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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Pseudomonas fluorescens EG-1053. Dagger G Biofungicide. Additional data submitted by Ecogen, Inc. as a conditional registration requirement (EPA Reg. No. 55638-5; Record No. 237309; MRID No. 40945801; Caswell No. 714G; HED Project No. 9-0611)

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THRU: Reto Engler, Ph.D., Chief
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Introduction

As a condition of registration, Ecogen, Inc. has submitted several pieces of product identity data on their Pseudomonas fluorescens EG-1053 product, Dagger G Biofungicide. Data are submitted in response to deficiencies noted in the 2/19/88 W.J. Hazel review and at FR 53(47):7739, a final rule announcing a tolerance exemption for P. fluorescens EG-1053 in or on cottonseed and cotton forage (40 CFR 180.1088).

Discussion of the data

Biovar determination. Nutritional/biochemical studies were conducted. These led to the placement of EG-1053 in biovar V of P. fluorescens. SACB agrees. Strain differentiation can also be aided by the electrophoretic patterns of genomic DNA fragments resulting from digestion with two restriction endonucleases (also submitted).

Growth curves. Growth curves were conducted in trypticase soy broth for 7 hours at 30, 37, and 42 C. Growth was monitored in terms of CFU/ml and absorbance at 600 nm. Rapid growth occurred at 30 C. Survival and the possibility of very slow growth at 37 C was evidenced by fluctuating small increases in CFU/ml and gradual increase in absorbance. No growth occurred at 42 C. The growth curves are inconclusive because the titer at time zero (10^8 CFU/ml) is much higher than should be used for growth curves such as this. A more acceptable initial titer would be 10^4 - 10^6 CFU/ml.

Analysis of commercial batches. Five 1988 commercial production batches of Dagger G Biofungicide were analyzed for bacterial titer. The batches contained between 1.6×10^7 and 4.8×10^7 CFU/ml. SACB finds these data acceptable.

Culture storage, maintenance, and quality assurance. Although not a condition of registration, Ecogen submitted procedures for storage and maintenance of cultures. They also outlined a wide array of morphological/biochemical characteristics and restriction endonuclease digest patterns to be used for quality assurance (QA) of each batch. SACB finds these procedures acceptable.

Conclusions

SACB finds the biovar determination, batch analyses, and QA data/information adequate. However, the following deficiency still remains:

- o The growth curve at 37 C must be repeated using an initial titer of 10^4 - 10^6 CFU/ml. A positive control conducted at 30 C, or the optimum growth temperature, should be run in parallel.

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