

***Aspergillus flavus* NRRL 21882 (006500) Fact Sheet**

Active Ingredient Name: *Aspergillus flavus* NRRL 21882

OPP Chemical Code: 006500

Summary

Aspergillus flavus is a widespread species of fungus. Certain strains produce aflatoxin, which is a potent liver carcinogen. However, some strains of *A. flavus*, including the active ingredient *A. flavus* NRRL 21882, do not produce aflatoxin. As a pesticide active ingredient, *A. flavus* NRRL 21882 displaces the aflatoxin-producing fungus that sometimes grows abundantly on peanuts in dry areas. The displacement is expected to reduce the amount of aflatoxin in peanuts and its byproducts, and thus reduce human health risks as well as economic losses. Preliminary evidence shows that treated peanut crops contain lower amounts of aflatoxin than untreated crops. *A. flavus* NRRL 21882 is not expected to harm humans or the environment when used according to label instructions.

I. Description of the Active Ingredient

Aspergillus flavus NRRL 21882 was isolated from a peanut in Georgia in 1991 by the United States Department of Agriculture (USDA), National Peanut Research Laboratory. This strain of *A. flavus* does not produce aflatoxin, a substance that can cause liver toxicity and liver cancer in animals. Other non-aflatoxin producing members of the *A. flavus* group have been domesticated and are used to produce products for human consumption. Examples include *A. niger* as a source of the enzyme found in Beano, and *A. oryzae*, which is used for production of soy sauce and miso.

Researchers have long sought ways of preventing potential adverse health effects and significant economic losses that occur when aflatoxin contaminates peanuts and other crops. As a pesticide active ingredient, *A. flavus* NRRL 21882 is expected to reduce those adverse effects by out-competing and displacing the *A. flavus* microbes that produce aflatoxin. *Aspergillus flavus* NRRL 21882 is highly unlikely to acquire the genes necessary for producing aflatoxin in the future because it does not appear to exchange genetic material with aflatoxin-producing strains.

II. Use Sites, Target Pests, and Application Methods

- Use Sites: Peanut crops.

- Target pests: Strains of the fungus *A. flavus* that produce aflatoxin.
- Application Methods: The registered end product consists of granules containing 0.01% *A. flavus* NRRL 21882. The pesticide product is applied to soil at a rate of approximately 1 gram (or 0.002 pound) active ingredient per acre once per year, 40-80 days after the peanuts are planted.

III. Assessing Risks to Human Health

No harmful effects are likely to occur to workers or the public from use of *A. flavus* NRRL 21882 on crops. Laboratory studies indicate that the active ingredient is not toxic or infective following lung or oral exposure in rats. In these studies and in an injection study, the microbe did not survive in rat tissues, indicating that the microbe is unlikely to cause infections in mammals. During laboratory research and field

Human exposure to *A. flavus* NRRL 21882 used as a pesticide active ingredient will be minimal with no expected adverse effects. In addition, use of this active ingredient is likely to decrease human dietary exposure to aflatoxin, based on studies showing that peanuts from treated crops contain much less aflatoxin than peanuts from untreated crops. Residual *A. flavus* NRRL 21882 will be killed when peanuts are roasted or processed into such products as peanut butter and oil. When this granular pesticide product is applied at low rates to soils of commercial peanut fields, its low potential for drift minimizes residential and worker exposure. Exposure to workers is further minimized because they are required to wear appropriate personal protective equipment (PPE).

IV. Assessing Risks to the Environment

No harmful environmental effects are expected from pesticidal uses of this microbial active ingredient. Published literature and submitted studies indicate that the active ingredient will not cause adverse effects to mammals, birds, honeybees, other non-target insects, or plants. Studies show that *A. flavus* NRRL 21882 returns to background levels soon after treatment of peanut fields. No adverse effects are expected to aquatic organisms because 1) the pesticide product will not be applied to bodies of water, 2) the microbe is mostly found in soil, 3) application rates are low, and 4) granules tend not to move far from the site of application.

Endangered Species. *A. flavus* NRRL 21882 is not expected to harm endangered or threatened species. This conclusion is based on the combined evidence in published literature, submitted toxicity/pathogenicity studies, approved use pattern, and other information (see Section III, above).

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 *A. 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. *A. flavus* NRRL 21882 meets these standards. Data from small scale field trials show that aflatoxin is reduced by 71% to 98 % in treated fields compared with control fields.

[* 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

In January 2004, the registrant applied for registration of two new products containing *A. flavus* NRRL 21882 as the active ingredient. On May 28, 2004, EPA registered the two products: one is a concentrated technical product (EPA Registration #75624-1) used only for making an end product; the second is the granular end product, afla-guard® (EPA Registration #75624-2), which is applied directly to soil. These registrations will expire in November 2006 (30 months after registration) unless the registrant meets certain conditions. These conditions require the registrant to submit data on 1) efficacy in large scale field trials, and 2) quality control during manufacture. After reviewing the submitted information, EPA will decide whether to register these products without special conditions.

VII. Registrant Information

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VIII. Additional Contact Information

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