



Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5 Application

Application Number: 2012-3300
Application: Product Chemistry – Guarantee
Product Chemistry – Identity of Formulants
Product Chemistry – Proportion of Formulants
Product Chemistry – Formulation Type
Product: Final Soft Bait
Registration Number: 31215
Active ingredients (a.i.): Brodifacoum
PMRA Document Number : 2277124

Purpose of Application

The purpose of this application was to register a new commercial class rodenticide containing brodifacoum at 0.0025%. The product consists of a soft bait formulation which is packaged into 15 g sachets. The product is for the control of rats and mice in various indoor locations.

Chemistry Assessment

Final Soft Bait is formulated as a solid containing brodifacoum at a minimum concentration of 0.0025%. This end-use product has a density of 1.22 g/mL. The chemistry requirements for this product are complete.

Health Assessments

Final Soft Bait is of low acute toxicity via the oral and dermal routes of exposure. It is not an eye or skin irritant, and is not considered to be a dermal sensitizer.

In the absence of toxicological endpoints, quantitative risk assessments cannot be conducted. Exposures to brodifacoum are adequately addressed through qualitative assessments for applicators and potential post-application contact with Final Soft Bait, bait stations, and dead rodents. Considering the product formulation, label precautions, and personal protective equipment, workers are considered to be adequately protected when following label instructions. In addition, label statements restrict treating areas accessible to children, pets, non-target animals, wildlife, or use tamper-resistant bait stations. Therefore, exposures to homeowners, including children, are not considered to be a concern.

A food residue assessment was not required for this application.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

Efficacy data from four experiments, conducted in a laboratory setting, demonstrated the effectiveness of Final Soft Bait. The submitted information are acceptable to support the label claims of control of rats and mice, from a value perspective.

Conclusion

The PMRA has completed an assessment of available information and is able to support the registration of Final Soft Bait, a new commercial class rodenticide to control rats and mice in various indoor locations.

References

| PMRA No. | References |
|----------|--|
| 2218925 | 2011, Product Properties of Brodifacoum Paste Bait, DACO: 3.0 CBI |
| 2342262 | Enforcement Analytical Method, DACO: 3.4.1 |
| 2218923 | Inhalation Waiver Request for Final Soft Bait, DACO: 4.6.3 |
| 2218927 | 2011, Acute Limit Oral Toxicity of 0.0025% Brodifacoum Paste Bait on Young Adult Sprague Dawley Rats, DACO: 4.6.1 |
| 2218929 | 2011, Acute Limit Dermal Toxicity Evaluation of 0.0025% Brodifacoum Paste Bait on Young Adult Sprague Dawley Rats, DACO: 4.6.2 |
| 2218931 | 2011, Acute Eye Irritation /Corrosion Evaluation of 0.0025% Brodifacoum Paste Bait on Young Adult New Zealand White Rabbits, DACO: 4.6.4 |
| 2218933 | 2011, Acute Dermal Irritation/Corrosion Evaluation of 0.0025% Brodifacoum Paste Bait on Young Adult New Zealand White Rabbits, DACO: 4.6.5 |
| 2218935 | 2011, Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6 |
| 2262628 | Use Description/Scenario for Final Soft Bait, Submission Number 2012-3300, DACO: 5.2 |
| 2218936 | 2011, Efficacy of 0.0025% Brodifacoum Paste Bait on Young Adult Swiss Webster Mice, DACO: 10.2.3 |
| 2218940 | 2011, Efficacy of 0.0025% Brodifacoum Paste Bait on Young Adult Wistar Rats, DACO: 10.2.3 |
| 2218941 | 2011, 0.0025% Brodifacoum Paste Bait Place Pack Penetration Study on Young Adult Swiss Webster Mice, DACO: 10.2.3 |
| 2218942 | 2011, 0.0025% Brodifacoum Paste Bait Place Pack Penetration Study on Young Adult Wistar Rats, DACO: 10.2.3 |

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