

## Benzidine; CASRN 92-87-5

Human health assessment information on a chemical substance is included in the IRIS database only after a comprehensive review of toxicity data, as outlined in the [IRIS assessment development process](#). Sections I (Health Hazard Assessments for Noncarcinogenic Effects) and II (Carcinogenicity Assessment for Lifetime Exposure) present the conclusions that were reached during the assessment development process. Supporting information and explanations of the methods used to derive the values given in IRIS are provided in the [guidance documents located on the IRIS website](#).

### STATUS OF DATA FOR Benzidine

**File First On-Line 03/31/1987**

Category (section)	Assessment Available?	Last Revised
Oral RfD (I.A.)	yes	01/01/1989
Inhalation RfC (I.B.)	message	07/01/1991
Carcinogenicity Assessment (II.)	yes	03/31/1987

## I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

### I.A. Reference Dose for Chronic Oral Exposure (RfD)

Substance Name — Benzidine

CASRN — 92-87-5

Last Revised — 01/01/1989

The oral Reference Dose (RfD) is based on the assumption that thresholds exist for certain toxic effects such as cellular necrosis. It is expressed in units of mg/kg-day. In general, the RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Please refer to the Background Document for an elaboration of these concepts. RfDs can also be derived for the noncarcinogenic health effects of substances that are also carcinogens. Therefore, it is essential to refer to other sources of

information concerning the carcinogenicity of this substance. If the U.S. EPA has evaluated this substance for potential human carcinogenicity, a summary of that evaluation will be contained in Section II of this file.

### I.A.1. Oral RfD Summary

Critical Effect	Experimental Doses*	UF	MF	RfD
<b>Brain cell vacuolization; liver cell alterations in females</b>	NOEL: None  LOAEL: 20 ppm in drinking water (2.7 mg/kg/day)	1000	1	3E-3 mg/kg/day
<b>Mouse Chronic Oral Bioassay</b>				
<b>Littlefield et al., 1983</b>				

\*Conversion Factors: Estimated by the body weight and water consumption data provided by the investigators. The transformed animal dose was calculated by multiplying experimental dose by ratio of molecular weight of the free base (184.23) to the dihydrochloride (257.16).

### I.A.2. Principal and Supporting Studies (Oral RfD)

Littlefield, N.A., C.J. Nelson and C.H. Frith. 1983. Benzidine dihydrochloride: Toxicological assessments in mice during chronic exposures. *J. Toxicol. Environ. Health.* 12: 671-685.

Male and female mice of two strains (monohybrids and F1 hybrids from Balb/C males and C57B1/65 females), 72 to 120/sex/strain, were exposed to benzidine dihydrochloride in the drinking water at 0 to 160 ppm (0 to 27.2 mg/kg/day) for 33 months. Dose-related decreases in body weight gain and survival at all levels were reported; most deaths were caused by tumors. Treatment-related effects included increased incidences of liver cell alterations in females at greater than or equal to 3.8 mg/kg/day, bile duct hyperplasia in females at greater than or equal to 8.2 mg/kg/day and in males at 30.4 mg/kg/day, megakaryocytosis of bone marrow in females at greater than or equal to 11.5 mg/kg/day and in males at greater than or equal to 22.8 mg/kg/day, bladder epithelial hyperplasia in males at 30.4 mg/kg/day, atrophy of the ovary in females at greater than or equal to 15.2 mg/kg/day, brain vacuolization in females at greater than or equal to 3.8 mg/kg/day and males at greater than or equal to 5.7 mg/kg/day, and hemosiderosis of the spleen at greater than or equal to 22.8 mg/kg/day.

### **I.A.3. Uncertainty and Modifying Factors (Oral RfD)**

UF — The UF of 1000 allows for uncertainty in the extrapolation of dose levels from laboratory animals to humans (10A), uncertainty in the threshold for sensitive humans (10H), and uncertainty in the estimation of a NOAEL from a LOAEL (10L).

MF — None

### **I.A.4. Additional Studies/Comments (Oral RfD)**

Budnick et al. (1984) reported no statistically significant increase in any particular type of birth defect or in all types of birth defects in residents in the area surrounding the Drake Superfund site in Clinton County, PA contaminated by beta-naphthylamine, benzidine and benzene.

### **I.A.5. Confidence in the Oral RfD**

Study — Medium

Database — Medium

RfD — Medium

The study used adequate numbers of both sexes of two strains of mice. Several other chronic studies support the RfD. Teratogenicity and reproductive studies are lacking. Confidence in the study is medium and the database and RfD are rated medium as well.

### **I.A.6. EPA Documentation and Review of the Oral RfD**

Source Document — This assessment is not presented in any existing U.S. EPA document.

Other EPA Documentation — None

Agency Work Group Review — 01/22/1986, 07/16/1987

Verification Date — 07/16/1987

Screening-Level Literature Review Findings — A screening-level review conducted by an EPA contractor of the more recent toxicology literature pertinent to the RfD for Benzidine conducted in November 2001 did not identify any critical new studies. IRIS users who know of important new studies may provide that information to the IRIS Hotline at [hotline.iris@epa.gov](mailto:hotline.iris@epa.gov) or (202)566-1676.

### **I.A.7. EPA Contacts (Oral RfD)**

Please contact the IRIS Hotline for all questions concerning this assessment or IRIS, in general, at (202)566-1676 (phone), (202)566-1749 (FAX) or [hotline.iris@epa.gov](mailto:hotline.iris@epa.gov) (internet address).

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### **I.B. Reference Concentration for Chronic Inhalation Exposure (RfC)**

Substance Name — Benzidine  
CASRN — 92-87-5

The health effects data for benzidine were reviewed by the U.S. EPA RfD/RfC Work Group and determined to be inadequate for derivation of an inhalation RfC. For additional information on the health effects of this chemical, interested parties are referred to the EPA documentation listed below.

U.S. EPA. 1978. Review of the Environmental Effects of Pollutants. II. Benzidine, Health Effects Research Laboratory. U.S. EPA, Cincinnati, OH. EPA 600/1-78-024. NTIS PB281076.

U.S. EPA. 1980a. Ambient Water Quality Criteria Document for Benzidine. Prepared by the Office of Health and Environmental Assessment, Environmental Assessment and Criteria Office, Cincinnati, OH, for the Office of Water Regulations and Standards, Washington, DC. EPA-440/5-80-023. NTIS PB81- 117343.

U.S. EPA. 1980b. TSCA Chemical Assessment Series: Preliminary Risk Assessment Phase I: Benzidine, Its Congeners, and Their Derivative Dyes and Pigments. U.S. EPA, Office of Pesticides and Toxic Substances, Washington, DC. EPA- 560/11-80-019.

U.S. EPA. 1987. Health Effects Assessment for Benzidine. Prepared by Environmental Criteria and Assessment Office, Office of Health and Environmental Assessment, Cincinnati, OH for the Office of Emergency and Remedial Response, Washington, DC. EPA/600/8-88/019.

Agency Work Group Review — 03/28/1991

Screening-Level Literature Review Findings — A screening-level review conducted by an EPA contractor of the more recent toxicology literature pertinent to the RfC for Benzidine conducted in November 2001 did not identify any critical new studies. IRIS users who know of important

new studies may provide that information to the IRIS Hotline at [hotline.iris@epa.gov](mailto:hotline.iris@epa.gov) or (202)566-1676.

#### EPA Contacts:

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## II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Benzidine

CASRN — 92-87-5

Last Revised — 03/31/1987

Section II provides information on three aspects of the carcinogenic assessment for the substance in question; the weight-of-evidence judgment of the likelihood that the substance is a human carcinogen, and quantitative estimates of risk from oral exposure and from inhalation exposure. The quantitative risk estimates are presented in three ways. The slope factor is the result of application of a low-dose extrapolation procedure and is presented as the risk per (mg/kg)/day. The unit risk is the quantitative estimate in terms of either risk per ug/L drinking water or risk per ug/cu.m air breathed. The third form in which risk is presented is a drinking water or air concentration providing cancer risks of 1 in 10,000, 1 in 100,000 or 1 in 1,000,000. The rationale and methods used to develop the carcinogenicity information in IRIS are described in The Risk Assessment Guidelines of 1986 (EPA/600/8-87/045) and in the IRIS Background Document. IRIS summaries developed since the publication of EPA's more recent Proposed Guidelines for Carcinogen Risk Assessment also utilize those Guidelines where indicated (Federal Register 61(79):17960-18011, April 23, 1996). Users are referred to Section I of this IRIS file for information on long-term toxic effects other than carcinogenicity.

### II.A. Evidence for Human Carcinogenicity

### **II.A.1. Weight-of-Evidence Characterization**

Classification — A; human carcinogen

Basis — Observation of increased incidence of bladder cancer and bladder cancer-related deaths in exposed workers

### **II.A.2. Human Carcinogenicity Data**

Sufficient. Several epidemiologic and case studies have shown that occupational exposure to benzidine results in bladder cancer. Zavon et al. (1973) observed 11 cases of bladder cancer in 25 workers exposed to levels of benzidine 0.005 to 17.6 mg/cu.m for a mean period of 11.46 years. A mean total accumulated dose of 130 mg/kg was estimated from urinary benzidine levels.

Meigs et al. (1986), in their 30-year follow-up study of a cohort of workers at a benzidine manufacturing facility when compared with the population of Connecticut, found a statistically significant excess incidence of bladder cancer in male workers exposed to the highest estimated level of benzidine (Standard Incidence Ratio = 343, observed = 8,  $p < 0.01$ ). No quantification of exposure was reported. Of the eight cases of bladder cancer, three were long-term cigarette smokers. Forni et al. (1972) reported 17 bladder cancers in a cohort of 858 benzidine dyestuff workers. The maximum latency period was 16 years after exposure was terminated. Populations in these two studies may have been exposed concurrently to substituted benzidines or other compounds. Case et al. (1954) reported 10 deaths from bladder cancer attributable to benzidine exposure only (total number of workers exposed to benzidine not specified). Tsuchiya et al. (1975) reported 72 cases of bladder cancer among a population of 1015 workers employed in benzidine production or use for 23 years or less. No exposure levels were quantified. Excess occurrence of bladder cancer in workers exposed simultaneously to benzidine and beta-naphthylamine has been reported by a number of authors.

### **II.A.3. Animal Carcinogenicity Data**

Benzidine has been shown to produce various tumor types at multiple sites in animal species exposed by several routes. For example, dogs fed benzidine in capsules for 5 years developed bladder tumors after a relatively long latency period (Spitz et al., 1950). Lymphomas, hepatomas and adenocarcinomas were observed in mice (strain not specified) treated by s.c. injection (Bonser et al., 1956; Prokof'eva, 1971). Benzidine given by gavage in sesame oil produced increased incidence of mammary tumors in Sprague-Dawley rats (Griswold et al., 1968). Rats exposed by inhalation developed myeloid leukemia (Zabehinskii, 1970). Benzidine dihydrochloride has also been shown to produce tumors when administered by gavage or in the diet or water.

#### II.A.4. Supporting Data for Carcinogenicity

Benzidine is mutagenic for *Salmonella typhimurium* upon addition of an exogenous metabolic system as well as for mouse lymphoma cells, but not for yeast (Waters et al., 1983; Oberly et al., 1984; Kada, 1981). Results of DNA damage assays are generally positive (Ashby and Kilbey, 1981; Parodi et al., 1981). In vivo treatment with benzidine has resulted in sister chromatid exchange and micronucleus formation (Parodi, 1983; Katz et al., 1981). Benzidine in the presence of rat liver homogenates transformed BHK21 Cl-13 cells and Syrian hamster embryo cells (Ashby et al., 1978; Pienta, 1980).

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#### II.B. Quantitative Estimate of Carcinogenic Risk from Oral Exposure

##### II.B.1. Summary of Risk Estimates

Oral Slope Factor — 2.3E+2 per mg/kg-day

Drinking Water Unit Risk — 6.7E-3 per ug/L

Extrapolation Method: One-hit with time factor, extra risk

Drinking Water Concentrations at Specified Risk Levels:

Risk Level	Concentration
E-4 (1 in 10,000)	2E-2 ug/L
E-5 (1 in 100,000)	2E-3 ug/L
E-6 (1 in 1,000,000)	2E-4 ug/L

##### II.B.2. Dose-Response Data (Carcinogenicity, Oral Exposure)

The oral risk estimates were calculated from the inhalation exposure data in Section II.C.2.

### **II.B.3. Additional Comments (Carcinogenicity, Oral Exposure)**

The unit risk should not be used if the water concentration exceeds 2 ug/L, since above this concentration the slope factor may differ from that stated.

### **II.B.4. Discussion of Confidence (Carcinogenicity, Oral Exposure)**

See II.C.2.

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## **II.C. Quantitative Estimate of Carcinogenic Risk from Inhalation Exposure**

### **II.C.1. Summary of Risk Estimates**

Inhalation Unit Risk 6.7E-2 per ug/cu.m

Extrapolation Method: One-hit with time factor, extra risk

Air Concentrations at Specified Risk Levels:

<b>Risk Level</b>	<b>Concentration</b>
<b>E-4 (1 in 10,000)</b>	2E-3 ug/cu.m
<b>E-5 (1 in 100,000)</b>	2E-4 ug/cu.m
<b>E-6 (1 in 1,000,000)</b>	2E-5 ug/cu.m



### II.C.2. Dose-Response Data for Carcinogenicity, Inhalation Exposure

-----Dose-----				
Species/Strain Tumor Type	Administered	Human Equivalent	Tumor Incidence	Reference
<b>Human, bladder tumors</b>	Route: Occupational exposure (inhalation)			Zavon, 1973
<b>An inhalation slope factor of 2.3E+2 per mg/kg-day was calculated.</b>				

The slope factor (B) was calculated using the model

$$P = 1 - \exp[-Bdt^{**3}]$$

or

$$B = [-\ln(1 - 13/25)] / [0.0063 \times (56.5/71.3)^{**3}] = 234.13 \text{ per mg/kg-day}$$

where:

<b>13/25</b>	=	observed bladder tumor incidence
<b>0.0063 mg/kg/day</b>	=	daily lifetime exposure calculated from a mean urine benzidine level of 0.04 mg/L at the end of workshift, 1.2 L/day average urine output, a 1.45% recovery factor in urine, 70 kg bw, 240 work days/ year, 11.46 average exposure duration, and 56.5 years average cohort age at the end of the study
<b>71.3 years</b>	=	average life span in U.S.

### II.C.3. Additional Comments (Carcinogenicity, Inhalation Exposure)

Of 13 cases of bladder tumors, 11 men had bladder cancers while 2 men had benign papillomas. The mean exposure was 13.61 years and the average age at the end of a 13-year exposure was 57 years. The 12 men who did not develop bladder tumors had a mean exposure of 8.91 years and an average age of 56.

The unit risk should not be used if the air concentration exceeds 2E-1 ug/cu.m, since above this concentration the slope factor may differ from that stated.

#### **II.C.4. Discussion of Confidence (Carcinogenicity, Inhalation Exposure)**

The cohort was very small, and the incidence of bladder cancer observed was 44% (11/25). The quantitative risk estimate included two benign tumors in the incidence rate (13/25). The incidence rate was calculated for the total cohort, which included whites as well as nonwhites. Out of the 25 workers, nine had multiple exposures to other potential bladder carcinogens such as beta-naphthylamine and dichlorobenzidine. The smoking history for the cohort was not available. It should be noted that bladder cancer is twice as common in whites as in nonwhites.

The 1.45% recovery factor (Rinde and Troll, 1975) in urine is based on a study of monkeys. Because of methodological problems and differences in exposures between monkeys and humans exposed in occupational settings, this factor may change significantly.

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#### **II.D. EPA Documentation, Review, and Contacts (Carcinogenicity Assessment)**

##### **II.D.1. EPA Documentation**

Source Document — U.S. EPA, 1980, 1986

The 1980 Ambient Water Quality Criteria document has received Agency and peer review. The 1986 Health and Environmental Effects Profile received OHEA review.

##### **II.D.2. EPA Review (Carcinogenicity Assessment)**

Agency Work Group Review — 12/17/1986

Verification Date — 12/17/1986

Screening-Level Literature Review Findings — A screening-level review conducted by an EPA contractor of the more recent toxicology literature pertinent to the cancer assessment for Benzidine conducted in November 2001 identified one or more significant new studies. IRIS users may request the references for those studies from the IRIS Hotline at [hotline.iris@epa.gov](mailto:hotline.iris@epa.gov) or (202)566-1676.

### **II.D.3. EPA Contacts (Carcinogenicity Assessment)**

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**III. [reserved]**

**IV. [reserved]**

**V. [reserved]**

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### **VI. Bibliography**

Substance Name — Benzidine  
CASRN — 92-87-5

#### **VI.A. Oral RfD References**

Budnick, L.D., J.N. Logue, D.C. Sokal, J.M. Fox and H. Falk. 1984. Cancer and birth defects near the Drake Superfund site, Pennsylvania. *Arch. Environ. Health*. 39(6): 409-413.

Littlefield, N.A., C.J. Nelson and C.H. Frith. 1983. Benzidine dihydro- chloride: Toxicological assessments in mice during chronic exposures. *J. Toxicol. Environ. Health*. 12: 671-685.

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#### **VI.B. Inhalation RfC References**

U.S. EPA. 1978. Review of the Environmental Effects of Pollutants. II. Benzidine, Health Effects Research Laboratory. U.S. EPA, Cincinnati, OH. EPA 600/1-78-024. NTIS PB281076.

U.S. EPA. 1980a. Ambient Water Quality Criteria Document for Benzidine. Prepared by the Office of Health and Environmental Assessment, Environmental Assessment and Criteria Office, Cincinnati, OH, for the Office of Water Regulations and Standards, Washington, DC. EPA-440/5-80-023. NTIS PB81- 117343.

U.S. EPA. 1980b. TSCA Chemical Assessment Series: Preliminary Risk Assessment Phase I: Benzidine, Its Congeners, and Their Derivative Dyes and Pigments. U.S. EPA, Office of Pesticides and Toxic Substances, Washington, DC. EPA- 560/11-80-019.

U.S. EPA. 1987. Health Effects Assessment for Benzidine. Prepared by Environmental Criteria and Assessment Office, Office of Health and Environmental Assessment, Cincinnati, OH for the Office of Emergency and Remedial Response, Washington, DC. EPA/600/8-88/019.

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### **VI.C. Carcinogenicity Assessment References**

Ashby, J. and B. Kilbey. 1981. Summary report on the performance of bacterial repair, phage induction, degranulation, and nuclear enlargement assays. *Prog. Mutat. Res.* 1: 33-48.

Ashby, J., J.A. Styles and D. Paton. 1978. In vitro evaluation of some derivatives of the carcinogen butter yellow: Implications for environmental screening. *Br. J. Cancer.* 38: 34-50.

Bonser, G.M., D.B. Clayson and J.W. Jull. 1956. Induction of tumors of the subcutaneous tissues, liver and intestine in the mouse by certain dyestuffs and their intermediates. *Br. J. Cancer.* 10: 653-667.

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Spitz, S., W.H. Maguigan and M.D. Dobner. 1950. The carcinogenic action of benzidine. *Cancer.* 3: 789-804.

Tsuchiya, K., T. Okubo and S. Ishizo. 1975. An epidemiological study of occupational bladder tumors in the dye industry in the industry of Japan. *Br. J. Ind. Med.* 32: 203-209.

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U.S. EPA. 1986. Health and Environmental Effects Profile for Benzidine. Prepared by the Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Cincinnati, OH for the Office of Solid Waste and Emergency Response, Washington, DC.

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## VII. Revision History

Substance Name — Benzidine  
CASRN — 92-87-5

Date	Section	Description
09/07/1988	I.A.	Oral RfD summary on-line
01/01/1989	I.A.1.	LOAEL and RfD corrected
07/01/1991	I.B.	Inhalation RfC message on-line
12/03/2002	I.A.6., I.B., II.D.2.	Screening-Level Literature Review Findings message has been added.

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## VIII. Synonyms

Substance Name — Benzidine

CASRN — 92-87-5

Last Revised — 03/31/1987

- 92-87-5
- BENZIDIN
- BENZIDINA
- Benzidine
- BENZYDYNA
- 4,4'-BIANILINE
- p,p'-BIANILINE
- (1,1'-BIPHENYL)-4,4'-DIAMINE
- 4,4'-BIPHENYLDIAMINE
- BIPHENYL, 4,4'-DIAMINO-
- 4,4'-BIPHENYLENEDIAMINE
- C.I. 37225
- C.I. AZOIC DIAZO COMPONENT 112
- 4,4'-DIAMINOBIIPHENYL
- 4,4'-DIAMINO-1,1'-BIPHENYL
- p,p'-DIAMINOBIIPHENYL
- 4,4'-DIAMINODIPHENYL
- p-DIAMINODIPHENYL
- p,p'-DIANILINE
- 4,4'-DIPHENYLENEDIAMINE
- FAST CORINTH BASE B
- NCI-C03361
- RCRA WASTE NUMBER U021
- UN 1885