US EPA ARCHIVE DOCUMENT

DATA EVALUATION RECORD

Reviewed by: **Susan Chang, M.S., Toxicologist, Oak Ridge National Labs**

Secondary Reviewer: Carl Etsitty, M.S., Microbiologist

STUDY TYPE:	Hypersensitivity Incidents (OPPTS 885.3400)
MRID NO:	457391-04
DP BARCODE NO:	D286705
CASE NO:	062458
SUBMISSION NO:	S624885
TEST MATERIAL:	*Aspergillus flavus* AF36
PROJECT NO:	IR-4 PR No. 52B
SPONSOR:	Submitted by IR-4 Project, Technology Centre of New Jersey, Rutgers University, North Brunswick, NJ
TESTING FACILITY:	Not applicable
TITLE OF REPORT:	*Aspergillus flavus* isolate AF36, Hypersensitivity Incidents AMENDMENT Number 1 to MRID 43972402 AMENDMENT Number 2 to MRID 43763404
AUTHOR:	Larry Antilla, Peter J. Cotty, and Michael Braverman
STUDY COMPLETED:	July 3, 2002
GOOD LABORATORY PRACTICE:	Non GLP, but rather a discussion.
CONCLUSION:	No recorded or reported adverse hypersensitivity reaction to the *Aspergillus flavus* AF36 was reported by one state council and six companies during use for 3 or 6 years.
CLASSIFICATION:	ACCEPTABLE

I. STUDY DESIGN:

1. **Test Material:** Biological pest control agent *Aspergillus flavus* AF36

2. **Methods:** Visual health observations of daily handlers and field workers via reports (via letters) from Arizona Cotton Research, Protection Council and six Companies are presented in memorandum form.

II. **RESULTS AND DISCUSSION:** Marathon Farming Company, Lyreedale Farms, Pierce Aviation, Arizona Cotton Growers Association, A Tumbling T Ranches, and H-Four Farms have sent in letters indicating that *Aspergillus flavus* AF36 did not cause any negative side effects, any health or respiratory reactions, any negative feedback or health related

complaints, no adverse effects, or any adverse health effects during their prolonged uses (3 or 6 years). Arizona Cotton Research and Protection Council reported that three employees involved with production/manufacturing of AF36 did not have any negative reactions after a period of 18,500 or more hours of exposure, seven employees (field personnel for AF36) had no adverse effects after 8300 employee hours of exposure, and seven employee (evaluation lab) performing > 250,000 procedures on more than 20,000 fungal isolates of AF36 (11,400 hours of work) had no reported negative respiratory or allergenic response.

The packet classification is **ACCEPTABLE.**

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R141816

Chemical: Aspergillus flavus 36 colonized wheat seed

PC Code:
006456

HED File Code: 41500 BPPD Tox/Chem
Memo Date: 7/3/2002
File ID: DPD286705
Accession #: 000-00-0002

HED Records Reference Center
4/13/2007