OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
WASHINGTON, D.C. 20460

May 13, 2025

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

Subject: PRIA (Pesticide Registration Improvement Act) Labeling and Formulation Amendment – To Amend the Occlusion Body (OB) Count on the CSF and Product Label
Product Name: Fawligen
EPA Registration Number: 87978-4
EPA Receipt Date: 10/11/2024
Action Case Number: 00632975

Dear Vickie 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, 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 04/24/2025

Any CSFs other than that listed above are superseded/no longer valid.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

If you have any questions, please contact Hector Maldonado by phone at (202) 566-1373 or via email at maldonado.hector@epa.gov.

Sincerely,

Cody Kendrick

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

Enclosure

FAWLIGEN

Biological insecticide for the integrated control of
Spodoptera frugiperda (fall armyworm) and
Spodoptera exigua (beet armyworm) on specified food and non-food crops

Spodoptera frugiperda Multiple Nucleopolyhedrovirus strain 3AP2	GROUP	31	INSECTICIDE

OMRI LISTED For Organic Use

FOR ORGANIC PRODUCTION

Active Ingredient:	
Spodoptera frugiperda Multiple Nucleopolyhedrovirus strain 3AP2*	32.7%
Other Ingredients	67.3%
Total:	100.0%

* Contains a minimum of 1 x10^{11} occlusion bodies per Liter of product

KEEP OUT OF REACH OF CHILDREN

EPA Registration No: 87978-4
EPA Est. Number: 87978-TX-001

Manufactured for:
AgBiTech Pty Ltd
8 Rocla Court
Glenvale, Queensland 4350
Australia
Net Contents:
Batch Code :

ACCEPTED
May 13, 2025
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 87978-4

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

Fall armyworm *Spodoptera frugiperda*

Beet armyworm *Spodoptera exigua*

INSTRUCTIONS FOR USE

Fawligen (active ingredient: *Spodoptera frugiperda* Multiple Nucleopolyhedrovirus strain 3AP2 occlusion bodies; SfMNPV) is a highly specific pathogen of *Spodoptera* spp. The effectiveness of Fawligen 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 Fawligen 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 Fawligen. 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 Fawligen (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 Fawligen does not reach these areas, initial control from the spray will be sub-optimal. However, larvae that die from the Fawligen spray will release large amounts of SfMNPV, which will spread throughout the crop canopy.

Fawligen will provide between 60 and 90% control, with greater control expected on smaller larvae under ideal application conditions. Fawligen should only be used to target larvae less than 0.5 inches 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 specified size spectrum will take longer to die and cause more significant damage prior to death.

Good coverage plus targeting actively feeding small larvae are the key factors in ensuring maximum performance of Fawligen. For this reason, apply Fawligen 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 coverage and performance.

Under high pest pressure or sub-optimal application conditions, or when immediate protection against damage is required, additional control options should be considered.

***Spodoptera* growth stage identification**

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

Instar	Age (days)	Size category	Length (inches)	Actual size	Fawligen timing
1st	0 - 1	Very Small	1/8"		✔✔
2nd	2 - 3	Small	5/32"		✔✔
3rd	4 - 5	Medium (small)	5/16"		✔
4th	6 - 7	Medium (large)	7/16"		✖
5th	8 - 9	Large	25/32"		✖
6th	10 - 14	Large (snake)	1 3/16"		

RAIN FASTNESS

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

CROPS, APPLICATION RATES AND CROP SPECIFIC INFORMATION

Crops	Rate of Fawligen per acre	Additional Information
Sorghum (milo)	0.5 to 2.0 fl. oz.	Use lower application 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 application rates when targeting larvae 0.3 inches in length (3rd instar) or under high pressure situations. Applications that are targeted when 50% of the heads have reached 100% flowering will provide good control.
Cereal Grains (Crop Group 15) (excluding Sweetcorn and Sorghum) including: Corn (maize), Popcorn, Rice[1] **Non-Grass Animal Feeds (Forage, Fodder, Straw and Hay) (Crop Group 18) including:** Alfalfa (hay and seed), Lupin, Vetch **Oilseeds (Crop Group 20) (excluding Cottonseed) including:** Flax seed, Canola, Safflower, Sunflower **Peanut** **Legume Vegetables (Dried Shelled Pea and Bean (except Soybean)) (Crop Subgroup 6C) including:** Adzuki bean, Chickpea, Cowpea, Faba bean, Field pea, Kidney bean, Lablab bean, Lentil, Lima bean, Sweet lupin, White lupin, Mung bean, Navy bean, Pigeon pea	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	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.
Sweetcorn	1.0 to 2.4 fl. oz.	Application should be made from the vegetative stages until silking. Applications during silking should employ higher application rates and be in conjunction with other control measures. Application of 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.
Turf and Pastures	0.5 to 2.0 fl. oz.	Use lower application rates when targeting larvae smaller than 0.3 inches in length (1st and 2nd instar). Use higher application rates when targeting larvae 0.3 inches in length (3rd instar) or under high pressure situations.

[1] Do not apply to flooded fields.

Crops	Rate of Fawligen per acre	Additional Information
Root and Tuber Vegetables (Crop Group 1) including: Carrot, Sweet potato, Sugar beet, Potato ***Brassica* (Cole) Leafy Vegetables (Crop Group 5) including:** Broccoli, Brussels sprouts, Cabbage, Cauliflower, Chinese broccoli, Kale, Mustard greens, Mustard spinach, Rape greens **Leafy Vegetables (except *Brassica* Vegetables) (Crop Group 4) including:** Arugula, Celery, Endive, Lettuce, Spinach[2] **Fruiting Vegetables (Crop Group 8 – 10) including:** Eggplant, Okra, Peppers, Tomato **Legume Vegetables (Edible-Podded Legume Vegetables and Succulent Shelled Pea and Bean) (Crop Subgroups 6A and 6B) including:** Bean, Edamame (immature seed soybean), Pea, Snow pea, Sugar snap pea **Cucurbit Vegetables (Crop Group 9) including:** Cucumber, Melons, Pumpkins, Summer and winter squash, Watermelon, Zucchini **Berry and Small Fruits (Crop Group 13 – 07) including:** Blackberry, Blueberry, Boysenberry, Cranberry,[2] Currants, Gooseberry, Raspberry, Strawberry **Pome Fruits (Crop Group 11 – 10) including:** Apples, Nashi, Pear **Ornamental Flowers and Plants** **Avocado** **Asparagus**	1.0 to 2.4 fl. oz.	Use higher application rates when flowers, fruit or economic parts of the crop are present, under high pest pressure conditions or to control 3rd instar larvae. Use lower application rates during vegetative stages of crop production. Application of lower application rates at regular (3- to 5-day) intervals, particularly via overhead irrigation water, is an effective strategy in horticultural crops.
Cotton	2.0 to 2.4 fl. oz.	High leaf pH in cotton causes rapid MNPV deactivation, giving Fawligen very short residual activity and resulting in highly variable performance in this crop. Fawligen should not be solely relied upon when larvae numbers are above economic threshold in cotton.
Hemp	1.2 to 2.4 fl. oz.	Use higher application rates under high pest pressure conditions or to control 3rd instar larvae. Use of lower application rates at regular intervals is an effective strategy in hemp.

[2] Do not apply to flooded fields.

MIXING INSTRUCTIONS

Shake the container well before use. Spray water pH should be neutral (pH 7.0) – spray water pH above 8 will 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 Fawligen to the spray tank after the other products are thoroughly diluted. Apply Fawligen within 10 hours after mixing. Do not let stand overnight.

Compatibility:

In water: Fawligen 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 Fawligen as higher pH levels will damage the virus.

In oil (ultra-low volume): For ULV application in oil, Fawligen 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 (Edible-Podded Legume Vegetables and Succulent Shelled Pea and Bean) (Crop Subgroups 6A and 6B) including: Bean, Edamame (immature seed soybean), Pea, Snow pea, Sugar snap pea, Asparagus; Root and Tuber Vegetables (Crop Group 1) including: Carrot, Sweet potato, Sugar beet, Potato; *Brassica* (Cole) Leafy Vegetables (Crop Group 5) including: Broccoli, Brussels sprouts, Cabbage, Cauliflower, Chinese broccoli, Kale, Mustard greens, Mustard spinach, Rape greens; Leafy Vegetables (Except *Brassica* Vegetables) (Crop Group 4) including: Arugula, Celery, Endive, Lettuce, Spinach;[3] Fruiting Vegetables (Crop Group 8 – 10) including: Eggplant, Okra, Peppers, Tomato; Cucurbit Vegetables (Crop Group 9) including: Cucumber, Melons, Pumpkins, Summer and winter squash, Watermelon, Zucchini; Berry and Small Fruits (Crop Group 13 – 07) including: Blackberry, Blueberry, Boysenberry, Cranberry,[3] Currants, Gooseberry, Raspberry, Strawberry; Pome Fruits (Crop Group 11 – 10) including: Apples, Nashi, Pear; Ornamental Flowers and Plants; Avocado; Tobacco; Hemp

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

II. Cereal Grains (Crop Group 15) including: Corn (maize), Popcorn, Sorghum (milo), Sweetcorn, Rice;[3] Non-Grass Animal Feeds (Forage, Fodder, Straw and Hay) (Crop Group 18) including: Alfalfa (hay and seed), Lupin, Vetch; Peanut; Soybean; Turf and Pastures; Cotton

   Ground Rig
   Apply Fawligen in a minimum of 10 gallons of water per acre.

[3] Do not apply to flooded fields.

Aerial – High Volume

Apply Fawligen 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 Fawligen 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 Fawligen in ULV, DO NOT tank mix with other pesticides or fertilizers (refer to Compatibility).

CHEMIGATION

Fawligen can be effectively applied to crops in overhead irrigation water. The product should be introduced 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 any diluted Fawligen 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 Fawligen into the irrigation water over the course of irrigation. Apply Fawligen 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 Fawligen into the irrigation water just prior to completion of the irrigation period to maximize the concentration of Fawligen applied and the amount that remains on the crop. See the CHEMIGATION section (following) for additional information.

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) 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.

DAYS TO HARVEST

There are no restrictions on applying Fawligen 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 Fawligen to high temperatures (>100 F). Packaged, sealed product can be exposed to sunlight for brief periods of time (<2 hours) but should be kept out of direct sunlight.

- Fawligen stored at ≤39° F (cool room, refrigerator, freezer) will be viable for 60 months.

PESTICIDE DISPOSAL

To avoid waste, use all 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 ordinances. If burned, stay out of smoke.

WARRANTY

This product is warranted to contain the amount of active ingredient 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 make 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.