



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

Application Number: 2012-5502
Application: Product chemistry - identity and proportion of formulants, formulation type
Product: Resolv Soft Bait
Registration Number: 31322
Active ingredients (a.i.): Bromadiolone
PMRA Document Number: 2362534

Purpose of Application

The purpose of this application was to register Resolve Soft Bait, a new commercial class rodenticide containing bromadiolone, for the control of rats and mice.

Chemistry Assessment

Resolv Soft Bait is formulated as a paste containing the active ingredient bromadiolone at 0.005 %. This product has a density of 1.251 g/mL. The chemistry requirements for ResolvTM Soft Bait have been completed.

Health Assessments

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

Environmental Assessment

No new environmental data were submitted for the registration of Resolv Soft Bait, nor were any required. The active ingredient in the formulated product, bromadiolone, has full registration status and the risks to the environment for the proposed use pattern have been previously assessed under the re-evaluation program (RRD2006-11). Resolv Soft Bait may pose a risk to non-target mammals and birds if ingested, however, the use limitations and precautions required for this product are identical to other registered bromadiolone bait products and are sufficient to mitigate the identified risks from the use of this rodenticide.

Value Assessment

Two laboratory studies (one each on mice and rats) demonstrated that $\geq 90\%$ of test animals died when presented with a choice situation of 0.005% bromadiolone bait and challenge diet. The value of bromadiolone has been widely established for the control of rats and mice and label use directions were consistent with bromadiolone baits available within the market.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Resolve Soft Bait, and has found the information sufficient to add the control of rats and mice with Bromadiolone on the label for use as a new commercial class rodenticide.

References

PMRA Doc No.	Reference
2257096	2011, CONFIDENTIAL ATTACHMENT - Product Identity, Composition and Analysis of Bromadiolone Paste 0901, DACO: 3.2,3.2.1,3.2.2,3.2.3,3.3.1,3.4.1 CBI
2257097	2012, Chemical and Physical Properties - SUMMARY, DACO: 3.5
2257098	2011, Color Determination of BDN Paste 1101 (Includes Confidential Appendix), DACO: 3.5.1 CBI
2257099	2011, Physical State Determination of BDN Paste 1101 (Includes Confidential Appendix), DACO: 3.5.2 CBI
2257101	2011, Odor Determination of BDN Paste 1101 (Includes Confidential Appendix), DACO: 3.5.3 CBI
2257102	2011, Density Determination of DFN Paste 11065 (Includes Confidential Appendix), DACO: 3.5.6 CBI
2257103	2011, Storage Stability and Corrosion Characteristics of BDN Paste 0901 (Includes Confidential Appendix), DACO: 3.5.10,3.5.14 CBI
2361243	2006, Methode Analytique, MRD-0205; Version No. 1; Bromadiolone Pate 50 mg/kg, DACO: 3.4.1 CBI
2361244	2006, Bromadiolone Paste 50 mg/kg Analytical Method Validation, DACO: 3.4.1 CBI
2361245	2008, Bromadiolone Red Paste 50 mg/kg; Specificity of Analytical Method Validation, DACO: 3.4.1 CBI
2257104	2012, Value and efficacy Summary / Waiver Request, DACO: 10.1,10.2,10.2.3.1
2257105	2011, Bromadiolone Paste 1101: Standard Mouse Acute Block / Pellet Laboratory Test 1.210, DACO: 10.2.3.2
2257106	2011, CONFIDENTIAL ATTACHMENT: Bromadiolone Paste 1101: Standard Mouse Acute Block / Pellet Laboratory Test 1.210, DACO: 10.2.3.2 CBI
2257107	2011, Bromadiolone Paste 1101: Standard Rat Acute Block / Pellet Laboratory Test 1.209, DACO: 10.2.3.2
2257108	2011, CONFIDENTIAL ATTACHMENT: Bromadiolone Paste 1101: Standard Rat Acute Block / Pellet Laboratory Test 1.209, DACO: 10.2.3.2 CBI

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2014

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.