption that monoglyme is used in commercial worker/consumer products.

Exposure to Children
Information provided suggests that monoglyme will be used in commercial/consumer products, including children's products. The IUR-based ranking for children's exposure to monoglyme is high due to the assumption it is used in products intended for use by children.

6. Risk Characterization

The statements and rationale provided below are intended solely for the purpose of this screening-level and qualitative risk characterization and will be used for prioritizing substances for future work in the U.S. HPV Challenge Program.

6.1. Risk Statement and Rationale

Potential Risk to Aquatic Organisms from Environmental Releases (*LOW CONCERN):* EPA assumes there is potential for exposure to aquatic organisms from environmental releases. Although monoglyme is considered moderately persistent in the environment, it has a low acute aquatic toxicity hazard, which suggests a low concern for potential risk to aquatic organisms from environmental releases.

Potential Risk to the General Population from Environmental Releases (MEDIUM CONCERN): EPA assumes there is potential for exposure to the general population from environmental releases. Monoglyme is considered to be moderately persistent in the environment. The high concern for hazard to human health (at relatively low doses in animal studies) combined with potential exposures suggests a medium concern for potential risk to the general population from environmental releases.

Potential Risk to Workers (HIGH CONCERN): Available IUR data indicate that workers are likely to be exposed to monoglyme. The high concern for hazard to human health (at relatively low doses in animal studies) combined with the likely exposures that occur in the occupational setting suggests a high concern for potential risk to workers.

Potential Risk to Commercial Workers and Consumers from Known Uses (HIGH CONCERN): Available IUR data indicate that commercial workers and consumers will be exposed to monoglyme. The high concern for hazard to human health (at relatively low doses in animal studies) combined with the possible exposures that occur in commercial worker and consumer use settings suggests a high concern for potential risk to both groups.

Potential Risk to Children from Possible Use of Products with Monoglyme (HIGH CONCERN):
Available IUR data indicate that children are exposed to monoglyme. The high concern for hazard to human health is important in the case of children's health because animal studies indicate this chemical is toxic to developing organisms at relatively low doses in animal studies. Therefore, the high hazard concerns combined with possible exposures suggest a high concern for potential risk to children.

6.2. Uncertainties

Monoglyme may have minor uses that were not reported in IUR.

6.3. Data Needs

No data needs have been identified at this time.

SCREENING-LEVEL HAZARD CHARACTERIZATION FOR HIGH PRODUCTION VOLUME CHEMICALS

SPONSORED CHEMICAL

1,2-Dimethoxyethane (CAS No. 110-71-4)
[9th CI Name: Ethane, 1,2-dimethoxy-]

SUPPORTING CHEMICALS

1,3-Dioxolane (CAS No. 646-06-0)
2-Methoxyethanol (CAS No. 109-86-4)

August 2007

Revised: February 2008

Prepared by

High Production Volume Chemicals Branch
Risk Assessment Division
and
Exposure Assessment Branch
Economics, Exposure and Technology Division

Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

SCREENING-LEVEL HAZARD CHARACTERIZATION OF HIGH PRODUCTION VOLUME CHEMICALS

The High Production Volume (HPV) Challenge Program[8] is a voluntary initiative aimed at developing and making publicly available screening-level health and environmental effects information on chemicals manufactured in or imported into the United States in quantities greater than one million pounds per year. In the Challenge Program, producers and importers of HPV chemicals voluntarily sponsor chemicals; sponsorship entails the identification and initial assessment of the adequacy of existing toxicity data/information, conducting new testing if adequate data do not exist, and making both new and existing data and information available to the public. Each complete data submission contains data on 18 internationally agreed to "SIDS" (Screening Information Data Set**Error! Bookmark not defined.**[9]) endpoints that are screening-level indicators of potential hazards (toxicity) for humans or the environment.

The Environmental Protection Agency's Office of Pollution Prevention and Toxics (OPPT) is evaluating the data submitted in the HPV Challenge Program on approximately 1,400 sponsored chemicals. OPPT is using a hazard-based screening process to prioritize review of the submissions. The hazard-based screening process consists of two tiers described below briefly and in more detail on the Hazard Characterization website[10].

Tier 1 is a computerized sorting process whereby key elements of a submitted data set are compared to established criteria to "bin" chemicals/categories for OPPT review. This is an automated process performed on the data as submitted by the sponsor. It does not include evaluation of the quality or completeness of the data.

In Tier 2, a screening-level hazard characterization is developed by EPA that consists of an objective evaluation of the quality and completeness of the data set provided in the Challenge Program submissions. The evaluation is performed according to established EPA guidance**Error! Bookmark not defined.**'[11] and is based primarily on hazard data provided by sponsors. EPA may also include additional or updated hazard information of which EPA, sponsors or other parties have become aware. The hazard characterization may also identify data gaps that will become the basis for a subsequent data needs assessment where deemed necessary. Under the HPV Challenge Program, chemicals that have similar chemical structures, properties and biological activities may be grouped together and their data shared across the resulting category. This approach often significantly reduces the need for conducting tests for all endpoints for all category members. As part of Tier 2, evaluation of chemical category rationale and composition and data extrapolation(s) among category members is performed in accord with established EPA**Error! Bookmark not defined.** and OECD[12] guidance.

The screening-level hazard characterizations that emerge from Tier 2 are important contributors to OPPT's existing chemicals review process. These hazard characterizations are technical documents intended to support subsequent decisions and actions by OPPT. Accordingly, the documents are not written with the goal of informing the general public. However, they do provide a vehicle for public access to a concise assessment of the raw technical data on HPV chemicals and provide information previously not readily available to the public. The public, including sponsors, may offer comments on the hazard characterization documents.

The screening-level hazard characterizations, as the name indicates, do not evaluate the potential risks of a chemical or a chemical category, but will serve as a starting point for such reviews. In 2007, EPA received data on uses of and exposures to high-volume TSCA existing chemicals, submitted in accordance with the requirements of the Inventory Update Reporting (IUR) rule. For the chemicals in the HPV Challenge Program, EPA will review the IUR data to evaluate exposure potential. The resulting exposure information will then be combined with the screening-level hazard characterizations to develop screening-level risk characterizations[4,13]. The screening-level risk characterizations will inform EPA on the need for further work on individual chemicals or categories. Efforts are currently underway to consider how best to utilize these screening-level risk characterizations as part of a risk-

[8] U.S. EPA. High Production Volume (HPV) Challenge Program; http://www.epa.gov/chemrtk/index.htm.
[9] U.S. EPA. HPV Challenge Program – Information Sources; http://www.epa.gov/chemrtk/pubs/general/guidocs.htm.
[10] U.S. EPA. HPV Chemicals Hazard Characterization website (http://www.epa.gov/hpvis/abouthc.html).
[11] U.S. EPA. Risk Assessment Guidelines; http://cfpub.epa.gov/ncea/raf/rafguid.cfm.
[12] OECD. Guidance on the Development and Use of Chemical Categories; http://www.oecd.org/dataoecd/60/47/1947509.pdf.
[13] U.S. EPA. Risk Characterization Program; http://www.epa.gov/osa/spc/2riskchr.htm.

based decision-making process on HPV chemicals which applies the results of the successful U.S. High Production Volume Challenge Program and the IUR to support judgments concerning the need, if any, for further action.

SCREENING-LEVEL HAZARD CHARACTERIZATION
1,2-Dimethoxyethane (CAS No. 110-71-4)

Introduction

The sponsor, Ferro Corporation, submitted a Test Plan and Robust Summaries to EPA for 1,2-Dimethoxyethane (CAS Number 110-71-4; 9th CI name: ethane, 1,2-dimethoxy-), or monoglyme, on December 27, 2001. EPA posted the submission on the ChemRTK HPV Challenge Website on January 3, 2002 (http://www.epa.gov/chemrtk/pubs/summaries/dimetho/c13455tc.htm). EPA comments on the original submission were posted to the website on July 3, 2002. Public comments were also received and posted to the website. The sponsor submitted updated/revised documents on August 27, 2002, which were posted to the ChemRTK website on September 5, 2002.

This screening-level hazard characterization is based primarily on the review of the test plan and robust summaries of studies submitted by the sponsor(s) under the HPV Challenge Program. In preparing the hazard characterization, EPA considered its own comments and public comments on the original submission as well as the sponsor's responses to comments and revisions made to the submission. Summary tables of SIDS endpoint data are provided herein and the structure(s) of the chemical(s) are provided in the appendix. The screening-level hazard characterization for environmental and human health toxicity is based largely on SIDS endpoints and is described according to established EPA or OECD effect level definitions and hazard assessment practices.

Supporting Chemical Justification

The sponsor submitted data for additional chemicals to support characterization of some endpoints. The supporting chemicals are: 1,3-dioxolane (CAS No. 646-06-0) and 2-methoxyethanol (CAS No. 109-86-4). EPA agrees that these chemicals are appropriate analogs for monoglyme. Chemical structures are provided in the data table in the Appendix.

Summary-Conclusion

Monoglyme is a liquid at room temperature. It has high water solubility and high vapor pressure. It is highly mobile in soil, does not bioaccumulate, and does not hydrolyze under environmental pHs. Biodegradation is expected to be slow. In the atmosphere, it is expected to photodegrade within slightly over one day. Based on these findings, monoglyme is expected to be moderately persistent (P2) and the bioaccumulation potential for monoglyme is ranked low (B1) based on its estimated bioconcentration factor (BCF) of 3.

The evaluation of available aquatic toxicity data on supporting chemicals (primarily 1,3-dioxalane) for fish, aquatic invertebrates and aquatic plants indicates that the potential acute hazard of monoglyme to aquatic organisms is low.

The acute toxicity of monoglyme is low via oral, dermal and inhalation routes of exposure. Repeated-dose studies with monoglyme have not been conducted. However, detailed information on the metabolic pathway of monoglyme justifies the use of 2-methoxyethanol, a major metabolite of this chemical, as a supporting chemical for assessing the repeated-dose toxicity of monoglyme. In 13-week drinking water studies of 2-methoxyethanol, testicular degeneration and adverse effects on hematopoiesis were seen in both rats and mice. Additional target organs in these studies were the thymus in rats and adrenal gland in mice. Adverse effects to reproduction are based on metabolism of monoglyme to 2-methoxy acetic acid, which interferes with sperm production. In a screening test performed by the National Toxicology Program (NTP), no viable pups were delivered from mice given single oral doses of monoglyme during days 7 through 14 of gestation. Body weight loss was seen in treated dams. The following effects were observed in oral developmental toxicity studies: increased numbers of stillborn pups, fetal edema, and increased gestation length in rats and decreased fetal body weight and skeletal defects in mice. Increases in gene mutations were observed in bacterial cells without metabolic activation, but not when metabolic activation was present. In mammalian cells, monoglyme did not show potential to induce gene mutations, but did

induce sister chromatid exchanges (SCE) and chromosomal aberrations.

The potential health hazard of monoglyme is high based on the results of the repeated-dose (blood, thymus, adrenal gland, and testicular degeneration) and developmental (increased fetal death and skeletal effects and decreased fetal body weight) toxicity studies at relatively low doses in animal studies. Available data indicate monoglyme has the potential to be genotoxic.

No data gaps were identified under the HPV Challenge Program.

1. Physical-Chemical Properties and Environmental Fate

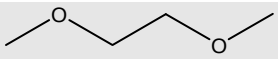
This report was prepared using the best available data from a number of sources, including information from the HPV test plan and robust summaries (Ferro, 2001), the Hazardous Substance Data Bank (HSDB, 2007) and estimations using EPI Suite™ (U.S. EPA, 2007).

Basic physical-chemical and environmental fate properties of monoglyme are listed in Tables 1a and 1b, respectively.

Physical-Chemical Properties Characterization
Monoglyme is a liquid at room temperature and has both high water solubility and a high vapor pressure.

Environmental Fate Characterization
Monoglyme will mainly exist in the vapor phase in the atmosphere because of its high vapor pressure. In the atmosphere, monoglyme has an estimated half-life of 25 hours due to photooxidation with hydroxyl radicals. Environmental fate information for monoglyme indicates that it is highly soluble in water. Volatilization of monoglyme may be possible from dry soil surfaces, based on its vapor pressure, but will be low from moist soil and water surfaces based on an estimated Henry's Law constant. It is highly mobile in soil, does not bioaccumulate, and does not hydrolyze under environmental pHs. Biodegradation is judged to be slow. Limited data, based on enrichment and pure culture studies, suggest that this compound may be resistant to biodegradation in both soil and water. This inference is supported by data for several ether analogs. Therefore, monoglyme is expected to be moderately persistent (P2). Bioaccumulation potential is ranked low (B1) based on its estimated BCF of 3It will have high mobility in soil. The estimated BCF value indicates it will not tend to bioaccumulate.

Table 1a. Physical-Chemical Properties of Monoglyme

Structure	
Property	**Value/Descriptor** [1]
CAS No.	110-71-4
IUPAC	monoglyme
MW	90.12
Physical State	colorless liquid
Melting Point	-58°C **(m)**
Boiling Point	82-83°C **(m)**
Vapor Pressure	48 mm Hg @ 20°C **(m)**
Water Solubility	$1x10^{+6}$ mg/L **(m)**
Density	0.863 @ 20/4°C
Log Kow	-0.21

[1] (m) denotes measured values and all values are from Ferro (2001).

Table 1b. Environmental Fate Characteristics of Monoglyme

Property	Value/Descriptor [1]	Reference
Photodegradation	Half life = 25 hours (calculated)	Ferro 2001 & US EPA 2007
Aerobic Degradation	No biodegradation over 33 weeks **(m)**	Ferro 2001 & HSDB 2007
hydrolysis	No information	
Bioaccumulation	BCF = 3	
Henry's Law Constant	$1.1x10^{-6}$ atm-cu m/mole	
Photolysis	Not significant	Ferro 2001 & HSDB 2007
K_{oc}	18 (calculated)	
Fugacity	Air 0.82-2.32%, Water 47.8-63.3%, Soil 35.8-50.2%, sediment <0.14% (Level III)	Ferro 2001 & US EPA 2007
Persistence	P2 (moderate)	
Bioaccumulation	B1 (low)	FR 1999

[1] (**m**) denotes measured value

2. Environmental Effects – Aquatic Toxicity

Because no adequate data were available on monoglyme, EPA accepted the use of 1,3-dioxalane as a supporting chemical for aquatic toxicity because it is similar to monoglyme in terms of chemical class (neutral organic/diether) and similar octanol-water partition coefficient. In addition, ECOSAR estimations for both compounds suggest low and similar toxicity. All data presented below are from the submission by the sponsor (Ferro, 2001) unless otherwise noted.

Acute Toxicity to Fish

1,3-Dioxolane (CAS No. 646-06-0, supporting chemical)
Bluegill sunfish (*Lepomis macrochirus*) were exposed to 0 or 95.4 mg/L of supporting chemical, 1,3-dioxolane (measured concentration), for 96 hours under static-renewal conditions. No fish died during the exposure period. No sub-lethal effects of the test substance were observed.
96-h LC_{50} > 95.4 mg/L

Acute Toxicity to Aquatic Invertebrates

1,3-Dioxolane (CAS No. 646-06-0, supporting chemical)
(1) *Daphnia magna* were exposed to measured concentrations of 0, 213, 411 or 772 mg/L of supporting chemical, 1,3-dioxolane, for 48 hours under static-renewal conditions. There was no mortality. No immobilization was seen at 24 hours in control or treated groups. At 48 hours, 0/20, 8/20, 6/20 and 9/20 daphnia were immobilized at 0, 213, 411 and 772 mg/L, respectively. Based on the lack of mortality and the lack of a concentration-dependent response, it appears that the stress of the renewal conditions may have contributed to the immobilization.
24-h EC_{50} > 764 mg/L
48-h EC_{50} > 772 mg/L (highest concentration tested)

2-methoxyethanol (CAS No. 109-86-4, supporting chemical)
(2) *Daphnia magna* were exposed to supporting chemical 2-methoxyethanol for 24 hours in a static test (no other details were provided).
24-h EC_{50} > 10,000 mg/L

Toxicity to Aquatic Plants

1,3-Dioxolane (CAS No. 646-06-0, supporting chemical)
(1) Green algae (*Pseudokirchneriella subcapitata*) were exposed to measured concentrations of 0 (<31.0), 36.9, 81.0, 163, 280 or 877 mg/L of supporting chemical, 1,3-dioxolane. After 72 hours, the percentage cell growth inhibition compared to the control was 19% at 877 mg/L. There was no significant statistical difference between the algal growth of the control and test solutions.
72-h EC_{50} (biomass) > 877 mg/L (highest measured concentration)
72-h EC_{50} (growth) > 877 mg/L

(2) A standard toxicity test for aquatic plants was not provided for monoglyme. A 96-hour EC_{50} for green algae, estimated by ECOSAR, was provided to evaluate the plant toxicity of monoglyme.
96-h EC_{50} = 4043 (estimated)

Conclusion: The evaluation of available aquatic toxicity data on supporting chemicals for fish, aquatic invertebrates and aquatic plants indicates that the potential hazard of monoglyme to aquatic organisms is low.

3. Human Health Effects

Acute Oral Toxicity

Monoglyme (CAS No. 110-71-4)
Female rats (4/group) were administered monoglyme via oral gavage at doses of 500, 1000, 2000 or 4000 mg/kg-bw and observed for 14 days. No mortality was seen; however, at 2000 and 4000 mg/kg-bw rats were unbalanced and lethargic after treatment. All surviving animals gained weight during the observation period. There were no abnormal findings during necropsy.
LD_{50} > 4000 mg/kg-bw

Acute Inhalation Toxicity

Monoglyme (CAS No. 110-71-4)
Rats (sex and number/group not specified) were administered monoglyme via whole-body vapor inhalation of 20 or 63 mg/L of for 6 hours and observed for 14 days. Exposure to 20 mg/L produced signs of irritation and slight ataxia. None of the animals died and all gained weight normally during the observation period. Rats exposed to 63 mg/L showed signs of irritation at the beginning of exposure, progressed to prostration after 1.5 hours and remained prostrate until the 6-hour exposure was terminated. Although all of the animals survived during the 6-hour exposure to 63 mg/L, all of them died within 72 hours post-exposure.
20 mg/L < LC_{50} < 63 mg/L

Acute Dermal Toxicity

Monoglyme (CAS No. 110-71-4)
Female rabbits (2/group) were administered dermal doses of monoglyme at 1000 or 2000 mg/kg-bw and observed for 14 days. Rabbits at the 1000 mg/kg-bw level appeared healthy and gained weight during the observation period. One of the two rabbits in the high-dose group died.
LD_{50} = 1000 - 2000 mg/kg-bw

Repeated-Dose Toxicity

2-Methoxyethanol (CAS No. 109-86-4, supporting chemical)
(1) Male and female rats (10/sex/dose) were administered supporting chemical, 2-methoxyethanol, in drinking water at concentrations of 0, 750, 1500, 3000, 4500 or 6000 ppm (70-800 mg/kg-bw/day) over a 13-week period. Mortality was observed at 4500 and 6000 ppm in males and females. Dose-related decreases in body weight gain were reported. Testicular degeneration in males and decreased thymus weights in males and females occurred at the lowest concentration. Treatment-related histopathology changes were observed in the testes, thymus and hematopoietic tissues (spleen, bone marrow and liver). Higher doses produced a progressive anemia. A dose-related degeneration of the germinal epithelium in the seminiferous tubules of the testes was observed. In special stop-exposure studies in male rats, in which administration of 2-methoxyethanol was stopped after 60 days, marked degeneration of the seminiferous tubules was present in rats treated with 3000 ppm and mild to moderate degeneration was observed in rats treated with 1500 ppm.
LOAEL = 750 ppm (approximately 70 mg/kg-bw/day; based on testicular degeneration in males and decreased thymus weights in both sexes**)**
NOAEL = Not established

(2) Male and female mice (10/sex/dose) were administered supporting chemical, 2-methoxyethanol, at doses of 0, 2000, 4000, 6000, 8000 or 10,000 ppm (300 to 1800 mg/kg-bw/day) daily in drinking water over a 13-week period. 2-methoxyethanol produced dose-related effects on the testes (4000 ppm and above), spleen and adrenal gland (females only). A dose-related degeneration of the germinal epithelium in seminiferous tubules of the testes was observed. A dose-related increase in splenic hematopoiesis was more prominent. 2-Methoxyethanol caused prominent lipid vacuolization of the X-zone of the adrenal gland in female mice. A NOAEL was not achieved for females since adrenal gland hypertrophy and increased hematopoiesis in the spleen occurred at the lowest concentration administered. Hematology evaluation showed progressive anemia associated with a cellular depletion of bone marrow and fibrosis of the splenic capsule.
LOAEL (male) = 4000 ppm (approximately 529 mg/kg-bw/day; based on testicular degeneration and increased hematopoiesis in the spleen**)**
NOAEL (male) = 2000 ppm (approximately 300 mg/kg-bw/day)
LOAEL (female) = 2000 ppm (approximately 492 mg/kg-bw/day; based on adrenal gland hypertrophy and increased hematopoiesis in the spleen at the lowest dose tested**)**
NOAEL (female) = Not established

Reproductive Toxicity

There were no specific reproductive toxicity tests reported by the submitter for monoglyme. However, positive effects (testicular degeneration) in the repeated-dose toxicity studies using the surrogate chemical 2-methoxyethanol along with the submitted developmental toxicity study (next section) were used to address the reproductive endpoints for the purposes of the HPV Challenge Program. Therefore, NOAEL/LOAELs for fertility and/or reproductive toxicity cannot be determined for these studies.

Developmental Toxicity

Monoglyme (CAS No. 110-71-4)
(1) Pregnant female Harlan Sprague-Dawley rats (6-28 per group) were administered monoglyme via oral gavage at doses of 0, 30, 60, 120, 250, 500 or 1000 mg/kg-bw/day on days 8 through 18 of gestation. On gestation day 19, dams were sacrificed for teratological evaluation of pups. Fetuses were assessed for litter size, early deaths, gross malformations, perinatal size, fetal body weight and skeletal examination. Dose levels of 120, 250, 500 and 1000 mg/kg-bw/day produced 100% resorptions. At the three highest doses, the necrotic masses were uniformly small; suggesting early embryonic death soon after treatment was initiated. At 120 mg/kg-bw/day, fetuses were larger, having survived for somewhat longer times. These observations are consistent with the dose-dependent reduction by the test substance in maternal weight gain. Animals at 60 mg/kg-bw/day showed a 7-fold increase in resorptions per litter. Fetal mortality was not elevated at 30 mg/kg-bw/day. In the 60 mg/kg-bw/day group, fewer than 1 pup per litter survived compared to 12.3 in controls. These pups did not receive maternal care and none survived beyond postnatal day 1. At 120 mg/kg-bw and above, there was complete early fetal death and possible maternal toxicity. The lower doses were associated with fetotoxicity including stillbirths and reduced body weight. No major external malformations were reported. There was a delay in parturition at the 60 mg/kg-bw dose and some delay was seen at

30 mg/kg-bw/day. Substantial edema of fetuses was seen at 60 mg/kg-bw/day. Edema was less frequent at 30 mg/kg-bw/day but may have been biologically significant since edema was not seen in control fetuses. Fetuses exposed to 60 mg/kg-bw/day showed a reduced stain rating in the skeletal assay (not restricted to specific bones), indicating less advanced bone ossification and consistent with overall retardation of growth and development. A NOEL for developmental effects was not established.
LOAEL (maternal toxicity) = 120 mg/kg-bw/day; based on decreased maternal body weight gain, partly due to early deaths**)**
NOAEL (maternal toxicity) = 60 mg/kg-bw/day
LOAEL (developmental toxicity) = 30 mg/kg-bw/day; based on increased stillborn, fetal edema, increased gestation length**)**
NOAEL (developmental toxicity) = Not established

(2) Pregnant female CRJ:CD-1 mice were administered via oral gavage 0, 250, 350 or 490 mg/kg-bw/day monoglyme on days 7 through 10 of gestation. At the end of the dosing period, the dams were sacrificed for evaluation of pups. Fetuses were assessed for litter size, early deaths, gross malformations, perinatal size, fetal body weight and skeletal examination. There was a clear dose-dependent increase in malformations (exencephaly) and embryo toxicity (mortality). Maternal data were scant and information on relevant parameters for gauging maternal toxicity was not provided. Administration of monoglyme was associated with increases in external and skeletal malformations (rib fusions and malformation of vertebrae). The 250 mg/kg-bw/day dose appears to be a NOAEL for external malformations but considerable skeletal defects and reduced fetal body weight suggest that the NOAEL was not established.
LOAEL (maternal toxicity) > 490 mg/kg-bw/day; based on no treatment-related effects at highest dose tested**)**
NOAEL (maternal toxicity) = 490 mg/kg-bw/day
LOAEL (developmental toxicity) = 250 mg/kg-bw/day; based on decreased fetal body weight and skeletal defects**)**
NOAEL (developmental toxicity) = Not established

(3) Fifty female CD-1 mice were administered monoglyme via oral gavage at 0 or 2000 mg/kg-bw/day on days 7 through 14 of gestation in a screening test conducted by the National Toxicology Program (NTP). If no pups were delivered by day 23 of gestation, mice were sacrificed. During day 8 and 18 of gestation, the body weight of controls increased 13.3% whereas treated animals showed a weight loss of 7%. No viable litters were produced from 49 pregnant mice dosed at 2000 mg/kg-bw/day. As the uteri of most of these were sodium sulfide positive, it was concluded that 1,2-dimehoxyethane causes embryotoxicity at 2000 mg/kg-bw/day.
LOAEL < 2000mg/kg-bw/day (based on no viable litters)
NOAEL = Not established

Genetic Toxicity – Gene Mutation

In vitro
Monoglyme (CAS No. 110-71-4)
(1) A Chinese hamster ovary cell mutation test (HGPRT) with monoglyme was conducted at 4.0, 4.5, 5.0, 5.5 and 6.0% v/v with and without metabolic activation. Positive and negative controls were used and responded appropriately. Cytotoxicity increased with increasing concentrations of monoglyme. No genotoxic activity was detected either with or without metabolic activation.
Monoglyme was not mutagenic in this assay.

Monoglyme (CAS No. 110-71-4)
(2) In an *in vitro* bacterial reverse mutation assay using *S. typhimurium* strains TA 98 and TA 100, monoglyme tested positive in both strains without mammalian metabolic activation and negative in both strains with metabolic activation. Concentrations tested were from 333 to 10,000 (assumed to be ug/plate). These data were not presented in the HPV Submission but may be found at the following URL from the National Toxicology Program (NTP): http://ntp-apps.niehs.nih.gov/ntp_tox/index.cfm?fuseaction=salmonella.salmonellaData&study_no=206306&cas_no=110%2D71%2D4&endpointlist=SA .
Monoglyme induced gene mutations in bacteria in the absence of metabolic activation in this assay

Genetic Toxicity – Chromosomal Aberrations

In vitro
In sister chromatid exchange test (SCE) using Chinese hamster ovary cells, monoglyme was tested at 2.0, 3.0 and 4.0% v/v with and without metabolic activation. Positive and negative controls were used and responded appropriately. Cytotoxicity was observed with increasing concentration. Monoglyme produced SCE in the absence and presence of metabolic activation. A high number of cells were also observed with significant types of chromosomal aberrations suggesting that the material was a clastogenic, especially in the presence of S9 activation. **Monoglyme induced sister chromatid exchange in the presence and absence of metabolic activation in this assay.**

Genetic Toxicity – Other

In vitro
Monoglyme (CAS No. 110-71-4)
Rat hepatocytes were exposed to 0, 0.03, 0.1, 0.3, 1.0, 3.0 and 6.0% v/v of monoglyme. Negative and positive controls were used. Monoglyme did not produce either statistically significant or dose-related increases in the amount of unscheduled DNA synthesis activity. There was no evidence of genotoxic activity.
Monoglyme was not mutagenic in this assay.

Conclusion:
The acute toxicity of monoglyme is low via oral, dermal and inhalation routes of exposure. Repeated-dose studies with monoglyme have not been conducted. However, detailed information on the metabolic pathway of monoglyme justifies the use of 2-methoxyethanol, a major metabolite of this chemical, as a supporting chemical for assessing the repeated-dose toxicity of monoglyme. In 13-week drinking water studies of 2-methoxyethanol, testicular degeneration and adverse effects on hematopoiesis were seen in both rats and mice. Additional target organs in these studies were the thymus in rats and adrenal gland in mice. Adverse effects to reproduction are based on metabolism of monoglyme to 2-methoxy acetic acid, which interferes with sperm production. In a screening test performed by the National Toxicology Program (NTP), no viable pups were delivered from mice given single oral doses of monoglyme during days 7 through 14 of gestation. Body weight loss was seen in treated dams. The following effects were observed in oral developmental toxicity studies: increased stillborn, fetal edema, and increased gestation length in rats and decreased fetal body weight and skeletal defects in mice. Increases in gene mutations were observed in bacterial cells without metabolic activation, but not when metabolic activation was present. In mammalian cells, monoglyme did not show potential to induce gene mutations, but did induce sister chromatid exchanges (SCE) and chromosomal aberrations.

The potential health hazard of monoglyme is high based on the results of the available repeated-dose and developmental toxicity studies.

4. Hazard Characterization

Monoglyme is a liquid at room temperature. It has high water solubility and high vapor pressure. It is highly mobile in soil, does not bioaccumulate, and does not hydrolyze under environmental pHs. Biodegradation is expected to be slow. In the atmosphere, it is expected to photodegrade within slightly over one day. Based on these findings, monoglyme is expected to be moderately persistent (P2) and the bioaccumulation potential for monoglyme is ranked low (B1) based on its estimated bioconcentration factor (BCF) of 3.

The evaluation of available aquatic toxicity data on supporting chemicals (primarily 1,3-dioxalane) for fish, aquatic invertebrates and aquatic plants indicates that the potential acute hazard of monoglyme to aquatic organisms is low.

The acute toxicity of monoglyme is low via oral, dermal and inhalation routes of exposure. Repeated-dose studies with monoglyme have not been conducted. However, detailed information on the metabolic pathway of monoglyme justifies the use of 2-methoxyethanol, a major metabolite of this chemical, as a supporting chemical for assessing the repeated-dose toxicity of monoglyme. In 13-week drinking water studies of 2-methoxyethanol, testicular degeneration and adverse effects on hematopoiesis were seen in both rats and mice. Additional target organs in

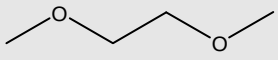
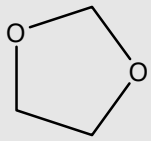
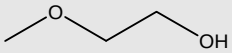
these studies were the thymus in rats and adrenal gland in mice. Adverse effects to reproduction are based on metabolism of monoglyme to 2-methoxy acetic acid, which interferes with sperm production. In a screening test performed by the National Toxicology Program (NTP), no viable pups were delivered from mice given single oral doses of monoglyme during days 7 through 14 of gestation. Body weight loss was seen in treated dams. The following effects were observed in oral developmental toxicity studies: increased numbers of stillborn pups, fetal edema, and increased gestation length in rats and decreased fetal body weight and skeletal defects in mice. Increases in gene mutations were observed in bacterial cells without metabolic activation, but not when metabolic activation was present. In mammalian cells, monoglyme did not show potential to induce gene mutations, but did induce sister chromatid exchanges (SCE) and chromosomal aberrations.

The potential health hazard of monoglyme is high based on the results of the repeated-dose (blood, thymus, adrenal gland, and testicular degeneration) and developmental (increased fetal death and skeletal effects and decreased fetal body weight) toxicity studies. Available data indicate monoglyme has the potential to be genotoxic.

5. Data Gaps

No data gaps were identified under the HPV Challenge Program.

APPENDIX

Summary Table of the Screening Information Data Set as submitted under the U.S. HPV Challenge Program			
Endpoints	**SPONSORED CHEMICAL Monoglyme (110-71-4)**	**SUPPORTING CHEMICAL 1,3-Dioxolane (CAS No. 646-06-0)**	**SUPPORTING CHEMICAL 2-Methoxyethanol (CAS No. 109-86-4)**
Structure			
Summary of Environmental Effects – Aquatic Toxicity Data			
Fish **96-h LC_{50} (mg/L)**	No Measured Data 7984 (est)	**> 95.4** 8148 (est.)	-
Aquatic Invertebrates **48-h EC_{50} (mg/L)**	No Measured Data 7344 (est.)	**> 772 mg/L** 7443 (est)	-
Aquatic Plants **72-h EC_{50} (mg/L)** **(growth)** **(biomass)**	4043 mg/L (est) (96-h)	4074 (est.) **> 877 mg/L** **> 877 mg/L**	-
Summary of Human Health Data			
Acute Oral Toxicity **LD_{50} (mg/kg-bw)**	**> 4000 (female rat)**	-	-
Acute Dermal Toxicity **LD_{50} (mg/kg-bw)**	**> 1000 (female rat)**	-	-
Acute Inhalation Toxicity **LC_{50} (mg/L)**	**20 - 63 (6-h)**	-	-
Repeated-Dose Toxicity **NOAEL/LOAEL**	No Data	-	**Rat**

Summary Table of the Screening Information Data Set as submitted under the U.S. HPV Challenge Program			
Endpoints	**SPONSORED CHEMICAL Monoglyme (110-71-4)**	**SUPPORTING CHEMICAL 1,3-Dioxolane (CAS No. 646-06-0)**	**SUPPORTING CHEMICAL 2-Methoxyethanol (CAS No. 109-86-4)**
(mg/kg-bw/day)	(RA) Rat (drinking water) (No NOAEL) LOAEL = 70 Mouse (drinking water) NOAEL = 300 (male) and none (female) LOAEL = 529 (male) and 492 (female)		**(drinking water)** **(No NOAEL)** **LOAEL = 70** **Mouse** **(drinking water)** **NOAEL = 300 (male) and none (female)** **LOAEL = 529 (male) and 492 (female)**
Reproductive Toxicity NOAEL/LOAEL **(mg/kg-bw/day)**	Addressed by positive findings in both repeated dose [testicular effects in 2-methoxyethanol study] and developmental [fetal death and effects] studies	-	**-**
Developmental Toxicity NOAEL/LOAEL **(mg/kg-bw/day)** **(maternal toxicity)**	**Rat**	**-**	

Summary Table of the Screening Information Data Set as submitted under the U.S. HPV Challenge Program			
Endpoints	**SPONSORED CHEMICAL Monoglyme (110-71-4)**	**SUPPORTING CHEMICAL 1,3-Dioxolane (CAS No. 646-06-0)**	**SUPPORTING CHEMICAL 2-Methoxyethanol (CAS No. 109-86-4)**
(developmental toxicity) **(maternal toxicity)** **(developmental toxicity)**	**LOAEL = 120** **NAOEL = 60** **LOAEL = 30** **NOAEL =Not established** **Mouse** **NOAEL/LOAEL = 490** **LOAEL = 250** **NOAEL = Not established**		**-**
Genetic Toxicity – **Gene Mutation** ***In vitro***	**Positive (bacteria – without activation)** **Negative (bacteria – with activation)**	-	**-**
Genetic Toxicity – **Gene Mutation** ***In vivo***	—	-	**-**
Genetic Toxicity – Chromosomal Aberrations ***In vitro***	**Positive**	-	**-**
Genetic Toxicity – Chromosomal Aberrations ***In vivo***	—	-	**-**
Genetic Toxicity – Other ***In vitro***	**Negative (UDS study)**	-	**-**

Summary Table of the Screening Information Data Set as submitted under the U.S. HPV Challenge Program			
Endpoints	**SPONSORED CHEMICAL Monoglyme (110-71-4)**	**SUPPORTING CHEMICAL 1,3-Dioxolane (CAS No. 646-06-0)**	**SUPPORTING CHEMICAL 2-Methoxyethanol (CAS No. 109-86-4)**
Additional Information	—	-	-

– indicates that the endpoint was not addressed for this chemical. **Bold values represent measured data.**
RA = Read Across

REFERENCES

EFDB, 2007. Environmental Fate Data Base. Accessed 2 January 2008 for several ether analogs (CAS nos. 628-81-9; 628-28-4; 60-29-7; 115-10-6; 540-67-0; 108-20-3; 6863-58-7; 142-96-1). http://www.syrres.com/esc/biodeg.htm

Ferro, 2001. Robust Summaries & Test Plans: monoglyme HPV Test Plan, submitted by Ferro Corporation http://www.epa.gov/chemrtk/pubs/summaries/dimetho/c13455tp.pdf

FR 1999, Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. *Federal Register* 64, Number 213 (November 4, 1999) Page 60194-60204

HSDB, 2007. Hazard Substances Data Base. As cited in HSDB record for monoglyme, accessed August 28, 2007. http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB.

USEPA, 2007. EPI Suite™ (version 3.2) PC-Computer software developed by EPA's Office of Pollution Prevention Toxics and Syracuse Research Corporation. http://www.epa.gov/opptintr/exposure/pubs/episuite.htm

Screening Level Exposure Characterization for HPV Challenge Chemical

1,2 Dimethoxyethane
(Monoglyme)

CAS #110-71-4

March 14, 2008

Prepared by

Exposure Assessment Branch
Chemical Engineering Branch
Economics Exposure and Technology Division
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Screening Level Exposure Characterization for HPV Challenge Chemical

1,2 Dimethoxyethane (CAS #110-71-4)

Non-CBI Executive Summary

This chemical has some public use and exposure information in the HPV Challenge Program submission. The information indicates that the 1,2-dimethoxyethane is used primarily as an industrial solvent, process aid, and as a component of lithium batteries and industrial coatings (Ferro, 2001).

1,2 Dimethoxyethane was manufactured and/or imported in the United States in calendar year 2005 (USEPA, 2007a). This chemical has an aggregated volume produced and/or imported in the range of 1,000,000 to 10,000,000 pounds. Persons submitting Inventory Update Reporting (IUR) information in 2006 asserted that some of the information was confidential business information (CBI) and therefore cannot be disclosed. Data and information that are CBI have been excluded from this summary.

Exposure was characterized using both public, non-confidential sources and one or more IUR submissions were available at the time the exposure characterization was written. If additional information warrants an update of the exposure characterization, the update will be posted on the EPA website.

A SIDS dossier has not been prepared for this chemical. The chemical is not on the Toxics Release Inventory (USEPA, 2007b).

Exposure to Workers

This chemical has a vapor pressure of 48 torr at 20°C (USEPA, 2007c). OPPT has established 0.001 torr as a value above which worker exposures to vapors should be estimated for chemical assessments. Therefore, this chemical's vapor pressure could result in significant worker exposure if workers are near to the chemical. This chemical does not have an OSHA Permissible Exposure Limit (NIOSH, 2007a).

The National Occupational Exposure Survey (NOES), conducted between 1981 and 1983 estimated a total of 3319 workers potentially exposed to this chemical (NIOSH, 2007b). Based on IUR reporting, the maximum total number of workers likely to be exposed to this chemical during manufacturing and industrial processing and use is less than 100. There may be additional potentially exposed workers that are not included in this estimate since not all production volume has been accounted for, and there is at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions. The IUR based ranking for worker exposure is high.

Differences between numbers of workers estimated by IUR submitters and by the NOES are attributable to many factors, including time, scope, and method of the estimates. For example,

NOES estimates are for all workplaces while IUR are for industrial workplaces only, and NOES used a survey and extrapolation method while IUR submitters simply provide their best estimates based on available information for the specific reporting year.

Exposures to General Population and the Environment

The chemical is not on the Toxics Release Inventory (USEPA, 2007a). The potential for exposure to the general population and the environment is likely, based on the totality of the information considered and expert judgment. EPA assumes, for the purposes of this risk based prioritization, that the potential for exposure to the general population and the environment is high.

Limited data suggest that 1,2-dimethoxyethane is resistant to biodegradation; therefore it is expected to be moderately persistent (P2). 1,2-dimethoxyethane is ranked (B1) for bioaccumulation because its' estimated BCF is 3 (USEPA, 2007c).

Exposure to Commercial Workers and Consumers

Non-CBI IUR information indicates there is potential exposure to 1,2-dimethoxyethane for commercial workers and consumers. This chemical has a vapor pressure of 48 torr at 20°C (USEPA, 2007c). The vapor pressure could result in significant worker exposures to vapors if commercial workers or consumers are near to products containing the chemical. Information provided suggests that 1,2-dimethoxyethane will be used in consumer products. The IUR ranking for commercial workers and consumers is high due to the likelihood that there will be exposure to this chemical based on IUR data.

Exposure to Children

Information provided suggests that 1,2-dimethoxyethane will be used in commercial/consumer products, including children's products. The IUR ranking for children is high due to the likelihood that there will be exposure to this chemical based on IUR data.

References

Ferro, 2001. 1,2-Dimethoxyethane U.S. EPA HPV Challenge Program Submission. December 2001. Ferro Corporation. http://www.epa.gov/chemrtk/pubs/summaries/dimetho/c13455tp.pdf

HSDB, 2007. Hazardous Substances Data Bank. Accessed December 2007. 1,2 DIMETHOXYETHANE http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?.temp/~6xho9e:1

NIOSH, 2007a. OSHA PEL Project Documentation. Accessed August, 2007. http://www.cdc.gov/niosh/pel88/npelcas.html

NIOSH, 2007b. National Occupational Exposure Survey (NOES). Accessed December 2007. http://www.cdc.gov/noes/noes2/83728occ.html

USEPA, 2007a. EPA database of 2006 Inventory Update Rule Reporting (contains Confidential Business Information). Accessed September 2007.

USEPA, 2007b. Toxic Release Inventory. United States Environmental Protection Agency, Accessed August, 2007. http://www.epa.gov/tri/

USEPA, 2007c. Physical/Chemical and Environmental Fate Characterization for High Production Volume Chemicals Chemical Name: 1,2 Dimethoxyethane