



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

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

December 20, 2016

Patricia Biggio
Agent for AEF Global, Inc.
c/o SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – To update the company address and add a toll free helpline and web address
Product Name: Bioprotec
EPA Registration Number: 89046-8
Application Date: October 28, 2016
OPP Decision Number: 523057

Dear Ms. Biggio:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The labeling submitted with this application has been stamped "Notification" and will be placed in our records. You must submit one (1) copy of the final printed labeling with the modifications.

Should you wish to add a reference to your company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

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If you have any questions, please contact me by phone at (703) 347-8920 or via email at kausch.jeannine@epa.gov.

Sincerely,

A handwritten signature in black ink, consisting of several overlapping, fluid strokes that form a stylized representation of the name Jeannine Kausch.

Jeannine Kausch, Acting Product Manager 92
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

MASTER LABEL

BIOPROTEC
AQUEOUS BIOLOGICAL INSECTICIDE

FOR FORESTRY AND OUTDOOR USE BY COMMERCIAL APPLICATORS

Active Ingredient:

Bacillus thuringiensis ssp. *kurstaki* strain EVB-113-19.....9.50%

Other ingredients.....90.50%

Total..... 100.00%

Potency: 11,400 Cabbage Looper Units (CLU) per mg of product (equivalent to 48 billion CLU per gallon)

There is no direct relationship between intended activity (potency) and the percent active ingredient by weight

KEEP OUT OF REACH OF CHILDREN

CAUTION

[See back/inside/side panel for additional precautionary statements.]

AEF Global, Inc.

925A des Calfats

Lévis, QC

Canada

G6Y 9E8

Toll free help line: 1-866-622-3222

www.aefglobal.com

EPA Reg. No.: 89046-8

EPA Est. No.:

Use this product within 12 months of the date of manufacture.

Date of Manufacture: _____

Lot Number: _____

Net contents:_____

NOTIFICATION

89046-8

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

12/20/2016

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If on skin:	<ul style="list-style-type: none">– 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 in eyes:	<ul style="list-style-type: none">– 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.
HOT LINE NUMBER <p>Have the product container or label with you when calling a poison control center, doctor, or going for treatment. You may contact the National Poison Control Hotline at 1-800-222-1222 for emergency and medical information.</p> <p>For information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time.</p>	

PERSONAL PROTECTIVE EQUIPMENT (PPE)
<p><u>Applicators and other handlers must wear</u></p> <ul style="list-style-type: none">• <u>long-sleeved shirt and long pants</u>• <u>waterproof gloves</u>• <u>shoes plus socks</u>• Mixers/loaders and applicators must wear a NIOSH approved particulate respirator, with any R or P filter with NIOSH approval number prefix TC-84A; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number TC-21C. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. When mixing and loading, wear a chemical-resistant apron. When cleaning equipment, wear a chemical resistant apron. <p>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.</p>

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker protections 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.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must provide all PPE specified above for “applicators and other handlers” and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

USER SAFETY RECOMMENDATIONS

Users should wash hands before eating, drinking, chewing gum, using tobacco products or using the toilet. Remove clothing/PPE immediately if pesticide gets inside. 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 ground application: Do not apply directly to water or to where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash waters or rinsate.

For aerial application: Except under the forest canopy, 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 cleaning equipment or disposing of equipment wash waters or rinsate.

This product must not be applied aerially within ¼ mile of any habitats of endangered species or threatened *Lepidoptera*. Do not make manual application within 300 feet 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 applications. For any requirements specific to your State or Tribe, consult the State or Tribal 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 (REI). 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 unless wearing appropriate PPE.

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

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to 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.

Keep unprotected persons out of treated areas until sprays have dried.

USE INFORMATION

Bioprotec is toxic to select species of *Lepidopteron* larvae. Bioprotec must be ingested by susceptible larvae to be effective. Thorough coverage of target foliage where larvae feed is essential. Treat larvae when they are newly hatched and actively feeding. After ingestion, larvae cease feeding within a few hours and death occurs in 2 - 5 days.

Bioprotec is a water-based formulation, which may be applied undiluted or diluted. Dilute with minimal quantities of clean water only when required to improve coverage. If diluting with water, add the recommended amount of Bioprotec to the required amount of water in the spray tank. Agitate as necessary to maintain suspension. Use diluted mixtures of Bioprotec within 18 hours of mixing and recirculate mixture before loading and/or application.

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

DO NOT store spray mixture in tank for more than 18 hours.

Avoid application when significant rainfall is imminent. For early morning applications, do not apply if foliage is wet with dew to the point of runoff.

Consult with recognized forest pest management authority or AEF Global representative regarding appropriate timing and method of application. The timing and number of applications required for effective forest protection will depend upon target pest, target foliage development, pest pressure and larval activity.

Coordinate applications with sufficient foliage development (shoot elongation or leaf expansion) to ensure maximum spray deposit. To the extent possible, apply treatments after egg hatch has been completed to assure that the maximum number of larvae is present during the treatment period. In conditions where egg hatch is extended and/or larval development is significantly advanced and/or larval populations are high, use of higher rates and/or additional applications, 3-10 days apart, is recommended. See dose rate table for pest specific recommendations.

As this pesticide is not registered for the control of pests in aquatic system, do not use to control aquatic pests.

USE RESTRICTIONS

Do not apply this product through any type of irrigation system.

Aerial Applications

Use Bioprotec according to the following table. Spray volumes of 32-107 fluid ounces of product per acre give optimum coverage. In the western U.S., use a minimum of 5-10 gallons per acre; in the eastern regions, use a normal minimum of 2-3 gallons per acre. The minimum amount of water needed per acre will depend upon crop size, weather conditions and spray equipment used. Apply only when meteorological conditions at the treatment site allow for complete and even coverage.

Ground Applications

Dilute required amount of Bioprotec with water to the volume required to provide thorough coverage. Wet foliage thoroughly. Avoid excessive runoff.

For mist blower applications, add Bioprotec to water at a mix ratio ranging of 1:20 to 1:50. Recommended maximum volume of spray mixture is 10 gallons per acre.

For high volume hydraulic sprayers, add Bioprotec to water at a mix ratio of 1:50 to 1:500.
Recommended maximum volume of spray mixture is 100 gallons per acre.

AERIAL AND GROUND APPLICATION RATES FOR NON-AGRICULTURAL USES:

Not for use on trees being grown for sale or other commercial use, or for commercial seed production, or for research purposes. For use on plants intended for aesthetic purposes, except wide-area public pest control programs sponsored by government entities, such as mosquito abatement, gypsy moth control, and Mediterranean fruit fly eradication.

CROP	TARGET PESTS	Rate ¹ (Pint/acre)
Forests, Shade trees, Ornamentals, Shrubs, Sugar Maple Trees, Ornamental Fruit, Nut & Citrus trees	Gypsy moth ²	2.1-3.4
	Bagworm Jackpine Budworm Elm Spanworm Fall Spanworm Eastern Spruce Budworm ³	1.4-2.1
	Eastern & Western Hemlock Western Spruce Budworm ³	2.1-2.7
	Spruce Budworm ³ Browntail moth Douglas fir tussock moth Coneworm Buck moth	1.2-5.1
	Satin Moth Tussock moths	3.4
	Pine butterfly Loopers Orangestriped Oakworm Blackheaded budworm Saddled prominent Saddleback Caterpillar Leafrollers Tortrix Moth Mimosa Webworm	1.0-2.7
	Tent Caterpillar ³	0.9-1.4
	Forest tent caterpillar Greenstriped mapleworm	0.6-1.9
	Redhumped Caterpillar Spring & Fall Cankerworm California Oakworm Fall Webworm	0.9-1.4
	Eastern Tent Caterpillar	1.2-2.4
	Oakmoth larvae	

¹Use the higher rates on advanced larval stages or under high density larval populations.

²Gypsy moths: In treating infested trees and shrubs in urban, rural, and semi-rural areas, exposure of non-target vegetation including, but not limited to, native and ornamental species and food or feed crops is permitted. Apply first application when larvae are in 2nd and 3rd instar and leaf expansion reaches 40 - 50%. If egg hatch is extended or reinfestation occurs, two or more applications, 7 - 10 days apart, may be required. Use higher rates for heavy infestations.

³For satisfactory control of Eastern Spruce Budworm at lower rates and volumes (less than or equal to 0.1 gallon/acre), Bioprotec must be applied using Micronaire AU4000 atomizers with appropriate flow rate, and blade angle settings to ensure a rotation of between 8000 and 9000 rpm. This ensures generation of sufficient spray droplets for impingement on conifer foliage (balasm fir, black spruce). Treat spruce budworms prior to fifth instar larval development, when bud flush/shoot development is sufficient to ensure good deposit on emerging needles. For heavy infestations, higher rates and a second application are recommended. In mountainous terrain, higher rates and volumes may be required to ensure adequate coverage. For forest stands with a high spruce component, in addition to fir, a second application may be necessary, after the spruce buds have opened.

AERIAL AND GROUND APPLICATION RATES FOR AGRICULTURAL USES:

For use on trees being grown for sale or other commercial use, such as for commercial seed production or research purposes.

CROP	TARGET PESTS	Rates¹ (.Pint/acre)
Forests, Shade trees, Ornamentals, Shrubs, Sugar Maple Trees, Seed Orchards, Ornamental Fruit, Nut & Citrus trees	Gypsy moth ²	1.3-2.2
	Bagworm Jackpine Budworm Elm Spanworm Fall Spanworm Eastern Spruce Budworm ³	0.9-1.3
	Eastern & Western Hemlock Western Spruce Budworm ³	1.3-1.7
	Spruce Budworm ³ Browntail moth Douglas fir tussock moth Coneworm Buck moth	0.8-3.2
	Satin Moth Tussock moths	2.2
	Pine butterfly Loopers Orangestriped Oakworm Blackheaded budworm Saddled prominent Saddleback Caterpillar Leafrollers Tortrix Moth Mimosa Webworm	0.6-1.7
	Tent Caterpillar ³	0.5-0.9

	Greenstriped mapleworm	0.4-1.2
	Redhumped Caterpillar Spring & Fall Cankerworm California Oakworm Fall Webworm	0.5-0.9
	Eastern Tent Caterpillar	
	Oakmoth larvae	0.8-1.5

¹Use the higher rates on advanced larval stages or under high density larval populations.

²Gypsy moths: In treating infested trees and shrubs in urban, rural, and semi-rural areas, exposure of non-target vegetation including, but not limited to, native and ornamental species and food or feed crops is permitted. Apply first application when larvae are in 2nd and 3rd instar and leaf expansion reaches 40 - 50%. If egg hatch is extended or reinfestation occurs, 2 or more applications, 7 - 10 days apart, may be required. Use higher rates for heavy infestations.

³For satisfactory control of Eastern Spruce Budworm at lower rates and volumes (less than or equal to 0.1 gallon/acre), Bioprotec HP must be applied using Micronaire AU4000 atomizers with appropriate flow rate, and blade angle settings to ensure a rotation of between 8000 and 9000 rpm. This ensures generation of sufficient spray droplets for impingement on conifer foliage (balsam fir, black spruce). Treat spruce budworms prior to fifth instar larval development, when bud flush/shoot development is sufficient to ensure good deposit on emerging needles. For heavy infestations, higher rates and a second application are recommended. In mountainous terrain, higher rates and volumes may be required to ensure adequate coverage. For forest stands with a high spruce component, such as fir, a second application may be necessary, after the spruce buds have opened.

Other pests: Apply after egg hatch is complete, when early instar larvae are feeding on exposed foliage. For broadleaf foliage, apply when leaf expansion reaches 40 - 50%. For coniferous foliage, apply when bud flush/shoot development is sufficient to ensure good deposit. If egg hatch is extended or larval populations are high, higher rates and/or additional applications, 3 -10 days apart, may be required.

STORAGE AND DISPOSAL

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

Pesticide Storage:

In order to ensure microbial purity and potency, store in the original container at temperatures between 39°F (4°C) and 59°F (15°C). Store away from direct sunlight, feed, or foodstuffs. Use within 12 months of the date of manufacture. Store container upright and keep tightly closed when not in use. After extended storage, shake or stir contents to assure a uniform suspension.

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:

For plastic containers equal to 5 gallons or less:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available 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.

For plastic containers greater than 5 gallons:

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Recap and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

For 264-gallon containers and/or larger returnable mini-bulk and bulk containers:

Return empty container for reuse. Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times, then offer for recycling if available or puncture and dispose in a sanitary landfill or by incineration or by other procedure approved by state and local authorities.

WARRANTY

To the extent consistent with applicable law, AEF Global makes no warranty, express or implied, of merchantability, fitness or otherwise concerning the use of this product other than as indicated on the label. User assumes all risks of use, storage or handling not in strict accordance with accompanying directions.

[Optional Marketing/Advertising Claims]

- Look for other AEF Global products at www.aefglobal.com.