

Evaluation Report for Category B Subcategory 2.1, 2.3, 2.4, 2.5, 3.4, 3.12 Application

Application Number: 2008-1842

Application: B.2.1 New End Product Chemistry – Guarantee

B.2.3 New End Product Chemistry – Identity

B.2.4 New End Product Chemistry – Proportion of Formulants

B.2.5 New End Product Chemistry – Formulation Type

B.3.4 Changes to Product Labels – Application Method

B.3.12 Changes to Product Labels – New Site

Product: *balEnce*TM Biological Fly Bait

Registration Number: 29529

Active ingredients (a.i.): *Beauveria bassiana* Strain HF23

PMRA Document Number : 2012222

Purpose of Application

The purpose of this application was to register *balEnce*TM Biological Fly Bait, a bait formulation of *Beauveria bassiana* Strain HF23, for use in poultry and livestock facilities for control of house flies.

Chemistry Assessment

*balEnce*TM Biological Fly Bait is a granular formulation. The active ingredient, *Beauveria bassiana* strain HF23, is contained in the formulation at a concentration of 0.095% by weight. In the absence of an appropriate storage stability study, a shelf-life value of 12 months has been assigned to this product. As a condition of full registration, additional confirmatory data will be required for potency estimation and storage stability. The product characterization and analysis database is complete.

Health Assessments

Toxicity studies testing *Beauveria bassiana* HF23 Technical (PCP Registration Number 28889) were cross-referenced in support of the registration of the new end-use product, *balEnce*TM Biological Fly Bait. These data showed that *Beauveria bassiana* HF23 Technical has low toxicity and is not irritating to the skin. Dermal toxicity and dermal irritation data are not required since the corresponding database for the active ingredient is complete and the formulation ingredients are not of toxicological concern. However, two of the formulants contained in *balEnce*TM Biological Fly Bait may exacerbate eye irritation; therefore, the signal words “CAUTION - EYE IRRITANT” appear on the label and the use of goggles is required as a precaution in the absence of an eye irritation study. As well, the proposed use pattern for this end-use product falls within the registered use pattern for this active ingredient. The human health and safety database for *balEnce*TM Biological Fly Bait is complete.

Environmental Assessment

An environmental assessment of the proposed EP, *balEnce*TM Biological Fly Bait was not required because the proposed use pattern fits into the use pattern of an existing registered end-use product (*balEnce ES*, PCP Registration Number 28890) with the exception of formulation and application method. Although the *balEnce*TM Biological Fly Bait is in a granular formulation rather than the spray formulation of *balEnce ES*, *balEnce*TM Biological Fly Bait contains the same concentration of the active ingredient as the *balEnce ES* formulation when applied as a 10% solution. As with *balEnce ES*, the proposed indoor use of *balEnce*TM Biological Fly Bait will be limited to poultry and livestock houses with no restriction on the total maximum amount of product that may be applied in a year. Therefore, the proposed use does not pose a significant risk to terrestrial or aquatic environments as determined by the review of the existing database for this active ingredient. The environmental database for *balEnce*TM Biological Fly Bait is complete.

Value Assessment

For the value assessment in support of this use, five efficacy studies were submitted. Of these studies, two studies (one operational study and one laboratory study) tested the *balEnce*TM Biological Fly Bait formulation. The remaining studies included one study testing alternative formulations of *Beauvaria bassiana* fly bait and several trials testing spray formulations of *Beauvaria bassiana*.

The submitted data demonstrated that *balEnce*TM Biological Fly Bait will kill flies within days after exposure to the bait, will reduce fly populations under operational conditions, and that flies are attracted to and will consume the bait under both operational conditions and in laboratory studies. While no studies were submitted which tested the scatter application method, it is reasonable to assume that as flies are attracted to and will consume the bait even when given a choice of other food, the bait should be effective when applied with this method. The scatter bait application method is consistent with other registered fly bait products (e.g., SNIP Fly Bait, PCP Registration Number 25808; AGITA Fly Bait, PCP Registration Number 28297; STIMUKIL Fly Bait, PCP Registration Number 24969). While, unlike *balEnce*TM Biological Fly Bait, the above mentioned products use z-9-tricosene as a fly attractant, it was found that when the *Beauvaria bassiana* bait was formulated with z-9-tricosene, it resulted in bait with poor to no control. The laboratory studies demonstrated that *balEnce*TM Biological Fly Bait requires 3 to 5 days before adult fly mortality is observed. The submitted data supports an application rate of 125 g per 46 m² of area in either bait stations or as scatter bait.

Conclusion

The Pest Management Regulatory Agency (PMRA) has completed an assessment of the subject application and found the information sufficient to support full registration of *balEnce*TM Biological Fly Bait for use in poultry and livestock facilities for control of house flies with the condition that additional confirmatory data are submitted for potency estimation and storage stability.

References

PMRA Document Number	Reference
1179026	2006, Efficacy Studies for balance-ES, DACO: M10.2.2
1179027	2005, Evaluation of <i>Beauveria bassiana</i> applications against adult house fly, <i>Musca domestica</i> , in commercial caged-layer poultry facilities in New York state, DACO: M10.2.2
1603447	Jabb bioassay for balence fly bait 5 E11 conidia per kg of carrier, DACO: M10.2.1
1603448	2008, Evaluation of the Efficacy of 0.1% Beauveria bassiana Fly Bait for the Control of Naturally Occurring Infestations of House Flies (<i>Musca domestica</i>), DACO: M10.2.2

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