



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 20, 2021

Jane M. Miller
Agent to Lesaffre Yeast Corporation
c/o Biologic Regulatory Consulting
10529 Heritage Bay Blvd.
Naples, Florida 34120

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – correct
Directions for Use and Storage and Disposal.
Product Name: Romeo
EPA Registration Number: 91810-2
Application Date: 7/14/2021
OPP Submission Number: 1072360
Case Number: 00310909

Dear Ms. Miller

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 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 Andrew Bryceland or via email at Bryceland.andrew@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Andrew C. Bryceland". The signature is fluid and cursive, with the first name "Andrew" and last name "Bryceland" clearly legible.

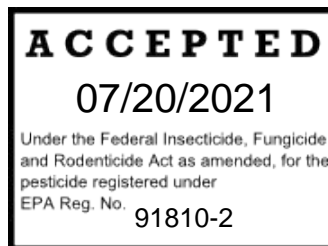
Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

ROMEO®

[Alternate Brand Name: ROMEO CA]



[For Organic Production] [For Use in Organic Production] [Can be used in organic production] [OMRI Listed™ [logo] placeholder]



Systemic Resistance Inducer

Active Ingredient: Cerevisane (cell walls of *Saccharomyces cerevisiae* strain LAS117) ..94.1%
Other ingredients:5.9%
Total:100.0%

Formulation: Wettable Powder (WP)

KEEP OUT OF REACH OF CHILDREN CAUTION

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 in eyes	<ul style="list-style-type: none"> • 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.
<p>HOT LINE 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. For non-emergency information on this product, call the National Pesticide Information Center (NPIC) at 1-800-858-7378 or at http://npic.orst.edu.</p>	

[See] [inside] [label] [booklet] [for] [First Aid][,] [additional] [Precautionary Statements][,] [and] [Directions for Use] [including] [Storage and Disposal] [instructions][.]

EPA Reg. No.: 91810-2

EPA Est. No.: XXXXX-XXX-XXX

Net Contents: _____[oz.][lbs.]

((Batch)(Lot) No: XXXX)

Manufactured for:

Lesaffre Yeast Corporation
7475 W. Main Street
Milwaukee, WI 53214

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE):

Applicators and other handlers must wear:

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

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: 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.

For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation. 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.

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.

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
- Protective eyewear
- Waterproof gloves
- Shoes plus socks

READ THE ENTIRE LABEL BEFORE USING

ROMEO is a Systemic Resistance Inducer (SRI) that acts preventively. Its active ingredient (CEREVISANE – cell walls of *Saccharomyces cerevisiae* strain LAS117) strongly induces plant defense mechanisms, and so prepares the plant to defend itself against fungal and bacterial attacks.

AERIAL DRIFT REDUCTION INFORMATION

General

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment- and weather-related factors determine the potential for spray drift. The applicator and grower are responsible for considering all these factors when making decisions. Where states have more stringent regulations, they should be observed. This section is advisory and does not supersede any mandatory label requirements.

Information on Droplet Size

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that will provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

Controlling Droplet Size

Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types, lower pressure produces larger droplets. When high flow

rates are needed, use higher flow rate nozzles instead of increasing pressure. Use the minimum number of nozzles that provide uniform coverage. Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential. Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and lowest drift.

Boom Width

For aerial applications, the boom width must not exceed 75% of the wingspan or 90% of the rotary blade. Use upwind swath displacement and apply only when wind speed is 3-10 mph as measured by an anemometer. Use medium or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles. If application includes a no-spray zone, do not release spray at a height greater than 10 feet above the ground or crop canopy.

Application Height

Do not make application at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure to droplets to evaporation and wind.

Swath Adjustment

When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for the displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.).

Wind

Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. Local terrain can influence wind patterns. Every applicator should be familiar with local windy patterns and how they affect spray drift.

Temperature and Humidity

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

Temperature Inversions

Do not apply during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small, suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an

inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

Sensitive Areas

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g., when wind is blowing away from the sensitive areas). Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, non-target crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals.

APPLICATION INSTRUCTIONS

ROMEIO can be applied as a foliar spray to field or greenhouse crops. Do not apply through any type of chemigation.

Apply using conventional spray equipment to the point of saturation, using a sufficient volume of mixture to ensure complete coverage of vegetation without run-off. The amount of spray solutions necessary will depend on the type of crop. Most crops require up to 100 gallons of spray per acre, with a recommended range of 20-100 gallons per acre. If possible, apply the product on both faces of the leaves and preferably early in the morning. Avoid application during periods of hot temperatures. In case of strong rains (rainfastness risk) during the period 48 hours after treatment, repeat the application.

USE RECOMMENDATIONS

Apply ROMEIO as a preventative treatment before a risk of disease contamination.

Spray interval: 7-10 days depending on the disease pressure.

In case of high pressure/risk, ROMEIO should be used in program with other fungicides (alternation or tank-mix).

Romeo has been evaluated for phytotoxicity on a variety of crops under various normal growing conditions. However, testing all crop varieties, in all mixtures and combinations, is not feasible. Prior to treating entire crop, test a small portion of the crop for sensitivity.

Mixing directions - Important – Do not add Romeo to the spray tank before introducing the correct amount of water.

Add water to the spray tank. Start the mechanical or hydraulic agitation to provide moderate circulation before adding Romeo. Maintain circulation while loading and spraying. Do not mix more Romeo than can be used in 24 hours.

Always ensure the sprayer is clean according to standard cleaning procedures, in good working order and calibrated accurately to the sprayer manufacturer recommendations.

Tank mixing

Do not combine Romeo in the spray tank with other pesticides, surfactants, adjuvants, or fertilizers if there has been no previous experience or use of the combination to show it is physically compatible, effective, and non-injurious under your use conditions. Follow the most

restrictive of the labeling limitations and precautions of all products used in mixtures.

To ensure compatibility of tank-mix combinations, they must be evaluated prior to use. To determine the physical compatibility of this product with other products, use a jar test. Using a quart jar, add the proportionate amounts of the products to one quart of water with agitation. Add dry formulations first, then flowables, and then emulsifiable concentrates last. After thoroughly mixing, let this mixture stand for 5 minutes. If the combination remains mixed or can be readily remixed, it is physically compatible. Once compatibility has been proven, use the same procedure for adding required ingredients to the spray tank.

Test the mix on a small portion of the crop to be treated to ensure that a phytotoxic response will not occur as a result of the application.

TARGET PLANT DISEASES

Alternaria leaf spot; Anthracnose; Asian soybean rust; Black sigatoka; Botrytis; Brown spot; Cercospora; Downy mildew; Early blight; Fire blight; Frogeye leaf spot; Fusarium; Late blight; *Monilinia* spp. (brown rot/blossom blight); Phytophthora; Powdery mildew; Rhizoctonia; Rust; Rumlalaria; Scab; Sour rot; White mold.

APPLICATION RATES

Thoroughly cover plant foliage with spray solution. Pre-harvest Interval (PHI) = 0 days.

CROPS	TARGET DISEASES	APPLICATION RATE
Berries and Small Fruits: Blackberry; Blueberry; Bushberry; Caneberry; Cranberry; Currant; Elderberry; Gooseberry; Huckleberry; Loganberry; Raspberry; Strawberry.	Botrytis Downy mildew Powdery mildew	0.45 - 0.68 lbs/acre
Brassica Head and Stem Vegetable Group: Broccoli; Brussels sprouts; Cabbage; Cabbage, Chinese, napa; Cauliflower; Cultivars, varieties, and/or hybrids of these.	Downy mildew Powdery mildew	0.23 - 0.68 lbs/acre
Bulb Vegetables: Chive, fresh leaves; Chive, Chinese, fresh leaves; Daylily, bulb; Elegans hosta; Fritillaria, bulb; Fritillaria, leaves; Garlic, bulb; Garlic, great headed, bulb; Garlic, Serpent, bulb; Kurrat; Lady's leek; Leek <i>Allium porrum</i> ; Leek, wild; Lily, bulb; Onion, Beltsville bunching; Onion, bulb; Onion, Chinese, bulb; Onion, fresh; Onion, green; Onion, macrostem; Onion, pearl; Onion, potato, bulb; Onion, tree, tops; Onion, Welsh; Shallot, bulb; Shallot, fresh leaves; cultivars, varieties, and/or hybrids of these.	Botrytis Downy mildew Powdery Mildew	0.23-0.91 lbs/acre
Cucurbit Vegetables: Cucumbers; Melons; Gourds; Pumpkins; Squash; Zucchini.	Botrytis Downy mildew Powdery Mildew	0.45 lbs/acre

CROPS	TARGET DISEASES	APPLICATION RATE
Fruiting Vegetables: Eggplant; Okra; Sweet and hot Peppers; Tomatillos; Tomatoes.	Alternaria leaf spot Botrytis Downy mildew Late blight Powdery Mildew	0.45 - 0.68 lbs/acre
Grapevine and Table Grapes	Botrytis Downy mildew Powdery mildew Sour rot	0.23 lbs/acre
Herbs and Spices: Angelica; Balm; Basil; Borage; Burnet; Chamomile; Catnip; Chervil; Chive; Clary; Coriander; Costmary; Cilantro; Curry; Dillweed; Horehound; Hyssop; Lavender; Lemongrass; Lovage; Marjoram; Nasturtium; Parsley (dried); Peppermint; Rosemary; Sage; Savory (summer and winter); Sweet bay; Tansy; Tarragon; Thyme; Wintergreen; Woodruff; Wormwood.	Botrytis Downy mildew Powdery mildew	0.23 - 0.68 lbs/acre
Leafy Vegetables and Cole Crops: Arugula; Celery; Chervil; Endive; Fennel; Lettuce (head and leaf); Parsley; Radicchio; Rhubarb; Spinach; Swiss Chard; Broccoli; Brussels Sprouts; Cabbage; Cauliflower; Collards; Kale; Kohlrabi Mustard Greens; Asparagus.	Botrytis Downy mildew Powdery Mildew Rhizoctonia	0.45 - 0.68 lbs/acre
Legume Vegetables (Succulent or Dried): Bean; Broad bean (fava); Chickpea; Guar; Jackbean; Lablab bean; Lentil; Pea; Pigeon pea; Soybean; Sword bean.	Alternaria leaf spot Anthracnose Asian Soybean Rust Botrytis Brown spot Cercospora Downy mildew Frogeye leafspot Phytophthora Powdery mildew Rust White mold	0.23 - 0.68 lbs/acre
Pome Fruits: Apple; Azarole; Crabapple; Loquat; Mayhaw; Hook. & Arn.; Medlar; Pear; Pear, Asian; <i>Pseudocarya sinensis</i> ; Quince; Quince, Chinese; Quince, Japanese; Tejocote; cultivars, varieties and/or hybrids of these.	Alternaria leaf spot Apple Scab Botrytis Fire blight Powdery mildew	0.23 - 0.91 lbs/acre

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in original container in a cool, dry place. Prevent exposure to moisture. Keep container tightly closed and out of reach of children. Avoid contamination with other pesticides or fertilizers.

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: [For pails with liner:] Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or dispose of in a sanitary landfill or by incineration. If pail is contaminated, triple rinse promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank. Fill the container ¼ full of water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

[For plastic bags:] Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. Then offer for recycling, if available, or dispose of empty bag in a sanitary landfill or by incineration. Do not burn unless allowed by state and local ordinances. If burned, stay out of smoke.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Lesaffre Yeast Corporation. All such risks shall be assumed by the user or buyer.

WARRANTY: Lesaffre Yeast Corporation warrants that this product complies with the specifications expressed in this label.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Lesaffre Yeast Corporation makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability or fitness for a particular purpose. No agent of Lesaffre Yeast Corporation is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Lesaffre Yeast Corporation disclaims any liability whatsoever for special, incidental, or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Lesaffre Yeast Corporation's election, the replacement of product.

