



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 16, 2021

Charles Levey
US Regulatory Team Lead Insecticides
Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, NC 27519

Subject: Non-Pesticide Registration Improvement Act (PRIA) Labeling Amendment – Add
Organic Production Language and OMRI Logo
Product Name: Afla-Guard GR
EPA Registration Number: 100-1469
Application Date: October 9, 2020
OPP Case Number: 00144417

Dear Mr. Levey:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable under FIFRA section 3(c)(5).

You must submit and/or cite all data required for registration or registration review of your product when the U.S. Environmental Protection Agency (EPA) requires all registrants of similar products to submit such data.

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 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

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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 Daniel Schoeff by phone at (703) 347-0143 or via email at schoeff.daniel@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Alexandra Boukedes".

Alexandra Boukedes, Risk Manager
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

[Master]

Afla-Guard® GR

For agricultural use to displace aflatoxin-producing fungi in almonds, peanuts, pistachios, and corn

[OMRI Listed][For Use in Organic Production][For Organic Production]



Active Ingredient:	
<i>Aspergillus flavus</i> NRRL 21882*	0.0094%
Other Ingredients:	99.9906%
<hr/>	
Total:	100.0000%

*Contains a minimum of 1.2 x 10⁸ CFU/lb of product

KEEP OUT OF REACH OF CHILDREN

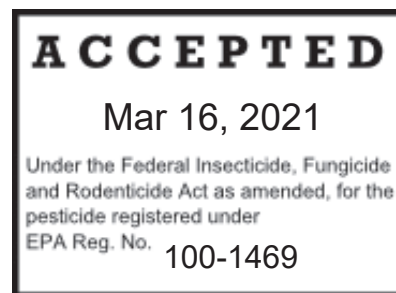
CAUTION

See additional precautionary statements and directions for use on the container label [to the right].

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EPA Est.

Manufactured for:
Syngenta Crop Protection, LLC
P. O. Box 18300
Greensboro, North Carolina 27419-8300



Not for sale or use after _____ [Date stamped/placed on labeling will be 4 months after the date of manufacture.]

Lot No.: _____

_____ Pounds
Net Weight

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 immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
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 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 by mouth-to-mouth, if possible.• Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
HOTLINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call 1-800-888-8372	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Causes moderate eye irritation. Harmful if absorbed through skin, swallowed, or inhaled. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. 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)

Applicators, mixers, loaders and other handlers must wear:

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

Mixers/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 the manufacturer's instructions for cleaning/maintaining PPE. If no instructions are available, use detergent and hot water for washables. 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 highwater mark. Do not contaminate water by cleaning equipment or disposal of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to apply 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. Do not apply in the vicinity of schools, daycares, nursing homes and residential areas. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

PRODUCT INFORMATION

Afla-Guard GR is a biological control agent for displacing the strains of *Aspergillus flavus* (*A. flavus*). The active ingredient in Afla-Guard GR is a nontoxigenic strain of *A. flavus* (NRRL 21882). Afla-Guard GR acts by competitively displacing toxigenic, aflatoxin-producing strains of *A. flavus* on labeled crops. Afla-Guard GR is for use on [almonds, peanuts, pistachios, and corn (field and popcorn)] only.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance 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 statement 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
- Waterproof gloves
- Shoes plus socks
- 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
- Goggles

USE DIRECTIONS

For aerial applications: Avoiding drift at the application site is the responsibility of the applicator. The interaction of many equipment- and weather-related factors determine the potential for drift. The applicator and treatment coordinator are responsible for considering all these factors when making decisions.

Peanuts

Ground Application: Apply Afla-Guard GR at 20 lb/Acre (A) in a band over crop rows by using a tractor-mounted Gandy box or by broadcast application. Apply at full canopy (40-80 days after planting). At the time of application, the width of a peanut row (measured from the outer edges of the foliage canopy) is ideally about 18 inches.

Aerial Application: Apply by air at 20 lb/A broadcast. Apply as soon as practical after closure of the peanut canopy, within 90 days after planting.

Do not exceed 20 lb/A per growing season.

Corn (field corn and popcorn)

Ground and Aerial Application: Apply Afla-Guard GR from growth stage V7 to R1 (the V7 growth stage is when there are 7 visible leaf collars present and the R1 growth stage is the onset of silking) using broadcast application equipment. Cultivation or other mechanical operations that may move soil so that it covers the Afla-Guard GR grain may preclude maximum performance. Therefore, DO NOT APPLY AFLA-GUARD GR UNTIL ALL CULTIVATION OR OTHER MECHANICAL OPERATIONS ARE COMPLETED.

Do not exceed 20 lb/A per growing season.

Apply Afla-Guard GR at a use rate of 10-20 lb/A.

Under environmental conditions that promote severe aflatoxin levels or when historically high levels of aflatoxin have occurred in the past in your area, use the 20 lb/A rate.

Rescue treatment: If an initial rate of 10 lb/A was applied, a rescue treatment of 10 lb/A may follow if environmental conditions are anticipated to reduce the efficacy of Afla-Guard GR (i.e. flooding), or when higher than usual levels of aflatoxin are expected.

Almond and Pistachio

Ground Application:

1. Apply Afla-Guard GR to the surface of the soil under the plant canopy with a granular applicator. DO NOT COVER THE APPLIED PRODUCT WITH SOIL.
2. Adjust the applicator to optimize delivery of Afla-Guard GR under the canopy and to minimize delivery of Afla-Guard GR to areas that do not get wet.
3. Afla-Guard GR has been shown to be effective when applied in Pistachio from late May through early July, and in Almond from late May through early July.
4. Rain or irrigation within 3 days after application of Afla-Guard GR will improve results.
5. Use 10 lb of Afla-Guard GR per acre.
6. Do not apply more than once per year.
7. Do not apply to almonds in bloom.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a dry, cool place out of direct sunlight and away from heat sources. Keep from overheating. Storage temperatures are not to exceed 90°F. Do not use product more than 4 months after purchase or save product for use in the subsequent season.

Pesticide Disposal: To avoid waste, use all material in this container by application according to label directions. If waste cannot be avoided, offer remaining products 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 by shaking and tapping the sides and bottom to loosen clinging particles. Then dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. Do not recycle.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. 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 manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC (hereafter SYNGENTA) or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be

modified except by written agreement signed by a duly authorized representative of SYNGENTA.

Afla-Guard®, The ALLIANCE FRAME, the SYNGENTA Logo, and the PURPOSE ICON are Trademarks of a Syngenta Group Company

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