Ammonium sulfamate; CASRN 7773-06-0

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 Ammonium sulfamate

File First On-Line 01/31/1987

Category (section)	Assessment Available?	Last Revised
Oral RfD (I.A.)	yes	01/01/1989
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)

Substance Name — Ammonium sulfamate CASRN — 7773-06-0 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

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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
Decrease in body weights	NOEL: 214.3 mg/kg/day	1000	1	2E-1 mg/kg/day
90-Day Rat Feeding Study	LEL: 428.6 mg/kg/day			
Gupta et al., 1979				

*Conversion Factors: Actual dose tested x 6/7 (6 days/week)

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

Gupta, B.N., R.N. Khanna and K.K. Datta. 1979. Toxicological studies of ammonium sulfamate in rat after repeated oral administration. Toxicology. 13(1): 45-49.

Rats were administered ammonium sulfamate 6 days/week for 90 days at the following dose levels: 0 (group 1), 100 (group 2), 250 (group 3) and 500 mg/kg/day (group 4) [Dose Conversion: 85.7, 214.3, and 428.6). No adverse effects were observed in respect of appearance, behavior or survival of animals. No significant difference in the body weights of rats was observed except in case of adult rats (group 4) where the body weight was significantly less than the controls after the end of 60 days. Results included gradually reduced food intake and increased water intake. No significant change in relative organ weights were noticed in all groups of rats.

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

UF — An uncertainty factor of 100 was to account for the inter- and intraspecies differences. An additional UF of 10 was used to account for the fact that the most sensitive toxicological endpoint has not been determined; i.e. the lack of chronic exposure studies.

MF — None

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

Data Considered for Establishing the RfD

1) 90-Day Feeding - rat: Principal study - see previous description; no core grade

2) 3-Generation Reproduction - rat: Reproduction NOEL=500 ppm (25 mg/kg/day); no core grade (du Pont, 1966)

3) 105-Day Feeding - rat: NOEL=10,000 ppm (500 mg/kg/day) (1%); LEL=20,000 ppm (1000 mg/kg/day) (inhibited growth weights and induced a slight cathartic action); no core grade (Rosen et al., 1965)

4) 6-Day Feeding - dog: Dogs fed 1 g of test material for 6 days; No systemic effects were observed: no core grade (Ambrose, 1943)

Data Gap(s): Chronic Rat Feeding Study; Chronic Dog Feeding Study; Rat Teratology Study; Rabbit Teratology

I.A.5. Confidence in the Oral RfD

Study — Medium Database — Low RfD — Low

The critical study is of fair quality and is given a medium confidence rating. Since there are major data gaps existing for ammonium sulfamate, the database is given a low confidence rating. Low confidence in the RfD follows.

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

Pesticide Registration Files

Agency Work Group Review — 06/24/1986, 07/20/1988

Verification Date — 07/20/1988

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 Ammonium sulfamate conducted in September 2002 did not identify any critical new studies. IRIS users who know of important new studies may provide that information to 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 hotline.iris@epa.gov (internet address).

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

Substance Name — Ammonium sulfamate CASRN — 7773-06-0

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Ammonium sulfamate CASRN — 7773-06-0

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 — Ammonium sulfamate CASRN — 7773-06-0

VI.A. Oral RfD References

Ambrose, A.M. 1943. Studies on the physiological effects of sulfamic acid and ammonium sulfamate. J. Ind. Hyg. Toxicol. 25(1): 26-28.

E.I. du Pont de Nemours & Company, Inc. 1966. MRID No. 00092903, 00143472, 00145269. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Gupta, B.N., R.N. Khanna and K.K. Datta. 1979. Toxicological studies of ammonium sulfamate in rat after repeated oral administration. Toxicology. 13(1): 45-49.

Rosen, D.E., C.J. Krister, H. Sherman, E.F. Stula. 1965. Toxicity studies on ammonium sulfamate. The Toxicologist. Fourth Ann. Meeting Society of Toxicology, Williamsburg, Va. March 8-10.

VI.B. Inhalation RfC References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

Substance Name — Ammonium sulfamate CASRN — 7773-06-0

Date	Section	Description
12/01/1988	I.A.	Withdrawn; new RfD verified (in preparation)
01/01/1989	I.A.	Oral RfD summary replaced; RfD changed

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

VIII. Synonyms

Substance Name — Ammonium sulfamate CASRN — 7773-06-0 Last Revised — 01/31/1987

- 7773-06-0
- AMCIDE
- AMICIDE
- AMMAT
- AMMATE
- AMMATE X
- AMMONIUM AMIDOSULFONATE
- AMMONIUM AMIDOSULPHATE
- AMMONIUMSALZ DER AMIDOSULFONSAURE
- Ammonium Sulfamate
- AMMONIUM SULPHAMATE
- AMS
- IKURIN
- MONOAMMONIUM SULFAMATE
- NA 9089
- SULFAMATE, AMMONIUM
- SULFAMIC ACID, MONOAMMONIUM SALT
- SULFAMINSAURE