



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 18, 2016

Susan MacIntosh
Regulatory Agent
AgBiTech
1203 Hartford Ave
Saint Paul, MN 55116-1622

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Adding OMRI logo
Product Name: Heligen
EPA Registration Number: 87978-2
Application Date: April 29, 2016
OPP Decision Number: 517409

Dear Ms. MacIntosh:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

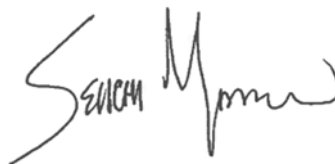
The labeling submitted with this application has been stamped “Notification” and will be placed in our records. You must submit one (1) copy of the final printed labeling with the modifications.

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 the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by the 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 false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance Assurance.

If you have any questions, please contact me by phone at (703) 347-0163 or via email at murasaki.seiichi@epa.gov.

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Sincerely,

A handwritten signature in black ink, appearing to read "SEIICHI MURASAKI". The signature is stylized with a large initial "S" and a long, sweeping underline.

Seiichi Murasaki
Acting Product Manager 92
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure: Label stamped "Notification"

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

 FOR ORGANIC PRODUCTION



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Active Ingredient*:

Polyhedral occlusion bodies of <i>Helicoverpa zea</i> ABA-NPV-U.....	32.0%
Other Ingredients:.....	68.0%
Total:	100.0%

* Contains 7.5 x10⁹ occlusion bodies per mL

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional precautionary and first aid statements on the back panel

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Net Contents: 0.25, 1, 2.5, 5 gallons

EPA Registration N°: 87978-E
EPA Est. Number: 87978-AUS-01

Manufactured by:



8 Rocla Court
Glenvale
Queensland Australia 4350

Product of Australia

Batch code: _____

NOTIFICATION

87978-2

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

05/18/2016

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes moderate eye irritation. Avoid inhalation and contact with eyes, skin or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information concerning this product, call the National Pesticide Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time. During other times, call your poison control center at 1-800-222-1222.	

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. 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 are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

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USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. 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 waters 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 requirement specific to your State and 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 the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, 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
- Waterproof gloves
- Shoes plus socks

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NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried.

PRODUCT INFORMATION

This product contains a biological insecticide for the control of the following moth larvae on a wide range of crops:

Corn earworm *Helicoverpa zea*

Tobacco budworm *Heliothis virescens*







GENERAL INSTRUCTIONS

Heligen (*Helicoverpa zea* nucleopolyhedrovirus - HzNPV) is a highly specific naturally occurring 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 behaviour of the pest. Because of the requirement for good conditions, the performance of Heligen is variable and at times, the level of control may be below expectations. The speed of activity of Heligen is also dependent on climatic conditions. Larvae can take up to 8 days to die, though the level of damage by NPV infected larvae is greatly reduced within 1 to 3 days post infection, dependant on larvae size. Daytime temperatures of 75°F to 95°F are ideal for the activity of NPV. Infected larvae will amplify the virus, and following death will release large amounts of viral occlusion bodies that can result in ongoing larval control, particularly under environmental conditions suitable for NPV.

Good coverage of the feeding sites of the larvae is essential, as the product needs to be ingested to be effective. Heligen will not control larvae that do not feed on treated areas, including when larvae are feeding inside protected feeding sites such as cotton bolls, lettuce hearts, bean pods, corn ears and flowers.

Heligen should only be used to target larvae less than half an inch long (3rd instar - 13 mm), though is most effective on larvae less than 0.3 of an inch (2nd instar - 7 mm). Larvae at the higher end of the recommended size spectrum will take longer to die and cause more significant damage prior to death.

Good coverage plus targeting actively feeding larvae less than half and inch

Helicoverpa Growth Stage Identification					
Showing the actual size of <i>H. zea</i> larvae at a given age (days since egg hatch) when reared at 77°F					
Instar	Age (days)	Size category	Length (mm)	Actual size	ARMIGEN timing
First	0-2	Very small	1-3		✓
Second	2-4	Small	4-7		✓
Third	4-8	Medium (small)	8-13		✓
Fourth	8-11	Medium (large)	14-23		✗
Fifth	11-14	Large	24-28		✗
Sixth	14-18+	Large (snake)	29-40+		✗

long are the key factors in ensuring maximum performance of Heligen. For this reason, apply Heligen to coincide with optimum environmental conditions for application and larval activity, such as periods of high humidity and warm (>65°F) conditions. Under sub-optimal conditions where application cannot be delayed, increasing application volume and droplet size can improve performance.

USES

Heligen is only effective against larvae of *Helicoverpa zea* (corn earworm, cotton bollworm, tomato fruitworm) and *Heliothis virescens* (tobacco budworm). Thorough coverage of the crop is essential, as the nucleopolyhedrovirus (NPV) in Heligen must be ingested by larvae to be effective. NPV is most effective on smaller larvae. Target application when the majority of larvae are less than 0.3 inches in length (2nd instar). Heligen should not be used to control larvae larger than 0.5 inches in length (3rd instar). Heligen will provide between 60 and 90% control, with greater control expected on smaller larvae under ideal application conditions. Larvae will continue to feed for 1 to 3 days following virus infection. Larvae will take between 3 to 8 days to die, with slower control occurring with larger larvae and during cool conditions. Under high pest pressure or sub-optimal application conditions, or when immediate protection against damage is required, additional control options should be considered. Avoid applying Heligen if heavy rain is expected within 1 hour after application.

CROPS, APPLICATION RATES AND CROP SPECIFIC INFORMATION

Crops	Rate per acre	Additional Information
Sorghum	0.7 to 1.4 fl. oz.	Use lower rates when targeting larvae smaller than 0.3 inches in length (1st and 2nd instar) and in mixtures with sprays for midge control (not ULV). Use higher rates when targeting larvae larger than 0.3 inches in length (3rd instar) or under high pressure situations. Applications that are targeted when 50% of heads have reached 100% flowering are likely to provide good control.
Cereal Grains (Maize, Popcorn) Alfalfa Oilseed (Linseed, Peanut, Canola, Safflower, Sunflower) Potatoes Pulses (Azuki bean, Broad bean, Chickpeas, Cowpea, Faba bean, Field pea, Kidney bean, Lablab, Lentil, Lima bean, Lupin, Mung bean, Navy bean, Pigeon pea, Soybean, Vetch)	1.0 to 1.6 fl. oz.	Use lower rates as a preventive measure in vegetative crop stages. Use the high rate when the pest population has reached economic threshold.
Cotton	2.0 fl. oz.	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 should not be solely relied upon when larvae numbers are above economic threshold in cotton.
Sweetcorn	1.2 to 2.4 fl. oz.	Application should be made from the vegetative stages until silking. Applications during silking should employ a high rate and be in conjunction with other control measures. Application of low rates at regular (3 to 5 day) intervals, particularly via overhead irrigation water, is an effective strategy from early row tassel to silking.
Berryfruit (Blackberries, Blueberries, Boysenberry, Cranberry, Currants, Gooseberry, Raspberries, Strawberry) Brassica vegetables (Broccoli, Brussels sprouts, Cabbages, Cauliflower, Chinese broccoli, Brassica leafy vegetables Celery Cucurbits (Cucumber, Melons, Pumpkins, Squash, Watermelon, Zucchini) Fruiting vegetables (Eggplant, Chilli, Okra, Peppers, Tomato) Leafy vegetables (Endive, Lettuce, Roquette, Silver beet, Spinach) Legume vegetables (Green beans, Green peas, Snow peas, Sugar snap peas) Ornamental flowers and plants Pome fruit (Apples, Nashi, Pears)	1.2 to 2.4 fl. oz.	Use a higher rate when flowers, fruit or economic parts of the crop are present, under high pest pressure conditions or to control larvae larger than 0.5 inches in length. Use lower rates during vegetative stages of crop production. Application of low rates at regular (3 to 5 day) intervals, particularly via overhead irrigation water, is an effective strategy in horticultural crops.

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MIXING GUIDLINES

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 Heligen to the spray tank after the other products are thoroughly diluted. Heligen should be applied as soon after mixing as possible. The virus in Heligen can be rendered inactive if the mixture is left to 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 of 8 or less before adding Heligen as higher pH levels will damage the virus.

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

APPLICATION INSTRUCTIONS

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

Horticultural crops:

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

Field crops:

Ground Rig

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

Aerial – High Volume

Apply 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 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 fertilisers (refer to Compatibility).

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Chemigation (via overhead irrigation water):

Heligen can be effectively applied to crops in overhead irrigation water. The product should be introduced to the irrigation water at the appropriate rate using fertigation / chemigation 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. Ensure any diluted Heligen is used within 10 hours of mixing.

For one-pass mobile irrigators (such as centre 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. It is recommended to 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 maximise 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 including drip (trickle) systems.
- 2) Reduced effectiveness 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.

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- 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, it is best to avoid applying 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 is not imminent.

DAYS TO HARVEST

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

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STORAGE and DISPOSAL

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

PESTICIDE STORAGE

Store in the closed, original container out of direct sunlight at or below 40°F. Storage in a domestic freezer (at 0°F) is suitable – the product will remain liquid. The product is stable for at least 2½ years if stored as indicated. The product can be stored for short periods (<24 hours) below 80°F. Reclose containers of unused portions of Heligen.

PESTICIDE DISPOSAL

To avoid wastes, use material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to 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 STATEMENT

This product as supplied is of a high grade and suitable for the purpose for which it is expressly intended and must be used according to the directions contained in this label. 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 allowed under the applicable law, AgBiTech Pty Ltd accepts no responsibility in respect of this product.