

Tebuthiuron; CASRN 34014-18-1

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 Tebuthiuron

File First On-Line 09/30/1987

Category (section)	Assessment Available?	Last Revised
Oral RfD (I.A.)	yes	08/22/1988
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 — Tebuthiuron

CASRN — 34014-18-1

Last Revised — 08/22/1988

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.

I.A.1. Oral RfD Summary

Critical Effect	Experimental Doses*	UF	MF	RfD
Depressed body weight gain in F1 females	NOEL: 100 ppm (7 mg/kg/day)	100	1	7E-2 mg/kg/day
2-Generation Rat Reproduction Study	LEL: 200 ppm (14 mg/kg/day)			
Elanco Products, 1981				

*Conversion Factors -- none

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

Elanco Products Company, Division of Eli Lilly and Company. 1981. MRID No. 00090108. HED Doc. No. 001459, 002160, 005822. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

Four groups of 25 Wistar rats/sex were fed 0, 100, 200, or 400 ppm (Time- weighted average: 0, 7, 14, 28 mg/kg/day) Tebuthiuron technical (98% a.i.) in the diet (Purina mash) for 101 days (F0 rats) or 121 days (F1 rats) and then for a further period sufficient to mate, deliver, and rear two successive litters of young to 21 days of age (i.e., test diet was fed throughout mating, gestation, and lactation). F1a rats were parents of the F2 offspring. No adverse effects were reported in this study except a lower body weight gain during the pre-mating period in F1 females at dietary levels of 200 and 400 ppm (14 and 28 mg/kg/day) Tebuthiuron.

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.

MF — None

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

Data Considered for Establishing the RfD

- 1) 2-Generation Reproduction - rat: Principal study - see previous description; core grade guideline
- 2) 2-Year Feeding - rat: Systemic NOEL=400 ppm (20 mg/kg/day); Systemic LEL=800 ppm (40 mg/kg/day) (growth suppression); core grade supplementary (Elanco, 1976)
- 3) 1-Year Feeding - dog: NOEL=25 mg/kg/day; LEL=50 mg/kg/day (increased liver-to-body weight ratios; increased alkaline phosphatase in high dose animals); core grade minimum (Eli Lilly, 1985)
- 4) Teratology - rat: Teratogenic NOEL=1800 ppm (90 mg/kg/day) (HDT); LEL=none; no core grade (Elanco, 1972a)
- 5) Teratology - rabbit: Teratogenic NOEL=25 mg/kg/day (HDT) (on gestation days 5 thru 18); LEL=none; core grade minimum (Elanco, 1975)

Other Data Reviewed:

- 1) 90-Day Feeding - rat: Systemic NOEL=1000 ppm (50 mg/kg/day); Systemic LEL=2500 ppm (125 mg/kg/day) (growth suppression, pancreatic lesions); core grade minimum (Elanco, 1972b)
- 2) 90-Day Feeding - dog: Systemic NOEL=500 ppm (12.5 mg/kg/day); Systemic LEL=100 ppm (2.5 mg/kg/day) (increased relative thyroid and spleen weights); no core grade (Elanco, 1972c)

Data Gap(s): Chronic Rat Feeding Study

I.A.5. Confidence in the Oral RfD

Study — High
Database — High
RfD — High

The critical study is of good quality and is given a high confidence rating. The supporting database is also of good quality; therefore, it is given a high confidence rating. High confidence in the RfD follows.

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

Pesticide Registration Files

Agency Work Group Review — 05/30/1986, 04/15/1987, 06/22/1988

Verification Date — 06/22/1988

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 Tebuthiuron 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 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 — Tebuthiuron

CASRN — 34014-18-1

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Tebuthiuron

CASRN — 34014-18-1

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 — Tebuthiuron
CASRN — 34014-18-1

VI.A. Oral RfD References

Elanco Products Company, Division of Eli Lilly and Company. 1981. MRID No. 00090108. HED Doc. No. 001459, 002160, 005822. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

Elanco Products Company, Division of Eli Lilly and Company. 1976. MRID No. 00020714. HED Doc. No. 000344, 005822, 007374. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

Eli Lilly and Company. 1985. MRID No. 00146801. HED Doc. No. 005822. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

Elanco Products Company, Division of Eli Lilly and Company. 1972a. MRID No. 00020803. HED Doc. No. 000344, 000347, 005822, 006857. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

Elanco Products Company, Division of Eli Lilly and Company. 1975. MRID No. 00020644, 40485801. HED Doc. No. 000344, 007527, 007598. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

Elanco Products Company, Division of Eli Lilly and Company. 1972b. MRID No. 00020662. HED Doc. No. 000344, 000347, 005822. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

Elanco Products Company, Division of Eli Lilly and Company. 1972c. MRID No. 00020663. HED Doc. No. 000344, 000347, 005822. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

VI.B. Inhalation RfD References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

Substance Name — Tebuthiuron

CASRN — 34014-18-1

Date	Section	Description
08/22/1988	I.A.1.	NOEL corrected; RfD changed
12/03/2002	I.A.6.	Screening-Level Literature Review Findings message has been added.

VIII. Synonyms

Substance Name — Tebuthiuron

CASRN — 34014-18-1

Last Revised — 09/30/1987

- 34014-18-1
- EL 103
- Graslan
- Perflan
- SPIKE
- Spike 80W
- Tebuthiuron
- Urea, N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N,N'-dimethyl-
- Urea, 1-(5-tert-butyl-1,3,4-thiadiazol-2-yl)-1,3-dimethyl-