2-24-92

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

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: SACB Review of the Response of Stine Microbial Products to a Previous Review of the Registration Data of Blue Circle Inoculant (Pseudomonas cepacia) (HED No. 2-1117, Caswell No. 714G, Product ID No.0F03885).

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

24 FEB 1992

FROM: Cindy Schaffer, Microbiologist CS 2/18/92 24 FEB 1992
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

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

ACTION REQUESTED:
SACB has been asked to review the response of Stine Microbial Products to a previous review of the submitted registration data of Blue Circle Inoculant (Pseudomonas cepacia).

CONCLUSION:
Each deficiency noted in the original review has been rectified and the product identity study may be upgraded to an acceptable status. SACB can now support the application for the registration of Blue Circle Inoculant.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

SACB REVIEW:

1. General Taxonomic Data for Pseudomonas cepacia:
   P. cepacia is a gram negative motile organism that is identified by its ability to grow on a selective media such as TB-T medium. P. cepacia biotypes cannot be distinguished by biochemical testing.

2. Identification [redacted] found in the TGAI and in Blue Circle:
   Wisconsin State Laboratory of Hygiene (WSLH) was asked to identify isolated samples of the [redacted] and batches of Blue Circle Inoculant. WSLH found [redacted] in these samples. The [redacted] are common soil organisms and are not considered human pathogens.

3. The TGAI must be evaluated for human pathogens, with an accompanying identification scheme, with the verification submitted to the agency:
   The TGAI and end-use product were analyzed for the presence of Salmonella, Shigella and Vibrio species. No potential human pathogens were found. Since the production method does not allow for the growth of these organisms (the final product must "cure" at a temperature of 70 F) further testing is not necessary.

4. Assessment of Storage Stability:
   One batch of Blue Circle Inoculant was analyzed for storage stability on two different media, Nutrient Agar (NA) and NA + rifampicin, for a period of approximately one year. The quality of the end-use product is acceptable if the concentration of P. cepacia remains above 10^5 CFU/[redacted].The results of this study demonstrate that Blue Circle Inoculant is viable for at least one year at 50 F.

5. The registrant must provide data and methods used to support the Certified Ingredient Limits:
   An analysis of five random samples from each batch is performed. Blue Circle Inoculant is diluted 1:10 in phosphate buffered saline (PBS) and shaken for 5 minutes at 1000 rpm. Several dilutions of this preparation are made and are plated on NA and TB-T medium. The plates are incubated at 35 C for 24 hours. Any batch that does not conform to certified ingredient limit values will be discarded.

6. The Component Formulation was incorrectly stated:
The corrected component formulation listed in the Confidential Statement of Formula is as follows: 3.8% Pseudomonas cepacia type Wisconsin is the active ingredient, [redacted]

DISCUSSION:
Each deficiency has been rectified and this product identity study may be upgraded to an acceptable status.

INERT INGREDIENT INFORMATION IS NOT INCLUDED