

## Evaluation Report for Category B, Subcategory 3.1 and 3.12 Application

**Application Number:** 2014-0199  
**Application:** New product labels – application rate and site  
**Product:** Tomcat Rat Killer Disposable Bait Station  
**Registration Number:** 31970  
**Active ingredients (a.i.):** Bromethalin  
**PMRA Document Number :** 2541311

### Purpose of Application

The purpose of this application was to register a new bromethalin-based bait station, Tomcat Rat Killer Disposable Bait Station (0.01% bromethalin) for domestic use indoors and outdoors, within 15 metres of buildings, for the control of Norway rat (*Rattus norvegicus*) and roof rat (*Rattus rattus*).

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Health Assessments

This product is identical in formulation to currently registered products with the only difference being an increase in block size. This increase in block size has no impact on the acute toxicology profile of the product.

The registration of Tomcat Rat Killer Disposable Bait Stations pre-filled with bait to control Norway and roof rats indoors and outdoors, within 15 m of buildings, at a rate of one bait station (containing 113 g of bait) every 5 to 10 m can be supported. Exposures to bromethalin are adequately addressed through qualitative assessments for handlers and potential post-application contact. Considering the product formulation, label precautions, and personal protective equipment, handlers are considered to be adequately protected when following label instructions. In addition, the product must be used in a tamper-resistant bait station, and label statements caution to not allow children or pets to handle the bait station. Therefore, exposures to homeowners, including children, are not considered to be of concern.

### Environmental Assessment

Bromethalin has a mode of action that differs from the anticoagulants. Its action results in rapid rodent mortality presenting fewer opportunities for predator exposure. Target animals tend to

stop feeding after consumption of toxic doses and are, thereby, less likely to carry residues in excess of toxic doses. Bromethalin is eliminated quickly from target and non-target animals relative to the other rodenticides, thus, bromethalin residues are not likely to accumulate after long-term low-dose exposure. Although the USEPA estimated that predators and scavengers (birds and mammals) would have to consume <1 bromethalin-intoxicated rodent to reach their LD<sub>50</sub>, the scenarios considered were quite conservative as continuous feeding on bromethalin-intoxicated rodents was assumed. In addition, these estimates do not consider the quick kill and stop-feed action of bromethalin, thereby, limiting the carryover of toxic doses to secondary consumers. By contrast, when bromethalin-intoxicated rat carcasses were fed to dogs to imitate exposure to predators and scavengers, the results showed that none of the dogs exhibited any signs of toxicity attributable to bromethalin. Together with the lack of reported incidents of secondary poisoning in the USEPA EIS system and incident reports for Canada, the risk of secondary exposure due to bromethalin use appears to be limited.

Label statements regarding disposal of dead rodents were included to minimize the exposure of non-target birds and wild mammals to contaminated carcasses.

### Value Assessment

Based on precedent products and three laboratory trials, the use of Tomcat Rat Killer Disposable Bait Station was supported to control Norway and roof rats indoors and outdoors, within 15 m of buildings, at a rate of one bait station (containing 113 g of bait) every 5 to 10 m.

### Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Tomcat Rat Killer Disposable Bait Station, and has found the information sufficient to register this new end-use product.

### References

PMRA Number	Document
2383579	2011, Efficacy of 0.01% Weatherized Bromethalin Block on Young Adult Wistar Rats, DACO: 10.2
2383580	2011, Efficacy of 0.01% Bromethalin Block on Young Adult Wistar Rats, DACO: 10.2
2383581	2012, Efficacy of a 0.01% Bromethalin Block in a Pre-Baited Bait Station on Young Adult Wistar Rats, DACO: 10.2
2425944	Value Summary for Sub. No. 2014-0189, DACO: 10.1
2425945	Statement of Weather Resistance for Tier 1 Rat Disposable Bait Stations, Sub. No. 2014-0189, DACO: 10.1
2383582	2010, Bait Security Test on a Sealed Rat Bait Station, DACO: 10.6,5.14
2383583	2010, Sealed, Plastic Rat Bait Station - Sequential Child Test, DACO: 10.6,5.14

2383585	Mechanical Drawing of Rat Bait Station, DACO: 10.6,5.14
2463343	2014, Secondary Poisoning to Predators Resulting from Feeding on Prey Poisoned from Bromethalin, DACO: 9.6.6
2463344	1988, The Toxicity and Mechanism of Action of Bromethalin: A New Single Feeding Rodenticide, DACO: 9.6.6
2463346	1988, Status of Bromethalin Outside the United States, DACO: 9.6.6
2463348	2000, Recognizing and Reducing Secondary and Tertiary Poisoning Risks Associated with Brodifacoum, DACO: 9.6.6
2463349	2013, Statement of Reasons and Factual Basis for Notice Intent to Cancel Registrations of, and Notice of Denial of Applications for; Certain Rodenticide Bait Products, DACO: 9.6.6
2463352	2011, Efficacy of Rodenticide Baits for the Control of Three Invasive Rodent Species in Hawaii, , DACO: 9.6.6
2463355	1982, Bromethalin - A Promising New Rodenticide, DACO: 9.6.6

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