Proposed Re-evaluation Decision PRVD2022-13

Bacillus sphaericus Strain 2362 and Its Associated End-use Products

Consultation Document

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Table of Contents

Proposed re-evaluation decision

Under the *Pest Control Products Act*, all registered pesticides must be re-evaluated regularly by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet health and environmental safety standards and continue to have value. The re-evaluation considers data and information from various sources such as information from pesticide manufacturers, incident reports, and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods, risk management approaches and policies to all re-evaluations.

This document presents the proposed regulatory decision for the re-evaluation of *Bacillus sphaericus* strain 2362.

Bacillus sphaericus strain 2362 is a microbial insecticide registered for control of mosquito larvae in various aquatic habitats. In *Bacillus sphaericus* strain 2362, insecticidal activity is attributed to two distinct toxin types: the mosquitocidal toxin (Mtx) and the binary toxin (Btx). Btx is produced during sporulation and contributes to the primary toxic activity of commercial insecticidal strains after ingestion by mosquito larvae. Mtx exhibits lower insecticidal activity. As production batches of *B. sphaericus* strain 2362 are produced in a manner to permit sporulation and formation of Btx, little Mtx is expected to remain and additional processing into the end-use products further inactivates the toxin.

End-use products are classified as Restricted Class and formulated as wettable granules, a granular, or as a granular packaged in water soluble pouches. These products are applied to catch basins, water bodies and to waste tires. Depending on the site of application, these products are applied by hand or using ground or aerial application equipment. Currently registered products containing *Bacillus sphaericus* strain 2362 are listed in Appendix I.

Bacillus sphaericus strain 2362 is of value for mosquito control targeting mosquito larvae. As a biological insecticide, *Bacillus sphaericus* strain 2362 provides a unique alternative to conventional chemical methods for mosquito control. The potential risks to human health (occupational, residential, bystander and dietary) and the environment are considered to be acceptable when products containing *Bacillus sphaericus* strain 2362 are used according to label directions. Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. In order to meet current standards, label updates to clarify use directions for products containing *Bacillus sphaericus* strain 2362 are proposed in Appendix II. The proposed label updates as a result of the re-evaluation of products containing *Bacillus sphaericus* strain are summarized below:

- Update warning statement on primary principle panel and Notice to User statement for all products.
- Add drift statement for products with aerial and ground applications.
- Update personal protection equipment (PPE) for Vectolex CG.
- Clarify application rate and include aerial application directions for Vectolex WDG.

- Add storage and handling instructions for Vectolex WSP.

Under the authority of the *Pest Control Products Act* and based on an evaluation of currently available scientific information, products containing *Bacillus sphaericus* strain 2362 (Appendix I) are being proposed for continued registration in Canada, with the proposed updates to label directions (Appendix II).

All products containing *Bacillus sphaericus* strain 2362 registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a public consultation,[1] during which written comments and additional information may be submitted to PMRA Publications. The final re-evaluation decision will be published taking into consideration the comments and information received during the consultation period.

Next steps

The public, including the registrant and stakeholders, are encouraged to submit written comments and additional information during the 90-day public consultation period upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of the re-evaluation decision document,[2] which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

Additional scientific information

Additional scientific data are not required.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science evaluation

1.0 Human health

Bacillus sphaericus strain 2362 is of low toxicity and is not pathogenic via the oral and pulmonary routes of exposure, is not pathogenic via the intravenous route of exposure and is of low toxicity via the dermal route. It is slightly irritating to the skin and mildly irritating to the eye. Furthermore, irritation studies for end-use product Vectolex WDG indicated that it was also minimally irritating to the eyes. For end-use products Vectolex CG and Vectolex WSP, irritation studies were waived, however, the products were considered to be potential eye irritants. *Bacillus sphaericus* strain 2362 is a potential sensitizer. Warning statements identifying eye irritant and potential sensitizer are currently present on the appropriate labels. Furthermore, there are no reports that would implicate *B. sphaericus* strain 2362 as a potential producer of genotoxins (Canada, 2006).

The potential occupational and bystander exposures resulting from the registered uses of *B. sphaericus* strain 2362 vary significantly between end-use products depending on the formulation and application method. *Bacillus sphaericus* strain 2362 end-use products are formulated as water soluble pouches (Vectolex WSP), wettable granules (Vectolex WDG) or granular products (Vectolex CG). Vectolex WSP is applied by hand to storm water catch basins to control mosquito larvae. Vectolex WDG and Vectolex CG are directly applied to freshwater marshes, salt marshes, flood plains, flooded fields and pastures, wetlands, ponds, storm water detention/retention and seepage ponds, wastewater sewage effluent, sewage lagoons, oxidation ponds, log ponds, impounded waste water, septic ditches, drainage ditches including open storm sewers, and irrigation ditches, using conventional ground or aerial application equipment. Vectolex CG is also applied by hand to individual waste tires.

For Vectolex WSP, when handling according to label instructions (for example, adding intact water soluble pouches to water basins), minimal occupational exposure is expected during application of the product (Canada, 2006). Current product label includes standard personal protective equipment (a long-sleeved shirt, long pants and shoes plus socks). The requirements for gloves, eye goggles and a respirator were waived based on the limited potential for exposure when handling intact water soluble pouches. Handling and storage instructions are proposed to be updated to meet current labelling standards. As such, potential risk is considered to be acceptable for workers handling the water soluble pouch product with the proposed label updates (Appendix II). No additional mitigation measures are required.

For Vectolex WDG and Vectolex CG, the potential for occupational exposure is greater as these products are broadcast over larger areas using conventional ground or aerial application equipment, or by hand into individual waste tires. Exposure from mixing, loading and clean-up activities is expected to be primarily via the dermal route; however, inhalation, oral and ocular exposure may also occur from fine particles that may be present in these formulations. During application, exposure to wettable granules and granular products is expected to be primarily via the dermal and inhalation routes, although ocular and oral exposure can also occur (Canada, 2006). Current end-use product labels include a long-sleeved shirt, long pants and shoes plus

socks, as well as waterproof gloves and a respirator with a NIOSH-approved particulate filtering facepiece respirator when handling, mixing/loading or applying and during all clean-up/repair activities. The respirator is required to reduce the possibility of workers developing allergies or other types of hypersensitive reactions following repeated inhalation exposure to *B. sphaericus* strain 2362. The wearing of a respirator would also prevent the possible gradual accumulation of B. sphaericus strain 2362 spores in the lungs after repeated exposures, since long clearance times were reported in acute pulmonary studies. Since Vectolex CG is formulated with oil, a label update for a NIOSH-approved particulate filtering facepiece respirator with an R or P filter is proposed to meet current standard. Furthermore, Vectolex CG is considered to be potential eye irritant, eye goggles are currently present on the label. For details of the occupational assessments, see REG2006-02 (Canada, 2006). Based on the low toxicity and the current use pattern, potential occupational risk is considered to be acceptable for workers handling these end-use products with the proposed label updates to meet current labelling standards (Appendix II). No additional mitigation measures are required.

Bystander exposure for water soluble pouch formulation (Vectolex WSP), is expected to be minimal. The use sites (storm water catch basins) also limit exposure as these are usually inaccessible to the general public. However, bystander exposure is possible when products are applied by ground or aerial application equipment; a standard drift statement is proposed for Vectolex WDG and Vectolex CG.

There are no registered domestic class products containing *B. sphaericus* strain 2362 registered. Therefore, direct residential exposure is not expected.

The end-use products containing *B. sphaericus* strain 2362 are not registered for use on food or feed crops or to treated, finished drinking water. However, there is a possibility that live *B. sphaericus* strain 2362 spores may be found on crops sown in treated fields or fields irrigated with treated water. The spores may also be found in drinking water as it is not known if municipal water treatment processes will destroy these spores. No adverse effects are expected from this exposure based on the lack of adverse effects noted in the mammalian toxicity and infectivity studies. Therefore, the health risks from residues of *B. sphaericus* strain 2362 on food and in drinking water are acceptable (Canada, 2006). No additional mitigation measures are proposed and the specification of a maximum residue limit (MRL) is not required for *B. sphaericus* strain 2362.

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways is assessed. *Bacillus sphaericus* strain 2362 is considered to be of low toxicity by the oral, pulmonary, intravenous and dermal routes and the end-use products will not be applied to food crops or drinking water. Furthermore, non-occupational exposure will be low when the end-use products are used with the proposed label update. Therefore, there is reasonable certainty that no harm will result from aggregate exposure of residues of *B. sphaericus* strain 2362 from the uses of the end-use products.

The *Pest Control Products Act* requires that the Health Canada considers the cumulative exposure to pesticides with a common mechanism of toxicity. In its assessment of common mechanism of toxicity, Health Canada considers both the taxonomy of microbial pest control agents (MPCAs) and the production of any potentially toxic metabolites. For the current re-evaluation, Health Canada has determined that *B. sphaericus* strain 2362 does not share a common mechanism of toxicity with other registered MPCAs. Consequently, no cumulative effect from exposure with other related MPCAs is anticipated and a cumulative assessment is not required at this time.

2.0 Environment

Bacillus sphaericus strain 2362 is a naturally occurring microorganism in the environment.

Significant adverse effects to most non-target organisms were not expected from the current use of the MPCA. *Bacillus sphaericus* strain 2362 is of low toxicity to birds, mammalian wildlife, honey bees, fish, chironomid larvae, mysid shrimp and unicellular algae and slightly toxic to amphipods. Bioassay data show that *B. sphaericus* strain 2362 may be toxic to some terrestrial arthropods from high dietary concentrations. Shell deposition in oysters was also affected at high concentrations. However, based on information from published literature and the current conditions of use, the potential risk to these non-target organisms are acceptable (Canada, 2010). *Bacillus sphaericus* strain 2362 is not known as a plant pathogen, and no incidents of adverse effects in plants have been reported (Canada, 2006).

Bacillus sphaericus strain 2362 and its end-use products do not meet the Track 1 criteria because the active ingredient is a biological organism and hence not subject to the criteria used to define persistence, bioaccumulation and toxicity properties of chemical control products.

3.0 Incident reports

As of 19 May 2022, no incidents involving *B. sphaericus* strain 2362 had been reported to Health Canada.

4.0 Value Assessment

Bacillus sphaericus strain 2362 is of value for mosquito control targeting mosquito larvae. As a biological insecticide, *B. sphaericus* strain 2362 provides an alternative to conventional chemical methods for mosquito control.

Label statements to correct and clarify use directions are proposed as outlined in Appendix II.

Appendix I Registered products containing *Bacillus sphaericus* strain 2362 in Canada

Table 1 Registered products containing *Bacillus sphaericus* strain 2362 in Canada[3]

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee
28006	T	Valent BioSciences LLC.	VectoLex Technical Powder	wettable powder	670 *Bs* ITU/mg
28007	R	Valent BioSciences LLC.	VectoLex WDG Biological Larvicide	wettable granules	650 *Bs* ITU/mg
28008	R	Valent BioSciences LLC.	VectoLex CG Biological Larvicide	granular	50 *Bs* ITU/mg
28009	R	Valent BioSciences LLC.	VectoLex WSP Biological Larvicide	granular (in a water soluble pouch)	50 *Bs* ITU/mg

T= Technical, R = Restricted

[3] As of 23 February 2022, excluding discontinued products or products with a submission for discontinuation.

Appendix II Proposed label updates for products containing *Bacillus sphaericus* strain 2362

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

For all end-use products (Reg Nos. 28007, 28008 and 28009):

1) The following statement must appear on the principal panel:

> "PREVENT ACCESS BY UNAUTHORIZED PERSONNEL"

2) Update Notice to User statement

For Vectolex WDG Biological Larvicide (Reg. No. 28007):

1) Under Restricted Uses: Directions for Use section:

> Replace: "Apply VectoLex WDG (0.56-1.68 kg/ha) in water."
>
> With: "Apply VectoLex WDG at 5.6-16.8 kg product/ha (0.56-1.68 g/m^2) of water surface area."

2) Add Drift Statement under Precautions section:

> "Apply only when the potential for drift beyond the area to be treated is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings."

3) The Aerial Application Instructions box is incomplete on the label; add the full aerial application statements under Directions for Use section:

> "Aerial Application Instructions: Apply only by fixed-wing or rotary aircraft equipment that has been functionally and operationally calibrated for the atmospheric conditions of the area and the application rates and conditions of this label. Label rates, conditions and precautions are product-specific. Apply only at the rate recommended for aerial application on this label. Where no rate for aerial application appears for the specific use, this product cannot be applied by any type of aerial equipment. Ensure uniform application by using appropriate marking devices and/or electronic guidance equipment.
>
> Use Precautions: Apply only when meteorological conditions at the treatment site allow for complete and even coverage. Apply only when meteorological conditions are in compliance with local and/or provincial authorities.

Operator Precautions: DO NOT allow the pilot to mix product to be loaded onto the aircraft. Loading of premixed product with a closed system is permitted. It is desirable that the pilot have communication capabilities at each treatment site at the time of application. The field crew and the mixer/loaders must wear the personal protective equipment described in the PRECAUTIONS section of this label. All personnel on the job site must wash hands and face thoroughly before eating and drinking. Protective clothing, aircraft cockpit and vehicle cabs must be decontaminated regularly."

For Vectolex CG Biological Larvicide (Reg. No. 28008):

1) Add Drift Statement under Precautions section:

"Apply only when the potential for drift beyond the area to be treated is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings."

2) Under Precautions section:

Replace: "…a dust/mist filtering respirator (MSH/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter…"

With: "…a dust/mist filtering respirator (MSH/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with an R-95, P-95 or HE filter…"

For Vectolex WSP Biological Larvicide (Reg. No. 28009):

1) Under Storage section, add:

"Keep WSP dry prior to use."

2) Under Directions For Use, add:

Handling Instructions
1. Keep the WSP(s) in outer packaging until just before use.
2. Keep WSP intact. Do not cut or puncture WSP.
3. Keep the WSP dry prior to use.

References

PMRA No.	Reference
3324990	Canada, 2006. Regulatory Note. *Bacillus sphaericus* Strain 2362. REG2006-02. 7 April 2006.
1836201	Canada, 2010. Evaluation Report for Category B, Subcategory 4.1 Application. Application Number: 2007-0302. *Bacillus sphaericus* (BTP). Registration No. 28006.