Initial Risk-Based Prioritization of High Production Volume Chemicals

Sponsored Chemical 3-Methyl benzonitrile (CASRN 620-22-4) (9th CI and CA Index Name: Benzonitrile, 3-methyl-)

Supporting Chemical Benzonitrile (CASRN 100-47-0)

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 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 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 America⁴ through the EPA Chemical Assessment and Management Program (ChAMP)⁵.

This chemical was considered in 2007 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 elements 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 test⁶. The sponsor did not provide all of the elements of this reduced data set for this chemical.

Hazard and Fate Summary:

• <u>Human Health</u>: The acute oral toxicity of this chemical is low. This chemical did not induce gene mutations. It is slightly irritating to rabbit skin and severely irritating to rabbit eyes. Developmental toxicity data and chromosomal aberration tests for genetic

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

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

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

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: <u>http://www.epa.gov/champ/</u>.

⁶ US EPA, Guidance for Testing Closed System Intermediates:

http://www.epa.gov/chemrtk/pubs/general/closed9.htm.

toxicity were not submitted, and were identified as a data gap under the HPV Challenge Program.

- <u>Environment</u>: The acute aquatic toxicity of 3-methylbenzonitrile to fish, aquatic invertebrates and plants is expected to be low based on data for the supporting chemical benzonitrile (CAS No. 100-47-0).
- <u>Persistence and Bioaccumulation</u>:
 - Available data indicate that this chemical is expected to have low 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.
- <u>Production Volume</u>: No IUR reports were submitted on this chemical in 2006, so the current production volume is unknown. The lack of IUR reports indicates that the chemical was not manufactured or imported at or above 25,000 pounds at any single site in 2005. It was included in the HPV Challenge program because it was reported at HPV levels in earlier years.
- <u>Uses</u>: Information submitted as part of the HPV Challenge Program indicates that this chemical is used as a chemical process intermediate in the synthesis of a fungicide. No information on commercial/consumer uses was found in the Hazardous Substances Data Bank.
- <u>General Population and Environment</u>: EPA identifies a low potential that the general population or the environment might be exposed to this chemical.
- <u>Workers</u>: EPA identifies a low relative ranking for potential worker exposure.
- <u>Consumers</u>: EPA identifies a low potential that consumers might be exposed.
- <u>Children</u>: EPA identifies a low potential that children might be exposed.

<u>Risk Characterization Summary</u>:

EPA reviewed the information in the HPV submission for this chemical, 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.
- <u>Potential Risk to the General Population from Environmental Releases</u>: *LOW CONCERN*.
- Potential Risk to Workers: LOW CONCERN.
- <u>Potential Risk to Consumers from Known Uses</u>: *LOW CONCERN*.
- <u>Potential Risk to Children</u>: *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.

- EPA assumes that standard industrial hygiene practices would address any potential irritation exposure to eyes and skin attributable to accidental occupational releases.
- 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, data were not provided. Accordingly, the potential for chromosomal aberrations and developmental toxicity 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 may reduce significantly the potential for worker exposure and environmental releases leads to a low concern for risk.
- The absence of 2006 IUR reports on this chemical suggests that its current production and importation volume is low.
- Accidental releases remain a partially uncharacterized potential concern because the potential for chromosomal aberrations and developmental toxicity have not been determined. The potential that an accidental release may occur cannot be determined from the available information.

Prioritization Decision:

- LOW PRIORITY No further action suggested at this time.
- This decision is based on the very low perceived potential for exposure to all populations, despite the lack of characterization on certain potential hazards. The voluntary completion of the outstanding, unsatisfied HPV Challenge Program data elements to permit the characterization of these hazards, or the voluntary submission of information documenting the low production volume suggested by the absence of IUR reports during the 2006 IUR cycle, could further resolve these potential concerns.
- EPA may consider revisiting this prioritization decision if future IUR reports indicate an increase in production or importation volume.

Supporting Documentation:

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