Initial Risk-Based Prioritization of High Production Volume Chemicals

4-Methyl-2-pentanol (CAS No. 108-11-2) (Methyl isobutyl carbinol, MIBC)

This document is based on screening-level characterizations done by EPA on the environmental fate, hazard, and exposure of the listed chemical. The information used by EPA includes data submitted under the HPV Challenge Program[1] and the 2006 Inventory Update Reporting (IUR)[2], and data publicly available through other selected sources[3]. This screening-level prioritization presents EPA's initial thinking regarding the potential risks presented by this chemical 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[4] through the EPA Chemical Assessment and Management Program (ChAMP)[5].

Hazard and Fate Summary:

- Human Health: Available data on this chemical and its two major metabolites indicate that the potential health hazard of this chemical is low, based on a lack of specific target organ effects of concern from repeated exposures. Acute exposures to high vapor concentrations cause general anesthetic effects in animals. This chemical is slightly irritating to skin and moderately to severely irritating to the eye. Although developmental effects and liver tumors were observed in mice following exposure to extremely high doses of one metabolite of this chemical (methyl isobutyl ketone, MIBK, CAS. No. 108-10-1), EPA does not consider those effects enough to elevate the human health hazard concern level for this chemical because the doses of MIBK that caused these effects in mice (3000 ppm and 1800 ppm, respectively) are much higher than levels of this chemical that are possibly irritating to humans (50 ppm).
- Environment: Available aquatic toxicity data indicate the acute hazard to fish, aquatic invertebrates and aquatic plants is low.
- Persistence and Bioaccumulation:
  - Available data indicate that this chemical has low persistence.
  - Available data indicate that this chemical has low bioaccumulation potential.

[1] US EPA, HPV Challenge Program information: http://epa.gov/hpv/.
[2] US EPA, IUR 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.
[5] US EPA, ChAMP information: http://www.epa.gov/champ/.

Exposure Summary:

- Both Confidential Business Information (CBI) and non-confidential information from IUR and other sources were used in developing this initial prioritization.
- Production Volume: This chemical is an HPV chemical manufactured and/or imported in the U.S. with an aggregated production volume in the range of 100 to 500 million pounds.
- Uses: Non-confidential IUR information indicates that the chemical is used as an intermediate in manufacturing other chemicals, and as a solvent, flotation agent, and lubricant.
- General Population and Environment: Based on the known uses of this chemical, it is likely that there would be some releases to water or air during manufacturing, processing, and use. EPA identifies a medium potential that the general population and the environment might be exposed to this chemical.
- Workers: EPA identifies a high relative ranking for potential worker exposure based on the relatively high production volume, the potential for significant dermal exposure and inhalation exposures to vapor and mist by a large number of workers in commercial settings including auto repair shops and spray coating facilities, and uncertainty regarding commercial use information reported in IUR submissions including the extent of use of personal protective equipment (PPE) at commercial facilities. This chemical has an OSHA Permissible Exposure Limit (PEL) of 25 ppm (eight hour time weighted average (TWA)).
- Consumers: IUR and public data sources indicate that this chemical is used in consumer products. Depending on the product, there may be dermal and/or inhalation exposures to consumers from vapors, mists, or particulates. EPA identifies a high potential that consumers might be exposed to this chemical in household products.
- Children: No uses in products specifically intended to be used by children were reported in the IUR, nor were any found in other data sources. Exposures to children, however, may be expected to occur through the household use of some consumer products. EPA identifies a medium potential that children might be exposed to this chemical.

Risk Characterization Summary:

- Potential Risk to Aquatic Organisms from Environmental Releases: *LOW CONCERN.* EPA identifies a medium potential that aquatic organisms might be exposed from environmental releases. This chemical has low persistence and low bioaccumulation. These characteristics in combination with the low acute toxicity for fish, invertebrates and aquatic plants suggest a low concern for potential risk to these organisms.
- Potential Risk to the General Population from Environmental Releases: *LOW CONCERN.* EPA identifies a medium potential that the general population might be exposed from environmental releases. The potential human health hazard is expected to be low. The low hazard and the environmental fate characteristics of low persistence and low bioaccumulation suggest a low concern for potential risk to the general population from environmental releases.
- Potential Risk to Workers: *LOW CONCERN.* Available IUR data indicate that workers may be exposed to this chemical. The potential human health hazard is expected to be low. However, there is potential for skin and eye irritation and for narcosis at high

concentrations. Adherence to the OSHA PEL would limit the exposure of workers. This suggests a low concern for potential risk to workers.

- Potential Risk to Consumers from Known Uses: *LOW CONCERN.* EPA identifies a high potential that consumers might be exposed. The potential human health hazard is expected to be low. To the extent that this chemical might be used as a solvent in consumer products, the hazard profile suggests that reversible effects (irritation and possibly narcosis) could occur only if concentrations in such products were high. This suggests a low concern for potential risk to consumers.
- Potential Risk to Children: *LOW CONCERN.* No uses in products specifically intended to be used by children were reported in the IUR or found in other data sources. Exposures to children, however, may be expected to occur through the household use of some consumer products. The available animal hazard data suggest a low hazard due to the lack of any specific toxicity in postnatally exposed animals following exposures to high doses. This suggests a low concern for potential risk to children.

Regulatory and Related Information Summary:

- This chemical is listed on the TSCA Inventory. It is not otherwise regulated under TSCA.
- This chemical is listed as a volatile air emission from major stationary sources of pollution regulated under section 111 of the Clean Air Act.
- OSHA designated a PEL of 25 ppm as an eight hour time weighted average (TWA) for this chemical.
- The National Institute of Occupational Safety and Health (NIOSH), an institute of the U.S. Centers for Disease Control and Prevention (CDC), includes safe handling recommendations for this chemical in an International Chemical Safety Card (September 10, 1997: http://www.cdc.gov/niosh/ipcsneng/neng0665.html).

Assumptions and Uncertainties:

- EPA has no information on releases of this chemical, and assumes potential exposures based on reported uses.

Rationale Leading To Prioritization Decision:

- The fate characteristics and low toxicity of this chemical present a low concern for risk from environmental and general population exposures.
- Adherence to the existing OSHA PEL would limit worker exposure, which otherwise could be high based on the potential number of workers and the chemical's vapor pressure. Existing hazard communication and standard industrial hygiene practices may be sufficient to address the potential risks arising from occupational uses of this chemical.
- Concerns for risk to consumers or children are not apparent at this time, given that the concentration in products to which they might be exposed would have to be high to present any potential even for reversible effects.

Prioritization Decision:

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

Supporting Documentation:

Screening-Level Risk Characterization: July 2008

Screening-Level Hazard Characterization: OECD SIDS Initial Assessment Report, 10/18-21/2005, http://www.chem.unep.ch/irptc/sids/OECDSIDS/108112.pdf

Note: OECD SIDS Initial Assessment Profiles (SIAP) and SIDS Initial Assessment Reports (SIAR) are publicly available through the United Nations Environmental Programme website. These documents are presented in an international forum that involves review and endorsement by governmental authorities around the world. The U.S. EPA is an active participant in these meetings and accepts these documents as reliable screening-level hazard assessments for the purpose of the U.S. HPV Challenge qualitative risk characterization process.

Screening-Level Exposure Characterization: July 2008