



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 9, 2018

Olav Messerschmidt
Consultant to Danstar Ferment AG
OMC Ag Consulting
828 Tanglewood Lane
East Lansing, MI 48823

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – To Add a New Packet Size, Add an Optional Word, Adjust the Directions for Use (in the Treatment Solution Application Section and Tables), and Make Other Changes (Including Those Requested by the EPA)
Product Name: Rotstop C Biofungicide WP
EPA Registration Number: 64137-12
Application Date: 09/11/2018
OPP Decision Number: 544827

Dear Mr. Messerschmidt:

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

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process. Therefore, should the 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 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 me by phone at (703) 347-8920 or via email at kausch.jeannine@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jeannine Kausch', with a stylized, cursive style.

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

Enclosure

{Note to reviewer: Text on pages 1 through 7 will be on the outer box and each of the packets in the box.} {Note to reviewer: Information in square brackets is optional text.}

Rotstop[®]C Biofungicide WP

For control of root and butt rot (species of the *Heterobasidion annosum* complex including *H. irregulare*) on conifers by treatment of freshly cut stumps

Active Ingredient:

Phlebiopsis gigantea strain VRA 1992* 10.0%

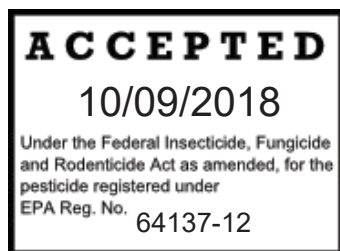
Other Ingredients 90.0%

Total 100.0%

* Contains >3 X 10⁶ cfu/g of active ingredient

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT



FIRST AID

If swallowed:

- 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 or clothing:

- 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 inhaled:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
- Call a poison control center or doctor for treatment advice.

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 non-emergency information concerning this product, call the National Pesticide Information Center (NPIC) at 1-800-858-7378 (NPIC Web site: www.npic.orst.edu). For emergencies, call your local poison control center at 1-800-222-1222.

PACKET NET WEIGHT: 0.13 oz, 0.27 oz, 0.67 oz, or 3.35 oz

BOX NET WEIGHT: Y oz (X 0.13 oz Packets, X 0.27 oz Packets, X 0.67 oz Packets, [and] X 3.35 oz Packets)

{Note to reviewer: "X" = # Packets; "Y" = Box Net Weight (# Packets X Packet weight)}

Batch No.:

EPA Reg. No. 64137-12

EPA Est. No. 91225-EST-001

Manufactured for:
Danstar Ferment AG
Poststrasse 30
Zug CH-6300
Switzerland

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks
- Waterproof gloves
- Protective eyewear

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 a 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 manufacturer's instructions for cleaning and 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)(4-5)), 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 be provided 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.
- 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 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.

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS. 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 interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard (WPS).

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

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
- Shoes plus socks
- Waterproof gloves
- Protective eyewear

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 (WPS) 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.

General Information

Rotstop C Biofungicide WP is a wettable powder formulation for the control of root and butt rot (species of the *Heterobasidion annosum* complex including *H. irregulare*) on conifers by treatment of freshly cut stumps.

Treatment Solution Preparation

Tear off one corner of the foil packet and, into the opened packet, pour approximately 1/2 cup cold or cool water for a 0.13 oz, 0.27 oz, or 0.67 oz packet and approximately 3 cups of cold or cool water for a 3.35 oz packet. Fold the packet top to close it and agitate the packet to prepare an even slurry. Add the slurry to water in the sprayer, rinse the packet and add rinsate water to the treatment solution, and mix thoroughly to produce a final concentration of 0.13 oz Rotstop C Biofungicide WP/gallon of water. For specific dilution and spray coverage instructions, see the tables below. *[A dye can be added to the treatment mixture to aid in monitoring application coverage.]*

Treatment Solution Application

For best results, apply the treatment solution on the freshly cut stump surface immediately after felling, but no later than 3 days after felling, using a backpack sprayer or hand-held sprayer, or apply during tree cutting by spraying with a device mounted on the harvester. Spray stump top surface to the point of wetness. See the tables below for specific dilution and spray coverage instructions.

Application Timing

Treat freshly cut stumps of conifers with Rotstop C Biofungicide WP throughout the entire rotation, from first thinning to final harvest. Treat stumps whenever there is a risk for infection by *Heterobasidion* spores.

Application of Rotstop C Biofungicide WP in Cold Weather

Addition of up to 10% (i.e. 13 fl oz propylene glycol/gallon of treatment solution) propylene glycol (not ethylene glycol) to the Rotstop C Biofungicide WP mixture will prevent the mixture from freezing to about 27° F, thus allowing stump treatment on days when temperatures are below freezing.

Manual Application with Backpack or Hand-Held Sprayer			
Packet Size	Final Spray Water Dilution	Stump Diameter	# of Stumps Treated*
0.13 oz	1 gallon	6-inch 8-inch 10-inch 12-inch	210-250 115-140 75-90 50-60
0.27 oz	2 gallons	6-inch 8-inch 10-inch 12-inch	420-500 230-280 150-180 100-120
0.67 oz	5 gallons	6-inch 8-inch 10-inch 12-inch	1050-1250 575-700 375-450 250-300
3.35 oz	25 gallons	6-inch 8-inch 10-inch 12-inch	5250-6250 2875-3500 1875-2250 1250-1500

* One gallon of spray solution treats up to 48 sq ft of stumps, depending on accuracy of application and amount of overspray.

Mechanized Applications			
Packet Size	Final Spray Water Dilution	Stump Diameter	# of Stumps Treated*
0.13 oz	1 gallon	6-inch 8-inch 10-inch 12-inch	125-250 70-140 45-90 30-60
0.27 oz	2 gallons	6-inch 8-inch 10-inch 12-inch	250-500 140-280 90-180 60-120
0.67 oz	5 gallons	6-inch 8-inch 10-inch 12-inch	625-1250 350-700 225-450 150-300

3.35 oz	25 gallons	6-inch 8-inch 10-inch 12-inch	3125-6250 1750-3500 1125-2250 750-1500
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* One gallon of spray solution treats up to 48 sq ft of stumps, depending on accuracy of application and amount of overspray.

STORAGE AND DISPOSAL

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

Pesticide Storage: Rotstop C Biofungicide WP contains living fungal spores. Store unopened packets up to 12 months in a cool, refrigerated (below 46°F), dry place. If an unopened packet is removed from cool conditions and kept at room temperature, use within one month. Do not expose product to temperatures above 104°F. Use an opened packet and the treatment solution within 24 hours.

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. Completely empty packet into application equipment. Then, offer for recycling if available or dispose of empty packet in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. If the outer box is contaminated, dispose of it in the same manner as required for the packets.

NOTICE TO USER

Danstar Ferment AG 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 Danstar Ferment AG. To the extent consistent with applicable law, Danstar Ferment AG shall not be liable for indirect or consequential damages resulting from the use, storage or handling of this product. DANSTAR FERMENT AG MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.