

71693-1

3/9/2011

1 of 6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 09 2011

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

Re: Arizona Cotton Research and Protection Council; *Aspergillus flavus* AF36
EPA Registration No. 71693-1
Amendment to add corn uses to the label
Submissions dated 11/30/2009 and 12/15/2010
Decision No. 424829

Dear Dr. Braverman:

The amendment referred to above, submitted in connection with registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that, within 15 days of the date of this letter, you submit a revised label to EPA, incorporating the changes listed below:

1. For the corn sublabel, add a restriction that the product is "FOR USE ONLY IN THE STATES OF TEXAS AND ARIZONA."
2. For the corn sublabel, add the EPA Registration Number, 71693-1.

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,

Keith A. Matthews, Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures (1):
-*Aspergillus flavus* AF36 Accepted Label

CONCURRENCES

SYMBOL	7511P	7511P	7511P					
SURNAME	KAUSCH	Reynolds	Matthews					
DATE	03/09/2011	3/9/11	03/09/11					

Aspergillus flavus AF36

MASTER LABEL

Sublabel A: Cotton

Sublabel B: Corn

Active Ingredient:

<i>Aspergillus flavus</i> strain AF36*.....	0.0008%
Other Ingredients	<u>99.9992%</u>
Total	100.0000%

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

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Registration No. 71693-1
EPA Est. No. 71693-AZ-001

Arizona Cotton Research and Protection Council
Phoenix, AZ 85040

**ACCEPTED
with COMMENTS
In EPA Letter Dated
MAR 09 2011**

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

Aspergillus flavus AF36

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

For displacing aflatoxin producing fungi

Aspergillus flavus AF36 is a strain of *Aspergillus flavus* that occurs naturally on the cotton crop. When applied to cotton just prior to first bloom, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing 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%
	100%

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

KEEP OUT OF REACH OF CHILDREN

CAUTION

First Aid Statement

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.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If 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 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 ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693-1
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

PRECAUTIONARY STATEMENTS

HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

For other pesticide handlers under the scope of Worker Protection Standard:

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

User Safety Recommendations:

User should: Remove clothing immediately if product 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 the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other

waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated cotton fields. 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 area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

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), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls; long sleeved shirt, long pants, waterproof gloves; shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to cotton 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. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insects in the same manner that the aflatoxin producing fungi are spread.

Ground Application:

1. Apply *Aspergillus flavus* AF36 with a cultivator mounted granular applicator to the surface of the soil under the plant canopy. 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 in late May or early 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 three days after application of *Aspergillus flavus* AF36 will provide the best results.
5. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Apply by air at the same rate as for ground application. Cultivation after application may diminish efficacy.

STORAGE AND DISPOSAL

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

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). Keep product dry.

PESTICIDE DISPOSAL: Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

CONTAINER DISPOSAL: Plastic Bags (50 lbs.) - completely empty bag into application equipment. 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.

Returnable/Refillable Bulk Containers- Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

Aspergillus flavus AF36

For displacing aflatoxin producing fungi

Aspergillus flavus AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied 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 so doing 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%

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

KEEP OUT OF REACH OF CHILDREN

CAUTION

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EPA Registration Number 71693
EPA Establishment Number 71693-AZ-001

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ENVIRONMENTAL HAZARDS

6066

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DIRECTIONS FOR USE

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Ground Application:

1. Apply *Aspergillus flavus* AF36 directly to the soil or over the plant canopy after last cultivation. Applications should be made 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 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
3. Rain or irrigation within three days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.

STORAGE AND DISPOSAL

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