

Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

Application Number: 2022-6319

Application: New End-use Product (Product Chemistry) – Identity of

Formulants, Proportion of Formulants

Product: Tomcat Mouse Killer Bait Station Advanced Formula

Registration Number: 34875 **Active ingredient (a.i.):** Bromethalin **PMRA Document Number:** 3451666

Purpose of Application

The purpose of this application was to register Tomcat Mouse Killer Bait Station Advanced Formula, a domestic class rodenticide product for indoor and outdoor structural use to control house mice (*Mus musculus*), based on a registered precedent product owned by the applicant.

Chemistry Assessment

Tomcat Mouse Killer Bait Station Advanced Formula is formulated as a solid containing bromethalin at a concentration of 0.01%. This end-use product has a density of 1.16-1.20 g/mL. The required chemistry data for Tomcat Mouse Killer Bait Station Advanced Formula have been provided, reviewed and found to be acceptable.

Health Assessments

Tomcat Mouse Killer Bait Station Advanced Formula is expected to be of low acute toxicity via the oral and dermal routes of exposure. It is expected to be minimally irritating to the eyes and not irritating to the skin. This product is expected to be a potential dermal sensitizer. Due to the product type (bait block), exposure via the inhalation route is not expected.

Tomcat Mouse Killer Bait Station Advanced Formula rodenticide bait is not expected to increase domestic (including children) exposures compared to the registered use of bromethalin. No risks of concern are expected when homeowners follow label directions and precautions as stated on the label.

A dietary exposure assessment was not required for this application.

Environmental Assessment

No additional risk to the environment is expected from the registration of Tomcat Mouse Killer Bait Station Advanced Formula, as its use pattern fits within the registered use pattern of bromethalin.



Value Assessment

Value information reviewed in support of Tomcat Mouse Killer Bait Station Advanced Formula included a scientific rationale based on similarity of formulation and bait station design to the registered precedent product and four mouse studies on bait attractant palatability. This information was sufficient to support the claim that Tomcat Mouse Killer Bait Station Advanced Formula will control house mice. The registration of Tomcat Mouse Killer Bait Station Advanced Formula will provide users with an alternative all-in-one product for use to manage house mice indoors and outdoors (within 15 m of buildings).

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of Tomcat Mouse Killer Bait Station Advanced Formula.

References

PMRA Document Number	Reference
1064893	2001, Storage Stability and Corrosion Characteristics of Bromethalin Blox Stored in Polyethylene Pail, DACO: 3.5.10 CBI
1067267	1999, Product Chemistry of Bromethalin Blox and Confidential Attachment and Material Safety Data Sheets, DACO: 3.1,3.2,3.3,3.4,3.5 CBI
3442835	2023, DACO 3.2 Formulation Process, DACO: 3.2 CBI
3445006	2023, DACO 3.5 Chemical and Physical Properties, DACO: 3.5 CBI
1262315	2003, Acute Limit Oral Toxicity Evaluation of Bromethalin Mole Bait on Young Adult Sprague Dawley Rats, DACO: 4.6.1
1262317	2006, Acute Inhalation Toxicity Waiver, DACO: 4.6.3 CBI
1262318	2003, Acute Eye Irritation/Corrosion Evaluation of Bromethalin Mole Bait on Young Adult New Zealand White Rabbits, DACO: 4.6.4
1262319	2003, Acute Limit Dermal Toxicity Evaluation of Bromethalin Mole Bait on Young Adult Sprague Dawley Rats, DACO: 4.6.5
1262320	2003, Bromethalin Mole Bait - Dermal Sensitization Study in Guinea Pigs (Buehler Method), DACO: 4.6.6
3081525	2020, 5.2, DACO: 5.2
3368583	2022, DACO 10.1 Value Summary - Tomcat Mouse Killer Bait Station Advanced Formula, DACO: 10.1
3368584	2010, Efficacy of 0.01% Bromethalin Blocks on Young Adult Swiss Webster Mice, DACO: 10.2.3
3368586	2010, Efficacy of 0.01% Bromethalin Blocks on Young Adult Swiss Webster Mice, DACO: 10.2.3
3368587	2019, Palatability of Inert EPA Registration Number 12455-95 Blocks against Inert EPA Registration Number 12455-132 Blocks on Young Adult Swiss Webster Mice, DACO: 10.2.3
3368589	2019, Palatability of Inert EPA Registration Number 12455-95 Blocks against Inert EPA Registration Number 12455-132 Blocks on Young Adult Swiss Webster Mice, DACO: 10.2.3

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