

70051-86

9/26/2013

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



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Susan Gallager
Regulatory Affairs Associate, Certis USA
9145 Guilford Road, Suite 175
Columbia, Maryland 21046

SEP 26 2013

RE: Product Name: Crymax® Bioinsecticide
EPA Reg. No: 70051-86
Decision No: D482893
Application for September 4, 2013
Notification Date:

Dear Ms. Gallager:

The Biopesticides and Pollution Prevention Division has received your application for Notification under PR Notice 98-10; we have determined that this action falls within the scope of this Notice. Our records have been duly noted, and an updated stamped label reflecting the following changes will be placed in the registration jacket and uploaded to the Agency's Pesticide Product Label System.

- ① An updated Establishment No (changed from 62171-MS-001 to 70051-CA-001); and
- ② A revised Warranty Statement to include the phrase "to the extent consistent with applicable law."

A stamped copy of the label is enclosed for your records. If you have any questions regarding this letter, please contact Kathleen Martin of my staff (martin.kathleen@epa.gov; 703-308-2857).

Sincerely,

Kimberly Nesci, Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division

Enclosure: Cymax® Bioinsecticide Stamped Label



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 70051-86	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CRYMAX	PM# Microbial Pesticides Branch	
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)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

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 of Change in Warranty Statement per PR Notice 98-10.

Please see attached Certification Statement.

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	If "Yes" Unit Packaging wgt. No. per 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" Package wgt	No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 5 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input checked="" type="checkbox"/> Other <u>pre-printed bag</u>		

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 Dir. 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 Sep 3, 2013	

CERTIS

Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046

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(301) 604-7340

Fax: 301-604-7015

www.certisusa.com

Hand Delivered

September 4, 2013

Document Process Desk (NOTIF)
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7540P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: Certis USA L.L.C. (EPA Company No. 70051)
Notification of change in Warranty/Establishment No. per PR Notice 98-10
Product: CRYMAX (EPA Reg. No. 70051-86)

On behalf of Certis USA, L.L.C., I am respectfully submitting a Notification to make minor modifications to the label of the registered pesticide product Crymax (EPA Reg. No. 70051-86) per PR Notice 98-10. The only changes that have been made to this label are the following:

- The Establishment No. has been updated to reflect the current establishment where this product is being produced
- The Warranty statement has been revised to include the phrase "To the extent consistent with applicable law"

No other changes have been made to this label. Included with this submission to support this Notification is the following documents:

- EPA Form 8570-1, with attached Certification Statement
- Crymax label, highlighted to show revisions
- Crymax label, clean copy

Please do not hesitate to contact me if you have any questions about this submission. I can be reached by telephone at 301-483-3810 or by email at sgallager@certisusa.com.

Sincerely,


Susan Gallager
Regulatory Affairs Associate

CC: Christine A. Dively
Director of Regulatory Affairs

Notification Accepted

Date: September 26, 2013

Reviewer: Kathleen Martin
MicroBial Products Branch

Crymax®

BIOINSECTICIDE

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Crymax® WDG water dispersible granule bioinsecticide is a biological insecticide for the control of lepidopteran pests

Active Ingredient:

<i>Bacillus thuringiensis</i> subspecies <i>kurstaki</i> strain EG7841 solids, spores and Lepidopteran active toxins*	40.0%
Other Ingredients:	60.0%
Total	100.0%

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

Net Contents:
5 U.S. Pound Bag

EPA Reg No. 70051-86
EPA Est No. 70051-CA-001
Lot No.
Manufactured by:
Certis USA L.L.C.
9145 Guilford Road
Suite 175
Columbia, MD 21046

KEEP OUT OF REACH OF CHILDREN

CAUTION

CERTIS

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

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.

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.

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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. Do not contaminate water when disposing of equipment washwaters. This product must not be applied aerially within ¼ mile of any habitats of endangered or threatened Lepidoptera. No manual application can be made within 300 ft. of any threatened or endangered Lepidoptera.

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 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.

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

MIXING INSTRUCTIONS

CRYMAX 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 CRYMAX. Continue agitation. Add remainder of water and other spray materials and agitate until mixed. Maintain suspension while loading and spraying. Do not mix more CRYMAX 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 recommendations in the APPLICATION RATE TABLE.

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APPLICATION INSTRUCTIONS

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.

CRYMAX is a biological insecticide for use against the lepidopteran larvae listed in the APPLICATION RATE TABLE. Larvae must consume deposits of CRYMAX 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 CRYMAX. 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 2 teaspoons per gallon of water or 1-½ pounds per 100 gallons of spray solution. Spray to wet, but not to runoff.

TANK MIX

CRYMAX may be tank mixed with contact pesticides. Combinations of CRYMAX 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 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. No label dosage rate should be exceeded. Application must be made in accordance with the more restrictive of label limitation 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

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I. VEGETABLE AND COLE CROPS		
Crop:		Insect Pest
Artichokes	Kohlrabi	Alfalfa looper
Arugala	Leeks	Armyworm*
Asparagus	Lentils	Artichoke plume moth
Beans	Lettuce (Head, Leaf, Romaine)	Beet armyworm*
Beets	Malanga	Cabbage budworm
Bok Choy	Melons (Cantaloupe, Crenshaw, Honeydew, Muskmelon, Watermelon, etc.)	Cabbage looper
Broccoli	Napa	Celery leaf-tier
Brussels sprouts	Okra	Corn earworm
Cabbage	Olives	Cross-striped cabbageworm
Cardoni	Onions	Diamondback moth**
Carrots	Parsley	European corn borer
Cauliflower	Parsnips	European Grapevine moth
Celeriac	Peas	Green cloverworm
Celery	Peppers	Imported cabbageworm
Chick peas	Potatoes	Light brown apple moth***
Chicory	Pumpkins	Melonworm
Chinese cabbage	Radishes	Omnivorous leafroller
Collards	Rutabaga	Pickleworm
Cucumber	Salsify	Rindworm complex
Cucurbits	Shallots	Saltmarsh caterpillar
Dry bulb onions	Soybean foliage	Soybean looper
Eggplants	Spinach	Tobacco budworm
Escarole	Squash	Tomato fruitworm
Endive	Sugar Beets	Tomato hornworm
Garlic	Sweet potatoes	Tomato pinworm
Green onions	Swiss Chard	Velvetbean caterpillar
Greens: Beets, China, Dandelion, Mustard, Turnip	Tomatoes	Yellowstriped armyworm*
Horseradish	Turnips	
Kale		
Rate/Acre: 0.5-2.0 pounds		
* Recommended rate is 1.0-1.5 pounds/acre unless tank-mixed with contact insecticide.		
** CRYMAX will control Bt resistant and susceptible diamondback moth.		
*** All crops		

II. HERBS AND SPICES	
Crop:	Insect Pest
Basil	Alfalfa looper
Chives	Armyworm
Cilantro	Diamondback moth
Dill	European corn borer
Oregano	Green cloverworm
Peppermint	Imported cabbageworm
Thyme	Loopers
	Saltmarsh caterpillar
Rate/Acre: 0.5-2.0 pounds	

III. PASTURE AND HAY CROPS	
Crop:	Insect Pest
Alfalfa (hay & seed)	Alfalfa caterpillar
Pasture (grasses & hay)	Armyworm
Silage	Beet Armyworm*
	European skipper
	Loopers*
	Webworm
	Yellowstriped armyworm*
Rate/Acre: 0.5-2.0 pounds	
* Product should be applied when early instar larvae first appear. If infestation persists, make a second application 7-10 days later. Combination of CRYMAX with contact insecticide is recommended for control of 4 th and 5 th instar larvae.	

IV. FRUIT, NUT AND VINE CROPS		
Crop:	Insect Pest	
Pome and Stone Fruit Trees:		
Apples	Cankerworm (Spring and Fall)	Oriental fruit moth
Apricots	Cherry fruitworm	Pandemis leafroller
Cherries	Eastern tent caterpillar	Peach twig borer
Nectarines	European grapevine moth*	Redbanded leafroller
Peaches	Fall webworm	Redhumped caterpillar
		Tortrix moth (Orange and Garden)
Pears	Fruittree leafroller	Tufted apple budmoth
Plums	Green fruitworm	Variegated leafroller
Prunes	Gypsy moth	Walnut caterpillar
Quince	Navel orangeworm	Western tent caterpillar
	Obliquebanded leafroller	
	Omnivorous leafroller	
Nut Trees:		
Almonds	Citrus cutworm	Omnivorous leafroller
Chestnuts	European grapevine moth*	Pecan nut casebearer
Filberts	Filbert leafroller	Peach twig borer
Pecans	Filbert webworm	Redhumped caterpillar
Pistachios	Fruittree leafroller	Roughskinned cutworm
Walnuts	Hickory shuckworm	Western tent caterpillar
	Navel orangeworm	
	Obliquebanded leafroller	
Citrus		
	Amorbia	Omnivorous leafroller
	Citrus cutworm	Orangedog
	Fruittree leafroller	
Small Fruit and Berries:		
Blackberries		Gypsy moth
Blueberries	Achema sphinx moth	Loopers
Boysenberries	Armyworms	Obliquebanded leafroller
Cranberries	Blackheaded fireworm	Omnivorous looper
Currants	Blueberry leafroller	Tobacco budworm
Longanberries	Cranberry girdler	
Raspberries	European grapevine moth*	
Strawberries	Fruittree leafroller	
	Grape berry moth	
Grapes:		
	European grapevine moth*	Green fruitworm
	Grape berry moth	Omnivorous leafroller
	Cherry fruitworm	Orange tortrix
	Grape leafroller	Saltmarsh caterpillar
		Yellowstriped armyworm

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	Grapeleaf skeletonizer	
Tropical and Other Fruit:	Amorbia	Omnivorous leafroller
Avocados	Loopers	Omnivorous looper
	Orange tortrix	Spanworm
Bananas	Banana skipper	Banana moth
Kiwi	Omnivorous leafroller	
Persimmons, Pomegranate	Citrus cutworm	Omnivorous leafroller
	European grapevine moth*	Redhumped caterpillar
	Fall webworm	Tent caterpillar
	Filbert webworm	
Pineapple	Gummosos-Batrachedra commosae	Thecla-Thecla basilides
Tropical fruits/	European grapevine moth*	Loopers
Subtropical fruits, Avocado,	Hornworms	Omnivorous leafroller
Guava, Lychee, Sugar Apple	Leafrollers	

Rate/Acre: 0.5-2.0 pounds

*Apply at blackhead egg stage or when larvae are newly hatched before leaves are rolled or larvae have entered fruit. Continue applications as necessary for larval control.

V. FIELD CROPS

Crop:	Insect Pest	
Canola/Rape Seed	Armyworm	Imported cabbageworm
Evening Primrose	Diamondback moth	Loopers
Meadow foam		
Corn	Armyworm	
(Field, Sweet, Popcorn, Seed)	European corn borer	
	Southwestern corn borer	
Cotton*	Beet armyworm**	Saltmarsh caterpillar
	Bollworm**	Soybean looper
	Cabbage looper	Tobacco budworm
	Cotton leaf perforator	Yellowstriped armyworm**
Hops	Armyworm	Omnivorous leaftier
	Loopers	Spotted cutworm
	Oblique banded leafroller	
Jojoba	Looper (<i>Anacamptodes</i> spp.)	
Peanuts	Green cloverworm	Podworms
	Loopers	Velvetbean caterpillar
Rice	Armyworm	Saltmarsh caterpillar
	Green cloverworm	Velvetbean caterpillar
	Loopers	
Safflower	Armyworm**	Saltmarsh caterpillar
	Loopers	
Small Grains	Armyworm**	

(Barley, Oats, Rye, Wheat, etc.)	Loopers	
Sorghum	European corn borer 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	
Coffee	Banana moth	

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Rate/Acre: 0.5-2.0 pounds

*Use CRYMAX at 0.25 lb/acre to control light to moderate populations of newly hatched tobacco budworm and bollworm in integrated pest management programs. Repeat treatments at four to five day intervals or as long as necessary until results are acceptable. Ovicides or synthetic pyrethroids can be combined with CRYMAX in accordance with the more restrictive of label limitations and precautions. No label dosage rates should be exceeded. This product cannot be mixed with any product containing a label prohibition against such mixing.

**Combination of CRYMAX with a contact insecticide is recommended for infestations that include 4th and 5th instar larvae.

VI. COMMERCIAL FLOWERS AND ORNAMENTAL PLANTS

Crop:	Insect Pest	
Bedding plants	Armyworm	lo moth
Flowers (Greenhouse and Field)	Azalea moth	Loopers
Greenhouse Ornamentals	Beet armyworm	Oleander moth
Greenhouse Vegetables	Diamondback moth	Omnivorous leafroller
Container Stock	Ello moth (hornworm) European Grapevine moth* Florida fern caterpillar	Omnivorous looper Tobacco budworm

Rate/Acre: 1.0-2.0 pounds

*Apply at blackhead egg stage or when larvae are newly hatched before leaves are rolled or larvae have entered fruit. Continue applications as necessary for larval control.

VII. FOREST, SHADE TREE AND NURSERY STOCK

Crop:	Insect Pest	
Forest	Bagworm	Pine butterfly
Shade trees	Blackheaded budworm	Redhumped caterpillar
Nursery trees	Browntail moth California oakworm Douglas fir tussock moth Elm spanworm Fall webworm Fruittree leafroller Greenstriped mapleworm	Saddleback caterpillar Saddle prominent caterpillar Spring and Fall cankerworm Spruce budworm Tent caterpillar Tortrix Western tussock moth

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	Gypsy moth	
	Jack pine budworm	
	Mimosa webworm	
Rate/Acre: 0.5-2.0 pounds		

VIII. TURF		
Crop such as:	Insect Pest	
Turf	Armyworms	Tropical sod webworm
	Sod webworm	
Rate/Acre: 0.5-2.0 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: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: 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. To the extent consistent with applicable law, 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.

Crymax is a trademark of Certis USA
 U.S. Patent No. 5441884, 5650308, 5776449, 5843744
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