



Department of Pesticide Regulation

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MEMORANDUM

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Environmental Protection

TO: Minh Pham, Chief
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VIA: Shelley DuTeaux, PhD MPH, Chief
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DATE: April 3, 2024

SUBJECT: HUMAN HEALTH REFERENCE LEVEL FOR TEBUTHIURON AND ITS
DEGRADATES IN GROUNDWATER

On January 22, 2024, the Department of Pesticide Regulation's (DPR) Human Health Assessment Branch (HHA) was requested by the Environmental Monitoring Branch (EMB) to provide a Human Health Reference Level (HHRL) for screening detections of tebuthiuron and its degradates in groundwater (see request, Appendix 1). This memorandum is in response to that request.

Conclusions and Recommendations:

1. HHA calculated a Human Health Reference Level (HHRL) to be used for detections of tebuthiuron residues in groundwater using (1) acute and chronic consumption rates for drinking water from the National Health and Nutrition Examination Survey (NHANES) 2005–2010 database; and (2) toxicological endpoints established by the United States Environmental Protection Agency (US EPA).
2. Maximum residue concentrations of tebuthiuron equal to or less than the DPR HHRL of 737 parts-per-billion (ppb) in drinking water are not expected to pose a risk to human health, including for sensitive subpopulations.
3. Tebuthiuron and its degradates of concern, N-(5-(1,1-dimethyl ethyl)-1,3,4-thiadiazol-2-yl)-N-methyl-urea (104), N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)urea (106), 2-dimethylethyl-5-amino-1,3,4-thiadiazole (108), and N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N'-hydroxymethyl-N-methylurea (109) are considered equivalent and should be summed if they are detected in the same samples.

Background

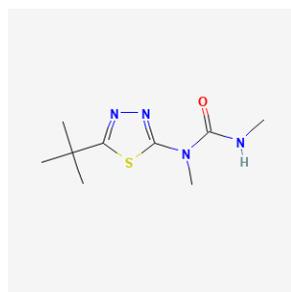
Technical Name: Tebuthiuron

Chemical Name: 1-(5-tert-Butyl-1,3,4-thiadiazol-2-yl)-1,3-dimethylurea

Chemical Abstracts Service Registry Number (CAS #): 34014-18-1

Molecular Weight: 228.32 g/mol

Chemical Structure:



NIH (2024a)

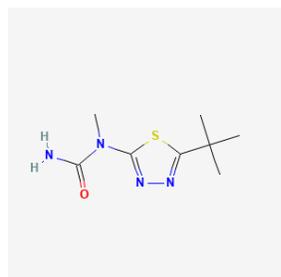
Technical Name: Degradate 104

Chemical Name: N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea

Chemical Abstracts Service Registry Number (CAS #): 59962-53-7

Molecular Weight: 214.29 g/mol

Chemical Structure:



(US EPA, 2014b; NIH, 2024d)

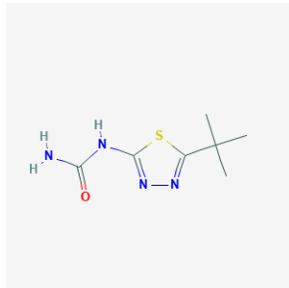
Technical Name: Degradate 106

Chemical Name: (5-*tert*-butyl-1,3,4-thiadiazol-2-yl)urea

Chemical Abstracts Service Registry Number (CAS #): 16279-27-9

Molecular Weight: 200.26 g/mol

Chemical Structure:



(US EPA, 2014b; NIH, 2024e)

Technical Name: Degradate 108

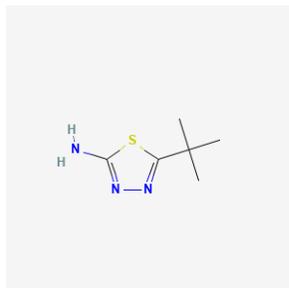
Chemical Name: 2-dimethylethyl-5-amino-1,3,4-thiadiazole;

5-*tert*-Butyl-1,3,4-thiadiazol-2-amine

Chemical Abstracts Service Registry Number (CAS #): 39222-73-6

Molecular Weight: 157.24 g/mol

Chemical Structure:



(US EPA, 2014b; NIH, 2024b)

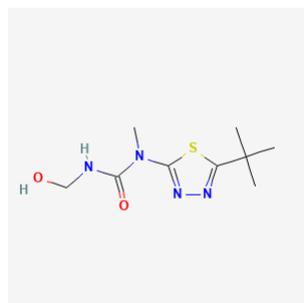
Technical Name: Degradate 109

Chemical Name: N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N'-hydroxymethyl-N-methylurea

Chemical Abstracts Service Registry Number (CAS #): 59962-54-8

Molecular Weight: 244.32 g/mol

Chemical Structure:



(US EPA, 2014b; NIH, 2024c)

Tebuthiuron is a non-selective photosynthesis inhibiting herbicide used to control broadleaf and woody weeds, grasses, and brush (US EPA, 1994a; US EPA, 2014b). It is registered for use as weed control for terrestrial feed crop sites such as pastures and rangeland, and for non-agricultural applications in airports/landing fields, outdoor industrial areas, rights-of-way/fencerows/hedgerows, and under newly applied asphalt and concrete (US EPA, 1994b). It may be applied in several forms, including as a spray, pellet, or powder (US EPA, 1994a).

Pesticide products containing tebuthiuron as an active ingredient were first registered by US EPA in 1974 (US EPA, 1994b). Between 2013–2017, US EPA estimated that 45,000 pounds of tebuthiuron were applied to approximately 75,400 acres of pastures and rangelands annually by the Bureau of Land Management in the United States (US EPA, 2018d).

Tebuthiuron was first registered in California in 1985. As of February 2024, there are eleven active registrations in California (DPR, 2024c). According to the most currently available data from DPR's Pesticide Use Reporting (PUR) database, 2,223 pounds of tebuthiuron active ingredient were applied in California for non-agricultural applications in 2021 (DPR, 2021).

Degradates

US EPA Identified the following tebuthiuron degradates of concern for drinking water:

- N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N-methyl-urea (104),
- N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)urea (106),
- 2-dimethylethyl-5-amino-1,3,4-thiadiazole (108), and
- N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N'-hydroxymethyl-N-methylurea (109).

These degradates are considered equivalent for risk assessment based on their structural similarities to the parent (US EPA, 2014b; eCFR, 2024). The US EPA residues of concern are consistent with residues DPR routinely monitors in groundwater (DPR, 2011).

Review of Regulatory Documents and Databases

A review of pertinent regulatory documents was performed to ensure that the most scientifically supportable toxicological data were used for this evaluation (summarized in Table 1, below). A comprehensive systematic review was beyond the scope of the request.

Table 1. Review of Regulatory Documents and Databases

Regulatory Agency	Year	Title	Reference(s)
US EPA	1994	Fact Sheet for Tebuthiuron	US EPA (1994a)
US EPA	1994	Reregistration Eligibility Decision (RED) for Tebuthiuron	US EPA (1994b)
DPR	2000	Summary of Toxicology Data Tebuthiuron	DPR (2000)
US EPA	2002	Tebuthiuron Acute and Chronic Dietary Exposure Assessments for the Tolerance Reassessment Eligibility Decision (TRED)	US EPA (2002a)
US EPA	2002	Tolerance Reassessment and Risk Management Decision (TRED) for Tebuthiuron	US EPA (2002b)
DPR	2009	Guidance for Dietary Exposure Assessment	DPR (2009)
US EPA	2014	Dietary Exposure Evaluation Model User's Guide	US EPA (2014a)
US EPA	2014	Tebuthiuron: Draft Human Health Risk Assessment for Registration Review	US EPA (2014b)
US EPA	2015	Human Health Ambient Water Quality Criteria: 2015 Update.	US EPA (2015)
US EPA	2018	2018 Edition of the Drinking Water Standards and Health Advisories Tables	US EPA (2018a)
US EPA	2018	Label Review Manual, Chapter 7: Precautionary Statements	US EPA (2018b)

Table 1. Review of Regulatory Documents and Databases

Regulatory Agency	Year	Title	Reference(s)
US EPA	2018	Review of Submitted Data and Impact to the Tebuthiuron: Draft Human Risk Assessment	US EPA (2018c)
US EPA	2018	Tebuthiuron Use and Usage, Benefits, and Mitigation Impacts for Registration Review Proposed Interim Decision (PID)	US EPA (2018d)
USGS	2018	Health-Based Screening Levels for Evaluating Water-Quality Data	USGS (2018)
US EPA	2019	Tebuthiuron Interim Registration Review Decision	US EPA (2019)
DPR	2021	2021 Annual Statewide Pesticide Use Report Chemical Totals	DPR (2021)
US EPA	2021	2021 Human Health Benchmarks for Pesticides	US EPA (2021a)
US EPA	2021	Human Health Benchmarks for Pesticides: Updated 2021 Technical Document	US EPA (2021b)
DPR	2023	California Code of Regulations Title 3. Food and Agriculture Division 6. Pesticides and Pest Control Operations	DPR (2023)
OEHHA	2023	The Proposition 65 List.	OEHHA (2023)
US EPA	2023	Integrated Risk Information System (IRIS) Glossary.	US EPA (2023a)
US EPA	2023	Status of Endocrine Disruptor Screening Program (EDSP) List 1 Screening Conclusions	US EPA (2023b)
DPR	2024	California Pesticide Illness Query CalPIQ	DPR (2024a)
DPR	2024	Environmental Monitoring Programs and Projects	DPR (2024b)
DPR	2024	Search for Chemical Ingredient by Partial Name, Chemical Code or CAS Number	DPR (2024c)
eCFR	2024	Code of Federal Regulation. § 180.390 Tebuthiuron; tolerances for residues	eCFR (2024)
US EPA	2024	CompTox Chemicals Dashboard: Tebuthiuron	US EPA (2024a)
US EPA	2024	Human Health Water Quality Criteria and Methods for Toxics	US EPA (2024b)
US EPA	2024	Incident Data System (IDS) - Incidents Submitted in Aggregate	US EPA (2024c)
DPR: Department of Pesticide Regulation; eCFR: online version of Code of Federal Regulation; EFSA: European Food Safety Authority; US EPA: United States Environmental Protection Agency; USGS: United States Geological Survey; OEHHA: Office of Environmental Health Hazard Assessment			

Summary of Toxicology

Tebuthiuron is classified as Toxicity Category¹ II for acute oral hazards, Toxicity Category IV for acute dermal hazards, and Toxicity Category III for acute inhalation hazards, based on median lethal doses. It is not a skin sensitizer or an eye or skin irritant (US EPA, 2014b). US EPA classified tebuthiuron as a Group D carcinogen chemical (“not classifiable as to human carcinogenicity”) based on lack of evidence of carcinogenicity in rats (US EPA, 1994b; US EPA, 1994a; US EPA, 2018a).

Tebuthiuron is not included on the Proposition 65 (the California Safe Drinking Water and Toxic Enforcement Act of 1986) list for chemicals known to cause cancer, reproductive toxicity, or developmental toxicity (OEHHA, 2023).

Decreased parental and fetal bodyweight gains were noted in a rat reproductive toxicity study and a rabbit developmental toxicity study (DPR, 2000; US EPA, 2018c). Anorexia, emesis, diarrhea, changes in hematological parameters (i.e., ALT, ALP, creatinine, thrombocytes), and decreased body weights, absolute and relative liver weights, relative kidney and thyroid weights were observed in a chronic study in dogs (DPR, 2000; US EPA, 2014b).

DPR’s Pesticide Illness Surveillance Program (PISP) maintains a database of pesticide-related illnesses and injuries reported in California from 1992 to 2019 (the most recent data available). There were two reported cases involving exposure to tebuthiuron. In the case that was exposed to tebuthiuron alone, the worker displayed shortness of breath and chest pain that returned periodically for 3–4 days after exposure (DPR, 2024a).

HHA has evaluated all required toxicity data submitted for tebuthiuron as part of registration in California but has not conducted a human health risk assessment (DPR, 2000). For purposes of this evaluation, HHA reviewed relevant regulatory documents (Table 1) and adopted toxicological endpoints and points of departure (PODs) established by US EPA (US EPA, 1994b; US EPA, 2002b; US EPA, 2014b; US EPA, 2018c). US EPA established a short-term (1-30 days) incidental oral POD (US EPA, 2018c). This POD was a no observed adverse effect level (NOAEL) of 14 mg/kg/day, based on decreased pup bodyweights on postnatal day 21 at the lowest observed adverse effect level (LOAEL) of 26 mg/kg/day in the F1 and F2 generations in a two-generation reproductive toxicity study in rats (US EPA, 2018c). The NOAEL was divided by a total uncertainty factor (UF_{TOTAL}) of 100 to calculate an acute reference dose (aRfD²) of

¹ Acute Toxicity Categories. US EPA Label Review Manual Chapter 7: Precautionary Statements. US Environmental Protection Agency, Office of Pesticide Programs, Registration Division. Revised March 2018. Available at <https://www.epa.gov/sites/default/files/2018-04/documents/chap-07-mar-2018.pdf> (US EPA, 2018b).

² An RfD is an estimate of a daily oral exposure for specific duration (acute or chronic) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Available at <https://www.epa.gov/iris/iris-glossary> (US EPA, 2023).

0.14 mg/kg/day. The UF_{TOTAL} included 10x for interspecies extrapolation (UF_A) and 10x for intraspecies variation (UF_H) (US EPA, 2018c). US EPA's chronic POD was a NOAEL of 14 mg/kg/day based on decreased body weights in F1 females in the same two-generation reproductive toxicity study in rats (US EPA, 2018c). The chronic (cRfD) of 0.14 mg/kg/day was calculated by dividing the chronic POD by UF_{TOTAL} of 100 (US EPA, 2018c).

Calculation of Human Health Reference Levels for Tebuthiuron

An HHRL is the threshold pesticide residue for a maximum water intake that results in the maximum safe oral exposure. HHRLs were calculated using the acute and chronic RfDs for tebuthiuron as the maximum safe exposure, and the 95th percentile of acute and chronic (mean) drinking water intake rates for non-nursing infants as the maximum water intake. Non-nursing infants are the population identified as having the highest consumption of drinking water per kilogram of bodyweight among the standard populations that HHA evaluates, including the general US population and other sensitive subpopulations such as children 1–2 years of age and women of childbearing age (13–49 years). The water consumption rates were extracted from the Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID, version 4.02, 05-10-c) and the What We Eat in America (WWEIA) database. WWEIA is the dietary intake interview component of the National Health and Nutrition Examination Survey (NHANES), which is a collection of two-day dietary survey data (including drinking water consumption) from 2005 to 2010 for the US population and select subgroups (US EPA, 2014a). HHA uses the 95th percentile of the exposure levels for each population subgroup as the default upper bound for acute exposures, while two-day nonconsecutive food intake is used as a surrogate for chronic consumption patterns (DPR, 2009).

HHA calculated acute and chronic HHRLs for tebuthiuron and its degradates of concern in groundwater or drinking water. The results are summarized in Table 2. The lower reference value, the acute HHRL level of **737 ppb**, was selected as the HHRL for residues of tebuthiuron in drinking water. Maximum residue concentrations of tebuthiuron and its degradates of concern in drinking water equal to or less than the DPR HHRL of **737 ppb** are not expected to pose a risk to human health, including for sensitive subpopulations.

Other Reference or Regulatory Levels for Tebuthiuron in Drinking Water

DPR considers other reference and regulatory levels for drinking water in the development of HHRLs, especially with regards to maintaining current best practices for dietary and drinking water exposure assessments. Common federal reference levels for drinking water include US

EPA enforceable Maximum Contaminant Levels (MCLs³), non-legally enforceable Health Advisories (HAs⁴), and Human Health Benchmark for Pesticides (HHBPs⁵), and United States Geological Survey (USGS) Health-Based Screening Levels (HBSLs⁶). US EPA has not issued either an MCL or an HHBP, but has HAs, for tebuthiuron. One- and ten-day HAs of 3000 ppb are expected to be protective for a 10-kg child consuming 1 liter of water per day. Other HAs include a Drinking Water Equivalent Level (DWEL) of 2000 ppb and a non-carcinogenic lifetime HA (NCHA) exposure level of 500 ppb for lifetime exposure (US EPA, 2018a). DWELs apply to situations where 100% of the residue intake are assumed to be from water sources, while NCHA exposure levels incorporate a relative source contribution (RSC) factor of 0.2, assuming that the exposure from water sources will be 20% of the total exposure while other intakes will make up the remainder (80%). This RSC factor is routinely used by regulatory agencies for deriving chronic screening levels for drinking water (US EPA, 2015). USGS's non-cancer HBSL for tebuthiuron was 900 ppb (USGS, 2018). The DPR's HHRL for tebuthiuron differed from US EPA's HAs and USGS's HBSL because they were calculated using different parameters/assumptions such as water consumption rates, RfDs, and RSC factors. The DPR HHRL of 737 ppb is the only reference level that is specifically intended to be used for screening maximum detected residue levels of tebuthiuron in groundwater.

The recommended HHRL for screening residue concentrations of tebuthiuron and its degradates of concern in drinking water is **bolded in Table 2, below**.

³ Maximum Contaminant Levels (MCLs) are used for the protection of public drinking water systems and do not apply to privately owned wells or any other individual water system. Available at <https://www.epa.gov/system/files/documents/2022-01/dwtable2018.pdf> (US EPA, 2018a).

⁴ Health Advisories (HAs) are estimated acceptable drinking water levels for chemicals based on information of adverse health effects and are not legally enforceable Federal standards, but rather serve as technical references to be used by federal, state, and local officials. Available at <https://www.epa.gov/system/files/documents/2022-01/dwtable2018.pdf> (US EPA, 2018a).

⁵ The 2021 US EPA Human Health Benchmark for Pesticides (HHBPs) contain 430 pesticides that currently have no federal drinking water standards. HHBPs are not legally enforceable, but rather are provided by US EPA for pesticides that have no drinking water standards or health advisory (HA). Available at <https://www.epa.gov/system/files/documents/2021-07/hh-benchmarks-technical-document-2021.pdf> (US EPA, 2021b).

⁶ USGS Health-Based Screening Levels (HBSLs) are “non-enforceable water-quality benchmarks” that were developed using (1) the latest US EPA Office of Water methods for establishing drinking-water guidelines and (2) the most recent US EPA peer-reviewed publicly available toxicity information. Available at <https://water.usgs.gov/water-resources/hbsl/> (USGS, 2018).

Table 2. DPR HHRLs^a for Tebuthiuron^b

Acute or Chronic	Consumption Rates for Non-Nursing Infants ^c (L water/ kg BW)	RfD ^d (mg/kg/day)	HHRL (ppb)	USGS Noncancer HSBL ^e	US EPA Health Advisories ^f		
					1-Day/ 10-Day ^f (10-kg Child) (ppb)	DWEL ^f (ppb)	NCHA ^f (ppb)
Acute	0.19	0.14	737	900	3000	2000	500
Chronic	0.10	0.14	1400				

BW: bodyweight; DWEL: Drinking Water Equivalent Level; HHRL: Human Health Reference Level; L: liter; NCHA: non-carcinogenic lifetime health advisory; RfD: reference dose; ppb: parts-per-billion.

^a The DPR HHRLs (ppb) for screening maximum pesticide residue levels were calculated as $[RfD \text{ (mg/kg/day)} \times 1000] / [\text{Daily water intake (L/kg/day)}]$. Daily water intake is 95th percentile for acute or chronic (mean) water consumption rates for non-nursing infants (see Note c).

^b Tebuthiuron’s degradates of concern, buthidazole urea, 5-tert-Butyl-1,3,4-thiadiazol-2-amine, N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N-methylurea, and N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N’-hydroxymethyl-N-methylurea are considered equivalent to tebuthiuron (US EPA, 2014b)

^c 95th percentile water consumption rates for non-nursing infants from NHANES database (2005–2010). Acute and chronic water consumption data were extracted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID, version 4.02, 05-10-c). A residue level of 1 ppm consumption defaults to the consumption rates by dimensional analysis (acute = 0.194566 L water/kg BW and chronic = 0.099559 L water/kg BW). The values were rounded to two decimal points for the calculation of HHRLs.

^d Acute and chronic RfDs (mg/kg/day) were based on toxicological endpoints established by US EPA (US EPA, 2014b; US EPA, 2018c) as described in the text.

^e USGS Health-Based Screening Levels (HBSLs) are “non-enforceable water-quality benchmarks” that were developed using (1) the latest US EPA Office of Water methods for establishing drinking-water guidelines and (2) the most recent US EPA peer-reviewed publicly available toxicity information. Available at <https://water.usgs.gov/water-resources/hbsl/> (USGS, 2018).

^f US EPA Health Advisories (HAs) are not legally enforceable Federal standards. HAs serve as a technical guidance to assist Federal, State, and local officials (US EPA, 2018a). 1-Day and 10-day parameters are concentrations intended to protect a 10-kg child consuming 1 liter of water per day for up to one day (1-day) and 10 days (10-day) exposure, respectively. A DWEL is a drinking water lifetime maximum noncarcinogenic safe exposure level assuming 100% exposure from that medium. A noncancer lifetime health advisory (NCHA) incorporates a relative source contribution (RSC) factor above DWEL, assuming that the exposure from water sources will be 20% of the total exposure while other intakes will make up the remainder (80%).

Conclusions

HHA calculated a Human Health Reference Level (HHRL) to be used when tebuthiuron and its and its degradates of concern, N-(5-(1,1-dimethyl ethyl)-1,3,4-thiadiazol-2-yl)-N-methyl-urea (104), N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)urea (106), 2-dimethylethyl-5-amino-1,3,4-thiadiazole (108), and N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N'-hydroxymethyl-N-methylurea (109), are detected in groundwater. Maximum concentrations of these residues, individually or in summation if detected in the same samples, equal to or less than the DPR HHRL of 737 ppb are not expected to pose a risk to human health, including for sensitive subpopulations.



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Minh Pham
April 3, 2024
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Appendix 1: DPR Memo: Human Health Reference Level Request for Tebuthiuron in
Groundwater 22 August 2023 (1 page)



Julie Henderson
Director

MEMORANDUM

Yana Garcia
Secretary for
Environmental Protection

TO: Shelley DuTeaux
Environmental Program Manager II
Human Health Assessment Branch

VIA: Minh Pham
Environmental Program Manager II
Environmental Monitoring Branch

Original Signed by 1/22/24

FROM: Joy Dias
Environmental Program Manager I
Environmental Monitoring Branch

Original Signed by 1/22/24

DATE: January 22, 2024

SUBJECT: HUMAN HEALTH REFERENCE LEVEL REQUEST FOR TEBUTHIURON IN
GROUNDWATER

The Environmental Monitoring Branch (EMB) monitors the environment to determine the fate of pesticides and protects the public and the environment from pesticide contamination by analyzing hazards and developing pollution prevention strategies. Consistent with EMB’s mission, the Groundwater Protection Program (GWPP) routinely monitors for tebuthiuron due to its occurrence in groundwater and status as a 3CCR 6800(b) pesticide. The GWPP also gathers data from all public agencies that report groundwater monitoring data of pesticides and their degradates and enters the data into the Well Inventory Database (WIDB).

To determine whether detections of tebuthiuron or any of its degradation products pose a significant risk to human health, EMB requests that the Human Health Assessment Branch provide a human health reference level to use for screening detections in groundwater.

Table 1. Summary information for tebuthiuron.

Chemical	DPR Chemical Code	CAS Number
Tebuthiuron	1810	34014-18-1

cc: Carissa Ganapathy, Senior Environmental Scientist (Supervisory)