

## p-Chloroaniline; CASRN 106-47-8

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 p-Chloroaniline

**File First On-Line 08/22/1988**

| Category (section)                      | Assessment Available? | Last Revised |
|---|-----------------------|--------------|
| <b>Oral RfD (I.A.)</b>                  | yes                   | 08/22/1988   |
| <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 — p-Chloroaniline

CASRN — 106-47-8

Last Revised — 08/22/1988

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>Nonneoplastic lesions of splenic capsule</b> | NOAEL: None  | 3000 | 1  | 4E-3 mg/kg/day |
| <b>Rat, Chronic Oral Bioassay</b>               | LOAEL: 250 ppm in diet converted to 12.5 mg/kg/day |      |    |                |
| <b>NCI, 1979</b>                                |  |      |    |                |

\*Conversion Factors: Food consumption = 5% bw/day; thus 250 mg/kg food x 0.05 kg/kg bw/day = 12.5 mg/kg/day

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

NCI (National Cancer Institute). 1979. Bioassay of p-chloroaniline for possible carcinogenicity. NCI Carcinogenesis Tech. Rep. Ser. No. 189. NTIS PB 295896.

Groups of 20 and 50 F344 rats of each sex were exposed to p-chloroaniline in the diet at concentration of 0, 250 or 500 ppm for 78 weeks followed by an observation period of 24 weeks. Gross and comprehensive histological examinations were performed on all animals after sacrifice. Significantly increased mortality occurred in the high-dose males and decreased average body weight gain occurred in the high-dose females. Nonneoplastic proliferative lesions of the capsule of the spleen (focal fibrosis with subcapsular mesenchymal proliferation) occurred in most of the treated rats. Fibrosis or fatty infiltration of the splenic parenchyma occurred in some of the high-dose males and one of the high-dose females. Splenic lesions did not occur in any of the control rats. This study did not define a NOEL. The 250 ppm level (12.5 mg/kg/day) is considered to be the LOAEL, which when divided by an uncertainty factor of 3000 results in a RfD of 0.004 mg/kg/day.

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

UF — 10 to extrapolate from a LOAEL to a NOEL, 10 to extrapolate from rats to humans and 10 to protect sensitive humans. An additional UF of 3 was added for lack of supporting reproductive and other toxicity data.

MF — None

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

A 2-year gavage rat bioassay is currently being conducted by the NTP. The RfD must be considered provisional until final results of the gavage bioassay are available.

Information regarding teratogenicity or other reproductive effects of p- chloroaniline is not available.

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

Study — Low

Database — Low

RfD — Low

Although the NCI (1979) bioassay is a well designed chronic oral study, confidence in the study is low because a NOEL or NOAEL was not defined. Confidence in the database is low because corroborating data are not available. Confidence in the RfD is also low, reflecting the low confidence in the study and database.

### **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 — 12/15/1987

Verification Date — 12/15/1987

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 p-Chloroaniline

conducted in August 2003 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.

### **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 — p-Chloroaniline  
CASRN — 106-47-8

Not available at this time.

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

Substance Name — p-Chloroaniline  
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This substance/agent has not undergone a complete evaluation and determination under US EPA's IRIS program for evidence of human carcinogenic potential.

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**III. [reserved]**

**IV. [reserved]**

**V. [reserved]**

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## **VI. Bibliography**

Substance Name — p-Chloroaniline  
CASRN — 106-47-8

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### VI.A. Oral RfD References

NCI (National Cancer Institute). 1979. Bioassay of p-chloroaniline for possible carcinogenicity. NCI Carcinogenesis Tech. Rep. Ser. No. 189. NTIS PB 295896.

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### VI.B. Inhalation RfC References

None

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### VI.C. Carcinogenicity Assessment References

None

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## VII. Revision History

Substance Name — p-Chloroaniline  
CASRN — 106-47-8

| Date       | Section | Description  |
|------------|---------|--|
| 08/22/1988 | I.A.    | Oral RfD summary on-line   |
| 10/28/2003 | I.A.6.  | Screening-Level Literature Review Findings message has been added. |

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## VIII. Synonyms

Substance Name — p-Chloroaniline  
CASRN — 106-47-8  
Last Revised — 08/22/1988

- 106-47-8

- 1-amino-4-chlorobenzene
- aniline, 4-chloro-
- aniline, p-chloro-
- benzeneamine, 4-chloro
- 4-chloranilin
- p-chloraniline
- 4-chloroaniline
- p-chloroaniline, liquid
- Chloroaniline, p-
- p-chloroaniline, solid
- 4-chlorobenzenamine
- 4-chlorophenylamine
- NCI-C02039
- RCRA waste number P024
- UN 2018
- UN 2019