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

OCT 6 2005

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Response to Waiver Requests Resubmittal for Registration Application of **Fungi-Phite®** Containing 45.5% Mono and Di-Potassium Salts of Phosphorous Acid (EPA Reg. Symbol 73771-R)

FROM: Carol E. Frazer, Ph.D., Toxicologist carol
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CONTENTS:

Waiver request MRIDs 466458-01 through -06 for Decision No. 353424; Submission S784217; DP Barcode D322150.

ACTION REQUESTED:

On September 15, 2005, James B. Messina of E$^{\chi}$ponent®, Authorized Representative of Biagro Western Sales, Inc., resubmitted waiver requests for **Fungi-Phite®**, a biochemical fungicide, containing 45.5% mono- and di-potassium salts of phosphorous acid. Toxicology and residue data waiver requests were originally detailed in MRID 464612-27, and were considered unacceptable, first, as the format was not appropriate and further, some of the support was incorrect.

Waiver Requests for 90-Day Oral Toxicity (OPPTS 870.3100), 90-Day Dermal Toxicity (OPPTS 870.3250), 90-Day Inhalation Toxicity (OPPTS 870.3465), Developmental Toxicity (OPPTS 870.4100), Immune Response (152-18), Residue Testing (153-3)

CONCLUSIONS:

Rationale: Waivers were requested based on in general:

1. Low exposure to the product due to rapid degradation in the environment: These phosphorous acid salts dissociate rapidly to hydrogen and phosphite ions once released into the environment. Natural means moderate any accumulation of these ions in plants.

2. Low acute toxicity and mutagenicity profile: Phosphorous acid dissociates rapidly to hydrogen and phosphite ions once released into the environment. Natural means moderate any accumulation of these ions in plants.

3. The current safe use as a fertilizer: Mono- and di-potassium salts of phosphorous acid have been used extensively as an agricultural fertilizer product. The registrant has been actively selling potassium phosphite based liquid fertilizer products for 9 years under the Nutri-Phite product name brand. Nutri-Phite P+K 0-28-26 contains slightly higher mono- and di-potassium salts of phosphorous acid than Fungi-Phite. The application rate is similar. No reports of human toxicity have been reported from consumption of treated crops.

4. Label requirements for handling: The label for Fungi-Phite is based on the use pattern and the product-specific acute toxicity data results and contains all of the necessary EPA PPE labeling language requirements.

Specific discussion additions included for those studies which were conditional:

A. The 90-Day Oral Toxicity Study (OPPTS 870.3100) in this situation is not required as repeated oral exposure is not initiated because of the rapid dissociation of the mono- and di-phosphites when applied to plants.

B. The use of this product will not result in direct application to human skin and will not result in prolonged human exposure, and therefore the 90-Day Dermal Toxicity (OPPTS 870.3250) would not be required.

C. **Fungi-Phite®** rapidly dissociates when applied to plants and the repeated use is not expected, therefore the 90-Day Inhalation Toxicity (OPPTS 870.3465) is not required.

The remaining waiver requests are also addressed independently, with public literature or database searches finding no indication of any kind of immune response alteration from these chemicals, leading to this request for a waiver for Immune Response (152-18). The low acute toxicity and minimal exposure to this product added to the presence of an Exemption to the Requirement for a Tolerance for these chemicals led to the request for a waiver for Developmental Toxicity (OPPTS 870.4100). Residue Testing (153-3) is not normally a requirement for those products which have an Exemption to the Requirement for a Tolerance.

Reviewer's conclusion: The reviewer finds the information submitted in support of the waiver request to be acceptable.

TOXICITY PROFILE

Acute oral toxicity	IV	MRID 464612-21
Acute dermal toxicity	IV	MRID 464612-22
Acute inhalation toxicity	IV	MRID 464612-23
Primary eye irritation	III	MRID 464612-24
Primary dermal irritation	IV	MRID 464612-25
Dermal sensitization	No	MRID 464612-26

LABELING: The Signal word is Caution from the Toxicity Rating of III for primary eye irritation. Precautionary labeling should include:

AGRICULTURAL USE REQUIREMENTS:

DIRECTIONS FOR USE:

For early entry to treated areas permitted under the Worker Protection Standard and involving contact with anything that has been treated, such as plants, soil, or water, coveralls over long-sleeved shirt and long pants, socks and chemical resistant footwear and waterproof gloves must be worn.

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wear long-sleeved shirt and long pants, socks and shoes. and waterproof gloves. Wash hands before eating, drinking, chewing gum, using tobacco or going to the toilet.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

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Chemical: Mono- and di- potassium salts of phosphorous acid

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