Prometon; CASRN 1610-18-0

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 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 Prometon

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 — Prometon CASRN — 1610-18-0 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.

I.A.1. Oral RfD Summary

Critical Effect	Experimental Doses*	UF	MF	RfD
No treatment related effects observed	NOAEL: 300 ppm (15 mg/kg/day)	1000	1	1.5E-2 mg/kg/day
Subchronic Rat Feeding Study	LOAEL: none			
Ciba-Geigy, 1982a				

^{*}Dose Conversion Factors & Assumptions: 1 ppm = 0.05 mg/kg/day (assumed rat food consumption)

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

Ciba-Geigy Corporation. 1982a. MRID No. 00129985, 00148609; HED Doc. No. 003700, 004781. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

Thirty Sprague-Dawley rats/sex/group were fed diets containing 0, 10, 50, 100, and 300 ppm technical-grade prometon (98% active ingredient) for 90 days. No treatment-related effects were demonstrated at levels up to 300 ppm (HDT).

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

UF — An uncertainty factor of 1000 was used to account for the inter- and intraspecies differences and for the lack of a chronic study.

MF — None

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

Although it appears that maternal toxicity (weight) was observed at 3.5 mg/kg/day in the teratology study, the use of this NOEL was not considered appropriate since the material was administered by gavage, maternal weight is a doubtful indicator in rabbits, and compound administration in teratology studies was of short but acute duration. Moreover, significant new studies are in progress, and the RfD should be reviewed once they are completed.

Data Considered for Establishing the RfD

- 1) 90-Day Feeding rat: Principal study see discussion above; core grade minimum
- 2) Teratology rat: Maternal NOEL=120 mg/kg/day; Maternal LEL=360 mg/kg/day (decreased weight gain); Fetotoxic NOEL=360 mg/kg/day (HDT); core grade minimum (Ciba-Geigy, 1981)
- 3) Teratology rabbit: Maternal NOEL=3.5 mg/kg/day; Maternal LEL=24.5 mg/kg/day (decreased weight); Fetotoxic NOEL=24.5 mg/kg/day (HDT); core grade minimum (Ciba-Geigy, 1982b)
- 4) 4-Week Feeding dog: LEL=1000 ppm (25 mg/kg/day) (LDT) (reduced body weight gain); core grade supplementary (Ciba-Geigy, 1976a)

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

Other Data Reviewed

1) 4-Week Feeding - rat: NOEL=600 ppm (30 mg/kg/day); LEL=1000 ppm (50 mg/kg/day) (reduced body gain); core grade supplementary (Ciba-Geigy, 1976b)

I.A.5. Confidence in the Oral RfD

Study — Medium Database — Low RfD — Low

The principal study appears to be of fair quality and is given a medium confidence rating. The database for prometon is lacking three important studies; therefore, 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 Registation Files

Agency Work Group Review — 05/30/1986

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 Prometon 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 — Prometon CASRN — 1610-18-0

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Prometon CASRN — 1610-18-0

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 — Prometon CASRN — 1610-18-0

VI.A. Oral RfD References

Ciba-Geigy Corporation. 1976a. MRID No. 00054309; HED Doc. No. 000712. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

Ciba-Geigy Corporation. 1976b. MRID No. 00054308; HED Doc. No. 000712. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

Ciba-Geigy Corporation. 1981. MRID No. 00129983, 00148609; HED Doc. No. 003700, 004781. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

Ciba-Geigy Corporation. 1982a. MRID No. 00129985, 00148609; HED Doc. No. 003700, 004781. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

Ciba-Geigy Corporation. 1982b. MRID No. 00129984, 00148609; HED Doc. No. 003700, 004781. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

VI.B. Inhalation RfC References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

Substance Name — Prometon CASRN — 1610-18-0

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

VIII. Synonyms

Substance Name — Prometon CASRN — 1610-18-0 Last Revised — 01/31/1987

- 1610-18-0
- 2,4-BIS(ISOPROPYLAMINO)-6-METHOXY-s-TRIAZINE
- 2,6-DIISOPROPYLAMINO-4-METHOXYTRIAZINE
- G-31435
- GESAFRAM
- GESAFRAM 50
- 2-METHOXY-4,6-BIS(ISOPROPYLAMINO)-1,3,5-TRIAZINE
- 2-METHOXY-4,6-BIS(ISOPROPYLAMINO)-s-TRIAZINE
- METHOXYPROPAZINE
- ONTRACIC 800
- ONTRACK
- ONTRACK-WE-2
- PRAMITOL
- PRIMATOL
- PRIMATOL 25E
- Prometon
- PROMETONE
- s-TRIAZINE, 2,4-BIS(ISOPROPYLAMINO)-6-METHOXY-