

6.8-93



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 8 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of Resubmission of New Chemical/Microbial Screen for *Bacillus subtilis*, MBI 600, (ATCC No. SD-1414), EPA File symbol: 7501-RUT, Product Name: GUS 376 Concentrate Biological Fungicide, PC Code 129082.

FROM: Anthony F. Maciorowski, Chief *A. Maciorowski*
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

TO: Clarence Lewis, Acting PM-21 & Julie Fairfax
Fungicide-Herbicide Branch
Registration Division (H7505C)

The initial screening review of 08/20/91 by the Ecological Effects Branch of the Environmental Fate and Effects Division found all of the data requirements were satisfactorily addressed except for the avian testing. The applicant, Gustafson, Inc., had asked for a waiver of this testing requirement based on natural occurrence, a lack of documented toxicity to birds in the published data and the use of precautionary language on the label to avoid exposure. However, since the product was intended for use as a seed treatment, it was expected that exposure to nontarget birds would occur due to ingestion of treated seeds. Therefore, an Avian oral Pathogenicity/Toxicity test (154A-16) using Bobwhite quail was required to be submitted by the applicant in order to assess potential risk from this exposure. The suggested use of a label statement stating that the applicator should cover or incorporate spilled seed or seed on the soil surface was not sufficient to alleviate the concern.

The study titled "*Bacillus subtilis* Strain MBI 600: An Avian Oral Pathogenicity and Toxicity Study in the Bobwhite" by Wildlife International, Ltd. Project No.: 301-102, FIFRA Guideline 154A-16, MRID No. 42682901 has been submitted to the Agency by the applicant and satisfactorily completes the new chemical/microbial screen requirements. This study superficially appears appropriate, but will be reviewed in depth upon request by the Registration Division.



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DP Barcode : D190728
PC Code No : 129082
EEB Out : JUN 8/1993

To: Susan Lewis
Product Manager 21
Registration Division (H7505C)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 007501-RUT
Chemical Name : Bacillus subtilis MBI 600
Type Product : biological
Product Name : GUS 376 Concentrate
Company Name : Gustafson, Inc.
Purpose : Review avian dietary study and comment on
adequacy of data set for risk assessment.

Action Code: 011
Reviewer: Robert Rose

Date Due: 5/12/93

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)			154-16	72682901		141-5		

Y=Acceptable (Study satisfied Guideline)/Concur

P=Partial (Study partially fulfilled Guideline but
additional information is needed)

S=Supplemental (Study provided useful information but Guideline was
not satisfied)

N=Unacceptable (Study was rejected)/Nonconcur