

264-693

10-24-2007

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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

OCT 24 2007

Greg Mattern  
Bayer CropScience  
2 T.W. Alexander Drive; P.O. Box 12014  
Research Triangle Park, NC 27709

SUBJECT: Fenamidone Technical; EPA Reg. No. 264-693  
Your Submission Dated December 31, 2004 (D353140) and Related Decisions  
(D355519, D355886, D355883, D356030, D353142, D353141, D370414, D355882,  
D55885, D370414, D355880)

Dear Mr. Mattern:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended to add the following new uses: cotton, carrot, sunflower, brassica vegetables (group 5), leafy (except brassica vegetables (group 4), fruiting vegetables (group 8), and strawberry (rotational crop), is acceptable provided that you submit the following data by December 31, 2009 in one comprehensive submission, and include this letter with that submission:

HEALTH EFFECTS DATA GAPS (See Risk Assessment dated June 21, 2007)

- 28 day inhalation study.
- The following is held in reserve: modified DNT in the Sprague Dawley rat with measurement of the following endpoint: brain weights (samples should be retained for possible morphometric measurements); this study is necessary to confirm the lack of brain weight changes in the Wistar rat DNT.
- Control experiments to determine if the parent/metabolites identified in the carrot metabolism study degrade to aniline when exposed to the base hydrolysis procedures used on the carrot metabolism study. If these experiments do not demonstrate degradation, then submit information concerning the identity and magnitude of the residues in the alkaline hydrolysate of the carrot top (organic and aqueous phase) and carrot root extracts from the metabolism study.
- Degradation of fenamidone to aniline was demonstrated in the tobacco

pyrolysis study. EPA is concerned that fenamidone may be degrading to aniline during the processing or cooking of treated crops. As a result, the petitioner must submit a processing study as designated in Annex 1 of the following European Union document:

(<http://ec.europa.eu/food/plant/protection/resources/app-e.pdf>). The procedure involves the hydrolysis of radio labeled fenamidone at various pHs and temperatures and identification of the resulting transformation products, if any (N-phenyl radio labeled fenamidone should be employed). Depending on the results from this study, additional data may be requested.

- Storage stability data validating the confined rotational crop study.
- Submit the Petition Method Validation study (PMV).

#### ENVIRONMENTAL FATE DATA GAPS

In order to reduce uncertainty in the aquatic risk assessment for fenamidone, submit another fish full life cycle study (72-5) performed to determine the chronic NOAEC. The study must be designed in order to determine the reproductive NOAEC for fish (i.e., test treatments below 8.6 µg/L must be included in the range of concentrations). Given the high variability in the previously submitted study, the study must be conducted using four replicates per treatment level as suggested in the guideline (rather than 2 replicates as in the submitted study).

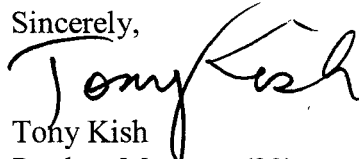
#### LABELING REQUIREMENTS

A spreader/sticker on tomatoes is acceptable providing you submit evidence that the tomato field trials actually included a spreader/sticker.

Submit one copy of your final printed labeling before you release the product for shipment. A copy of the label stamped "Accepted With Comments" is enclosed.

If you have any questions regarding this correspondence, contact Rose Kearns of my staff by phone at 703-305-5611 or via email at [kearns.rosemary@epa.gov](mailto:kearns.rosemary@epa.gov) or myself at 703-308-9443 or via email at [kish.tony@epa.gov](mailto:kish.tony@epa.gov).

Sincerely,



Tony Kish  
Product Manager (22)  
Fungicide Branch  
Registration Division (7505P)

Enclosure

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# 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

<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Immediately call a poison control center or doctor for treatment advice.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>

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.

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
OCT 24 2007  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.**

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Only For Formulation into a Fungicide for use on crops (potatoes and other tuberous and corm vegetables, leafy vegetables, bulb vegetables, carrots, cotton, cucurbit crops, brassica vegetables, tomatoes, peppers and other fruiting vegetables, and sunflower (seed treatment)) or greenhouse ornamentals. 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 must 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:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, 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. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

**LIMITATIONS OF LIABILITY:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, 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.

PRODUCED FOR



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)

Fenamidone Technical (PENDING) Submitted 02/25/05, Resubmitted 03/30/06, Resubmitted 04/20/06, Resubmitted 07/30/07, Resubmitted 09/26/07