

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 21, 2023

Amy Plato Roberts Director of Regulatory Affairs Danstar Ferment AG/ Lallemand Plant Care PO Box 990 Hailey, Idaho 83333

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling and Formulation

Amendment - remove expiration date, add for organic production statement, IRAC

code and a crop, and to add an additional formulation site to the CSF.

Product Name: LALGUARD M52 GR EPA Registration Number: 64137-31 EPA Receipt Date: 04/16/2022

Action Case Number: 00355726

Dear Ms. Roberts:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are 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.

Please note that the record for this product currently contains the following acceptable CSF:

Basic CSF dated 04/10/2023

Any CSFs other than that listed above are superseded/no longer valid.

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 EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the

Page 2 of 2 EPA Reg. No. 64137-31 Action Case No. 00355726

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.

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 Queen by phone at 202-566-1539 or via email at queen.andrew@epa.gov.

Sincerely,

CODY

Digitally signed by CODY KENDRICK

Date: 2023.04.21
14:57:33 -07'00'

Cody Kendrick, Senior Regulatory Advisor Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511M) Office of Pesticide Programs

Enclosure: Stamped Label

[Text in brackets is optional] (Text in parenthesis is for the reviewer) (Front Panel)

LALGUARD® M52 GR

ACCEPTED

Apr 21, 2023

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 64137-31

Metarhizium brunneum (formerly known as Metarhizium anisopliae)
Strain F52

GROUP

INSECTICIDE

- Bioinsecticide

- (For Organic Production) (For Use in Organic Production) (Can be used in organic production)

ACTIVE INGREDIENT: Metarhizium brunneum (formerly known as Metarhizium	
anisopliae) Strain F52*	2.0%
OTHER INGREDIENTS:	98.0%
TOTAL:	100.0%
**	

^{*}Contains a minimum of 9.0 x 108 Colony Forming Units (CFU) per gram of product.

KEEP OUT OF REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Causes moderate eye irritation. Harmful if inhaled, absorbed through skin, or swallowed. 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.

[REFER TO DIRECTIONS OF USE WITHIN THIS BOOKLET]

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.	
IF INHALED:	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 further treatment advice.	
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 SWALLOWED:	Call a poison control center or doctor immediately for treatment advice. Have a 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.	

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents) call the National Pesticide Information Center at 1-800-858-7378 8:00AM – 12:00PM Pacific Time (PT), Mon-Fri. During other times call the poison control center at 1-800-222-1222.

Batch No.: see printing on bag

(Expiration Date: see printing on bag)

Net Contents: [2.2 Lbs.][3 Lbs.][5 Lbs.][22 Lbs.][25 Lbs.][bag][XX Kg.]

Manufactured for:

Danstar Ferment AG / LALLEMAND PLANT CARE Poststrasse 30

Zug CH-6300 Switzerland

EPA Establishment Number: XXXXX-XX-XXX

EPA Registration Number: 64137-31 [Made in] [USA] [Canada] [Brazil] [Germany]

Marketed and distributed by:

Lallemand Specialties Inc. / LALLEMAND PLANT CARE 6120 West Douglas Avenue Milwaukee, WI 53218 United States

[LALLEMAND LOGO]

[Peel back for instructions. PRESS TO RESEAL]

(End Front Panel)

PERSONAL PROTECTIVE EQUIPMENT

Mixer/loaders, applicators and other handlers must wear:

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

Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any R, or P filter; <u>OR</u> a NIOSH-approved elastomeric particulate respirator with any, R, or P filter; <u>OR</u> a NIOSH-approved powered air- purifying respirator with an HE filter. Repeated exposures to high concentrations of microbial proteins can cause allergic sensitization.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, 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 170.607(d) and (e)], 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 break-down.

I	USER SAFETY RECOMMENDATIONS
I	Users should remove clothing immediately if pesticide gets inside, then wash thoroughly and put on
I	clean clothing.
	Remove personal protection equipment 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. 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.

Do not enter or allow worker entry into treated areas during the Restricted Entry Interval (REI) of 12 hours.

EXCEPTION: If the product is soil incorporated or soil injected, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas requiring a REI that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water are:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear
- NIOSH-approved particulate filtering facepiece respirator with any R, or P filter; <u>OR</u> a NIOSH-approved elastomeric particulate respirator with any, R, or P filter; <u>OR</u> a NIOSH-approved powered air- purifying respirator with an HE filter.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses that are NOT within the scope of the Worker Protection Standard 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.

PRODUCT INFORMATION

LALGUARD M52 GR is composed of spores of the insect pathogenic fungus *Metarhizium brunneum* (formerly known as Metarhizium anisopliae). Once the product is incorporated into the growing medium, insects that come into contact with the fungus will become infected. The spores of *Metarhizium brunneum* (formerly known as Metarhizium anisopliae) attach to the surface of the insect, germinate, and begin to grow. It will penetrate the exoskeleton of the insect and grow inside the insect, causing the insect to die. Under moderate temperatures it usually takes 3 to 7 days once the insect is exposed for death to occur. At very cold or hot temperatures death may occur more slowly. The fungal spores will be more persistent when incorporated in the soil, especially in potting media, than when applied to foliage.

Note: LALGUARD M52 GR contains live spores that may be harmed by storage at high temperatures. See storage and disposal section for more information.

MODE OF ACTION AND APPLICATION TIMING: Application frequency will depend on the environment to which LALGUARD M52 GR is applied and the target insects' life cycle. Persistence of LALGUARD M52 GR will generally be higher when incorporated into soil. Applications to leaf litter and turf may be done on a four to six week interval with an expected residual efficacy of a few months.

When possible, application to soil should be done in advance of when target insect will be passing through the top six inches of soil. A residual efficacy of a few months can be expected. Although the

penetration of LALGUARD M52 GR into soil will vary greatly with soil type and level of irrigation it is best to target populations as close to the surface as possible or time application of LALGUARD M52 GR with a soil incorporation event.

Once the product is incorporated into the growing medium, insects that come into contact with the fungus become infected. The spores attach to the surface of the insect, germinate and grow. Under moderate temperatures it usually takes 3 to 7 days, once the insect is exposed for death to occur. At very cold or hot temperatures death may occur more slowly. The fungal spores will be more persistent when incorporated in the soil, especially in potting media, than when applied to foliage. LALGUARD M52 GR has been demonstrated to last through two black vine weevil egg laying seasons when incorporated into growing media in the spring before egg lay. Other insects that come into contact with infected insects may also be infected extending the control period.

PRE-HARVEST INTERVAL: The pre-harvest interval for LALGUARD M52 GR is zero (0) days. LALGUARD M52 GR may be applied up to the day of harvest.

SITES FOR USE

TERRESTRIAL NON-FOOD: Greenhouse ornamental, nurseries, institutional lawns and landscape perimeters. Do not apply on poinsettias after bract formation.

FOOD CROPS: LALGUARD M52 GR can be applied to the crops listed in Table 1. LALGUARD M52 GR has shown plant safety but has not been tested on all varieties. Test LALGUARD M52 GR on a small number of plants to check for potential damage before applying to a large number of plants.

APPLICATION INSTRUCTIONS

NURSERY PLANTING MIX: Apply LALGUARD M52 GR prior to or during planting by thoroughly mixing the product into the growing medium, ensuring even distribution. It may help distribution to first apply the full concentration to a smaller volume of growing media such as to 1/3 to 1/10 of the total volume and then mix this concentrated growing media with the full volume. Apply at a rate of 1.5 to 3.0 lbs. of product per cubic yard of growing medium (or 25 to 50 grams per cubic foot of growing medium). Use higher label rates when larval pressure is expected to be high.

LALGUARD M52 GR is grown on rice grains that will decompose in the growing media. Pests likely to be attracted by grains, such as rodents, must be controlled prior to use of this product.

APPLICATION TO TURF: Apply 1 to 3 pounds of LALGUARD M52 GR to 1000 square feet in institutional lawns and landscape perimeters. Applications for blacklegged ticks should focus on the border of manicured lawns and paths creating a minimum of a 9 foot border. Applications for more mobile ticks such as the lonestar tick should cover a wider area and include the entire lawn. Initial applications should begin in the spring before ticks become active and continue at 4 to 8 week intervals throughout their active season.

TABLE 1: CROPS ON WHICH LALGUARD M52 GR MAY BE USED:

CROP	PEST	APPLICATION	RATE
Onions	thrip pupae	nursery planting mix	1.5-3.0 lbs/ yd³
Celery, lettuce, spinach	thrip pupae	nursery planting mix	1.5-3.0 lbs/ yd³
Peppers, tomatoes	thrip pupae	nursery planting mix	1.5-3.0 lbs/ yd³
Grape, strawberry, cranberry, raspberry, blackberry, blueberry	thrip pupae, vine weevils (larvae)	nursery planting mix	1.5-3.0 lbs/ yd³

Ornamental plants and grasses: shrubs, vines, trees, bedding plants, etc.	thrip pupae, vine weevils (larvae)	nursery planting mix	1.5-3.0 lbs/ yd³
Turf: institutional lawns	ticks	broadcast	1.0-3.0 lbs/ 1000 ft ²

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store LALGUARD M52 GR in its original container below 73°F (23°C), in a dry, locked place out of reach of children and out of direct sunlight. Do not use or store near heat or open flame.

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.

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.

[Text in brackets is optional] (Text in parenthesis is for the reviewer)

LALGUARD® M52 GR

Metarhizium brunneum (formerly known as Metarhizium anisopliae) GROUP UNF INSECTICIDE
Strain F52

- Bioinsecticide

- (For Organic Production) (For Use in Organic Production) (Can be used in organic production)

ACTIVE INGREDIENT: Metarhizium brunneum (formerly known as Metarhizium	
anisopliae) Strain F52*	2.0%
OTHER INGREDIENTS:	
TOTAL:	

^{*}Contains a minimum of 9.0 x 10⁸ Colony Forming Units (CFU) per gram of product.

KEEP OUT OF REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Causes moderate eye irritation. Harmful if inhaled, absorbed through skin, or swallowed. 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.

[Refer to dirctions of use within this booklet]

FIRST AID		
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15 - 20 minute	
	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 INHALED:	ED: 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 further treatment advice.	
IF ON SKIN OR	Take off contaminated clothing. Rinse skin immediately with plenty of water for	
CLOTHING:	15 – 20 minutes. Call a poison control center or doctor for treatment advice.	
IF SWALLOWED:	Call a poison control center or doctor immediately for treatment advice. Have a	
	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.	

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents) call the National Pesticide Information Center at 1-800-858-7378 8:00AM – 12:00PM Pacific Time (PT), Mon-Fri. During other times call the poison control center at 1-800-222-1222.

Net Contents: [2.2 Lbs.][3 Lbs.][5 Lbs.][22 Lbs.][25 Lbs.][bag][XX Kg.]

Manufactured for: EPA Establishment Number: XXXXX-XXX

Danstar Ferment AG / LALLEMAND PLANT CARE

Poststrasse 30 EPA Registration Number: 64137-31

Zug CH-6300 Switzerland

Marketed and distributed by:

Lallemand Specialties Inc. / LALLEMAND PLANT CARE 6120 West Douglas Avenue Milwaukee, WI 53218 United States

[LALLEMAND LOGO]

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store LALGUARD M52 GR in its original container below 73°F (23°C), in a dry, locked place out of reach of children and out of direct sunlight. Do not use or store near heat or open flame.

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.

(End Back Panel)