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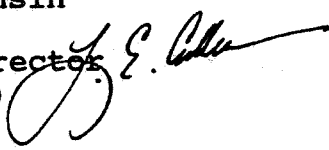
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 2 1992

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

BRIEFING MEMORANDUM

SUBJECT: Registration of New Chemical (Biological Pesticide) -
Pseudomonas cepacia type Wisconsin

FROM: Lawrence E. Culleen, Acting Director 
Registration Division (H-7505C)

TO: Douglas D. Campt, Director
Office of Pesticide Programs (H-7501C)

BACKGROUND

Stine Microbial Products submitted, on June 6, 1990, a petition for an exemption from the requirement of a tolerance for residues of the biological pesticide Pseudomonas cepacia type Wisconsin in or on all raw agricultural commodities when applied as a seed treatment for growing agricultural crops in accordance with good agricultural practices. Concurrently, applications for registration of a manufacturing-use product, SMP PcpWi, and an end-use product, Blue Circle, were submitted. Both products contain 3.8% active ingredient, which is equivalent to 10^7 viable cells/gram.

The product SMP PcpWi is intended for formulating the end-use product Blue Circle. Blue Circle is intended to be applied at planting as a planter box seed treatment to control damping-off fungi and certain nematodes on a variety of field crops and vegetables. Dosage rates range from 1.0 to 8.6 ounces/100 pounds of seed.

The active ingredient in the product is a naturally occurring biotype of the species Pseudomonas cepacia which is found worldwide. The original isolates of Pseudomonas cepacia type Wisconsin were identified as colonizers of the roots and rhizosphere of maize. Further testing indicated that this biotype will colonize roots of many crop plants. Pseudomonas cepacia type Wisconsin has been shown to produce antibiotics which are effective against a diverse range of pathogenic fungi.

SCIENCE FINDINGS

Summary Science Statement

The results of the toxicity/pathogenicity studies submitted

indicated that the active ingredient was not pathogenic or infective to rats when administered orally or intratracheally, was not pathogenic, infective or toxic when administered intravenously and was not toxic when applied dermally. Eye irritation studies were not submitted since, under the conditions of use, no irritation is expected from the inert ingredients. No incidents of hypersensitivity have been reported for this organism.

The environmental effects studies submitted indicate that the product is practically non-toxic to bobwhite quail, honeybees and three beneficial insect species. Non-target aquatic organism testing and the acute avian study using mallard duck were waived for the product due to lack of exposure of aquatic organisms to the product. Non-target plant studies demonstrated that the active ingredient is not pathogenic to a number of commercially important crop plants and selected plants which have been reported as susceptible to other strains of Pseudomonas cepacia. Due to lack of toxicity in the rat studies which were conducted, the product should not pose a risk to wild mammalian species.

The need for data on environmental fate was not triggered under current requirements for the proposed products since the organism is naturally occurring and the results of initial Tier I tests did not trigger the need for additional testing.

The broad designation "Wisconsin biotype" can include a number of isolates of this organism. Each isolate comprising the active microbial ingredient must meet the criteria for the biotype. The nutritional/biochemical and antibiotic susceptibility patterns must be the same as the isolate being registered. Flagellar antigen serotype analyses, ribotyping analyses and patterns of cepacian production/sensitivity must confirm that each isolate is distinct from clinical isolates of this organism and each batch of product must be free of significant human pathogens. Additionally, for any change in isolates comprising the active ingredient, an onion pathogenicity test must be conducted to confirm lack of pathogenicity since some strains of Pseudomonas cepacia have been reported to be pathogenic to onions.

Toxicological Characteristics

Acute oral toxicity/pathogenicity test: Pseudomonas cepacia was neither pathogenic nor infective to rats when orally dosed with approximately 2×10^8 colony forming units (CFU) in culture/nutrient broth mixture per animal.

Acute dermal toxicity test: The product was not toxic to rats when a single 2 gram/animal dose was administered dermally for 15 days.

Acute pulmonary toxicity/pathogenicity test: Pseudomonas cepacia was neither pathogenic nor infective to rats when dosed

intratracheally with approximately 1.9×10^8 CFU of test material.

Acute intravenous toxicity/pathogenicity test: Pseudomonas cepacia was not infective, pathogenic or toxic to rats when dosed intravenously with approximately 1.2×10^7 CFU of test material.

Hypersensitivity: No incidents of hypersensitivity were reported from personnel working with this organism.

Ecological Characteristics

Avian studies: In an avian oral pathogenicity/toxicity study, the acute oral LD₅₀ value for northern bobwhite quail exposed to Pseudomonas cepacia as a single encapsulated oral dose was greater than 5,000 mg/kg (1×10^{10} CFU/kg). The LD₅₀ was greater than the maximum hazard dose level which indicates that the product is practically non-toxic to birds and should not cause any adverse effects to avian species.

Aquatic studies: Data waivers were granted for the acute oral pathogenicity/toxicity study using mallard duck, and for studies on fish and aquatic invertebrates because of lack of exposure of aquatic species due to the use pattern of the product and the facts that Pseudomonas cepacia has never been reported as a pathogen of fish and this organism is a common colonizer of natural bodies of water.

Non-target plant studies: The results of testing of 12 plant species indicated that Pseudomonas cepacia type Wisconsin is not pathogenic to any of the plant species tested and therefore, should not cause any adverse effects to non-target plants.

Non-target insect and honeybee studies: Studies were submitted which demonstrated that Pseudomonas cepacia type Wisconsin is practically non-toxic to parasitic wasps, green lacewings, ladybird beetles and honeybees. It was concluded that the products should not cause any adverse effects to non-target insect species, including honeybees.

Mammalian wildlife considerations: Toxicological studies indicated that there is no significant toxicity to rodents from acute oral testing at the maximum hazard dose. Therefore, risk to mammalian wildlife is expected to be minimal to nonexistent.

Endangered species considerations: It was concluded from the data submitted that there would not be a "may affect" situation for endangered mammals, birds, plants and aquatic species from the proposed use of the products.

BENEFITS

The bacteria in these products, when applied to seeds, will

colonize the plant roots upon germination of the seed and by producing antibiotic compounds, protect the seedling from attack by a range of plant pathogenic fungi and nematodes. Protection of seedlings from plant pathogenic organisms would result in increased plant stands and more vigorous growth. This biological pesticide may be an effective alternative to chemical seed treatment fungicides and may reduce the need for treatments with nematicides, resulting in a decrease in the use of more hazardous products.

TOLERANCE ASSESSMENT

An exemption from the requirement of a tolerance is proposed to be established for the residues of Pseudomonas cepacia type Wisconsin in or on all raw agricultural commodities when applied as a seed treatment for growing agricultural crops in accordance with good agricultural practices. Based upon the lack of toxicity of this organism in the Tier I mammalian toxicity/pathogenicity studies, an exemption from tolerance requirements is warranted.

SUMMARY OF MAJOR DATA GAPS

There are no data gaps remaining for the use of Pseudomonas cepacia type Wisconsin as a seed treatment.

RECOMMENDATIONS

I recommend that you concur with this section 3(c)(5) registration for Pseudomonas cepacia type Wisconsin.

Concur: ALAZ

Do Not Concur: _____

Date: DEC 8 1974