

71693-1

05/05/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 05 2011

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

Re: Arizona Cotton Research and Protection Council; *Aspergillus flavus* AF36
EPA Registration No. 71693-1
Amendment to make label changes requested by EPA in March 9, 2011 letter
Submissions dated 03/21/2011, 05/03/2011, and 05/05/2011
Decision No. 447185

Dear Dr. Braverman:

The Environmental Protection Agency (EPA) has reviewed your request to amend the subject product registration, which included the following changes to the product label:

- 1) Combination of corn and cotton sublabels into one label.
- 2) Addition of an explicit use restriction for applications to corn ("Corn: For Use Only in the States of Texas and Arizona").
- 3) Correction of minor formatting inconsistencies and typographical errors.
- 4) Reorganization and modification of First Aid Statements in accordance with information presented in Chapter 7, Section III(F) of the Label Review Manual.
- 5) Removal of ingestion treatment statements from the First Aid Box given data submitted to and reviewed by EPA that indicates a Toxicity Category of IV for this particular route of exposure.
- 6) Addition of physical street address information for the registrant in accordance with 40 C.F.R. § 156.10(a)(1)(ii).
- 7) Replacement of "Net Contents" with "Net Weight" as *Aspergillus flavus* AF36 is a solid (granular) formulation.
- 8) Reorganization and addition of Hazards to Humans and Domestic Animals Statements, in accordance with information presented in Chapter 7, Section III(D) of the Label Review Manual, to align with toxicity data submitted to and reviewed by EPA.
- 9) Modification of the respirator reference for both handlers and early-entry workers ("a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95") and addition of the following microbial pesticide-related precaution in the Personal Protective Equipment section: "Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization."

CONCURRENCES

SYMBOL	7511P	7511P	7511P					
SURNAME	Kausch	Reynolds	Rully					
DATE	05/05/2011	5/5/11	5/5/11					

Michael Braverman
EPA Registration No. 71693-1

- 10) Addition of User Safety Requirements (“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.”) in accordance with Chapter 10, Section VI(B) of the Label Review Manual.
- 11) Removal of National Pollutant Discharge Elimination System permit language from the Environmental Hazards section given that this product does not meet all of the scope criteria described in Pesticide Registration Notice 95-1.
- 12) Addition of the following subheadings to cover statements made in relation to how *Aspergillus flavus* AF36 works (“Product Information”) and how to properly apply *Aspergillus flavus* AF36 (“Application Instructions”).
- 13) Removal of “General” from the “Use Precautions” subheading given that the associated statements are both mandatory and advisory.
- 14) Modification of certain statements in the Application Instructions section for purposes of enhanced clarity (e.g., “Apply by air at the appropriate rate, timing, and frequency as described for corn and cotton ground applications.”).
- 15) Modification of the Storage and Disposal statements in accordance with Chapter 13 of the Label Review Manual, Pesticide Registration Notice 2007-4, and 40 C.F.R. part 156, subpart H.
- 16) Modification of the Warranty Statement in accordance with information presented in Chapter 12, Section IX of the Label Review Manual.

The changes referred to above, submitted in connection with registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable provided that you submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description of final printed labeling.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any questions regarding this letter, please contact Ms. Jeannine Kausch by telephone (703-347-8920) or email (kausch.jeannine@epa.gov).

A stamped copy of the label is enclosed for your records.

Sincerely,



Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures (2):
- *Aspergillus flavus* AF36 Accepted Label
- A-79 Enclosure

Aspergillus flavus AF36

MAY 05 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 71693-1

COTTON: FOR USE ONLY IN THE STATES OF ARIZONA, TEXAS AND CALIFORNIA (Imperial, Riverside and San Bernardino counties only)

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

For displacing aflatoxin-producing fungi

Aspergillus flavus AF36 is a strain of Aspergillus flavus that occurs naturally. When applied to cotton just prior to first bloom or to corn from the 7 leaf stage (V7) until silking, 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: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized).....	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.: 71693-1
EPA Establishment No.: 71693-AZ-001

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

NET WEIGHT: 50 lb bags, 1000-3000 lb bulk bags or boxes

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)

Mixers/loaders, flaggers, markers, and applicators must wear a long-sleeved shirt, long pants, socks, shoes, waterproof gloves, goggles, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

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 coveralls, waterproof gloves, shoes, socks, goggles, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95.

PRODUCT INFORMATION

Aspergillus flavus AF36 is for application to cotton and corn to displace aflatoxin-producing strains of *Aspergillus flavus*.

Aspergillus flavus AF36 is a living fungus growing on sterile wheat seed, which serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur at irrigation), **Aspergillus flavus AF36** will grow out and the seed 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** 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) is minimal.

Aspergillus flavus AF36 may be applied to irrigated cotton and corn fields.

APPLICATION INSTRUCTIONS

Ground Application: COTTON

1. Apply *Aspergillus flavus* AF36 to the surface of the soil under the plant canopy with a tractor-mounted, granular applicator. DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 under the canopy and to minimize delivery of *Aspergillus flavus* AF36 to furrows.
3. *Aspergillus flavus* AF36 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 will provide best results.
5. Use 10 lbs of *Aspergillus flavus* AF36 per acre of cotton (per 13,000 linear feet based on 40-inch rows).

Ground Application: CORN

1. Apply *Aspergillus flavus* AF36 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 AF36 COLONIZED WHEAT SEEDS WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 under the canopy and to minimize delivery of *Aspergillus flavus* AF36 to areas without corn.
3. Rain or irrigation within 3 days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre of corn (per 13,000 linear feet based on 40-inch rows).

Aerial Application: COTTON or CORN

1. Apply by air at the appropriate rate, timing, and frequency as described for corn and cotton ground applications.
2. Cultivation after application may diminish efficacy.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE AND 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:

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. Return empty container to point of purchase. Refill this container with *Aspergillus flavus* AF36 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. Then offer for recycling if available or dispose of empty bag (or box) in a sanitary landfill, or by incineration, or by other procedures allowed 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 strict accordance with directions provided on this label.