



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

10 APR 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: SACB Review of a Tolerance Exemption Request by Stine Microbial Products for Pseudomonas cepacia SMP-1 ("Blue Circle Inoculant SMP-1") [Submission S393216; ID No. OF03885; HED Project No. 1-0960; Caswell No. 714BC].

TO: Carl Grable/Susan Lewis (PM-21)
Herbicide-Fungicide Branch
Registration Division (H7505C)

FROM: Roy D. Sjoblad, Ph.D., Microbiologist
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

R. D. Sjoblad

THROUGH: Reto Engler, Ph.D., Senior Science Advisor
Health Effects Division (H7509C)

Reto Engler

Background: In the Registration Screen, SACB recommended that Stine Microbial Products specify the number of isolates which comprise the "Wisconsin biotype" and the parameters that allow for placement of an isolate within or without the biotype. On 9/28/91, SACB (Memorandum from C. Schaffer to S. Lewis/C. Grable) concluded from review of the data that the Mammalian Toxicity/Pathogenicity studies submitted were complete and Acceptable, and showed that the active bacterial ingredient - namely Ps. cepacia - strain 36 was not toxic to, pathogenic for, or infective in the rat.

SACB Recommendation:

W. Schaffer

Stine Microbial Products is requesting an exemption from the requirement for the "Wisconsin biotype" which could include a number of isolates provided they met the criteria of the biotype (see 9/2/91 Memorandum). SACB supports the request for the tolerance exemption petition for the "Wisconsin" biotype provided that each isolate comprising the active microbial ingredient meets the specified criteria of the biotype. Namely, the nutritional/biochemical and antibiotic susceptibility patterns of each isolate must be the same as strain 36. Further, flagellar antigen serotype analyses, ribotyping analyses, and patterns of cepacian production/sensitivity must confirm that each isolate is distinct from clinical isolates. Further, each batch must be free of significant human pathogens.

It should be noted that there still are certain outstanding issues as specified in the 9/2/91 Memorandum. Pertinent to the tolerance exemption petition are the SACB discussions on analysis for human pathogens, and the basic taxonomic information still outstanding.