

Evaluation Report for Category B, Subcategory 2.3 and 2.4 Application

Application Number: 2015-1719
Application: Changes to and end-use product chemistry: Identity and proportion of formulants
Product: Contrac Rodenticide
Registration Number: 22235
Active ingredients (a.i.): Bromadiolone
PMRA Document Number : 2569032

Purpose of Application

The purpose of this application was to amend the formulation of Contrac Rodenticide (Registration Number 22235, 0.005% bromadiolone).

Chemistry Assessment

Contrac Rodenticide is formulated as a pellet containing bromadiolone at a minimum concentration of 0.005%. This end-use product has a density of 1.39 g/cm³. The required chemistry data for Contrac Rodenticide have been provided, reviewed and found to be acceptable.

Health Assessments

The changes in formulation are not expected to alter the acute toxicity profile of the product.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

Data submitted from eight efficacy trials confirmed that the new formulation is accepted as food by both mice and rats, even in the presence of an alternative food source, resulting in a high level of mortality. The results support the label claims that Contrac Rodenticide controls rats and mice, and that rodent mortality may be evident within 4-5 days.

Conclusion

The PMRA completed a review of all available information and found it sufficient to support the Contrac Rodenticide formulation change.

References

PMRA Document Number	Reference
2529002	2014, Product Properties of Bromadiolone Pellets, DACO: 2.14, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1, 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
2575022	2015, Storage Stability Characteristics of Contraceptive Rodenticide, Reg No 22235, DACO: 3.5.10
2529006	2014, Efficacy of 0.005% Bromadiolone Pellets on Young Adult Swiss Webster Mice, BEL/0114/BE857, DACO: 10.2, 10.2.3.1, 10.2.3.2
2529007	2014, Efficacy of 0.005% Bromadiolone Pellets on Young Adult Swiss Webster Mice, BEL/0114/BE858, DACO: 10.2, 10.2.3.1, 10.2.3.2
2529008	2014, Efficacy of 0.005% Bromadiolone Pellets on Young Adult Swiss Webster Mice, BEL/0114/BE859, DACO: 10.2, 10.2.3.1, 10.2.3.2
2529009	2014, Efficacy of 0.005% Bromadiolone Pellets on Young Adult Swiss Webster Mice, BEL/0114/BE860, DACO: 10.2, 10.2.3.1, 10.2.3.2
2529010	2014, Efficacy of 0.005% Bromadiolone Pellets on Young Adult Wistar Rats, BEL/0214/BE861, DACO: 10.2, 10.2.3.1, 10.2.3.2
2529011	2014, Efficacy of 0.005% Bromadiolone Pellets on Young Adult Wistar Rats, BEL/0214/BE862, DACO: 10.2, 10.2.3.1, 10.2.3.2
2529012	2014, Efficacy of 0.005% Bromadiolone Pellets on Young Adult Wistar Rats, BEL/0214/BE863, DACO: 10.2, 10.2.3.1, 10.2.3.2
2529013	2014, Efficacy of 0.005% Bromadiolone Pellets on Young Adult Wistar Rats, BEL/0214/BE864, DACO: 10.2, 10.2.3.1, 10.2.3.2

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