



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 30, 2017

Michael Braverman, Ph.D.
Agent to Arizona Cotton Research and Protection Council
IR-4 Project, Rutgers University
500 College Road East, Suite 201W
Princeton, NJ 08540

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Correct
Typographical Error and Change Font Size on the Heading of the Storage and Disposal
Box
Product Name: *Aspergillus flavus* AF36 Prevail
EPA Registration Number: 71693-2
Application Date: 09/15/2017
OPP Decision Number: 535437

Dear Dr. Braverman:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The labeling submitted with this application has been stamped “Notification” and will be placed in our records. You must submit one (1) copy of the final printed labeling with the modifications.

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 the Federal Insecticide, Fungicide, and Rodenticide Act (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 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.

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If you have any questions, please contact Alex Boukedes by phone at (703) 347-0305 or via email at boukedes.alexandra@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jeannine Kausch', with several overlapping loops and a long horizontal stroke at the end.

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

Enclosure



Aspergillus flavus AF36 Prevail

For displacing aflatoxin-producing fungi

Arizona Cotton Research and Protection Council

“for growers by growers”

COTTON: FOR USE ONLY IN THE STATES OF ARIZONA, TEXAS AND CALIFORNIA (Imperial, Riverside and San Bernar-di-no counties only)

CORN: FOR USE ONLY IN THE STATES OF ARIZONA AND TEXAS

PISTACHIO, ALMOND AND FIG: FOR USE ONLY IN THE STATES OF CALIFORNIA, ARIZONA, TEXAS AND NEW MEXICO

Aspergillus flavus AF36 is a strain of *Aspergillus flavus* that was isolated in Arizona and is native and endemic to many states. Apply to cotton just prior to first bloom, to corn from the 7 leaf stage (V7) until silking, to pistachio from late May through early July, to almond from late May to early July, or to fig from early May to late June. **Aspergillus flavus AF36** competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and, in doing so, limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: *Aspergillus flavus* strain AF36* 0.0008%
 Other ingredients: 99.9992%
 Total: 100.0000%

*Contains a minimum of 3,000 CFU/gram in the End-Use Product

KEEP OUT OF REACH OF CHILDREN

CAUTION

| First Aid | |
|--|---|
| 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 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. |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |

SEE PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration No.: 71693-2
 EPA Establishment No.: 71693-AZ-001

Arizona Cotton Research and Protection Council
 3721 E. Wier Avenue
 Phoenix, Arizona 85040

NET WEIGHT: 50 lb. bags or variable weight bulk bags 1,000 to 3,000 lb

BATCH CODE:

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled or absorbed through skin. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. 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. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear: protective eyewear, 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), long-sleeved shirt and long pants, waterproof gloves, shoes and socks.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are available for washables, 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 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. Read all label directions before using.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and 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 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: protective eyewear, 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, coveralls, waterproof gloves, shoes and socks.

PRODUCT INFORMATION

Aspergillus flavus AF36 Prevail is for application to cotton, corn, pistachio, almond and fig to displace aflatoxin-producing strains of *Aspergillus flavus*. **Aspergillus flavus AF36 Prevail** contains a fungus, *Aspergillus flavus*, that displaces aflatoxin-producing fungi within the crop environment. **Aspergillus flavus AF36** has been shown to reduce aflatoxin both in laboratory studies and commercial field studies. **Aspergillus flavus AF36** is a living fungus growing on grain, which serves as both a carrier and a nutrient source. After application and once the colonized grain is exposed to sufficient moisture (this may occur at irrigation), **Aspergillus flavus AF36** will grow out and the grain will be covered with green spores. This growing fungus will first appear as white fuzz and later as green fuzz. The green spores will eventually be spread to the crop by wind and insects in the same manner that aflatoxin-producing fungi are spread.

USE PRECAUTIONS

Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. Apply **Aspergillus flavus AF36 Prevail** only when the potential for drift to adjacent, sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, nontarget crops on surrounding farms) is minimal. **Aspergillus flavus AF36 Prevail** may be applied to the approved crops that are irrigated.

APPLICATION INSTRUCTIONS

Ground Application: COTTON

1. Apply **Aspergillus flavus AF36 Prevail** to the surface of the soil under the plant canopy with a tractor-mounted, granular applicator. DO NOT COVER THE APPLIED PRODUCT WITH SOIL.
2. Adjust the applicator to optimize delivery of **Aspergillus flavus AF36 Prevail** under the canopy and to minimize delivery of **Aspergillus flavus AF36 Prevail** to furrows.
3. **Aspergillus flavus AF36 Prevail** has been shown to be effective when applied from late May through June, prior to first bloom. Make a single application during the last cultivation before bloom.
4. Furrow irrigating the crop with at least 2 inches of water within 3 days after application of **Aspergillus flavus AF36 Prevail** will provide best results.
5. Use 10 lbs of **Aspergillus flavus AF36 Prevail** per acre of cotton (per 13,000 linear feet based on 40-inch rows).

Ground Application: CORN

1. Apply **Aspergillus Flavus AF36 Prevail** directly to the soil or under the plant canopy after last cultivation with a tractor-mounted, granular applicator. Make a single application from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. DO NOT COVER THE APPLIED PRODUCT WITH SOIL.
2. Adjust the applicator to optimize delivery of **Aspergillus Flavus AF36 Prevail** under the canopy and to minimize delivery of **Aspergillus Flavus AF36 Prevail** to areas without corn.
3. Rain or irrigation within 3 days of application of **Aspergillus Flavus AF36 Prevail** will improve results.
4. Use 10 lbs of **Aspergillus Flavus AF36 Prevail** per acre of corn (per 13,000 linear feet based on 40-inch rows).

Ground Application: PISTACHIO, ALMOND AND FIG

1. Apply **Aspergillus Flavus AF36 Prevail** 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 **Aspergillus Flavus AF36 Prevail** under the canopy and to minimize delivery of **Aspergillus Flavus AF36 Prevail** to areas that do not get wet.
3. **Aspergillus Flavus AF36 Prevail** has been shown to be effective when applied in **Pistachio** from late May through early July, in **Almond** from late May through early July, and in **Fig** from early May through late June.
4. Rain or irrigation within 3 days after application of **Aspergillus Flavus AF36 Prevail** will improve results.
5. Use 10 lbs of **Aspergillus Flavus AF36 Prevail** per acre; a single application should be made each year.
6. Do not apply to almonds in bloom.

Aerial Application: COTTON, CORN

1. Apply by air at the appropriate rate, timing, and frequency as described for ground applications.
2. Cultivation after application may diminish efficacy.
3. Rain or irrigation within 3 days after application of **Aspergillus Flavus AF36 Prevail** will improve results.

STORAGE AND DISPOSAL STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

PESTICIDE STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F).

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-HANDLING:

Paper Bags (50 lb) – Nonrefillable container. Do not reuse or refill 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 or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Bags and Boxes (1000-3000 lb) - Refillable container. Refill this container with *Aspergillus flavus AF36 Prevail* only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, completely empty bag (or box) into application equipment. Return empty container to point of purchase, offer for recycling if available, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

WARRANTY STATEMENT

To the extent consistent with applicable law, user assumes all risks of use, storage, and handling of this material not in accordance with directions provided on this label.

NOTIFICATION

71693-2

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

11/30/2017