

***Aspergillus flavus* strain AF36 (006456) Fact Sheet**

Summary

Aspergillus flavus is a widespread species of fungus. Certain strains produce aflatoxin, which is a potent liver carcinogen. However, some strains of *Aspergillus flavus*, including the active ingredient *Aspergillus flavus* strain AF36, do not produce aflatoxin. As a pesticide active ingredient, *Aspergillus flavus* strain AF36 is applied in cotton fields to decrease the amount of aflatoxin-producing fungus on cotton. The goal is to reduce the amount of aflatoxin that workers and the public may be exposed to from cotton and its byproducts. *Aspergillus flavus* strain AF36 is not expected to harm humans or the environment when used according to label instructions.

I. Description of the Active Ingredient

Aspergillus flavus strain AF36 was initially isolated in Arizona as a non-aflatoxin producing strain of the fungus. Other non-aflatoxin-producing strains occur in Texas and elsewhere. Aflatoxin, a chemical produced by many strains of *A. flavus*, can cause harmful effects, including liver cancer, when ingested by humans or animals. Researchers have long sought ways of preventing potential adverse health effects and significant economic losses caused by aflatoxin contamination of cotton and other crops. For use on cotton, *A. flavus* strain AF36 is applied to the soil pre-bloom in the growing season. It then germinates and apparently outcompetes the aflatoxin-producing strains in colonizing cotton plants. The result is a decrease in aflatoxin-producing colonies on treated cotton plants.

II. Use Sites, Target Pests, And Application Methods

- **Use Sites:** Cotton fields in Arizona and Texas.
- **Target pests:** Strains of the fungus *Aspergillus flavus* that produce aflatoxin.
- **Application Methods:** The currently registered pesticide product is sold as sterilized wheat seeds colonized by *A. flavus* strain AF36. The wheat seed granules are applied by aerial or ground equipment once per year before the cotton plants bloom.

III. Assessing Risks to Human Health

No harmful health effects to humans are expected from use of *A. flavus* strain AF36 as a pesticide active ingredient. Tests with laboratory mammals showed no oral or lung infectivity or toxicity. No reports of allergic incidents or other adverse effects have been associated with use of the pesticide during six years of research, manufacture and field experiments.

Exposure to viable fungi is expected to be minimal for the following reasons: (a) soil and air monitoring studies over several years have demonstrated that levels of strain AF36 return to background levels soon after treatment; (b) pesticide drift is not likely, based on the granular nature of the product and methods of application; (c) *A. flavus* strain AF36 does not survive processing of cottonseed into oil or meal. To prevent inadvertent exposure of handlers and users, the product label requires the use of appropriate personal protective equipment (PPE).

IV. Assessing Risks to the Environment

No harmful environmental effects are expected. Tests on non-target organisms, such as birds and honeybees, showed no adverse effects. Exposure to fish, non-target insects, and other animals, including wildlife, is not expected to be above background levels.

Endangered species. EPA requires registrants to provide evidence that use of a pesticide product will not harm threatened or endangered species. Agency review indicated that several species of endangered or threatened birds (e.g. certain species of plovers, birds of prey, bobwhite quail) may be exposed to *A. flavus* strain AF36 from pesticide use. Studies showed that these birds are either not found in cotton fields or do not eat cotton or wheat seed. A bird study, in which the pesticide was injected into the lungs of the bobwhite quail, demonstrated no adverse effects from the fungus. Therefore, EPA finds that use of this pesticide product containing *A. flavus* AF36 is not expected to harm endangered or threatened species.

V. Products Directed Against Public Health Pests

EPA has created a list of pests of significant public health importance.* The list consists of pest species that can cause or transmit human disease, or can cause human discomfort or injury. Cockroaches, rats, and many microbes are on the list, including *Aspergillus flavus* strains that produce aflatoxin. To help protect the public's health, EPA requires pesticide products directed against listed pests to meet specific standards for effectiveness as well as for safety. Efficacy has been demonstrated over multiple years of experimental use in Arizona and in small scale trials in Texas. As a condition of registration, the Agency requires that the registrant must provide efficacy of *A. flavus* strain AF36 against aflatoxin-producing **A. flavus** strains during large scale trials in Texas before EPA considers a full registration.

[* NOTE: Microbes in or on living humans or other living animals are specifically excluded from this EPA list. These excluded microbes, which often cause human disease, are under the jurisdiction of FDA.]

VI. Regulatory Information

The single registered product, "*Aspergillus flavus* AF36," containing this active ingredient was conditionally registered on June 24, 2003. Within 30 months of the registration date, the registrant must provide EPA with data to show that (a) quality control and quality assurance standards are maintained during large-scale production of the pesticide, and (b) the product is effective when applied to cotton fields in Texas. (Effectiveness has already been shown for cotton fields in Arizona.) After reviewing the new data, EPA will decide whether to issue a full registration in place of the conditional registration.

Since 1996, *Aspergillus flavus* strain AF36 has been used as a pesticide on limited cotton acreage under Experimental Use Permits and temporary tolerance exemptions issued by EPA.

VII. Registrant Information

Arizona Cotton Research and Protection Council
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VIII. Additional Contact Information:

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