Antimony; CASRN 7440-36-0

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 <u>IRIS assessment</u> <u>development process</u>. 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 <u>guidance documents located</u> on the IRIS website.

STATUS OF DATA FOR Antimony

File First On-Line 01/31/1987

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

I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

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

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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

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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
Longevity, blood glucose, and cholesterol	NOEL: none	1000	1	4E-4 mg/kg/day
Rat Chronic Oral Bioassay	LOAEL: 0.35 mg/kg bw/day			
Schroeder et al., 1970				

*Conversion Factors: 5 mg/L (5 ppm) given as 0.350 mg/kg/day in the discussion section of the critical study

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

Schroeder, H.A., M. Mitchner and A.P. Nasor. 1970. Zirconium, niobium, antimony, vanadium and lead in rats: Life term studies. J. Nutrition. 100: 59-66.

An experimental group of 50 male and 50 female rats was administered 5 ppm potassium antimony tartrate in water. Over the period of study, growth rates of treated animals were not affected, but male rats survived 106 and females 107 fewer days than did controls at median lifespans. Nonfasting blood glucose levels were decreased in treated males, and cholesterol levels were altered in both sexes. Since there was only one level of antimony administered, a NOEL was not established in this study. A decrease in mean heart weight for the males was noted. No increase in tumors was seen as a result of treatment. Although not precisely stated, the concentration of 5 ppm antimony was expressed as an exposure of 0.35 mg/kg/day by the authors.

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

UF — An uncertainty factor of 1000 (10 for interspecies conversion, 10 to protect sensitive individuals, and 10 because the effect level was a LOAEL and no NOEL was established) was applied to the LOAEL of 0.35 mg/kg bw/day.

MF — None

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

In a similar study (Kanisawa and Schroeder, 1969), groups of CD-1 mice (54/sex) were given potassium antimony tartrate in drinking water at 0 or 5 mg/L (5 ppm) for 540 days (18 months). Lifespans were significantly reduced in both males and females, but the degree of antimony toxicity was less severe in mice than rats. Bradley and Fredrick (1941) and Browning (1969) reported disturbances in glucose and cholesterol metabolism in rats ingesting 5 mg/L antimony, but no signs of injury to the heart were observed in rats receiving doses up to 100 mg/kg/day. Substantially higher doses of antimony trioxide were tolerated by rats in studies by Sunagawa (1981) and Gross et al. (1955a,b), suggesting a NOAEL of 500 mg/kg, but these studies are of inadequate duration to assess adverse effects on toxicity.

Seventy people became acutely ill after drinking lemonade containing 0.013% antimony (Dunn, 1928 and Monier-Williams, 1934). The lemonade had been prepared and left overnight in buckets coated with an enamel containing 2.88% antimony trioxide. Fifty-six people were taken to the hospital with burning stomach pains, colic, nausea and vomiting. Most recovered within 3 hours, but in some cases recovery was not complete for several days. It is estimated that a person consuming 300 mL of lemonade would have received a dose of approximately 36 mg antimony, or approximately 0.5 mg/kg for a 70-kg adult.

According to U.S. EPA (1980), multimedia antimony exposures are essentially negligible by comparison to occupational exposures at which discrete clinical health effects have been observed. Myocardial effects are among the best- characterized human health effects associated with antimony exposure. Studies by Brieger et al. (1954) suggest an inhalation NOEL for myocardial damage to be approximately 0.5 mg/cu.m. This exposure is approximately equivalent to an oral reference dose of 0.003 mg/kg bw/day (i.e., 0.5 mg/cu.m x 10 cu.m/day x 0.5 / 1.0 x 5 days/7 days / 70 kg / 10). Parallel studies in rats and rabbits resulted in observation of EKG alterations following exposure to 3.1-5.6 mg/cu.m. There are, however, no adequate data on oral exposure to antimony which permit reasonable estimate of no effect levels regarding heart damage.

One study (Belyaeva, 1967) indicated that women workers exposed in an antimony plant experienced a greater incidence of spontaneous abortions than did a control group of nonexposed working women. A high rate of premature deliveries among women workers in antimony smelting and processing was also observed (Aiello, 1955).

I.A.5. Confidence in the Oral RfD

Study --Low Database — Low RfD — Low

Confidence in the chosen study is rated as low because only one species was used, only one dose level was used, no NOEL was determined, and gross pathology and histopathology were not well described. Confidence in the data base is low due to lack of adequate oral exposure investigations. Low confidence in the RfD follows.

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

U.S. EPA. 1980. Ambient Water Quality Criteria Document for Antimony. Prepared by the Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Cincinnati, OH for the Office of Water Regulations and Standards, Washington, DC. EPA-440/5-80-020. NTIS PB 81- 117319.

The ADI in the 1980 Ambient Water Quality Criteria Document was extensively reviewed by the Agency and was reviewed by the public.

U.S. EPA. 1985. Health and Environmental Effects Profile for Antimony Oxides. 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.

Limited peer review and extensive Agency-wide review, 1985.

Agency Work Group Review — 11/06/1985

Verification Date — 11/06/1985

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 Antimony conducted

in September 2002 identified one or more significant new studies. IRIS users may request the references for those studies from the IRIS Hotline at <u>hotline.iris@epa.gov</u> 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 <u>hotline.iris@epa.gov</u> (internet address).

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

Substance Name — Antimony CASRN — 7440-36-0

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Antimony CASRN — 7440-36-0

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

III. [reserved]IV. [reserved]V. [reserved]

VI. Bibliography

Substance Name — Antimony CASRN — 7440-36-0

VI.A. Oral RfD References

Aiello, G. 1955. Pathology of antimony. Folia Med. (Naples). 38: 100. (Ital.)

Belyaeva, A.P. 1967. The effect of antimony on reproduction. Gig. Truda Prof. Zabol. 11: 32.

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Brieger, H., C.W. Semisch, III, J. Stasney and D.A. Platnek. 1954. Industrial antimony poisoning. Ind. Med. Surg. 23: 521.

Browning, E. 1969. Antimony. In: Toxicity of Industrial Metals, 2nd ed. Appleton-Century-Craft, New York. p. 23-38.

Dunn, J.T. 1928. A curious case of antimony poisoning. Analyst. 53: 532-533.

Gross, P., J.H.V. Brown, M.L. Westrick, R.P.Srsic, N.L. Butler and T.F. Hatch. 1955a. A toxicological study of calcium halophosphate phospher and antimony trioxide. I. Acute and chronic toxicity and some pharmacological aspects. Arch. Ind. Health. 11: 473-479.

Gross, P., M.L. Westrick, J.H.V. Brown, R.P. Srsic, H.H. Schrenk and T.F. Hatch. 1955b. Toxicologic study of calcium halophosphate phosphors and antimony trioxide. II. Pulmonary studies. Arch. Ind. Health. 11: 479-486.

Kanisawa, M. and H.A. Schroeder. 1969. Life term studies on the effect of trace elements on spontaneous tumor in mice and rats. Cancer Res. 29: 892-895.

Monier-Williams, G.W. 1934. Antimony in enamelled hollow-ware. Report on Public Health and Medical Subjects, No. 73, Ministry of Health, London. p. 18. (Cited in U.S. EPA, 1985)

Schroeder, H.A., M. Mitchner and A.P. Nasor. 1970. Zirconium, niobium, antimony, vanadium and lead in rats: Life term studies. J. Nutr. 100(1): 59-68.

Sunagawa, S. 1981. Experimental studies on antimony poisoning. Igaku Kenkyu. 51(3): 129-142. (Jap.) (CA 096/080942D)

U.S. EPA. 1980. Ambient Water Quality Criteria Document for Antimony. Prepared by the Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office,

Cincinnati, OH for the Office of Air Quality Planning and Standards, Washington, DC. EPA 440/5-80-020.

U.S. EPA. 1985. Health and Environmental Effects Profile for Antimony Oxides. Prepared by the Office of Health and Environmental Assessment, Environmental Criteria and Assessment, Cincinnati, OH for the Office of Solid Waste and Emergency Response, Washington, DC.

VI.B. Inhalation RfC References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

Substance Name — Antimony CASRN — 7440-36-0

Date	Section	Description
12/03/2002	I.A.6.	Screening-Level Literature Review Findings message has been added.

VIII. Synonyms

Antimony CASRN — 7440-36-0 Last Revised — 01/31/1987

• 7440-36-0

• Antimony

• ANTIMONY BLACK

- ANTIMONY POWDER
- ANTIMONY, REGULUS
- ANTYMON
- C.I. 77050
- STIBIUM
- UN 2871