



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: March 20, 2020

SUBJECT: Bromethalin. Draft Human Health Risk Assessment for Registration Review.

PC Codes: 112802	DP Barcode: D456337
Decision No.: 559638	Registration No.: Multiple
Petition No.: NA	Regulatory Action: Registration Review
Risk Assessment Type: Qualitative	Case No.: 2765
TXR No.: NA	CAS No.: 63333-35-7
MRID No.: NA	40 CFR: NA

FROM: Shawn Garred, Industrial Hygienist
Risk Assessment Branch 3 (RAB3; 7509P)
Health Effects Division (HED, 7509P)

Handwritten signature of Shawn Garred in black ink.

THROUGH: Thomas Moriarty, Chief, RAB3
HED (7509P)

Handwritten signature of Thomas Moriarty in black ink.

TO: Kent Fothergill, Chemical Review Manager
Joshua Godshall, Acting Team Leader
Dana Friedman, Branch Chief,
Risk Management and Implementation Branch 1 (RMIB1)
Pesticide Re-evaluation Division (PRD; 7508P)

As part of Registration Review, PRD of the Office of Pesticide Programs (OPP) has requested that the Health Effects Division (HED) evaluate the hazard and exposure data and conduct occupational and residential exposure assessments, as needed, to estimate the risk to human health that will result from the currently registered uses of pesticides. This memorandum serves as HED's qualitative draft human health risk assessment of the registered uses of the active ingredient bromethalin.

Table of Contents

1.0 Introduction..... 3
2.0 Use Pattern Summary..... 3
3.0 Hazard Characterization Summary..... 4
4.0 Exposure Considerations 6
5.0 Data Requirements 6
6.0 Incident and Epidemiological Data Review..... 6
7.0 Conclusions..... 8
8.0 References..... 9
Appendix A. Bromethalin Use Pattern Summary 10
Appendix B. Literature Study Summary..... 14

1.0 Introduction

Bromethalin is a non-anticoagulant rodenticide that acts through damage to the central nervous system, causing paralysis, convulsions, and death. It is formulated into numerous baits in packs, blocks, granules, pellets, tablets, and impregnated materials for control rats, mice and moles for use in and around residential, industrial, commercial, and agricultural buildings and structures; transport vehicles; residential lawns; golf courses; and non-crop areas.

The most recent comprehensive human health risk assessment for bromethalin is the HED Chapter of the Reregistration Eligibility Decision (RED) Document completed in 1996 (Myers, T., 06/06/1996). In 2008, the Agency issued the Risk Mitigation Decision for Rodenticides (RMD) with the intent to allow rodenticide products to remain available without causing adverse effects to human health and the environment. The RMD set restrictions on rodenticides intended to minimize exposure to children and non-target wildlife, including domestic animals¹. A Bromethalin Human Health Scoping Document in Support of Registration Review was completed in May 2016.

While the scoping document identified certain quantitative analysis, the Agency's human health risk management goals for the registration review of bromethalin reflect those articulated in the RMD and include minimizing non-target (e.g., human) exposures. To support the registration review human health risk management goals for bromethalin, HED is providing a qualitative analysis of risks in the draft human health risk assessment for bromethalin.

2.0 Use Pattern Summary

The 2008 RMD for rodenticides, of which bromethalin was included, required all rodenticide bait products marketed to consumer/residential consumers be sold only in bait stations, with loose baits (e.g., pellets and meal) prohibited. The mitigation decision set restrictions in order to minimize exposure to children, wildlife, and domestic animals. Details of the RMD include:

Consumer-based products (≤ 1 lb)

- When applied outdoors above ground and in areas accessible to children, non-target wildlife or domestic animals, baits must be contained in bait stations.
- Products for use outdoors and above-ground must be placed within 50 feet of a building.

Commercial/Professional-based products

- Must be sold in quantities of ≥ 4 lb (first-generation anticoagulants/non-anticoagulants),
- May not be offered for sale in consumer stores (hardware, grocery, etc.).

¹ Available at www.regulations.gov in document ID EPA-HQ-OPP-2006-0955-0820.

- Must also be placed within 100 feet of a structure when used outdoors and above ground, see *50-foot Document Clarification Letter to Bell (03.20.12) (signed)* in docket number EPA-HQ-OPP-2006-0955-0820 found at www.regulations.gov.
- For uses of first-generation or non-anticoagulants, product labels require bait stations if children, wildlife or domestic animals may be exposed.

The RMD did not apply to rodenticide field uses, tracking powder products, or island conservation uses. Risks associated with field uses and tracking powder products were addressed in the 1998 Zinc Phosphide and Rodenticide Cluster Reregistration Eligibility Decision (RED) documents. In those REDs, the Agency required restricted use classification for all field use products (except manual underground baiting) and for all tracking powder products.

Currently, the use sites for bromethalin include use in and around residential, industrial, commercial, and agricultural buildings and structures; transport vehicles; residential lawns; golf courses; and non-crop areas. Products intended for occupational use are packaged as 4 lb or more. The majority of bromethalin products are applied using tamper resistant bait stations, which are required for all rodenticides where children and pets may be present per 2008 anticoagulant rodenticide mitigation. However, for bromethalin, there are three end use products targeted for control of house mice that do not to adhere to these mitigation stipulations, since they are labeled for non-tamper resistant bait stations (i.e., EPA Reg. Nos. 67517-88, 67517-89, and 67517-91). Three end-use products that are targeted for the control of moles (i.e., EPA Reg. Nos. 149-19, 12455-101, and 90780-2) are not required to be in tamper-resistant bait stations.

Bromethalin end-use products are formulated into numerous forms in place packs, blocks, granules, pellets, tablets, and impregnated materials. Some of these formulations may be sold in ready-to use (RTU) bait stations or may be used in refillable bait stations. The labeled target pests are rats, mice, and moles. Use sites include in and around residential, industrial, commercial, and agricultural buildings and structures; transport vehicles; residential lawns; golf courses; and non-crop areas.

Use pattern details for bromethalin are provided in Appendix A.

3.0 Hazard Characterization Summary

The toxicity database for bromethalin consists of oral subchronic studies in rats and dogs, acute and subchronic neurotoxicity studies in rats, prenatal developmental toxicity studies in rats and rabbits and a mutagenicity battery.

Bromethalin mechanism of action, as elucidated in laboratory animals, is the uncoupling of oxidative phosphorylation, which leads to decreased cellular ATP production and failure of the Na⁺, K⁺-ATPase pumps. As a result, cells lose their ability to maintain osmotic control, sodium is retained intracellularly, and the cells swell with water, leading to edema (<http://www.aspcapro.org/sites/pro/files/0903toxbrief.pdf>; Myers, T., 06/06/1996). This edema is observed as a build-up of cerebrospinal fluid pressure, resulting in chronic convulsions and respiratory arrest. Multiple low doses or sublethal intoxication yield hind leg weakness and loss of tactile sensation in rodents. Histopathology of the brain and spinal cord of these animals revealed a spongy degeneration of the white matter which was shown upon ultramicroscopic

examination to be intramyelonic edema (MRID 42795603). This spongy degeneration of white matter was observed in rats and dogs in the 90-day subchronic studies, and in the subchronic neurotoxicity study in rats. In addition, salivation and hypoactivity, followed by trembling, myoclonia, hyperesthesia, groaning, and decubitus were observed in dogs.

In the developmental toxicity studies in rats and rabbits, clinical signs similar to those described above were observed, along with abortions and maternal deaths at the highest dose tested. No developmental effects were observed in either species, apart from the fetal death (abortion) observed at the high-dose level. A concern for susceptibility in the offspring was not indicated. A reproduction fertility study was not available.

HED has determined that a weight of the evidence approach supports a low dermal absorption rate. Using the National Institute for Occupational Health and Safety (NIOSH) finite dose skin permeation calculator (<http://www.cdc.gov/niosh/topics/skin/finiteSkinPermCalc.html>) and the physical chemical properties of bromethalin (see Appendix D for a full list), a predicted dermal absorption factor of 0.02% was obtained over an 8 hour period with a dermal load of 0.0872 $\mu\text{g}/\text{cm}^2$. Based on a weight of the evidence approach, the dermal absorption of bromethalin is expected to be lower than 10%; however, HED chose to use a dermal absorption value of 10% as a conservative estimate based on the available data.

The available pharmacokinetics data for bromethalin indicate that the plasma half-life is 134 hours (5.6 days). Identification of desmethyl bromethalin, a major bromethalin metabolite, was demonstrated in the blood and liver of treated animals. The study did not provide further information on the absorption, distribution, metabolism or excretion of bromethalin.

Bromethalin has high acute toxicity (Toxicity Category I) via the oral and inhalation routes. Via the dermal route, it has moderate toxicity (Toxicity Category III). It is in Toxicity Category III for eye irritation, Toxicity Category IV for dermal irritation and is not a dermal sensitizer.

The available toxicity databases were evaluated for several rodenticides, including bromethalin. Based on a weight of evidence approach, the HED Hazard and Science Policy Council (HASPOC) waived the requirements for the following studies, as they were not expected to provide a lower POD for risk assessment (Habiba, U., 06/08/2016, TXR 0050666):

- 870.3200, subchronic dermal toxicity
- 870.3465, subchronic inhalation toxicity
- 870.3800, reproduction and fertility study
- 870.5385, *in vivo* chromosomal aberration study
- 870.6200, acute and subchronic neurotoxicity studies
- 870.7800, immunotoxicity study

The toxicology profile for bromethalin is available in Bromethalin Human Health Scoping Document in Support of Registration Review (O'Keefe, B., 05/16/2016, D432763). As part of registration review, a literature study survey was completed; a summary of results is available in Appendix B.

4.0 Exposure Considerations

All uses of bromethalin are considered non-food uses; therefore, food exposures are not anticipated. Additionally, use of bromethalin in accordance with label directions will not likely result in exposure via drinking water, so there is no need for a quantitative drinking water assessment during this registration review.

The 2008 RMD for rodenticides placed limits on the allowable rodenticide registrations in order to minimize exposure to children, non-target wildlife, and domestic animals. Bromethalin end-use product formulations with limited potential dermal and inhalation exposures include impregnated bait blocks, RTU bait stations, disposable placement packs, or other packaging which prevents exposure.

Bromethalin end-use products with anticipated dermal and inhalation exposures include “loose” formulations not in ready-to-use (RTU) bait stations or other formulation or packaging which prevents exposure. These formulations include granules, and paraffinized and non-paraffinized pellets/tablets. HED anticipates these formulations generate particulates and therefore potential inhalation and/or dermal exposure as they are applied distributed, used to fill/refill bait stations, or otherwise contacted.

For loose formulations, occupational dermal and inhalation exposures are anticipated for handlers (e.g. application by hand,). While residential handler exposures and post-application exposures to adults or children to bromethalin, including loose formulations, are not expected provided they comply with the 2008 RMD for rodenticides². Most, but not all bromethalin products specify personal protection equipment of gloves, if a residential handler or other person comes into contact with these loose formulations, dermal and inhalation exposures are anticipated (see Appendix A for use pattern details).

Occupational post-application dermal or inhalation exposures are not anticipated because the formulations are expected to be of low volatility and no significant contact with surface residues are expected for workers in areas previously treated with rodenticides.

Exposure from spray drift and volatilization is not anticipated for the current bromethalin use pattern.

5.0 Data Requirements

Given the hazard profile and known toxicity of bromethalin, no additional hazard or exposure data is currently identified for bromethalin.

6.0 Incident and Epidemiological Data Review

The purpose of the review and database search is to identify potential patterns in the frequency and severity of the health effects attributed to commensal rodenticide exposure. For this

² Available at www.regulations.gov. Document number EPA-HQ-OPP-2006-0955-0820. The 2008 Risk Mitigation Decision required all residential consumer use products be in securable bait form, in a tamper resistant bait station, within 50 ft of a building, and ≤1 lb of bait.

evaluation, OPP evaluated its Incident Data System (IDS) and aggregate data reported in the American Association of Poison Control Centers (AAPCC) Annual Report for rodenticide incident trends over time, as a result of the 2008 RMD. Additionally, OPP evaluated NIOSH Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides, California Pesticide Illness Surveillance Program (PISP), and IDS for occupational incidents. The rodenticides in the report included the first-generation anticoagulant rodenticides (FGARs), second-generation anticoagulant rodenticides (SGARs) and non-anticoagulant rodenticides. Rodenticides were previously reviewed in 2015 (Recore, S. and Evans, E., D426573, 11/24/2015). At that time, the 2008 RMD had only recently been fully implemented so insufficient information was available to determine if the RMD impacted the frequency or severity of incidents for the anticoagulant rodenticides.

HED completed a Tier I updated analysis of exposure incidents for the anticoagulant and non-anticoagulant rodenticides (Recore, S., 03/04/2020; D456699). In IDS the total number of rodenticide incidents slightly decreased from 198 incidents in 2009 to 146 incidents reported in 2018. AAPCC data were also reviewed for reduction in reported rodenticide incidents in children under the age of six years old. A comparison of child rodenticide exposures from 2011 to 2017 identified a 46% decline in child rodenticide incident reports.

Further analysis of the data indicates that the number of second-generation anticoagulant incidents has decreased by 79% from 164 incidents in 2009 to 34 incidents in 2018. However, first-generation anticoagulant incidents and non-anticoagulant incidents both increased over this time period by 60% and 81% respectively. This increase in the FGARs is a trend reflected only in IDS; however, the reported incident counts are low. Overall review of IDS and AAPCC data suggest that the 2008 RMD may have contributed to an overall decrease in exposure incidents involving rodenticide products. See Figures 1 and 2 below.

Figure 1. Total Rodenticide Incidents, First-generation anticoagulants, Second-generation anticoagulants, and Non-anticoagulant Incidents Reported to Main and Aggregate IDS from 2009 to 2018.

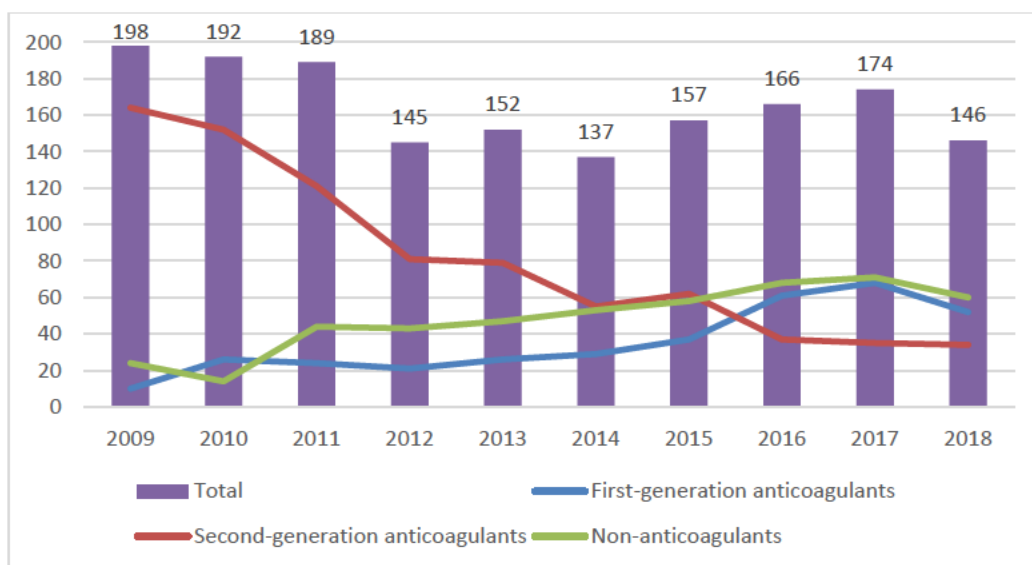
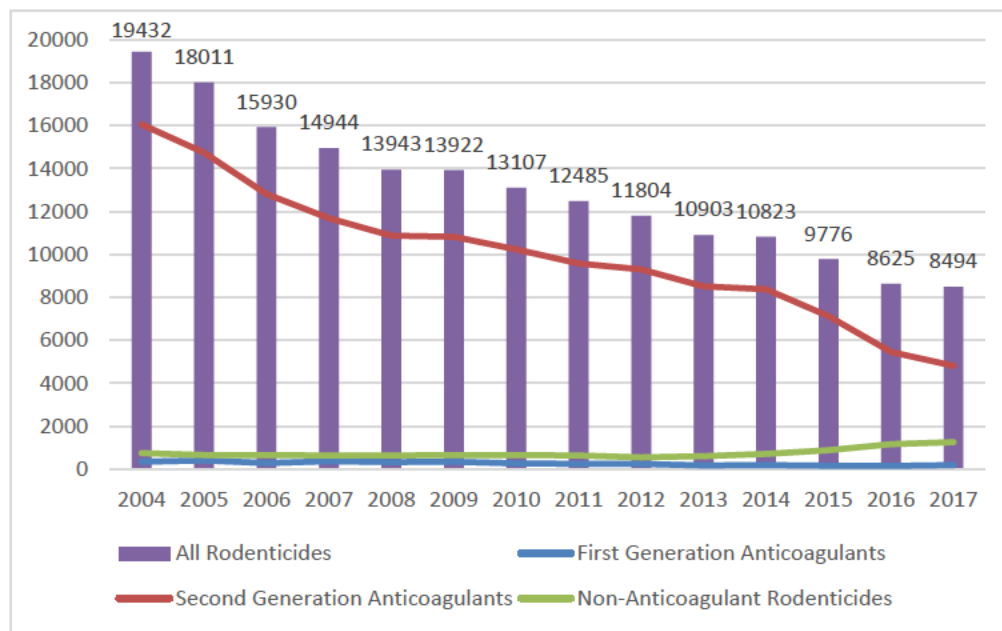


Figure 2. First-Generation Anticoagulant Rodenticides, Second-Generation Anticoagulant Rodenticide, Non-Anticoagulant Rodenticides Incidents Reported to AAPCC from 2004 to 2017.



In Main IDS, 37 incidents were reported that involved the active ingredient bromethalin (January 1, 2015 – July 12, 2019). Thirty-five were of moderate severity, two incidents resulted in death, which were suicides. In Aggregate IDS, there were 195 incidents reported involving bromethalin (January 1, 2015 – July 12, 2019; all were classified as minor severity).

Additionally, HED evaluated NIOSH Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides, California Pesticide Illness Surveillance Program (PISP), and IDS for occupational incidents. Overall, there was a low frequency of occupational incidents reported in SENSOR-Pesticides, State SENSOR Pesticide Data, California PISP, and Main IDS for rodenticides including the non-anticoagulants. From 2011-2015, only one reported case involved bromethalin.

7.0 Conclusions

Bromethalin is used to control rodent pests in and around residential, industrial, commercial, and agricultural buildings and structures; transport vehicles; residential lawns; golf courses; and non-crop areas. Bromethalin active ingredients are highly toxic, and the MOA and toxicity profiles for these active ingredients are well understood. Bromethalin end-use products are formulated into numerous baits. Bromethalin end-use products with limited/negligible potential exposures include place packs, bait blocks, or other enclosed or RTU products. Some bromethalin products are considered “loose” formulations such as granules and waxy/paraffinized or non-paraffinized pellets. Occupational and residential exposures are anticipated from contact with loose formulations. Residential handler exposures and post-application exposures to adults or children to bromethalin, including loose formulations, are not expected provided products comply with the 2008 RMD for rodenticides

Incident data suggests that the 2008 RMD may have contributed to an overall decrease in residential exposure incidents involving rodenticide products. Incident data indicate a low frequency of reported occupational bromethalin incidents.

Based upon available hazard data and toxicity profile, HED concludes that bromethalin is acutely toxic by all routes of exposure. Labeled uses of these products should be modified, as needed, to assure that occupational dermal and inhalation exposures, particularly exposures are limited to the extent possible. HED notes that while many bromethalin product labels indicate gloves among the PPE for handlers, but not all do so. Likewise, any non-occupational exposures should also be limited to the extent possible.

8.0 References

Habiba, U., 06/08/2016, TXR 0050666, Rodenticides. Summary of Hazard and Science Policy Council (HASPOC) Meeting on October 1, 2015: Recommendations on Data Requirements for Rodenticides.

Myers, T., 06/06/1996, N/A, The HED Chapter of the Reregistration Eligibility Decision Document (RED) for Bromethalin (Case No. 2765).

O'Keefe, B., 05/16/2016, D432763, Bromethalin. Human Health Scoping Document in Support of Registration Review.

Recore, S., 03/04/2020; D456699, Rodenticide: Tier I Update Review of Human Incidents and Epidemiology Assessment.

Appendix A. Bromethalin Use Pattern Summary

Table A.1 Use Profile for Bromethalin.							
Product Name	EPA Reg. No.	Formulation	% Active Ingredient	Target Pests	Application Rate	Tamper Resistant Bait Station	Personal Protective Equipment ¹
SL566	149-19	Soluble Concentrate/Solid	0.025	Moles in below ground holes in lawns, parks, gardens, nurseries, & non-crop areas.	Drop bait into tunnel hole & cover with dirt.	NA	Gloves to retrieve dead moles
d-Con® Hideaway™ d-Con® Bait Shield™ VII	3282-96	Pelleted/Tableted	0.01	House Mice	Bait Station	Yes	None
d-Con® Bait Station™ VIII	3282-97	Pelleted/Tableted	0.01	House Mice	Bait Station (5 oz block)	Yes	None
Bromethalin Block 1003	7173-301	Pelleted/Tableted	0.01	Norway rats, roof rats & house mice	Bait Block - Mice 1 to 2 blocks per placement. Rats 2 to 12 blocks per placement.	Yes	None
Hot Shot SUDDEN DEATH™ Brand Mouse Killer 1	8845-125	Granular	0.01	House Mice	1 to 2 place packs	Yes	None
Hot Shot SUDDEN DEATH™ Brand Rat Killer 1	8845-126	Granular	0.01	Rats	1 to 4 place packs	Yes	None
Hot Shot SUDDEN DEATH™ Brand Mouse & Rat Killer	8845-127	Pelleted/Tableted	0.01	Norway rats, roof rats & house mice	Mice 1 to 2 place packs. Rats 2 to 8 place packs.	Yes	None
Hot Shot SUDDEN DEATH™ Brand Mouse Killer Bait Station	8845-128	Pelleted/Tableted	0.01	Mice	1 to 2 bait stations	Yes	None
Chemsico Disposable Bait Station	9688-285	Granular	0.01	House Mice	1 unit station	Yes	Gloves to retrieve dead mice
Chemsico Refillable Bait Station	9688-291	Granular	0.01	House Mice	1 unit station	Yes	Gloves to refill bait station & retrieve dead mice
Chemsico Refillable Bait Station	9688-308	Pelleted/Tableted	0.01	Norway rats, roof rats & house mice	1 to more bait stations	Yes	Gloves to refill bait station & retrieve dead mice
F-TRAC ALL-WEATHER BLOX	12455-95	Pelleted/Tableted	0.01	Norway rats, roof rats & house mice	Bait Block - Mice 1 to 2 blocks per placement. Rats 2 to 12 blocks per placement.	Yes	Gloves to retrieve dead rodents
F-TRAC RODENTICIDE	12455-95	Pelleted/Tableted	0.01	Norway rats, roof rats & house mice	Mice ¼ to 2 oz of bait per placement. Rats 1 to 6 oz of bait per placement. In bait stations & into burrow holes.	Yes	Gloves to retrieve dead rodents
F-TRAC PLACE PACS	12455-97	Pelleted/Tableted	0.01	Norway rats, roof rats & house mice	Mice 1 to 2 place pacs per placement. Rats 2 to 12 place pacs per placement.	Yes	Gloves to retrieve dead rodents
TALPIRID	12455-101	Impregnated Material	0.025	Moles in below ground holes in lawns, parks, gardens, nurseries, & non-crop areas.	Drop bait into tunnel hole & cover with dirt.	NA	Gloves to handle bait & retrieve dead moles.

Table A.1 Use Profile for Bromethalin.							
Product Name	EPA Reg. No.	Formulation	% Active Ingredient	Target Pests	Application Rate	Tamper Resistant Bait Station	Personal Protective Equipment ¹
TOMCAT® MOUSE KILLER I	12455-120	Pelleted/Tableted	0.01	House Mice	1 oz Bait Blocks & Refillable Bait Stations.	Yes	Gloves to retrieve dead rodents
TOMCAT® MOUSE KILLER	12455-121	Impregnated Material	0.01	House Mice	1 oz Bait Stations	Yes	Gloves to retrieve dead rodents
TOMCAT® RAT KILLER	12455-122	Impregnated Material	0.01	Rats & Mice	1 to 4 oz Bait Stations	Yes	Gloves to retrieve dead rodents
TOMCAT® MOUSE KILLER II	12455-123	Impregnated Material	0.01	House Mice	1 oz Bait Stations	Yes	Gloves to retrieve dead rodents
TOMCAT® MOUSE KILLER IV	12455-124	Impregnated Material	0.01	House Mice	1 oz Bait Block Stations	Yes	Gloves to retrieve dead rodents
TOMCAT® RAT KILLER I	12455-125	Impregnated Material	0.01	Rats & Mice	1 to 4 oz Bait Stations	Yes	Gloves to retrieve dead rodents
TOMCAT® MOUSE KILLER III	12455-129	Pelleted/Tableted	0.01	House Mice	1 oz Refillable Bait Stations	Yes	Gloves to handle bait & retrieve dead rodents
TOMCAT® BAIT CHUNX	12455-129	Pelleted/Tableted	0.01	Norway rats, roof rats & house mice	Bait Block - Mice 1 to 2 blocks per placement. Rats 1 to 6 blocks per placement.	Yes	Gloves to handle bait & retrieve dead rodents
RAMPAGE PELLETED BAIT	12455-137	Pelleted/Tableted	0.01	Norway rats, roof rats & house mice	Bait Block - Mice ¼ to 2 oz of bait per placement. Rats 1 to 6 oz of bait per placement. For structures & for burrow baiting.	Yes	Gloves to handle bait & retrieve dead rodents
TOMCAT® MOUSE KILLER X	12455-138	Pelleted/Tableted	0.01	House Mice	½ oz Bait Blocks & Refillable Bait Stations	Yes	Gloves to handle bait blocks & retrieve dead rodents
TOMCAT® RAT KILLER II	12455-140	Pelleted/Tableted	0.01	Rats & Mice	30 g Bait Blocks & Refillable Bait Stations	Yes	Gloves to handle bait blocks & retrieve dead rodents
RAMPAGE MEAL BAIT	12455-141	Granular	0.01	Norway rats, roof rats & house mice	Mice ¼ to 2 oz of bait per placement. Rats 1 to 6 oz of bait per placement.	Yes	Gloves to handle bait & retrieve dead rodents
TOMCAT® MOUSE KILLER XI	12455-142	Pelleted/Tableted	0.01	House Mice	½ oz Bait Blocks & Refillable Bait Stations	Yes	Gloves to handle bait blocks & retrieve dead rodents
TOMCAT QUICK KILL PLACE PACS	12455-143	Pelleted/Tableted	0.01	Norway rats, roof rats & house mice	3 oz Place Pacs. Mice, open place pac, apply ¼ to 2 oz of bait per placement. Rats, 1 to 6 place pacs per placement.	Yes	Gloves to handle place pacs & retrieve dead rodents
BROMETHALIN MOUSE BAIT STATION	36488-51	Pelleted/Tableted	0.01	House Mice	One 0.75 oz bait station per placement	Yes	Gloves to retrieve dead rodents
BROMETHALIN 0.01% PELLET II	36488-52	Pelleted/Tableted	0.01	Norway rats, roof rats & house mice	0.75 oz place pacs. Mice 1 to 2 place pacs per placement. Rats 2 to 8 place pacs per placement.	Yes	Gloves to retrieve dead rodents
BROMETHALIN RAT & MOUSE BLOCK II	36488-53	Pelleted/Tableted	0.01	Norway rats, roof rats & house mice	0.75 oz bait blocks. Mice 1 to 2 bait blocks per placement. Rats 2 to 8 bait blocks per placement.	Yes	Gloves to retrieve dead rodents

Table A.1 Use Profile for Bromethalin.							
Product Name	EPA Reg. No.	Formulation	% Active Ingredient	Target Pests	Application Rate	Tamper Resistant Bait Station	Personal Protective Equipment ¹
BROMETHALIN REFILLABLE MOUSE BAIT STATION	36488-62	Pelleted/Tableted	0.01	House Mice	0.75 oz bait blocks, 1 to 2 bait blocks per placement.	Yes	Gloves to handle bait blocks & to retrieve dead rodents
ASSAULT® ALL WEATHER BAIT	67517-66	Granular	0.01	Norway rats, roof rats & house mice	0.5 oz bait blocks. Mice 1 to 2 bait blocks per placement. Rats 2 to 8 bait blocks per placement.	Yes	Gloves to handle bait blocks & to retrieve dead rodents
ASSAULT® MEAL RODENTICIDE	67517-67	Granular	0.01	Norway rats, roof rats & house mice	Mice ¼ to 3 oz per placement. Rats 1 to 6 oz per placement.	Yes	Gloves to handle bait & to retrieve dead rodents
ASSAULT® MOUSE PELLETS	67517-68	Pelleted/Tableted	0.01	House Mice	¼ to 3 oz per placement	Yes	Gloves to handle bait & to retrieve dead rodents
ASSAULT® MOUSE PLACE PACK	67517-69	Pelleted/Tableted	0.01	House Mice	1.5 oz place packs, place 1 place pack per placement	Yes	Gloves to handle place packs & to retrieve dead rodents
ASSAULT® MOUSE PLACE PACK II	67517-70	Impregnated Material	0.01	House Mice	0.75 oz place packs, place 1 place pack per placement	Yes	Gloves to handle place packs & to retrieve dead rodents
ASSAULT® MOUSE/RAT PELLETS	67517-71	Pelleted/Tableted	0.01	Norway rats, roof rats & house mice	Mice ¼ to 3 oz per placement. Rats 1 to 8 oz per placement.	Yes	Gloves to handle bait & to retrieve dead rodents
ASSAULT® MOUSE RAT PLACE PACK	67517-72	Pelleted/Tableted	0.01	Norway rats, roof rats & house mice	Mice 1 to place packs per placement. Rats 2 to 12 place packs per placement.	Yes	Gloves to handle place packs & to retrieve dead rodents
ASSAULT® RAT PELLETS	67517-73	Pelleted/Tableted	0.01	Norway rats & roof rats	Rats 1 to 6 oz per placement.	Yes	Gloves to handle bait & to retrieve dead rodents
ASSAULT® RAT PLACE PACK	67517-74	Pelleted/Tableted	0.01	Norway rats & roof rats	0.75 oz place packs, place 1 to 4 place packs per placement	Yes	Gloves to handle place packs & to retrieve dead rodents
ASSAULT® RAT PLACE PACK II	67517-75	Pelleted/Tableted	0.01	Norway rats & roof rats	0.75 oz place packs, place 3 to 8 place packs per placement	Yes	Gloves to handle place packs & to retrieve dead rodents
ASSAULT® W.R. WEATHER RESISTENT BAIT	67517-76	Pelleted/Tableted	0.01	Norway rats & roof rats	1 oz bait cups, Mice 1 to 2 bait cups per placement, Rats 2 to 6 bait cups per placement	Yes	Gloves to handle bait cups & to retrieve dead rodents
ASSAULT® MOUSE KILLER STATION	67517-77	Pelleted/Tableted	0.01	House Mice	1.5 oz bait stations, doesn't specify the number of bait stations per placement	Yes	Gloves to handle bait stations & to retrieve dead rodents
ASSAULT® MOUSE/RAT PLACE PACK II	67517-79	Pelleted/Tableted	0.01	Norway rats, roof rats & house mice	0.75 oz place packs, Mice 1 to 3 place packs per placement, Rats 2 to 8 place packs per placement	Yes	Gloves to handle place packs & to retrieve dead rodents
ASSAULT® MOUSE/RAT PLACE PACK	67517-81	Granular	0.01	Norway rats, roof rats & house mice	1.5 oz place packs, Mice 1 place pack per placement. Rats 1 to 4 place packs per placement.	Yes	Gloves to handle place packs & to retrieve dead rodents
ASSAULT® ALL WEATHER BAIT II	67517-84	Granular	0.01	Norway rats, roof rats & house mice	1 oz bait blocks, Mice 1 bait block per placement. Rats 1 to 6 bait blocks per placement.	Yes	Gloves to handle bait blocks & to retrieve dead rodents
ASSAULT® MOUSE BAIT STATION	67517-88	Impregnated Material	0.01	House Mice	0.5 oz bait blocks, place 8 to 12 feet apart	No	Gloves to retrieve dead rodents
ASSAULT® MOUSE BAIT STATION CU	67517-89	Impregnated Material	0.01	House Mice	0.5 oz bait blocks, place 8 to 12 feet apart	No	Gloves to retrieve dead rodents

Table A.1 Use Profile for Bromethalin.							
Product Name	EPA Reg. No.	Formulation	% Active Ingredient	Target Pests	Application Rate	Tamper Resistant Bait Station	Personal Protective Equipment ¹
ASSAULT® MOUSE BAIT STATION II CU	67517-90	Pelleted/Tableted	0.01	House Mice	0.5 oz bait blocks, place bait stations 8 to 12 feet apart	Yes	Gloves to retrieve dead rodents
ASSAULT® MOUSE BAIT STATION II	67517-91	Pelleted/Tableted	0.01	House Mice	0.5 oz bait blocks, place bait stations 8 to 12 feet apart. Not allowed in residential settings.	No	Gloves to retrieve dead rodents
ASSAULT® MOUSE BAIT STATION II CU D	67517-92	Impregnated Material	0.01	House Mice	0.5 oz bait blocks, place bait stations 8 to 12 feet apart.	Yes	Gloves to retrieve dead rodents
ASSAULT® MOUSE BAIT STATION III D	67517-93	Impregnated Material	0.01	House Mice	0.5 oz bait blocks, place bait stations 8 to 12 feet apart.	Yes	Gloves to retrieve dead rodents
ASSAULT® MOUSE BAIT STATION I	67517-94	Impregnated Material	0.01	Norway rats, roof rats & house mice	0.5 oz bait blocks, place bait stations 8 to 12 feet apart.	Yes	Gloves to handle bait blocks & to retrieve dead rodents
ASSAULT® MOUSE BAIT STATION I CU	67517-95	Impregnated Material	0.01	House Mice	0.5 oz bait blocks, place bait stations 8 to 12 feet apart.	Yes	Gloves to retrieve dead rodents
TC Mouse Killer 129	90780-1	Pelleted/Tableted	0.01	House Mice	1 oz bait blocks, place refillable bait stations 8 to 12 feet apart.	Yes	Gloves to handle bait blocks & to retrieve dead rodents
TALPIRID 101	90780-2	Bait Worms	0.025	Moles	Drop bait worms into tunnel hole & cover with dirt.	NA	Gloves to handle bait worms & to retrieve dead rodents
TC MOUSE KILLER 138	90780-5	Bait blocks	0.01	House Mice	0.5 oz bait blocks, place refillable bait stations 8 to 12 feet apart.	Yes	Gloves to handle bait blocks & to retrieve dead rodents
TC MOUSE KILLER 121	90780-6	Bait blocks	0.01	House Mice	1 oz bait blocks, place refillable bait stations 8 to 12 feet apart.	Yes	Gloves to handle bait blocks & to retrieve dead rodents
TC MOUSE KILLER 123	90780-7	Bait blocks	0.01	House Mice	1 oz bait blocks, place refillable bait stations 8 to 12 feet apart.	Yes	Gloves to handle bait blocks & to retrieve dead rodents
TC MOUSE KILLER 142	90780-8	Impregnated Material	0.01	House Mice	0.5 oz bait blocks, place refillable bait stations 8 to 12 feet apart.	Yes	Gloves to handle bait blocks & to retrieve dead rodents
TC RAT KILLER 122	90780-8	Granular	0.01	Rats & House Mice	4 oz bait station, place bait stations 15 to 30 feet apart.	Yes	Gloves to handle bait stations & to retrieve dead rodents
TC MOUSE KILLER 120	90780-10	Granular	0.01	House Mice	1 oz bait blocks, place refillable bait stations 8 to 12 feet apart.	Yes	Gloves to handle bait blocks & to retrieve dead rodents
TC RAT KILLER 140	90780-11	Pelleted/Tableted	0.01	Norway rats, roof rats & house mice	1.06 oz bait blocks, place bait stations 15 to 30 feet apart.	Yes	Gloves to handle bait stations & to retrieve dead rodents

Appendix B. Literature Study Summary

As part of registration review for bromethalin, a broad survey of the literature was conducted to identify studies that report toxicity following exposure to bromethalin via exposure routes relevant to human health pesticide risk assessment not accounted for in the agency's toxicology databases. The search strategy employed terms restricted to the name of the chemical plus any common synonyms, and common mammalian models to capture as broad a list of publications as possible for the chemical of interest. The search strategy returned numerous studies/articles from the literature. During the title or abstract and/or full text screening of these studies, none of the studies or articles were deemed to contain potentially relevant information (either quantitative or qualitative) for the bromethalin human health risk assessment. Search details are listed below.

Search Details:

((*Bromethalin*)) AND (rat OR mouse OR dog OR rabbit OR monkey OR mammal)

PubMed hits: 31

Number of Swift Articles: 31 for Animal

Number of Swift Articles: 15 for Human

Number of Swift Articles: 0 for No Tag