Carl

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

NOV 28 1990

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: First Food Use Screen for Pseudomonas cepacia type Wisconsin (Blue Circle Inoculant SMP-1): Review of Package by SACB for Completeness With Respect to Product Identity/Chemistry and Mammalian Pathogenicity/Toxicity Data (EPA ID No. 006419-6; Tolerance Petition No. OF 3885; MRID Nos. 416284-01, -02; 415466-01, -02, -03, -04; HED Project No. 0-1982). TOXCHEM 714J

TO: 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., Chief
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

Data/information was submitted by Stine Microbial Products to support the Registration of Pseudomonas cepacia as a seed coating treatment at planting to control plant pathogenic fungi and nematodes on a number of crops including corn, cotton, tomatoes, lettuce, carrots, soybeans and potatoes. Ps. cepacia SMP-1 represents a group of strains that can be defined as a biotype, namely, Pseudomonas cepacia type Wisconsin.

The following data/information were submitted:

- Product Identity and Disclosure of Ingredients (per 151A-10, -11, and -12 of Subdivision M):

Four "soil" isolates were characterized (and were compared with ATCC strains and/or certain clinical isolates, and, in certain instances with Ps. fluorescens) with respect to growth on selective medium, biochemical/nutritional tests, temperatures permissive for growth, antibiotic susceptibilities, bacteriocin production, flagellar antigen serotype analysis. Also, ribosomal RNA probes were used to distinguish among the soil isolates, certain plant pathogenic isolates, and clinical isolates. Other parameters investigated with the soil isolates and compared to clinical isolates included, root colonizing ability and antifungal activity. Plant pathogenicity of the soil isolates was assessed.

The ingredients of the formulation were submitted, and the manufacturing process was described, along with a discussion

of the formation of unintentional ingredients.

2. Analysis of Samples, Certification of Limits, and Physical and Chemical Properties (151A-13, -15, and -16).

A report on the preliminary analysis of samples for the end-use product was not provided, and was not considered necessary because the blending process did not involve a "chemical reaction". A Table of upper and lower limits for the active ingredient, and [redacted] added inerts was provided. Stability of the active bacterial ingredient in the end use product was determined over 314 days. Quality control methods and an analytical procedure for enforcement were discussed. Certain (presumably appropriate) physical and chemical parameters were submitted.

3. Acute toxicity/pathogenicity battery:

The following studies were submitted with SMP-1 as the test material: acute oral in rats; acute pulmonary in rats; acute intravenous in rats. An acute dermal toxicity study in rabbits was done with the end-use product.

SACB Discussion: INERT INGREDIENT INFORMATION IS NOT INCLUDED

SACB recommends that Ps. cepacia pass the Registration screen. Since review was not given to all the studies/data at this time, SACB is not stating that the studies have been adequately performed. Rather, a screen of the submitted information indicates that there are no apparent major gaps in data/studies submitted for product registration.

There is at least one issue that the Registrant needs to clarify prior to registration, but which should not necessarily cause Ps. cepacia SMP-1 to fail the screen. The registrant should specify which Ps. cepacia isolates comprised the SMP-1 test material, and the numbers of each of these isolates present in the acute toxicity study test material. If the numbers are too low, then the studies might be unacceptable.

Because SMP-1 represents a mixture of perhaps [redacted] different bacterial isolates, there probably will be some Agency discussion on what defines the active bacterial ingredient. The Registrant has not designated those specific parameters of Ps. cepacia which will allow for placement of any isolate into the "Wisconsin" biotype, or those parameters which would allow for placement of any isolate outside the "Wisconsin" biotype.