

75624-2

3/9/2010

10 of 5



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

MAR 09 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Jerry Wells
Circle One Global, Inc.
Subsidiary Syngenta Crop Protection, Inc.
410 Swing Road
P.O. Box 18300
Greensboro, NC 27419-8700

Subject: Label Amendment Request Dated October 19, 2009
Formulation Amendment Application Dated October 19, 2009 / Your Confidential Statements of
Formula Dated March 8, 2010 - Alternate Formulation -
and March 9, 2010 - Basic Formulation
Afla-Guard® - EPA Registration Number 75624-2

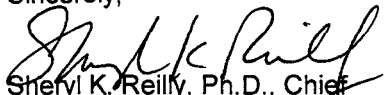
Dear Mr. Wells:

The amendments referred to above, submitted in connection with registration under the Federal Insecticide,
Fungicide and Rodenticide Act (FIFRA) section 3(c)(7)(C), are acceptable provided that you:

1. Submit and/or cite all data required for registration or registration review of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit final printed labels before the product is released for shipment as noted in the updated registration notice dated March 9, 2010.
3. Use the suppliers and sources as specified in the acceptable Confidential Statements of Formula (CSFs) dated March 8, 2010 for the alternate formulation and March 9, 2010 for the basic formulation. These supersede all previous CSFs and will be filed as the official CSFs for formulation of Afla-Guard®.
4. Submit by September 20, 2011, data required for the conditions of pesticide registration as noted in the registration notice dated March 9, 2010, for the subject product. If you would like to proceed to unconditional registration under FIFRA Section 3(c)(5) for sweet and pop corn, you must provide efficacy data to support application of the pesticide to these commodities.

If the conditions as stated in the enclosed registration notice dated March 9, 2010, are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the amended product constitutes acceptance of these conditions.

Sincerely,


Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch

Biopesticides and Pollution Prevention Division (7511P)

Encl:

2095

{full label}

Afla-Guard®

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

ACTIVE INGREDIENT:

Aspergillus flavus NRRL 21882*..... 0.0094%

INERT INGREDIENTS:..... 99.9906%

TOTAL..... **100.00%**

*Contains 0.0094% active ingredient with a minimum of 1.2×10^8 CFU/lb.

ACCEPTED

MAR 09 2010

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 75624-2

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If in eyes:	<ul style="list-style-type: none"> • Hold eye(s) open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first five minutes, and continue rinsing. • 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 further 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 and directions for use on the label to the right.

EPA Reg. No. 75624-2

Manufactured for:
Circle One Global, Inc.
P. O. Box 18300
Greensboro, North Carolina 27419-8300

EPA Est. No.

Net Contents: 50 lbs, 2000 lbs
Not for sale or use after _____

Lot No.: _____

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. Wear the appropriate Personal Protective Equipment (PPE) as specified below.

Personal Protective Equipment (PPE)

Applicators, mixers, loaders and other handlers must wear:

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

Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow the manufacturer's instructions for cleaning and 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 washwaters 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.

General Information: **Afla-Guard**[®] is a biological control agent for displacing the strains of *Aspergillus flavus* (*A. flavus*) that produce the carcinogen aflatoxin. The active ingredient in **Afla-Guard**[®] is a naturally occurring, nontoxic strain of *A. flavus* (NRRL 21882). The primary mode of action is by competition of the nontoxic strain of *A. flavus* with the toxic strains of *A. flavus*, which displaces aflatoxin-producing fungi in treated crops. **Afla-Guard**[®] is for use on peanuts and corn (field, sweet, 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.

Restricted-Entry Interval

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours unless wearing appropriate PPE.

Early Entry PPE

- Coveralls
- Waterproof gloves.
- Shoes plus socks.
- Dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95.
- 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**[®] at 20 lb/acre 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/acre broadcast. Apply as soon as practical after closure of the peanut canopy, within 90 days after planting.

Do not exceed 20 lb/acre per growing season.

Corn (field corn, sweet corn and popcorn):

Ground and Aerial Application: Apply **Afla-Guard®** between growth stages V10-V12 and R1 (this is a period from about 14 days before tasselling with 10-12 visible leaf collars present until the onset of active silking) using broadcast application equipment.

Do not exceed 20 lb/acre per growing season.

Apply **Afla-Guard®** at a use rate of 10-20 lb/acre.

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/acre rate.

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

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and 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. Any product not used within 4 months of purchase should be properly disposed. Do not hold product for use in the subsequent season.

Pesticide Disposal: To avoid wastes, use all material in this container by application according to label directions. If wastes 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); or dig a trench, place product in trench, and cover with soil; or scatter on farmland and disk to cover with soil.

Container Disposal: 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. Do not recycle. Do not burn, unless allowed by state and local ordinances.

WARRANTY

To the extent consistent with applicable law, Circle One Global, Inc. warrants that the product conforms to the description on the label and is reasonably fit for the purposes set forth on the label, when used according to directions under normal use conditions. To the extent consistent with applicable law, neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, expressed or implied, extends to the use of this product contrary to the label instructions; the buyer assumes the risk of any such uses.

Circle One Global, Inc. has a federal trademark registration for **Afla-Guard®**.
U.S. Pat. Nos.: 5,292,661; 5,294,442; 6,027,724; 6,306,386.

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