

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 13, 2023

Amy Plato Roberts Director of Regulatory Affairs Danstar Ferment AG / LALLEMAND PLANT CARE P.O. Box 990 Hailey, ID 83333

 Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Correct a Typographical Error to the Signal Word in the Hazards to Human and Domestic Animals Section
Product Name: Bio-Save 10 LP Biological Fungicide
EPA Registration Number: 64137-23
EPA Receipt Date: 04/07/2023
Action Case Number: 00446184

Dear Ms. Roberts:

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/retain 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 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 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 EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to EPA's Office of Enforcement and Compliance Assurance.

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If you have any questions, please me by phone at (202) 566-1511 or via email at boukedes.alexandra@epa.gov.

Sincerely,

Alwanden Boukedes Alwanden Boukedes Date: 2023.04.13 18:16:50 -04'00'

Alexandra Boukedes, Product Manager 92 Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511M) Office of Pesticide Programs

Enclosure

# **Bio-Save<sup>®</sup> 10 LP Biological Fungicide**

Active Ingredient: Pseudomonas syringae Strain ESC-10	28.61%*
Other Ingredients:	<u>71.39%</u>
Total:	100.00%

\* Contains a minimum of 9 X 10<sup>10</sup> cfu/g of formulated product.

# KEEP OUT OF REACH OF CHILDREN WARNING

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.)

#### **FIRST AID**

If in eyes • Hold eye open and rinse slowly and gently with water for 15-20 minutes.

- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

#### HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies, call the poison control center at 1-800-222-1222.

[See ([back][side][inside][enclosed]) ([panel][pamphlet]) for additional ([precautionary statements] [and] [directions for use]).]

EPA Reg. No: 64137-23 EPA Est. No.: 89198-WI-001 Net Weight: 500 g (1.1 lb.), 250 g (8.8 oz.), 150 g (5.3 oz.) (Batch)(Lot) No: XXXX (Use Before: [optional])

#### Manufactured for:

Danstar Ferment AG / LALLEMAND PLANT CARE Poststrasse 30 Zug CH-6300 Switzerland

#### Marketing Company:

JET Harvest LLC PO Box 915139 Longwood, FL 32791-5139 Telephone: 407-523-7842 Toll Free: 877-866-5773 Patent No. 5,554,368

# NOTIFICATION

#### 64137-23

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:

04/13/2023



LALLEMAND PLANT CARE



Note to Reviewer: Language in Brackets is optional. When parenthesis and brackets are paired together, one of the options in the parenthesis must be chosen.

# **PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS - WARNING:** Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (such as goggles, face shield, or safety glasses) when mixing. 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.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE):

Applicators and other handlers must wear:

- long-sleeved shirt and long pants
- shoes plus socks
- protective eyewear

Mixer/loaders and applicators must wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N, R, or P filter; OR a NIOSH approved elastomeric particulate respirator with any N, R, or P filter; OR a NIOSH-approved powered air- purifying respirator with an HE filter. (Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.)

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

#### USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

**ENVIRONMENTAL HAZARDS:** 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.

## PRODUCT INFORMATION

- Compatible with many common post-harvest practices, including fungicide applications.
- Easy to apply with most conventional application equipment.
- Ideal for integrated disease management programs.

#### **USE RESTRICTIONS**

Bio-Save<sup>®</sup> 10 LP Biological Fungicide is a biological control agent for post-harvest applications only. Do not add directly to waxes, soaps or sanitizers. Do not add to chlorinated water. Apply most chemical fungicides after Bio-Save<sup>®</sup> 10 LP Biological Fungicide has been applied. Contact your JET Harvest Solutions or Lallemand Plant Care technical advisor for more information.

#### MIXING INSTRUCTIONS

Bio-Save<sup>®</sup> 10 LP Biological Fungicide must be suspended in water for at least 10-30 minutes prior to use. Water is a carrier for the Bio-Save 10 LP. When needed, increase or decrease the amount of water in the mixture based on the wetness of the labeled commodity. Wetness is defined as

dry, damp or labeled commodity is dripping with water. Labeled commodity, once product is applied in water suspension, should have minimal water appearance. No water dripping is preferred. Agitate periodically to maintain suspension and agitate the suspension prior to application to fruit or vegetables. After opening sealed container, use entire contents of Bio-Save<sup>®</sup> 10 LP Biological Fungicide.

## CITRUS FRUIT (Lemons, Oranges, and Grapefruit)

Bio-Save<sup>®</sup> 10 LP Biological Fungicide controls decay of citrus fruit caused by green mold *(Penicillium digitatum)*, blue mold *(Penicillium italicum)*, and sour rot *(Geotrichum candidum)* during storage and transport.

**Non-recovery Spray:** Add 150 grams (5.3 oz.) of product to 10 gallons of water / 250 grams (8.8 oz.) of product to 15 gallons of water / 500 grams (1.1 lb.) of product to 25 gallons of water. Water is a carrier for the Bio-Save 10 LP. When needed, increase or decrease the amount of water in the mixture based on the wetness of the labeled commodity. Wetness is defined as dry, damp or labeled commodity is dripping with water. Labeled commodity, once product is applied in water suspension, should have minimal water appearance. No water dripping is preferred. Agitate the mixture to ensure proper suspension. Apply by drip or spray system to freshly cleaned citrus fruit, prior to waxing. Apply over soft, clean brushes or donut rolls. Best control is obtained by applying entire suspension to 40,000/60,000/100,000 pounds of citrus.

## CHERRIES

Bio-Save<sup>®</sup> 10 LP Biological Fungicide controls decay of cherries by blue mold (*Penicillium expansum*) and gray mold (*Botrytis cinerea*).

**Conventional Dip or Drench:** Add 150 grams (5.3 oz.) of product to 10 gallons of water / 250 grams (8.8 oz.) of product to 15 gallons of water / 500 grams (1.1 lb.) of product to 25 gallons of water. Agitate the mixture to ensure proper suspension. Drench cherries thoroughly. Recycled dip/drench suspension will need to be recharged at intervals dependent on individual customer use; consult a JET Harvest Solutions or Lallemand Plant Care technical advisor for more information.

**Overhead Spray Application System:** Add 150 grams (5.3 oz.) of product to 10 gallons of water / 250 grams (8.8 oz.) of product to 15 gallons of water / 500 grams (1.1 lb.) of product to 25 gallons of water. Water is a carrier for the Bio-Save 10 LP. When needed, increase or decrease the amount of water in the mixture based on the wetness of the labeled commodity. Wetness is defined as dry, damp or labeled commodity is dripping with water. Labeled commodity, once product is applied in water suspension, should have minimal water appearance. No water dripping is preferred. Agitate the mixture to ensure proper suspension. Apply over conveyor belt or rollers by drip or spray to cherries prior to packaging. Uniform coverage is required. Recycled suspension will need to be recharged at intervals dependent on individual customer use; consult a JET Harvest Solutions or Lallemand Plant Care technical advisor for more information. Best control is obtained by applying entire suspension to 40,000/60,000/100,000 pounds of cherries.

# POME FRUIT (Apples and Pears)

Bio-Save<sup>®</sup> 10 LP Biological Fungicide controls decay caused by blue mold (*Penicillium expansum*), including benzimidazole-resistant strains, gray mold (*Botrytis cinerea*), and mucor rot (*Mucor piriformis*) on apples and pears in both cold storage and controlled atmosphere storage. Bio-Save<sup>®</sup> 10 LP Biological Fungicide is effective on these and other pome fruits: d'Anjou pears and

the following apple cultivars: Red Delicious, Golden Delicious, Granny Smith, Fuji, Rome, Empire, Gala, Ida red, Jonathan, and Macintosh.

**Conventional Dip or Drench:** Add 150 grams (5.3 oz.) of product to 25 gallons of water / 250 grams (8.8 oz.) of product to 40 gallons of water / 500 grams (1.1 lb.) of product to 80 gallons of water. Agitate the mixture to ensure proper suspension. Treat pome fruit for at least one minute. Recycled dip/drench suspensions will need to be recharged at intervals dependent on individual use conditions; consult a JET Harvest Solutions or Lallemand Plant Care technical advisor for more information. Bio-Save<sup>®</sup> 10 LP Biological Fungicide can be tank-mixed with the anti-scald compound diphenylamine (DPA) when used according to label directions.

**Non-recovery Spray:** Add 150 grams (5.3 oz.) of product to 25 gallons of water / 250 grams (8.8 oz.) of product to 40 gallons of water / 500 grams (1.1 lb.) of product to 80 gallons of water. Water is a carrier for the Bio-Save 10 LP. When needed, increase or decrease the amount of water in the mixture based on the wetness of the labeled commodity. Wetness is defined as dry, damp or labeled commodity is dripping with water. Labeled commodity, once product is applied in water suspension, should have minimal water appearance. No water dripping is preferred. Agitate the mixture to ensure proper suspension. Apply to freshly cleaned pome fruit, prior to waxing. Apply over soft, clean brushes or donut rolls. Best control is obtained by applying entire suspension to 100,000/160,000/240,000 pounds of pome fruit.

## POTATOES

Bio-Save<sup>®</sup> 10 LP Biological Fungicide controls the decay caused by dry rot (*Fusarium sambucinum*) and silver scurf (*Helminthosporium solani*) on both seed and storage potatoes.

**Overhead Spray Application:** Add 150 grams (5.3 oz.) of product to 9 gallons of water / 250 grams (8.8 oz.) of product to 15 gallons of water / 500 grams (1.1 lb.) of product to 30 gallons of water. Water is a carrier for the Bio-Save 10 LP. When needed, increase or decrease the amount of water in the mixture based on the wetness of the labeled commodity. Wetness is defined as dry, damp or labeled commodity is dripping with water. Labeled commodity, once product is applied in water suspension, should have minimal water appearance. No water dripping is preferred. Agitate the mixture to ensure proper suspension. Apply over conveyor belt or rollers by drip or spray to potatoes prior to storage. Uniform coverage is required. Apply the entire suspension to 900 /1500 / 3000 sacks (100 pounds each) of potatoes.

# SWEET POTATOES

Bio-Save<sup>®</sup> 10 LP Biological Fungicide controls the decay of Rhizopus soft rot (*Rhizopus stolonifer*) on sweet potatoes.

**Overhead Spray Application:** Add 150 grams (5.3 oz.) of product to 9 gallons of water / 250 grams (8.8 oz.) of product to 15 gallons of water / 500 grams (1.1 lb.) of product to 30 gallons of water. Water is a carrier for the Bio-Save 10 LP. When needed, increase or decrease the amount of water in the mixture based on the wetness of the labeled commodity. Wetness is defined as dry, damp or labeled commodity is dripping with water. Labeled commodity, once product is applied in water suspension, should have minimal water appearance. No water dripping is preferred. Agitate the mixture to ensure proper suspension. Apply over conveyor belt or rollers, soft, clean brushes or donut rolls by drip or spray to sweet potatoes prior to storage. Uniform coverage is required. Apply the entire suspension to 90,000 / 150,000 / 300,000 pounds of stored sweet potatoes.

#### SUGAR BEETS

Bio-Save<sup>®</sup> 10 LP Biological Fungicide controls the decay caused by *Penicillium* sp. and gray mold *(Botrytis cinerea)* on sugar beets.

**Overhead Spray Application:** Add 150 grams (5.3 oz.) of product to 9 gallons of water / 250 grams (8.8 oz.) of product to 15 gallons of water / 500 grams (1.1 lb.) of product to 30 gallons of water. Water is a carrier for the Bio-Save 10 LP. When needed, increase or decrease the amount of water in the mixture based on the wetness of the labeled commodity. Wetness is defined as dry, damp or labeled commodity is dripping with water. Labeled commodity, once product is applied in water suspension, should have minimal water appearance. No water dripping is preferred. Agitate the mixture to ensure proper suspension. Apply over conveyor belt or rollers by drip or spray to sugar beets prior to storage. Uniform coverage is required. Apply the entire suspension to 45 / 75 / 150 tons of sugar beets. Bio-Save<sup>®</sup> 10 LP Biological Fungicide can be tank-mixed with the fungicide thiabendazole when used according to label directions.

# STORAGE AND DISPOSAL

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

**Pesticide Storage:** Store only in original containers under refrigerator conditions. Do not expose to heat or warm temperatures during storage and transportation. Keep refrigerated until used. Store product separately from food.

**Pesticide Disposal:** To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Completely empty pouch into application equipment. Then offer for recycling if available or dispose of empty pouch in a sanitary landfill or by incineration. Do not burn, unless allowed by state and local ordinances. (For instances where state and local ordinances do allow burning: If burned, stay out of smoke.)

## WARRANTY

Lallemand Specialties Inc. / LALLEMAND PLANT CARE warrants only that this product conforms to the product description on this label and is reasonably fit for the purposes set forth in the Directions for Use when used in accordance with them. However, ineffectiveness or other unintended consequences may result because of such factors as the use, storage or handling of the product contrary to the label instructions, all of which are beyond the control of Lallemand Specialties Inc. / LALLEMAND PLANT CARE. To the extent consistent with applicable law, Lallemand Specialties Inc. / LALLEMAND PLANT CARE shall not be liable for indirect or consequential damages resulting from the use, storage or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, LALLEMAND SPECIALTIES INC. / LALLEMAND PLANT CARE MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

# **Optional Label Claims:**

- A post-harvest biological disease preventative for citrus fruit (lemons, oranges, and grapefruit), pome fruit (apples and pears), cherries, potatoes, sweet potatoes and sugar beets.
- Aids in the control of blue mold (Penicillium expansum) and gray mold (Botrytis cinerea) on cherries.
- Aids in the control of dry rot (Fusarium sambucinum) and silver scurf (Helminthosporium solani) on potatoes.
- Aids in the control of green mold (*Penicillium digitatum*), blue mold (*Penicillium italicum*), and sour rot (*Geotrichum candidum*) on citrus fruit (lemons, oranges, and grapefruit).
- Aids in the control of blue mold (*Penicillium expansum*), gray mold (*Botrytis cinerea*), and mucor rot (*Mucor piriformis*) on pome fruit (apples and pears).
- Aids in the control of *Penicillium* sp. and gray mold (*Botrytis cinerea*) on sugar beets.
- Aids in the control of Rhizopus soft rot (*Rhizopus stolonifer*) on sweet potatoes.
- Biological Fungicide