

86174-3

9/4/2013

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

SEP 4 2013

bio-ferm GmbH
c/o Mr. Fred Smith
SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

RE: Label Amendment
Product name: Botector
Active Ingredients: *Aureobasidium pullulans* strains DSM14940 and DSM 14941
EPA File Symbols: 86174-3
OPP Decision Number: D480344

Dear Mr. Smith:

The Agency has reviewed your request to amend the Botector label to add berries and almonds to the crop listing, add lot number, add a sensitization statement on residential sub-label, revise the directions for use for all listed crops, revise compatibility text, and revise the pesticide storage text.

The label amendments referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, are acceptable provided that you:

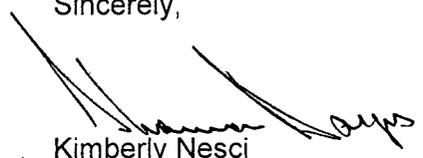
1. Submit and/or cite all data required for registration of your products under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit two (2) copies each of the final printed labeling prior to releasing these products for shipment.

CONCURRENCES

SYMBOL	▶ 7511P	7511P						
SURNAME	▶ <i>Smith</i>	<i>Borg</i>						
DATE	▶ 9-4-13	9/4/13						

If these conditions are not complied with, these registrations will be subject to cancellation in accordance with FIFRA § 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any further questions regarding this, please do not hesitate to contact Susanne Cerrelli, at 703-308-8077 (cerrelli.susanne@epa.gov).

Sincerely,

for

Kimberly Nesci

Chief, Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)

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Master Label Botector

Sub-label A: Agricultural/Commercial Use

Sub-label B: Residential Use

Active Ingredients:

<i>Aureobasidium pullulans</i> strain DSM 14940*	40%
<i>Aureobasidium pullulans</i> strain DSM 14941*	40%
Other Ingredients:	<u>20%</u>
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)

ACCEPTED

SEP 4 2013

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No.

86174-3

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Sub-label A

Botector

For Agricultural/Commercial Use

ACCEPTED

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... ..
... ..

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Botector

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



Active Ingredients:

<i>Aureobasidium pullulans</i> strain DSM 14940*	40%
<i>Aureobasidium pullulans</i> strain DSM 14941*	40%
Other Ingredients:	<u>20%</u>
Total	100%

*Contains a minimum of 1.06 x 10⁹ 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)**

**Lot No.
Manufactured on:**

Lot No. 11111111

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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 do so by a poison control center or doctor. • Do not give anything by mouth 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 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.	

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 *Pezizula*. Botector is effective against *Botrytis cinerea* on grapes, and against *Botrytis*, *Anthraco*se, *Phomopsis* and *Rhizopus* fruit rot in berries, and against *Monilinia* on 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 aeri ally 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>Pezizula</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.)

** 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. 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 blossoms or fruit. Ensure thorough coverage of fruit.

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**	<50	6
GRAPE	51 to 100	8
POME FRUIT**		
STONE FRUIT**	101 to 200	10

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	201 to 300	12
	>300	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

* Treat bunch zone only.

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. Store at less than 46°F (8°C). Do not freeze. In the absence of cold storage, products that are stored at 68°F (20°C) or below have a shelf life of 10 months. 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, other than the officer of the Seller, is authorized to make any warranty or guarantee concerning this product. Because the time, place, rate of application and other conditions of use are beyond Seller's control, to the extent consistent with applicable law, Seller's liability from 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 1B
 3430 Tulln, Austria

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

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Sub-label B
Botector
For Residential Use

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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

FOR ORGANIC GARDENING

Active Ingredients:

<i>Aureobasidium pullulans</i> strain DSM 14940*	40%
<i>Aureobasidium pullulans</i> strain DSM 14941*	40%

Other Ingredients:.....20%

Total.....100%

*Contains a minimum of 1.06 x 10⁹ 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)**

**Lot No.
Manufactured on:**

12/14

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 do so by a poison control center or doctor. • Do not give anything by mouth 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 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.	

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 *Pezicula*. Botector is effective against *Botrytis cinerea* (gray mold) on grapes and against *Botrytis*, *Anthraco*se, *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, 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>Pezizula</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.)

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

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**	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

* 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. Store at less than 46°F (8°C). Do not freeze. In the absence of cold storage, products that are stored at 68°F (20°C) or below have a shelf life of 10 months. 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, other than the officer of the Seller, is authorized to make any warranty or guarantee concerning this product. Because the time, place, rate of application and other conditions of use are beyond Seller's control, to the extent consistent with applicable law, Seller's liability from 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 1B
3430 Tulln
Austria

For Product Information, contact:

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