

Initial Risk-Based Prioritization of High Production Volume Chemicals

Chemical/Category: Dibasic Esters Category

CAS 106-65-0, dimethyl succinate (DMS)

CAS 1119-40-0, dimethyl glutarate (DMG)

CAS 627-93-0, dimethyl adipate (DMA)

CAS 95481-62-2, dibasic ester mixture

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 health effects studies indicate generally low toxicity for all category members. Developmental effects (delayed hardening of bones) were seen only at high doses. Repeated inhalation exposures indicated hormonal effects not considered toxicologically significant, and local nasal effects probably due to irritation.
- Available environmental effects studies indicate the potential acute hazard of all dibasic esters category members to aquatic organisms is low.

Persistence and Bioaccumulation Summary:

- Category members are not persistent.
- Category members are not bioaccumulative.

Exposure Summary:

- Both IUR Confidential Business Information (CBI) and non-CBI information from IUR and other sources were used in developing this overall ranking.
- Production volume: All category members are HPV chemicals. DMS and DMG were each manufactured or imported at between 10 and 50 million pounds in 2005, while DMA was between 1 and 10 million pounds.

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>.

- Uses: HPV Challenge Program submissions and other public information indicate that category members are used as solvents, plasticizers, polymer intermediates, specialty chemical intermediates, and as components in consumer paint strippers, polishes, and lacquer thinners. DMS is used as a food additive.
- General Population and Environment: None of the chemicals are listed on the Toxics Release Inventory. Based on the known uses, it is likely that there would be some releases to water during manufacturing, processing, and use. EPA assumes for the purpose of this prioritization that the potential for exposure to the general population and the environment is likely.
- Workers: Data suggest the potential for a high number of exposed workers and use sites. The National Occupational Exposure Survey (NOES), conducted between 1981 and 1983, estimated from 15,000 to 25,000 workers exposed to each category member. The more recently submitted IUR data indicate that the maximum total number of workers likely to be exposed to the category members during manufacturing, industrial processing, and use are: 1,000 or greater (DMS); less than 1,000 (DMA); and less than 5,000 (DMG). (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.) The vapor pressure of the chemicals could result in significant exposure if workers are close to the liquid. Based on the reported uses, there may be inhalation and dermal exposures. None of the category members have an OSHA Permissible Exposure Limit (PEL). The IUR-based ranking for worker exposure is high for all three chemicals.
- Commercial Workers and Consumers: There are potential exposures to commercial workers and/or consumers from the use of products containing DMS, DMA and DMG, including paint strippers, polishes, and lacquer thinners. Paint stripping uses present the potential for high exposures to individuals working in poorly ventilated areas.
- Children: Based on IUR data, the likelihood that DMS, DMA and DMG will be used in products intended for use by children is low.

Assumptions and Uncertainties:

- The extent of occupational and consumer exposures to category members, particularly in paint stripping scenarios, is 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 low acute aquatic hazard and the overall environmental fate characteristics (e.g., not persistent or bioaccumulative) of all members of the dibasic esters category suggest a low concern for potential risk to aquatic organisms from environmental releases.
- *Potential Risk to the General Population from Environmental Releases (LOW CONCERN)*: EPA assumes there is potential for exposure to the general population from environmental releases. The low overall hazard of the dibasic esters to human health and

the environmental fate characteristics of the category members suggest a low concern for potential risk to the general population from environmental releases.

- *Potential Risk to Workers (LOW CONCERN):* Worker exposures to all four category members are likely; although hazard communication and standard industrial hygiene practices, if properly followed, may be sufficient to address this concern. The available hazard data suggest a low overall hazard profile to human health. Thus, the information suggests a low concern for potential risk to workers.
- *Potential Risk to Commercial Workers and Consumers from Known Uses (MEDIUM CONCERN):* A study of paint stripping activity in 1994 has shown the potential for high exposures to consumers working with members of the dibasic esters category in poorly ventilated areas. These conditions may also apply to commercial workers, although hazard communication and standard industrial hygiene practices, if properly followed, may be sufficient to address this occupational concern. Under these exposure conditions, coupled with the available hazard data showing irritation effects in respiratory passages in animals and developmental toxicity at high exposures, there may be a potential concern for risk to commercial workers and consumers. It is not known whether concern for this exposure scenario still exists. Thus, the information suggests a medium concern for potential risk to commercial workers and consumers.
- *Potential Risk to Children (LOW CONCERN):* Although no children-specific exposure scenarios were identified, it is likely that children would be exposed to dibasic esters as part of the general consumer population. The paint stripping consumer use described above is not likely to involve children. The available hazard data suggest a low overall hazard profile to human health, although some developmental effects (delayed hardening of bones) were observed in animals following exposure to high doses. Thus, the information suggests a low concern for potential risk to children.

Rationale Leading To Prioritization Decision:

- Hazard communication and standard industrial hygiene practices, if properly followed, may be sufficient to address concerns for occupation exposures.
- Consumer paint stripping was assessed by EPA and CPSC in 1994, and public information materials were published jointly by both agencies to convey safe use recommendations for all paint stripping product types, including dibasic esters. The extent to which these recommendations may be followed by consumers is unknown.
- EPA received a significant number of studies on these chemicals in response to an enforceable consent agreement issued under section 4 of the Toxic Substances Control Act (TSCA) (64 FR 42692, 8/5/1999). Based in part on that information indicating low health hazards, EPA recently issued an exemption from the requirement of a tolerance for residues of dibasic esters used as pesticide inerts (73 FR 10396, 2/27/2008).
- Despite the lack of information concerning both the extent of potentially high consumer exposures to these chemicals in poorly ventilated paint stripping activities and the use of these chemicals in other consumer products, the apparently low overall hazard presented by these chemicals combined with the generally episodic nature of home paint stripping suggest that further action to assess or control risk is not currently needed.

Prioritization Decision:

- **LOW PRIORITY:** Follow-up action not suggested at this time.

- Additional information on the presence and scope of consumer education efforts intended to mitigate exposures to and encourage safe use of these products could address existing uncertainty and concern on the part of the public.

Supporting Documentation:

Screening-Level Risk Characterization: 3/13/2008

Screening-Level Hazard Characterization: 2/25/2008

Screening-Level Exposure Characterizations: 3/13/2008

Copy of 1995 EPA/CPSC brochure, “What You Should Know About Using Paint Strippers”