Re-evaluation Decision RVD2023-16

Bacillus sphaericus Strain 2362 and Its Associated End-use Products

Final Decision

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Re-evaluation Decision for *Bacillus sphaericus* Strain 2362 and Its Associated End-Use Products

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

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 granules, wettable granules, or granules 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 can be found in the Pesticide Product Information Database and in Appendix I.

The Proposed Re-evaluation Decision, PRVD2022-13 *Bacillus sphaericus Strain 2362 and Its Associated End-use Products* [1] containing the evaluation of *Bacillus sphaericus* strain 2362 underwent a 90-day consultation period ending on 3 October 2022. PRVD2022-13 proposed continued registration of *Bacillus sphaericus* strain 2362 for sale and use in Canada, with label updates to meet current labelling standards (Appendix II).

No comments were received during the consultation period. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2022-13, which lists all information used as the basis for the re-evaluation decision.

This document presents the final re-evaluation decision[2] for the re-evaluation of *Bacillus sphaericus* strain 2362, including the label amendments required to meet the current labelling standards. All products containing *Bacillus sphaericus* strain 2362 that are registered in Canada are subject to this re-evaluation decision.

[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*.

Re-evaluation Decision for *Bacillus sphaericus* strain 2362

Health Canada has completed the re-evaluation of *Bacillus sphaericus* strain 2362. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing *Bacillus sphaericus* strain 2362 is acceptable with the label updates (Appendix II). Following a scientific review of the available information, Health Canada has determined that the health and environmental risks and the value of *Bacillus sphaericus* strain 2362 continue to be acceptable provided that the required mitigation measures are implemented. Label amendments, as summarized below and listed in Appendix II, are required.

Risk mitigation measures

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. The required updated label statements, as a result of the re-evaluation of *Bacillus sphaericus* strain 2362, are summarized below. Refer to Appendix II for details.

Label improvements to meet current standards:

- Update the taxonomic designation of the microbial pest control agent (MPCA) to *Lysinibacillus* sphaericus 2362, serotype H5a5, strain ABTS 1743 followed by this statement: "*Formerly known as Bacillus sphaericus strain 2362*".
- Update potency units to *Bacillus sphaericus* toxic units (BsTUs)/mg.
- Indicate product type (Biological Insecticide) and that the products contain a live organism on the principal panels of the labels. Include date of manufacture and phone number of Canadian contact on principal panels.
- Update warning statement on primary principal 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 handling instructions and update the water-soluble packaging (WSP) statement on Vectolex WSP label.

Next steps

To comply with this decision, the required label amendments must be implemented on all product labels no later than 24 months after the publication date of this decision document. Accordingly, both registrants and retailers will have up to 24 months from the date of this decision document to transition to selling the product with the newly amended labels. Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available on the Public Registry.

Refer to Appendix I for details on specific products impacted by this decision.

Other information

Any person may file a notice of objection[3] regarding this decision on *Bacillus sphaericus* strain 2362 within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact PMRA's Pest Management Information Service.

The relevant confidential test data on which the decision is based (as referenced in PRVD2022-13) are available for public inspection, upon application, in PMRA's Reading Room. For more information, please contact the Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.

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

Table 1 Products containing *Bacillus sphaericus* strain 2362 requiring (label) amendments[1]

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (BsITU/mg[2])
28007	Restricted	Valent Biosciences LLC.	Vectolex WDG Biological Larvicide	Wettable Granules	650
28008	Restricted		Vectolex CG Biological Larvicide	Granular	50
28009	Restricted		Vectolex WSP Biological Larvicide	Granular	50

[1] As of 14 September 2023, excluding discontinued products or products with a submission for discontinuation.

[2] BsITU – Bacillus sphaericus International Toxic Units; mg – milligram

Table 2 Products containing *Bacillus sphaericus* strain 2362 that do not require (label) amendments[1]

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active ingredient (BsITU/mg[2])
28006	Technical	Valent Biosciences LLC.	Vectolex Technical Powder	Wettable Powder	670

[1] As of 14 September 2023, excluding discontinued products or products with a submission for discontinuation.

[2] BsITU – Bacillus sphaericus International Toxic Units; mg – milligram

Appendix II Label amendments for products containing *Bacillus sphaericus* strain 2362

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 taxonomic designation of the MPCA must be updated to *Lysinibacillus sphaericus* 2362, serotype H5a5b, strain ABTS 1743 followed by this statement: "Formerly known as *Bacillus sphaericus* strain 2362".

2) Update potency units to *Bacillus sphaericus* toxic units (BsTUs)/mg on the principal panel.

3) The product type (Biological Insecticide) and a statement that the products contain a live organism must appear on the principal panel. Also on the principal panel the date of manufacture and the phone number of the Canadian contact must appear.

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

"PREVENT ACCESS BY UNAUTHORIZED PERSONNEL"

5) 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:

"**Using Water-Soluble Packages Dissolved Directly in Catch Basins:**
Water-Soluble Packages (WSPs) are designed to dissolve in water. Failure to follow handling and mixing instructions can increase your exposure to the pesticide products in WSPs.

Handling Instructions
Follow these steps when handling pesticide products in WSPs.

1. Apply directly to catch basins.
2. Handle WSP(s) in a manner that protects package from breakage and/or unintended release of contents. If package is broken, put on protective eyewear (goggles), waterproof gloves, and a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter and then continue with application or clean-up.
3. Keep the WSP(s) in outer packaging until just before use.
4. Keep the WSP dry prior to application.

5. Handle with dry hands and according to the label instructions for PPE.
6. Keep WSP intact. Do not cut or puncture WSP. ”

3) Under Precautions section, remove:

“Do not allow bags to become wet prior to application.”