

70051-89

11/3/2009

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

November 3, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Christine A. Dively
Director of Regulatory Affairs
Certis USA, LLC
9145 Guilford Road, Suite 175
Columbia, MD 21046

RE: Product Name: Lepinox WDG
EPA Reg. No: 70051-89
Application for Label Notification Dated September 18, 2009 to update
storage and disposal statement.

Dear Ms.Dively:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration (PR) Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10 and it has been determined that the action(s) requested falls within the scope of PR Notice 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received and reviewed" and will be placed accordingly in our records.

If you have any questions concerning this action, please feel free to contact Ms. Menyon Adams at (703) 347-8496 or email at adams.menyon@epa.gov.

Sincerely,

Linda Hollis

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)

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Please read instructions on reverse before completing form.

Form Approved, 8 No. 2070-0060

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70051-89	2. EPA Product Manager Microbial Pesticides Branch	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Lepinox WDG	PM# <u>12</u>	
5. Name and Address of Applicant (Include ZIP Code) Certis U.S.A, L.L.C. 9145 Guilford Road, Suite 175 Columbia, MD 21046 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

Section - II NOTIFICATION

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed label in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Date Reviewed: 11/03/09
Reviewed By: MRK

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, 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.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. _____ No. per container _____	If "Yes" Package wgt. _____ No. per container _____

3. Location of Net Contents Information
 Label Container

4. Size(s) Retail Container
5 pounds

5. Location of Label Directions
 On Label On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
 Lithograph Paper glued Stenciled Other _____

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	Telephone No. (Include Area Code) 301-483-3806
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Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature
Christine A. Dively

3. Title
Director of Regulatory Affairs

4. Typed Name
Christine A. Dively

5. Date
Sept. 18, 2009

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

September 17, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington DC 20460-0001

Re: **Notification of label change per PR Notice 2007-4.**

Certis U.S.A, L.L.C. respectfully submits the following change to the label for Lepinox WDG (EPA Registration Number 70051-89) to comply with the requirements of PR Notice 2007-4:

Container reuse statements were added to the Storage and Disposal section of the label.

No other changes were made to the label.

Enclosed in this submission are the following:

- Application for Registration – EPA Form 8570-1
- A copy of the final label
- A copy of draft labeling with the changes underlined

Please do not hesitate to contact me if you have any questions about this submission. I can be contacted by telephone at 301-483-3806 or by email at cdively@certisusa.com.

Respectfully,

A handwritten signature in cursive script that reads "Christine A. Dively".

Christine A. Dively
Director of Regulatory Affairs

Lepinox® WDG

INSECTICIDE

LEPINOX® WDG water dispersible granule is a biological insecticide for the control of lepidopteran pests.

Active Ingredient:

Bacillus thuringiensis subspecies *kurstaki* strain EG7826 solids, spores, and Lepidopteran active toxins*40.0%

Other Ingredients:60.0%

TOTAL100.0%

*The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

**Net Contents:
5 Pounds**

EPA REG. No. 70051-89
EPA EST No. 70051-CA-001
Lot No.:

**KEEP OUT OF REACH OF CHILDREN
WARNING / AVISO**
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID
If in eyes: Hold eyes 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.

Call a poison control center or doctor for further treatment advice.
Hot Line Number: 1-800-255-3924

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



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear goggles or faceshield. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Personal Protective Equipment (PPE):
Applicators and other handlers must wear:
• Long sleeved shirt and long pants
• Shoes plus socks
• Waterproof gloves
• Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.
• Protective eyewear

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 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.

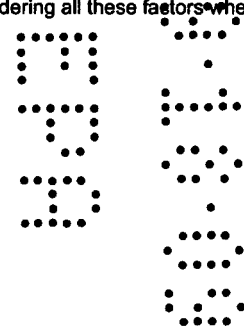
ENVIRONMENTAL HAZARDS
Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark.

This product must not be applied aerially within 1/4 mile of any habitats of endangered or threatened Lepidoptera. No manual application can be made within 300 ft. of any threatened or endangered Lepidoptera.

Do not contaminate water when disposing of equipment washwaters.

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.

Aerial Application
Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.



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 intervals. The requirements in this section 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 12 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, protective eyewear, shoes plus socks.

Preharvest Interval: LEPINOX WDG may be applied to the crops listed in the APPLICATION RATE TABLE at any time, up to and on the day of harvest.

Mode of Action: After consuming a lethal dose of LEPINOX WDG, larvae will cease to feed, but may remain alive on foliage for several days before disappearing. Immediately after ingestion of LEPINOX WDG, larvae begin to move slowly, become discolored, shrivel and blacken prior to death.

MIXING INSTRUCTIONS

LEPINOX WDG may be applied with conventional ground, aerial or hand-held application equipment with quantities of water sufficient to provide thorough coverage of infested plants. Do not apply this product through any type of irrigation system. To obtain a suitable mixture with water, add enough water to allow maximum agitation. With agitator running, slowly add in the LEPINOX WDG. Continue agitation. Add remainder of water and other spray materials and agitate until mixed. Maintain suspension while loading and spraying. Do not mix more LEPINOX WDG than can be used in a 12-hour period. Rinse and flush spray equipment thoroughly following each use. Do not contaminate water when disposing of equipment washwaters.

In order to make proper decisions on application rates to be used, follow the recommendations in the APPLICATION RATE TABLE and these guidelines:

APPLICATION INSTRUCTIONS

LEPINOX WDG is a biological insecticide for use against the lepidopteran larvae listed in the APPLICATION RATE TABLE. Larvae must consume deposits of LEPINOX WDG to be affected. Always follow these directions:

- Make applications when larvae are still small (early instars <1/2" in length) and actively feeding on foliage or other plant parts.
- Make applications before noticeable foliar damage occurs.
- Thorough spray coverage is essential for good insect control.
- For ground applications, directed drop nozzles should be used for certain vegetable crops. For orchard applications, a spray volume of 100 gallons per acre and treatment of each orchard row is recommended.
- Do not use screens smaller than 50 mesh.
- For ground applications, use a minimum spray volume of 20 gallons per acre. For aerial applications, use a spray volume of at least 5 gallons per acre. (See cotton and soybeans for special instructions.)
- When insect infestations are heavy, use the higher label rates, shorten the spray interval, and/or use larger total spray volume to improve spray coverage.
- Applications should be repeated at an interval sufficient to maintain control, depending upon plant growth, insect pressure and weather conditions after spraying.
- Local conditions may affect the use of LEPINOX WDG. Consult

your State Agricultural Extension Specialist for specific recommendations related to local crop protection problems.

- Spray water/spray tank solutions should not exceed pH 8.0. If necessary, buffer water to near neutral pH.

HAND-HELD EQUIPMENT

When using hand-held equipment, mix 4 teaspoons per gallon of water or 3 pounds per 100 gallons of spray solution. Spray to wet, but not to runoff.

TANK-MIX

Lepinox WDG may be tank mixed with contact pesticides. Combinations of LEPINOX WDG with commonly used insecticides, fungicides or other spray tank adjuvants are generally not deleterious to performance. It is advisable to test physical compatibility by mixing all components in small containers in proportionate quantities prior to mixing in spray tank. This product cannot be mixed with any product containing a label prohibition against such mixing. No label dosage rate should be exceeded. Application must be made in accordance with the more restrictive of label limitations and precautions.

For improved durability of spray deposits, a spreader/sticker approved for use on growing crops may be used for hard-to-wet crops such as cole crops.

APPLICATION RATE TABLE

I. VEGETABLE AND COLE CROPS

Crops such as:	Insect Pest
Artichokes	Alfalfa looper
Arugala	Armyworm
Asparagus	Artichoke plume moth
Beans	Beet armyworm
Beets	Cabbage budworm
Bok Choy	Cabbage looper
Broccoli	Celery leaf-tier
Brussels sprouts	Corn earworm
Cabbage	Cross-striped cabbageworm
Cardoni	Diamondback moth
Carrots	European corn borer
Cauliflower	Fall armyworm
Celeriac	Green cloverworm
Celery	Imported cabbageworm
Chick peas	Melonworm
Chicory	Omnivorous leafroller
Chinese cabbage	Pickleworm
Collards	Rindworm complex
Cucumber	Saltmarsh caterpillar
Cucurbits	Soybean looper
Dry bulb onions	Tobacco budworm
Eggplants	Tomato fruitworm
Escarole	Tomato hornworm
Endive	Tomato pinworm
Garlic	Velvetbean caterpillar
Green onions	Yellowstriped armyworm
Greens (Beets, China, Dandelion, Mustard, Turnip)	
Horseradish	
Kale	
Kohlrabi	
Leeks	
Lentils	
Lettuce (Head, Leaf, Romaine)	
Malanga	
Melons (Cantaloupe, Crenshaw, Honeydew, Muskmelon, Watermelon, etc.)	

Rate/Acre: 1.0 - 2.0 pounds

II. HERBS & SPICES

Crops such as:	Insect Pest
Basil Chives Cilantro Dill Oregano Peppermint Thyme	Alfalfa looper Armyworm Diamondback moth European corn borer Green cloverworm Imported cabbageworm Loopers Saltmarsh caterpillar

Rate/Acre: 1.0 - 2.0 pounds

III. PASTURE AND HAY CROPS

Crops such as:	Insect Pest
Alfalfa (hay & seed) Pasture (grasses & hay) Silage	Alfalfa caterpillar Armyworm Beet armyworm* European skipper Fall armyworm Loopers* Webworm Yellowstriped armyworm*

Rate/Acre: 1.0 - 2.0 pounds

*Product should be applied when early instar larvae first appear. If infestation persists, make second application 7-10 days later. Combination of LEPINOX WDG with a contact insecticide is recommended for control of 4th and 5th instar larvae.

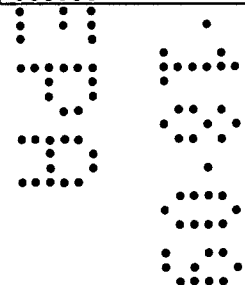
IV. FRUITS, NUTS AND VINE CROPS

Crops such as:	Insect Pest
Pome and Stone Fruit Trees: Apples Apricots Cherries Nectarines Peaches Pears Plums Prunes Quince	Cankerworm (Spring & Fall) Cherry fruitworm Eastern tent caterpillar Fall webworm Fruittree leafroller Green fruitworm Gypsy moth Navel orangeworm Obliquebanded leafroller Omnivorous leafroller Oriental fruit moth Pandemis leafroller Peach twig borer Redbanded leafroller Redhumped caterpillar Tortrix moth (Orange & Garden) Tufted apple budmoth Variegated leafroller Walnut caterpillar Western tent caterpillar
Nut Trees: Almond Chestnuts Filberts Pecans Pistachios Walnuts	Citrus cutworm Filbert leafroller Filbert webworm Fruittree leafroller Hickory shuckworm Navel orangeworm Obliquebanded leafroller Omnivorous leafroller Pecan nut casebearer Peach twig borer Redhumped caterpillar Roughskinned cutworm Western tent caterpillar

IV. FRUITS, NUTS AND VINE CROPS, continued

Crops such as:	Insect Pest
Citrus	Amorbia Citrus cutworm Fruittree leafroller Omnivorous leafroller Orangedog
Small Fruit and Berries: Blackberries Blueberries Boysenberries Cranberries Currants Loganberries Raspberries Strawberries	Achema sphinx moth Armyworm Blackheaded fireworm Blueberry leafroller Cranberry girdler Fruittree leafroller Grape berry moth Gypsy moth Loopers Obliquebanded leafroller Omnivorous looper Tobacco budworm
Grapes	Cherry fruitworm Grape berry moth Grape leafroller Grapeleaf skeletonizer Green fruitworm Omnivorous leafroller Orange tortrix Saltmarsh caterpillar Yellowstriped armyworm
Tropical and Other Fruit: Avocados	Amorbia Loopers Orange tortrix Omnivorous leafroller Omnivorous looper Spanworm
Bananas	Banana skipper
Kiwi	Omnivorous Leafroller
Persimmons Pomegranate	Citrus cutworm Fall webworm Filbert webworm Omnivorous leafroller Redhumped caterpillar Tent caterpillar
Pineapple	Gummosos-Batrachedra commosae Thecla-thecia basilides
Tropical fruits	Hornworms Leafrollers Loopers Omnivorous leafroller

Rate/Acre: 1.0 - 2.0 pounds



V. FIELD CROPS

Crops such as:	Insect Pest
Canola/Rape Seed Evening Primrose Meadow Foam	Armyworm Diamondback moth Imported cabbageworm Loopers
Corn (Field, Sweet, Popcorn, Seed)	Armyworm European corn borer Fall armyworm Southwestern corn borer
Cotton*	Beet armyworm Cabbage looper Bollworm Cotton leaf perforator Fall armyworm Saltmarsh caterpillar Soybean looper Tobacco budworm Yellowstriped armyworm
Hops	Armyworm Loopers Obliquebanded leafroller Omnivorous leaftier Spotted cutworm
Jojoba	Looper (<i>Anacamptodes</i> spp.)
Peanuts	Fall armyworm Green cloverworm Loopers Podworm Velvetbean caterpillar
Rice	Armyworm Green cloverworm Loopers Saltmarsh caterpillar Velvetbean caterpillar
Safflower	Armyworm Loopers Saltmarsh caterpillar
Small grains (Barley, Oats Rye, Wheat, etc.)	Armyworm Loopers
Sorghum	European corn borer Fall armyworm Saltmarsh caterpillar Velvetbean caterpillar
Soybeans	Green cloverworm Soybean Looper Velvetbean caterpillar
Sunflowers	Banded sunflower moth Beet armyworm Headmoth Loopers Sunflower Moth
Tobacco	Tobacco budworm Tobacco hornworm Loopers

Rate/Acre: 1.0 - 2.0 pounds

- * Use of Lepinox WDG in integrated pest management programs:
- Lepinox WDG can be used alone to control light to moderate populations of newly hatched worms at the rates specified above. Repeat treatments at four to five day intervals or as long as necessary until results are acceptable. A banded application can be applied at 0.5 lb/acre.
 - For control of bollworm and tobacco budworm, Lepinox WDG can be mixed with conventional chemicals, such as carbamates, organophosphates, pyrethroid, or spinosads, in accordance with the more restrictive of label limitations and precautions. No label dosage rates should be exceeded. The product cannot be mixed with any product containing a label prohibition against such mixing.
 - Treat only 1st and 2nd instar larvae 1/4" or less in length.
 - For ground applications, use a minimum of 5 gallons of water per acre. For aerial applications, use a minimum of 3 gallons of water per acre.
 - Short residual contact action materials may be tank mixed with Lepinox WDG to control secondary pests such as boll weevil, aphid, and lygus bugs.

- Under low level infestations (less than 5% insect or egg infestation per acre), Lepinox WDG can be used at 0.25 pounds per acre alone or in combination with foliar fertilizers or other approved applications.

** For ground applications, use a minimum of 5 gallons of water per acre. For aerial applications, use a minimum of 3 gallons of water per acre.

VI. COMMERCIAL FLOWERS AND ORNAMENTAL PLANTS

Crop such as:	Insect Pest
Bedding plants Flowers (Greenhouse and Field) Greenhouse ornamentals Greenhouse vegetables Container stock	Armyworm Azalea moth Beet armyworm Diamondback moth Ello moth (hornworm) Florida fern caterpillar Loopers Oleander moth Omnivorous leafroller Omnivorous looper Tobacco budworm lo moth

Rates/Acre: 1.0 - 2.0 pounds

VII. FOREST, SHADE TREES, AND NURSERY STOCK

Crops such as:	Insect Pest
Forest trees Shade trees Nursery trees	Bagworm Blackheaded budworm Browntail moth California oakworm Douglas fir tussock moth Elm spanworm Fall webworm Fruitree leafroller Greenstriped mapleworm Gypsy moth Jack pine budworm Mimosa webworm Pine butterfly Redhumped caterpillar Saddleback caterpillar Saddle prominent caterpillar Spring & Fall Cankerworm Spruce budworm Tent caterpillar Tortrix Western tussock moth

Rate/Acre: 1.0 - 2.0 pounds

VIII. TURF

Crop such as:	Insect Pest
Turf	Armyworms Fall armyworm Sod webworm Tropical sod webworm

Rate/Acre: 1.0 - 2.0 pounds

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place inaccessible to children.

Pesticide Disposal: Do not contaminate water when disposing of equipment washwaters. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY

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 in strict accordance with directions given herein. **NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.**

Lepinox is a registered trademark of Certis USA
U.S. Patent No. 5080897, 5441884, 5650308, 5776447, 5843744
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NOTIFICATION

Date Reviewed: 11/03/09

Reviewed By: MKA

11/03/09