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



United States Environmental Protection Agency Office of Pesticide Programs

Ms. Jayne Walz United Phosphorus, Inc. 630 Freedom Business Center, Suite 402 King of Prussia, PA 19406

DEC 3 0 2009

Subject:

Endothall Technical

EPA Reg. No.: 70506-178

Amendment application dated July 21, 2008

Dear Ms. Walz,

The amendment referred to above, submitted in connection under the Federal Insecticide, Funcidie, and Rodenticide Act (FIFRA), as amended, has been reviewed. The requested amendment is acceptable, provided you comply with the following:

1. Fulfill all data requirements outlined in the Reregistration Eligibility Decision (RED) for endothall. These include:

Guideline Number	Study/Requirements
71-4	Avian Chronic Reproduction study in quail or duck using N,N-dimethylalkylamine
(850.2300)	salt
72-4C (850.1400)	Estuarine/Marine Fish Early Life-Stage Study using N,N-dimethylalkylamine salt
72-4B	Estuarine/Marine Invertebrate Early Life -Stage study using N,N-
(850.1350)	dimethylalkylamine salt
72-5 (850.1500)	Fish Life-Cycle study using N,N-dimethylalkylamine salt
850.1735	Acute Freshwater Sediment study using N,N-dimethylalkylamine salt
850.1740	Acute Estuarine/Marine Sediment study using N,N-dimethylalkylamine salt
Special Study	Chronic Estuarine/Marine Sediment Testing using N,N-dimethylalkylamine salt
Special Study	65-day Test in Chironomus tentans using N,N-dimethylalkylamine salt
83-3B (870.3700B)	Developmental/Teratology in Non-rodent (rabbit) study
82-4 (870.3465)	28-day Inhalation study (This has been submitted to the Agency and is currently under review)
870.6200	Neurotoxicology study (new, per revised 40 CFR part 158)
870.7800	Immunutoxicity study (new, per revised 40 CFR part 158)
171-4C & D (860.1340)	Residue Analytical Method-Plants and Animals. Radiovalidation data needed to determine whether the current enforcement methods for plants and the required enforcement method(s) for animals can adequately extract and convert aged residues of the monomethyl ester to endothall.
171-4D (860.1340)	Data collection and regulatory analytical methods are needed for the determination of endothall, per se, in animal commodities

171-4	Submission of analytical reference standards for dipotassium and mono-N,N-
(860.1340)	dimethylalkylamine salts of endothall
171-4E	Storage stability data for processed plant commodities, animal commodities, and
(860.1380)	fish
171-4J (860.1480)	Livestock (ruminant and poultry) feeding studies
171-4H (860.1400)	Magnitude of residues in irrigated crops
171-4L (860.1520)	Magnitude of residue studies in potato, alfalfa seed, cotton seed, and cotton gin products. Magnitude of residue studies in raw agricultural commodities of sugar beet and rice if the registrant is supporting these uses
171-4L	Processing studies on apples, field corn, grapes, orange, rice, sorghum, soybeans,
(860.1520)	sugar beet, tomato, and wheat to cover irrigation uses
165-1	A confined, rotational crop study after treatment at the proper maximum labeled
(860.1850)	rate for irrigation water

2. Make the following label modifications:

- a. The signal work, which includes DANGER and POISON, must be revised to also include the skull and crossbones symbol.
- b. Per the acute toxicity review performed during reregistration this product, the "IF ON SKIN" heading in the First Aid Statements must be revised to read, "IF ON SKIN OR CLOTHING."
- c. The Agency recommends that additional text be added to the Note to Physician that addresses eye and skin irritation concerns.
- d. The text, "Have the product container or label with you when calling a poision control center or doctor or going for treatment. You may also contact XXX-XXX-XXXX for emergency medical treatment information" should be added to the first aid section of the label.
- e. Per the RED, the Environmental Hazards Statement must be revised to read as follows: "This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency."
- f. The text, "Only for formulation into an herbicide for the following use(s)...," must be added to the label and the uses that the registrant is supporting must be specified. Any new application sites other than those that appear on the currently federally-registered end-use endothall pesticide products must be submitted as an application for amended registration and must be supported by all applicable data. Appropriate PRIA fees will be required.

- g. Note: While the Container Disposal language in the Storage and Disposal section of the label submitted for review fulfills current requirements, the registrant should consider updating their labeling to meet the requirements of Pesticide Registration (PR) Nocite 2007-4: Labeling Revisions Required by the Final Rule "Pesticide Management and Disposal: Standards for Pesticide Containers and Containment." For further information, please refer to EPA Web Site: http://www.epa.gov/PR Notices/pr2007-4.pdf
- h. Submit 1 copy of the final printed label before releasing this product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. The amended label supersedes all previous labeling for this product. A copy of the label stamped "Accepted with Comments" is included for your records. If you have any questions, please contact Kathryn Montague (703-305-1243 or montague.kathryn@epa.gov).

Sincerely,

Kathryn V. Montague

Acting Product Manager 23

Herbicide Branch

Registration Division (7505P)

ENDOTHALL TECHNICAL

ACTIVE INGREDIENT:

Endothall:

7-oxabicyclo [2.2.1] heptane-2,3-dicarboxylic acid

80.0%*

OTHER INGREDIENTS:

20.0%*

TOTAL

100.0%

*PERCENT OF ENDOTHALL VARIES WITH EACH BATCH. ACTUAL PERCENT OF ENDOTHALL IN THIS DRUM IS STENCILED ON SIDE OF CONTAINER.

DANGER POISON

FIRST AID IF SWALLOWED:

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

· Have person sip a glass of water if able to swallow.

- Do not induce vomiting unless told by a poison control center or doctor.
 - Do not give anything by mouth to an unconscious person.

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.

IF ON SKIN:

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

IF INHALED:

- Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- · Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

See side panel for additional precautionary statements.

EPA Registration No. 70506-178 United Phosphorus, Inc 630 Freedom Business Center, Suite 402 King of Prussia, PA 19406 ACCEPTED with COMMENTS In EPA Letter Dated:

Under the Federal In ticide, Fungicide, and Rodelmicide Act as amended, for the pesticide registered under EPA Reg. No.

70506-178

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EPA Establishment No. 4581-MI-1

Net Contents: 225 lbs/ 102 kg.

FOR MANUFACTURING PURPOSES ONLY

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS) DANGER

FATAL IF SWALLOWED. CORROSIVE, CAUSES IRREVERSIBLE EYE DAMAGE. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. DO NOT GET IN EYES, ON SKIN OR ON CLOTHING. WEAR PROTECTIVE CLOTHING, RUBBER GLOVES, AND GOGGLES OR FACE SHIELD WHEN HANDLING. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage Instructions: Store in a dry area. Do not store in a manner where cross-contamination with other pesticides, fertilizers, food or feed could occur. If spilled during storage or handling, sweep up spillage and dispose of in accordance with the Pesticide Disposal Instructions listed below.

Pesticide Disposal Instructions: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal Instructions: Completely empty drum liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

IMPORTANT INFORMATION READ BEFORE USING PRODUCT

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product reflect the opinion of experts based on field use and tests, and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of United Phosphorus, Inc. or Seller. Handling, storage, and use of the product by Buyer or User are beyond the control of United Phosphorus, Inc. and Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold United Phosphorus, Inc. and Seller harmless for any claims relating to such factors.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, UNITED PHOSPHORUS, INC. AND SELLER MAKE NO WARRANTIES OR MERCHANTABILITY OF OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ON THIS LABEL.

To the extent consistent with applicable law, United Phosphorus, Inc. or Seller shall not be liable for any incidental, consequential or special damages resulting from the use or handling of this product and THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF UNITED PHOSPHORUS, INC. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF UNITED PHOSPHORUS, INC. OR SELLER, THE REPLACEMENT OF THE PRODUCT.

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EMERGENCY TELEPHONE NUMBERS
CHEMTREC: (800) 424-9300
MEDICAL: (303) 623-5716
Rocky Mountain Poison Control Center