

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



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

OCT 15 2004

Greg Mattern
Bayer CropScience
2 TW Alexander Drive
Research Triangle Park, NC 27709

Subject: Fenamidone Technical
EPA Reg. No.: 264-693
Submission dated Oct 5, 2004

Dear Mr. Mattern:

The submission in connection with the registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided that you meet the following conditions:

1. As a condition of this amended registration, submit the following data:
 - a. **Guideline No. 870.6300** - Developmental Neurotoxicity (DNT) study in rats. Due Date: Oct 31, 2007. The Agency understands that this study is in progress and will be submitted prior to this due date.
 - b. **Guideline No. 860.1300** - Nature of the Residue. The registrant must hydrolyze the extractable and nonextractable residues from the N-phenyl studies to determine if conjugated anilines(s) are present (data supporting the storage interval are also needed). Due Date: Oct 31, 2005.
 - c. **Guideline No. 860.1300** - Nature of the Residue. Additional identification/characterization on the N-phenyl livestock samples to determine the fate of the N-phenyl ring in livestock (data supporting the storage interval are also needed). Due Date: Oct 31, 2005.
 - d. **Guideline No 850.1735** - Whole Sediment Acute Toxicity Invertebrates, Freshwater and the midge *Chironomous tenansas* the test species. The parent fenamidone must be monitored throughout the duration of the study, and degradates should be identified. It is

24

also recommended that the same sediment used in the anaerobic aquatic studies is also used in the sediment toxicity studies. In addition to the conditions and measurements required in the guideline, it is recommended that the levels of dissolved oxygen (DO) and the redox potential be monitored throughout the duration of the study. Due Date: Mar 31, 2006

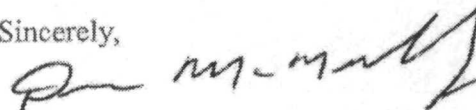
- e. You will submit **production information** (pounds or gallons produced) for this product for the fiscal year in which the product is conditionally registered, in accordance with FIFRA section 29. The fiscal year begins October 1 and ends September 30. The production information will be submitted to the Agency no later than November 15, following the end of the preceding fiscal year. This information should be submitted to:

U.S. Environmental Protection Agency
Office of Pesticide Programs (7504C)
Document Processing Desk
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

2. Make the following labeling change before you release the product for shipment: revise "corn vegetables" to "corn vegetables".

3. Enclosed is a copy of the stamped label. Please submit (1) one copy of the final printed labeling before you release the product for shipment. If the conditions enumerated above are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Sincerely,



Dennis McNeilly
Acting Product Manager (22)
Fungicide Branch
Registration Division (7505C)

Enclosure: stamped label

FENAMIDONE Technical

For Formulation Of Fungicides Only.

Formulators who use this product are responsible for obtaining EPA supplemental distributor registration for their formulated products.

ACTIVE INGREDIENT:

Fenamidone: (5S)-3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-4H-imidazol-4-one 98.5%

INERT INGREDIENTS: 1.5%

EPA Reg. No. 264-693

EPA Est. No. 036990-FR-002

KEEP OUT OF REACH OF CHILDREN CAUTION

For **MEDICAL** And **TRANSPORTATION** Emergencies **ONLY** Call 24 Hours A Day 1-800-334-7577

For **PRODUCT USE** Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • 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 SWALLOWED:	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> • 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.

For **MEDICAL** Emergencies Call 24 Hours A Day 1-800-334-7577.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

NOTE TO PHYSICIAN: Possible mucosal damage may contraindicate the use of gastric lavage. May pose an aspiration pneumonia hazard.

PRECAUTIONARY STATEMENTS

**HAZARD TO HUMANS AND DOMESTIC ANIMALS
CAUTION**

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant 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 treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

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

For use only by manufacturers in the formulation of fungicides. Subsequent formulators are responsible for providing documentation to support registration of their product. This product requires further mixing before use.

CoRM

Only For Formulation Into a Fungicide for use on lettuce, cucurbits, bulb vegetables, tomatoes, and tuberous and com vegetables. This product may be used to formulate product for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding support of such use(s). This product is not registered for use at residential sites.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not contaminate water, food, or feed by storage or disposal.
PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
CONTAINER DISPOSAL: Completely empty bag into application equipment. Then dispose of bags in a sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned, stay out of smoke.

DISCLAIMER AND INDEMNITY FOR FORMULATORS' USES

THE MANUFACTURER EXPRESSLY DISCLAIMS ALL LIABILITY FOR CLAIMS AND ACTIONS (WHETHER BASED ON CONTRACT, TORT, STRICT LIABILITY OR BREACH OF WARRANTY) ARISING OUT OF, RESULTING FROM OR CONNECTED WITH A FORMULATION CONTAINING THIS PRODUCT WHEN USED FOR ANY PURPOSE OTHER THAN THOSE USES SET FORTH IN (1) ABOVE. THE MANUFACTURER HAS NOT DEVELOPED SCIENTIFIC DATA TO SUPPORT, NOR HAS IT EXPLICITLY OR IMPLICITLY APPROVED, ANY USES OTHER THAN THOSE IN (1) ABOVE.

ANY FORMULATOR OR BUYER WHO USES THIS PRODUCT IN FORMULATIONS FOR ANY USE OTHER THAN THOSE STATED IN (1) ABOVE ASSUMES ALL LIABILITY FOR CLAIMS AND ACTIONS ARISING OUT OF, CONNECTED WITH OR RESULTING FROM SUCH USE AND AGREES BY SO USING THIS PRODUCT TO INDEMNIFY AND HOLD HARMLESS THE MANUFACTURER FROM SUCH CLAIMS AND ACTIONS.

THIS DISCLAIMER AND INDEMNITY IS IN ADDITION TO, NOT IN LIEU OF, THE BELOW DISCLAIMER AND LIMITATIONS.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and should be followed carefully. However, 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 weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.



Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

OCT 15 2004

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.**

264-693