

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 24, 2023

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

Subject: PRIA (Pesticide Registration Improvement Act) Labeling and Formulation Amendment –

to Revise the Label to Remove Signal Word, Expiration Date, and Organic Production Claim, Update Ingredient Statement and Add Engineering Control Worker Protection Standard Text and Minor Revisions and to Update CSF Supplier information and

Certified Limits

Product Name: CHRYSOGEN EPA Registration Number: 87978-5 EPA Receipt Date: 7/30/2022 Action Case Number: 00382278

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 4/12/2023

Any CSFs other than that listed above are superseded/no longer valid.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

Page 2 of 2 EPA Reg. No. 87978-5 Action Case No. 00382278

12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements 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 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 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 Susanne Cerrelli by phone at (202) 566-1516 or via email at cerrelli.susanne@epa.gov.

Sincerely,

CODY

Digitally signed by CODY KENDRICK KENDRICK Date: 2023.04.24 10:30:25 -07'00'

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

Enclosures

- -EPA Accepted Label for 87978-5
- Storage Stability DER dated 3-22-2023
- Chrysogen Certified Limits DER dated 3-22-2023
- Full Science Review Memo dated 3-22-2023
- Acute Dermal Toxicity DER dated 3-21-2023

ACCEPTED

Apr 24, 2023

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 07070 F

87978-5

C. includens NPV isolate #460 | GROUP | 31 | INSECTICIDE

CHRYSOGEN

Biological insecticide for the integrated control of *Chrysodeixis includens* (soybean looper) and

Trichoplusia ni (cabbage looper) on specified food and non-food crops

Active Ingredient*:	
Occlusion bodies of Chrysodeixis includens Nucleopolyhedrovirus	s, isolate #46032.7%
Other Ingredients:	67.3%
Total:	100.0%

KEEP OUT OF REACH OF CHILDREN

See additional precautionary statements on the back panel

Net Contents: 0.25, 1, 1.3, 2.5, 5 gallons

EPA Registration N°: 87978-5 EPA Est. Number: 87978-TX-001

Manufactured by: AgBiTech LLC 14401 Sovereign Road, Suite 111 Fort Worth TX 76155 USA

Product of USA

Batch code:

^{*} Contains 6.75 x10⁹ occlusion bodies per milliliter

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 a minimum of a NIOSH-approved particulate filtering facepiece respirator with any R or P filter; <u>OR</u> a NIOSH-approved elastomeric particulate respirator with any R or P filter; <u>OR</u> 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.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.607(d) and (e), the handler PPE requirements may be reduced or modified as specified in the WPS

USER SAFETY RECOMMENDATIONS

USERS SHOULD: Wash hands thoroughly with soap and water after handling and 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.

For information on this pesticide product (including general health concerns or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378, Monday through Friday, 8:00 AM to 12:00 PM Pacific Standard Time.

In the event of a medical emergency, call your poison control center at 1-800-222-1222.

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 requirement 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 larvae on labeled crops:

Soybean looper (Chrysodeixis includens)

Cabbage looper (Trichoplusia ni)

INSTRUCTIONS

Chrysogen (*Chrysodeixis includens* Nucleopolyhedrovirus, isolate #460) is a highly specific pathogen of *Chrysodeixis includens* (soybean looper) and *Trichoplusia ni* (cabbage looper). The effectiveness of Chrysogen is dependent on a number of important factors, such as: larval size, environmental conditions, quality of the application and the feeding behavior of the pest. Because of the requirement for good application and climatic conditions, the performance and speed of activity of Chrysogen can be variable. Larvae can take up to 8 days to die, though the rate of damage by NPV infected larvae 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 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 control, particularly under warm and humid environmental conditions suitable for NPV.

If larvae are feeding low down in a heavy soybean crop canopy, and application of Chrysogen does not reach these areas, initial control from the spray will be sub-optimal. However, larvae that die from the Chrysogen spray will release large amounts of NPV, which will then spread throughout the crop canopy.

Only use Chrysogen to target larvae that are 3rd instar (7/16" long) or younger, though it is most effective on larvae that are 2nd instar or younger (up to 1/4" long). Larvae at the higher end of the recommended size spectrum will take longer to die and will cause more damage prior to death.

Chrysogen will provide between 60 and 90% control of larvae present at the time of spraying, with greater control expected on smaller larvae. Apply Chrysogen 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, adjustments to application parameters such as spray volume and droplet size can improve coverage and consequently performance. Avoid applying Chrysogen if heavy rain (greater than 0.4 inches per hour) is expected within 1 hour after application.

CROPS, APPLICATION RATES AND CROP SPECIFIC INFORMATION

Crops	Rate of Chrysogen per acre	Additional Information
Sorghum	0.7 to 1.4 fl. oz.	Use lower application rates when targeting small larvae (1 st and 2 nd instar) and in mixtures with chemical insecticide sprays for midge control (not ULV). Use higher application rates when targeting 3 rd instar larvae or under high pressure situations. Applications made when 50% of heads have reached 100% flowering will provide good control.
Cereal Grains – Commodities (Crop Group 15) including: Corn (maize), Popcorn, Rice Alfalfa (hay and seed) Oilseed Group (Crop Group 20) including: Flax seed, Canola, Safflower, Sunflower Peanuts Legume Vegetables (Succulent or Dried) (Crop Group 6) including: Adzuki bean, Broad bean, Chickpea, 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 the high application rate 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.
Sweet corn	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 vegetative stages through row tassel to silking.

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) (Crop Group 4) including: Celery, Endive, Lettuce, Roquette, Silver beet, Spinach Fruiting Vegetable Group (Crop Group 8 - 10) including: Chili, Eggplant, Okra, Pepper, Tomato Legume Vegetables (Succulent or Dried) (Crop Group 6) including: Green bean, Green pea, Snow pea, Sugar snap pea Cucurbit Vegetables (Crop Group 9) including: Cucumber, Melon, Pumpkin, Summer and winter squash, Watermelon, Zucchini Berry and Small Fruit Crop Group (Crop Group 13 - 07) including: Blackberry, Blueberry, Boysenberry, Cranberry, Currant, Gooseberry, Raspberry, Strawberry Pome Fruit Group (Crop Group 11 - 10) including:	fl. oz.	Use a higher application rate when flowers, fruits or marketable parts of the crop are present, under high pest pressure conditions, or to control 3 rd instar larvae. Use the lower application rate 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.
Raspberry, Strawberry Pome Fruit Group (Crop Group 11 - 10) including: Apple, Nashi, Pear Ornamental Flowers and Plants Avocado Asparagus		
Cotton	2.0 to 2.4 fl. oz.	High leaf pH in cotton causes rapid NPV deactivation, giving Chrysogen very short residual activity and resulting in highly variable performance in this crop. Chrysogen should not be solely relied upon.
Tobacco, Hemp	1.2 to 2.4 fl. oz.	Use a higher application rate under high pest pressure conditions or to control 3 rd instar larvae. Use of the lower application rate at regular intervals is an effective strategy in tobacco and hemp.

MIXING INSTRUCTIONS

Shake the container well before use. Spray water pH must be below 8 as higher pH 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 Chrysogen to the spray tank after the other products are thoroughly diluted. Apply Chrysogen as soon as possible after mixing. Do not let stand overnight.

Compatibility:

<u>In water:</u> Chrysogen is highly compatible with the majority of herbicides, insecticides fungicides and foliar fertilizers when mixed in water. Ensure that the mixture has a pH below 8 before adding Chrysogen, as pH above 8 will damage the virus.

<u>In oil (ultra-low volume)</u>: For ULV application in oil, Chrysogen 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.

I. Vegetable, Legume (succulent and dried), 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 (Crop Group 4) including: Celery, Endive, Lettuce, Roquette, Silver beet, Spinach; Fruiting Vegetables (Crop Group 8 - 10) including: Chili, Eggplant, Okra, Pepper, Tomato; Cucurbit Vegetables (Crop Group 9) including: Cucumber, Melon, Pumpkin, Summer and winter squash, Watermelon, Zucchini; Berries Group (Crop Group 13 - 07) including: Blackberry, Blueberry, Boysenberry, Cranberry, Currant, Gooseberry, Raspberry, Strawberry; Pome Fruit (Crop Group 11 - 10) including: Apple, Nashi, Pear; Ornamental Flowers and Plants; Avocado; Asparagus; Tobacco, Hemp.

Ground Rig

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

II. Sorghum, Grain Cereal, Alfalfa, Oil Seeds, Peanut, Soybean, Sweet Corn, Cotton

Ground Rig

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

Aerial - High Volume

Apply Chrysogen 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 Chrysogen in a minimum of 1 gallon of water per acre and include an antievaporation 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 Chrysogen in ULV, DO NOT tank mix with other pesticides or fertilizers (refer to Compatibility).

Chemigation (via overhead irrigation water):

Chrysogen 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 < 8 and ensure there is constant agitation. Preferably, rainwater should be used for dilution. Ensure any diluted Chrysogen is used 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 Chrysogen into the irrigation water over the course of irrigation. It is recommended to apply Chrysogen 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 Chrysogen into the irrigation water just prior to completion of the irrigation period, to maximize the concentration of Chrysogen 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) 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 Chrysogen if heavy rain is expected within one hour following application. However, do not delay application if only moderate rain is expected, and heavy rain (greater than 0.4 inches per hour) is not imminent.

DAYS TO HARVEST

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

■ Chrysogen stored in the refrigerator at $\leq 39^{\circ}$ F will be viable for 60 months.

PESTICIDE DISPOSAL

To avoid waste, apply product in this container according to label directions. If waste 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

Nonrefillable container. Do not reuse or refill this container. Triple rinse container 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 the container 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 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 the control of AgBiTech Pty Ltd. 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.