



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 7, 2016

Patricia Biggio
Authorized Agent to bio-ferm GmbH
SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Update California Restriction For Use on Stone Fruits, Almonds, and Tomatoes; Revision of the First Aid Statement to Match Current Statement; and Revision of Hot Line Number
Product Name: Botector
EPA Registration Number: 86174-3
Application Date: 02/02/2016
OPP Decision Number: 514474

Dear Ms. Biggio:

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

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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 Nicola Steinmetz of my team by phone at (703) 347-8567 or via email at steinmetz.nicola@epa.gov.

Sincerely,

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

Alan Reynolds, Team Leader
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

Master Label
Botector

Sub-label A: Agricultural/Commercial Use

Sub-label B: Residential Use

Active Ingredients:

Aureobasidium pullulans strain DSM 14940* 40%

Aureobasidium pullulans strain DSM 14941* 40%

Other Ingredients:.....20%

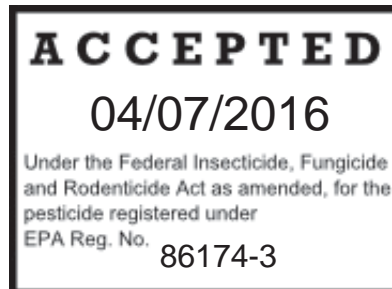
Total..... 100%

*Contains a minimum of 1.06×10^9 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. 86174-3
EPA Est. No. 86174-AUT-001
Net Contents: 20 oz (0.57 Kg)**



Sub-label A

Botector

For Agricultural/Commercial Use

Botector

A Biological Agent for the Protection of Pome Fruit from storage diseases, Grapes, and tomatoes from Botrytis, Berries from Anthracnose, Botrytis, Phomopsis, and Rhizopus Fruit Rot, and Stone Fruit from Monilinia



Active Ingredients:

Aureobasidium pullulans strain DSM 14940*..... 40%

Aureobasidium pullulans strain DSM 14941*..... 40%

Other Ingredients:..... 20%

Total..... 100%

*Contains a minimum of 1.06×10^9 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. 86174-3
EPA Est. No. 86174-AUT-001
Net Contents: 20 oz (0.57 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 waterproof gloves. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- long-sleeved shirt and long pants
- waterproof gloves
- shoes plus socks

Mixer/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 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.

IMPORTANT: Read the entire label before using this product.

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.

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

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

Botector consists of two strains of *Aureobasidium pullulans*. *Aureobasidium pullulans* is a ubiquitous microorganism in the environment. Botector must be used as a preventative measure before infection by the pathogens. The product competes for space and nutrients with the pathogens. Using competitive inhibition, Botector is effective against fruit rot on pome fruits due to *Penicillium*, *Botrytis*, *Monilinia*, *Nectria*, and *Pezicula*. Botector is effective against *Botrytis cinerea* on berries, grapes, and tomatoes, as well as, Anthracnose, Phomopsis and Rhizopus fruit rot in berries. Botector also controls *Monilinia* ssp. in stone fruit.

Botector can be applied up to the day of harvest.

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

Crops Treated + Diseases Controlled

	Crops Treated	Disease Controlled
BERRIES	Strawberry, Raspberry, Blueberry, Blackberry, Huckleberry, Red and Black current, Loganberry	Gray mold (<i>Botrytis cinerea</i>), Anthracnose, Phomopsis sp., Rhizopus Fruit Rot
GRAPE	American bunch grapes (Table Grapes, Wine Grapes and Raisin Grapes), Muscadine grape and Vinifera grape	Gray mold (<i>Botrytis cinerea</i>)
POME FRUIT**	Apple, Crabapple, Loquat, Mayhaw, Pear, Oriental pear, Quince	Storage diseases such as: <i>Botrytis cinerea</i> , <i>Penicillium</i> ssp., <i>Monilinia</i> ssp., <i>Nectria galligena</i> and <i>Pezicula</i> ssp.)
STONE FRUIT ALMOND	Apricot, Cherry (including sweet and tart), Nectarine, Peach, Plum (including Chickasaw, Damson and Japanese), Plumcot, Prune (fresh), Almonds	Blossom blight, Brown rot (<i>Monilinia</i> ssp.)
TOMATO	Fresh and processing tomatoes (greenhouse and field production)	Gray mold (<i>Botrytis cinerea</i>)

** Use not permitted in California unless otherwise directed by supplemental labeling.

Preparation of Botector Mixture:

Ensure the temperature of the tank mixture is below 86°F (30°C). Agitate mixture before and during application. Use the spray mixture within 8 hours after tank-mixing.

Compatibility:

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

PRE-HARVEST APPLICATION

Apply specified rate of Botector, as a directed spray to the target crop. Ensure thorough coverage wherever infection is likely to occur. For tomatoes, ensure full plant spray coverage.

Application Rate

Use sufficient water for adequate and even coverage without runoff:

Crop	Water Volume (gallons/acre)	Amount of Botector (ounces/acre)
BERRIES	100-500	5-10
ALMOND GRAPE POME FRUIT** STONE FRUIT	<50	6
	51 to 100	8
	101 to 200	10
	201 to 300	12
	>300	14
TOMATO	20 to 400	7-14

Application Instructions

Crop	Time of application	Number of applications
BERRIES	From beginning of bloom until harvest	With intervals of 5-7 days depending on infection pressure
GRAPE*	Between early and late bloom (10-80%)	1-3 applications depending on infection pressure
	Before bunch closure	1 application
	During veraison/berry softening	1 application
	During ripening	Additional applications with intervals of 3-7 days depending on infection pressure
POME FRUIT**	Starting 5 weeks before harvest	Up to 6 applications, with intervals of 5-7 days depending on infection pressure
STONE FRUIT ALMOND	At 10, 40, 70 and 90% open flowers	4 applications
	Starting 5 weeks before harvest	Up to 6 applications with intervals of 5-7 days depending on infection pressure
TOMATO	Starting at emergence or transplant until harvest	Apply every 5 to 10 days depending on growth rate and infection pressure

* Treat bunch zone only.

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STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Botector 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 (47-68°F; 9-20°C) or 24 months at cold temperature (34-46°F; 1-8°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 may be disposed of on site or at an approved waste disposal facility.

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

Sub-label B

Botector

For Residential Use

Botector

A Biological Agent for the Protection of Pome Fruit from storage diseases, Grapes and Berries from Gray Mold, and Stone Fruit from Brown Rot



Active Ingredients:

Aureobasidium pullulans strain DSM 14940* 40%

Aureobasidium pullulans strain DSM 14941* 40%

Other Ingredients:.....20%

Total..... 100%

*Contains a minimum of 1.06×10^9 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. 86174-3
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Net Contents: 20 oz (0.57 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 waterproof gloves. Remove and wash contaminated clothing before reuse. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

IMPORTANT: Read the entire label before using this product.

Environmental Hazards

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

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

General Information

Botector consists of two strains of *Aureobasidium pullulans*. *Aureobasidium pullulans* is a ubiquitous microorganism in the environment. Botector must be used as a preventative measure before infection by the pathogens. The product competes for space and nutrients with the pathogens. Using competitive inhibition, Botector is effective against fruit rot on pome fruits due to *Penicillium*, *Botrytis*, *Monilinia*, *Nectria*, and *Pezizula*. Botector is effective against *Botrytis cinerea* (gray mold) on grapes and against *Botrytis*, Anthracnose, *Phomopsis* and *Rhizopus* fruit rot in berries, and against *Monilinia* (brown rot) on stone fruit.

Botector can be applied up to the day of harvest.

Crops Treated + Diseases Controlled

	Crops Treated	Disease Controlled
BERRIES	Strawberry, Raspberry, Blueberry, Blackberry, Huckleberry, Red and Black current, Loganberry	Gray mold (<i>Botrytis cinerea</i>), Anthracnose, <i>Phomopsis</i> sp., <i>Rhizopus</i> Fruit Rot

GRAPE	American bunch grapes (Table Grapes, Wine Grapes and Raisin Grapes), Muscadine grape and Vinifera grape	Gray mold (<i>Botrytis cinerea</i>)
POME FRUIT**	Apple, Crabapple, Loquat, Mayhaw, Pear, Oriental pear, Quince	Storage diseases such as: <i>Botrytis cinerea</i> , <i>Penicillium</i> ssp., <i>Monilinia</i> ssp., <i>Nectria galligena</i> and <i>Pezicula</i> ssp.)
STONE FRUIT ALMOND	Apricot, Cherry (including sweet and tart), Nectarine, Peach, Plum (including Chickasaw, Damson and Japanese), Plumcot, Prune (fresh), Almonds	Blossom blight, Brown rot (<i>Monilinia</i> ssp.)
TOMATO	Fresh and processing tomatoes (greenhouse and field production)	Gray mold (<i>Botrytis cinerea</i>)

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PRE-HARVEST APPLICATION

Apply specified rate of Botector as a directed spray to blossoms or fruit. Use cold water [below 86°F (30°C)] when preparing Botector spray mixture.

Application Rate

Use a quantity of spray sufficient to thoroughly cover foliage, especially flowers or blooms. Spray to wet, but avoid runoff. One gallon is sufficient to cover approximately 300 sq. ft.

Crops Treated	Water Volume	Amount of Botector
ALMOND BERRIES GRAPE POME FRUIT** STONE FRUIT TOMATO	1 gallon	1 teaspoon (approximately 2.5g)

Application Instructions

Crops Treated	Time of application	Number of applications
BERRIES	From beginning of bloom until harvest	Every 5-7 days, depending on infection pressure
GRAPE*	Between early and late bloom (10-80%)	1-3 applications, depending on infection pressure
	Before bunch closure	1 application
	During veraison/berry softening	1 application
	During ripening	Additional applications with intervals of 3-7 days, depending on infection pressure
POME FRUIT**	Starting 5 weeks before harvest	Up to 6 applications, with intervals of 5-7 days, depending on infection pressure
STONE FRUIT ALMOND	at 10, 40, 70 and 90% open flowers	4 applications
	Starting 5 weeks before harvest	Up to 6 applications with intervals of 5-7 days, depending on infection pressure

TOMATO	Starting at emergence or transplant until harvest	Apply every 5 to 10 days depending on growth rate and infection pressure
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* Treat bunch zone only.

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STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Botector 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 (47-68°F; 9-20°C) or 24 months at cold temperature (34-46°F; 1-8°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 may be disposed of on site or at an approved waste disposal facility.

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