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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 2, 2016

Alexander Pierce
Regulatory Affairs Associate
Certis USA LLC
9145 Guilford Road
Columbia, MD 21046

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Adding Pest and Updating Control Language
Product Name: Gemstar LC
EPA Registration Number: 70051-45
Application Date: 06/29/2016
OPP Decision Number: 519536

Dear Mr. Pierce:

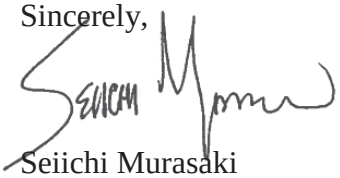
The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under 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 Nicola Steinmetz by phone at (703) 347-8567 or via email at steinmetz.nicola@epa.gov.

Sincerely,



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

Enclosure: Stamped Label

Gemstar LC

Insecticidal Virus

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

[**OMRI Placeholder**]
For Organic Production

Gemstar LC is an Insecticidal Virus for control of the caterpillars of the corn earworm, *Helicoverpa zea* (also known as the cotton bollworm, and the tomato fruitworm), old world budworm (*Helicoverpa armigera*) and the tobacco budworm, *Heliothis virescens*. Read this label carefully.

Active Ingredient:

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of *Helicoverpa zea* (corn earworm).....	0.64%
Inert Ingredients.....	99.36%
Total.....	100.00%

*Contains at least 2 billion OBs/ml.

KEEP OUT OF REACH OF CHILDREN

CAUTION

Net contents: 2.5 Gallons
EPA Reg. No. 70051-45
EPA Est. No. 70051-CA-001

Manufactured by:
Certis U.S.A. L.L.C.
9145 Guilford Rd. Suite 175
Columbia, MD 20146

NOTIFICATION
70051-45
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:
08/02/2016

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

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.
If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
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 treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going in for treatment. **Hotline Number: 1-800-255-3924**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): CAUTION: Causes moderate eye irritation. Avoid inhalation or 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.

PERSONAL PROTECTIVE EQUIPMENT:

Applicators and other handlers must wear:

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

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.

Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-05. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

USER SAFETY RECCOMENDATIONS

USERS SHOULD:

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly with water for 15-20 minutes.
- 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 cleaning equipment or disposing of equipment wash waters or rinsate.

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 pests. 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 DISPOSAL: Plastic 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. 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 or local ordinances. Batch code _____.

GLASS: 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 dispose of in a sanitary landfill or by other procedures approved by state and local authorities. Batch code _____.

DIRECTIONS FOR USE

SHAKE WELL BEFORE USING

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 maybe 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 the 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 (REI). The statements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow 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 a naturally-occurring 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. Viruses released from dead larvae may infect other larvae feeding nearby.

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 per acre for conventional aerial application. For aerial ULV application, apply in a minimum of 2 quart 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. Silicone-based spreaders may interfere with adhesion of virus particles to the plant surface and should not be used with this product.

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

ADDITIONAL INFORMATION

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

Larvae ingesting the virus stop feeding within seveal 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.

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.

Lower rates may be used during vegetative stages of crop growth or when tank mixed with other insecticides also effective against the old world bollworm.

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.

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

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

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.

Sweet corn: Application should be made from early vegetative growth stage 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 application via overhead sprinkler irrigation:

GEMMSTAR®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.

Do not apply GEMSTAR®LC through any other type of irrigation system.

Tank mixing and compatibility:

GEMSTAR®LC may be mixed with registered ovicides and/or larvicicdes to kill eggs and larger larvae and provide 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, a compatibility test ("jar test") should be conducted 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 should not be tank mixed with *Bacillus thuringiensis* (Bt) spray products, which may reduce larval feeding rate and virus uptake. GEMSTAR®LC may be used on Bt transgenic crop varieties unless prohibited due to refuge requirements for resistance management. Consult your seed supplier for further information.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is responsibly fit for the purposes referred to in its directions for use. Timing and method of application, weather, watering practices, nature of the soil, the insect 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. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESSED OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

Chemigation Bulletin

GENERAL INFORMATION

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 or lack of effectiveness 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 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 out of the year.

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.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow back toward the injection.

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.

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.

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.

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

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 pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
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 (i.e., 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. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
8. Do not apply when wind speed favors drift beyond the area intended for treatment.