

Evaluation Report for Category B, Subcategories 2.3, 2.4, 2.5 Application

Application Number: 2022-5843
Application: New End Use Product (Product Chemistry) – Identity of Formulants, Proportion of Formulants, Formulation Type
Product: Fastrac Soft Bait
Registration Number: 35087
Active ingredient (a.i.): Bromethalin
PMRA Document Number: 3550500

Purpose of Application

The purpose of this application was to register a paste bait rodenticide, Fastrac Soft Bait, containing bromethalin, for indoor rodent control.

Chemistry Assessment

Fastrac Soft Bait is formulated as a paste containing bromethalin at a concentration of 0.01%. This end-use product has a density of 1.22 g/mL. The required chemistry data for Fastrac Soft Bait have been provided, reviewed and found to be acceptable.

Health Assessments

Fastrac Soft Bait is of low acute toxicity via the oral and dermal routes of exposure and is not considered to pose an acute inhalation hazard. It is minimally irritating to the eyes and non-irritating to the skin. Fastrac Soft Bait is not expected to produce an allergic skin reaction.

Exposures to bromethalin are adequately addressed through qualitative assessments for applicators and potential postapplication contact with Fastrac Soft Bait. Considering the product formulation in pre-measured place packs, label precautions, and personal protective equipment, workers are adequately protected when following label instructions. In addition, the product must be used in bait stations when placed in sites accessible to children, pets, livestock, and non-target animals. Therefore, exposures to the public and homeowners, including children, are not considered to be of concern.

A dietary exposure assessment was not required for this application.

Environmental Assessment

The uses of Fastrac Soft Bait are within the currently registered use pattern of bromethalin. Therefore, no additional environmental risk is expected when the product is used in accordance with the label, which includes statements to mitigate the risks to non-target organisms.

Value Assessment

Seven laboratory choice trials were reviewed, which tested Fastrac Soft Bait against Swiss Webster Mice (*Mus musculus*; three trials), Wistar Rats (*Rattus norvegicus domestica*; three trials), and Eastern deer mice (*Peromyscus maniculatus*; one trial). Trials included fresh bait both in and removed from place packs and weathered bait removed from place packs. The six trials on rats or house mice were sufficient to demonstrate that Fastrac Soft Bait will provide control of Norway and roof rats and house mice with one session of feeding, whether in place packs or removed from place packs, and when weathered. The trial on *Peromyscus maniculatus* (Eastern deer mice) demonstrated 95% mortality and sufficient levels of bait acceptance to meet the target set out by the study. Based on the weight of evidence, including the submitted study on Eastern deer mice, the non-selective mode of action of bromethalin and the similar size of deer mice to house mice, control of *Peromyscus* spp. with Fastrac Soft Bait was supported.

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 Fastrac Soft Bait.

References

PMRA

Document

Number	Reference
3404192	2019, Determination of Physical/Chemical Properties and Accelerated Storage Stability of Bromethalin Soft Bait, 100 ppm, DACO: 3.5
3404193	2019, Determination of Physical/Chemical Properties and Accelerated Storage Stability of Bromethalin Soft Bait, 100 ppm, DACO: 3.2,3.5 CBI
3404194	2019, One Year Storage Stability and Corrosion Characteristics of Bromethalin Soft Bait, 100 ppm, DACO: 3.5.10,3.5.14
3404195	2019, One Year Storage Stability and Corrosion Characteristics of Bromethalin Soft Bait, 100 ppm, DACO: 3.5.10,3.5.14 CBI
3404182	2019, Acute Limit Oral Toxicity Evaluation of 0.01% Bromethalin Soft Bait on Young Adult Sprague Dawley Rats, DACO: 4.6.1
3404184	2019, Acute Limit Dermal Toxicity Evaluation of 0.01% Bromethalin Soft Bait on Young Adult Sprague Dawley Rats, DACO: 4.6.2
3404186	2020, Waiver Request - Acute Inhalation, DACO: 4.6.3
3404187	2019, Acute Eye Irritation/Corrosion Evaluation of 0.01% Bromethalin Soft Bait on Young Adult New Zealand White Rabbits, DACO: 4.6.4
3404189	2019, Acute Dermal Irritation/Corrosion Evaluation of 0.01% Bromethalin Soft Bait on Young Adult New Zealand White Rabbits, DACO: 4.6.5
3404191	2019, 0.01% Bromethalin Soft Bait: Dermal Sensitization Test in Guinea Pigs - Buehler Method, DACO: 4.6.6
3445771	2023, DACO 5 , DACO: 5.1, 5.2, 5.3, 5.6
3404196	2019, Efficacy of 0.01% Bromethalin Soft Bait on Young Adult Wistar Rats, DACO: 10.2
3404197	2019, Efficacy of 0.01% Bromethalin Soft Bait on Young Adult Wistar Rats, DACO: 10.2
3404198	2019, Efficacy of 0.01% Bromethalin Soft Bait on Young Adult Swiss Webster Mice, DACO: 10.2
3404199	2019, Efficacy of 0.01% Bromethalin Soft Bait on Young Adult Swiss Webster Mice, DACO: 10.2
3404200	2019, 0.01% Bromethalin Soft Bait Place Pack Penetration Study on Young Adult Wistar Rats, DACO: 10.2
3404202	2019, 0.01% Bromethalin Soft Bait Place Pack Penetration Study on Young Adult Wistar Rats, DACO: 10.2
3404203	2019, 0.01% Bromethalin Soft Bait Place Pack Penetration Study on Young Adult Swiss Webster Mice, DACO: 10.2
3404204	2019, 0.01% Bromethalin Soft Bait Place Pack Penetration on Young Adult Swiss Webster Mice, DACO: 10.2
3404205	2019, Efficacy of 0.01% Bromethalin Soft Bait on Young Adult Peromyscus spp., DACO: 10.2
3404206	2019, Efficacy of 0.01% Bromethalin Soft Bait on Young Adult Peromyscus spp., DACO: 10.2
3404212	2021, Efficacy of 0.01% Weatherized Bromethalin Soft Bait on Young Adult Swiss Webster Mice, DACO: 10.2

- 3404213 2021, Efficacy of 0.01% Weatherized Bromethalin Soft Bait on Young Adult Swiss Webster Mice, DACO: 10.2
- 3404214 2021, Efficacy of 0.01 Weatherized Bromethalin Soft Bait on Young Adult Wistar Rats, DACO: 10.2
- 3404215 2021, Efficacy of 0.01% Weatherized Bromethalin Soft Bait on Young Adult Wistar Rats, DACO: 10.2

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