



Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2007-2175
Application: New / Changes EP or MA Product Chemistry-Guarantee
Product: Summit B.t.i. BRIQUETS and Mosquito Dunks, Biological Mosquito Control
Registration Number: 28888
Active ingredients (a.i.): *Bacillus thuringiensis israelensis* serotype H-14
PMRA Document Number: 1542193

Background

Summit B.t.i. BRIQUETS and Mosquito Dunks, Biological Mosquito Control is a new end-use product (EP) formulated from the registered technical grade of active ingredient (TGAI) Aquabac Primary Powder (Reg No. 26861). The dunks are formulated into solid ‘pucks’ that are to be applied in areas such as standing water wholly confined to the property of the user where there is no existing outflow beyond the property limits that remains for more than a week and cannot be drained (for example, flooded depressions, ponds; and containerized water (for example, bird baths, flower planters, discarded tires, ornamental ponds and rain barrels) that cannot be emptied, drained, flushed or changed at least weekly. This product is proposed as a domestic class EP.

Purpose of Application

The purpose of this application is to register a new domestic class EP to control mosquito larvae.

Characterization Assessment

Summit B.t.i. BRIQUETS and Mosquito Dunks, Biological Mosquito Control is formulated as a solid ‘puck’ weighing 13 grams. The active ingredient, *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, is contained in the formulation at a concentration of 10.31% by weight. The guarantee of the product is 722 *Aedes aegypti* International Toxicity Units (AA ITU)/mg. In the absence of an appropriate storage stability study, a shelf-life value of 1 year has been assigned to this product. The product characterization and analysis database requirements for Summit B.t.i. BRIQUETS and Mosquito Dunks, Biological Mosquito Control is complete.

Health Assessment

Toxicity studies testing a material that is identical to (i.e., differing only in brand name) Aquabac Primary Powder were submitted in support of the Aquabac Primary Powder registration. These data showed the TGAI, Aquabac Primary Powder, has low toxicity and is not irritating to the skin. Dermal toxicity and dermal irritation data are not required for this EP, Summit B.t.i. BRIQUETS and Mosquito Dunks, Biological Mosquito Control, since the corresponding database for the TGAI is complete and the formulation ingredients contained in this EP are all classified as EPA List 4A and are not of toxicological concern. As well, the proposed use pattern is congruent with an existing registered EP that is also formulated with Aquabac Primary Powder. The human health and safety database for Summit B.t.i. BRIQUETS and Mosquito Dunks, Biological Mosquito Control is complete.

Environmental Assessment

An environmental assessment of the proposed EP was not required because the proposed use pattern fits into the use pattern of an existing registered EP (Aquabac 200G Biological Larvicide Granules) with the exception of higher application rates. Although the proposed rates are higher than the currently registered rates, when the product's longer re-application interval is factored, the application rates of Summit B.t.i. BRIQUETS and Mosquito Dunks, Biological Mosquito Control fits into the currently register use pattern with the exception of sites less than 1.37 m². These smaller water bodies, however, are not considered to be potentially environmentally sensitive as most are expected to be primarily artificial (e.g., bird baths, decorative ponds, and eaves troughs). Therefore, the proposed use does not pose a significant risk to aquatic environments as has been determined by the review of the existing database for this active ingredient. The environmental database for Summit B.t.i. BRIQUETS and Mosquito Dunks, Biological Mosquito Control is complete.

Value Assessment

Four efficacy studies indicated that Summit B.t.i. BRIQUETS and Mosquito Dunks, Biological Mosquito Control can control mosquito larvae when applied to standing water sites for up to 30 days. Evaluation of these efficacy studies, combined with consideration of the use patterns for other registered products with the same strain of active ingredient, supports the claim of controls mosquito larvae in outdoor standing water sites (excluding preflood treatments) for up to 30 days at an application rate of ¼ dunk per 0.1 to 3.0 m², ½ dunk per 3.0 to 6.0 m² and 1 dunk per 6.0 m².

Conclusion

The Agency has completed an assessment of available information for Summit B.t.i. BRIQUETS and Mosquito Dunks, Biological Mosquito Control and has found the information sufficient to allow for full registration.

References

- PMRA 1395974 2007, DIR2001-02 Parts 2 and 2.7 Characterization of the MPCA & analysis, N/A, MRID: Not available, DACO: M2.0,M2.7
- PMRA 1395975 2007, DIR2001-02, Part 2.8 Manufacturing Methods and Quality Assurance, No lab report number, MRID: Not available, DACO: 0.8.11,M2.8
- PMRA 1395976 2007, DIR2001-02, Part 2.9 Disclosure of Ingredients, No lab report number, MRID: Not available, DACO: M2.9
- PMRA 1395977 2007, DIR2001-02, Part 2.10 Analytical Data and Methodology, No lab report number, MRID: Not available, DACO: M2.10
- PMRA 1395978 2007, DIR2001-02 Part 2.11 Storage Stability Testing, as relevant to the EP, No lab report number, MRID: Not available, DACO: M2.11
- PMRA 1395979 2007, DIR2001-02, Part 2.12 Summary of Physical and Chemical Properties, No lab report number, MRID: Not available, DACO: M2.12
- PMRA 1395980 2007, DIR2001-02, Part 2.13 Characterization and Analysis, No lab report number, MRID: Not available, DACO: M2.13
- PMRA 1432687 2007, Data waiver request and rationale, No report number, MRID: N/A, DACO: M2.9
- PMRA 1444664 2007, Storage Stability Performance Evaluation of Summit B.t.i. Briquet/Dunk, ICR Proj. No. 343-0031, MRID: No MRID No. assigned yet, DACO: M10.0, M10.2, M2.11
- PMRA 1395981 2007, DIR2001-02, Part 4.4 Acute Dermal Toxicity, No lab report number, MRID: Not available, DACO: M4.4
- PMRA 1395982 2007, DIR2001-02, Part 4.5.2 Dermal Irritation Study, No lab report number, MRID: Not available, DACO: M4.5.2
- PMRA 1395983 2007, DIR2001-02, Summary and Performance Assessment. DACO: M10.1, M10.2

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