

SCREENING-LEVEL HAZARD CHARACTERIZATION

Indigo Blue (CASRN 482-89-3)

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.

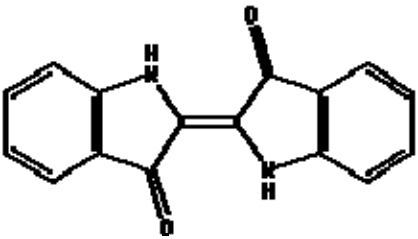
OPPT does not develop HCs for those HPV chemicals which have already been assessed internationally through the HPV program of the Organization for Economic Cooperation and Development (OECD) and for which Screening Initial Data Set (SIDS) Initial Assessment Reports (SIAR) and SIDS Initial Assessment Profiles (SIAP) are available. These documents are presented in an international forum that involves review and endorsement by governmental 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.

<p>Chemical Abstract Service Registry Number (CASRN)</p>	<p>482-89-3</p>
<p>Chemical Abstract Index Name</p>	<p>3H-Indol-3-one,2-(,3-oxo-2H-indol-2-ylidene)-1,2-dihydro</p>
<p>Structural Formula</p>	
<p style="text-align: center;">Summary</p> <p>CASRN 482-89-3 (indigo blue) is a solid with low water solubility and negligible vapor pressure. It is expected to have low mobility in soil. Indigo blue is not readily biodegradable. The rate of volatilization is considered low. The rate of hydrolysis is considered negligible. The rate of atmospheric photooxidation is high; however, this compound is not expected to exist in the particulate phase in the atmosphere. Bioconcentration factors (BCF) of 2.5-4.5, measured in fish suggest bioconcentration is low. Indigo blue is expected to have moderate persistence (P2) and low bioaccumulation potential (B1).</p> <p>The acute toxicity of CASRN 482-89-3 to rats is low via the oral and inhalation routes, and low in rabbits via the dermal route. CASRN 482-89-3 is not irritating to the rabbit skin or eye. CASRN 482-89-3 is not a skin sensitizer in humans. A two-year oral gavage study in rats showed no macroscopic or histopathological changes. The NOAEL for systemic toxicity is 1200 mg/kg/day. In an oral three-generation reproductive toxicity study in rats, no dose-related effects are observed for systemic, reproductive or developmental toxicity up to 500 mg/kg-bw/day, the highest dose tested. The NOAEL for systemic, reproductive and developmental toxicity is 500 mg/kg-bw/day. A prenatal developmental toxicity study in rats and rabbits noted no significant maternal or developmental effects at 500 mg/kg-bw/day. The NOAEL for both species is 500 mg/kg/day. CASRN 482-89-3 is negative for mutagenicity in bacteria and in a mouse micronucleus test <i>in vivo</i>. CASRN 482-89-3 induced chromosomal aberration <i>in vitro</i>.</p> <p>The 96-hr LC₅₀ acute toxicity value of CASRN 482-89-3 for fish is > 1000 mg/L. For aquatic invertebrates the 48-hr EC₅₀ value is > 500 mg/L, and for aquatic plants, the 72-hr acute toxicity value is 6.5 mg/L (biomass). The 21-day EC₅₀ for aquatic invertebrates for CASRN 482-89-3 is 2.6 mg/L (mortality) and 1.6 mg/L (reproduction).</p> <p>No data gaps were identified for SIDS endpoints.</p>	

The sponsor country, Japan, presented the SIDS documents at the OECD SIAM 2 during July 4-6, 1994. The SIAR, SIAP and Dossier were finalized by OECD and published by the UNEP in March 2005 (<http://www.chem.unep.ch/irptc/sids/OECDSIDS/482893.pdf>). This hazard characterization includes EPA review of the SIDS documents and any 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/482893.pdf>.

1.2 Physical-Chemical Properties

See physical-chemical properties at:

<http://www.chem.unep.ch/irptc/sids/OECDSIDS/482893.pdf>.

2. General Information on Exposure

2.1 Production Volume and Use Pattern

CASRN 482-89-3 had an aggregated production and/or import volume in the United States between 1 and 10 million pounds during calendar year 2005.

Non-confidential information in the IUR indicated that the industrial processing and uses of the chemical include coloring agents, dye, and other. Non-confidential commercial and consumer uses of this chemical include fabrics, textiles, apparel, and other.

2.2 Environmental Exposure and Fate

See environmental exposure and fate at:

<http://www.chem.unep.ch/irptc/sids/OECDSIDS/482893.pdf>.

3. Human Health Hazard

See human health hazard data at: <http://www.chem.unep.ch/irptc/sids/OECDSIDS/482893.pdf>.

4. Hazard to the Environment

See environmental hazard data at: <http://www.chem.unep.ch/irptc/sids/OECDSIDS/482893.pdf>.