

Initial Risk-Based Prioritization of High Production Volume Chemicals

Chemical/Category: CAS No. 111-96-6, (bis(2-methoxyethyl)ether (Diglyme)

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 Program¹ and the 2006 Inventory Update Reporting (IUR)², and data publicly available through other selected sources³. 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 America⁴.

Human Health and Environmental Hazard Summary:

- Available data indicate low acute toxicity to mammals, but concern for the potential health hazard of diglyme is high based on repeated-dose toxicity to blood and blood-forming organs and developmental toxicity. Available data also indicate diglyme has the potential to cause reproductive toxicity.
- Available environmental effects studies indicated low potential for acute toxicity hazards to aquatic organisms.

Persistence and Bioaccumulation Summary:

- Diglyme is expected to be moderately persistent.
- Bioaccumulation potential for diglyme 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: Diglyme is an HPV chemical manufactured or imported in the U.S. in amounts ranging from 1 million to 10 million pounds annually.
- Uses: The HPV submission indicates that diglyme is used primarily as a specialty solvent in a wide variety of applications, including as a reaction solvent and in applications in the coating industry and in photolithography for manufacture of semiconductor chips. Specific examples of uses from non-CBI information include use in sealants and adhesives, automotive care products, and paints and coatings.

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

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

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

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

- General Population and Environment: Diglyme is not reported on the Toxics Release Inventory (TRI), and the IUR does not collect information regarding environmental releases. 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: IUR data indicate that potential exposures to workers are likely, 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 207 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 between 100 and 999. (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 exposures to vapors if workers are near diglyme liquid. OSHA has not established a permissible exposure limit (PEL) for diglyme.
- Commercial Workers and Consumers: Non-CBI IUR information indicates that commercial workers or consumers might be exposed to diglyme through adhesives and sealants, automotive care products, and paints and coatings.
- Children: Information from IUR submissions indicates the possibility of exposure to children. The submitter(s) indicated that product use information for children was not readily obtainable.

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. Although diglyme 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. Concentrations in the environment are expected to be low and diglyme 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 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 may be exposed to diglyme. The high concern for hazard to human health combined with the likely exposures that occur in occupational settings 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 may be exposed to diglyme. The high concern for hazard to human health combined with the possible exposures that occur in both 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 Diglyme (HIGH CONCERN):* Available IUR data indicate that children may be exposed to diglyme. The high concern for hazard to human health is important in the case of children's health because animal studies indicate that 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, concerns for potential risk to children include possible parental exposures that might affect development.
- Further information specifically addressing releases to the environment and potential uses in 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 could also inform appropriate actions to take in order to manage risk.

Prioritization Decision:

- *HIGH PRIORITY, SPECIAL CONCERN:* In order to confirm or refute the high 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 diglyme to the environment;
 - Worker exposures to diglyme (including engineering and process controls, industrial hygiene practices, and stewardship activities that would affect the potential for exposure);
 - Potential exposures to diglyme 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 diglyme.
- 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 diglyme might be a candidate for the Voluntary Children's Chemical Evaluation Program.

Supporting Documentation:

Screening-Level Risk Characterization: 3/14/2008

Screening-Level Hazard Characterization: 2/21/2008

Screening-Level Exposure Characterization: 3/14/2008