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

AUG 1 0 2005

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Secondary Scientific Review of Product Chemistry and Acute Toxicity Studies of Registration Application for **Fungi-Phite®** Containing 45.5% Mono and Di-Potassium Salts of Phosphorous Acid (EPA Reg. Symbol 73771-R)

FROM: Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National laboratory

THROUGH: Carol E. Frazer, Ph.D., Toxicologist carol
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

TO: Tasha Gibbons, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

CONTENTS:

Product chemistry (MRID Nos. 464612-02 through -17, 464612-19 and 46480-01), acute toxicity studies (MRID Nos. 464612-21 through-26) and waiver requests MRID Nos. 464612-18, -20 and -27); Decision No. 353424; DP Barcode D318352).

ACTION REQUESTED:

Oak Ridge National Laboratory reviewed product chemistry and acute toxicity studies on **Fungi-Phite®**. On February 2, 2005, James B. Messina of E ponent®, Authorized Representative of Biagro Western Sales, Inc., submitted registration of this biochemical fungicide, containing 45.5% mono- and di-potassium salts of phosphorous acid. To support the registration, the registrant sent in product chemistry comprised of 880.1100-1300; acute oral (870.1100), dermal (870.1200) and inhalation (870.1300) toxicity studies, primary eye (870.2400) and dermal (870.2500) irritation studies, a dermal sensitization (870.2600) study and assorted waiver requests.

The manufacturer provided all chemistry data for Fungi-Phite® in MRID 464612-02 through -17, and -19, and product chemistry waiver requests in MRID 464612-18 and -20. Acute toxicologic studies were conducted by Product Safety Laboratories (MRIDs 464612-21 through -26); toxicology and residue data waiver requests were specified in MRID 464612-27.

CONCLUSIONS:

1. The product chemistry and mammalian toxicology studies submitted are acceptable.

2. One-year storage stability and corrosion characteristics studies are in progress, and the final results to be completed around November 2005, will need to be submitted.

3. Only the data waiver requests for the physical/chemical attributes are approved. The remaining data waiver requests are unacceptable. The requesting document for the toxicity and residue requests merely lists the six waiver requests desired, but does not address each of them independently as required. One of the reasons listed in the waiver request is based on "Mineral acids RED: Phosphorous Acid; Exemption From the Requirement of a Tolerance, Final rule (65 FR, 10/5/2000, pp. 59346-59350). This regulation establishes an exemption from the requirement of a tolerance for residues of phosphorous acid and its ammonium, sodium and potassium salts in or on all food commodities when used as an agricultural fungicide on food crops." This statement is incorrect, as the Mineral acids RED does not include phosphorous acid, but instead phosphoric acid. Therefore, the basis of the waiver requests previously granted the Mineral acids RED are not valid reasons for these waiver requests.

   The cited Bayer mammalian and ecological toxicity studies listed in the data matrix may answer the data requirements, but merely listing in the data matrix is insufficient. More specific information on the results of those studies submitted are required. Since this is not the same active ingredient, but one merely proposed as identical, Foli-R-Fos, without the product chemistry information for the actual active ingredient, BPPD can not make that justification.

   Another one of the bases for a waiver request was the fact that "Many of these (hydrogen and phosphite ions) are considered GRAS and are of low toxicity concerns." Unfortunately, a review of the GRAS material included in the waiver request document (MRID 464612-27), made no mention of any phosphite. There were several phosphates, and a mention of phosphoric acid, but no phosphites, or phosphorous acid. In order to make sure any information of this sort, from among a list of several chemical substances is not missed, the registrant should be sure to highlight it in the submission. Further, a simple statement that a chemical is GRAS is not considered sufficient for unconcern. GRAS is only for the amounts and uses listed by FDA, which are not pesticide uses.

[**NOTE to RAL**: The primary reviewer made several comments throughout the physical/chemical characteristics review that are incorrect In many places when discussing the submitted material, the reviewer commented that the information was not required, as the data wasn't needed for an EP. This product is both a TGAI and an EP, and both sets of data are required.]

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:

PRODUCT ID #: **073771-00001**

PRODUCT NAME: **Fungi-Phite®**

PRECAUTIONARY STATEMENTS

SIGNAL WORD: **CAUTION**

Hazards to Humans and Domestic Animals:

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

First Aid:

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.
-Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

BPB's reviews of **Fungi-Phite®** data are summarized below.

Study Summaries:

PRODUCT CHEMISTRY OF **Fungi-Phite®**

Guideline §880.1100: Product identity and disclosure of ingredients (MRID 464840-01, CSF)

Fungi-Phite® contains 45.5% mono- and di-potassium salts of phosphorous acid and 54.5% other ingredients. This product is to be used as a systemic fungicide for the suppression of Phytophthora, Pythium and downy mildew.

The following table summarizes information regarding the active ingredient.

Chemical Names:	phosphonic acid, monopotassium salt phosphonic acid, dipotassium salt
Synonyms:	monopotassium salt of phosphorous acid, potassium dihydrogen phosphite, monopotassium phosphite, monopotassium phosphonate dipotassium salt of phosphorous acid, dipotassium hydrogen phosphite, dipotassium phosphite, dipotassium phosphonate
CAS Registry Nos.:	13977-65-6 13492-26-7
Molecular Formulae:	KH_2PO_3 K_2HPO_3
Chemical Family:	metallic salts
Source of Biochemical:	manufactured
Mode of Action:	fungicide

BPB's Comment Regarding §880.1100: Data submitted on the product identity of Fungi-Phite® satisfies the requirements of 40 CFR 158 155, guideline §151B-10, 880.1100.

Guideline §880.1200: Manufacturing process (MRIDs 464612-02 and -03)

BPB's Comment Regarding §151B-11: Data submitted on the manufacturing process of Fungi-Phite® satisfy the requirements of 40 CFR 158.160 and 40 CFR.165, guideline §151B-11, 880.1200. No additional data required.

Guideline §880.1400: Discussion on the formation of unintentional ingredients (MRID 464612-04)

BPB's Comment Regarding §880.1400: Data submitted on the formation of unintentional ingredients of Fungi-Phite® satisfy the requirements of 40 CFR 158.167, guideline §151B-12, 880.1400. No additional data required.

Guideline §880.1700: Preliminary Analysis (MRID 464612-05)

BPB's Comment Regarding §880.1700: This satisfies requirements of 40 CFR 158.170, guideline §151B-13, 880.1700 No additional data required.

Guideline §880.1750: Certification of ingredient limits (MRID 464612-06)

BPB's Comment Regarding §880.1750: This satisfies the requirements of 40 CFR 158.175, guideline §151B-15, 880.1750 No additional data required.

Guideline §880.1800: Enforcement analytical methods (MRID 464612-07)

BPB's Comment Regarding §80.1800: Data submitted on the enforcement analytical methods for certified limits of Fungi-Phite® satisfy the requirements of 40 CFR 158.180, guideline §151B-16, 880.1800. No additional data required.

PRODUCT TOXICOLOGY FOR Fungi-Phite®

Guideline 870.1100: Acute oral toxicity up-and-down procedure in rats (MRID 464612-21)

The LD_{50} of Fungi-Phite® is >5,000 in three female rats. Clinical symptoms included hypoactivity and one death on the first day in a fourth rat. Weight gain and later activity normal in surviving animals. Necropsy finding in the deceased animal showed slight reddening of intestines, other animals normal. Classification: Acceptable; Toxicity Category IV.

Guideline 870.1200: Acute dermal toxicity study in rats - Limit test (MRID 464612-22)

A single limit dose of Fungi-Phite® tested in male and female rats (5/sex). The LD_{50} > 5,000 mg/kg. No deaths, overt toxicity or dermal irritation observed. Weight gain and all animal necropsies normal. Classification: Acceptable; Toxicity Category IV

Guideline 870.1300: Acute inhalation toxicity study in rats - Limit test (MRID 464612-23)

No deaths observed at the maximum achievable LC_{50} of this product for rats (5/sex) of >2.10 mg/L, MMAD 3.0 µM, maximum GSD of 1.90, and 52.1 % of particles below 3.3 µM.. Minor clinical signs during exposure included hunched posture and/or hypoactivity, ocular and nasal discharge. Necropsy and weight gain in animals normal. Classification: Acceptable; Toxicity Category IV

Guideline 870.2400: Primary eye irritation study in rabbits (MRID 464612-24)

Single (0.1 ml) dose of Fungi-Phite® applied to 3 rabbits' (1M, 2F) right eyes. This substance is a minor irritant to rabbit eyes, causing grade 3 hyperemia and grade 1 chemosis and discharge in all rabbits at the first reading, with grade 3 hyperemia in one animal and grade 2 in the remaining 2 at 24 hours (no chemosis). By 48 hours. only two rabbits still had grade 2 hyperemia and the other grade 1, and all were down to 0 by 72 hours. Classification: Acceptable; Toxicity Category III.

Guideline 870.2500: Primary skin irritation study in rabbits (MRID 464612-25)

Single (0.5 ml) dose of Fungi-Phite® applied to skin of 3 male rabbits. This substance is minorly irritating. demonstrating grade 1 erythema in all rabbits at the first reading, but reduced to only 2/3 at 24 hours. By 72 hours. all were free of dermal irritation. Classification: Acceptable; Toxicity Category IV.

Guideline 870.2600: Dermal sensitization study in guinea pigs (Buehler method) (MRID 464612-26)

Twenty female guinea pigs were treated with Fungi-Phite® (0.4 ml) and tested for sensitization. Results were compared to 10 female control animals. A positive control (hexylcinnamaldehyde) had been performed in the past six months in the laboratory to validate the study. All animals survived, weight gain normal and no clinical signs of toxicity noted. A slight erythematic response was noted in 8 of 20 test animals at challenge, and in 3 of 10 control animals. Classification: Acceptable; Toxicity Category Non-sensitizer.

BPB's Comment: Data submitted on the product toxicology of **Fungi-Phite®** satisfies the requirements of 40 CFR 158.690.

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE FUNGICIDE)

STUDY TYPE: ACUTE ORAL TOXICITY - RAT (870.1100) MRID 46461221

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 05-022

Primary Reviewer:
Susan Chang, M.S. Signature: _____
Date: _____

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T. Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader Signature: _____
Date: _____

Quality Assurance:
Eric Lewis, M.S. Signature: _____
Date: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC 05-00OR22725.

Pending Marketing Process Information Is NOT Included

DATA EVALUATION RECORD

EPA Secondary Reviewer: Carol E. Frazer, Ph.D.

STUDY TYPE:	Acute Oral Toxicity - Rats (OPPTS 870.1100)
MRID NO:	46461221
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite Fungicide (EPA Reg No. 73771-R; [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite, a.i.)
PROJECT NO:	15952
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	Product Safety Laboratories, Dayton, NJ
TITLE OF REPORT:	Acute Oral Toxicity Up and Down Procedure in Rats
AUTHOR:	Daniel J. Merkel, B.S.
STUDY COMPLETED:	December 6, 2004
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	The oral LD_{50} for female rats was greater than 5000 mg/kg.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY IV

1. **STUDY DESIGN:**

ii **Test material:** Fungi-Phite Fungicide, Lot M08130402, containing 45.5% mono- and di-potassium salts of phosphorus acid, a.i.

2. **Test animals:** Four female Sprague-Dawley rats were received from Ace Animals, Inc., Boyertown, PA, and weighed 173-230 g on the day of dosing. The young adult animals, 9-11 weeks old, were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Purina Rodent Chow No. 5012 Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-25°C and

photoperiod, 12 hour light/dark cycle. Relative humidity and air changes per hour were not reported.

3. **Methods:** Rats were ear-tagged: Nos. 7005, 7038, 7039, and 7075. The rats were acclimated for 8-21 days and fasted overnight prior to dosing. The test material (5000 mg/kg body weight) was dosed by gavage (Table 1). Body weight was recorded prior to dosing, and on days 7 and 14. The test animals were observed for clinical signs of toxicity during the first several hours post-dosing and at least daily for 14 days. All animals were necropsied.

II. RESULTS:

1. **Mortality:** One animal died on day 1. All other rats survived the study.

TABLE 1. Doses, mortality/animals treated

Dose (mg/kg)	Males	Females	Combined
5000	-	1/4	-

Data taken from p. 9, MRID 46461221.

2. **Body Weight:** All surviving animals gained weight during the study.

3. **Clinical observations:** Two animals were hypoactive three hours post dosing. One animal recovered by 4 hours, but one animal died. Another surviving animal had reduced fecal volume on days 1 and 2 with recovery by day 3. The fourth animal and the recovered animals were active and healthy through the end of the study.

4. **Gross necropsy:** The decedent showed slightly red intestines. No gross abnormalities were noted from the survivors.

III. DISCUSSION:

The oral LD_{50} for female rats was greater than 5000 mg/kg. This places Fungi-Phite Fungicide in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE FUNGICIDE)

STUDY TYPE: ACUTE DERMAL TOXICITY - RAT (870.1200) MRID 46461222

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 05-022

Primary Reviewer:
Susan Chang, M.S. Signature: _____
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DATA EVALUATION RECORD

EPA Secondary Reviewer: Carol E. Frazer, Ph.D.

STUDY TYPE:	Acute Dermal Toxicity - Rats (OPPTS 870.1200)
MRID NO:	46461222
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite Fungicide (EPA Reg No. 73771-R; [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite, a.i.)
PROJECT NO:	15953
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	Product Safety Laboratories, Dayton, NJ
TITLE OF REPORT:	Acute Dermal Toxicity Study in Rats - Limit Test
AUTHOR:	Daniel J. Merkel, B.S.
STUDY COMPLETED:	December 6, 2004
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	The dermal LD_{50} for males, females, and combined was greater than 5000 mg/kg.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY IV

I. **STUDY DESIGN:**

1. **Test material:** Fungi-Phite Fungicide, Lot M08130402, containing 45.5% mono- and di-potassium salts of phosphorus acid, a.i.

2. **Test animals:** Five male and five female Sprague-Dawley rats were received from Ace Animals, Inc., Boyertown, PA, were assigned, and weighed 282-325 g (males) and 193-204 g (females) on the day of treatment. The young adult animals, 9-10 weeks old, were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Purina Rodent Chow No. 5012 and filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-22°C and

photoperiod, 12 hour light/dark cycle. The relative humidity and air changes per hour were not reported.

3. **Methods:** Rats were ear-tagged: Male – Nos. 7402 to 7406; Female – Nos. 7407 to 7411 The rats were acclimated for 13 days. The test material (5000 mg/kg body weight) was applied evenly over a 2 inch x 3 inch area (approximately 10% of the body surface) of the dorsal trunk and covered with a gauze pad. The gauze pad and entire trunk were wrapped with Durapore tape. The coverings were removed after 24 hours and excess test material removed. The test animals were observed during the first several hours after treatment for mortality, signs of gross toxicity, and behavior changes and daily thereafter for 14 days. The rats were weighed prior to treatment and on days 7 and 14. The rats were euthanized on day 14 and necropsied.

II. RESULTS:

1. **Mortality:** All rats survived the study

2. **Clinical observations:** All animals were active and healthy throughout the study

3. **Body weights:** All animals had normal body weight gains.

4. **Gross necropsy:** No gross abnormalities were noted.

III. DISCUSSION: The dermal LD_{50} for males, females, and combined was greater than 5000 mg/kg. This places Fungi-Phite Fungicide in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE FUNGICIDE)

STUDY TYPE: ACUTE INHALATION TOXICITY - RAT (870.1300) MRID 46461223

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 05-022

Primary Reviewer:
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Quality Assurance:
Eric Lewis, M.S. Signature: _____
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MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

DATA EVALUATION RECORD

EPA Secondary Reviewer: Carol E. Frazer, Ph.D.

STUDY TYPE:	Acute Inhalation Toxicity - Rats (OPPTS 870.1300)
MRID NO:	46461223
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite Fungicide (EPA Reg No. 73771-R; [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite, a.i.)
PROJECT NO:	15954
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	Product Safety Laboratories, Dayton, NJ
TITLE OF REPORT:	Acute Inhalation Toxicity Study in Rats - Limit Test
AUTHOR:	Daniel J. Merkel, B.S
STUDY COMPLETED:	December 6, 2004
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	The inhalation LC_{50} for males, females, and combined was > 2.10 mg/L.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY IV

1. **STUDY DESIGN:**

A. **Test material:** Fungi-Phite Fungicide, Lot M08130402, containing 45.5% mono- and di-potassium salts of phosphorus acid, a.i.

2. **Test animals:** Five male and five female Sprague-Dawley rats were received from Ace Animals, Inc., Boyertown, PA, were assigned, and weighed 330-363 g (males) and 208-243 g (females) on the day of treatment. The young adult animals, 10-11 weeks old, were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Purina Rodent Chow No. 5012. Tap water was available *ad libitum*. The environmental

conditions of the animal room were as follows: temperature, 21-23°C and photoperiod, 12 hour light/dark cycle. The relative humidity and air changes per hour were not reported.

3. **Methods**: Rats were ear-tagged: Male – Nos. 7324 to 7328; Female – Nos. 7329 to 7333. The rats were acclimated for 21 days prior to exposure. The animals were exposed under the concentration shown in Table 1. The rats were exposed whole body in a Plexiglas dynamic flow inhalation chamber for four hours and 15 minutes. They were observed at least every 30 minutes during exposure, upon removal from the chamber, and at least once daily thereafter for 14 days. They were weighed prior to test material exposure and on days 7 and 14. All rats were sacrificed and necropsied on day 14.

TABLE 1. Concentrations, exposure conditions, mortality/animals treated

Nominal Conc. (mg/L)	Gravimetric Conc. (mg/L)	MMAD (µm)	GSD (µm)	Particles ≤3.3 µm (%)	Temp (°C)	Humidity (%)	Mortality		
							Male	Female	Combined
45.80	2.10	3.0	1.87-1.90	~78	21-22	58-90	0/5	0/5	0/10

Data taken from Tables 4-6, pp. 9, 11, and 16-18, MRID 46461223

Generation of the test atmosphere and description of the chamber: The exposure atmosphere was generated using a 1/4 inch JCO atomizer, FC4 fluid cap and AC1502 air cap (Spraying Systems Inc.). The test material was metered to the atomization nozzle through Tygon tubing using a pump. Filtered air was supplied by an air compressor connected to the spray atomization nozzle. Additional diluent air was supplied directly to the exposure chamber from conditioned room air. The average total airflow was 45.5-45.9 liters/min and the whole body exposure chamber volume was 150 L. Time to equilibrium was approximately 15 min.

Test atmosphere concentration - During exposure, gravimetric samples were collected from the breathing zone of the animals six times, using glass fiber filters. Filter papers were weighed before and after collection to determine the mass collected. The value was divided by the total volume of air sampled to determine the chamber concentration. The average results are in Table 1 above.

Particle size determination - Particle size for each exposure concentration was determined twice using an eight-stage Andersen cascade impactor. The test material concentration collected at each stage was determined gravimetrically. The mass median aerodynamic diameter and geometric standard deviation were determined graphically using two-cycle logarithmic probit axes. Results are in Table 1 above.

II. RESULTS:

1. **Mortality**: All rats survived the study.

2. **Clinical observations:** During exposure, the animals were hypoactive and had ocular discharge, nasal discharge, and hunched posture. All animals recovered upon removal from the chamber and were active and healthy throughout the remainder of the observation period.

3. **Body weight:** All animals had normal body weight gains.

4. **Gross necropsy:** No gross abnormalities were noted.

III. DISCUSSION: The inhalation LC_{50} for males, females, and combined was > 2.10 mg/L. This places Fungi-Phite Fungicide in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE FUNGICIDE)

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT (870.2400) MRID 46461224

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
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MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

DATA EVALUATION RECORD

EPA Secondary Reviewer: Carol E. Frazer, Ph.D.

STUDY TYPE:	Acute Eye Irritation - Rabbits (OPPTS 870.2400)
MRID NO:	46461224
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite Fungicide (EPA Reg No. 73771-R, [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite, a.i.)
PROJECT NO:	15955
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	Product Safety Laboratories, Dayton, NJ
TITLE OF REPORT:	Primary Eye Irritation Study in Rabbits
AUTHOR:	Daniel J. Merkel, B.S.
STUDY COMPLETED:	December 6, 2004
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	No corneal opacity or iritis were noted on any rabbit. Positive conjunctival irritation (score 2 or 3) was noted on all rabbits one hour after test material instillation with resolution on one rabbit by 48 hours and on two rabbits by 72 hours. The maximum average score was 10.0 at one hour after test material instillation. Fungi-Phite Fungicide was minimally irritating.
CLASSIFICATION:	ACCEPTABLE – TOXICITY CATEGORY III

I. STUDY DESIGN:

1. **Test material:** Fungi-Phite Fungicide, Lot M08130402, containing 45.5% mono- and di-potassium salts of phosphorus acid, a.i

2. **Test animals:** One male and two female young adult New Zealand White rabbits were received from Robinson Services, Inc., Clemmons, NC. The animals were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Pelleted Purina Chow No. 5326. Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-22°C and photoperiod. 12 hour light/dark cycle. The relative humidity and air changes per hour were not reported

3. **Methods:** Rabbits were ear-tagged: Nos. 12650 (male) and 12649 and 12651 (females). The rabbits were acclimated for 5 days. The test material (0.1 mL/eye/animal) was applied in the conjunctival sac of the right eye, and the eye held closed for approximately one second. The left eye served as control. The eyes were examined and scored 1, 24, 48 and 72 hours after test material instillation.

II. RESULTS:

1. **Mortality:** All animals survived the study.

2. **Ocular Lesions:** No corneal opacity or iritis were noted on any rabbit. Positive conjunctival irritation (score 2 or 3) was noted on all rabbits one hour after test material instillation with resolution on one rabbit by 48 hours and on two rabbits by 72 hours (Table 1). The maximum average score was 10.0 at one hour after test material instillation (Table 2).

TABLE 1. Summary of Eye Irritation Scores with Time: Conjunctiva and Iris

Score Conditions	1 hour	24 hours	48 hours	72 hours
Conjunctiva				
Erythema	3	2 to 3	1 to 2	0
Chemosis	1	0	0	0
Discharge	1	0	0	0
Iris	0	0	0	0

Irritation score is based on Draize Method

Scale for Scoring Ocular Lesions

Cornea

A. Opacity-degree of density (area most dense taken for reading)

No Opacity 0
Scattered or diffuse area, details of iris clearly visible 1*
Easily discernible translucent areas, details of iris slightly obscured 2*
Opalescent areas no details of iris visible, size of pupil barely discernible 3*
Opaque, iris invisible 4*

B. Area of cornea involved

One quarter (or less) but not zero 1
Greater than one quarter, but less than half 2
Greater than half but less than three quarters 3

Greater than three quarters, up to whole area 4

Score = A x B x 5 Total Maximum Score = 80

Iris

A. Values

Normal 0

Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combination of any thereof), iris still reacting to light (sluggish reaction is positive). . . 1

No reaction to light, hemorrhage, gross destruction (any or all of these). 2

Score = A x 5 Total Maximum Score = 10

Conjunctive

A. **Redness (refers to palpebral and bulbar conjunctive excluding cornea and iris)**
- Vessels normal 0
- Vessels definitely injected above normal 1
- More diffuse, deeper crimson red, individual vessels not easily discernible 2*
- Diffuse beefy red 3*

B. **Chemosis**
- No swelling 0
- Any swelling above normal (includes nictitating membrane) 1
- Obvious swelling with partial eversion of lids 2*
- Swelling with lids about half closed 3*
- Swelling with lids about half closed to completely closed 4*

C. **Discharge**
- No discharge 0
- Any amount different from normal (does not include small amounts observed in inner canthus of normal animals) 1
- Discharge with moistening of the lids and hairs just adjacent to lids 2
- Discharge with moistening of the lids and hairs, and considerable area around the eye 3

Score = (A + B + C) x 2 Total Maximum Score = 20

*** represents a positive response**

TABLE 2. Summary of Total[a] and Primary Eye Irritation Scores with Time

Animal #	1 h	24 h	48 h	72 h
12649	10	6	4	0
12650	10	4	4	0
12651	10	4	2	0
[b]Total	10.0	4.7	3.3	0.0

[a]Formula: Total Irritation Score = I + II + III, where,
I = Corneal Score = [Density (A) x Area (B)] x 5
II = Iris Score = Severity x 5
III = Conjunctival Score = [Erythema (A) + Chemosis (B) + Discharge (C)] x 2
[b]Primary Irritation = Sum of Total Irritation Scores ÷ 3

III. **DISCUSSION:** No corneal opacity or iritis were noted on any rabbit. Positive conjunctival irritation (score 2 or 3) was noted on all rabbits one hour after test material instillation with resolution on one rabbit by 48 hours and on two rabbits by 72 hours. The maximum average score was 10.0 at one hour after test material instillation. Fungi-Phite Fungicide was minimally irritating and is in TOXICITY CATEGORY III. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE FUNGICIDE)

STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT (870.2500) MRID 46461225

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 05-022

Primary Reviewer:
Susan Chang, M.S.
Signature: _____
Date: _____

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.
Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader
Signature: _____
Date: _____

Quality Assurance:
Eric Lewis, M.S.
Signature: _____
Date: _____

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This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Secondary Reviewer: Carol E. Frazer, Ph.D.

STUDY TYPE:	Primary Dermal Irritation - Rabbits (OPPTS 870.2500)
MRID NO:	46461225
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite Fungicide (EPA Reg No. 73771-R; [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite, a.i.)
PROJECT NO:	15956
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	Product Safety Laboratories, Dayton, NJ
TITLE OF REPORT:	Primary Skin Irritation Study in Rabbits
AUTHOR:	Daniel J. Merkel, B.S.
STUDY COMPLETED:	December 6, 2004
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	Very slight erythema was noted on 3/3 rabbits one hour after patch removal with clearance on one rabbit by 24 hours, but persisted on two rabbits through 24 hours with clearance by 48 hours. The primary irritation index was 0.4. Fungi-Phite Fungicide was essentially nonirritating.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY IV

I. STUDY DESIGN:

1. **Test material**: Fungi-Phite Fungicide, Lot M08130402, containing 45.5% mono- and di-potassium salts of phosphorus acid, a.i.

2. **Test animals**: Three male young adult New Zealand White rabbits were received from Robinson Services, Inc., Clemmons, NC. The animals were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Pelleted Purina

Chow No. 5326. Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-22°C and photoperiod, 12 hour light/dark cycle. The relative humidity and air changes per hour were not reported

3. **Methods:** Rabbits were ear-tagged: Nos. 12599 to 12601. The rabbits were acclimated for 13 days. The fur on the dorsal trunk of each rabbit was clipped on the day prior to treatment. The rabbits were given 0.5 mL of test material applied on a 6 cm^2 clipped intact dose site, and the site covered with a gauze pad. The pad and entire trunk were wrapped with a semi-occlusive Microspore tape. Elizabethan collars were placed on the rabbits. The covering and the collar were removed 4 hours later and the site cleansed to remove any residual test material. The animals were observed at least once daily for gross toxicity and behavior changes during the study. Dermal examination was recorded at 1, 24, 48, and 72 hours after removal of the patch.

II. RESULTS:

1. **Mortality:** All rabbits survived the study.

2. **Dermal responses:** Very slight erythema was noted on 3/3 rabbits one hour after patch removal with clearance on one rabbit by 24 hours, but persisted on two rabbits through 24 hours with clearance by 48 hours. The primary irritation index was 0.4

Irritation scores:

TABLE 1. Summary of individual rabbit's dermal irritation scores with time				
	Hours			
Animal No.	1	24	48	72
12599	1/0 [a]	1/0	0/0	0/0
12600	1/0	0/0	0/0	0/0
12601	1/0	1/0	0/0	0/0

Data taken from Table 1, p. 12, MRID 46461225
[a]Erythema/Edema

Description of rating method:

Evaluation of skin reaction:	**Score**
Erythema formation:	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Edema formation:	
No edema	0
Very slight edema (barely perceptible)	1

Slight edema (edges of area well-defined by definite raising) 2
Moderate edema (raised approximately 1 mm) 3
Severe edema (raised by more than 1 mm extending beyond the area of exposure) 4

III. DISCUSSION: Very slight erythema was noted on 3/3 rabbits one hour after patch removal with clearance on one rabbit by 24 hours, but persisted on two rabbits through 24 hours with clearance by 48 hours. The primary irritation index was 0.4. Fungi-Phite Fungicide was essentially nonirritating and is in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE FUNGICIDE)

STUDY TYPE: SKIN SENSITIZATION - GUINEA PIG (870.2600) MRID 46461226

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 05-022

Primary Reviewer:
Susan Chang, M.S. Signature: _____
Date: _____

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T. Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader Signature: _____
Date: _____

Quality Assurance:
Eric Lewis, M.S. Signature: _____
Date: _____

Disclaimer

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Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Secondary Reviewer: Carol E. Frazer, Ph.D.

STUDY TYPE:	Skin Sensitization - Guinea Pigs (OPPTS 870.2600)
MRID NO:	46461226
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite Fungicide (EPA Reg No. 73771-R; [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite, a.i.)
PROJECT NO:	15957
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	Product Safety Laboratories, Dayton, NJ
TITLE OF REPORT:	Dermal Sensitization Study in Guinea Pigs (Buehler Method)
AUTHOR:	Daniel J. Merkel, B.S.
STUDY COMPLETED:	December 6, 2004
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	After three consecutive inductions, the test animals showed no positive signs of reactivity 24 and 48 hours after challenge. Fungi-Phite Fungicide was not a dermal sensitizer.
CLASSIFICATION:	ACCEPTABLE

I. STUDY DESIGN:

1. **Test material:** Fungi-Phite Fungicide, Lot M08130402. containing 45.5% mono- and di-potassium salts of phosphorus acid, a.i.

2. **Test animals:** Thirty female Hartley guinea pigs from Elm Hill Breeding Labs, Chelmsford, MA were assigned to groups and weighed 354-415 g at experiment start. The young adult animals were housed individually in suspended stainless steel cages with mesh floors or plastic perforated bottoms. The animals were fed pelleted Purina Guinea Pig Chow No. 5025. Filtered tap water was available *ad libitum*. The environmental conditions of the

animal room were as follows: temperature, 18-23°C and photoperiod, 12 hour light/dark cycle. Relative humidity and air changes per hour were not reported.

3. **Methods:** Female guinea pigs were ear-tagged and grouped: Test – Nos. 20727 to 20746; Naive Control – Nos. 20747 to 20756. The guinea pigs were acclimated for 13-52 days The animals were induced and challenged according to the method of Buehler. The dorsal and flank areas of 20 test guinea pigs and 10 naive control animals were clipped prior to each treatment. For the induction phase, 0.4 mL of undiluted test material was applied to the animal using a Hill Top Chamber and secured with non-allergenic adhesive tape. The chamber was removed after six hours and excess test material cleansed. The procedure was repeated once each week for three consecutive weeks. Twenty-seven days after the first induction, the test animals were challenged with 0.4 mL of undiluted test material under occlusion to naive sites. At challenge, a naive control group (10 animals) was treated with 0.4 mL of undiluted test material. Reactions were scored at approximately 24 and 48 hours following induction and challenge application.

II. RESULTS:

1. **Mortality:** No deaths were observed in any group.

2. **Body weights:** All guinea pigs gained weight during the study.

3. **Skin effects:** Very faint erythema usually non-confluent was noted on 3/20 and 2/20 test animal after the first and second inductions, respectively, with clearance by 48 hours. No reaction was noted on any animal after the third induction. Very faint erythema usually non-confluent was noted on 8/20 test animal after challenge with clearance on six animals by 48 hours. Very faint erythema usually non-confluent was noted on 3/10 naive control animals after challenge with clearance on two animals by 48 hours. No positive reaction was noted on any test or naive control animals after challenge.

TABLE 1. *Summary of Individual Erythema Challenge Scores with Time* [a]

Time	24 hours				48 hours			
Erythema Score	0	0.5	1	2	0	0.5	1	2
Treated	12	8	0	0	18	2	0	0
Naive Control	7	3	0	0	9	1	0	0

[a]Number of animals affected

Evaluation score is based on Buehler Grading Scale.

Scale for Scoring Skin Reaction

Buehler sensitization scoring scale

Erythema	**Score**
No reaction	0
Very faint, usually nonconfluent	0.5
Faint, usually confluent	1
Moderate	2
Severe with or without edema	3

III. **DISCUSSION:** Very faint erythema usually non-confluent was noted on 3/20 and 2/20 test animals after the first and second inductions, respectively, with clearance by 48 hours. No reaction was noted on any animal after the third induction. No positive reaction was noted on any test or naive control animals after challenge. The study included a alpha-hexylcinnamaldehyde Technical (HCA) positive control study which was carried out within six months of the study and the results were appropriate. Fungi-Phite Fungicide was not a dermal sensitizer. The packet is classified as **ACCEPTABLE.**

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE FUNGICIDE)

STUDY TYPES: **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)
MRID 46461227

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No 05-022

Primary Reviewer:
Susan Chang, M.S. Signature: _____
Date: _____

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T. Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader Signature: _____
Date: _____

Quality Assurance:
Eric Lewis, M.S. Signature: _____
Date: _____

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Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Secondary Reviewer: Carol E. Frazer, Ph.D.

STUDY TYPE:	Waiver Requests for 90-Day Oral Toxicity (OPPTS 870.3100) 90-Day Dermal Toxicity (OPPTS 870.3250) 90-Day Inhalation Toxicity (OPPTS 870.3485) Chronic Toxicity (OPPTS 870.4100) Developmental Toxicity (OPPTS 870.3700) Immune Response (152-18) Residue Testing (153-3)
MRID NO:	46461227
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite Fungicide (EPA Reg No. 73771-R; [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite, a.i.)
PROJECT NO:	Phosphorous Acid 01
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	E'ponent®, Inc., Washington, DC
TITLE OF REPORTS:	Mono- and Di-potassium Salts of Phosphorous Acid, Waiver Request from Further Testing
AUTHOR:	James B. Messina
STUDY COMPLETED:	January 7, 2005
GOOD LABORATORY PRACTICE:	Not applicable
CONCLUSION:	A waiver is requested for Fungi-Phite Fungicide based on the acute toxicity and mutagenicity profile, its rapid degradation in the environment, its current safe use as a fertilizer, label requirements for handling, its status as a required substance in the human body, and approval of previous waivers cited in the Mineral Acids RED (EPA 738-R-029, December 1993). The BPPD reviewer finds the information submitted in support of the waiver request to be unacceptable.
CLASSIFICATION:	UNACCEPTABLE

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Product description: Fungi-Phite (EPA Reg. No. 73771-R) is a systemic fungicide and an end-use product (EP) for the suppression and control of phytophthora, pythium and downy mildew The active ingredients are [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite. The label indicates that the active ingredient is 45.5% mono- and di-potassium salts of phosphorous acid and Fungi-Phite contains 5.14 lbs/gal of the active ingredients, equivalent to 3.33 lbs phosphorous acid per gallon (29.5% w/w). The inert is [redacted] as diluent

Waiver request: The registrant is requesting waivers for 90-day oral toxicity, 90-day dermal toxicity, 90-day inhalation toxicity, chronic toxicity, developmental toxicity, immune response, and residue testing, in regard to further testing.

Rationale: A waiver is requested based on the acute toxicity and mutagenicity profile, its rapid degradation in the environment, its current safe use as a fertilizer, label requirements for handling, its status as a required substance in the human body, and approval of previous waivers cited in the Mineral Acids RED (EPA 738-R-029, December 1993).

Acute toxicity and mutagenicity: The acute oral and dermal LD_{50} are >5000 mg/kg. The acute inhalation LC_{50} is > 2.10 mg/L. Fungi-Phite Fungicide was essentially nonirritating to the skin of rabbits, minimally irritating to the eyes of the rabbits, and not a dermal sensitizer. The registrant indicates that mutagenicity data on the active ingredient are negative.

Rapid degradation: Phosphorous acid dissociates rapidly to hydrogen and phosphite ions once released into the environment The registrant claims phosphite salts are GRAS, but provided no proof. The simple statement that a chemical is GRAS is insufficient to claim a waiver request, as GRAS refers only to the amounts necessary in the final product to provide the requirement that FDA allows, and FDA has nothing to do with pesticide use. Natural means moderate any accumulation of these ions in plants

History of use: 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.

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.

Required human substance: Phosphorous is a constituent of human bone tissue and forms compounds needed for energy conversion reactions (e.g. ATP), but there has been no evidence provided that potassium phosphites are required human substances, and there is no indication that biologically usable phosphorous ions are produced from potassium phosphites.

Mineral acids RED: Phosphorous Acid; Exemption From the Requirement of a Tolerance, Final rule (65 FR, 10/5/2000, pp. 59346-59350). This regulation establishes an exemption from the requirement of a tolerance for residues of phosphorous acid and its ammonium, sodium and potassium salts in or on all food commodities when used as an agricultural fungicide on food crops. The Mineral acids RED includes Phosphoric Acid, not phosphorous acid, therefore, the reference to this document is unacceptable for the purpose of a waiver request.

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

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE)

STUDY TYPES: Product Identity and Composition (OPPTS 830.1550)
Description of Beginning Materials (OPPTS 830.1600)
Description of Production Process (OPPTS 830.1620)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)
MRIDs 46484001 and 46461202-46461220

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 05-022

Primary Reviewer:
Susan Chang, M.S.

Signature: _____
Date: _____

Secondary Reviewers:
Eric Lewis, M.S.

Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
Eric Lewis, M.S.

Signature: _____
Date: _____

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Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer: Carol E. Frazer, Ph.D.

STUDY TYPE:	Product Identity and Composition (OPPTS 830.1550) Description of Beginning Materials (OPPTS 830.1600) Description of Production Process (OPPTS 830.1620) Discussion of Formation of Impurities (OPPTS 830.1670) Preliminary Analysis (OPPTS 830.1700) Certified Limits (OPPTS 830.1750) Enforcement Analytical Method (OPPTS 830.1800) Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)
MRID NOS:	46484001, 46461202, 46461203, 46461204, 46461205, 46461206, 46461207, 46461208, 46461209, 46461210, 46461211, 46461212, 46461213, 46461214, 46461215, 46461216, 46461217, 46461218, 46461219, 46461220
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite (EPA Reg No. 73771-R: [redacted] w/w monopotassium phosphite and [redacted]% w/w dipotassium phosphite, a.i.)
PROJECT NOS:	BWS-FPC-01 (MRID 46484001), BWS-FPC-02 (MRID 46461202), BWS-FPC-03 (MRID 46461203), BWS-FPC-04 (MRID 46461204), BWS-FPC-05 (MRID 46461205), BWS-FPC-06 (MRID 46461206), BWS-FPC-07 (MRID 46461207), BWS-FPC-08 (MRID 46461208), BWS-FPC-07 (MRID 46461209), BWS-FPC-10 (MRID 46461210), BWS-FPC-11 (MRID 46461211), BWS-FPC-15 (MRID 46461212), BWS-FPC-20 (MRID 46461213), BWS-FPC-17a (MRID 46461214), BWS-FPC-16 (MRID 46461215), BWS-FPC-19 (MRID 46461216), BWS-FPC-14 (MRID 46461217), BWS-FPC-13 (MRID 46461218), BWS-FPC-12 (MRID 46461219), PHOSPHOROUS ACID 02 (MRID 46461220)
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	Biagro Western Sales in house Laboratory, Inc., Visalia, CA

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

TITLE OF REPORT: Product Identity and Composition (MRID 46484001), Description of Materials Used to Produce the Product (MRID 46461202), Description of Production Process (MRID 46461203), Discussion of the Formation of Impurities and Method of Analysis (MRID 46461204), Preliminary Analysis (MRID 46461205), Certified Limits (MRID 46461206), Color (MRID 46461207), Physical State (MRID 46461208), Odor (MRID 46461209), Boiling Point (MRID 46461210), Density (MRID 46461211), pH Test (MRID 46461212), Viscosity (MRID 46461213), Storage Stability and Container Corrosion Characteristics, 30-Day Preliminary Report (MRID 46461214), Stability to Normal and Elevated Temperature (MRID 46461215), Oxidation Reduction Data (MRID 46461216), Dissociation Constant Data (MRID 46461217), Waiver Request for Vapor Pressure Data (MRID 46461218), Water Solubility Data (MRID 46461219), Mono- and Di-Potassium Salts of Phosphorous Acid -- Waiver Request from Further Testing (MRID 46461220)

AUTHORS: John Peterson (MRIDs 46484001, 46461202, 46461203, 46461204, 46461205, 46461206, 46461207, 46461208, 46461209, 46461210, 46461211, 46461212, 46461213, 46461214, 46461215, 46461216, 46461217, 46461218, and 46461219) and James B. Messina (MRID 46461220)

STUDY COMPLETED: December 8, 2004 (MRIDs 46484001, 46461202, 46461203, 46461204, 46461205, 46461206, 46461207, 46461208, 46461209, 46461210, 46461211, 46461212, 46461214, 46461215, 46461216, 46461217, 46461218, 46461219), January 12, 2005 (MRID 46461213), and January 7, 2005 (MRID 46461220)

GOOD LABORATORY PRACTICE: Not GLP Compliant

CONCLUSION: Fungi-Phite is a systemic fungicide and an EP for the suppression and control of phytophthora, pythium and downy mildew. The active ingredients are [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite. The label indicates that the active ingredient is 45.5% mono- and di-potassium salts of phosphorous acid and Fungi-Phite contains 5.14 lbs/gal of the active ingredients, equivalent to 3.33 lbs phosphorous acid per gallon (29.5% w/w). The inert is [redacted] as

CONCLUSION (CONT.)

diluent. The beginning materials are [redacted] The production process was adequately addressed. No impurities are formed in the manufacture of Fungi-Phite and no single impurity at a level of more than 1000 mg/kg (0.1%) is carried over from the starting material to the final product. Five lots of Fungi-Phite were analyzed for phosphorus and potassium. The average of five batch results was 46.10% which was within the strongest and most dilute formulas (45.50-46.20%) and within the sum of the certified limits as given on the CSF (34.5+9.5% to 36.5+10.5%). The upper and lower certified limits of the ingredients are within the recommended range in guideline OPPTS 830.1750. The range of phosphorous acid equivalent would range from 3.30-3.40 pounds (3.33 lbs) of phosphorous acid equivalent per gallon and the pounds of total salts per gallon would range from 5.12-5.24 pounds (label 5.14 lbs). The methods of analysis for potassium and phosphite in potassium phosphite solutions are modifications of standard methods (AOAC 983.02 17th ed. and AOAC 958.01 17th ed., respectively) for the analysis of potassium ions (flame emission spectrophotometry) and for the analysis of phosphate ions (spectrophotometric molybdovanadophosphate assay). The physical/chemical properties were adequately addressed. One-year storage stability and corrosion characteristics studies are in progress.

CLASSIFICATION: **ACCEPTABLE**, the registrant needs to submit the results of the one-year storage stability and corrosion characteristics studies upon completion.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

INERT INGREDIENT INFORMATION IS NOT INCLUDED

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Test material: Fungi-Phite containing [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite

I. **PRODUCT IDENTITY AND COMPOSITION:** Fungi-Phite (EPA Reg. No. 73771-R) is a systemic fungicide and an end-use product (EP) for the suppression and control of phytophthora, pythium and downy mildew. The active ingredients are [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite. The label indicates that the active ingredient is 45.5% mono- and di-potassium salts of phosphorous acid and Fungi-Phite contains 5.14 lbs/gal of the active ingredients, equivalent to 3.33 lbs phosphorous acid per gallon (29.5% w/w). The inert is [redacted] as diluent.

Deficiencies: None

II. **DESCRIPTION OF BEGINNING MATERIALS:** [redacted] 40 CFR 1210 exempt from the requirement of a tolerance). The MSDSs of the starting materials are provided in the study (MRID 46461202).

Deficiencies: None

III. **DESCRIPTION OF PRODUCTION PROCESS:** [redacted]

Deficiencies: None

IV. **DISCUSSION OF FORMATION OF IMPURITIES:** No impurities are formed in the manufacture of Fungi-Phite and no single impurity at a level of more than 1000 mg/kg (0.1%) is carried over from the starting material to the final product (MRID 46461204).

Deficiencies: None

V. **PRELIMINARY ANALYSIS:** Five lots of Fungi-Phite were analyzed for phosphorus and potassium. The data were used to calculate the total of mono- and di-potassium phosphite salts. The ranges of % PO_3-P, K, and salts were 11.21-11.34, 16.6-16.7, and 45.82-46.20, respectively. The average of five batch results was 46.10% which was within the strongest and most dilute formulas (45.50-46.20%) and within the sum of the certified limits as given on the CSF (34.5+9.5% to 36.5+10.5%).

Deficiencies: None

VI. **CERTIFIED LIMITS:** According to the CSF, Fungi-Phite contains [redacted] by weight ([redacted]%, [redacted] monopotassium phosphite and [redacted] by weight [redacted] dipotassium phosphite (Table 1). The lower and upper certified limits for [redacted] The certified limits of the ingredients are within the recommended range in guideline OPPTS 830.1750. MRID 46461206 states that the strongest, normal, and most dilute formulas contain 46.2, 45.8, and 45.5% salts,

respectively. The study also states that "[redacted]". The range of phosphorous acid equivalent would range from 3.30-3.40 pounds (label states 3.33 lbs) of phosphorous acid equivalent per gallon and the pounds of total salts per gallon would range from 5.12-5.24 pounds (label states 5.14 lbs).

Deficiencies: None

TABLE 1. Nominal CSF concentrations and limits for Fungi-Phite[a]

Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient					
Monopotassium phosphite (13977-65-6)	076416	Active	[redacted]		
Dipotassium phosphite (13492-26-7)	076416	Active			
Inert ingredient					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[a] Data from CSF.

VII. ENFORCEMENT ANALYTICAL METHOD: The method of analysis for potassium in potassium phosphite solutions is a modification of a standard method (AOAC 983.02 17th ed.) for the analysis of potassium ions (flame emission spectrophotometry; MRID 46461205). The modification is in the use of an atomic absorption spectrophotometer in absorbance mode. Dilute solutions of potassium ions are excited in a flame and emit quantitative amounts of light, which are measured by a photoelectric detector and compared to known standard solutions. A sample containing 0.05 to 0.10 g potassium is diluted to 1000 mL with deionized water. Five mL of this sample dilution, 10 mL lanthanum chloride solution (background correction for phosphorous), and 5 mL of 1N HCl solution are diluted to 500 mL with deionized water. Blank solution, standard solution, and spike solution are prepared. The instrument is set up for flame emission mode. Percent potassium is calculated. This method is primarily intended for quality control analysis of simple solutions of potassium salts such as Fungi-Phite.

The method of analysis for phosphite in potassium phosphite solutions is a modification of a standard method (AOAC 958.01 17th ed.) for the analysis of phosphate ions (spectrophotometric molybdovanadophosphate assay). The modification is based on the oxidation of phosphite ions to phosphate ions and subsequent analysis. A sample containing 0.05 to 0.25 g phosphorous from phosphate ions is diluted to 1000 mL with deionized water. To a 100 mL volumetric flask, 10 mL of the sample dilution, 10 mL deionized water, 5 mL 2N HCl, and 1.0 mL potassium permanganate solution are added, mixed, and reacted for at

least 30 minutes at room temperature. To the flask, 1 mL hydroxylamine hydrochloride solution is added, then 20 mL deionized water is rinsed down the neck of the flask. Ammonium molybdate-ammonium meta-vanadate reagent (20 mL) is added to the flask and reacted for 30 minutes. Blank solution, standard solution, and spike solution are prepared. The absorbance is read at 420 nm on a spectrophotometer. Percent phosphite phosphorous is calculated. This method is primarily intended for quality control analysis of solutions manufactured from phosphorous acid and its salts.

Deficiencies: None

VIII. PHYSICAL AND CHEMICAL CHARACTERISTICS:

1. **Methods:** See Table 2. The test material is Fungi-Phite Lot No. M11040401, except as indicated

2. **Results:** The physical/chemical properties are listed in Table 2.

3) **Deficiencies:** One-year storage stability and corrosion characteristics studies are in progress.

TABLE 2. Physical and chemical properties for Fungi-Phite[a]

Guideline reference no./property	Description of result	Methods
830.6302 Color	Clear, water-white	Visual inspection
830.6303 physical state	Liquid at -10°C and 54°C	Visual inspection
830.6304 Odor	No significant odor at 20°C	Olfactory inspection
830.6313 Stability	Product is stable and no degradation was found after 14 days at 55°C. Fungi-Phite, lot no. M11040401 contains 45.8% a.i. initially and 45.7% a.i. after 14 days at 55°C	Enforcement analytical method
830.6314 oxidation/reduction: Chemical incompatibility	Waiver request; No increase in temperature after mixing with monoammonium phosphate (firefighting compound) or with ammonium nitrate (liquid fertilizer and an oxidizing agent). Phosphorous acid is an oxidizing/reducing material: the reducing potential of Fungi-Phite is not sufficiently high to produce vigorous or violent reactions with materials normally encountered in the course of use.	
830.6315 Flammability	Waiver request, Product is not flammable and does not contain any combustible ingredient.	

Guideline reference no./property		Description of result	Methods
830.6316	Explodability	Waiver request; Product is not explodable and does not contain any explodable ingredient.	
830.6317	Storage stability	In progress. Fungi-Phite, lot no. P11040401 contains 45.9% a.i. initially and 46.1% a.i. after 30 days at warehouse storage	Enforcement analytical method
830.6319	Miscibility	Waiver request; Product is not an emulsifiable liquid and is not to be diluted with petroleum solvents	
830.6320	corrosion characteristics	In progress. No corrosion or degradation was evident after 30 days at warehouse storage	Enforcement analytical method
830.6321	dielectric breakdown voltage	Waiver request; product is not intended for use around electrical equipment. Not required for EP	
830.7000	pH	6.20 at 20°C	Using pH meter
830.7050	UV/Visible	Not required for EP	
830.7100	Viscosity	16.1 seconds at 20°C (flow time, water flow time is 16.2 seconds). 1.36 centipoise at 20°C (by calculation)	Using a Zahn flow cup viscosity tester; The test material is Fungi-Phite Lot No. M11180401
830.7200	melting range	Waiver request; Product is a liquid at room temperature. Not required for EP	
830.7220	Boiling range	109°C at 30.1" Hg	Using a reflux condenser apparatus
830.7300	Bulk density	1.37 g/cc at 60°F (density); 11.4 lb/gal (bulk density by calculation)	Using hydrometer, range 1.200 to 1.400 calibrated at 60°F
830.7370	Dissociation constant in water	Not required for EP. pK_1 2.00 and pK_2 6.59 are reported for the two ionization steps of phosphorous acid.	CRC Handbook of Chemistry and Physics, 70th edition
830.7520	Particle size/distribution	Not applicable	
830.7550	Partition coefficient	Waiver request; Product is inorganic. Not required for EP	
830.7840	Water solubility	Not required for EP; The registrant addressed this data requirement based on the observed solubility of Fungi-Phite in water, the physical state data, and the published data and stated that no additional information would be learned by conducting a formal water solubility study.	

Guideline reference no./property	Description of result	Methods
830.7950 Vapor pressure	Not required for EP; Waiver request; The registrant indicated that the vapor pressure of most inorganic salts to be relatively insignificant at ambient temperature and presented vapor pressure of several salts.	

[a] Data from MRIDs 46461207 to 46461220.

IX. ADDITIONAL REVIEWER'S COMMENTS: None

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE)

STUDY TYPES: Product Identity and Composition (OPPTS 830.1550)
Description of Beginning Materials (OPPTS 830.1600)
Description of Production Process (OPPTS 830.1620)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)
MRIDs 46484001 and 46461202-46461220

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 05-022

Primary Reviewer:
Susan Chang, M.S.

Robert H. Ross

Signature:
Date: JUN 10 2005

Secondary Reviewers:
Eric Lewis, M.S.

Eric B. Lewis

Signature:
Date: JUN 10 2005

Robert H. Ross, M.S., Group Leader

Robert H. Ross

Signature:
Date: JUN 10 2005

Quality Assurance:
Eric Lewis, M.S.

Eric B. Lewis

Signature:
Date: JUN 10 2005

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

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DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Product Identity and Composition (OPPTS 830.1550) Description of Beginning Materials (OPPTS 830.1600) Description of Production Process (OPPTS 830.1620) Discussion of Formation of Impurities (OPPTS 830.1670) Preliminary Analysis (OPPTS 830.1700) Certified Limits (OPPTS 830.1750) Enforcement Analytical Method (OPPTS 830.1800) Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)
MRID NOS:	46484001, 46461202, 46461203, 46461204, 46461205, 46461206, 46461207, 46461208, 46461209, 46461210, 46461211, 46461212, 46461213, 46461214, 46461215, 46461216, 46461217, 46461218, 46461219, 46461220
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite (EPA Reg No. 73771-R; [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite, a.i.)
PROJECT NOS:	BWS-FPC-01 (MRID 46484001), BWS-FPC-02 (MRID 46461202), BWS-FPC-03 (MRID 46461203), BWS-FPC-04 (MRID 46461204), BWS-FPC-05 (MRID 46461205), BWS-FPC-06 (MRID 46461206), BWS-FPC-07 (MRID 46461207), BWS-FPC-08 (MRID 46461208), BWS-FPC-07 (MRID 46461209), BWS-FPC-10 (MRID 46461210), BWS-FPC-11 (MRID 46461211), BWS-FPC-15 (MRID 46461212), BWS-FPC-20 (MRID 46461213), BWS-FPC-17a (MRID 46461214), BWS-FPC-16 (MRID 46461215), BWS-FPC-19 (MRID 46461216), BWS-FPC-14 (MRID 46461217), BWS-FPC-13 (MRID 46461218), BWS-FPC-12 (MRID 46461219), PHOSPHOROUS ACID 02 (MRID 46461220)
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	Biagro Western Sales in house Laboratory, Inc., Visalia, CA

TITLE OF REPORT: Product Identity and Composition (MRID 46484001), Description of Materials Used to Produce the Product (MRID 46461202), Description of Production Process (MRID 46461203), Discussion of the Formation of Impurities and Method of Analysis (MRID 46461204), Preliminary Analysis (MRID 46461205), Certified Limits (MRID 46461206), Color (MRID 46461207), Physical State (MRID 46461208), Odor (MRID 46461209), Boiling Point (MRID 46461210), Density (MRID 46461211), pH Test (MRID 46461212), Viscosity (MRID 46461213), Storage Stability and Container Corrosion Characteristics, 30-Day Preliminary Report (MRID 46461214), Stability to Normal and Elevated Temperature (MRID 46461215), Oxidation Reduction Data (MRID 46461216), Dissociation Constant Data (MRID 46461217), Waiver Request for Vapor Pressure Data (MRID 46461218), Water Solubility Data (MRID 46461219), Mono- and Di-Potassium Salts of Phosphorous Acid -- Waiver Request from Further Testing (MRID 46461220)

AUTHORS: John Peterson (MRIDs 46484001, 46461202, 46461203, 46461204, 46461205, 46461206, 46461207, 46461208, 46461209, 46461210, 46461211, 46461212, 46461213, 46461214, 46461215, 46461216, 46461217, 46461218, and 46461219) and James B. Messina (MRID 46461220)

STUDY COMPLETED: December 8, 2004 (MRIDs 46484001, 46461202, 46461203, 46461204, 46461205, 46461206, 46461207, 46461208, 46461209, 46461210, 46461211, 46461212, 46461214, 46461215, 46461216, 46461217, 46461218, 46461219), January 12, 2005 (MRID 46461213), and January 7, 2005 (MRID 46461220)

GOOD LABORATORY PRACTICE: Not GLP Compliant

CONCLUSION: Fungi-Phite is a systemic fungicide and an EP for the suppression and control of phytophthora, pythium and downy mildew. The active ingredients are [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite. The label indicates that the active ingredient is 45.5% mono- and di-potassium salts of phosphorous acid and Fungi-Phite contains 5.14 lbs/gal of the active ingredients, equivalent to 3.33 lbs phosphorous acid per gallon (29.5% w/w). The inert is [redacted] as diluent. The beginning materials are [redacted] The

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

CONCLUSION (CONT.) production process was adequately addressed. No impurities are formed in the manufacture of Fungi-Phite and no single impurity at a level of more than 1000 mg/kg (0.1%) is carried over from the starting material to the final product. Five lots of Fungi-Phite were analyzed for phosphorus and potassium. The average of five batch results was 46.10% which was within the strongest and most dilute formulas (45.50-46.20%) and within the sum of the certified limits as given on the CSF (34.5+9.5% to 36.5+10.5%). The upper and lower certified limits of the ingredients are within the recommended range in guideline OPPTS 830.1750. The range of phosphorous acid equivalent would range from 3.30-3.40 pounds (3.33 lbs) of phosphorous acid equivalent per gallon and the pounds of total salts per gallon would range from 5.12-5.24 pounds (label 5.14 lbs). The methods of analysis for potassium and phosphite in potassium phosphite solutions are modifications of standard methods (AOAC 983.02 17th ed. and AOAC 958.01 17th ed., respectively) for the analysis of potassium ions (flame emission spectrophotometry) and for the analysis of phosphate ions (spectrophotometric molybdovanadophosphate assay). The physical/chemical properties were adequately addressed. One-year storage stability and corrosion characteristics studies are in progress.

CLASSIFICATION: **ACCEPTABLE**, the registrant needs to submit the results of the one-year storage stability and corrosion characteristics studies upon completion.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Test material: Fungi-Phite containing [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite

I. **PRODUCT IDENTITY AND COMPOSITION:** Fungi-Phite (EPA Reg. No. 73771-R) is a systemic fungicide and an end-use product (EP) for the suppression and control of phytophthora, pythium and downy mildew. The active ingredients are [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite. The label indicates that the active ingredient is 45.5% mono- and di-potassium salts of phosphorous acid and Fungi-Phite contains 5.14 lbs/gal of the active ingredients, equivalent to 3.33 lbs phosphorous acid per gallon (29.5% w/w). The inert is [redacted] as diluent.

Deficiencies: None

II. **DESCRIPTION OF BEGINNING MATERIALS:** The beginning materials are [redacted]

[redacted]The MSDSs of the starting materials are provided in the study (MRID 46461202)

Deficiencies: None

III. DESCRIPTION OF PRODUCTION PROCESS: [redacted]

Deficiencies: None

IV. DISCUSSION OF FORMATION OF IMPURITIES: No impurities are formed in the manufacture of Fungi-Phite and no single impurity at a level of more than 1000 mg/kg (0.1%) is carried over from the starting material to the final product (MRID 46461204).

Deficiencies: None

V. PRELIMINARY ANALYSIS: Five lots of Fungi-Phite were analyzed for phosphorus and potassium. The data were used to calculate the total of mono- and di-potassium phosphite salts. The ranges of % PO_3-P, K, and salts were 11.21-11.34, 16.6-16.7, and 45.82-46.20, respectively. The average of five batch results was 46.10% which was within the strongest and most dilute formulas (45.50-46.20%) and within the sum of the certified limits as given on the CSF (34.5+9.5% to 36.5-10.5%).

Deficiencies: None

VI. CERTIFIED LIMITS: According to the CSF, Fungi-Phite contains [redacted]monopotassium phosphite and [redacted]dipotassium phosphite (Table 1). The lower and upper certified limits for [redacted]. The certified limits of the ingredients are within the recommended range in guideline OPPTS 830.1750. MRID 46461206 states that the strongest, normal, and most dilute formulas contain 46.2, 45.8, and 45.5% salts, respectively. The study also states that [redacted] The range of phosphorous acid equivalent would range from 3.30-3.40 pounds (label

states 3.33 lbs) of phosphorous acid equivalent per gallon and the pounds of total salts per gallon would range from 5.12-5.24 pounds (label states 5.14 lbs).

Deficiencies: None

TABLE 1. Nominal CSF concentrations and limits for Fungi-Phite[a]

Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient					
Monopotassium phosphite (13977-65-6)	076416	Active	[redacted]		
Dipotassium phosphite (13492-26-7)	076416	Active			
Inert ingredient					
[redacted]					

[a] Data from CSF.

VII. ENFORCEMENT ANALYTICAL METHOD: The method of analysis for potassium in potassium phosphite solutions is a modification of a standard method (AOAC 983.02 17th ed.) for the analysis of potassium ions (flame emission spectrophotometry; MRID 46461205). The modification is in the use of an atomic absorption spectrophotometer in absorbance mode. Dilute solutions of potassium ions are excited in a flame and emit quantitative amounts of light, which are measured by a photoelectric detector and compared to known standard solutions. A sample containing 0.05 to 0.10 g potassium is diluted to 1000 mL with deionized water Five mL of this sample dilution, 10 mL lanthanum chloride solution (background correction for phosphorous), and 5 mL of 1N HCl solution are diluted to 500 mL with deionized water. Blank solution, standard solution, and spike solution are prepared. The instrument is set up for flame emission mode. Percent potassium is calculated. This method is primarily intended for quality control analysis of simple solutions of potassium salts such as Fungi-Phite.

The method of analysis for phosphite in potassium phosphite solutions is a modification of a standard method (AOAC 958.01 17th ed.) for the analysis of phosphate ions (spectrophotometric molybdovanadophosphate assay). The modification is based on the oxidation of phosphite ions to phosphate ions and subsequent analysis. A sample containing 0.05 to 0.25 g phosphorous from phosphate ions is diluted to 1000 mL with deionized water. To a 100 mL volumetric flask, 10 mL of the sample dilution, 10 mL deionized water, 5 mL 2N HCl, and 1.0 mL potassium permanganate solution are added, mixed, and reacted for at least 30 minutes at room temperature. To the flask, 1 mL hydroxylamine hydrochloride solution is added, then 20 mL deionized water is rinsed down the neck of the flask. Ammonium molybdate-ammonium meta-vanadate reagent (20 mL) is added to the flask and reacted for 30 minutes. Blank solution, standard solution, and spike solution are prepared. The absorbance is read at 420 nm on a spectrophotometer. Percent phosphite phosphorous is calculated. This method is primarily intended for quality control analysis of solutions manufactured from phosphorous acid and its salts.

Deficiencies: None

VIII. PHYSICAL AND CHEMICAL CHARACTERISTICS:

1. **Methods:** See Table 2. The test material is Fungi-Phite Lot No. M11040401, except as indicated.

2. **Results:** The physical/chemical properties are listed in Table 2.

3. **Deficiencies:** One-year storage stability and corrosion characteristics studies are in progress.

TABLE 2. Physical and chemical properties for Fungi-Phite[a]

Guideline reference no./property	Description of result	Methods
830.6302 Color	Clear, water-white	Visual inspection
830.6303 physical state	Liquid at -10°C and 54°C	Visual inspection
830.6304 Odor	No significant odor at 20°C	Olfactory inspection
830.6313 Stability	Product is stable and no degradation was found after 14 days at 55°C. Fungi-Phite, lot no. M11040401 contains 45.8% a.i. initially and 45.7% a.i. after 14 days at 55°C.	Enforcement analytical method
830.6314 oxidation reduction: Chemical incompatibility	Waiver request: No increase in temperature after mixing with monoammonium phosphate (firefighting compound) or with ammonium nitrate (liquid fertilizer and an oxidizing agent). Phosphorous acid is an oxidizing/reducing material, the reducing potential of Fungi-Phite is not sufficiently high to produce vigorous or violent reactions with materials normally encountered in the course of use.	
830.6315 Flammability	Waiver request. Product is not flammable and does not contain any combustible ingredient.	
830.6316 Explodability	Waiver request: Product is not explodable and does not contain any explodable ingredient.	
830.6317 Storage stability	In progress; Fungi-Phite, lot no. M11040401 contains 45.9% a.i. initially and 46.1% a.i. after 30 days at warehouse storage.	Enforcement analytical method
830.6319 Miscibility	Waiver request; Product is not an emulsifiable liquid and is not to be diluted with petroleum solvents	

Guideline reference no./property	Description of result	Methods
830.6320 corrosion characteristics	In progress. No corrosion or degradation was evident after 30 days at warehouse storage.	Enforcement analytical method
830.6321 dielectric breakdown voltage	Waiver request: product is not intended for use around electrical equipment Not required for EP	
830.7000 pH	6.20 at 20°C	Using pH meter
830.7050 UV/V sobs	Not required for EP	
830.7100 Viscosit	16.1 seconds at 20°C (flow time; water flow time is 16.2 seconds). 1.36 centipoise at 20°C (by calculation)	Using a Zahn flow cup viscosity tester; The test material is Fungi-Phite Lot No. M11180401.
830.7200 melting range	Waiver request: Product is a liquid at room temperature. Not required for EP	
830.7220 Boiling range	109°C at 30.1" Hg	Using a reflux condenser apparatus
830.7300 Bulk density	1.37 g/cc at 60°F (density) 1.4 lb/gal (bulk density by calculation)	Using hydrometer, range 1.200 to 1.400 calibrated at 60°F
830.7370 Dissociation constant in water	Not required for EP; pK 2.00 and pK$_2$ 6.59 are reported for the two ionization steps of phosphorous acid.	CRC Handbook of Chemistry and Physics, 70th edition
830.7520 Particle size/distribution	Not applicable	
830.7550 Partition coefficient	Waiver request: Product is inorganic. Not required for EP	
830.7840 Water solubility	Not required for EP; The registrant addressed this data requirement based on the observed solubility of Fungi-Phite in water, the physical state data, and the published data and stated that no additional information would be learned by conducting a formal water solubility study.	
830.7950 Vapor pressure	Not required for EP; Waiver request: The registrant indicated that the vapor pressure of most inorganic salts to be relatively insignificant at ambient temperature and presented vapor pressure of several salts.	

[4] Data from MRIDs 46461207 to 46461220

IX. ADDITIONAL REVIEWER'S COMMENTS: None

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE FUNGICIDE)

STUDY TYPE: ACUTE DERMAL TOXICITY - RAT (870.1200) MRID 46461222

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 05-022

Primary Reviewer:
Susan Chang, M.S.

Signature:
Date: JUN 10 2005

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: H.T Borges
Date: JUN 10 2005

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: JUN 10 2005

Quality Assurance:
Eric Lewis, M.S.

Signature: Eric B. Lewis
Date: JUN 10 2005

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

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DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Acute Dermal Toxicity - Rats (OPPTS 870.1200)
MRID NO:	46461222
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite Fungicide (EPA Reg No. 73771-R; [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite, a.i.)
PROJECT NO:	15953
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	Product Safety Laboratories, Dayton, NJ
TITLE OF REPORT:	Acute Dermal Toxicity Study in Rats - Limit Test
AUTHOR:	Daniel J. Merkel, B.S.
STUDY COMPLETED:	December 6, 2004
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	The dermal LD_{50} for males, females, and combined was greater than 5000 mg/kg.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY IV

I. STUDY DESIGN:

1. **Test material:** Fungi-Phite Fungicide, Lot M08130402, containing 45.5% mono- and di-potassium salts of phosphorus acid, a.i.

2. **Test animals:** Five male and five female Sprague-Dawley rats were received from Ace Animals, Inc., Boyertown, PA, were assigned, and weighed 282-325 g (males) and 193-204 g (females) on the day of treatment. The young adult animals, 9-10 weeks old, were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Purina Rodent Chow No. 5012 and filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-22°C and photoperiod, 12 hour light/dark cycle. The relative humidity and air changes per hour were not reported.

3. **Methods:** Rats were ear-tagged: Male - Nos. 7402 to 7406; Female Nos. 7407 to 7411. The rats were acclimated for 13 days. The test material (5000 mg/kg body weight) was applied evenly over a 2 inch x 3 inch area (approximately 10% of the body surface) of the dorsal trunk and covered with a gauze pad. The gauze pad and entire trunk were wrapped with Durapore tape. The coverings were removed after 24 hours and excess test material removed. The test animals were observed during the first several hours after treatment for mortality, signs of gross toxicity, and behavior changes and daily thereafter for 14 days. The rats were weighed prior to treatment and on days 7 and 14. The rats were euthanized on day 14 and necropsied.

II. **RESULTS:**

1. **Mortality:** All rats survived the study.

2. **Clinical observations:** All animals were active and healthy throughout the study.

3. **Body weights:** All animals had normal body weight gains.

4. **Gross necropsy:** No gross abnormalities were noted.

III. **DISCUSSION:** The dermal LD_{50} for males, females, and combined was greater than 5000 mg/kg. This places Fungi-Phite Fungicide in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE FUNGICIDE)

STUDY TYPE: ACUTE ORAL TOXICITY - RAT (870.1100) MRID 46461221

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 05-022

Primary Reviewer:
Susan Chang, M.S.

Signature:
Date: JUN 10 2005

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: H.T Borges
Date: JUN 10 2005

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: JUN 10 2005

Quality Assurance:
Eric Lewis, M.S.

Signature: Eric B. Lewis
Date: JUN 10 2005

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Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Acute Oral Toxicity - Rats (OPPTS 870.1100)
MRID NO:	46461221
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite Fungicide (EPA Reg No. 73771-R; [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite, a.i.)
PROJECT NO:	15952
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	Product Safety Laboratories, Dayton, NJ
TITLE OF REPORT:	Acute Oral Toxicity Up and Down Procedure in Rats
AUTHOR:	Daniel J. Merkel, B.S.
STUDY COMPLETED:	December 6, 2004
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	The oral LD_{50} for female rats was greater than 5000 mg/kg.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY IV

I. STUDY DESIGN:

1. **Test material:** Fungi-Phite Fungicide, Lot M08130402, containing 45.5% mono- and di-potassium salts of phosphorus acid, a.i.

2. **Test animals:** Four female Sprague-Dawley rats were received from Ace Animals, Inc., Boyertown, PA, and weighed 173-230 g on the day of dosing. The young adult animals, 9-11 weeks old, were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Purina Rodent Chow No. 5012. Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-25°C and photoperiod 12 hour light/dark cycle. Relative humidity and air changes per hour were not reported.

3. **Methods:** Rats were ear-tagged: Nos. 7005, 7038, 7039, and 7075. The rats were acclimated for 8-21 days and fasted overnight prior to dosing. The test material (5000 mg/kg body

weight) was dosed by gavage (Table 1). Body weight was recorded prior to dosing, and on days 7 and 14. The test animals were observed for clinical signs of toxicity during the first several hours post-dosing and at least daily for 14 days. All animals were necropsied.

II. RESULTS:

1. **Mortality:** One animal died on day 1. All other rats survived the study.

TABLE 1. Doses, mortality/animals treated			
Dose (mg/kg)	Males	Females	Combined
5000	-	1/4	-

Data taken from p. 9, MRID 46461221.

2. **Body Weight:** All surviving animals gained weight during the study.

3. **Clinical observations:** Two animals were hypoactive three hours post dosing. One animal recovered by 4 hours, but one animal died. Another surviving animal had reduced fecal volume on days 1 and 2 with recovery by day 3. The fourth animal and the recovered animals were active and healthy through the end of the study.

4. **Gross necropsy:** The decedent showed slightly red intestines. No gross abnormalities were noted from the survivors.

III. DISCUSSION: The oral LD_{50} for female rats was greater than 5000 mg/kg. This places Fungi-Phite Fungicide in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE FUNGICIDE)

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT (870.2400) MRID 46461224

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 05-022

Primary Reviewer:		
Susan Chang, M.S.	Signature:	
	Date:	JUN 10 2005
Secondary Reviewers:		
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.	Signature:	H.T Borges
	Date:	JUN 10 2005
Robert H. Ross, M.S., Group Leader	Signature:	Robert H Ross
	Date:	JUN 10 2005
Quality Assurance:		
Eric Lewis, M.S.	Signature:	Eric B. Lewis
	Date:	JUN 10 2005

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Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Acute Eye Irritation - Rabbits (OPPTS 870.2400)
MRID NO:	46461224
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite Fungicide (EPA Reg No. 73771-R; [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite, a.i.)
PROJECT NO:	15955
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	Product Safety Laboratories, Dayton, NJ
TITLE OF REPORT:	Primary Eye Irritation Study in Rabbits
AUTHOR:	Daniel J. Merkel, B.S.
STUDY COMPLETED:	December 6, 2004
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	No corneal opacity or iritis were noted on any rabbit. Positive conjunctival irritation (score 2 or 3) was noted on all rabbits one hour after test material instillation with resolution on one rabbit by 48 hours and on two rabbits by 72 hours. The maximum average score was 10.0 at one hour after test material instillation. Fungi-Phite Fungicide was minimally irritating.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY III

I. STUDY DESIGN:

1. **Test material:** Fungi-Phite Fungicide, Lot M08130402, containing 45.5% mono- and di-potassium salts of phosphorus acid, a.i

2. **Test animals:** One male and two female young adult New Zealand White rabbits were received from Robinson Services, Inc., Clemmons, NC The animals were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Pelleted Purina Chow No. 5326. Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-22°C and

photoperiod. 12 hour light/dark cycle. The relative humidity and air changes per hour were not reported

3. **Methods:** Rabbits were ear-tagged: Nos. 12650 (male) and 12649 and 12651 (females). The rabbits were acclimated for 5 days. The test material (0.1 mL/eye/animal) was applied in the conjunctival sac of the right eye, and the eye held closed for approximately one second. The left eye served as control. The eyes were examined and scored 1, 24, 48 and 72 hours after test material instillation.

II. RESULTS:

1. **Mortality:** All animals survived the study.

2. **Ocular Lesions:** No corneal opacity or iritis were noted on any rabbit. Positive conjunctival irritation (score 2 or 3) was noted on all rabbits one hour after test material instillation with resolution on one rabbit by 48 hours and on two rabbits by 72 hours (Table 1). The maximum average score was 10.0 at one hour after test material instillation (Table 2).

TABLE 1. Summary of Eye Irritation Scores with Time: Conjunctiva and Iris

Score Conditions	1 hour	24 hours	48 hours	72 hours
Conjunctiva				
Erythema	3	2 to 3	1 to 2	0
Chemosis	1	0	0	0
Discharge	1	0	0	0
Iris	0	0	0	0

Irritation score is based on Draize Method

Scale for Scoring Ocular Lesions

Cornea

A. Opacity-degree of density (area most dense taken for reading)

No Opacity 0
Scattered or diffuse area, details of iris clearly visible 1*
Easily discernible translucent areas, details of iris slightly obscured 2*
Opalescent areas, no details of iris visible, size of pupil barely discernible 3*
Opaque, iris invisible 4*

B. Area of cornea involved

One quarter (or less) but not zero 1
Greater than one quarter, but less than half 2
Greater than half, but less than three quarters 3
Greater than three quarters, up to whole area 4
Score A x B x 5 Total Maximum Score = 80

Iris

A. Values

Normal 0
Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combination of any thereof), iris still reacting to light (sluggish reaction is positive). 1*
No reaction to light, hemorrhage, gross destruction (any or all of these). 2*
Score = A x 5 Total Maximum Score = 10

Conjunctive

A. Redness (refers to palpebral and bulbar conjunctive excluding cornea and iris)

Vessels normal 0
Vessels definitely injected above normal 1
More diffuse, deeper crimson red, individual vessels not easily discernible 2*
Diffuse beefy red 3*

B. Chemosis

No swelling 0
Any swelling above normal (includes nictitating membrane) 1
Obvious swelling with partial eversion of lids 2*
Swelling with lids about half closed 3*
Swelling with lids about half closed to completely closed 4*

C. Discharge

No discharge 0
Any amount different from normal (does not include small amounts observed in inner canthus of normal animals) 1
Discharge with moistening of the lids and hairs just adjacent to lids 2
Discharge with moistening of the lids and hairs, and considerable area around the eye 3

Score = (A + B + C) x 2 Total Maximum Score = 20

*** represents a positive response**

TABLE 2. Summary of Total[a] and Primary Eye Irritation Scores with Time

Animal #	1 h	24 h	48 h	72 h
2645	10	6	4	0
2654	10	4	4	0
2658	10	4	2	0
[b]Total	10.0	4.7	3.3	0.0

[a]Formula: Total Irritation Score = I + II + III, where,
I = Corneal Score = [Density (A) x Area (B)] x 5
II = Iris Score = Severity x 5
III = Conjunctival Score = [Erythema (A) + Chemosis (B) + Discharge (C)] x 2
[b]Primary Irritation = Sum of Total Irritation Scores ÷ 3

III. DISCUSSION: No corneal opacity or iritis were noted on any rabbit. Positive conjunctival irritation (score 2 or 3) was noted on all rabbits one hour after test material instillation with resolution on one rabbit by 48 hours and on two rabbits by 72 hours. The maximum average score was 10.0 at one hour after test material instillation. Fungi-Phite Fungicide was minimally irritating and is in TOXICITY CATEGORY III. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE FUNGICIDE)

STUDY TYPE: ACUTE INHALATION TOXICITY - RAT (870.1300) MRID 46461223

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 05-022

Primary Reviewer:
Susan Chang, M.S.

Signature:
Date: JUN 10 2005

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: H.T Borges
Date: JUN 10 2005

Robert H. Ross, M.S., Group Leader

Signature: Robert H Ross
Date: JUN 10 2005

Quality Assurance:
Eric Lewis, M.S

Signature: Eric B. Lewis
Date: JUN 10 2005

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DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Acute Inhalation Toxicity - Rats (OPPTS 870.1300)
MRID NO:	46461223
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite Fungicide (EPA Reg No. 73771-R; [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite, a.i.)
PROJECT NO:	15954
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	Product Safety Laboratories, Dayton, NJ
TITLE OF REPORT:	Acute Inhalation Toxicity Study in Rats - Limit Test
AUTHOR:	Daniel J. Merkel, B.S.
STUDY COMPLETED:	December 6. 2004
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	The inhalation LC_{50} for males, females, and combined was > 2.10 mg/L.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY IV

I. STUDY DESIGN:

1. **Test material:** Fungi-Phite Fungicide, Lot M08130402, containing 45.5% mono- and di-potassium salts of phosphorus acid, a.i.

2. **Test animals:** Five male and five female Sprague-Dawley rats were received from Ace Animals, Inc., Boyertown, PA, were assigned, and weighed 330-363 g (males) and 208-243 g (females) on the day of treatment. The young adult animals, 10-11 weeks old, were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Purina Rodent Chow No. 5012. Tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 21-23°C and photoperiod, 12 hour light/dark cycle. The relative humidity and air changes per hour were not reported.

3. **Methods:** Rats were ear-tagged: Male Nos. 7324 to 7328; Female – Nos. 7329 to 7333. The rats were acclimated for 21 days prior to exposure. The animals were exposed under the concentration shown in Table 1. The rats were exposed whole body in a Plexiglas dynamic flow inhalation chamber for four hours and 15 minutes. They were observed at least every 30 minutes during exposure, upon removal from the chamber, and at least once daily thereafter for 14 days. They were weighed prior to test material exposure and on days 7 and 14 All rats were sacrificed and necropsied on day 14.

TABLE 1. Concentrations, exposure conditions, mortality/animals treated									
Nominal Conc. (mg/L)	Grav. Conc. (mg/L)	MMAD (µm)	GSD (µm)	Particles ≤3.3 µm (%)	Temp (°C)	Humidity (%)	Mortality		
							Male	Female	Combined
45.80	2)	3.0	1.87-1.90	~78	21-22	58-90	0/5	0/5	0/10

Data taken from Tables 4-6, pp. 9, 11, and 16-18, MRID 46461223

Generation of the test atmosphere and description of the chamber: The exposure atmosphere was generated using a 1/4 inch JCO atomizer, FC4 fluid cap and AC1502 air cap (Spraying Systems Inc.). The test material was metered to the atomization nozzle through Tygon tubing using a pump. Filtered air was supplied by an air compressor connected to the spray atomization nozzle. Additional diluent air was supplied directly to the exposure chamber from conditioned room air. The average total airflow was 45.5-45.9 liters/min and the whole body exposure chamber volume was 150 L. Time to equilibrium was approximately 15 min.

Test atmosphere concentration: During exposure, gravimetric samples were collected from the breathing zone of the animals six times, using glass fiber filters. Filter papers were weighed before and after collection to determine the mass collected. The value was divided by the total volume of air sampled to determine the chamber concentration. The average results are in Table 1 above.

Particle size determination: Particle size for each exposure concentration was determined twice using an eight-stage Andersen cascade impactor. The test material concentration collected at each stage was determined gravimetrically. The mass median aerodynamic diameter and geometric standard deviation were determined graphically using two-cycle logarithmic probit axes. Results are in Table 1 above.

II. RESULTS:

1. **Mortality:** All rats survived the study.

2. **Clinical observations:** During exposure, the animals were hypoactive and had ocular discharge, nasal discharge, and hunched posture. All animals recovered upon removal from the chamber and were active and healthy throughout the remainder of the observation period.

3. **Body weight:** All animals had normal body weight gains.

4. **Gross necropsy:** No gross abnormalities were noted.

III. DISCUSSION: The inhalation LC_{50} for males, females, and combined was > 2.10 mg/L. This places Fungi-Phite Fungicide in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE FUNGICIDE)

STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT (870.2500) MRID 46461225

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 05-022

Primary Reviewer:
Susan Chang, M.S.

Signature:
Date: JUN 10 2005

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: H.T Borges
Date: JUN 10 2005

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: JUN 10 2005

Quality Assurance:
Eric Lewis, M.S

Signature: Eric B. Lewis
Date: JUN 10 2005

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DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Primary Dermal Irritation - Rabbits (OPPTS 870.2500)
MRID NO:	46461225
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite Fungicide (EPA Reg No. 73771-R; [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite, a.i.)
PROJECT NO:	15956
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	Product Safety Laboratories, Dayton, NJ
TITLE OF REPORT:	Primary Skin Irritation Study in Rabbits
AUTHOR:	Daniel J. Merkel, B.S.
STUDY COMPLETED:	December 6, 2004
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	Very slight erythema was noted on 3/3 rabbits one hour after patch removal with clearance on one rabbit by 24 hours, but persisted on two rabbits through 24 hours with clearance by 48 hours. The primary irritation index was 0.4. Fungi-Phite Fungicide was essentially nonirritating.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY IV

I. STUDY DESIGN:

1. **Test material:** Fungi-Phite Fungicide, Lot M08130402, containing 45.5% mono- and di-potassium salts of phosphorus acid, a.i.

2. **Test animals:** Three male young adult New Zealand White rabbits were received from Robinson Services, Inc., Clemmons, NC. The animals were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Pelleted Purina Chow No. 5326. Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-22°C and photoperiod, 12 hour light/dark cycle. The relative humidity and air changes per hour were not reported.

3. **Methods:** Rabbits were ear-tagged: Nos. 12599 to 12601. The rabbits were acclimated for 13 days. The fur on the dorsal trunk of each rabbit was clipped on the day prior to treatment. The rabbits were given 0.5 mL of test material applied on a 6 cm^2 clipped intact dose site, and the site covered with a gauze pad. The pad and entire trunk were wrapped with a semi-occlusive Microspore tape. Elizabethan collars were placed on the rabbits. The covering and the collar were removed 4 hours later and the site cleansed to remove any residual test material. The animals were observed at least once daily for gross toxicity and behavior changes during the study. Dermal examination was recorded at 1, 24, 48, and 72 hours after removal of the patch.

II. RESULTS:

1. **Mortality:** All rabbits survived the study.

2. **Dermal responses:** Very slight erythema was noted on 3/3 rabbits one hour after patch removal with clearance on one rabbit by 24 hours, but persisted on two rabbits through 24 hours with clearance by 48 hours. The primary irritation index was 0.4.

Irritation scores:

TABLE 1. Summary of individual rabbit's dermal irritation scores with time

	Hours			
Animal No.	1	24	48	72
12599	1/0 [a]	1/0	0/0	0/0
12600	1/0	0/0	0/0	0/0
12601	1/0	1/0	0/0	0/0

Data taken from Table 1, p. 12, MRID 46461225.
[a]Erythema/Edema

Description of rating method:

Evaluation of skin reaction:	**Score**
Erythema formation:	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Edema formation:	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised by more than 1 mm extending beyond the area of exposure)	4

III. DISCUSSION: Very slight erythema was noted on 3/3 rabbits one hour after patch removal with clearance on one rabbit by 24 hours, but persisted on two rabbits through 24 hours with clearance by 48 hours. The primary irritation index was 0.4. Fungi-Phite Fungicide was essentially nonirritating and is in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE FUNGICIDE)

STUDY TYPE: SKIN SENSITIZATION - GUINEA PIG (870.2600) MRID 46461226

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 05-022

Primary Reviewer:
Susan Chang, M.S.

Signature: Susan Chang
Date: JUN 10 2005

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: H.T. Borges
Date: JUN 10 2005

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: JUN 10 2005

Quality Assurance:
Eric Lewis, M.S

Signature: Eric B. Lewis
Date: JUN 10 2005

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DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Skin Sensitization - Guinea Pigs (OPPTS 870.2600)
MRID NO:	46461226
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite Fungicide (EPA Reg No. 73771-R; [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite, a.i.)
PROJECT NO:	15957
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	Product Safety Laboratories, Dayton, NJ
TITLE OF REPORT:	Dermal Sensitization Study in Guinea Pigs (Buehler Method)
AUTHOR:	Daniel J. Merkel, B.S.
STUDY COMPLETED:	December 6, 2004
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	After three consecutive inductions, the test animals showed no positive signs of reactivity 24 and 48 hours after challenge. Fungi-Phite Fungicide was not a dermal sensitizer.
CLASSIFICATION:	ACCEPTABLE

I. STUDY DESIGN:

1. **Test material:** Fungi-Phite Fungicide, Lot M08130402, containing 45.5% mono- and di-potassium salts of phosphorus acid, a.i.

2. **Test animals:** Thirty female Hartley guinea pigs from Elm Hill Breeding Labs, Chelmsford, MA were assigned to groups and weighed 354-415 g at experiment start. The young adult animals were housed individually in suspended stainless steel cages with mesh floors or plastic perforated bottoms. The animals were fed pelleted Purina Guinea Pig Chow No. 5025. Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 18-23°C and photoperiod, 12 hour light/dark cycle. Relative humidity and air changes per hour were not reported.

3. **Methods:** Female guinea pigs were ear-tagged and grouped: Test Nos. 20727 to 20746; Naive Control - Nos. 20747 to 20756. The guinea pigs were acclimated for 13-52 days. The animals were induced and challenged according to the method of Buehler. The dorsal and flank areas of 20 test guinea pigs and 10 naive control animals were clipped prior to each treatment. For the induction phase, 0.4 mL of undiluted test material was applied to the animal using a Hill Top Chamber and secured with non-allergenic adhesive tape. The chamber was removed after six hours and excess test material cleansed. The procedure was repeated once each week for three consecutive weeks. Twenty-seven days after the first induction, the test animals were challenged with 0.4 mL of undiluted test material under occlusion to naive sites. At challenge, a naive control group (10 animals) was treated with 0.4 mL of undiluted test material. Reactions were scored at approximately 24 and 48 hours following induction and challenge application.

II. RESULTS:

1. **Mortality:** No deaths were observed in any group.

2. **Body weights:** All guinea pigs gained weight during the study.

3. **Skin effects:** Very faint erythema usually non-confluent was noted on 3/20 and 2/20 test animal after the first and second inductions, respectively, with clearance by 48 hours. No reaction was noted on any animal after the third induction. Very faint erythema usually non-confluent was noted on 8/20 test animal after challenge with clearance on six animals by 48 hours. Very faint erythema usually non-confluent was noted on 3/10 naive control animals after challenge with clearance on two animals by 48 hours. No positive reaction was noted on any test or naive control animals after challenge.

TABLE 1. Summary of Individual Erythema Challenge Scores with Time [a]

Time	24 hours				48 hours			
Erythema Score	0	0.5	1	2	0	0.5	1	2
Treated	12	8	0	0	18	2	0	0
Naive Control	7	3	0	0	9	1	0	0

[a]Number of animals affected

Evaluation score is based on Buehler Grading Scale.

Scale for Scoring Skin Reaction

Buehler sensitization scoring scale

Erythema	Score
No reaction	0
Very faint, usually nonconfluent	0.5
Faint, usually confluent	1
Moderate	2
Severe with or without edema	3

III. DISCUSSION:

Very faint erythema usually non-confluent was noted on 3/20 and 2/20 test animals after the first and second inductions, respectively, with clearance by 48 hours. No reaction was noted on any animal after the third induction. No positive reaction was noted on any test or naive control animals after challenge. The study included a alpha-

hexylcinnamaldehyde Technical (HCA) positive control study which was carried out within six months of the study and the results were appropriate. Fungi-Phite Fungicide was not a dermal sensitizer. The packet is classified as **ACCEPTABLE.**

DATA EVALUATION RECORD

MONO- AND DI-POTASSIUM SALTS OF PHOSPHOROUS ACID (FUNGI-PHITE FUNGICIDE)

STUDY TYPES: **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)
MRID 46461227

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 05-022

Primary Reviewer:
Susan Chang, M.S.
Signature: _____
Date: JUN 10 2005

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.
Signature: H.T Borges
Date: JUN 10 2005

Robert H. Ross, M.S., Group Leader
Signature: Robert H. Ross
Date: JUN 10 2005

Quality Assurance:
Eric Lewis, M.S.
Signature: Eric B. Lewis
Date: JUN 10 2005

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

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DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Waiver Requests for 90-Day Oral Toxicity (OPPTS 870.3100) 90-Day Dermal Toxicity (OPPTS 870.3250) 90-Day Inhalation Toxicity (OPPTS 870.3485) Chronic Toxicity (OPPTS 870.4100) Developmental Toxicity (OPPTS 870.3700) Immune Response (152-18) Residue Testing (153-3)
MRID NO:	46461227
DP BARCODE NO:	DP316330
CASE NO:	Not reported
DECISION NO:	353424
TEST MATERIAL:	Fungi-Phite Fungicide (EPA Reg No. 73771-R; [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite, a.i.)
PROJECT NO:	Phosphorous Acid 01
SPONSOR:	Biagro Western Sales, Inc., Visalia, CA
TESTING FACILITY:	E'ponent®, Inc., Washington, DC
TITLE OF REPORTS:	Mono- and Di-potassium Salts of Phosphorous Acid, Waiver Request from Further Testing
AUTHOR:	James B. Messina
STUDY COMPLETED:	January 7, 2005
GOOD LABORATORY PRACTICE:	Not applicable
CONCLUSION:	A waiver is requested for Fungi-Phite Fungicide based on the acute toxicity and mutagenicity profile, its rapid degradation in the environment, its current safe use as a fertilizer, label requirements for handling, its status as a required substance in the human body, and approval of previous waivers cited in the Mineral Acids RED (EPA 738-R-029, December 1993). The reviewer finds the information submitted in support of the waiver request to be acceptable.
CLASSIFICATION:	ACCEPTABLE

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Product description: Fungi-Phite (EPA Reg. No. 73771-R) is a systemic fungicide and an end-use product (EP) for the suppression and control of phytophthora, pythium and downy mildew. The active ingredients are [redacted] w/w monopotassium phosphite and [redacted] w/w dipotassium phosphite. The label indicates that the active ingredient is 45.5% mono- and di-potassium salts of phosphorous acid and Fungi-Phite contains 5.14 lbs/gal of the active ingredients, equivalent to 3.33 lbs phosphorous acid per gallon (29.5% w/w). The inert is [redacted] as diluent.

Waiver request: The registrant is requesting waivers for 90-day oral toxicity, 90-day dermal toxicity, 90-day inhalation toxicity, chronic toxicity, developmental toxicity, immune response, and residue testing, in regard to further testing.

Rationale: A waiver is requested based on the acute toxicity and mutagenicity profile, its rapid degradation in the environment, its current safe use as a fertilizer, label requirements for handling, its status as a required substance in the human body, and approval of previous waivers cited in the Mineral Acids RED (EPA 738-R-029, December 1993).

Acute toxicity and mutagenicity: The acute oral and dermal LD_{50} are >5000 mg/kg. The acute inhalation LC_{50} is > 2.10 mg/L. Fungi-Phite Fungicide was essentially nonirritating to the skin of rabbits, minimally irritating to the eyes of the rabbits, and not a dermal sensitizer. The registrant indicates that mutagenicity data on the active ingredient are negative.

Rapid degradation: Phosphorous acid dissociates rapidly to hydrogen and phosphite ions once released into the environment. Phosphite salts are GRAS. Natural means moderate any accumulation of these ions in plants.

History of use: 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.

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.

Required human substance: Phosphorous is a constituent of human bone tissue and forms compounds needed for energy conversion reactions (e.g. ATP).

Mineral acids RED: Phosphorous Acid; Exemption From the Requirement of a Tolerance, Final rule (65 FR, 10/5/2000, pp. 59346-59350). This regulation establishes an exemption from the requirement of a tolerance for residues of phosphorous acid and its ammonium, sodium and potassium salts in or on all food commodities when used as an agricultural fungicide on food crops.

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

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

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