



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 70051-94	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 OF	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 _____	

NOTIFICATION
Date Reviewed: 6/30/04
Reviewed By: [Signature]

Section - II

<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" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

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	Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper Other (Specify) _____		
Certification must submitted		If "Yes" Unit Packaging wgt. No. per container			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2.5 Gallons		5. Location of Label Directions <input checked="" type="checkbox"/> on container	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph 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 June 2, 2004	

LEPINOX® XL OF Biological Insecticide

LEPINOX® XL OF is a biological insecticide for the control of lepidopterous pests.

Active Ingredient:

Bacillus thuringiensis subspecies *kurstaki* strain EG7826 solids, spores, and Lepidopteran active toxins 25.00%

Other Ingredients: 75.00%

TOTAL 100.00%

2.0 lbs. active ingredient per gallon.

*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.)

EPA REG. No. 70051-94
EPA EST No. 62171-MS-001

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

Net Contents:
2.5 U.S. Gallons

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

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.
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 swallowed: Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.

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.

NOTE TO PHYSICIAN: Contains petroleum distillate- vomiting may cause aspiration pneumonia.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING:**

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles, faceshield, or safety glasses). Harmful if absorbed through skin. Avoid contact

with skin, eyes or clothing. 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 washwaters 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.

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 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, protective eyewear, shoes plus socks.

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 OF 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® XL OF, larvae will cease to feed, but may remain alive on foliage for several days before disappearing. Immediately after ingestion of LEPINOX® XL OF, larvae begin to move slowly, become discolored, shrivel and blacken prior to death.

MIXING INSTRUCTIONS

LEPINOX® XL OF 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® XL OF. Continue agitation. Add remainder of water and other spray materials and agitate until mixed. For best results, shake container well, empty 1/2 of contents, reshake. Mix Lepinox® XL OF well and never add before introducing water into the tank. If a sticker approved for use on growing crops is to be used, add after the addition of Lepinox® XL OF. Maintain suspension while loading and spraying. Do not mix more LEPINOX® XL OF than can be used in a 24-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 OF is a bioinsecticide for use against the lepidopteran larvae listed in the APPLICATION RATE TABLE. Larvae must consume deposits of LEPINOX® XL OF 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.
- 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 minimum spray volume of 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.
- Repeat applications 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® XL OF. 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.

TANK-MIX

Lepinox® XL OF may be tank mixed with contact pesticides. Combinations of LEPINOX® XL OF with commonly used insecticides, fungicides or other spray tank adjuvants are generally not deleterious to performance (see TANK MIX PRECAUTIONS). Test physical compatibility by mixing all components in a small container in proportionate quantities prior to mixing in spray tank. 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.

TANK MIX PRECAUTIONS

- Use caution when mixing Lepinox® XL OF with other oil based products or surfactants approved for use on growing crops as such combinations could increase the risk of phytotoxicity. If unsure, test on a small area first.
- If any phytotoxicity occurs, discontinue use immediately.

APPLICATION RATE TABLE

I. PASTURE AND HAY CROPS

Crops:	Insect Pest	Rate/acre
Alfalfa (hay & seed)	Insect Pest	
Pasture (grasses & hay)	Alfalfa caterpillar	1/2-1 pint
Silage	Armyworms	3/4-2 pints
	European skipper	3/4-2 pints
	Fall armyworm	3/4-2 pints
	Loopers	3/4-2 pints
	Webworm	3/4-2 pints
	Fall armyworm*	3/4-2 pints

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

II. FRUIT AND NUT CROPS

Crops:	Insect Pest	Rate/Acre
Pome & Stone Fruit Trees: Apples Apricots Cherries Nectarines Peaches Pears Plums Prunes Quince	Cankerworm (Spring & Fall) Eastern tent caterpillar Fall webworm Fruittree leafroller Gypsy moth Navel orangeworm Omnivorous leafroller Oriental fruit moth Peach twig borer Redbanded leafroller Redhumped caterpillar Tortrix moth (Orange & Garden) Tufted apple Budmoth Variegated leafroller Walnut caterpillar	1-2 pints
Nut Trees: Almond Chestnuts Filberts Pecans Walnuts	Citrus cutworm Filbert leafroller Filbert webworm Navel orangeworm Obliquebanded leafroller Peach twig borer Roughskinned cutworm	1-2 pints
Citrus	Amorbia Citrus cutworm Fruittree leafroller Orangedog	1-2 pints
Small Fruit and Berries: Blackberries Blueberries Cranberries Currants Raspberries Strawberries	Achema sphinx moth Armyworms Blueberry leafroller Fruittree leafroller Grape berry moth Gypsy moth Loopers Oblique banded leafroller Tobacco budworm	1-2 pints

III. FIELD CROPS

Crops:	Insect Pest	Rate/Acre
Cotton*	Beet armyworm Cabbage looper Cotton Bollworm Cotton leaf perforator	1-2 pints 1-2 pints ¼-2 pints ½-1 pint

	Fall armyworm	1-2 pints
	Saltmarsh caterpillar	½-1 pint
	Soybean looper	1-1 ½ pints
	Tobacco budworm	¼-2 pints
	Yellowstriped armyworm	1-2 pints
Peanuts	Fall armyworm	1-2 pints
	Green Cloverworm	½-1 pint
	Loopers	1-1 ½ pints
	Podworms	1-2 pints
	Velvetbean caterpillar	½-1 pint
Sorghum	European corn borer	1 pint
	Fall armyworm	1-2 pints
	Saltmarsh caterpillar	1 pint
	Velvetbean caterpillar	½-1 pint
Soybeans**	Green Cloverworm	½-1 pint
	Soybean looper	1-1 ½ pints
	Velvetbean caterpillar	½-1 pint
Tobacco	Tobacco budworm	1-2 pints
	Tobacco hornworm	½-1 pint
	Loopers	1-2 pints

* Use of LEPINOX® XL OF in integrated pest management programs:

- LEPINOX® XL OF can be used alone to control light to moderate populations of newly hatched worms at the rates specified above. Repeat treatments at 4 to 5 day intervals or as long as necessary until results are acceptable.
- For early season control of cotton bollworm and tobacco budworm, LEPINOX® XL OF can be mixed with an ovicide for control of first generation worms. For mid- to late-season control, Lepinox® XL OF can be mixed with a conventional chemical, such as a synthetic pyrethroid, 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, as 3rd, 4th, and 5th instar larvae tend to feed in squares and bolls and will not be exposed to Lepinox® XL OF.
- For ground applications, use a minimum of 5 gallons of water per acre. For aerial applications, use a minimum of 2 gallons of water per acre.
- Short residual contact materials may be tank mixed with LEPINOX® XL OF to control secondary pests such as boll weevil.
- Under low level infestations (less than 5% insect or egg infestation per acre), LEPINOX® XL OF can be used at 2 fluid ounces 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 2 gallons of water per acre.

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: 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 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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