



QA: N/A



MOL.20010719.0359

## Boron (Boron and Borates only) CASRN 7440-42-8

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Boron (Boron and Borates only); CASRN 7440-42-8

Health assessment information on a chemical substance is included in IRIS only after a comprehensive review of chronic toxicity data by U.S. EPA health scientists from several Program Offices and the Office of Research and Development. The summaries presented in Sections I and II represent a consensus reached in the review process. Background information and explanations of the methods used to derive the values given in IRIS are provided in the Background Documents.

#### STATUS OF DATA FOR Boron (Boron and Borates only)

File On-Line 10/01/1989

Category (section)	Status	Last Revised
Oral RfD Assessment (I.A.)	on-line	06/01/1995
Inhalation RfC Assessment (I.B.)	no data	
Carcinogenicity Assessment (II.)	no data	05/01/1993

**I. CHRONIC HEALTH HAZARD ASSESSMENTS FOR NONCARCINOGENIC EFFECTS**

**I.A. REFERENCE DOSE FOR CHRONIC ORAL EXPOSURE (RfD)**

Substance Name -- Boron (Boron and Borates only)  
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 Last Revised -- 06/01/1995

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.

NOTE: The Oral RfD for boron may change in the near future pending the outcome of a further review now being conducted by the RfD/RfC Work Group.

**I.A.1. ORAL RfD SUMMARY**

Critical Effect	Experimental Doses*	UF	MF	RfD
Testicular atrophy, spermatogenic arrest	NOAEL: 350 ppm (8.8 mg/kg/day)	100	1	9E-2 mg/kg/day

2-Year Dog Study  
 Oral Exposure (diet) LOAEL: 1170 ppm  
 (29 mg/kg/day)

Weir and Fisher, 1972

\*Conversion Factors: 1 ppm = 0.025 mg/kg/day (assumed dog food consumption).  
 Author converted borax and boric acid doses to boron equivalents.

**I.A.2. PRINCIPAL AND SUPPORTING STUDIES (ORAL RfD)**

Weir, R.J., Jr. and R.S. Fisher. 1972. Toxicological studies on borax and boric acid. Toxicol. Appl. Pharmacol. 23: 351-364.

Groups of 4 male and 4 female dogs were fed borax and boric acid in the diet for 2 years. The NOAEL was established at 350 ppm of boron equivalents (8.8 mg/kg/day), highest dose tested. In an additional study, dogs were fed 1170 ppm (29 mg/kg/day) for 38 weeks. At this dose, severe testicular atrophy and spermatogenic arrest occurred.

Groups of 35 male and 35 female rats were fed borax and boric acid in the diet for 2 years at boron-equivalent doses of 117, 350, and 1170 ppm (5.9, 17.5 or 58.5 mg B/kg/day). No treatment-related effects were seen at 5.9 or 17.5 mg/kg/day, so the highest NOAEL is 17.5 mg/kg/day. The LOAEL is 58.5 mg/kg/day, based on the following: significantly decreased testes weights and testes-to-body weight ratios; atrophied seminiferous epithelium; and decreased tubular size in the testes. Brain and brain-to-body weight ratios were also significantly decreased.

Schroeder and Mitchener (1975) reported a lifetime study in which mice were administered boron in drinking water at 5 mg/L (equivalent to 8.1 mg B/kg/day). No effects were observed with regard to body weight, longevity or survival. The NOAEL in this study was 8.1 mg/kg/day.

### I.A.3. UNCERTAINTY AND MODIFYING FACTORS (ORAL RfD)

UF -- Used in accordance with Agency guidelines for a NOAEL from a lifetime animal study.

MF -- None

### I.A.4. ADDITIONAL COMMENTS (ORAL RfD)

The two principal studies indicate that the dog is more sensitive than the rat, with more severe testicular effects occurring at half the dose level in the dog vs. the rat (29 mg/kg/day vs. 58 mg/kg/day).

Other studies reviewed:

- 1) 70-Day Study - rats: Groups of 15 rats were exposed to boron in drinking water. LOAEL=23.7 mg/kg/day (150 mg B/L) (LDT: decreased body weights; decreased weights of testes, seminal vesicles, spleens, and right femurs; lower fat content of bones; and lower plasma triglycerides and protein concentrations). At 300 mg B/L (44.7 mg/kg/day), spermatogenesis was impaired. There was no NOAEL in this study (Seal and Weeth, 1980).
- 2) 13-Week Study - mice: Male and female mice were fed boric acid. LOAEL=34-47 mg/kg/day (1200 ppm) (LDT: extramedullary hematopoiesis of spleen of minimal to mild severity was observed in all groups). At the higher doses, 68 mg/kg/day (2500 ppm) to 544 mg/kg/day (20,000 ppm), degeneration or atrophy of seminiferous tubules was observed in males (NTP, 1987).
- 3) 90-Day Study - rats: Boric acid and borax were administered in the diet at 52.5, 175, 525, 1750, and 5250 ppm (2.6, 8.8, 26, 88, and 260 mg B/kg/day). The low dose caused an increase in the weight of the brain, spleen, kidneys, liver, and ovaries in females. Increased kidney weight occurred at 175 ppm in males. No organ weight changes were seen at 525 ppm in either sex. Severe effects in both sexes were seen at 1750 ppm and above (organ and body weight decreases) (Weir and Fisher, 1972).
- 4) 90-Day Feeding Study - dogs: Fed boron at levels of 17.5, 175, and 1750 ppm (0.44, 4.4, or 44 mg/kg/day). The lowest dose resulted in decreased spleen/body weight ratio in male dogs; 175 ppm resulted in decreased testes/body weight ratio; the highest dose produced severe testicular atrophy. No changes in female organ weights were observed at 17.5 or 175 ppm. No histologic changes were seen in dogs fed 175 ppm or below. Severe testicular atrophy seen at highest dose (Weir and Fisher, 1972).
- 5) Multigeneration Reproductive Study - rats: Dosed at 117, 350, and 1170 ppm

(5.9, 17.5, 58.5 mg/kg/day). NOAEL=17.5 mg/kg/day; LOAEL=58.5 mg/kg/day; (HDT: males showed lack of spermatazoa in atrophied testes; females showed decreased ovulation) (Weir and Fisher, 1972).

6) 90-Day Reproductive Study - rats: Males were dosed with 0.3, 1.0, or 6.0 mg B/L (0.02, 0.072, or 0.426 mg/kg/day). NOAEL=0.426 mg/kg/day (HDT) (Dixon et al., 1976).

7) 60-Day Reproductive Study - rats: Doses were 0, 500, 1000, or 2000 mg/kg diet (equivalent to 25, 50, or 100 mg/kg/day). NOAEL=25 mg/kg/day; LOAEL=50 mg/kg/day; (decreased weights in liver, testes, and epididymis, and reduced fertility) (Dixon et al., 1979).

### I.A.5. CONFIDENCE IN THE ORAL RfD

Study -- Medium  
Data Base -- Medium  
RfD -- Medium

The referenced lifetime dog study provides both a NOAEL and a LOAEL and examines many biological endpoints, but has a limited number of experimental animals; it rates a medium confidence. Several sub-chronic, chronic and reproductive toxicity studies provide supportive data, but developmental data do not exist; hence the data base rates a medium level of confidence. Medium confidence in the RfD follows.

### 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 -- 06/23/1988, 07/20/1989, 06/15/1993, 08/03/1994, 05/09/

Verification Date -- 07/20/1989

### I.A.7. EPA CONTACTS (ORAL RfD)

Please contact the Risk Information Hotline for all questions concerning this assessment or IRIS, in general, at (513)569-7254 (phone), (513)569-7159 (FAX) or RIH.IRIS@EPAMAIL.EPA.GOV (internet address).

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### I.B. REFERENCE CONCENTRATION FOR CHRONIC INHALATION EXPOSURE (RfC)

Substance Name -- Boron (Boron and Borates only)  
CASRN -- 7440-42-8

Not available at this time.

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## II. CARCINOGENICITY ASSESSMENT FOR LIFETIME EXPOSURE

Substance Name -- Boron (Boron and Borates only)  
CASRN -- 7440-42-8

Not available at this time.

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## VI. BIBLIOGRAPHY

Substance Name -- Boron (Boron and Borates only)  
CASRN -- 7440-42-8  
Last Revised -- 10/01/1989

### VI.A. ORAL RfD REFERENCES

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Dixon, R.L., R.J. Sherins, and I.P. Lee. 1979. Assessment of environmental factors affecting male fertility. Environ. Health Perspec. 30: 53-68.

Seal, B.S. and H.J. Weeth. 1980. Effect of boron in drinking water on the male laboratory rat. Bull. Environ. Contam. Toxicol. 25: 782-789.

Schroeder, H.A. and M. Mitchener. 1975. Life-term effects of mercury, methyl mercury and nine other trace metals in mice. J. Nutr. 105: 452-458.

NTP (National Toxicology Program). 1987. Toxicology and carcinogenesis studies of boric acid in B6C3F1 mice (feed studies). NTP Technical Report Series No. 324. Research Triangle Park, NC.

Weir, R.J., Jr. and R.S. Fisher. 1972. Toxicologic studies on borax and boric acid. Toxicol. Appl. Pharmacol. 23: 351-364.

### VI.B. INHALATION RfD REFERENCES

None

VI.C. CARCINOGENICITY ASSESSMENT REFERENCES

None

VII. REVISION HISTORY

Substance Name -- Boron (Boron and Borates only)  
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Date	Section	Description
10/01/1989	I.A.	Oral RfD summary on-line
10/01/1989	VI.	Bibliography on-line
11/01/1989	I.A.6.	Work group review date corrected
08/01/1990	I.A.	Text edited
01/01/1992	IV.	Regulatory Action section on-line
01/01/1993	II.	Carcinogenicity assessment now under review
05/01/1993	II	Work group review date added
07/01/1993	I.A.	Oral RfD noted as pending change
07/01/1993	I.A.6.	Work grp. rev. date added; mtg. & verif. date corrected
09/01/1994	I.A.6.	Work group review date added
06/01/1995	I.A.6.	Work group review date added

VIII. SYNONYMS

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