



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 28, 2021

Vickie A. Forster
Authorized Agent to AgBiTech Pty Ltd
V.A. Forster Consulting, Inc.
P.O. Box 4097
Wilmington, DE 19807

Subject: Pesticide Registration Improvement Act (PRIA) Labeling and Formulation Amendment – To Add a 30-Month Storage Stability Claim to the Labeling, Update the Basic Confidential Statement of Formula (CSF) and Labeling to Account for the Product Being Manufactured in a Particular Way (Ingredient Calculations Adjusted), Update the First Aid and Hazard to Humans/Animals Statements on the Labeling to Align with Previously Submitted and Reviewed Toxicological Data/Information, and Make Other Changes to the Labeling, including those Requested by the EPA
Product Name: Heligen
EPA Registration Number: 87978-2
Application Date: April 28, 2020
OPP Decision Number: 563068
Action Code Case Numbers: 00134799 and 00136837

Dear Ms. Forster:

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 (FIFRA), 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 02/24/2021

Any CSFs other than that listed above are superseded/no longer valid.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

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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 (EPA). 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.

If you have any questions, please contact Monica Thapa by phone at (703) 347-8688 or via email at thapa.monica@epa.gov.

Sincerely,



Jeannine Kausch, Product Manager 92
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

HELIGEN

Biological insecticide for the integrated control of
Helicoverpa zea (corn earworm, cotton bollworm, tomato fruitworm) and
Heliothis virescens (tobacco budworm) on specified food and non-food crops



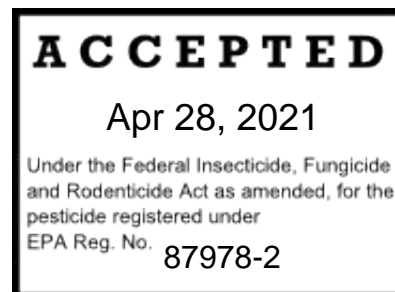
Active Ingredient*:	
<i>Helicoverpa zea</i> Nucleopolyhedrovirus strain ABA-NPV-U	32.7%
Other Ingredients:.....	<u>67.3%</u>
Total:	100.0%

* Contains a minimum of 7.5 x10⁹ occlusion bodies per milliliter of product

KEEP OUT OF REACH OF CHILDREN

EPA Registration No. 87978-2
EPA Est. Number: 87978-AUS-01

Manufactured by:
AgBiTech Pty Ltd
8 Rocla Court
Glenvale, Queensland
Australia 4350
Net Contents:



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 NIOSH-approved particulate respirator with any P or R filter with NIOSH approval number prefix TC-84A or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C. Repeated exposure 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 PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

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

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 exemptions 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 the following moth larvae on a wide range of crops, as specified in the table below:

Corn earworm *Helicoverpa zea*

Tobacco budworm *Heliothis virescens*

INSTRUCTIONS FOR USE







Heligen (active ingredient: Occlusion bodies of *Helicoverpa zea* Nucleopolyhedrovirus strain ABA-NPV-U; HzNPV) is a highly specific pathogen of *Helicoverpa* spp. and *Heliothis* spp. The effectiveness of Heligen is dependent on a number of important factors: 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 Heligen may be variable. Once infected, larvae can take up to 8 days to die, although feeding activity is greatly reduced within 1 to 3 days post infection, dependent on larvae size. Daytime temperatures of 65°F to 95°F are ideal for the infectivity by Heligen. 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 Heligen (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 Heligen does not reach these areas, initial control from the spray will be sub-optimal. However, larvae that die from the Heligen spray will release large amounts of HzNPV, which will spread throughout the crop canopy.

Heligen will provide between 60 and 90% control, with greater control expected on smaller larvae under ideal application conditions. Heligen must only be used to target small larvae (1st, 2nd and 3rd instars). Larvae at the higher end of the specified size spectrum will take longer to die and cause more significant 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. Do not apply Heligen if heavy rain (greater than 0.4 inches per hour) is expected within 1 hour after application.

Helicoverpa growth stage identification
 Showing the actual size of *H. zea* larvae at a given age (days since egg hatch) when reared at 77°F.

Instar	Age (days)	Size category	Length (inches)	Actual size	Heligen timing
1st	0 - 2	Very Small	1/8"		✓✓
2nd	2 - 4	Small	1/4"		✓✓
3rd	4 - 8	Medium (small)	1/2"		✓
4th	8 - 11	Medium (large)	3/4"		✗
5th	11 - 14	Large	1"		✗
6th	14 - 18+	Large (snake)	1 1/4"		✗



CROPS, APPLICATION RATES AND CROP SPECIFIC INFORMATION

Crops	Rate of Heligen per acre	Additional Information
Sorghum (milo)	0.7 to 1.4 fl. oz.	Use lower application rates when targeting larvae smaller than 1st and 2nd instar, and in mixtures with sprays for midge control (not ULV). Use higher application rates when targeting larvae larger than 3rd instar, or under high pressure situations. Applications that are targeted when 50% of heads have reached 100% flowering will provide good control.
Grain Cereal (Crop Group 15 excluding Sweet corn) including: Corn (maize), Popcorn, Rice ¹ Alfalfa (hay and seed) Oilseeds (Crop Group 20) including: Flax seed, Canola, Safflower, Sunflower Peanuts Legume Vegetables (Succulent or Dried) (Crop Group 6) including: Adzuki bean, Broad bean, Chickpeas, Cowpea, Fava bean, Field pea, Kidney bean, Lablab bean, Lentil, Lima bean, Sweet Lupin, White Lupin, Mung bean, Navy bean, Pigeon pea Vetch	1.0 to 1.6 fl. oz.	Use lower application rates as a preventive measure in vegetative crop stages. Use higher application rates when the pest population has reached economic threshold.
Soybean, including Edamame (immature soybean)	1.0 to 1.6 fl. oz.	Use lower application rates as a preventive measure in vegetative crop stages. Use the high application rate when the pest population has reached economic threshold.
Sweetcorn	1.2 to 2.4 fl. oz.	Application should be made from the vegetative stages until silking. Applications during silking must employ a high rate and be in conjunction with other control measures. Using lower application rates at regular (3 to 5 day) intervals, particularly via overhead irrigation water, is an effective strategy from vegetative stages, through row tassel to silking.

¹ Do not apply to flooded fields
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HELIGEN

<p>Root and Tuber Vegetables (Crop Group 1) including: Carrot, Sweet potato, Sugar beet, Potato</p> <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>Leafy Vegetables (Except Brassica Vegetables) (Crop Group 4) including: Celery, Endive, Lettuce, Roquette, Silver beet, Spinach</p> <p>Fruiting Vegetables (Crop Group 8 - 10) including: Chili, Eggplant, Okra, Pepper, Tomato</p> <p>Legume Vegetables (Succulent or Dried)(Crop Group 6) including: Green bean, Green pea, Snow pea, Sugar snap pea</p> <p>Cucurbit Vegetables (Crop Group 9) including: Cucumber, Melon, Pumpkin, Summer and winter Squash, Watermelon, Zucchini</p> <p>Berry and Small Fruit Group (Crop Group 13 - 07) including: Blackberry, Blueberry, Boysenberry, Cranberry², Currant, Gooseberry, Raspberry, Strawberry</p> <p>Pome Fruit (Crop Group 11 - 10) including: Apple, Nashi, Pear</p> <p>Ornamental Flowers and Plants Avocado Asparagus</p>	<p>1.2 to 2.4 fl. oz.</p>	<p>Use a higher application rate when flowers, fruit or economic parts of the crop are present, under high pest pressure conditions or to control 3rd instar larvae. Using lower application rate during vegetative stages of crop production. Using lower application rates at regular (3 to 5 day) intervals, particularly via overhead irrigation water, is an effective strategy in horticultural crops.</p>
<p>Cotton</p>	<p>2.0 to 2.4 fl. oz.</p>	<p>High leaf pH in cotton causes rapid NPV deactivation, giving Heligen very short residual activity and resulting in highly variable performance in this crop. Heligen must not be solely relied upon when larvae numbers are above economic threshold in cotton.</p>
<p>Tobacco, Hemp</p>	<p>1.2 to 2.4 fl. oz.</p>	<p>Use a higher application rate under high pest pressure conditions or to control 3rd instar larvae. Using lower application rate at regular intervals is an effective strategy in tobacco.</p>

² Do not apply to flooded fields
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HELIGEN

MIXING INSTRUCTIONS

Shake the container well before use. Spray water must be between pH 7.0 and 8.0; spray water with a pH below 7.0 or above 8.0 could damage the virus and reduce product performance. If needed, use a suitable buffer or acidifier. If mixing with other pesticides or foliar fertilizers in water, add Heligen to the spray tank after the other products are thoroughly diluted. Apply Heligen within 10 hours after mixing. Do not let stand overnight.

Compatibility:

In water: Heligen is highly compatible with the majority of herbicides, insecticides, fungicides and foliar fertilizers when mixed in water. Ensure that the mixture has a pH between 7.0 and 8.0 before adding Heligen as higher or lower pH levels will damage the virus.

In oil (ultra low volume): For ULV application in oil, Heligen is not compatible with other pesticides or fertilizers, since the undiluted solvents in these products can 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.

- I. Legume Vegetables (Succulent and Dried) Group (Crop Group 6 excluding Soybean), Root and Tuber Vegetables Group (Crop Group 1) including: Carrot, Sweet potato, Sugar beet, Potato; *Brassica* (Cole) Leafy Vegetables Group (Crop Group 5) including: Broccoli, Brussels sprouts, Cabbage, Cauliflower, Chinese broccoli, Kale, Mustard greens, Mustard spinach, Rape greens); Leafy Vegetables (except *Brassica* Vegetables) Group (Crop Group 4) including: Celery, Endive, Lettuce, Roquette, Spinach; Fruiting Vegetable Group (Crop Group 8 - 10) including: Chili, Eggplant, Okra, Pepper, Tomato; Cucurbit Vegetables Group (Crop Group 9) including: Cucumber, Melon, Pumpkin, Summer and winter squash, Watermelon, Zucchini; Berries Group (Crop Group 13 - 07) including: Blackberry, Blueberry, Boysenberry, Cranberry³, Currant, Gooseberry, Raspberry, Strawberry; Pome Fruit Group (Crop Group 11 - 10) including: Apple, Pear; Ornamental Flowers and Plants; Avocado; Asparagus; Tobacco; Hemp.

Ground Rig

Apply Heligen by ground rig or hand-held equipment in a minimum of 40 gallons of water per acre.

- II. Sorghum, Cereal Grains Group⁴, Alfalfa, Oilseed Group, Peanut, Soybean, Sweet Corn, Cotton

Ground Rig

Apply Heligen in a minimum of 10 gallons of water per acre.

³ Do not apply to flooded fields

⁴ Rice - Do not apply to flooded fields

Aerial - High Volume

Apply Heligen in a minimum of 3 gallons of water per acre. This application method is particularly susceptible to droplet evaporation, especially during hot and dry conditions (temperature greater than 85°F and relative humidity less than 40%). Droplet evaporation will reduce coverage, which can have a detrimental impact on performance. During hot and dry conditions, avoid using this application method; wait until conditions favor good coverage or apply in ULV (see below). Alternatively, if application in water by air during hot and dry conditions cannot be avoided, increase application volume and/or use an anti-evaporation additive (such as an emulsifiable oil) to improve coverage.

Aerial - Low Volume (Sorghum Only)

Apply Heligen in a minimum of 1 gallon of water per acre and include an anti-evaporation additive (such as 2% emulsifiable oil).

Aerial - Ultra-Low Volume (ULV)

Use an approved oil carrier and apply in a minimum volume of 1 quart per acre using micronair nozzles. When applying Heligen in ULV, DO NOT tank mix with other pesticides or fertilizers (refer to Compatibility).

Chemigation (via overhead irrigation water):

Heligen 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 between 7.0 and 8.0 and ensure there is constant agitation. Preferably, rainwater should be used for dilution. Use diluted Heligen 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 Heligen into the irrigation water over the course of irrigation. Apply Heligen 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 Heligen into the irrigation water just prior to completion of the irrigation period, to maximize the concentration of Heligen applied and the amount that remains on the crop. See the CHEMIGATION section (following) for additional information.

CHEMIGATION

General Requirements:

- 1) Apply this product only through sprinkler (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 any other type of irrigation system.
- 2) Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water.
- 3) If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers, or other experts.
- 4) 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.

- 5) 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 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, do not apply Heligen 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 Heligen 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 Heligen to high temperatures (above 104°F). Packaged, sealed product can be exposed to direct sunlight for brief periods of time (< 2 hours), but must be stored out of direct sunlight.

- Heligen stored at $\leq 54^{\circ}\text{F}$ (cool room, refrigerator, freezer) will be viable for at least 30 months.

Note. Exposure of Heligen to temperature from 54°F to 104°F for short periods (<36 hours) will not affect efficacy. Transport time of 36 hours or less in non-refrigerated, covered trucks is acceptable as long as the product does not exceed 104°F.

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.