

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg. Number:

75624-2

Date of Issuance:

5/28/04

Term of Issuance:

Conditional

Name of Pesticide Product:

Afla-Guard™

NOTICE OF PESTICIDE:

- X Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Circle One Global, Inc.
P.O. Box 28
One Arthur Street
Shellman, GA 39886-0028

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under § 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions.

- 1. Change the label by revising the EPA Registration Number 750624-E to read, "EPA Reg. No. 75624-2."
2. Submit five copies of the final printed label before you release the product for shipment.
3. Within 30 months of the date of this conditional registration, analyses of 5 batches are required at production and must include data relevant to detection, identification, enumeration and rejection limits of potential human pathogens (bacterial and fungal), using quality control and assurance methods to be used during large scale production. Batch analysis must also include:
(i) certifications of limits;
(ii) identification of Aspergillus flavus NRRL 21882 by either DNA analysis or some other method different from the vegetative compatibility method now in use;
(iii) analysis and quantification of metabolites and other unintentional ingredients, to include aflatoxin by High Pressure Liquid Chromatography (HPLC), cyclopiiazinic acid (CPA) and kojic acid by HPLC;
(iv) identification and enumeration of potential human pathogens;
(v) storage stability; and
(vi) viability data.

Signature of Approving Official:

[Handwritten Signature]

Date:

5/28/04

(See second page for signature)

EPA Form 8

CONCURRENCES

Table with 4 columns and 3 rows (SYMBOL, SURNAME, DATE) containing handwritten entries for 7511C, Pfeifer, and 5/28/04.

4. The Agency also requires the registrant to provide efficacy data for Afla-Guard™ from one large scale field trial. This condition includes: the visual inspection of peanuts for fungal growth (per USDA tests); VICAM and HPLC tests for the regulatory levels of aflatoxin on peanuts as required by the USDA and FDA; and an accounting of the levels of aflatoxin in the pesticide itself using HPLC analysis.

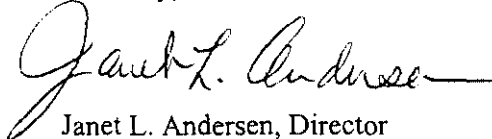
All batches containing human pathogen, metabolites and unintentional ingredients above regulatory levels must be destroyed.

5. Submit five (5) copies of the final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section 6(e).

A stamped copy of the label is enclosed for your records

Sincerely,



Janet L. Andersen, Director
Biopesticides and Pollution
Prevention Division

Enclosure

afla-guard®

For agricultural use to reduce/control aflatoxin in peanuts

ACTIVE INGREDIENT:

Aspergillus flavus NRRL 21882*0.01%

INERT INGREDIENTS:.....99.99%

TOTAL.....100.00%

*Contains a minimum of 4.54 x 10⁷ CFU/lb.

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID

If swallowed: * Have person sip a glass of water if able to swallow.
* Do not induce vomiting unless told to by a poison control center or doctor.
* Do not give anything to an unconscious person.

If inhaled: * 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.

If on skin or clothing: * Take off contaminated clothing.
* Rinse skin immediately with plenty of water for 15-20 minutes.

If in eyes: * 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. Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

EPA Reg. No. 075624-

EPA Est. No. 75624-GA-01

Circle One Global, Inc.

P.O. Box 28

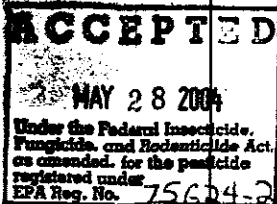
One Arthur Street

Shellman, GA 39886-0028

Phone No.: 229-768-2538

Net Contents: 50 lbs.

Not for sale or use after _____



PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Harmful if inhaled. Avoid breathing dust. Harmful if swallowed. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse. Wear the appropriate Personal Protective Equipment (PPE).

Personal Protective Equipment (PPE)

Applicators, mixers, loaders and other handlers must wear

- Long-sleeved shirts and long pants.
- Waterproof gloves.
- Shoes plus socks.
- Goggles.
- Dust Masks with MSHA/NIOSH approval prefix N-95, R-95, P-95 or HE Filter.

User Safety Requirements

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. 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

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application.

General Information: afla-guard® is a biological control agent for reducing and controlling the strains of *Aspergillus flavus* (*A. flavus*) that produce the carcinogen aflatoxin. The active ingredient in afla-guard® is a naturally occurring, nontoxigenic strain of *A. flavus* (NRRL 21882). The primary mode of action is by competition of the nontoxigenic strain of *A. flavus* with the toxigenic strains of *A. flavus*, which reduces aflatoxin contamination in peanuts. afla-guard® is for use on peanut crops only.

AGRICULTURAL

Use this product only in accordance with the label. This Standard contains requirements for training, testing, and certification of applicators. It also contains specific information on the use of this product. For more information on this statement on this label about personal protective equipment, see the Worker Protection Standard.

Restricted Entry Interval

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

Early Entry PPE

- Long-sleeved shirts and long pants.
- Shoes plus socks.
- Waterproof gloves.
- Goggles.
- Dust Masks with MSHA/NIOSH approval.

Use Directions:

Apply at rate of 1.0 lb. of afla-guard per acre. Apply 40-80 days after planting. Apply formulation over the soil. afla-g is applied from a tractor-mounted Gandy box. At least 1000 lbs. of peanuts per acre (measured from the outer edges of the rows) must be present. Optimum results will be obtained if peanuts are available, such as soon after a rain.

STORAGE

Do not contaminate

Pesticide Storage: Store in a dry, cool, well-ventilated area. Keep from overheating. Do not store product not used within 4 months of the date of manufacture. Do not use product for use in the subsequent year.

Pesticide Disposal: Wastes resulting from the use of this product should be disposed of on site or at an approved waste disposal facility.

Container Disposal: Completely empty the container and dispose of empty package in a safe and local authorities, by burning.

To the fullest extent of the law, Circle One Global, Inc. warrants that the product conforms to the description on the label, when used according to the label. This warranty does not constitute an expressed or implied, extends to the buyer assumes the risk of any

Circle One Global, Inc. has a pending U.S. Pat. Nos.: 5,292,661; 5,294,661