

## SCREENING-LEVEL HAZARD CHARACTERIZATION

### Acetone (CASRN 67-64-1)

The High Production Volume (HPV) Challenge Program<sup>1</sup> was conceived as a voluntary initiative aimed at developing and making publicly available screening-level health and environmental effects information on chemicals manufactured in or imported into the United States in quantities greater than one million pounds per year. In the Challenge Program, producers and importers of HPV chemicals voluntarily sponsored chemicals; sponsorship entailed the identification and initial assessment of the adequacy of existing toxicity data/information, conducting new testing if adequate data did not exist, and making both new and existing data and information available to the public. Each complete data submission contains data on 18 internationally agreed to “SIDS” (Screening Information Data Set<sup>1,2</sup>) endpoints that are screening-level indicators of potential hazards (toxicity) for humans or the environment.

The Environmental Protection Agency’s Office of Pollution Prevention and Toxics (OPPT) is evaluating the data submitted in the HPV Challenge Program on approximately 1400 sponsored chemicals by developing hazard characterizations (HCs). These HCs consist of an evaluation of the quality and completeness of the data set provided in the Challenge Program submissions. They are not intended to be definitive statements regarding the possibility of unreasonable risk of injury to health or the environment.

The evaluation is performed according to established EPA guidance<sup>2,3</sup> and is based primarily on hazard data provided by sponsors; however, in preparing the hazard characterization, EPA considered its own comments and public comments on the original submission as well as the sponsor’s responses to comments and revisions made to the submission. In order to determine whether any new hazard information was developed since the time of the HPV submission, a search of the following databases was made from one year prior to the date of the HPV Challenge or OECD HPV submission to the present: (ChemID to locate available data sources including Medline/PubMed, Toxline, HSDB, IRIS, NTP, ATSDR, IARC, EXTOXNET, EPA SRS, etc.), STN/CAS online databases (Registry file for locators, ChemAbs for toxicology data, RTECS, Merck, etc.) and Science Direct. OPPT’s focus on these specific sources is based on their being of high quality, highly relevant to hazard characterization, and publicly available.

OPPT does not develop HCs for those HPV chemicals which have already been assessed internationally through the HPV program of the Organization for Economic Cooperation and Development (OECD) and for which Screening Initial Data Set (SIDS) Initial Assessment Reports (SIAR) and SIDS Initial Assessment Profiles (SIAP) are available. These documents are presented in an international forum that involves review and endorsement by governmental authorities around the world. OPPT is an active participant in these meetings and accepts these documents as reliable screening-level hazard assessments.

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<sup>1</sup> U.S. EPA. High Production Volume (HPV) Challenge Program; <http://www.epa.gov/chemrtk/index.htm>.

<sup>2</sup> U.S. EPA. HPV Challenge Program – Information Sources; <http://www.epa.gov/chemrtk/pubs/general/guidocs.htm>.

<sup>3</sup> U.S. EPA. Risk Assessment Guidelines; <http://cfpub.epa.gov/ncea/raf/rafguid.cfm>.

These hazard characterizations are technical documents intended to inform subsequent decisions and actions by OPPT. Accordingly, the documents are not written with the goal of informing the general public. However, they do provide a vehicle for public access to a concise assessment of the raw technical data on HPV chemicals and provide information previously not readily available to the public.

<b>Chemical Abstract Service Registry Number (CASRN)</b>	<b>67-64-1</b>
<b>Chemical Abstract Index Name</b>	<b>2-Propanone</b>
<b>Structural Formula</b>	<b>CH<sub>3</sub>-CO-CH<sub>3</sub></b>
<b>Summary</b>	
<p>Acetone (CASRN 67-64-1) is a liquid with high water solubility and high vapor pressure. It is expected to possess high mobility in soil. CASRN 67-64-1 is readily biodegradable. The rate of volatilization is considered moderate. The rate of hydrolysis is considered negligible. The rate of atmospheric photooxidation is negligible. Bioconcentration factors (BCF) of 0.65 is low. CASRN 67-64-1 is expected to have low persistence (P1) and low bioaccumulation potential (B1).</p> <p>The acute toxicity of CASRN 67-64-1 in rats by the oral and inhalation routes is low. CASRN 67-64-1 is not a skin irritant in rabbits or a skin sensitizer in mice, but it is a severe eye irritant in rabbits. Thirteen week repeated-dose oral toxicity studies have been conducted in mice and rats. Male rats appeared to be the most sensitive species, with the kidney, hematological system, and testes identified as target organs. The LOAEL for systemic toxicity is 1,700 mg/kg-day based on mild nephropathy in males; the NOAEL is 900 mg/kg-day. No studies specifically addressing reproductive toxicity were available, however, data from a repeated-dose toxicity study conducted in rats via drinking water showed increases in relative testicular weight, reduced sperm motility, decreases in caudal and epididymal weights, and increases in abnormal sperm at 3,400 mg/kg-day. There are no prenatal developmental toxicity studies following oral exposures to CASRN 67-64-1. Prenatal developmental toxicity studies via the inhalation route in rats and mice indicated that reduced fetal body weight is the most consistent effect observed at 6,600 ppm (approximately 15 mg/L) in mice and 11,000 ppm (approximately 26 mg/L) in rats. The NOAEC for developmental toxicity in both rats and mice is 2,200 ppm (approximately 5mg/L). No signs of maternal toxicity were reported in rats. The NOAEC for maternal toxicity in rats is 11,000 ppm (approximately 26 mg/L). Signs of maternal toxicity in mice observed at 6,600 ppm (approximately 15 mg/L) consisted of statistically significant increases in absolute and relative liver weights, which may be indicative of enzyme induction. The NOAEC for maternal toxicity in mice is 2,200 ppm (approximately 5 mg/L). CASRN 67-64-1 did not induce gene mutations or chromosomal aberrations when tested <i>in vitro</i>. Although a chronic bioassay has not been conducted for oral or inhalation exposure routes, CASRN 67-64-1 has frequently been used as a solvent or vehicle control to dissolve test chemicals in dermal animal studies with no evidence of increased tumor incidence. Human data on CASRN 67-64-1 are available, however, according to the 2003 IRIS assessment, human data by the oral and inhalation routes were considered inadequate for use in generation of an RfC or RfD.</p> <p>The acute 96-hour LC<sub>50</sub> for CASRN 67-64-1 to fish ranges from 6,070 mg/L to 15,000 mg/L and the EC<sub>50</sub> for aquatic invertebrates ranges from 2,100 mg/L to 16,700 mg/L. The NOECs for CASRN 67-64-1 to aquatic plants range from 5,400 to 7,500 mg/L.</p> <p>No data gaps were identified for SIDS endpoints.</p>	

The sponsor country, the USA, presented the SIDS documents at the OECD SIAM 7 during June 29-30, 1999. The SIAR, SIAP and Dossier were finalized by OECD and published by the UNEP in July 1999 (<http://www.chem.unep.ch/irptc/sids/oecd/sids/67641.pdf>). This hazard characterization includes the May 2003 IRIS assessment (<http://www.epa.gov/ncea/iris/toxreviews/0128-tr.pdf>), SIDS documents, and any relevant studies obtained through EPA's literature search.

## 1. **Chemical Identity**

### 1.1 Identification and Purity

See identification and purity information at:

<http://www.chem.unep.ch/irptc/sids/oecd/sids/67641.pdf>.

### 1.2 Physical-Chemical Properties

See physical-chemical properties at:

<http://www.chem.unep.ch/irptc/sids/oecd/sids/67641.pdf>.

## 2. **General Information on Exposure**

### 2.1 Production Volume and Use Pattern

CASRN 67-64-1 had an aggregated production and/or import volume in the United States of 1 billion pounds and greater during calendar year 2005.

Non-confidential information in the IUR indicated that the industrial processing and uses of the chemical include intermediates, solvents (for cleaning or degreasing), solvents (which become part of product formulation or mixture), solvents (for chemical manufacture and processing and are not part of product at greater than 1% by weight), and other. Non-confidential commercial and consumer uses of this chemical include artists supplies, paints and coatings, photographic supplies, rubber and plastic products, and other.

### 2.2 Environmental Exposure and Fate

See environmental exposure and fate data at:

<http://www.chem.unep.ch/irptc/sids/oecd/sids/67641.pdf>.

## 3. **Human Health Hazard**

See human health hazard data at <http://www.chem.unep.ch/irptc/sids/oecd/sids/67641.pdf>. The U.S. EPA evaluated acetone in 2003 for the IRIS program and the assessment is available at:

<http://www.epa.gov/ncea/iris/toxreviews/0128-tr.pdf>.

4. **Hazard to the Environment**

See environmental hazard data at:

<http://www.chem.unep.ch/irptc/sids/oecdsids/67641.pdf>.