Pronamide; CASRN 23950-58-5

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 Pronamide

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)

Substance Name — Pronamide CASRN — 23950-58-5 Last Revised — 01/31/1987

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 pronamide 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
No effects	NOEL: 300 ppm 7.5 mg/kg/day)	100	1	7.5E-2 mg/kg/day
2-Year Dog Feeding				
Study	LEL: None			
Rohm & Haas, Co., 1970a				

^{*}Conversion Factors: 1 ppm = 0.025 mg/kg/day (assumed dog food consumption)

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

Rohm and Haas, Company. 1970a. MRID No. 00085508, 00107949, 00133113. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Groups of 4 purebred beagle dogs of each sex were fed diets containing 0, 30, 100, or 300 ppm pronamide for two years. Body weights were determined weekly and food consumption daily. Weights of heart, lung, liver, and testes were determined and major tissues/organs examined histologically. There were no effects of compound administration on clinical studies, estrus findings, organ weights, or histopathologic findings.

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

UF — An uncertainty factor of 100 was used to account for inter- and intra- species differences.

MF — Even though the database is not complete, the use of an MF was not considered necessary since the studies at hand do not indicate that the most sensitive toxicologic endpoint will be substantially <7.5 mg/kg/day.

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

The use of a 100-fold uncertainty factor applied to the NOEL (5.0 mg/kg/day) for maternal toxicity in the rabbit teratology study yields a value that is not significantly different than the RfD. Alteration of the RfD value can be made when the 2-year rat feeding study is reviewed.

Data Considered for Establishing the RfD

- 1) 2-Year Feeding dog: Principal study see discussion above; core grade minimum
- 2) 90-Day Feeding dog: NOEL=33.7 mg/kg/day; LEL=101.25 mg/kg/day (increased liver weight); core grade supplementary (Rohm and Haas, 1967a)
- 3) 90-Day Feeding rat: NOEL=2.5 mg/kg/day; LEL=7.5 mg/kg/day (increased liver/body weight ratio in males; increased liver weight in females); core grade supplementary (Rohm and Haas, 1967b)
- 4) 3-Generation Reproduction rat: NOEL=15 mg/kg/day (HDT); core grade supplementary (Rohm and Haas, 1970b)
- 5) Teratology rabbit: Maternal NOEL=5 mg/kg/day; Maternal LEL=20 mg/kg/day (punctate vacuolation of hepatocyctes and anorexia); core grade minimum (Rohm and Haas, 1985)
- 6) 2-Year Feeding (oncogenic) rat: NOEL=15 mg/kg/day (HDT); core grade supplementary) (Rohm and Haas, 1970c)

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

I.A.5. Confidence in the Oral RfD

Study — High
Database — Medium
RfD — Medium

The principal study appears to be of good quality and is given a high confidence rating. Additional studies are of fair quality, but since there are data gaps, the database is given a medium confidence rating. Medium confidence in the RfD follows.

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

Pesticide Data Evaluation Record and Registration Standard, May 1985

Pesticide Registration Files

Agency Work Group Review — 05/30/1986, 12/14/1993

Verification Date — 05/30/1986

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 Pronamide 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 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 — Pronamide CASRN — 23950-58-5

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Pronamide CASRN — 23950-58-5

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 — Pronamide CASRN — 23950-58-5

VI.A. Oral RfD References

Rohm and Haas, Company. 1967a. MRID No. 00085507. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rohm and Haas, Company. 1967b. MRID No. 00085506. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rohm and Haas, Company. 1970a. MRID No. 00085508, 00107949, 00133113. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rohm and Haas, Company. 1970b. MRID No. 00085510, 00107950, 00133114. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rohm and Haas, Company. 1970c. MRID No. 00083666, 00083667, 00133111. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rohm and Haas, Company. 1985. MRID No. 00148065. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

VI.B. Inhalation RfC References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

Substance Name — Pronamide CASRN — 23950-58-5

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

VIII. Synonyms

Substance Name — Pronamide CASRN — 23950-58-5 Last Revised — 01/31/1987

- 23950-58-5
- BENZAMIDE, 3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL)-
- 3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL)BENZAMIDE
- KERB
- KERB 50W
- N-(1,1-DIMETHYLPROPYNYL)-3,5-DICHLOROBENZAMIDE
- PROMAMIDE
- Pronamide

- PROPYZAMIDE
- RCRA WASTE NUMBER U192
- RH 315