

## Chloramben; CASRN 133-90-4

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 Chloramben

**File First On-Line 01/31/1987**

Category (section)	Assessment Available?	Last Revised
<b>Oral RfD (I.A.)</b>	yes	01/31/1987
<b>Inhalation RfC (I.B.)</b>	not evaluated	
<b>Carcinogenicity Assessment (II.)</b>	not evaluated	

## I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

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

Substance Name — Chloramben

CASRN — 133-90-4

Last Revised — 01/31/1987

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>Hepatocyte degeneration</b>	NOEL: none	1000	1	1.5E-2 mg/kg/day
<b>18-Month Feeding Study in CD-1 Mice</b>	LEL: 100 ppm diet (15 mg/kg/day)			
<b>Union Carbide, 1978</b>				

\*Conversion Factors -- 1 ppm = 0.15 mg/kg/day (assumed mouse food consumption)

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

Union Carbide Agricultural Products Company, Inc. 1978. MRID No. 00040392, 00040398. Available from EPA. Write for FOI, EPA, Washington DC 20460.

Five hundred (250 male and 250 female) Crl:COBS CD-1 mice (approximately 4 weeks of age) were assigned 50/sex/group, to one control and three test groups. The test groups were fed diets containing the following levels of chloramben: 100, 1000, and 10,000 ppm. All animals were observed once a day for signs of illness or toxicity. All animals found dead or in extremis were subjected to gross necropsy examination. After 18 months, surviving animals were sacrificed. Nonneoplastic lesions were mainly observed in the liver and included hepatocyte degeneration.

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

UF — An uncertainty factor of 100 was used to account for the inter- and intra-species differences. An additional UF of 10 was used to account for the fact that a NOEL was not established.

MF — None

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

##### Data Considered for Establishing the RfD

1. 18-Month Oncogenic (dietary) - Principal study - see description above; core grade supplementary
2. Teratology - rat: Fetotoxic NOEL=500 ppm (25 mg/kg/day); Fetotoxic LEL=1500 ppm (75 mg/kg/day) (reduced ossification of skeletal bones); Maternal and Teratogenic NOEL=4500 ppm (HDT); core grade minimum (Union Carbide, 1976)
3. 2-Year Feeding - rat: Systemic NOEL=1000 ppm (50 mg/kg/day); no core grade (Union Carbide, 1963a)
4. 2-Year Feeding - dog: Systemic NOEL=10,000 ppm (250 mg/kg/day) (HDT); no core grade (Union Carbide, 1963b)
5. 3-Generation Reproduction - rat: Systemic NOEL=4500 ppm (225 mg/kg/day) (HDT); Reproductive NOEL=4500 ppm (HDT); no core grade (Union Carbide, 1966)

Data Gap(s): Rabbit Teratology Study

##### Other Data Reviewed

1) 80-Week Oncogenic - mice: Systemic NOEL=20,000 ppm (300 mg/kg/day); core grade supplementary (NCI, 1977)

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

Study — Medium

Database — Medium

RfD — Medium

The principal study appears to be of acceptable quality and is given a medium confidence rating. Since there is a data gap existing for chloramben and other studies do not show effects at much higher dose levels, confidence in the database can be considered medium to low. Confidence in the RfD can also be considered medium to low.

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

Pesticide Registration Standard, July 1981

Pesticide Registration Files

Agency Work Group Review — 06/24/1986

Verification Date — 06/24/1986

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 Chloramben conducted in August 2003 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 — Chloramben  
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Not available at this time.

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### **II. Carcinogenicity Assessment for Lifetime Exposure**

Substance Name — Chloramben  
CASRN — 133-90-4

Not available at this time.

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**III. [reserved]**

**IV. [reserved]**

**V. [reserved]**

## **VI. Bibliography**

Substance Name — Chloramben  
CASRN — 133-90-4

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

NCI (National Cancer Institute). 1977. Bioassay of chloramben for possible carcinogenicity. U.S. DHEW Pub. No. (NIH) 77-825, Bethesda, MD.

Union Carbide Agricultural Products Company, Inc. 1963a. MRID No. 00100200, 00104543, 00104548. Available from EPA. Write for FOI, EPA, Washington DC 20460.

Union Carbide Agricultural Products Company, Inc. 1963b. MRID No. 00100201, 00139708. Available from EPA. Write for FOI, EPA, Washington DC 20460.

Union Carbide Agricultural Products Company, Inc. 1966. MRID No. 00100202. Available from EPA. Write for FOI, EPA, Washington DC 20460.

Union Carbide Agricultural Products Company, Inc. 1976. MRID No. 00096618. Available from EPA. Write for FOI, EPA, Washington DC 20460.

Union Carbide Agricultural Products Company, Inc. 1978. MRID No. 00040392, 00040398. Available from EPA. Write for FOI, EPA, Washington DC 20460.

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

None

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

None

## VII. Revision History

Substance Name — Chloramben  
CASRN — 133-90-4

Date	Section	Description
10/28/2003	I.A.6.	Screening-Level Literature Review Findings message has been added.

## VIII. Synonyms

Substance Name — Chloramben  
CASRN — 133-90-4  
Last Revised — 01/31/1987

- 133-90-4
- ACP-M-728
- AMBIBEN
- AMIBEN
- AMIBEN DS
- AMIBIN
- 3-AMINO-2,5-DICHLOROBENZOIC ACID
- AMOBEN
- BENZOIC ACID, 3-AMINO-2,5-DICHLORO-
- CHLORAMBED
- Chloramben
- CHLORAMBENE
- 2,5-DICHLORO-3-AMINOBENZOIC ACID
- NCI-C00055
- VEGABEN
- VEGIBEN