B17-1.0 TEBUTHIURON

B17-1.1 Background Information

IUPAC: 1-(5-*tert*-butyl-1,3,4-thiadiazol-2-yl)-1,3-dimethylurea

CAS: *N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N*,*N*′-dimethylurea

CASRN: 34014-18-1

TEBUTHIURON USAGE:

Tebuthiuron is a relatively non-selective, soil activated herbicide currently used to control broadleaf and woody weeds, grasses and brush on feed crop and non-food crop sites (U.S. EPA, 1994). The current primary uses of tebuthiuron include rangeland, near railroads and other industrial facilities.

Tebuthiuron was used at CFB Gagetown between 1977 and 1983 (JW, 2006). Tebuthiuron was utilized for five years to treat the range and training area (RTA) on a yearly basis.

Table B17-1 Tebuthiuron Usage at CFB Gagetown[a]

Year	Total Tebuthiuron Applied (kg)	Total Area Treated (ha)
1977	139.5	16.6
1978	249.5	36.1
1979	347.0	41.3
1981	913.9	102
1983	785.4	178.5
Total	**2.4E+03**	**3.7E+02**

[a] Adapted from JW, 2006.
[b] Average maximum yearly application rate (kg/ha).

B17-1.0 CHEMICAL AND PHYSICAL PROPERTIES

Formula: $C_9H_{16}N_4OS$

Activity: Substituted Urea [inhibits photosynthesis]

Structure:

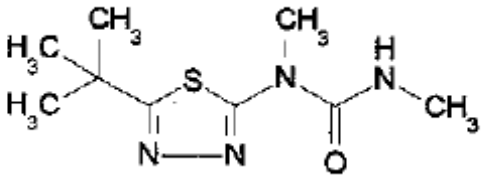

Figure B17-1 Structure of Tebuthiuron [CASRN: 34014-18-1]

Table B17-2 Chemical and Physical Properties of Tebuthiuron

Chemical/Physical Property	Result	Reference
Colour/Form	Colourless to white Crystalline solid at 25°C	U.S. EPA, 1994
Dissociation Constant (pKa)	1.2	JW, 2006
Henry's Law constant	$1.2x10^{-10}$ atm·m^3/mol at 25°C	JW, 2006
Log K_{ow}	1.79	JW, 2006
Melting Point	159-161 °C at 760 mm Hg	U.S. EPA, 1994
Molecular Weight	228.32 g/mol	JW, 2006
Vapour Pressure	$2.00x10^{-6}$ mm Hg at 25°C	JW, 2006; U.S. EPA, 1994
Water Solubility	2,500 mg/L at 25°C	JW, 2006; U.S. EPA, 1994

B17-2.0 PMRA EVALUATION

No information found.

B17-3.0 TOXICOLOGICAL SUMMARY

B17-3.1 Human Health Effects

Table B17-3 Human Health Effects Resulting from Acute Exposure to Urea-Substituted Herbicides [a,b]

Exposure	Effects	Response
Acute	HEENT	Eye exposure may result in ocular irritation. Irritation of the respiratory mucous membranes may be noted following prolonged contact.
	Cardiovascular	Central nervous system depression and hypoxemia may be noted if methemoglobinemia is present.
	Gastrointestinal	Nausea, vomiting, and diarrhea may be noted following ingestion.
	Genitournary	Some metabolites may cause irritation of the urinary tract.
	Hematologic	Methemoglobinemia may result from effects of metabolites of some urea-based herbicides.
	Dermatologic	Cyanosis unresponsive to oxygen therapy may be noted in patients with methemoglobinemia due to absorption of excessive amounts of these agents.

[a] Rumack and Hall, 2006.
[b] MEDITEXT®, 2006.

B17-3.2 Health Effects by Route of Exposure

B17-4.2.1 Oral Exposure

In acute studies tebuthiuron is moderately toxic by the oral route (U.S. EPA, 1994). Tebuthiuron was placed in toxicity category III for mice and dogs, and in category II for rats, cats and rabbits. Signs of toxicity were generally associated with the central nervous system, and included symptoms such as ataxia, anorexia, dyspnea, hypothermia, hyperirritability, loss of righting reflex, vomiting and tremors (U.S. EPA, 1994).

Table B17-4 Mammalian Acute LD_{50} Values Resulting from Oral Exposure to Tebuthiuron

Test Organism (Species/Sex)	LD_{50} (mg/kg)	Reference
Mice (M/F)	528/620	U.S. EPA, 1994
Rat (M/F)	477/387	Negilski and Hawkins, 1988
Rabbit	286	U.S. EPA, 1994
Cat	>200	U.S. EPA, 1994
Dog	>500	U.S. EPA, 1994

Tebuthiuron does not appear to cause any adverse developmental or reproductive effects (U.S. EPA, 1994) (Table B17-5 and Table B17-6).

Table B17-5 Reproductive and Developmental Effects Resulting from Oral Exposure to Tebuthiuron

Test Organism (Species)	Exposure	Dose (Duration)	Response	Reference
Rat	Diet	28 mg/kg/day (3 generation stu1. 2 days)	Reduced mean body weight gain in weanling pups	Todd *et al*., 1975b

B17-4.2.1.1 No Observed Adverse Effect Levels

Table B17-6 NOAELs and LOAELs for Oral Exposure to Tebuthiuron[a]

Test Organism (Species)	Effect	Value (mg/kg/day)	Endpoint	Reference
Sub-Chronic				
Rat	LOAEL	125	Reduced body weight; increased relative liver , kidney and gonad weight; slight vacuolation of pancreatic acinar cells	Todd *et al*., 1972a
Rat	NOAEL	50	--	Todd *et al*., 1972a
Dog	LOAEL	25	Anorexia; weight loss; increased blood urea nitrogen and alkaline phosphatase; and increased spleen and thyroid gland weights	Todd *et al.*, 1972b
Dog	NOAEL	12.5	--	Todd *et al.*, 1972b
Chronic				
Rat	LOAEL	80	Systemic toxicity (reduced weight gain; elevated kidney weights)	Todd *et al*., 1976a
Rat	NOAEL	40	Systemic toxicity	Todd *et al*., 1976a
Rat	NOAEL	228[b]	Systemic toxicity	Todd *et al*., 1976b

Table B17-6 NOAELs and LOAELs for Oral Exposure to Tebuthiuron[a]

Test Organism (Species)	Effect	Value (mg/kg/day)	Endpoint	Reference
Dog	LOAEL	50	Anorexia; diarrhea; emesis; increased thrombocyte count, alanine transferase and alkaline phosphatase levels, weight of the liver, kidney and thyroid gland.	Todd *et al*., 1985
Dog	LOAEL	50	Clinical signs; decreased body weight; increased ALT and ALP (M); increased absolute and relative liver sand relative thyroid weight (M); increased absolute liver weight.	Todd, 1985
Dog	NOAEL	25	--	Todd *et al*., 1985; Todd, 1985

[a] Obtained from U.S. EPA, 1994.
[b] Highest dose tested.

Table B17-7 Tebuthiuron Reproductive and Developmental NOAEL and LOAEL Values[a]

Test Organism (Species)	Effect	Value (mg/kg/day)	Endpoint	Reference
Rat	LOAEL	45 (gestation days 6-15)	Maternal toxicity (reduced body weight gain and food consumption)	Todd *et al*., 1972c
Rat	NOAEL	7 (2 generation study)	Systemic toxicity (Reduced body weight gain)	Hoyt *et al*., 1981
Rat	NOAEL	28[b] (2 generation study)	Reproductive toxicity	Hoyt *et al*., 1981
Rat	NOAEL	30 (gestation days 6-15)	Maternal toxicity	Todd *et al*., 1972c
Rat	NOAEL	45 [b] (gestation days , 6-15)	Developmental toxicity	Todd *et al*., 1972c
Rabbit	NOAEL	>25 [b] (gestation days 6-18)	Maternal and Developmental toxicity	Todd *et al*., 1975a

[a] Obtained from U.S. EPA, 1994.
[b] Highest dose tested.

B17-4.2.2 Dermal Exposure

Tebuthiuron is practically non-toxic by the dermal route (Toxicity Category IV) (U.S. EPA, 1994). In addition, tebuthiuron is not a dermal irritant or sensitizer (U.S. EPA, 1994). Slight eye irritation in rabbits occurred following tebuthiuron application (Toxicity Category IV) (U.S. EPA, 1994).

Table B17-8 Mammalian Acute LD_{50} Value Resulting from Dermal Exposure to Tebuthiuron

Test Type	Test Organism (Species/Sex)	LD_{50} (mg/kg)	Reference
Acute	Rabbit	>5,000	U.S. EPA, 1994

Table B17-9 Sub-chronic Effects Resulting from Dermal Exposure to Tebuthiuron

Test Organism (Species)	Dose (Duration)	Response	Reference
Rabbit	1,000 mg/kg (21 days)	Slight erythema which cleared within seven days; increased blood glucose levels	Brown, 1985

B17-4.2.3 Inhalation Exposure

Tebuthiuron is slightly toxic *via* the inhalation route (Toxicity category III) (U.S. EPA, 1994).

Table B17-10 Mammalian LD_{50} Value Resulting From Inhalation Exposure to Tebuthiuron

Test Type	Test Organism (Species/Sex)	LC_{50} (mg/L)	Reference
Acute	Rat	>3.696	U.S. EPA, 1994

B17-3.3 Carcinogenicity

Based on two animal studies tebuthiuron was classified as a Group D carcinogen (not classifiable as to human carcinogenicity) (U.S. EPA, 1994; 2002a,b). Although neither of the studies (Table B17-11) showed any treatment-related increase in the incidence of neoplasms, the IARC concluded that the dose levels were too low to assess the carcinogenicity of tebuthiuron. In addition, tebuthiuron does not appear to be mutagenic based upon the available data (U.S. EPA, 1994).

Table B17-11 Animal Carcinogenicity Data[a]

Test Organisms (strain)	Exposure	Dose	Response	Reference
Rat (Harlan)	Diet	20-80 mg/kg for 2 years	No compound-related carcinogenic effects observed	Todd *et al*., 1976a
Mice (Harlan ICR)	Diet	60-240 mg/kg for 2 years	No carcinogenic effects observed	Todd *et al*., 1976b

[a] Obtained from U.S. EPA, 1994.

B17-3.4 Populations at Special Risk

No data found.

B17-3.5 Toxicokinetics

B17-3.5.1 Absorption

Tebuthiuron was rapidly absorbed after gavage administration to four species (rats, rabbits, dogs and mice) (Hoffman, 1988).

B17-3.5.2 Distribution

A metabolism study in the rat showed that no significant residual radioactivity was observed in any tissue examined in rats dosed with a single oral dose of ^{14}C-tebuthiuron (Eschbach and Hackett, 1993; 1994). However, the skin showed the highest levels of radioactive tebuthiuron relative to the other tissues.

B17-3.5.3 Metabolism

Tebuthiuron was rapidly metabolized after gavage administration to four species (rats, rabbits, dogs and mice) (Hoffman, 1988). Only 0.4 to 0.7% of tebuthiuron was excreted in the urine as the unchanged parent compound in rats, rabbits and dogs. In rats, 31% of the administered dose was excreted as the parent compound in the urine (Hoffman, 1988).

B17-3.5.4 Elimination and Excretion

Radio-labeled tebuthiuron was rapidly excreted after gavage administration to four species (rats, rabbits, dogs, and mice) (Hoffman, 1988). Most of the radioactivity was eliminated over a period of 24 hours after the administration of a 10 mg/kg dose.

In rats, dogs and rabbits, tebuthiuron and its metabolites were mainly excreted in the urine. In a study conducted by Hoffman (1988), 84 to 95% of the administered dose was excreted in the urine while only 1 to 31% occurred in the feces. Biliary excretion has also been observed in rats. Mice, however, were observed to excrete a smaller fraction of the administered dose through the urine (66%) and more through the feces (31%) compared to the other species studied (Hoffman, 1988).

B17-4.6 Exposure Limits

Table B17-12 Existing RfD Values for Tebuthiuron Exposures

Reference Dose (mg/kg/day)	Reference	Endpoint	Study	Reference	NOEL (mg/kg/day)	Uncertainty Factor	Study Classification
Acute/Short-term (1-7 days)							
Not available (general population)	U.S. EPA, 2002a	No appropriate effects attributed to a single exposure was identified					
0.25[a]	U.S. EPA, 2002a,b	Increased early resorptions	Developmental rabbit toxicity study	Todd *et al*., 1975a; Negliski and Hawkins, 1988; Megilski *et al*., 1989	25	100	--
Intermediate-term (7 days- Several months)							
No information found	--	--	--	--	--	--	--
Long-term (6 months to lifetime)							
0.07	U.S. EPA, 1987	Reduction in body weight gain	2 generation rat reproduction study	Elanco Products Company, 1981	7	100	Acceptable, confidence in the RfD is High
0.07	U.S. EPA, 1994	Reduced body weight gain	2 generation rat reproduction study	Hoyt *et al.*, 1981	7	100	--
0.14	U.S. EPA, 2002a,b	Decreased body weight and feed consumption	2 generation rat reproduction study	Adams *et al.*, 1981	14	100	--

[a] Acute dietary RfD for females 13-50 years of age.

Acute and chronic RfDs of 0.25 (U.S. EPA, 2002a,b) and 0.14 mg/kg/day (U.S. EPA, 2002a,b), respectively, were selected for the risk assessment purposes of this report. The acute RfD of 0.25 mg/kg/day (U.S. EPA, 2002a,b) is an acute dietary RfD for females 13 to50 years of age. However, tebuthiuron was utilized for 5 years at CFB Gagetown between 1977 and 1983. Therefore, it is unlikely that female occupational workers (*e.g.*, mixer/loader, sprayer) would have been involved in herbicide application at this time. Although, this acute RfD may not be the most appropriate value, it was utilized for the risk assessment purposes of this report as it was the only acute RfD available.

B17-5.0 ENVIRONMENTAL FATE AND EXPOSURE

B17-5.1 Air

During spraying, tebuthiuron formulations released into the atmosphere will be removed by gravitation settling. A small fraction of tebuthiuron will remain in the vapour phase where it may react with photochemically produced hydroxyl radicals, with a half life of 14.7 hours (Meylan and Howard, 1993).

B17-5.2 Water

Tebuthiuron is likely to persist in an aquatic environment as it is resistant to metabolism by anaerobic and aerobic photodegradation (U.S. EPA, 1994). The principal route of dissipation appears to be through movement to ground and surface water, due to its high mobility in soil (U.S. EPA, 1995).

Groundwater monitoring studies in Texas indicated that tebuthiuron was persistent and mobile enough to leach to a minimum of 15 feet to the water table. In groundwater tebuthiuron persisted above levels of detection for longer than four years following application (U.S. EPA, 1994).

Table B17-13 Half-life of Tebuthiuron in Water

Conditions	Half-life	Reference
Aerobic aquatic metabolism	< 1 month	U.S. EPA, 1994
Anaerobic aquatic metabolism	> 1 year	U.S. EPA, 1994
Hydrolysis and photodegradation	> 30 years	U.S. EPA, 1994

B17-5.3 Sediment and Soil

Tebuthiuron is considered mobile to very mobile in soil (U.S. EPA, 1994). Tebuthiuron has a soil adsorption coefficient (K_{oc}) ranging from 4 to 23 (U.S. EPA, 1994) and adsorption factors (K_{ads}) of 0.11, 0.62, 0.82, and 1.82 in sandy, sandy loam, loam and clay loam soil types, respectively. In field studies little to no lateral movement of tebuthiuron was observed, and the compound was found only in the upper 24 inches of the soil (JW, 2005).

Table B17-14 Half-life of Tebuthiuron in Soil

Conditions	Half-life	Reference
Photolysis	39.7 days	U.S. EPA, 1994
Anaerobic soil metabolism	> 2 months	U.S. EPA, 1994
>40 inches of annual rainfall	12-15 months	JW, 2005
Terrestrial field dissipation	1-2 years	U.S. EPA, 1994
Aerobic soil metabolism	~3 years	U.S. EPA, 1994

B17-5.4 Other Environmental Media

Based on its Log K_{ow} of 1.79, there is a slight potential for tebuthiuron residues to accumulate in fish (U.S. EPA, 1994). Bioconcentration factors of 1.98, 3.40 and 2.63 were reported for the edible tissue, non-edible tissue and whole fish, respectively (U.S. EPA, 1994). JW reported a bioconcentration factor of 4.768 (JW, 2006).

B17-6.0 SUMMARY

Tebuthiuron is a relatively non-selective, soil-activated herbicide used to control broadleaf and woody weeds (U.S. EPA, 1994). The primary uses of tebuthiuron include rangeland, near railroads and other industrial facilities. Tebuthiuron was used at CFB Gagetown between 1977 and 1983 (JW, 2006) to treat the range and training area on a yearly basis. Approximately, 2,400 kg was applied over an area of 370 hectares.

In acute studies tebuthiuron was shown to be moderately toxic by the oral route (U.S. EPA, 1994). Signs of toxicity were generally associated with the central nervous system, and included symptoms such as ataxia, anorexia, dyspnea, hypothermia, hyper-irritability, loss of righting reflex, vomiting and tremors (U.S. EPA, 1994). Tebuthiuron is practically non-toxic by the dermal route (Toxicity Category IV) (U.S. EPA, 1994). In addition, tebuthiuron is not a dermal irritant or sensitizer, only slight eye irritation in rabbits occurred following tebuthiuron application (Toxicity Category IV) (U.S. EPA, 1994). Tebuthiuron is slightly toxic *via* the inhalation route (Toxicity category III) (U.S. EPA, 1994). Based on two animal studies tebuthiuron was classified as a Group D carcinogen (not classifiable as to human carcinogenicity) (U.S. EPA, 1994; 2002a,b). Although, neither of the studies showed any treatment-related increase in the incidence of neoplasms, IARC concluded that the dose levels were too low to assess the carcinogenicity of tebuthiuron. In addition, tebuthiuron does not appear to be mutagenic based upon the available data (U.S. EPA, 1994).

B17-7.0 REFERENCES

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