

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.12 Application

Application Number: 2011-1967
Application: Changes to: Product Guarantee, Identity of Formulants, Proportion of Formulants and New Product Labels: New Site/Host
Product: balEnce Biological Beetle Bait
Registration Number: 30546
Active ingredients (a.i.): *Beauveria bassiana* strain HF23[BHF]
PMRA Document Number: 2187069

Background

Beauveria bassiana HF23 Technical is registered in Canada (registration number 28889) in two end-use products for controlling house flies in poultry production facilities.

Purpose of Application

The purpose of this application is to register a new commercial end-use product, balEnce Biological Beetle Bait, containing the registered technical grade active ingredient, *Beauveria bassiana* strain HF23 (registration number 28889) for control of darkling beetles in poultry and livestock production facilities.

Chemistry Assessment

BalEnce Biological Beetle Bait is a granular formulation to be used to control Darkling Beetles in poultry and livestock production facilities. The active ingredient, *Beauveria bassiana* strain HF23, is contained in the new formulation at 9.17×10^8 conidia/g. The product characterization and analysis database is complete.

Health Assessments

Toxicity studies testing *Beauveria bassiana* HF23 Technical were cross-referenced in support of the registration of the new end-use product, BalEnce Biological Beetle Bait. These data showed the TGAI, *Beauveria bassiana* HF23 Technical, has low toxicity and is not irritating to the skin. Dermal toxicity and dermal irritation data are not required for this end-use product, since the corresponding database for the TGAI is complete and the formulation ingredients contained in this end-use product are not of toxicological concern.

The proposed use pattern is congruent with an existing registered end-use product, balEnce Biological Fly Bait, which is also formulated with *Beauveria bassiana* HF23 Technical; no additional risks to human health and safety are anticipated. Existing precautionary and first aid statements on the labels are sufficient to cover any health risks from occupational, bystander, and dietary exposure routes that may arise from the new use pattern. The human health and safety database for balEnce Biological Beetle Bait is complete.

Environmental Assessment

The proposed use pattern of the new end-use product formulation, balEnce Biological Beetle Bait, fits into the use pattern of the existing registered EP (balEnce Biological Fly Bait) with the exception of a new target pest (Darkling Beetle), and a new formulation which includes a slightly higher guarantee, 9.17×10^{11} conidia/kg, compared to the original balEnce Fly Bait formulation (5×10^{11} conidia/kg). The proposed use of balEnce Biological Beetle Bait is limited to indoor uses in poultry and livestock houses with no restriction on the amount of product used in a year.

Based on a review of the existing database for this active ingredient, no additional risks to the environment are anticipated from the use of balEnce Biological Beetle Bait, and the existing precautionary statements on the labels are sufficient to cover any environmental risks arising from the use of this new end-use product. The environmental database for balEnce Biological Beetle Bait is complete.

Adverse Effects

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website www.healthcanada.gc.ca/pesticideincident. As of October 19, 2011, there were no incidents related to health or the environment reported in the PMRA Incident reporting database or the California Department of Pesticide regulation (CalDPR) for products containing *B. bassiana* strain HF23 for use as pesticides. Nor were there any incidents related to the environment in the US EPA's Ecological Incident Information System (EIS) for products containing *B. bassiana* strain HF23 for use as pesticides.

Value Assessment

The efficacy data demonstrated that balEnce Biological Beetle Bait suppressed darkling beetle population growth over the course of multiple flocks of broilers and turkeys. From a value and sustainability perspective, use of balEnce Biological Beetle Bait in poultry houses for suppression of darkling beetle is acceptable at a rate of 8.9-17.8 g product/m² (8.2×10^9 - 1.63×10^{10} conidia/m²). Application should be made prior to bird placement. Re-treatment may be necessary if beetle numbers are high at the start of a flock and should be done at four week intervals.

Conclusion

Following the review of all available data, the registration of balEnce Biological Beetle Bait for control of darkling beetles in poultry and livestock production facilities has been approved. When used according to the label balEnce Biological Beetle Bait will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

References

- PMRA 2050730 2011, M2.0, Product Characterization and Analysis DACO: M2.0,M2.1,M2.10,M2.10.1,M2.10.2,M2.10.3,M2.11,M2.12, M2.13, M2.2,M2.3,M2.4,M2.5,M2.6,M2.7, M2.8,M2.9,M2.9.1,M2.9.2,M2.9.3
- PMRA 2050731 2010, Siliker Lab CoA, DACO: M2.10.2,M2.10.3 CBI
- PMRA 2050732 2010, Evaluation of Viability Degradation - Beetle Feed Base, DACO: M2.11 CBI
- PMRA 2125225 2011, Reply to Request for Clarification Oct 19/2011
- PMRA 2125227 2011, Reply to Request for Clarification Oct 21/2011
- PMRA 2050733 2011, M.4, Human Health and Safety Testing DACO: M4.0,M4.1,M4.2,M4.3,M4.4,M4.5,M4.6
- PMRA 2050735 2011, M4 Data Waiver Request, DACO: M4.0
- PMRA 2050737 2011, M7 Data Waiver Request, DACO: M7.0
- PMRA 2050736 2011, M5 Data Waiver Request, DACO: M5.0
- PMRA 2125225 2011, Reply to Request for Clarification Oct 19/2011
- PMRA 2125227 2011, Reply to Request for Clarification Oct 21/2011
- PMRA 2050738 2011, M8 Data Waiver Request, DACO: M8.0
- PMRA 2050739 2011, M9 Data Waiver Request, DACO: M9.0
- PMRA 2050740 2011, M9, DACO: M9.0
- PMRA 2125225 2011, Reply to Request for Clarification Oct 19/2011
- PMRA 2125227 2011, Reply to Request for Clarification Oct 21/2011
- ERC2008-04 *Beauveria bassiana* strain HF23

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