



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 24, 2021

Keeva Shultz
Authorized Agent to Lesaffre Yeast Corporation
c/o Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707-0640

Subject: Pesticide Registration Improvement Act (PRIA) Labeling Amendment – Update the Application Frequency and Timing in the Directions for Use and Make Changes Requested by the EPA (e.g., Update the Storage Instructions)
Product Name: Nexy
EPA Registration Number: 91810-4
Application Date: 07/31/2020
Action Code Case Number: 00141256

Dear Ms. Shultz:

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 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 Jennifer Odom by phone at (703) 347-0565 or via email at odom.jennifer@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'JKausch', written in a cursive style.

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

Enclosure

NEXY

Biofungicide for the post-harvest control of *Botrytis cinerea* (gray mold) and *Penicillium expansum* (blue mold) on apples and pears

ACTIVE INGREDIENT:	WT. BY %
<i>Candida oleophila</i> strain O*	57.0%
OTHER INGREDIENTS:	43.0%
TOTAL:	100.0%

**Contains a minimum of 6 x 10⁹ colony forming units (CFU) per gram*

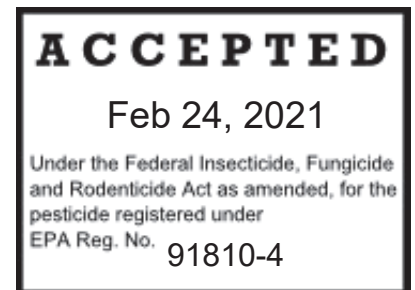
KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
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.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • 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 additional precautionary statements on the back panel

EPA Reg. No. 91810-4
 EPA Est. Number:
 Net Weight: 1.1 lbs., 2.2 lbs., or 11.1 lbs.
 Batch No. _____
 Use before date: _____

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



PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Causes moderate eye irritation. Harmful if absorbed through skin or inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. 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):

Mixers/loaders and applicators of the product, as well as individuals handling crates of treated apples and pears, must wear:

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

Mixers/loaders and applicators of the product, as well as individuals entering storage areas after the reentry interval of 24 hours has elapsed and working on the fruit packing line while applications are being applied, 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 exposures 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 exist, 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 the labeling.

General Information

NEXY is a selective fungal antagonist for control of *Botrytis cinerea* (gray mold) and *Penicillium expansum* (blue mold) on apples and pears.

Use Restrictions

- Do not use this package if vacuum has been breached. Dispose of unused product in accordance with the storage and disposal instructions.
- NEXY is designed for use only with the NEXY ADDITIVE and is not to be sold separately.
- For use only as an indoor post-harvest treatment to control *Botrytis cinerea* (gray mold) and *Penicillium expansum* (blue mold) on pears and apples.

- Residues of some chemical fungicides from pre-harvest treatments to apples or pears may reduce the efficacy of NEXY and should be avoided when possible.
- If fruit is intended for processing, consult processor before treatment with NEXY to ensure treatment is acceptable to processor.

Mixing Instructions

- Activate NEXY biomass before use. To activate: Add the required quantity of NEXY indicated in the Application Rate Table to a mixing jar or other suitable container. Then add one pint of water for each ounce of NEXY and seal the container. Agitate mixture thoroughly for several minutes, 2-3 times as needed, over a period of at least one hour.
- Then half-fill the application tank with clean water.
- Add the activated NEXY and the amount of NEXY ADDITIVE indicated in the Application Rate Table to the application tank.
- Complete filling the application tank with clean water and maintain agitation of the suspension.

Application Instructions

Apply the treatment mixture of NEXY biomass, NEXY ADDITIVE, and water to apples and pears, after harvest by dipping, drenching or indoor spraying before cold storage. NEXY can also be applied as aqueous line spray after cold storage on the packing line.

Drench apples and pears with the treatment mixture for at least 30 seconds, or dip apples and pears in the treatment mixture between 30 seconds and 2 minutes. In the case of dipping, ensure homogenization of the treatment mixture by constant agitation. For indoor spray application, fill the cold room with filled apple/pear bins, seal the room and make sure all personnel are outside the room at the time of application. At the end of treatment, detach the application tank set up outside the room from the spray line and seal the room. Do not allow reentry into the sealed room for 24 hours after the treatment is applied.

The treatment mixture protects against gray mold and blue mold through the storage season, while a treatment after cold storage protects the fruit during the packing and distribution period. Apply NEXY soon after harvest when fruit is placed in the storage rooms. One treatment using dipping/drenching/in room spraying system must be done immediately after harvest following the Application Rate Table. If required, a second application in storage could be done using the indoor spray system. For the second application, use the same application rate.

After the storage period, NEXY can be applied as an aqueous line spray in the apple and pear packing line. Follow the Application Rate Table below and mixing instructions above to properly apply the treatment mix. Ensure constant homogenization during on line aqueous spray application.

After treatment, neutralize the yeast in tank with disinfectant such as Peracetic acid (PAA), hydrogen peroxide at 0.1% or sodium hypochlorite at 0.5% by volume (sodium hypochlorite with 15% active chlorine). This neutralization is to help to reduce the BOD (Biological Oxygen Demand) of the wastewater. In the case of drenching, run the application equipment with the mixture containing the disinfectant for at least 10 minutes before rinsing twice with clean water.

APPLICATION RATE TABLE	
NEXY:	0.9 ounce of product/20 gallons water
NEXY ADDITIVE:	5.4 ounces of additive/20 gallons water
TOTAL APPLICATION VOLUME:	2.4 to 7.3 gallons treatment mixture/ton of apples or pears

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

If Unopened: Store in original, tightly closed container in cool, dry place and between temperatures of 40°F to 70°F. Temperatures above 70°F will damage the quality of the product. Protect product from frost.

If Opened: Store in original, tightly closed container in cool, dry place and between temperatures of 40°F to 50°F. Temperatures above 50°F will damage the quality of the product. Protect product from frost. Use product within one week.

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 bag into application equipment. 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.

NOTICE OF WARRANTY

Lesaffre Yeast Corporation warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for the purposes stated on such label only when used in accordance with label directions under normal use conditions. It is impossible to eliminate all risks inherently 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. To the extent consistent with applicable law, Lesaffre Yeast Corporation shall not be liable for consequential, special or indirect damages resulting from the use or handling of this product. To the extent consistent with applicable law, all such risks shall be assumed by the buyer. To the extent consistent with applicable law, Lesaffre Yeast Corporation MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESSED OR IMPLIED WARRANTY EXCEPT AS WARRANTED IN THIS LABEL.