

SCREENING-LEVEL HAZARD CHARACTERIZATION

Phenol (CASRN 108-95-2)

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 or OECD HPV submission, a search of the following databases was made from one year prior to the date of the HPV Challenge 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.

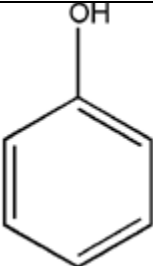
OPPT does not develop HCs for those HPV chemicals which have already been assessed internationally through the HPV program of the Organization for Economic Cooperation and Development (OECD) and for which Screening Initial Data Set (SIDS) Initial Assessment Reports (SIAR) and SIDS Initial Assessment 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.

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>.

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)	108-95-2
Chemical Abstract Index Name	Phenol
Structural Formula	

Summary

Phenol (CASRN 108-95-2) is a colorless to light pink crystalline solid with high water solubility and moderate vapor pressure. It is expected to have high mobility in soil. CASRN 108-95-2 is readily biodegradable under aerobic conditions and also readily biodegrades in soil and water. The rate of volatilization is considered low. The rate of hydrolysis is considered negligible. The rate of atmospheric photooxidation is moderate. A bioconcentration factor of 17.5 suggests bioconcentration is low. CASRN 108-95-2 is expected to have low persistence (P1) and low bioaccumulation potential (B1).

The acute toxicity of CASRN 108-95-2 in rats by the oral and dermal routes is moderate. CASRN 108-95-2 is a severe eye irritant causing irreversible damage in rabbits. Dermal exposure to CASRN 108-95-2 causes chemical burns. CASRN 108-95-2 does not cause dermal sensitization in tests with guinea pigs or mice. Repeated-dose toxicity studies in mice and rats have been conducted via drinking water and gavage. Generally, there is greater toxicity observed in gavage studies for phenol. In a 13-week specialized neurotoxicity drinking water study, decreased motor activity was seen in female rats and decreased body weight in both males and females consuming the high concentration of CASRN 108-95-2 (5000 mg/l, corresponding to 360 mg/kg-day). The NOAEL is 107 mg/kg-day. There is a 2-year drinking water bioassay in rats. On the basis of increased kidney inflammation and decreased body weight as compared with controls at the high dose of 5000 mg/l (585 mg/kg-day for males and 630 mg/kg-day for females), the overall study LOAEL is 585 mg/kg-day and the NOAEL is 260 mg/kg-day. In a two-generation (drinking water) reproductive toxicity study of CASRN 108-95-2 in rats, decreased parental and pup weight occurred at a LOAEL of 301 mg/kg-day, with a NOAEL of 71 mg/kg-day. However, these lower body weights, compared with control, are likely to be secondary to decreased water consumption and not an indication of test substance toxicity. No reproductive toxicity effects were reported for males or females across two generations. In a rat prenatal developmental toxicity study, following gavage exposures to CASRN 108-95-2, decreased maternal body weight gain is the basis for a LOAEL for maternal toxicity of 120 mg/kg-day and a corresponding NOAEL of 60 mg/kg-day. In this study, the developmental NOAEL is 120 mg/kg-day, the highest dose tested. CASRN 108-95-2 is generally negative in bacterial gene mutation assays but is positive or equivocal in mammalian cell chromosomal

aberration assays *in vitro*. CASRN 108-95-2 is negative in chromosomal aberration assays when administered to mice orally *in vivo*. CASRN 108-95-2 is negative in 2-year chronic drinking water cancer bioassays with rats and mice. Human data on CASRN 108-95-2 are available, however according to the 2002 IRIS assessment, human data were considered inadequate for use in generation of an RfC or RfD.

The 96-hour acute aquatic toxicity of CASRN 108-95-2 for fishes is in the range of 5.02 – 47.5 mg/L. The 48-hour acute toxicity to aquatic invertebrates for CASRN 108-95-2 is in the range of 3.1 – 12.6 mg/L, and for aquatic plants, the 72-hour acute toxicity for CASRN 108-95-2 is in the range of 61.1 – 370 mg/L.

No data gaps were identified for SIDS endpoints.

The risk assessment was prepared in the EU, and documents were presented at the OECD SIAM 19 during 19-22 October 2004. The documents can be found at:

http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/phenolreport060.pdf

This hazard characterization includes EPA's IRIS Toxicological Profile (<http://www.epa.gov/ncea/iris/toxreviews/0088-tr.pdf>), and review of the 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://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/phenolreport060.pdf

1.2 Physical-Chemical Properties

See physical-chemical properties at: http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/phenolreport060.pdf

2. **General Information on Exposure**

2.1 Production Volume and Use Pattern

CASRN 108-95-2 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 adhesives and binding agents, intermediates, and other. Non-confidential commercial and consumer uses of this chemical include adhesives and sealants, agricultural products (non-pesticidal), and other.

2.2 Environmental Exposure and Fate

See environmental exposure and fate data at:

http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/phenolreport060.pdf

3. **Human Health Hazard**

See human health hazard data at: http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/phenolreport060.pdf.

The U.S. EPA evaluated phenol in 2002 for the IRIS program and the assessment is available at: <http://www.epa.gov/ncea/iris/toxreviews/0088-tr.pdf>. ATSDR's Toxicological Profile for phenol was updated September 2008: <http://www.atsdr.cdc.gov/toxprofiles/tp115.html>.

4. **Hazard to the Environment**

See environmental hazard data at: http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/phenolreport060.pdf.