Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2007-0305
Application: B.4.1 (Conversion to full registration without consultation)
Product: Vectolex WSP Biological Larvicide
Registration Number: 28009
Active ingredients (a.i.): *Bacillus sphaericus* (BTP)
PMRA Document Number : 1836219

Purpose of Application

The purpose of these applications was to convert the registration of Vectolex Technical Powder (Registration Number 28006), Vectolex WDG Biological Larvicide (Registration Number 28007), Vectolex CG Biological Larvicde (Registration Number 28008) and Vectolex WSP Biological Larvicide (Registration Number 28009) from conditional to full. These products were granted conditional registration in Canada and the detailed review supporting the conditional registration can be found in Regulatory Note REG2006-02, *Bacillus sphaericus* Strain 2362.

This document will present the evaluation of the information provided in support of the conversion of the registration of these products from conditional to full.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A health assessment was not required for this application.

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Environmental Assessment

Environmental effect studies previously submitted for the initial registration decision, suggested that *B. sphaericus* is of low toxicity to birds, mammals, honey bees, fish, chironomid larvae, mysid shrimp and unicellular algae and slightly toxic to amphipods. Some of these studies, however, suggested that *B. sphaericus* strain 2362 may be toxic to some terrestrial arthropods from dietary exposure at high concentrations. Shell deposition in oysters was also affected at high concentrations. Oysters may not feed at levels expected from application at the maximum rate. Consequently the PMRA requested replacement studies to properly define the host range of non-target terrestrial species, and to address the observed sublethal effects (disrupted feeding, body weight gain, etc.) in oysters.

Waiver rationales were submitted instead of the replacement studies. The rationales to waive the required testing were based on a reduction of the application rate as well as published literature, which indicated no adverse effects to these non-target organisms at the anticipated levels. Based on this information, the risk to non-target organisms from the maximum proposed rate of VectoLex CG Biological Larvicide, VectoLex WDG Biological Larvicide, and VectoLex WSP Biological Larvicide is expected to be minimal.

Value Assessment

A value assessment was not required for this application.

Conclusion

To mitigate the risk to non-target organisms, the labels will restrict the number of applications to 6 per treatment site per season, and increase the interval between applications from 1 week to 2 weeks.

The key risk-reduction measures that are required on the labels of VectoLex CG Biological Larvicide, VectoLex WDG Biological Larvicide, and VectoLex WSP Biological Larvicide addresses the potential risks identified in the initial environmental assessment.

The PMRA has completed an assessment of the submitted data and is able to support the full registration of Vectolex Technical Powder, Vectolex WDG Biological Larvicide, Vectolex CG Biological Larvicide and Vectolex WSP Biological Larvicide.

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