

Evaluation Report for Category B, Subcategories 2.1, 3.4 Application

Application Number: 2023-3418
Application: New End-use Product (Product Chemistry) - Guarantee;
New Product Labels - Application Method
Applicant: Bell Laboratories Inc.
Product: Ditrac Soft Bait
Registration Number: 35317
Active ingredient (a.i.): Diphacinone (present in free form or as sodium salt)
PMRA Document Number: 3622577

Purpose of Application

The purpose of this application was to register a new commercial-class rodenticide end-use product, Ditrac Soft Bait.

Chemistry Assessment

Ditrac Soft Bait is formulated as a paste containing diphacinone at a minimum concentration of 0.005%. This end-use product has a density of 1.2009 – 1.2116 g/mL and the pH was not determined as the product is not soluble in water. The required chemistry data for Ditrac Soft Bait have been provided, reviewed and found to be acceptable.

Health Assessments

Ditrac Soft Bait is considered to be of low acute toxicity via the oral and dermal routes, and is not expected to pose an acute inhalation hazard. It is considered to be minimally irritating to the eye, and is not expected to be a skin irritant or a potential dermal sensitizer.

The use of the new end-use product, Ditrac Soft Bait, is not expected to result in potential occupational or bystander exposure greater than the registered use of the active ingredient, diphacinone. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

A dietary exposure assessment was not required for this application.

Environmental Assessment

The uses of Ditrac Soft Bait are within the currently registered use pattern of the active ingredient diphacinone. Ditrac Soft Bait is to be used with tamper-resistant bait stations or placed in locations not accessible to non-target wildlife. Therefore, no additional risk is expected when Ditrac Soft Bait is used in accordance with the label, which includes statements to mitigate the risks to non-target wildlife.

Value Assessment

To support the claim to use Ditrac Soft Bait against rats and mice, data from two laboratory cage studies were provided testing the efficacy of the product on Norway rat (*Rattus norvegicus*) and house mice (*Mus musculus*) in the USA. The submitted value information was found to be adequate to support the claim that Ditrac Soft Bait will control rats and mice.

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 Ditrac Soft Bait.

References

PMRA Document Number	Reference
3482417	2023, Value Dossier 06-09-2023, DACO: 10.1
3482425	2023, Efficacy of 0.005% Diphacinone Soft Bait on Young Adult Wistar Rats, DACO: 10.2.3
3482426	2023, Efficacy of 0.005% Diphacinone Soft Bait on Young Adult Wistar Rats, DACO: 10.2.3
3482427	2023, Efficacy of 0.005% Diphacinone Soft Bait on Young Adult Swiss Webster Mice, DACO: 10.2.3
3482428	2023, Efficacy of 0.005% Diphacinone Soft Bait on Young Adult Swiss Webster Mice, DACO: 10.2.3
3482420	2023, Waiver Req - Acute Inhalation - Ditrac Soft Bait - 06-09-223, DACO: 4.2.3
3531346	1992, Acute Oral Limit Test of PCQ Rodenticide in Young Adult Wistar Rats, DACO: 4.6.1
3531347	2003, Acute Limit Dermal Toxicity Evaluation of Diphacinone All-Weather Blox on Young Adult Sprague Dawley Rats, DACO: 4.6.2
3531348	1992, Primary Eye Irritation Evaluation of PCQ Rodenticide in Young Adult Rabbits, DACO: 4.6.4
3531349	2004, Acute Dermal Irritation/Corrosion of Diphacinone Pellets on Young Adult New Zealand White Rabbits, DACO: 4.6.5
3531350	2000, Dermal Sensitization Study on Guinea Pigs (Buehler Method), DACO: 4.6.6
3482421	2023, Determination of Physical/Chemical Properties, Accelerated Storage Stability, and Enforcement Analytical Method of 0.005% Diphacinone Soft Bait, DACO: 3.4, 3.5
3482422	2023, Determination of Physical/Chemical Properties, Accelerated Storage Stability, and Enforcement Analytical Method of 0.005% Diphacinone Soft Bait, DACO: 3.4, 3.5
3482423	2023, Formulating Process of 0.005% Diphacinone Soft Bait, DACO: 3.2, 3.5.5 CBI
3482414	2023, Occupational Exposure Summary, DACO: 5.1

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