Initial Risk-Based Prioritization of High Production Volume Chemicals

2-Amino-2,3-dimethylbutanenitrile (CASRN 13893-53-3)
(9th CI and CA Index Name: Butanenitrile, 2-amino-2,3-dimethyl-)

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].

This chemical was considered in 2002 to have met the HPV Challenge Program guidance for a closed-system intermediate, a chemical manufactured and processed only in closed systems to produce other chemicals. Because closed-system intermediates have a limited potential for exposure generally attributable only to isolated accidental releases, toxicity testing requirements in the HPV Challenge Program were reduced for those chemicals, and consisted of the Screening Information Data Set (SIDS) minus the tests for repeated dose toxicity and reproductive toxicity, but including a developmental toxicity test[6]. For this chemical, the sponsor submitted data for all endpoints in the reduced set and included a repeated-dose study, but the data submitted by the sponsor for chromosomal aberrations and developmental toxicity were not considered adequate for the purposes of the HPV Challenge Program.

Hazard and Fate Summary:

- Human Health: The acute oral toxicity of this chemical is moderate in rats. Both acute inhalation toxicity in rats and acute dermal toxicity in rabbits are high. Mortality was observed following instillation of this chemical into the eyes of rabbits. A dermal repeated-dose toxicity study in rats showed skin irritation, but there were no signs of toxicity in any treatment group. It did not induce gene mutations. The data submitted by the sponsor for chromosomal aberrations and developmental toxicity were not considered adequate for characterization.

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[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/.
[6] US EPA, Guidance for Testing Closed System Intermediates: http://www.epa.gov/chemrtk/pubs/general/closed9.htm.

- Environment: The acute toxicity of this chemical is high to fish and aquatic plants and moderate to aquatic invertebrates.
- Persistence and Bioaccumulation:
  - Measured data were not provided, but EPA judges this chemical to have moderate persistence.
  - Available data indicate that this chemical has low bioaccumulation potential.

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 with an aggregated production and/or import volume in the United States of 1 to 10 million pounds in 2005.
- Uses: Non-confidential IUR information for this chemical indicates that it is used as a site-limited intermediate. No commercial/consumer uses were reported in the Hazardous Substances Data Bank. Information submitted as part of the HPV Challenge Program indicates that it is used solely as an intermediate for the production of herbicides.
- General Population and Environment: EPA identifies a low potential that the general population or the environment might be exposed to this chemical.
- Workers: EPA identifies a low relative ranking for potential worker exposure.
- Consumers: EPA identifies a low potential that consumers might be exposed.
- Children: EPA identifies a low potential that children might be exposed.

Risk Characterization Summary:

EPA reviewed the information in the HPV submissions in 2002 and determined that it met the guidance for a closed-system intermediate. Therefore, there is a low concern for potential risk to aquatic organisms and the general population from environmental releases, and also to workers, consumers, and children.

- Potential Risk to Aquatic Organisms from Environmental Releases: *LOW CONCERN*.
- Potential Risk to the General Population from Environmental Releases: *LOW CONCERN*.
- Potential Risk to Workers: *LOW CONCERN*.
- Potential Risk to Consumers from Known Uses: *LOW CONCERN*.
- Potential Risk to Children: *LOW CONCERN*.

Regulatory and Related Information Summary:

- This chemical is listed on the TSCA Inventory. It is not otherwise regulated under TSCA.

Assumptions and Uncertainties:

- EPA assumes that potential exposures are very limited, based on the reported use.
- The HPV Challenge Program allowed for a reduced set of testing for chemicals that qualified as closed-system intermediates, reflecting the information needed to evaluate the hazards in the event of an accident. For two of the required endpoints, however, the sponsor provided data on proposed supporting chemicals that the Agency did not consider adequate for the purpose of the Challenge Program. Accordingly, the potential

for chromosomal aberrations and developmental toxicity thus cannot be determined on the basis of the available data.

Rationale Leading To Prioritization Decision:

- The manufacture and processing of this chemical only as an intermediate to produce other chemicals in systems that are expected to reduce the potential for worker exposure and environmental releases lead to a low concern for risk.
- Accidental releases remain a partially uncharacterized potential concern because the potential for chromosomal aberrations and developmental toxicity have not been determined. In addition, the high acute inhalation and dermal toxicity of this chemical, together with the mortality observed in rabbit studies when the chemical was instilled into the eyes, could present a concern for workers in the event of an accidental release of the substance. The potential that an accidental release may occur cannot be determined from the available information. The use of appropriate engineering controls and personal protective equipment (i.e., gloves, respirators, and goggles) could mitigate risks to workers.

Prioritization Decision:

- MEDIUM PRIORITY, POTENTIAL CONCERN – Although concern for risk would generally be low because potential exposures to this chemical are expected to be very limited given its reported use only as an intermediate in closed systems, this HPV chemical demonstrates high acute toxicity based on the available information, as well as uncertainty introduced by the incomplete base set of hazard data provided on this closed-system intermediate. EPA accordingly identifies this chemical as presenting a medium priority for further work based on policy needs and potential risk issues. EPA has identified possible next steps involving efforts to better understand the hazards and resolve potential concerns for risk from accidental releases. Examples of information that would assist EPA in its analysis include, but are not limited to:
    - The voluntary completion of the outstanding, unsatisfied HPV Challenge Program data elements to permit the characterization of these hazards; and
    - Other information pertinent to hazard and exposure.
- EPA will share information on this chemical with other Agencies, including the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH), given the concerns for workers that may be presented by its high acute toxicity in the event of an accidental release.
- EPA may consider referring this chemical to the National Advisory Committee for Acute Exposure Guideline Levels (NAC/AEGLs) as a potential candidate for the development of an AEGL.

Supporting Documentation:

Screening-Level Risk Characterization: September 2008
Screening-Level Hazard Characterization: September 2008
Screening-Level Exposure Characterization: September 2008