

SCREENING-LEVEL HAZARD CHARACTERIZATION

SPONSORED CHEMICAL Ethylene (CASRN 74-85-1)

The High Production Volume (HPV) Challenge Program¹ 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^{1,2}) 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^{2,3} 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 submission 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

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

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

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

authorities around the world. OPPT is an active participant in these meetings and accepts these documents as reliable screening-level hazard assessments.

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.

Chemical Abstract Service Registry Number (CASRN)	74-85-1
Chemical Abstract Index Name	Ethylene
Structural Formula	CH₂=CH₂
Summary	
<p>Ethylene (CASRN 7485-1) is a gas with moderate water solubility and high vapor pressure. At a very low temperature, it is a liquid. It is expected to have high mobility in soil. CASRN 7485-1 is expected to biodegrade in the environment. The rate of volatilization is considered high. The rate of hydrolysis is considered negligible. The rate of atmospheric photooxidation is moderate. An EPISuite (v4.00) estimated bioaccumulation factor of 2.0 suggests bioconcentration is low. CASRN 7485-1 is expected to have low persistence (P1) and low bioaccumulation potential (B1).</p> <p>Acute toxicity of CASRN 74-85-1 to rats is low via the inhalation route. There is no evidence to suggest that the liquid ethylene gas is irritating to skin or eyes; however, it might cause frost injuries. In a 13-week repeated-dose toxicity study in rats via inhalation-exposure, CASRN 74-85-1 did not show test substance-related toxicity; the NOAEC is 10,000 ppm (11.5 mg/L). In a combined reproductive/developmental toxicity screening test in rats via inhalation, no effects on reproductive and developmental parameters were seen; the NOAEC is 5000 ppm (5.75 mg/L). CASRN 74-85-1 did not induce gene mutations in an <i>in vitro</i> test or chromosomal aberrations in <i>in vitro</i> and <i>in vivo</i> tests. CASRN 74-85-1 showed a equivocal evidence for carcinogenicity in rats when exposed up to 3000 ppm (3.45 mg/L). CASRN 74-85-1 showed equivocal evidence for carcinogenicity in animals.</p> <p>The acute aquatic toxicity values for CASRN 74-85-1 from the SIDS documents are as follows: for fish, the 96-hour LC₅₀ (QSAR estimated) is 50-119.5 mg/L; for aquatic invertebrates, the 48-hour EC₅₀ (QSAR estimated) is 53-153 mg/L and for aquatic plants, the measured 72-hour EC₅₀ values are 40 mg/L (biomass) and 72 mg/L (growth rate). EPA provided the ECOSAR predicted values to support these data—the 96-hour LC₅₀ for fish is 96 mg/L, the 48-hour EC₅₀ for aquatic invertebrates is 48.4 mg/L, and the 96-hour EC₅₀ for aquatic plants is 16.7 mg/L.</p> <p>No data gaps were identified for SIDS endpoints.</p>	

The sponsor country, Norway, presented the SIDS documents at the OECD SIAM 5 during October 28-30, 1996. The SIAR, SIAP and Dossier were finalized and published by the UNEP in October 1998 (<http://www.chem.unep.ch/irptc/sids/OECDSIDS/74851.pdf>). This hazard characterization includes EPA review of the SIDS documents and relevant studies obtained through literature search.

1. **Chemical Identity**

1.1 **Identification and Purity**

See identification and purity information at:

<http://www.chem.unep.ch/irptc/sids/OECDSIDS/74851.pdf>.

1.2 **Physical-Chemical Properties**

See physical-chemical properties at: <http://www.chem.unep.ch/irptc/sids/OECDSIDS/74851.pdf>.

2. **General Information on Exposure**

2.1 **Production Volume and Use Pattern**

CASRN 74-85-1 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, surface active agents, and other. Non-confidential commercial and consumer uses of this chemical include rubber and plastic products.

2.2 **Environmental Exposure and Fate**

See environmental exposure and fate data at:

<http://www.chem.unep.ch/irptc/sids/OECDSIDS/74851.pdf>.

3. **Human Health Hazard**

See human health data at: <http://www.chem.unep.ch/irptc/sids/OECDSIDS/74851.pdf>.

4. Hazard to the Environment

See environmental hazard data at: <http://www.chem.unep.ch/irptc/sids/OECDSIDS/74851.pdf>.

The acute aquatic toxicity values for CASRN 74-85-1 from the SIDS documents are supported by the ECOSAR (v 1.00a) predicted values as follows:

Acute Toxicity to Fish

96-h LC₅₀ = 50-119.5 mg/L (QSAR estimate)

96-h LC₅₀ = 96 mg/L (ECOSAR)

Acute Toxicity to Aquatic Invertebrates

48-h EC₅₀ = 53-153 mg/L (QSAR estimate)

48-h EC₅₀ = 48.4 mg/L (ECOSAR)

Toxicity to Aquatic Plants

72-h EC₅₀ = 40 mg/L (biomass) (measured)

72-h EC₅₀ = 72 mg/L (growth rate) (measured)

96-h EC₅₀ = 16.7 mg/L (ECOSAR)