Initial Risk-Based Prioritization of High Production Volume Chemicals

Cyclohexanone, Oxime (CASRN 100-64-1)

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 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[6]. For this chemical, the sponsor provided more than the minimum data set relative to health endpoints, including a repeated-dose toxicity test, but did not provide all requested environmental data.

Hazard and Fate Summary:

- Human Health: Acute oral toxicity of this chemical to rats is moderate and acute dermal toxicity to rabbits is low. An oral repeated-dose study in rats showed high systemic toxicity. However, a repeated-dose study of mice exposed via drinking water showed low systemic toxicity. A prenatal developmental toxicity study of CASRN 108-94-1, a major metabolite of this chemical, showed low maternal and developmental toxicity in rats. This chemical induced gene mutations and gave an equivocal response for chromosomal aberrations *in vitro*. However, it did not induce chromosomal aberrations *in vivo*.

[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 to fish is low. Acute toxicity to aquatic invertebrates and aquatic plants endpoints were identified as data gaps under the HPV Challenge Program.
- Persistence and Bioaccumulation:
  - Available data indicate that this chemical has 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.
- Production Volume: This chemical is an HPV with an aggregated production and/or import volume in the United States of 100 to 500 million pounds in 2005.
- 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. The HPV Challenge Program submission indicates that it is used in the chemical industry for synthesis of caprolactam, which is used to produce polycaprolactam fibers and resins.
- 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 2005 and determined that it met the Challenge Program 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.
- This chemical is included on the Equipment Leaks Chemical List established under section 111 of the Clean Air Act, which establishes new source performance standards (NSPS) to impose federal technology-based requirements on emissions from new or modified major stationary sources of pollution.

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 considered as closed-system intermediates, reflecting the information needed to evaluate the hazards in the event of an accident. That reduced set of data was not fully provided on this chemical, however, and the potential acute hazard to aquatic invertebrates and aquatic plants 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 leads to a low concern for risk.
- Accidental releases to water remain a partially uncharacterized potential concern because the potential acute hazards to aquatic invertebrates and aquatic plants have not been determined. The potential that an accidental release may occur cannot be determined from the available information. The acute toxicity to fish is low.
- On July 29, 2008, the sponsor company submitted an amended test plan (http://www.epa.gov/chemrtk/pubs/summaries/cycloxim/c16215rt.pdf) proposing to complete the missing acute aquatic invertebrate and acute aquatic plant toxicity studies. The company further proposed to conduct an acute fish toxicity test, but EPA has indicated that the existing data for this endpoint are considered adequate.

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 of certain potential hazards. The voluntary completion of the outstanding, unsatisfied HPV Challenge Program data elements to permit the characterization of these hazards, as proposed in the sponsor's recently submitted revised test plan submission, could further resolve these potential concerns.

Supporting Documentation:

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