

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

### Primene™ 81-R Amines (CASRN 68955-53-3) (9<sup>th</sup> CI and CA Index Name: Amines, C12-14-tert-alkyl)

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>.

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

- **Human Health:** Acute oral, dermal, and inhalation toxicity of this chemical is moderate. An oral reproductive toxicity study showed evidence of toxicity to the parental animals and postnatal developmental toxicity in the pups at the mid- and high doses. This chemical is corrosive to skin and eyes and irritating to the respiratory tract.
- **Environment:** Available data indicate that the potential acute hazard of this chemical to fish and aquatic invertebrates is moderate and to aquatic plants is high. Chronic hazard to fish is high.
- **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-CBI 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 1 to 10 million pounds in 2005.
- **Uses:** According to the IUR submissions, the non-confidential uses include processing of the chemical as a fuel in organic chemical manufacturing. The HPV Challenge Program

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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/>

submission for this chemical indicates that it is used as a fuel and lubricant additive, and in surfactants, dyes, refinery processing and metal working fluids.

- General Population and Environment: It is likely that there would be some releases to water or air during manufacturing, processing, and use. EPA identifies a high potential that the general population and the environment might be exposed.
- Workers: EPA identifies a high relative ranking for potential worker exposure. The high relative ranking is based on the potential for dermal exposure to liquids and inhalation exposure to vapors by workers during manufacturing, industrial processing and use operations; the high concentrations of the chemical used; the potential for exposure to mist at high concentrations during industrial and commercial uses; and the potentially high number of workers during commercial activities.
- Consumers: Depending on the consumer product, there may be dermal and/or inhalation exposures to consumers from vapors, mists, or particulates. EPA identifies a high potential that consumers may be exposed from products containing this chemical based on IUR data and information from public data sources that indicate this chemical is found 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. Therefore, EPA identifies a medium potential that children might be exposed.

#### **Risk Characterization Summary:**

- Potential Risk to Aquatic Organisms from Environmental Releases: *MEDIUM/HIGH CONCERN*. EPA identifies a high potential that aquatic organisms may be exposed from environmental releases of this chemical. The moderate acute and high chronic hazard to fish considered in combination with the environmental fate characteristics of moderate persistence and low bioaccumulation suggests a medium concern for potential risk to fish. The moderate acute hazard combined with the fate characteristics suggests a medium concern for potential risk to aquatic invertebrates. The high acute hazard combined with fate characteristics suggests a high concern for potential risk to aquatic plants.
- Potential Risk to the General Population from Environmental Releases: *LOW CONCERN*. EPA identifies a high potential that the general population might be exposed from environmental releases of this chemical. The potential human health hazard is expected to be moderate due to postnatal developmental toxicity and other toxic effects in animal tests following repeated exposures. The chemical is corrosive to skin and eyes and irritating to the respiratory tract, but EPA assumes that potential exposures from environmental releases would not reach those concentrations. Although the hazard and persistence are moderate, the low bioaccumulation potential combined with the assumption that concentrations would not reach those of concern for irritation suggests 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 have potential for exposure to this chemical by dermal and inhalation routes. The potential human health hazard is expected to be moderate. There is some evidence of delayed hypersensitivity in guinea pig studies, and a potential for severe skin, respiratory tract and eye irritation at similar concentrations. Because of these point-of-contact

effects at high concentrations, workers would be immediately aware and uncomfortable if they had exposure. Adherence to standard good industrial hygiene practices to prevent irritation will limit the exposure of workers. Therefore, taken together, the available information suggests a low concern for potential risks to workers.

- Potential Risk to Consumers from Known Uses: *LOW CONCERN*. Available IUR data indicate that there is a high potential that consumers might be exposed to this chemical in some consumer products. The potential human health hazard is expected to be moderate. However, this chemical is corrosive to skin and eyes and irritating to the respiratory tract at concentrations similar to those producing the toxic effects contributing to the moderate health hazard call, and EPA assumes that the chemical's concentration in consumer products would not reach those concentrations. Given the assumption that concentrations in consumer products would not reach those of concern for irritation or toxicity, the available information suggests a low concern for potential risk to consumers.
- Potential Risk to Children: *MEDIUM CONCERN*. 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. The potential human health hazard is expected to be moderate due to postnatal developmental toxicity and other toxic effects in animal tests following repeated exposures. The available information suggests a medium concern for potential risks to children.

#### **Regulatory and Related Information Summary:**

- This chemical is listed on the TSCA Inventory. It is not otherwise regulated by EPA.
- This chemical is listed on Canada's Domestic Substances List (DSL) and was categorized as a medium priority. It meets Canada's criteria as having both human health and environmental concerns.

#### **Assumptions and Uncertainties:**

- EPA has no information on releases of this chemical, and assumes potential exposures based on reported uses.
- There is uncertainty regarding the extent of personal protective equipment used by workers.

#### **Rationale Leading To Prioritization Decision:**

- Hazard communication and standard industrial hygiene practices, if properly followed, may be sufficient to address concerns for occupational exposures.
- Although the potential human health hazard is expected to be moderate, this chemical is corrosive to skin and eyes and irritating to the respiratory tract, and therefore potential exposures to industrial concentrations would tend to be self-limiting.
- The medium to high concern for potential risk to aquatic organisms is driven by acute and chronic toxicity data combined with assumptions about the potential for environmental exposures. Information concerning environmental releases and exposures would be useful in determining the extent of potential concern.
- The concern for potential risk to children is driven by potential exposures through the household use of some consumer products that contain this chemical combined with

postnatal developmental toxicity data. Information concerning use of this chemical in household products would be useful in determining the extent of potential concern.

**Prioritization Decision:**

- **MEDIUM PRIORITY, POTENTIAL CONCERN:** In order to further evaluate the medium to high concern for potential risk to aquatic organisms and the medium concern for potential risk to children from this chemical, EPA has identified possible next steps involving efforts to develop a better understanding of exposure to and uses of this chemical. Examples of information that would assist EPA in its analysis include, but are not limited to:
  - Information concerning potential releases to water from manufacturing, use and disposal of the chemical and products containing the chemical;
  - Information concerning the use of this chemical in household products; and
  - Other information pertinent to environmental exposures to this chemical.

As an initial step in developing this understanding, companies that manufacture, process, or use this chemical are encouraged to provide available information on a voluntary and non-confidential basis.

**Supporting Documentation:**

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

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

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