

## 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)**

This document is based on screening-level characterizations done by EPA on the environmental fate, hazard, and exposure of the listed chemicals. The information used by EPA includes data submitted under the HPV Challenge Program<sup>1</sup> and the 2006 Inventory Update Reporting (IUR)<sup>2</sup>, and data publicly available through other selected sources<sup>3</sup>. This screening-level prioritization presents EPA's initial thinking regarding the potential risks presented by these chemicals and future possible actions that may be needed. These initial characterization and prioritization documents do not constitute a final Agency determination as to risk, nor do they determine whether sufficient data are available to characterize risk. Rather, they are interim evaluations. Recommended actions may be considered by EPA in the future based on a relative judgment regarding this chemical in comparison with others evaluated under this program, and in light of the uncertainties presented by gaps in the available data that may be determined to exist. These evaluations contribute to meeting U.S. commitments under the chemicals cooperation work being done in North America<sup>4</sup>.

#### **Human Health and Environmental Hazard Summary:**

- Although data indicate the acute toxicity of monoglyme is low via oral, dermal and inhalation routes, the potential health hazard is considered high based on the results of repeated-dose studies using a major metabolite, 2-methoxyethanol (CAS No. 109-86-4) (effects on blood, thymus, and adrenal gland), and on reproductive/developmental toxicity found in studies on monoglyme (effects on sperm production, fetal body weight, and fetal skeletal defects).
- The potential aquatic toxicity of monoglyme was assessed using data from the analog 1, 3-dioxolane (CAS No. 646-06-0). Available data on the analog indicates that the potential acute hazard for fish, aquatic invertebrates and aquatic plants is low.

#### **Persistence and Bioaccumulation Summary:**

- Monoglyme is expected to be moderately persistent.
- Bioaccumulation potential for monoglyme is ranked low.

#### **Exposure Summary:**

- Both IUR Confidential Business Information (CBI) and non-CBI information from IUR and other sources were used in this initial prioritization.
- Production volume: Monoglyme is an HPV chemical manufactured or imported in the U.S. in amounts ranging from 1 million to 10 million pounds in 2005.
- Uses: The HPV submission indicates that the chemical is used primarily as an industrial solvent, a process aid, and a component of lithium batteries and industrial coatings.

<sup>1</sup> US EPA, HPV Challenge Program information: <http://www.epa.gov/hpv/>.

<sup>2</sup> US EPA, IUR Reporting information: <http://www.epa.gov/oppt/iur/index.htm>.

<sup>3</sup> US EPA, Information on additional public databases used: <http://www.epa.gov/hpvis/pubdtsum.htm>.

<sup>4</sup> US EPA, U.S. Commitments to North American Chemicals Cooperation: <http://www.epa.gov/hpv/pubs/general/sppframework.htm>.

- General Population and Environment: Monoglyme is not reported on the Toxics Release Inventory (TRI). 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.
- Workers: Based on IUR data, workers are reasonably likely to be exposed to this chemical, and the IUR-based ranking for worker exposure is high. The National Occupational Exposure Survey (NOES), conducted between 1981 and 1983, estimated a total of 3319 workers potentially exposed. 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. (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.) Because of its high vapor pressure, there could be significant worker exposures to vapors if workers are close to liquid. OSHA has not established a permissible exposure limit (PEL).
- Commercial Workers and Consumers: Non-CBI IUR information indicates potential exposure to monoglyme for commercial workers and consumers because monoglyme will be used in commercial and consumer products.
- Children: Information provided suggests that monoglyme will be used in commercial/consumer products, including children's products.

**Assumptions and Uncertainties:**

- Minor uses are not reported under the IUR, and are thus unknown.

**Risk Characterization Summary:**

- *Potential Risk to Aquatic Organisms from Environmental Releases (LOW CONCERN)*: EPA assumes there is potential for exposure to aquatic organisms from environmental releases. The concern for potential environmental risk is low because although monoglyme is considered moderately persistent in the environment, it has a low acute aquatic toxicity hazard.
- *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. The concentrations in the environment are expected to be low and monoglyme is considered moderately persistent in the environment. The high concern for hazard to human health (at relatively low doses in animal studies) combined with the low expected exposure concentrations (but moderate persistence) 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, although to a relatively small number of workers, 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.

**Rationale Leading To Prioritization Decision:**

- The high suggested concern for potential risk to workers, consumers, and children and the medium suggested concern for potential risk to the general population are driven by a combination of high hazard concerns with assumptions about the potential for exposure based on limited data, including available IUR data concerning uses, and the general absence of environmental release data.
- Because studies indicate reproductive and developmental toxicity, suggested concerns for potential risk to children include possible parental exposures that might affect development.
- Further information specifically addressing releases to the environment, worker exposures, and potential exposures through consumer and children's products could directly affect the suggested level of concern for potential risk by replacing exposure assumptions with data. Data moderating exposure assumptions could reduce the level of concern for potential risk. Conversely, data confirming exposure assumptions would also inform appropriate actions to take in order to manage risk.
- EPA already promulgated a Significant New Use Rule (SNUR) on a major metabolite of monoglyme, 2-methoxyethanol (2-ME, CAS No. 109-86-4), requiring notice to the Agency before 2-ME would be used in a consumer product (40 CFR 721.10001).

**Prioritization Decision:**

- *HIGH PRIORITY, SPECIAL CONCERN:* In order to confirm or refute the high suggested concern for potential risk currently based on release and exposure assumptions and on limited available exposure data, particularly concerning potential exposures to consumers and children, companies are encouraged to provide available information on a voluntary and non-confidential basis. Examples of information that would assist EPA in its analysis include, but are not limited to:
  - Releases of monoglyme to the environment;
  - Worker exposures to monoglyme (including engineering and process controls, industrial hygiene practices, and stewardship activities that would affect the potential for exposure);
  - Potential exposures to monoglyme in consumer and children's products (including data on its presence and concentration in products and formulations, and on consumer use activity patterns, considering the frequency and duration of exposures); and
  - Other information pertinent to potential exposures to monoglyme.

- Additional information promptly provided by companies would assist EPA in making further decisions on this chemical, such as whether there may be a need for additional toxicity testing and whether monoglyme might be a candidate for the Voluntary Children's Chemical Evaluation Program.

**Supporting Documentation:**

**Screening-Level Risk Characterization: 3/13/2008**

**Screening-Level Hazard Characterization: 2/22/2008**

**Screening-Level Exposure Characterization: 3/14/2008**