

PLEASE NOTE

This image contains more than one label approved for this product on this date.



United States Environmental Protection Agency Washington, DC 20460

Registration Amendment Other NOTIFICATION

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70051-45
2. EPA Product Manager / Branch Chief Dennis Szuhay
3. Proposed Classification None Restricted
4. Company/Product (Name) Gemstar LC
5. Name and Address of Applicant Certis USA, L.L.C.
6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name

Section - II

Amendment - Explain below. Resubmission in response to Agency letter dated. Notification - Explain below. Final printed labels in response to Agency letter dated. "Me Too" Application. Other - Explain below. Date Reviewed: Jun 16, 2004

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification to reverse the order of the "Keep out of reach of children" and "Caution" statements (KOROC statement is now above "Caution"). Also revised the phrase "Gemstar LC is an IVP (Insecticidal Virus Product)..." on page 1, to read "Gemstar LC is an Insecticidal Virus...". Added the word (heading) "Warranty" over the warranty statement. Revised "net weight" to read "net contents". Revised "Oz. per acre" in the application rates table to read "Fl. Oz. per acre". This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Three copies of final printed labeling are also included in this submission.

Section - III

1. Material This Product Will Be Packaged In: Child-Resistant Packaging, Unit Packaging, Water Soluble Packaging, 2. Type of Container, 3. Location of Net Contents Information, 4. Size(s) Retail Container, 5. Location of Label Directions, 6. Manner in Which Label is Affixed to Product

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name: Christine A. Dively, Title: Director of Regulatory Affairs, Telephone No.: 301-483-3806. Certification: I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. 2. Signature: Christine A. Dively, 3. Title: Director of Regulatory Affairs, 4. Typed Name: Christine A. Dively, 5. Date: April 5, 2004, 6. Date Application Received (Stamped)

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Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046
(301) 604-7340
FAX (301) 604-7015
www.certisusa.com

April 7, 2004

Mr. Dennis Szuhay
Branch Chief, Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs
US Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

**Re: Final printed labeling and Notifications for Certis USA, L.L.C.,
EPA Co. No. 70051**

Dear Mr. Szuhay:

Certis USA, L.L.C. is respectfully submitting the enclosed final printed labeling that incorporates minor revisions (Notifications) for the following product labels:

- 1) Javelin WG, EPA Reg. No. 70051-66
- 2) Thuricide HPC for Home and Gardens, EPA Reg. No. 70051-65
- 3) Thuricide HPC, EPA Reg. No. 70051-52
- 4) Deliver (San 420 I WG), EPA Reg. No. 70051-69
- 5) Gemstar LC, EPA Reg. No. 70051-45

Enclosed in support of this action are: EPA Form 8570-1, a copy of the previously approved label with changes highlighted, and 3 copies of each final printed label with incorporated changes. No other changes have been made to these labels. Please do not hesitate to contact me if you have any questions about this submission. I can be reached by telephone at 301-483-3806 or by email at cdively@certisusa.com.

Sincerely,

Christine A. Dively
Christine A. Dively
Director of Regulatory Affairs

Enclosures

5745748385

Gemstar[®] LC

INSECTICIDAL VIRUS

A Liquid Concentrate Biological Insecticide For Control of Corn earworm
(Cotton bollworm, Tomato fruitworm), and Tobacco budworm

 FOR ORGANIC PRODUCTION



GEMSTAR[®] LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the corn earworm, *Helicoverpa zea* (also known as the cotton bollworm and the tomato fruitworm), 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%

*This lot contains at least 2 billion OBs/ml.

CAUTION
KEEP OUT OF REACH OF CHILDREN

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

Manufactured by
Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046



NOTIFICATION
Date Reviewed: Jan 16, 2004
Reviewed By: [Signature]

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

FIRST AID
If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing 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 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 for treatment.
Hot Line Number: 1-800-255-3924.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): CAUTION: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

PERSONAL PROTECTIVE EQUIPMENT:

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks.

Follow 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 RECOMMENDATION
Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90°F. Bioactivity may be impaired by storage above 90°F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or in an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.
Glass container - triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

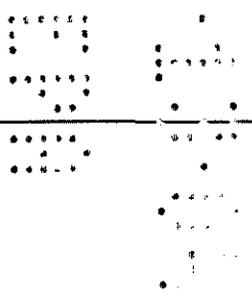
DIRECTIONS FOR USE

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 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 exemptions 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 for use against the insects and on the crops listed on this label.

Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred.

When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. Apply GEMSTAR® LC by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff.

The amount of water needed per acre will depend on weather, spray equipment, and local experience. Use the application amount of GEMSTAR® LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

Use of a spreader/sticker and ultraviolet screening agent can enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If 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 water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

APPLICATION RATES

CROP	RATE		
	Billions Obs Per Acre	Mls Per Acre	Oz Per Acre
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber broccoli, onion, strawberries, okra	600	300	10
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets, sorghum, various flowers, & border plants.	600	300	10

USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX.

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

Certis USA, L.L.C. 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 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 EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

SHAKE WELL BEFORE USING

M081103
M081803 OMRJ

NEXT

LABEL

Gemstar[®] LC

INSECTICIDAL VIRUS

A Liquid Concentrate Biological Insecticide For Control of Corn earworm (Cotton bollworm, Tomato fruitworm), and Tobacco budworm

 **FOR ORGANIC PRODUCTION**

Active Ingredient:*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of

Helicoverpa zea (corn earworm):0.64%

Other Ingredients:100.00%

Total:100.00%

*This lot contains at least 2 billion OBs/ml.

NOTIFICATION
Date Reviewed: 6-16-2004
Reviewed By: [Signature]
Net Contents: 72.5 Gallons
EPA REG. NO. 70051-45
EPA EST. NO. 70051-CA-001



Manufactured by
Certis USA, L.L.C.
9145 Guilford Road
Suite 175
Columbia, MD 21046



**KEEP OUT OF REACH OF CHILDREN
CAUTION**

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

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), and the tobacco budworm, *Heliothis virescens*. Read this label carefully.

USER SAFETY RECOMMENDATION
Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

FIRST AID
If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
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If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Hot Line Number: 1-800-255-3924.

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CAUTION:
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STORAGE AND DISPOSAL
Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.
STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90°F. Bioactivity may be impaired by storage above 90°F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PERSONAL PROTECTIVE EQUIPMENT:
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• Long-sleeved shirt and long pants
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Glass container - triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

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CROP	RATE		
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Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoll, onion	600	300	10
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	600	300	10

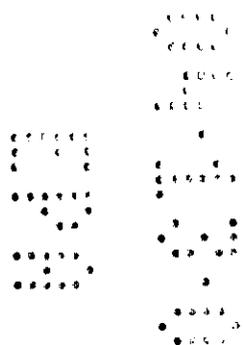
USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX.

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WARRANTY

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SHAKE WELL BEFORE USING



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