



Evaluation Report for Category B, Subcategory 3.11 Application

Application Number: 2007-5862
Application: Category B, Subcategory 3.11 (New changes to product labels - New pests)
Product: Rode-Trol Rodent Control Bait for Mice and Rats-Domestic
Registration Number: 28916
Active ingredients (a.i.): cellulose (from powdered corn cobs)
PMRA Document Number: 1554941

Purpose of Application

An application was submitted to register a new domestic class rodenticide, Rode-trol Rodent Control Bait for Mice and Rats-Domestic, to control mice and rats in buildings, warehouses, barns and empty feed storage areas. The domestic end use product Rode-trol Rodent Control Bait for Mice and Rats-Domestic is identical to the currently registered commercial end-use product, Rode-trol Rodent Control Bait for Mice (PCP # 28684).

Chemistry Assessment

A chemistry assessment was not required as there was no change in the product chemistry compared to the currently registered product.

Health Assessment

As per Rode-trol Rodent Control Bait for Mice (PCP # 28684), the active ingredient, cellulose from powdered corn cobs, is of low acute toxicity, based on tests performed using microcrystalline cellulose on test animals. The acute oral LD₅₀ (♂) is > 3160 mg/kg, the acute dermal LD₅₀ (♂♀) is > 2000 mg/kg, and the acute inhalation LC₅₀ (♂♀) is > 5.35 mg/L. In both the acute oral and acute dermal situations, adverse effects were not observed, but in the acute inhalation study, chromodacryorrhea and chromorhinorrhea were observed on removal of the test animals from the test chambers. In addition, one male displayed decreased locomotion, but all adverse effects were fully resolved within one day following dosing. No other adverse clinical effects were observed, nor were any lesions observed on necropsy.

Skin irritation has been categorized as non-irritating and ocular irritation as minimally irritating. Topical application of the active ingredient did not result in dermal sensitization in test animals. Due to the low toxic nature of this end use product and the fact that the product is in the form of pellets, dermal, ocular, and inhalation exposure is not of concern for those applying the product or for bystanders. Precautionary statements currently listed on the label are considered adequate.

Environmental Assessment

An environmental assessment was not required as use of the domestic product Rode-trol Rodent Control Bait for Mice and Rats, is not expected to increase environmental exposure.

Value Assessment

The efficacy and value of the domestic class product, Rode-trol Rodent Control Bait for Mice and Rats, is supported based on the similarity of the formulation and use directions compared to the commercial class rodenticides containing the active ingredient cellulose from powdered corn cobs.

Conclusion

The PMRA has completed an evaluation of this application and has found the information sufficient to support the registration of Rode-trol Rodent Control Bait for Mice and Rats-Domestic.

References

List of Studies/Information Submitted by Registrant

Health Assessment

PMRA 1462352 (2007) DACO 5.2 - Use pattern/exposure scenario, Rode-trol, LLC., 24-August-2007. Unpublished.

PMRA 1471677 (2007) Rode-trol rodent control bait for mice and rats draft label, Rode-trol, LLC., 04-September-2007. Unpublished.

ISSN: 1911-8082

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