

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

Application Number: 2011-1965
Application: Changes to: Product Guarantee, Identity of Formulants, Proportion of Formulants and New Product Labels: New Site/Host
Product: balEnce ES-Beetle
Registration Number: 30545
Active ingredients (a.i.): *Beauveria bassiana* strain HF23[BHF]
PMRA Document Number: 2185619

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 was to register a new commercial end-use product, balEnce ES-Beetle, containing the registered Technical Grade Active Ingredient (TGAI), *Beauveria bassiana* strain HF23 (registration number 28889) for control of darkling beetles in poultry and livestock production facilities.

Chemistry Assessment

balEnce ES-Beetle is a liquid 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 2.22×10^{10} conidia/mL. The product characterization and analysis database is complete.

Health Assessments

Toxicity studies testing from *Beauveria bassiana* HF23 Technical were cross-referenced in support of the registration of the new end-use product, balEnce ES-Beetle. 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 new use pattern is consistent with an existing registered end-use product, balEnce ES-Beetle, 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 ES-Beetle is complete.

Environmental Assessment

The new use pattern of the new end-use product formulation, balEnce ES-Beetle, fits into the use pattern of the registered end-use product, balEnce ES-Beetle, with the exception of a new target pest (Darkling Beetle), and a formulation change which includes a higher level of the MPCA (2.22×10^{10} conidia/mL) compared to the original formulation, balEnce ES-Beetle (5.6×10^9 conidia/mL). The new use of balEnce ES-Beetle 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 ES-Beetle, 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 ES-Beetle 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 (EIIS) for products containing *B. bassiana* strain HF23 for use as pesticides.

Value Assessment

The efficacy data provided demonstrated that balEnce ES-Beetle applied at the rate of 4 ml product/m² (5.56×10^9 conidia/m²) provided control of darkling beetle adults and larvae. The level of control observed was better than that demonstrated by products registered in the US. From a value and sustainability perspective, use of balEnce ES-Beetle in poultry houses for control of darkling beetle is acceptable. The product is to be applied at the rate of 5.56×10^9 conidia/m² in sufficient water to ensure even coverage of the treated area. Repeat applications may be made between flocks and in areas where beetles accumulate.

Conclusion

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

References

- PMRA 2050693 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 CBI
- PMRA 2050694 2010, Storage Stability study 2007 to 2010, DACO: M2.11
- PMRA 2089306 2011, Reply to Request for Clarification, Aug 10, 2011, DACO: 0.8
- PMRA 2125227 Response to Clarifications from Oct 21
- PMRA 2050695 2011, M4.0 Human Health and Safety Testing, DACO: M4.0,M4.1,M4.2,M4.3,M4.4,M4.5,M4.6
- PMRA 2050696 2011, M4. Data Waiver Request, DACO: M4.0
- PMRA 2050697 2011, M5 Data Waiver Request, DACO: M5.0
- PMRA 2050698 2011, M7 Data Waiver Request, DACO: M7.0
- PMRA 2050699 2011, M8 Data Waiver Request, DACO: M8.0
- PMRA 2050700 2011, M9 Data Waiver Request, DACO: M9.0
- PMRA 2050701 2011, M9, DACO: M9.0
- ERC2008-04 *Beauveria bassiana* strain HF23 (Section 4)

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