



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

October 28, 2024

Vickie A. Forster
Authorized Agent to AgBiTech Pty Ltd
Forster & Associates Consulting, LLC
P.O. Box 4097
Greenville, DE 19807

Subject: PRIA (Pesticide Registration Improvement Act) Labeling and Formulation Amendment – To Change the Potency Claim and Active Ingredient Percentage on the Label and Basic Confidential Statement of Formula (CSF); Remove the Signal Word, Acute Dermal Toxicity First Aid, and Precautionary Statements from the Label; and Update the Expiration Date

Product Name: LEPIGEN
EPA Registration Number: 87978-7
EPA Receipt Date: 03/05/2024
Action Case Number: 00502327

Dear Vickie:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, are acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSF:

- Basic CSF dated 07/26/2024

Any CSFs other than that listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 § CFR 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S.

Environmental Protection Agency. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

Additionally, in a memorandum dated August 28, 2024, the EPA rated storage stability and corrosion characteristics data (MRID No. 52328702) as acceptable. Thus, you have fulfilled term #2 of the April 17, 2020, LEPIGEN Registration Notice.

If you have any questions, please contact Hannah Dean via email at dean.hannah@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Cody Kendrick". The signature is written in a cursive, flowing style.

Cody Kendrick, Senior Regulatory Advisor
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511M)
Office of Pesticide Programs

Enclosure

ACCEPTED

Oct 28, 2024

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. **87978-7**

LEPIGEN

Biological insecticide for the integrated control of
Plutella xylostella (diamondback moth)
on labeled food and non-food crops



FOR ORGANIC PRODUCTION



Active Ingredient:

Autographa californica Multiple Nucleopolyhedrovirus strain R3*..... 32.7%

Other Ingredients: 67.3%

Total: 100.0%

* Contains a minimum of 1×10^{10} occlusion bodies per liter of product

Net Contents: 50, 100 or 200 mL

0.25, 1, 2.5 or 5 gallons

KEEP OUT OF REACH OF CHILDREN

EPA Registration No. 87978-7

EPA Est. Number: 87978-TX-01

Manufactured for:

AgBiTech Pty Ltd

8 Rocla Court

Glenvale, Queensland

Australia 4350

Batch code: _____

PRECAUTIONARY STATEMENTS**PERSONAL PROTECTIVE EQUIPMENT (PPE)****Applicators and other handlers must wear:**

- **Long-sleeved shirt and long pants**
- **Shoes plus socks**

Mixers/loaders and applicators must wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N,R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N,R or P filter; OR a NIOSH-approved powered air-purifying respirator with an HE filter. Repeated exposures to high concentrations of microbial proteins can cause allergic sensitization.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

USERS SHOULD: Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing/PPE.

ENVIRONMENTAL HAZARDS

This product may be pathogenic to nontarget Lepidoptera exposed to direct treatment. Do not apply this product while nontarget Lepidoptera are actively visiting the treatment area. Minimize spray drift away from target area to reduce effects to nontarget Lepidoptera.

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean highwater mark.

Do not contaminate water when disposing of equipment wash water or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not use this product until you have read the entire label. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

Do not apply by aerial application.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farm, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box apply only to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water) is:

- Coveralls
- Shoes plus socks
- Chemical-resistant gloves (made of any waterproof material)

PRODUCT INFORMATION

This product contains a biological insecticide
for the control of Diamondback moth (*Plutella xylostella*) larvae on labeled crops:

INSTRUCTIONS





LEPIGEN, active ingredient polyhedral occlusion bodies of *Autographa californica* Multiple Nucleopolyhedrovirus, (ACMNPV) is a pathogen of *Plutella xylostella*. The effectiveness of LEPIGEN is dependent on important factors, such as larval size, environmental conditions, application and the feeding behavior of the pest. Because of the requirement for adequate timing of application, coverage, and weather conditions, the performance of LEPIGEN may be variable. Once infected, larvae can take up to 8 days to die, although feeding activity is greatly reduced within 3 days post infection, dependent on larvae size. Daytime temperatures of 65°F to 95°F are ideal for the infectivity by LEPIGEN. Infected larvae will amplify the virus, and following death will release large amounts of viral occlusion bodies that can result in ongoing control, particularly under environmental conditions suitable for the virus in LEPIGEN (warm and humid conditions).


Good coverage of the feeding sites of the larvae is essential, as the product needs to be ingested to be effective. If larvae are feeding low down in a heavy crop canopy, and application of LEPIGEN does not reach these areas, initial control from the spray will be sub-optimal. However, larvae that die from the LEPIGEN spray will release large amounts of ACMNPV, which will spread throughout the crop canopy.

LEPIGEN will provide between 60 and 90% control, with greater control expected on smaller larvae under ideal application conditions. LEPIGEN should only be used to target small larvae (1st and 2nd instars). Larvae at the higher end of the recommended size spectrum will take longer to die and cause more damage prior to death. Under high pest pressure or sub-optimal application conditions, or when immediate protection against damage is required, additional control options should be considered.

Plutella xylostella Identification

Showing the actual size of *P. xylostella* at a given age
(days since egg hatch) when reared at 77°F.

Instar	Age (days)	Size Category	Length (inches)	Actual Size	Lepigen Timing
1 st	3-4	Very Small	1/16"		✓✓
2 nd	3-5	Small	1/8"		✓✓
3 rd	3-5	Medium	1/4"		✗
4 th	5	Large	1/2"		✗



CROPS, APPLICATION RATES AND CROP SPECIFIC INFORMATION

Crops	Rate of LEPIGEN per acre	Additional Information
<p>Brassica (Cole) Leafy Vegetables (Crop Group 5) Including: Broccoli, Brussels sprouts, Cabbage, Cauliflower, Chinese broccoli, Kale, Mustard greens, Mustard spinach, Rape greens)</p> <p>Oilseeds (Crop Group 20) Including: Flax seed, Canola, Safflower, Sunflower, Brassica carinata</p>	1.6 to 2.4 fl. oz.	<p>Use the lower rate at the beginning of the crop cycle when weather is cooler and DBM larval infestation level is low.</p> <p>Use higher rate as temperature increases and crop starts to form marketable yield.</p> <p>Lepigen works best when the field is inoculated early in the crop cycle and the product is used proactively as a pest population suppressor and resistance management tool, in tank mixture or rotation with other insecticides.</p> <p>Do not use as a stand-alone treatment in curative, high pest pressure conditions.</p>

MIXING INSTRUCTIONS

Shake the container well before use. Spray water pH should be neutral (pH 7.0) - spray water pH above 8 may damage the virus and performance will be reduced. If needed, use a suitable buffer or acidifier. If mixing with other pesticides or foliar fertilizers in water, add LEPIGEN to the spray tank after the other products are thoroughly diluted. Apply LEPIGEN within 10 hours after mixing. Do not let stand overnight.

Compatibility:

In water: LEPIGEN is highly compatible with most herbicides, insecticides, fungicides and foliar fertilizers when mixed in water. Ensure that the mixture has a pH of 8 or less before adding LEPIGEN. Higher pH levels will damage the virus.

APPLICATION INSTRUCTIONS

Use application parameters (nozzles, swath width, pressure, boom height, speed, volume, etc.) to ensure thorough coverage of the target area.

Ground Rig

Apply LEPIGEN by ground rig or hand-held equipment in a minimum of 40 gallons of water per acre (Crop Group 5) and a minimum of 15 gallons of water per acre (Crop Group 20) – ensure crop is well covered.

Chemigation (via overhead irrigation water):

LEPIGEN can be effectively applied to crops in overhead irrigation water. Introduce the product to the irrigation water at the appropriate rate using irrigation equipment. If the product is diluted in water prior to injection into the irrigation water, ensure that the dilution water is clean and not silty with a pH of 7 or less and ensure there is constant agitation. Preferably, rainwater should be used for dilution. Use diluted LEPIGEN within 10 hours of mixing.

For one-pass mobile irrigators (such as: center-pivot, lateral-move, end-tow, side-roll, traveler, big-gun), continuously and evenly introduce the required quantity of LEPIGEN into the irrigation water over the course of irrigation. Apply

LEPIGEN in no more than 0.5 inches of irrigation water. For static irrigators (such as: solid-set or hand-move), introduce the required amount of LEPIGEN into the irrigation water just prior to completion of the irrigation period, to maximize the concentration of LEPIGEN applied and the amount that remains on the crop. See the CHEMIGATION section (following) for additional information.

CHEMIGATION

General Requirements:

Apply this product only through overhead sprinklers (including center-pivot, lateral-move, end-tow, side-(wheel) roll, traveler, big-gun, solid-set, or hand-move) irrigation systems. Do not apply this product through soil (root uptake) irrigation systems such as drip (trickle)irrigation. Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water. If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers, or other experts. Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place. A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make any necessary adjustments should the need arise.

Requirements for Chemigation Systems Connected to Public Water Systems:

- 1) Public water supply means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of 25 individuals daily at least 60 days throughout the year.
- 2) Chemigation systems connected to the public water systems must contain a functional, reduced-pressure zone (RPZ), backflow preventer or the functional equivalent in the water supply upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the flow outlet end of the fill pipe and the top or the overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.
- 3) The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- 4) The pesticide injection pipeline must contain a functional, normally closed, solenoid- operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- 5) The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.
- 6) Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump), effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
- 7) Do not apply when wind speed favors drift beyond the area intended for treatment.

Requirements for Overhead Sprinkler Chemigation:

- 1) The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from back flow.
- 2) The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- 3) The pesticide injection pipeline must also contain a functional, normally closed, solenoid- operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- 4) The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.

- 5) The irrigation line or water pump must include a functional pressure switch, which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- 6) Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump), effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
- 7) Do not apply when wind speed favors drift beyond the area intended for treatment.

RAIN FASTNESS

The majority of virus uptake by larvae occurs within 1-hour post-application. For this reason, it is best to avoid applying LEPIGEN if heavy rain is expected within one hour following application. However, do not delay application if only moderate rain is expected, or heavy rain (greater than 0.4 inches per hour) is not imminent.

DAYS TO HARVEST

There are no restrictions on applying LEPIGEN up to the time of harvest.

STORAGE and DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE

Care must be taken to avoid exposure of LEPIGEN to high temperatures (above 104°F). Packaged, sealed product can be exposed to direct sunlight for brief periods of time (<2 hours) but should be stored out of direct sunlight.

- LEPIGEN stored in refrigerators/cool rooms/ freezers ($\leq 39^{\circ}\text{F}/4^{\circ}\text{C}$) will be viable for at least 60 months.

PESTICIDE DISPOSAL

To avoid waste, use material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER HANDLING

Plastic containers with capacities equal to or less than 5 gallons:] Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinance. If burned, stay out of smoke.

WARRANTY

This product is warranted to contain the amount of active ingredients as described in this label and that the product will be as effective as intended if properly transported, used, and applied per the label instructions. The effectiveness of this product may be degraded by improper storage, transportation or handling and may be subject to environmental factors out of AgBiTech Pty Ltd.'s control. The user must monitor the performance of the product as climatic, geographical, or biological variables and/or developed resistance may affect the results obtained. To the extent consistent with applicable law, AgBiTech Pty Ltd and its subsidiaries makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label or accepts no responsibility in respect of this product. To the extent consistent with applicable law, AgBiTech Pty Ltd and its subsidiaries disclaim any liability whatsoever for special, incidental, or consequential damages resulting from the use or handling of this product.