

70051-52

06/16/2004

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Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other *NOTIFICATION*

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 70051-52	2. EPA Product Manager / Branch Chief Dennis Szuhay	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Thuricide HPC	PM# Microbial Pesticides Branch	
5. Name and Address of Applicant (Include ZIP Code) Certis USA, 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 to revise the heading over the warranty statement to read "Warranty" instead of "Conditions of Sale and Warranty" to be consistent with other Certis USA, L.L.C. product labels. Also removed the statement "IMPORTANT: Read the entire Directions for Use and the Conditions of Sale and Warranty before using this product. If terms are not acceptable, return the unopened product container at once." Also added descriptive language "Biological Insecticide" under product name to be consistent with other Certis USA, L.L.C. Bt products. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Three copies of final printed labeling are also included in this submission.

### Section - III

1. Material This Product Will Be Packaged In:				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
<i>Certification must be submitted</i>		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 53 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 <input 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
<b>Certification</b> 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>April 5, 2004</i>	

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# Thuricide HPC

## HIGH POTENCY AQUEOUS CONCENTRATE

For control of insect pests in vegetables, fruits, nuts, field crops, shade trees, ornamentals and forests.

### ACTIVE INGREDIENT:

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

(at least 6 million viable spores per milligram)\*.....15.0%

INERT INGREDIENTS:.....85.0%

TOTAL:.....100.0%

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

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

EPA Reg. No.: 70051-52  
EPA Est No.: 70051-CA-001

Net Contents: 53 gallons (200L)  
Lot Number: \_\_\_\_\_

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

NOTIFICATION  
Date Reviewed: 6-16-04  
Reviewed By: [Signature]

### Precautionary Statements

#### Hazards to Humans and Domestic Animals

Harmful if swallowed or inhaled. Avoid breathing vapors or spray mist. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Apply this product only as specified on this label.

#### FIRST AID

**If inhaled:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

**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 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.

### **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 through any type of irrigation system.

Thorough coverage is essential when using Thuricide HPC Concentrate.

#### **Personal Protective Equipment:**

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks
- Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, and P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### **Engineering Controls Statements:**

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

#### **User Safety Recommendation:**

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing 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.

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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 interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- coveralls
- waterproof gloves
- shoes plus socks

**GENERAL**

Apply at first sign of infestation when worms are small and repeat at weekly intervals as needed to maintain control. Thuricide HPC attacks the larval gut and must be eaten by the insect to be effective. Thorough underleaf coverage is, therefore, essential for best results. After eating Thuricide HPC, worms stop feeding and die within 2-3 days. Since the active ingredient, *Bacillus thuringiensis*, is exempt from tolerance requirements, Thuricide HPC may be applied up to the day of harvest.

**MIXING**

Always shake or stir Thuricide HPC thoroughly before use. Pour application rate amount of Thuricide HPC onto the surface of water in a nearly filled spray tank. Maintain agitation. Use the higher rates against very heavy worm infestations or where it is difficult to get good coverage due to rank foliage. Do not allow dilute sprays to stand in the tank for more than 12 hours. Combinations with chemical insecticides, fungicides, spreader-stickers, and stickers in the tank are generally not deleterious to Thuricide HPC if the mix is used promptly.

**GROUND APPLICATION**

Use application rate amount of Thuricide HPC in a minimum of 5 to 50 gallons of water, depending on the type of crop and requirements of state regulations. Add a sticker, adhesive or deposit builder where heavy dew or rain is encountered.

**GROUND APPLICATION, TREES**

Use application rate amount of Thuricide HPC in 100 gallons of water in high pressure, high gallonage, hydraulic sprayers. Wet foliage thoroughly with spray but not to the point of excessive runoff. For mist blowers use application rate amount in 10 gallons of water. To prevent washoff by rain add a sticker to the finished spray.

**AERIAL APPLICATION**

Use application rate amount of Thuricide HPC in 5 to 20 gallons of water. A sticker should be added under conditions of heavy dew or rain. Apply early morning or evening when the air is calm.

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

Crop	Pest	Quarts per acre
ALFALFA	Alfalfa Caterpillar	1/4
ALMONDS <sup>1</sup>	Redhumped Caterpillar	1 - 2
ALMONDS <sup>1</sup> , CHERRIES <sup>1</sup> Apply when caterpillars are actively feeding (2nd - 4th instar).	Tent Caterpillar	1 - 2
APPLES <sup>1</sup> , PEARS <sup>1</sup> Apply when eggs or newly hatched larvae first appear. Continue applying as a part of the normal cover spray program until pest is adequately controlled.	Redbanded Leafroller, Tufted Apple Budmoth, Variegated Leafroller, Tent Caterpillar, Fruit Tree Leafroller, Gypsy Moth	1 - 2
BROCCOLI, BRUSSELS SPROUTS, CABBAGE, CAULIFLOWER, COLLARDS, KALE, MUSTARD GREENS, TURNIP GREENS	Diamondback Moth Imported Cabbage Worm Green Cloverworm Cabbage Looper	1/2- 1 1/2- 1 1/2 1/2- 1 1/2 1 - 2
BEANS, BEETS, CARROTS, CELERY, CHARD, CHINESE CABBAGE (Choy sum), COS LETTUCE, ENDIVE, ESCAROLE, GARLIC, KOHLRABI, LENTILS, LETTUCE, ONIONS, PARSLEY, RADISHES, SPINACH, SQUASH	Cabbage Looper	1 - 2
CUCUMBERS, MELONS Begin treatment when worms are small to avoid damage and scarring to the crop.	Cabbage Looper	1 - 2
EGGPLANT, PEPPERS	Tomato Hornworm Tomato Fruitworm <sup>2</sup> Cabbage Looper	1/2- 1 1/2 1-2

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CURRENTS, BLUEBERRIES, CANEBERRIES (BLACKBERRIES, DEWBERRIES, RASPBERRIES) Apply by ground equipment only. Begin treatment as soon as possible after hatching and before larvae are protected by leaf folds.	Omnivorous Leafroller	1-2
COTTON	Tobacco Budworm, Cotton Bollworm	1-2

For the suppression of light to moderate infestations, apply at first sign of egg laying or newly hatched worms (1st and 2nd instar larvae). Reapply at 3-5 day intervals to sustain worm suppression or until adequate reduction of worm population is achieved. Use THURICIDE HPC under a pest management program that includes close scouting. If heavy worm populations occur, it may be necessary to apply an insecticide with rapid knockdown and good larvicidal activity as a replacement. Apply from 5-15 gallons total spray per acre with ground equipment and from 2-5 gallons total spray per acre with aerial equipment.

**DIRECTIONS FOR USE OF TANK-MIX COMBINATIONS OF THURICIDE HPC AND CHLORDIMEFORM (FUNDAL<sup>3</sup> OR GALECRON<sup>4</sup> OR 4EC).\***

Crop	Insecticide	Pest	Rate per acre
COTTON	Thuricide HPC + chlordimeform SP* or chlordimeform 4EC*	Tobacco Budworm Cotton Bollworm	1/2-1 pt. + 1/8-1/4 lb. or 1/4-1/2 pt.

Use Thuricide HPC plus chlordimeform for a combined ovicide/ larvicide effect. Use the low rates for suppression of light infestations, and the high rates for suppression of moderate infestations. Apply at first sign of egg laying or newly hatched worms. Reapply at 3-5 day intervals to sustain suppression, or until adequate worm reduction is achieved. Apply from 2-5 gallons total spray per acre with aerial equipment. Follow all restrictions, safety precautions and directions contained on the FUNDAL or GALECRON labels.

**DIRECTIONS FOR USE OF TANK-MIX COMBINATIONS OF THURICIDE HPC AND ELCAR INSECTICIDE (EPA RE. NO. 55947-59) IN THE SOUTHWEST ONLY**

Crop	Insecticide	Pest	Rate per acre
COTTON	Thuricide HPC + ELCAR*	Cotton Bollworm Tobacco Budworm	1 pt. - 1 qt. + 1/16-1/8 lb.

Use Thuricide HPC in combination with ELCAR for an increased larvicide effect. Use the low rate combination for light infestations, and the high rate combination for control of moderate infestations. Apply at first sign of egg deposition or newly hatched worms, and repeat at 3-7 day intervals, as long as egg deposition continues.

\*Not registered for use in California

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Crop	Pest	Quarts per Acre
COTTON	Cabbage Looper	1 - 2
PEANUTS	Cabbage Looper Velvetbean Caterpillar Podworm <sup>2</sup>	1/2 - 1 1/2 1 - 2
POTATOES	Cabbage Looper	1 - 2
SOYBEANS	Soybean Looper Cabbage Looper, Green Cloverworm, Velvetbean Caterpillar Podworm <sup>2</sup>	1 - 1 1/2 1/2 - 1 1/2 1 - 2
SUGARBEETS	Cabbage Looper, Omnivorous Leafroller	1 - 2
TOBACCO	Cabbage Looper, Tobacco Budworm, Tobacco Hornworm	1 - 1 1/2
TOMATOES TOMATOES (CONT...)	Tomato Hornworm Cabbage Looper Tomato Fruitworm <sup>2</sup>	1/2-1 1/2 1 - 2
WATERMELONS (Florida)	Rindworm Complex	1/2-1 1/2
GRAPES Start treating as soon as possible after hatching and before larvae are protected by leaf folds. Apply by ground equipment in up to 200 gallons total spray per acre to obtain thorough coverage of leaf surfaces.	Grape Leaf Folder	1 - 2
GRAPES	Omnivorous Leafroller	1/2-1 1/2
MINT	Cabbage Looper	1 - 2
STRAWBERRIES Use 20 gallons water minimum per acre when using ground equipment and 5 gallons water minimum per acre by aircraft.	Cabbage Looper, Roughskinned Cutworm	1 - 2
SUGAR MAPLE	Spring & Fall Cankerworm, Fall Webworm, Tent Caterpillar, Gypsy Moth	1 - 2
PEACHES, NECTARINES	Redhumped Caterpillar, Tent Caterpillar, Omnivorous Leafroller	1 - 2
BANANAS (Hawaii) Use calibrated ground equipment with adequate water to apply to point of runoff.	Banana Skipper	1 - 2
ORANGES	Fruit Tree Leafroller Orange Dog	1 - 2 1/2 - 1
ORANGES Use 50 gallons water minimum to 600 gallons maximum per acre when using ground equipment,	Citrus Cutworm	1 - 2

and 10 gallons water minimum per acre by aircraft.		
FILBERTS <sup>1</sup> * Apply when caterpillars are actively feeding (2nd-4th instar.) ** Apply at 10% egg hatch.	Tent Caterpillar*, Filbert Leafroller**	1 - 2

Crop	Pest	Quarts per Acre
PECANS <sup>1</sup>	Redhumped Caterpillar, Fall Webworm, Tent Caterpillar	1 - 2
WALNUTS <sup>1</sup> Use 100 gallons water minimum per acre when using ground equipment, and 10 gallons water minimum per acre by aircraft.	Tent Caterpillar, Fall Webworm Omnivorous Leafroller Redhumped Caterpillar	1 - 2 1/4 - 1
KIWI	Omnivorous Leafroller, Fruittree Leafroller, Cabbage Looper	1 - 2
SHADE TREES, ORNAMENTALS, FOREST	Spring & Fall Cankerworm, Fall Webworm Tent Caterpillar Redhumped Caterpillar Oakmoth Larvae, Gypsy Moth	1/2 - 1 1/2 - 2 1 - 2
STORED SOYBEANS, GRAINS	Indian Meal Moth, Almond Moth	1 - 2

<sup>1</sup> To achieve adequate coverage of large trees or dense foliage, aerial application of not less than 15 gpa is preferred.

<sup>2</sup> Suppression only.

<sup>3</sup> FUNDAL 4EC (EPA Reg. No. 2139-100) Nor-Am Ag Prod., Inc.  
FUNDAL SP (EPA Reg. No. 2139-98) Nor-Am Ag Prod., Inc.

<sup>4</sup> GALECRON 4EC (EPA Reg. No. 100-551-AA) Ciba-Geigy Corp.  
GALECRON SP (EPA Reg. No. 100-554-AA) Ciba-Geigy Corp.

<sup>5</sup> Gypsy Moth: Aerial Application.

THURICIDE HPC may also be applied by air to prevent excessive defoliation by Gypsy Moth. For best results, spray when leaf expansion reaches 40% - 50%, and respray 14 days later. Use two quarts of THURICIDE HPC in 1-4 gallons finished spray per acre. Incorporate in the spray mix an evaporation retardant, such as molasses, Cargill's Insecticide Base polyethylene glycol E-400, and a film forming sticker. To obtain thorough coverage use spray equipment suitable to deliver droplets with an average diameter of less than 300 microns.

To control and prevent Indian Meal Moth and Almond Moth infestations of stored grains and soybeans, prepare a spray mixture which includes one gallon of water for every 6 ounces THURICIDE HPC. The spray mixture may be applied either by treating the top 4 inches of grain



as it is being augured into storage (applying 0.6 pint of mixture per bushel in the grain stream), or by treating the surface of grain after it is in the bin. The table below can be used as a guide in determining the total amount of THURICIDE HPC needed according to the bin diameter or the number of bushels to be treated.

Bin Diameter (ft.)	Surface Area (sq. ft.)	Bushels (to 4 inch depth)	THURICIDE HPC Rate
8	50	13	6 oz.
12	113	30	14 oz.
16	201	53	24 oz.
20	314	84	1 qt. 2 oz.
24	452	120	1 qt. 20 oz.
28	615	163	2 qts. 8 oz.
32	804	214	2 qts. 28 oz.

To insure thorough coverage when making applications to the grain surface after it is in the bin, apply spray mixture in three applications. Mix the grain with a scoop or rake to a depth of 4 inches after each application.

Stored grain may be treated anytime, but for best results, treat grain at the time it is placed into storage or shortly thereafter, or in the early spring prior to egg laying. Full season control is normally experienced. Retreat only if reinfestation occurs.

For the protection of bagged grain, apply spray mixture to entire grain mass, and mix thoroughly prior to bagging. THURICIDE HPC at 1 1/2 qts. per 10 gallons of water will treat approximately 100 bushels.

Treated grain may be used at any time after treatment.

#### **Greenhouse Application**

THURICIDE HPC may also be used in the greenhouse and on flowers at 1/2 - 1 qt. per 100 gallons of water for control of listed insects on crops on this package label.

#### **STORAGE AND DISPOSAL**

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

**Storage:** Store in a cool place. Activity may be impaired by storage at temperatures above 90°F. Protect from freezing.

**Pesticide Disposal:** Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Disposal:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by incineration if allowed by State and local authorities.

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## CONDITIONS OF SALE AND WARRANTY

**IMPORTANT:** Read the entire Directions for Use and the Conditions of Sale and Warranty before using this product. If terms are not acceptable, return the unopened product container at once.

### Conditions of Sale and 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 OF MERCHANTABILITY IS MADE.**

M090203  
M090303

# CERTIS

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

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March 25, 2004

Ms. Janet Anderson  
Director  
Biopesticides and Pollution Prevention Division (7511C)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
1921 Jefferson Davis Highway  
Arlington, VA 22202

*Mari Dussanet*  
*ADD*  
*FYI - pull all packets*  
*+ copy list to each*  
*lystair & product names*

**Re: Clarification of product names for Certis USA, L.L.C., EPA Co. No. 70051**

Dear Ms. Anderson:

It has recently come to our attention that there is some confusion in the States regarding the correct product names for Certis USA, L.L.C.'s products. Language on the label that describes the type of product (i.e. Biological Insecticide, Fungicide, etc.) has been incorrectly incorporated into the product name for several of our products. In order to avoid further confusion, we are requesting that EPA update its records (maintenance fee listing, etc.) with the following corrected brand names that do not include the descriptive language:

<i>Product Name</i>	<i>EPA Reg. No.</i>	
1. Neem Oil 70%	70051-2	
2. Margosan-O	70051-5	
3. Superneem 4.5-B	70051-9	
4. Agree	70051-47	
5. Thuricide HPC	70051-52	5758325
6. Thuricide HPWP	70051-53	
7. Javelin	70051-60	
8. Javelin WP	70051-61	
9. Trident	70051-64	
10. Javelin WG	70051-66	
11. San 420 I WG	70051-69	
12. Condor	70051-78	
13. Cutlass	70051-79	
14. Condor WP	70051-80	
15. Raven Technical Powder	70051-81	
16. Raven	70051-82	
17. Condor Technical Powder	70051-83	
18. Cutlass Technical Powder	70051-84	
19. Condor XL	70051-85	

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- |                   |          |
|-------------------|----------|
| 20. Crymax        | 70051-86 |
| 21. Lepinox       | 70051-87 |
| 22. Lepinox WDG   | 70051-89 |
| 23. Crymax WP     | 70051-90 |
| 24. Lepinox XL OF | 70051-94 |
| 25. Javelin WG 2  | 70051-98 |
| 26. Agree 50 WP   | 70051-99 |

Please note that any alternate brand names listed under these registration numbers should not include the descriptive language as part of the brand name. 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](mailto:cdively@certisusa.com).

Sincerely,

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