

water. Applications of *Aspergillus flavus* AF36 do not increase the long-term populations of *Aspergillus flavus* in the environment, and thus are not expected to influence the relationship of *Aspergillus flavus* to water sources. Applications merely change the composition of the *Aspergillus flavus* community so that aflatoxin producing strains are less common in the environment.

2. *Non-dietary exposure.* The potential for non-occupational, non-dietary exposure to the general population is not expected to be significant and is not expected to present any risk of adverse health effects.

E. Cumulative Exposure

There are no other registered products containing *Aspergillus flavus* AF36 or any other isolates (strains) of the microbial active ingredient. Data submitted show that the fungal metabolite of concern, which is aflatoxin, is not produced by *Aspergillus flavus* AF36 in the crop or in artificial media in the lab. When applied prior to flowering, *Aspergillus flavus* AF36 has been shown to exclude aflatoxin producing fungi competitively from the developing crop and to reduce aflatoxin contamination of cottonseed. Data show that the proposed use will not result in appreciable increases in the long-term population of *Aspergillus flavus* on the crop beyond naturally occurring levels. Furthermore, there is no expectation of cumulative effects with other pesticides.

F. Safety Determination

1. *U.S. population.* *Aspergillus flavus* AF36 is a naturally occurring organism. This isolate has low toxicity as demonstrated by the acute oral toxicity study in rats. *Aspergillus flavus* is ubiquitous throughout the hot desert valleys in Arizona. Studies have shown that treatment of cotton fields just prior to flowering with sterile wheat seed colonized by *Aspergillus flavus* AF36 at 10 lb per acre does not increase the long-term populations of *Aspergillus flavus* either on the crop at maturity or in the soil 1 year after application. Based on this information, Interregional Research Project Number-4 is of the opinion that the aggregate exposure to *Aspergillus flavus* over a lifetime should not change with application of *Aspergillus flavus* AF36, and exposure to both aflatoxin producing *Aspergillus flavus* strains and aflatoxin should decrease. This should be beneficial to human health. Thus, there is a reasonable certainty that no harm will result from aggregate exposure to *Aspergillus flavus* AF36.

2. *Infants and children.* Based on the lack of toxicity and natural occurrence, there is reasonable certainty that no harm to infants, children, or adults will result from aggregate exposure to *Aspergillus flavus* AF36. Exempting *Aspergillus flavus* AF36 from the requirement of a tolerance should pose no significant risk to humans or the environment.

G. Effects on the Immune and Endocrine Systems

Aspergillus flavus AF36 is a naturally occurring organism, which does not produce aflatoxin, and is thus safer than the *Aspergillus flavus* isolates that produce aflatoxin. To date there is no evidence to suggest that *Aspergillus flavus* AF36 functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

H. Efficacy

Existence of aflatoxins in the environment is a public health hazard. Data were submitted to demonstrate that proper use of *Aspergillus flavus* AF36 results in reductions in the average aflatoxin producing potential of fungi resident in treated areas and in reductions in the quantity of aflatoxins in crops. In field tests prior to 1996, the aflatoxin content of cottonseed was shown to be inversely related to the proportion of the *Aspergillus flavus* community on the crop composed of *Aspergillus flavus* AF36. Detailed analyses of the aflatoxin content of commercial fields from 1996 through 1998 confirmed that reduced aflatoxin levels were associated with displacement of aflatoxin producers by *Aspergillus flavus* AF36 from treated crops and that treatments were associated with up to 90% reductions in crop aflatoxin content.

Efficacy of applications of *Aspergillus flavus* AF36 in displacing aflatoxin producers was demonstrated for fungal communities both on cottonseed from treated crops at harvest and in soils of treated fields 1 year after treatment. This included cotton crops treated in 1996 (112 acres treated), 1997 (463 acres treated), 1998 (499 acres), 1999 (10,488 acres), 2000 (16,725 acres), and 2001 (19,975 acres treated). The proportion of *Aspergillus flavus* communities composed of *Aspergillus flavus* AF36 indicates the extent to which aflatoxin producers were displaced. In 1996 average incidence of AF36 on treated crops was 88.5% and in the soil, 1 year after treatment, incidence of AF36 was 85.2%. Incidences of AF36 on treated crops were 78% and 67% in 1997 and 1998, respectively, and in soil 1 year after treatment, AF36 incidences were

72% and 77%, respectively. Successful displacement was also observed as the acreage treated rapidly expanded from 1999 to 2001 with average incidences of AF36 on treated crops ranging from 57% in 1999 to 66% in 2001.

Aflatoxin-producing S strain isolates of *Aspergillus flavus* are prominent in soils of cotton producing areas of Arizona and south Texas. They produce more aflatoxins than other *Aspergillus flavus* isolates such as the non-aflatoxin-producing L strain *Aspergillus flavus* AF36. Applications of AF36 during the experimental program were effective at displacing the high aflatoxin producing S strain of *Aspergillus flavus*. During the course of the experimental use program, *Aspergillus flavus* AF36 also caused long-term reductions in the aflatoxin producing potential of fungal communities in agricultural fields. *Aspergillus flavus* AF36 retained atoxigenicity (failure to produce aflatoxins) upon repeated reisolation from treated fields 1, 2, or 3 years after treatment. Thus, there was a long-term reduction in the potential of fungal communities to produce aflatoxins in treated areas. The average aflatoxin producing potential of *Aspergillus flavus* communities resident in soils of treated fields was reduced on average 73% 1 year after treatment over the 3 year period (1996 to 1999). S strain isolates, which produced very high levels of aflatoxins, with field averages ranging from 7,100 ppb, aflatoxin to 22,700 ppb, aflatoxin, were effectively displaced. Their incidence was reduced from initially composing 46% of *Aspergillus flavus* soil communities to composing on average of 11%.

I. Existing Tolerances

The registrant is not aware of any existing tolerances or tolerance exemptions for *Aspergillus flavus* AF36, other than the temporary tolerance exemption on cotton (40 CFR 180.1206) in conjunction with an EUP, which expires on December 30, 2004.

J. International Tolerances

There are no Codex maximum residue levels established for residues of *Aspergillus flavus* AF36. *Aspergillus flavus* AF36 containing products are presently not registered for pest control outside of the United States.

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