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Asulam; CASRN 3337-71-1

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 Asulam

File First On-Line 06/30/1988

Category (section)	Assessment Available?	Last Revised
Oral RfD (I.A.)	yes	06/30/1988
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 — Asulam

CASRN — 3337-71-1

Last Revised — 06/30/1988

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.

NOTE: The Oral RfD for asulam 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
Lower ovarian weight, lower liver/body weight 2-Generation Reproduction Rat Study Rhone-Poulenc, 1981a	NOEL: None LEL: 1000 ppm (50 mg/kg/day)	1000	1	5E-2 mg/kg/day

*Conversion Factors -- none

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

Rhone-Poulenc Chemical Company. 1981a. MRID No. 00098540. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Asulam was administered to Charles River CD rats at levels of 0, 1000, 5000, and 25,000 ppm (equivalent to 50, 250, and 1250 mg/kg/day). The systemic NOEL was less than 1000 ppm. Effects noted in F1 female organ weights were: mean ovarian weight significantly lower at 25,000 ppm as compared with controls; mean absolute liver weight lower at 25,000 ppm; and mean relative weight significantly lower than controls at 1000, 5000, and 25,000 ppm. The reproductive NOEL was 1000 ppm. Fewer live births per litter were noted at 5000 and 25,000 ppm. There was a slightly lower fertility index in the F1 parents at 5000 and 25,000 ppm. The developmental NOEL was greater than 25,000 ppm. No abnormalities related to test substance were noted.

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

UF — An uncertainty factor of 100 was used to account for the inter- and intraspecies differences. An additional UF of 10 was used to account for the lack of an established systemic NOEL in the rat reproduction study.

MF — None

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

Upon submission of additional information, the 6-month dog study maybe upgraded to core minimum and considered acceptable to fulfill the chronic and subchronic nonrodent feeding data gaps.

Data Considered for Establishing the RfD:

- 1) 2-Generation Reproduction - rat: Principal study - see previous description; core grade minimum
- 2) 107-108 Week Feeding (oncogenic) - rat: Systemic NOEL=1000 ppm (36 mg/kg/day); Systemic LEL=5000 ppm (180 mg/kg/day) (hyperplasia of thyroid follicles and adrenal medulla); core grade minimum (Rhone-Poulenc, 1981b)
- 3) 6-Month Feeding - dog: NOEL=60 mg/kg/day; LEL=300 mg/kg/day (increased mean absolute thyroid weights in females; in males and females at 1500 mg/kg/day); core grade supplementary (information missing) (Rhone-Poulenc, 1981c)
- 4) Developmental toxicity - rat: Maternal and Developmental NOEL=1500 mg/kg/day; core grade minimum (Rhone-Poulenc, 1981d)
- 5) Developmental toxicity - rabbits: Maternal and Developmental NOEL=750 mg/kg/day; [Severe weight loss (>20%) and mortality at 1500 mg/kg/day early in the study caused the high dose (1500 mg/kg/day) to be lowered to 750 mg/kg/day]; core grade minimum (Rhone-Poulenc, 1981e)

Other Data Reviewed:

- 1) 18-Month (oncogenic) - mice: Systemic NOEL=none; LEL=214 mg/kg/day (hyperkeratosis of skin and subcutis); core grade minimum (Rhone-Poulenc, 1981f)

Data Gap(s): Chronic Nonrodent Feeding Study; Subchronic Rodent and Nonrodent Feeding Study

I.A.5. Confidence in the Oral RfD

Study — Medium

Database — Medium

RfD — Medium

The critical study is of adequate quality and is given a medium confidence rating. Additional studies are also of adequate quality; therefore, the data base is given a medium confidence rating. 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 — Pesticide Registration Standard, August 1987; Pesticide Registration Files

Agency Work Group Review — 08/12/1987, 12/08/1994

Verification Date — 08/12/1987

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 Asulam conducted in November 2001 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 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 — Asulam
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Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Asulam
CASRN — 3337-71-1

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 — Asulam
CASRN — 3337-71-1

VI.A. Oral RfD References

Rhone-Poulenc Chemical Company. 1981a. MRID No. 00098540. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rhone-Poulenc Chemical Company. 1981b. MRID No. 00098543, 00134021. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rhone-Poulenc Chemical Company. 1981c. MRID No. 00098536, 40977601. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rhone-Poulenc Chemical Company. 1981d. MRID No. 00098538. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rhone-Poulenc Chemical Company. 1981e. MRID No. 00098539. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rhone-Poulenc Chemical Company. 1981f. MRID No. 00081183. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

VI.B. Inhalation RfD References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

Substance Name — Asulam

CASRN — 3337-71-1

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

VIII. Synonyms

Substance Name — Asulam

CASRN — 3337-71-1

Last Revised — 06/30/1988

- 3337-71-1
- 4-AMINO-BENZOLSULFONYL-METHYLCARBAMAT
- ASILAN
- Asulam
- ASULFOX F
- ASULOX 40
- CARBAMIC ACID, SULFANILYL-, METHYL ESTER
- JONNIX
- MB 9057
- METHYL 4-AMINO-BENZENESULPHONYL CARBAMATE
- METHYL ((4-AMINOPHENYL)SULFONYL)CARBAMATE
- METHYL 4-AMINOPHENYLSULPHONYL CARBAMATE
- METHYL N-(4-AMINO-BENZENESULFONYL)CARBAMATE
- METHYL SULFANILYL CARBAMATE