

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

Application Number: 2007-4500
Application: B.2.3 Identity of formulants, B.2.4 Porportion of Formulants, B.2.5 Formulation type
Product: Difethialone Paste Place Packs Rodenticide
Registration Number: 29504
Active ingredients (a.i.): Difethialone (DFL)
PMRA Document Number : 1832593

Purpose of Application

The purpose of this application was to register a new domestic rodenticide containing the active ingredient difethialone .

Chemistry Assessment

Difethialone Paste Place Packs Rodenticide contains the active ingredient difethialone at a nominal concentration of 0.0025% This product has a density of 1.1444 g/mL. The chemistry requirements for Difethialone Paste Place Packs Rodenticide are complete.

Health Assessments

With the exception of the allergens wheat and soy, the formulation does not contain any formulants of toxicological concern. The formulation is similar enough to formulations currently registered such that toxicology data on the formulation is not required.

The use pattern of Difethialone Paste Place Pack Rodenticide falls within the current use pattern noted for registered rodenticide products containing difethialone. Therefore, a new exposure risk assessment was not conducted. Label amendments were required. In addition, when the Agency makes a decision on the risk mitigation measures proposed in REV2009-05, Proposed Risk Mitigation Measures for Eight Rodenticides, measures including Canadian Labelling Requirements for Commercial and Domestic Class End-use Products containing difethialone, will be required for this products.

Environmental Assessment

The formulation for Difethialone Paste Place Packs Rodenticide is similar to those already registered. These consist of bulk pellet, pellet place pack and meal bait place pack end-use products while Difethialone Paste Place Packs Rodenticide is a paste product. No additional environmental exposure to non-target organisms was expected as a result of this new formulation.

Value Assessment

Four laboratory trials demonstrated that Difethialone Paste Place Packs Rodenticide, in the presence of an alternative food source, is consumed in sufficient quantity to result in 90-100% mortality of mice and rats.

Conclusion

The PMRA has completed the assessment and found the provided data to be sufficient to permit the registration of the new domestic rodenticide, Difethialone Paste Place Packs Rodenticide, containing the active ingredient difethialone.

References

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- 1627219 2006, Difethialone Paste 0601:Standard Mouse Acute Anticoagulant Laboratory Test 1.210, 06079, DACO: 10.2.3.2 CBI
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- 1627221 2007, Difethialone Paste 0601:Standard Mouse Placepack Penetration Laboratory Method 1.218, 07007, DACO: 10.2.3.2 CBI
- 1436771 2007, End-Use Product Chemistry - SUMMARY, DACO: 3.1, 3.1.2, 3.1.3, 3.1.4
- 1436776 2007, Product Identity, Composition and Analysis of Difethialone Paste 0601, DACO: 0.9.1, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1 **CBI.**
- 1436777 2007, Method Validation: Analytical Technique for the Concentration of Difethialone in DFN Paste 0601, DACO: 3.4.1 **CBI.**
- 1436778 2007, Chemical and Physical Properties - SUMMARY, DACO: 3.5
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- 1436781 2007, Odor Determination of DFN Paste 0601, DACO: 3.5.3 **CBI.**
- 1436782 2007, Density Determination of DFN Paste 0601, DACO: 3.5.6 **CBI.**
- 1436783 2007, Storage Stability Determination of DFN Paste 0601 - 3 Month Interim "Report", DACO: 3.5.10 **CBI.**
- 1560828 2008, Storage Stability and Corrosion Characteristics of DFN Paste 0601, DACO: 3.5.10 **CBI**
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