

## Initial Risk-Based Prioritization of High Production Volume Chemicals

### 2-[Ethyl(3-methylphenyl)amino]-acetonitrile (CASRN 63133-74-4) (9<sup>th</sup> CI Name: Acetonitrile, [ethyl(3-methylphenyl)amino]-)

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<sup>1</sup> and the 2006 Inventory Update Reporting (IUR)<sup>2</sup>, and data publicly available through other selected sources<sup>3</sup>. 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<sup>4</sup> through the EPA Chemical Assessment and Management Program (ChAMP)<sup>5</sup>.

This chemical was considered in 2005 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 test<sup>6</sup>. For this chemical, the sponsor provided more than the reduced set of information, including a combined reproductive/developmental toxicity test.

#### **Hazard and Fate Summary:**

- **Human Health:** An acute oral study in rats showed moderate toxicity and a dermal study on guinea pigs showed low toxicity. In a combined reproductive/developmental study in rats, there were body weight reductions in the mid- and high-dose parental males, and clinical signs of toxicity at the high doses in both sexes. There was no evidence of reproductive or developmental toxicity. It was not mutagenic and did not induce chromosomal aberrations.
- **Environment:** Available aquatic toxicity data indicate the acute hazard of this chemical is low to fish and aquatic invertebrates and moderate to aquatic plants.

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

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

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

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

<sup>5</sup> US EPA, ChAMP information: <http://www.epa.gov/champ/>.

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

- Persistence and Bioaccumulation:
  - Available data indicate that this chemical has 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: Based on the 2006 IUR submissions, this chemical is currently a moderate production volume (MPV) chemical with an aggregated production and/or import volume in the United States of 10,000 to 500,000 pounds. It was included in the HPV Challenge program because it was reported at HPV levels in earlier years.
- Uses: Non-confidential IUR information indicates that the chemical is used as an industrial intermediate in manufacturing other basic organic compounds. There are no reported commercial uses.
- 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 submission, test plan, and subsequent revisions and correspondence, 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.

**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.

**Prioritization Decision:**

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

**Supporting Documentation:**

**Screening-Level Risk Characterization: September 2008**

**Screening-Level Hazard Characterization: September 2008**

**Screening-Level Exposure Characterization: September 2008**