

70051-92

06/30/2004

1/11

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0080, Approval expires 2-28-95



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 70051-92	2. EPA Product Manager /Branch Chief Mr. Dennis Szuhay	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Lepinox XL WDG	PM# Microbial Pesticides Branch	
5. Name and Address of Applicant (Include ZIP Code) Certis USA, L.L.C. 9145 Guilford Road, Suite 175 Columbia, Maryland 21046 <input type="checkbox"/> Check if this is a new address	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

NOTIFICATION

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Approved By: <i>[Signature]</i>
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Date Reviewed: *6-30-04*

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

Notification to revise descriptive language under product name to read "Biological Insecticide". Three copies of final printed labeling are also included in this submission. 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.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
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		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 5 lbs. and 20 lbs.		5. Location of Label Directions <input checked="" type="checkbox"/> on bag	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> 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 Director of Regulatory Affairs	Telephone No. (Include Area Code) 301-483-3806
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.		6. Date Application Received (Stamped)
2. Signature <i>Christine A. Dively</i>	3. Title Director of Regulatory Affairs	
4. Typed Name Christine A. Dively	5. Date <i>June 2, 2004</i>	

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

June 2, 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 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 changes (Notifications) into the labeling for the following products:

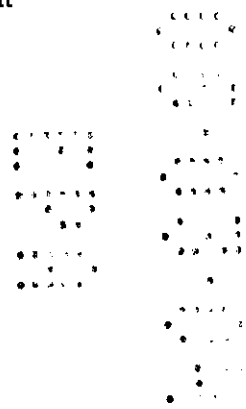
- 1) Spod-X LC, EPA Reg. No. 70051-46
- 2) Agree, EPA Reg. No. 70051-47
- 3) CLV LC, EPA Reg. No. 70051-41
- 4) Thuricide HPWP, EPA Reg. No. 70051-53
- 5) San 420 I Technical Concentrate, EPA Reg. No. 70051-70
- 6) Lepinox XL WDG, EPA Reg. No. 70051-92
- 7) Lepinox XL OF, EPA Reg. No. 70051-94
- 8) Javelin WG 2, EPA Reg. No. 70051-98
- 9) Agree 50 WP, EPA Reg. No. 70051-99

Enclosed in support of this action are: form 8570-1 and 3 copies of each final printed label with changes incorporated. No other changes have been made to these labels. Thank you for your assistance in this matter. 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
Director of Regulatory Affairs

Enclosures



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Lepinox® XL WDG BIOLOGICAL INSECTICIDE

LEPINOX® XL WDG water-dispersible granule insecticide is for the control of lepidopterous pests.

Active Ingredient:

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

Cry1Aa, Cry1Ac, Cry1Ac/1F, Cry2A*31.00%

Other Ingredients:69.00%

TOTAL100.00%

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

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.)

NOTIFICATION

Date Reviewed: 6-30-04
Reviewed By: [Signature]

EPA REG. No. 70051-92
EPA EST No. 62171-MS-001

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

Net Contents:
5 Pounds and 20 U.S. Pound Bags

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. 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. Hot Line Number: 1-800-255-3924.

**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
- 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
- Waterproof gloves

Follow 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

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 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.

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, shoes plus socks and protective eyewear.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to the uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Do not enter treated areas without protective clothing until sprays have dried.

Preharvest Interval: LEPINOX XL 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: LEPINOX XL WDG contains a mixture of lepidopteran toxic proteins. The primary active components are Cry1Ac/1F chimeric, Cry1Ac and Cry2A proteins. After consuming a lethal dose of LEPINOX XL WDG, larvae will cease to feed, but may remain alive on foliage for several days before disappearing. Immediately after ingestion of LEPINOX XL WDG, larvae begin to move slowly, become discolored, shrivel and blacken prior to death.

MIXING INSTRUCTIONS

LEPINOX XL 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. To obtain a suitable mixture with water, add enough water to allow maximum agitation. With agitator running, slowly add in the LEPINOX XL WDG. Continue agitation. Add remainder of water and other spray materials and agitate until mixed. When more than one product is being added to the spray mix, always add LEPINOX XL WDG first. Maintain suspension while loading and spraying. Do not mix more LEPINOX XL 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 rates in the APPLICATION RATE TABLE.

APPLICATION INSTRUCTIONS

LEPINOX XL WDG is an insecticide for use against the lepidopterous larvae listed in the APPLICATION RATE TABLE. Larvae must consume deposits of LEPINOX XL 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, use directed drop nozzles for certain vegetable crops.
- For ground applications, use a spray volume of at least 20 gallons of water per acre. For aerial applications, use a spray volume of at least 5 gallons of water per acre. (See cotton and soybeans for special instructions.)
- For orchard applications, use a spray volume of 100 gallons per acre and treat each orchard row.
- Do not use screens smaller than 50 mesh.
- 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.
- Repeat applications at an interval sufficient to maintain control, depending upon plant growth, insect pressure and weather conditions after spraying.
- For crops such as Fruits, Nuts and Vines, applications are often timed to stage of development and recommendations from local Extension personnel should always be followed.
- Local conditions may affect the use of LEPINOX XL WDG. Consult your State Agricultural Extension Specialist for specific recommendations related to local crop protection problems.
- Do not allow spray water/spray tank solutions to exceed pH 8.0. If necessary, buffer water to near neutral pH.

HAND-HELD EQUIPMENT

When using hand-held equipment, mix 2 teaspoons per gallon of water or 1.5 pounds per 100 gallons of spray solution. Spray to wet, but not to runoff.

TANK-MIX

Combinations of LEPINOX XL WDG with commonly used insecticides, fungicides or other spray tank adjuvants are generally not deleterious to performance. Test physical compatibility by mixing all components in a small container in proportionate quantities prior to mixing in spray tank. When more than one product is being added to the spray mix, always add LEPINOX XL WDG first. This product cannot be mixed with any product containing a label prohibition against such mixing. Do not exceed label dosage rates. Application must be made in accordance with the more restrictive of label limitations and precautions.

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

CHEMIGATION

Apply this product only through center pivot, lateral move, end tow, side (wheel) roll, traveler, big gun, solid set or hand move sprinkler 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 your 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.

CHEMIGATION SYSTEMS CONNECTED TO PUBLIC WATER SYSTEMS:

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.

Chemigation systems connected to public water systems must contain a functional, reduced pressure zone (RPZ), backflow preventer 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 of fluid back toward the injection pump.

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.

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

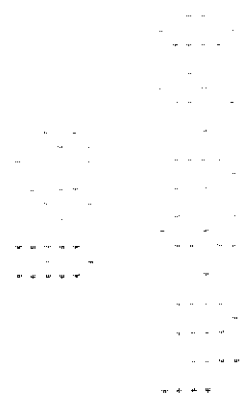
The active ingredient in LEPINOX XL WDG will settle in the tank and injection lines; adequate agitation must be provided before and during the injection period. Use only is systems that apply uniformly and have appropriate check valves. When application is complete, thoroughly flush the injection system and sprinkler lines.

MIXING RATES FOR CHEMIGATION:

Follow general MIXING INSTRUCTIONS and keep the ratio at three parts water to one part LEPINOX XL WDG. Also, provide mild uniform agitation throughout the suspension but do not agitate excessively.

SPRAY VOLUME:

For chemigation, use irrigation levels of 0.15 to 0.5 inches of water per acre. Up to 1.0 inch of irrigation water may be used, but efficacy may be reduced. The product should be applied continuously for the duration of the water application.



APPLICATION RATE TABLE

I. VEGETABLES (Fresh and Processed)

Crops:	Insect Pest
Asparagus	Armyworm
Beans	Beet armyworm
Beets	Cabbage looper
Celery	Corn earworm
Chick peas	European corn borer
Cucumber	Fall armyworm
Cucurbits	Melonworm
Leeks	Omnivorous leafroller
Lentils	Pickleworm
Melons (Cantaloupe, Crenshaw, Honeydew, Muskmelon, Watermelon, etc.)	Rindworm
Okra	Tobacco budworm
Parsley	Yellowstriped armyworm
Peas	
Pumpkins	
Soybean foliage	
Spinach	
Squash	
Sugar beets	
Tomatoes	

Rate/Acre: 0.5-1.5 pounds

II. PASTURE AND HAY CROPS

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

Rate/Acre: 0.5-1.5 pounds

*Apply product when early instar larvae first appear. If infestation persists, make a second application 7-10 days later. Combination of LEPINOX XL WDG with a contact insecticide can be used for control of 4th and 5th instar larvae.

III. TURF

Crops:	Insect Pest
Turf	Armyworm
	Fall armyworm
	Sod webworm
	Tropical sod webworm

Rate/Acre: 0.5-1.5 pounds

IV. FIELD, NUT & VINE CROPS

Crops:	Insect Pest
Pome & Stone Fruit Trees: Apples Apricots Cherries Nectarines Peaches Pears Plums Prunes Quince	Cankermoth (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
Citrus	Amorbia Citrus cutworm Fruittree leafroller Omnivorous leafroller Orangedog
Grapes	Grape berry moth Cherry fruitworm Grape leafroller Grapeleaf skeletonizer Green fruitworm Omnivorous leafroller Orange tortrix Saltmarsh caterpillar Yellowstriped armyworm

Rate/Acre: 0.5-1.5 pounds

V. FIELD CROPS

Crops:	Insect Pest
Corn (Field, Sweet, Popcorn, Seed)	Armyworm European corn borer Fall armyworm Southwestern corn borer
Cotton*	Bollworm Cabbage looper Cotton leaf perforator Fall armyworm Saltmarsh caterpillar Soybean looper Tobacco budworm
Peanuts	Fall armyworm Green Cloverworm Loopers Podworm Rednecked peanut worm Velvetbean caterpillar
Small Grains (Barley, Oats, Rye, Wheat, etc.)	Armyworm Loopers Fall armyworm
Sorghum	European corn borer Fall armyworm Headworm Saltmarsh caterpillar Velvetbean caterpillar
Soybeans**	Fall armyworm Green Cloverworm Podworm Soybean looper Velvetbean caterpillar
Tobacco	Loopers Tobacco budworm Tobacco hornworm

Rate/Acre: 0.5-1.5 pounds

Cotton

* Use of Lepinox XL WDG in integrated pest management programs:

- Lepinox XL WDG can be used alone to control light to moderate populations of newly hatched worms at the rates specified above, depending on insect pressure. Repeat treatments at 4 to 5 day intervals or as long as necessary until results are acceptable. Banded applications can be applied at 0.25 to 0.5 lb/acre pre-bloom.
- For control of bollworm and tobacco budworm, Lepinox XL WDG can be mixed with conventional chemicals, such as carbamates, organophosphates, pyrethroids, or spinosads, in accordance with the more restrictive of label limitations and precautions. Do not exceed label dosage rates. This 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. Increasing total spray volume per acre will improve coverage and product performance.



- Short residual contact materials may be tank mixed with Lepinox XL WDG to control secondary pests such as boll weevil, aphids, and lygus bugs.
- Under low level infestations (less than 5% insect or eggs per acre), Lepinox XL WDG can be used at 0.25 pounds per acre alone or in combination with foliar fertilizers or other approved applications.

Soybeans

** 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. Increasing total spray volume per acre will improve coverage and product performance.

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: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Disposal: Completely empty bag into application equipment. Then 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 not in strict accordance with directions given herein. **NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.**

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