



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 22, 2016

Frederick T. Smith
Authorized Agent to bio-ferm GmbH
SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – To Revise the “If Swallowed” first aid statements; include the Fungicide Resistance Action Committee (FRAC) code; convert metric rates from acres to hectares; update the respirator description, pesticide disposal and container handling text, and residential application instructions; and make other revisions requested by EPA
Product Name: Blossom Protect
EPA Registration Number: 86174-4
Application Date: June 27, 2016
OPP Decision Number: 519177

Dear Mr. Smith:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (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.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Susanne Cerrelli by phone at (703) 308-8077 or via email at cerrelli.susanne@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jeannine Kausch', with a stylized flourish at the end.

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

Enclosure

Master Label
Blossom Protect

Sub-label A: Agricultural/Commercial Use

Sub-label B: Residential Use

Active Ingredients:

Aureobasidium pullulans strain DSM 14940* 25.8%

Aureobasidium pullulans strain DSM 14941* 25.8%

Other Ingredients:..... 48.4%

Total..... 100.0%

*Contains a minimum of 8.8×10^8 cfu/gram of active ingredient.

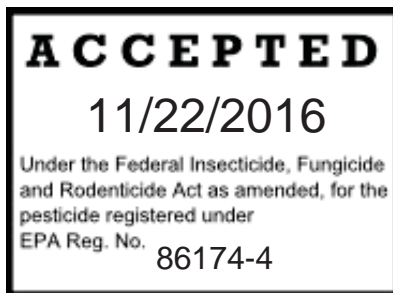
KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for First Aid and additional Precautionary Statements

EPA Reg. No. 86174-4

EPA Est. No. 86174-AUT-001



Sub-label A

Blossom Protect

For Agricultural/Commercial Use

Blossom Protect

A Biological Agent for Preventing Fire Blight in Pome Fruits and Walnut Blight in Walnuts



Active Ingredients:

| | |
|--|--------------|
| <i>Aureobasidium pullulans</i> strain DSM 14940* | 25.8% |
| <i>Aureobasidium pullulans</i> strain DSM 14941* | 25.8% |
| Other Ingredients: | <u>48.4%</u> |
| Total | 100.0% |

*Contains a minimum of 8.8×10^8 cfu/gram of active ingredient.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for First Aid and additional Precautionary Statements

EPA Reg. No. 86174-4

EPA Est. No. 86174-AUT-001

Net Contents: 2.5 Lbs (1.1 Kg)

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.)

Lot No.

Manufactured on:

| FIRST AID | |
|---|---|
| If swallowed: | <ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything to an unconscious person. |
| 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. |
| HOT LINE NUMBER | |
| <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Poison Control Hotline at 1-800-222-1222 for emergency medical treatment information 24 hours a day, 7 days a week.</p> | |

PRECAUTIONARY STATEMENTS
Hazards To Humans And Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin. 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. Wear chemical resistant gloves and protective eyewear. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- long-sleeved shirt and long pants
- protective eyewear
- chemical resistant gloves
- shoes plus socks

Mixer/loaders and applicators must wear a NIOSH-approved particulate respirator with any N, R, or P filter with NIOSH approval number prefix TC-84A; or NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow manufacturers' 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.

Engineering Controls

When handlers use closed systems or enclosed cabs 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.

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 remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should 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 cleaning equipment or disposing of equipment wash waters 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 State or Tribal agency responsible for pesticide regulation.

IMPORTANT: Read the entire label before using this product.

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
- Protective eyewear
- Chemical resistant gloves
- Shoes plus socks

OBSERVE THE FOLLOWING PRECAUTIONS WHEN SPRAYING IN THE VICINITY OF AQUATIC AREAS SUCH AS LAKES; RESERVOIRS; RIVERS; PERMANENT STREAMS, MARSHES OR NATURAL PONDS; ESTUARIES AND COMMERCIAL FISH FARM PONDS.

Spray Drift Reduction Management:

The interaction of many equipment and weather-related factors determines the potential for spray drift. The applicator is responsible for considering all of these factors when making application decisions. Avoiding spray drift is the responsibility of the applicator. Use the following as a guide for reducing drift onto non-target sites.

Buffer Zone Requirements:

Ground/Foliar Applications: Do not apply by ground within 25 feet of lakes; reservoirs; rivers; permanent streams, marshes or natural ponds; estuaries and commercial fish farm ponds.

Wind Speed Restrictions: Drift potential increases at wind speeds of less than 3 mph (due to inversion potential) or more than 10 mph. However, many factors, including droplet size, canopy and equipment specifications determine drift potential at any given wind speed. Do not apply when winds are greater than 15 mph and avoid gusty and windless conditions. Avoiding applications when wind direction is toward the aquatic area can reduce risk of exposure to sensitive aquatic areas.

Runoff Management:

Do not cultivate within 10 feet of the aquatic areas to allow growth of a vegetative filter strip. When used on erodible soils, consult your local Soil Conservation Service before using this product in your area. Do not apply if soil is saturated with water. Do not apply under conditions that favor runoff from drift.

General Information:

Blossom Protect is a microbial plant protection product consisting of two strains of *Aureobasidium pullulans*. *Aureobasidium pullulans* is a ubiquitous microorganism in the environment.

Blossom Protect must be used as a preventative measure before the occurrence of infection with the causal agent of fire blight, *Erwinia amylovora*, and walnut blight, *Xanthomonas arbuticola*. Apply Blossom Protect only during primary bloom, prior to or when environmental conditions for the growth of *Erwinia amylovora* or *Xanthomonas arbuticola* are present.

Mode of Action:

The microorganisms in Blossom Protect colonize on the blossoms of the trees and compete with the pathogen for space and nutrients. Using competitive inhibition, Blossom Protect prevents the development of fire blight and walnut blight by colonizing the blossom and reducing the ability of the bacteria to thrive.

FRAC Code: NC (not classified)

Compatibility:

Not all chemicals or fertilizers can be mixed with Blossom Protect during application. Many fungicides are not compatible and may be detrimental to Blossom Protect. Do not tank mix with copper-based products. Observe the most restrictive of the labeling limitations and precautions of all products used in mixtures. For product compatibility information, contact Westbridge Agricultural Products.

Phytotoxicity: Perform a phytotoxicity test on a few trees before large-scale application.

Preparation of Blossom Protect Spray Mixture:

Ensure the temperature of the spray mixture is below 86°F (30°C). Maintain agitation of the spray mixture.

In 50-200 gallons water per acre, add 1.25 lbs of Blossom Protect per acre.

Metric Units:

In 467-1868 L water per hectare, add 1.4 kg of Blossom Protect per hectare.

To accelerate the propagation of *Aureobasidium pullulans* in the flower, the addition of Buffer Protect to the mixture is beneficial. If using Buffer Protect, prepare the spray suspension as directed below.

In 50-200 gallons of water per acre, add 1.25 lbs of Blossom Protect + 8.75 lbs of Buffer Protect per acre. Add Blossom Protect to the spray mix last.

Metric Units:

In 467-1868 L water per hectare, add 1.4 kg of Blossom Protect + 9.8 kg of Buffer Protect per hectare.

Application Instructions:

Apply the spray mixture while maintaining agitation. Use the prepared Blossom Protect Spray Mixture within 8 hours after tank-mixing. Apply Blossom Protect to thoroughly wet the blossoms and foliage. Apply as a foliar application only. Do not apply spray mixture through any type of irrigation system. Do not apply spray mixture aerially. Do not apply when fruit is present.

Pome fruit: Applications the day before predicted infection conditions (according to disease forecasting models) provide optimum protection against fire blight. If the risk for fire blight is high, up to four applications provide optimum protection. Spray Blossom Protect at 10%, 40%, 70%, and 90% bloom, according to the BBCH-scale: BBCH 61-69. For susceptible pome fruit varieties, the product may contribute to russetting when applied during late blossom and wet conditions. Cool, wet weather conditions can increase the potential for russetting.

Walnuts: For walnut blight, up to six applications may be needed between 10% and 100% bloom.

For application rates, refer to the Application Table below.
One, 2.5 pound (1.1 kg) container of Blossom Protect treats 2 acres.

APPLICATION TABLE

POME FRUITS such as:

Apple, Crabapple, Loquat, Mayhaw, Pear, Oriental pear, Quince

| Disease Controlled | Rate | Time of Application |
|--|--|--|
| Fire Blight (<i>Erwinia amylovora</i>) | Use 1.25 lbs of Blossom Protect per 1 acre. Adjust spray volume to assure thorough coverage. | up to 4 treatments at 10, 40, 70 and 90% bloom |

WALNUTS

| Disease Controlled | Rate | Time of application |
|---|--|---|
| Walnut Blight (<i>Xanthomonas arbuticola pv. juglandis</i>) | Use 1.25 lbs of Blossom Protect per 1 acre. Adjust spray volume to assure thorough coverage. | up to 6 treatments between 10% bloom and 100% bloom |

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Blossom Protect must be stored out of direct sunlight in a cool dry place. Do not freeze. From date of manufacture, product can be stored: 10 months at room temperature (47°F to 68°F; 9°C to 20°C) or 24 months at cold temperature (34°F to 46°F; 1°C to 8°C). Store only in original container in an area designated for pesticide storage. Keep out of reach of 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 HANDLING: Nonrefillable 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 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank, or store rinsate for later disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then, 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.

Conditions of Sale

Seller warrants that this product consists of the ingredient specified and is reasonably fit for the purposes stated on this label when used in accordance with the directions under normal conditions of use. No one is authorized to make any other warranty or guaranty concerning this product. To the extent consistent with applicable law, any liability arising from the handling, storage and use of this product is limited to replacement of product or refund of purchase price.

Manufactured by

bio-ferm GmbH
Technologiezentrum Tulln
Technopark 1
3430 Tulln
Austria

For Product Information, contact:

Westbridge Agricultural Products
1260 Avenida Chelsea, Vista, CA 92081
USA
Phone: (800) 876-2767

Sub-label B

Blossom Protect

For Residential Use

Blossom Protect

A Biological Agent for Preventing Fire Blight in Pome Fruits and Walnut Blight in Walnuts



Active Ingredients:

Aureobasidium pullulans strain DSM 14940* 25.8%

Aureobasidium pullulans strain DSM 14941* 25.8%

Other Ingredients:..... 48.4%

Total..... 100.0%

*Contains a minimum of 8.8×10^8 cfu/gram of active ingredient.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for First Aid and additional Precautionary Statements

EPA Reg. No. 86174-4

EPA Est. No. 86174-AUT-001

Net Contents: 2.5 Lbs (1.1 Kg)

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.)

Lot No.

Manufactured on:

| FIRST AID | |
|---|---|
| If swallowed: | <ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything to an unconscious person. |
| 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. |
| HOT LINE NUMBER | |
| <p style="text-align: center;">Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Poison Control Hotline at 1-800-222-1222 for emergency medical treatment information 24 hours a day, 7 days a week.</p> | |

PRECAUTIONARY STATEMENTS
Hazards To Humans And Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin. 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. Wear chemical resistant gloves and protective eyewear. Remove and wash contaminated clothing before reuse.

Environmental Hazards

To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

IMPORTANT: Read the entire label before using this product.

General Information:

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Blossom Protect must be used as a preventative measure before the occurrence of infection with the causal agent of fire blight, *Erwinia amylovora*, and walnut blight, *Xanthomonas arbuticola*. Apply Blossom Protect only during primary bloom, prior to or when environmental conditions for the growth of *Erwinia amylovora* or *Xanthomonas arbuticola* are present.

Mode of Action:

The microorganisms in Blossom Protect colonize on the blossoms of the trees and compete with the pathogen for space and nutrients. Using competitive inhibition, Blossom Protect prevents the development of fire blight and walnut blight by colonizing the blossom and reducing the ability of the bacteria to thrive.

Preparation of Blossom Protect Mixture:

Ensure the temperature of the tank-mixture is below 86°F (30°C).

Measure ½ gallon of cold water. Add ¾ teaspoon of Blossom Protect.

To accelerate the propagation of *Aureobasidium pullulans* in the flower, the addition of Buffer Protect to the mixture is beneficial. If using Buffer Protect, prepare the spray suspension as directed below.

Measure ½ gallon of cold water. Add 3/4 teaspoon of Blossom Protect + 5½ teaspoons of Buffer Protect.

Application Instructions:

Apply the spray mixture while maintaining agitation. Use the prepared Blossom Protect Spray Mixture within 8 hours after tank-mixing. Apply Blossom Protect to thoroughly wet the blossoms and foliage. Apply as a foliar application only. Do not apply when fruit is present.

Pome fruit: Applications the day before predicted infection conditions (according to disease forecasting models) provide optimum protection against fire blight. If the risk for fire blight is high, up to four applications provide optimum protection. Spray Blossom Protect at 10%, 40%, 70%, and 90% bloom. For susceptible pome fruit varieties, the product may contribute to russeting when applied during late blossom and wet conditions. Cool, wet weather conditions can increase the potential for russeting.

Walnuts: For walnut blight, up to six applications may be needed between 10% and 100% bloom.

For application rates, refer to the Application Table below

APPLICATION TABLE

POME FRUITS such as:

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| Disease Controlled | Rate | Time of application |
|--|---|--|
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WALNUTS

| Disease Controlled | Rate | Time of application |
|---|---|---|
| Walnut Blight (<i>Xanthomonas arbuticola pv. juglandis</i>) | ½ gallon of prepared Blossom Protect Spray Mixture per tree | up to 6 treatments between 10% bloom and 100% bloom |

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Blossom Protect must be stored out of direct sunlight in a cool dry place. Do not freeze. From date of manufacture, product can be stored: 10 months at room temperature (47°F to 68°F; 9°C to 20°C) or 24 months at cold temperature (34°F to 46°F; 1°C to 8°C). Store only in original container in an area designated for pesticide storage. Keep out of reach of children.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Conditions of Sale

Seller warrants that this product consists of the ingredient specified and is reasonably fit for the purposes stated on this label when used in accordance with the directions under normal conditions of use. No one is authorized to make any other warranty or guaranty concerning this product. To the extent consistent with applicable law, any liability arising from the handling, storage and use of this product is limited to replacement of product or refund of purchase price.

Manufactured by

bio-ferm GmbH
Technologiezentrum Tulln
Technopark 1
3430 Tulln
Austria

For Product Information, contact:

Westbridge Agricultural Products
1260 Avenida Chelsea, Vista, CA 92081
USA
Phone: (800) 876-2767