



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

August 10, 2025

SENT BY EMAIL

Ana Koster
akoster@certisbio.com
CERTIS USA, LLC

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling and Formulation Amendment - Update Label and Basic Confidential Statement of Formula to Reflect Updated Active Ingredient Taxonomy
Product Name: Gemstar
Admin Number: 70051-45
EPA Receipt Date: 12/20/2024
Action Case Number: 00648838

Dear Ana Koster:

The amended label 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 conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6) you must submit one copy of the final printed labeling before you release the 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.

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

- Basic CSF dated 07/24/2025

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 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, FIFRA section 12(a)(1)(B). Therefore, should the Agency 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 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 questions, please contact Joseph Mabon via email at mabon.joseph@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Cody Kendrick". The script is elegant and cursive, with the first letters of "Cody" and "Kendrick" being capitalized and prominent.

Cody Kendrick, Senior Regulatory Advisor
MPB, BPPD
Office of Pesticide Programs

Gemstar® LC

INSECTICIDAL VIRUS

{Alternate Brand Names: See Last Page of Master Label for List of ABNs}

A Liquid Concentrate Biological Insecticide For Control of Corn Earworm (Cotton Bollworm, Tomato Fruitworm), Old World Bollworm, and Tobacco Budworm



[For [Use in]] {or} [Can Be Used in] [Organic Production]



Active Ingredient*:

Polyhedral occlusion bodies (OBs) of the *Alphabaculovirus helarmigerae* strain I-14 (formerly known as Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of *Helicoverpa zea*). 0.64%

OTHER INGREDIENTS: 99.36%

TOTAL 100.00%

*Contains at least 2 billion OBs/mL of product

KEEP OUT OF REACH OF CHILDREN

CAUTION

MANUFACTURED BY:

Certis USA LLC
9145 Guilford Road, Suite 175
Columbia, MD 21046



EPA Reg. No. 70051-45

EPA Est. No.

Lot Number:

Net Contents:

ACCEPTED

Aug 10, 2025

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

70051-45

FIRST AID

If in eyes: Hold eye open and rise slowly with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. Call a poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

Hotline Number: 1-800-255-3924 [Chemtel].

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin or inhaled. Avoid contact with eyes, clothing, or skin. 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.

PERSONAL PROTECTIVE EQUIPMENT:

Applicators and other handlers must wear:

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

Mixer/loaders and applicators must wear a NIOSH-approved particulate respirator with any R or P 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 and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

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:

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 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 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 (REI). The requirements in this box only apply 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

GENERAL INFORMATION

Gemstar® LC is a highly-selective [insecticide containing an insect virus] {or} [insecticidal virus] that infects and kills only larvae (caterpillars) of the corn earworm (*Helicoverpa zea* also known as the tomato fruitworm or cotton bollworm), the old world bollworm (*Helicoverpa armigera*), and the tobacco budworm (*Heliothis virescens*). Larvae ingesting the virus stop feeding within several days, become pale and lethargic, and then die as the virus replicates throughout their bodies. Virus released from dead larvae may infect other larvae feeding nearby.

Read this label carefully.

SHAKE WELL BEFORE USING.

APPLICATION INSTRUCTIONS

Because the virus must be ingested by larvae in order to initiate infection, thorough spray coverage is essential for good insect control. Several days may elapse between treatment and cessation of larval feeding due to the virus infection. Large larvae may cause considerable damage as they continue to feed, even if they eventually succumb to virus infection. Therefore, treat when larvae are young (early instars) and are actively feeding, before extensive damage has occurred. When insect infestations are heavy, use the higher label rates and/or spray more frequently. Increasing the frequency of applications is usually more effective than raising the application rates at improving the level of insect control.

Gemstar® LC can be applied by ground or aerial sprayers (both conventional and ultra-low volume) or with overhead sprinkler irrigation equipment (chemigation), as long as the equipment provides thorough coverage of plants with minimal runoff. The amount of water or other carrier needed per acre will depend on weather, spray equipment, and local experience. Typical spray volumes are 20-100 gallons of water per acre for ground application and 5-20 gallons of water per acre for conventional aerial application. For aerial ULV application, apply in a minimum of 2 quarts of an approved oil-based carrier.

Use of a non-ionic or oil-based spreader/sticker and ultraviolet screening agent may enhance the performance of this product. Do not use silicone-based spreaders as they may interfere with adhesion of virus particles to the plant surface.

Fill the mix tank with desired quantity of clean water. Ideal pH is between 6 and 8; adjust highly alkaline (pH>8) or acidic (pH<6) water to pH 7 with a buffering agent before adding Gemstar® LC. Shake the Gemstar® LC container well, or invert it several times before pouring to ensure uniform suspension. Keep the tank agitated during mixing. If a spreader/sticker or ultraviolet screen is used, add prior to the addition of Gemstar® LC. Mixing time can be reduced by premixing Gemstar® LC with a small amount of clean water and agitating vigorously before adding to the tank. Spray as soon as possible after mixing; do not allow the spray mix to stand overnight.

Gemstar® LC can be applied up to and including the day of harvest and storage.

APPLICATION RATES AND OTHER INFORMATION

CROPS	PRODUCT RATE/ACRE
Vegetables and Fruits such as: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion, soybeans, potatoes, corn, sweet potatoes, sugar beets, strawberries, okra, and artichokes (globe and Jerusalem).	4-10 fl. oz.
Other Crops: Cotton, alfalfa, peanuts, tobacco, wheat, sunflower, sorghum, hemp, and floriculture and border plants.	

Larvae ingesting the virus stop feeding within several days, become pale and lethargic, and then die as the virus replicates throughout their bodies. Virus released from dead larvae may infect other larvae feeding nearby.

Frequent application at low rates is usually more effective than infrequent application at high rates.

Lower rates can be used during vegetative stages of crop growth or when tank-mixed with other insecticides that are also effective against *Heliothis* or *Helicoverpa* (see more information on tank-mixing below).

When insect infestations are heavy, use the higher label rates and/or spray more frequently. Increasing the frequency of label applications is usually more effective than raising application rates at improving the level of insect control.

When flowers, fruit, or other harvested structures are present, use higher rates and/or increased frequency of sprays, or tank mix with an insecticide having contact knockdown activity.

Gemstar® LC can be applied by ground or aerial sprayers (both conventional and ultra-low volume) or with overhead sprinkler irrigation equipment (chemigation), as long as the equipment provides through coverage of plants with minimal runoff.

Use of a non-ionic or oil-based spreader/sticker and ultraviolet screening agent may enhance performance of this product.

For Sweet Corn: Make applications from early vegetative growth to tasseling and before emergence of silks. Retreatment may be required at 2-3 day intervals depending on egg counts and crop growth rate due to short residual activity of the virus.

For Old World Bollworm (*Helicoverpa armigera*): Treat when larvae are young (early instars) and are actively feeding, before extensive damage has occurred.

For application via overhead sprinkler irrigation:

Gemstar® LC can be applied in overhead sprinkler irrigation water using standard equipment and methods for overhead sprinkler chemigation. For center pivot, lateral move or other single-pass irrigators, apply in ½ inch of irrigation water, injecting the required amount of Gemstar® LC continuously over the course of irrigation. For static irrigation systems (such as solid set pipe with risers), inject the required amount of Gemstar® LC into the irrigation water just before completion of the irrigation period to maximize the concentration applied and minimize runoff. See [attached] “Chemigation Bulletin” for additional information.

Tank mixing and compatibility:

Gemstar® LC may be mixed with registered ovicides and/or larvicides to kill eggs and larger larvae and provides a unique mode of action for reduced risk of pest resistance. Do not mix with any product if its label prohibits mixtures. Gemstar® LC is physically compatible with most insecticides and fungicides. However, when first considering such a tank mix, conduct a compatibility test (“jar test”) by mixing proportional quantities of Gemstar® LC and these products in a small volume of water. If mixing with products that may raise the pH of the spray mix (such as some foliar fertilizers), add those products to the water first, then check the pH and buffer to 7 before adding Gemstar® LC.

Gemstar® LC may be used on *Bacillus thuringiensis* (Bt) transgenic crop varieties unless prohibited due to refuge requirements for resistance management. Consult your seed supplier for further information.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store this product in the original sealed container in a cool, dry place inaccessible to children and pets. Bioactivity may be impaired by storage above 90°F. Product can be stored at room temperature for up to 60 days, but should be refrigerated for longer storage. Freezing will not harm this product.

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: 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 ¼ 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

Certis USA LLC warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the disease problem, condition of the crop, incompatibility with other chemicals not specifically recommended and other influencing factors in the use of this product are beyond the control of the seller. To the extent consistent with applicable law, buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. To the extent consistent with applicable law, NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY IS MADE.

{The following text may or may not appear, in whole or part, on the final label, as necessary to accommodate the type of packaging used:}

- Referral Statements
 - See [side][back][right][left][inside][other] panel for [additional] [[precautionary] [and] [first aid] statements] [[use] directions [for use]]
 - See [attached] [booklet] [book] for [additional] [[precautionary] [and] [first aid] statements] [[use] directions [for use]]
 - Refer to [inside of] label booklet for [additional] [precautionary] [first aid] information [and] [[Directions] for Use] [including] [First Aid] [and] [Storage and Disposal]
 - Peel [back] [book] [booklet] [label] [here] [►] [→] {may be accompanied by an arrow or other indicator}

CHEMIGATION INSTRUCTIONS

Precautions:

Apply this product through pressurized sprinkler irrigation systems (impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side roll, center pivot, or hand move, including mist-type systems). Do not apply this product through any other type of irrigation system.

Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water.

If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Public water system chemigation:

“Public water system” 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 at least 25 individuals daily at least 60 days out of the year.

1. Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line 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 outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.
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 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 or, in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

5. 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.
6. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. For center pivot, lateral move or other single-pass irrigators, application must be continuous in sufficient water to apply the specified rate evenly to the entire treated area. For static irrigation systems (such as solid set pipe with risers), inject the required amount of Gemstar® LC into the irrigation water just before completion of the irrigation period to maximize the concentration applied and minimize runoff.
7. Do not apply when wind speed favors drift beyond the area intended for treatment.
8. Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

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 backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pipeline.
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 that 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. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. For center pivot, lateral move or other single-pass irrigators, application must be continuous in sufficient water to apply the specified rate evenly to the entire treated area. For static irrigation systems (such as solid set pipe with risers), inject the required amount of Gemstar® LC into the

irrigation water just before completion of the irrigation period to maximize the concentration applied and minimize runoff.

8. Do not apply when wind speed favors drift beyond the area intended for treatment.

Optional Label Statements/Elements (applicable to any/all Sublabels unless otherwise specified):

{The following items may or may not appear on the final printed labeling}

Graphics

- {OMRI Seal(s)}



- {Logos}



List of Alternate Brand Names:

- Gemstar

- Diplomata K