264-787 09/20/2005 1/6

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
X Registration
__ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
264-787	SEP 20 2005

Term of Issuance: Conditional

Name of Pesticide Product: Fluoxastrobin Technical

Name and Address of Registrant (include ZIP Code):

Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(C) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA Section 4.

2. Make the following label changes before you release the product for shipment:

a. Revise the EPA Registration Number to read, "EPA Reg. No. 264-787."

Signature of Approving Official:

Tony Kish, Acting Product Manager (22)
Fungicide Branch, Registration Division (7505C)

Date: SEP 20 2005

EPA Form 8570-6

3. Submit the following studies and information or perform the following actions within the required timeframes. Further details concerning the required submissions and actions can be found in the scientific reviews and risk assessments.

a. Submit, by June 30, 2006, additional information (definitive identification of the test substance, spleen weights at necropsy, and competence of the laboratory to perform this type of assay) that will potentially allow upgrade of the assessment of the mouse subacute immunotoxicity study (Guideline Requirement No. 870.7800; Immunotoxicity – Mouse (Subacute Feeding Study), as detailed in the Human Health Risk Assessment for Fluoxastrobin.

b. Submit, by June 30, 2006, additional data concerning the chromatograms and chromatography from the goat metabolism study, (Guideline Requirement No. 860.1300; Nature of the Residue in Livestock), as detailed on pages. 5 and 6 of the Summary of Analytical Chemistry and Residue Data document for Fluoxastrobin, to allow the Agency to determine that the metabolite profile in fat, liver, and kidney did not change during the study.

c. For Guideline Requirement No. 860.1340 (Residue Analytical Method – Plant Commodities), as detailed on page 6 in the Summary of Analytical Chemistry and Residue Data document for Fluoxastrobin and page 2 of the Review of Bayer Response to ACB TMV Memo Re: Fluoxastrobin Enforcement Methods document, rewrite and submit to the Agency, by June 30, 2006, the proposed enforcement method (No. 00604), including instructions for the analysis of all crops and their associated processed commodities for which the petitioner is requesting tolerances, and including information on additional mass spectrometric ion transitions which may be used to positively confirm residues of fluoxastrobin and its regulated metabolites.

d. For Guideline Requirement No. 860.1340 (Residue Analytical Method – Livestock Commodities), as detailed on page 6 in the Summary of Analytical Chemistry and Residue Data document for Fluoxastrobin, modify, and submit to the Agency by June 30, 2006, residue enforcement method no. 00691 to specify whether calculated results for the phenoxy-hydroxypyrimidine metabolite (HEC 7154) are reported in terms of that metabolite or in terms of parent equivalents. The wording of the method that was submitted initially is unclear on this point.

e. For Guideline Requirement No. 860.1380 (Storage Stability), as detailed on page 7 in the Summary of Analytical Chemistry and Residue Data document for Fluoxastrobin, submit, by June 30, 2006, additional information and confirmatory raw data for the residue storage stability study, including detailed description of sample preparation, storage conditions, dates of fortification, and whether sample storage conditions differed from those of the actual crop field trials and rotational crop studies. This information may allow upgrade of the crop field residue trial studies.

f. For Guideline Requirement No. 860.1500 (Crop Field Trials), as detailed on page 7 in the Summary of Analytical Chemistry and Residue Data document for Fluoxastrobin, submit, by June 30, 2006, additional, summary information concerning the weather conditions for the growing season for each crop field residue trial, including whether conditions were normal and/or whether any unusual condition(s) was observed. This information may allow upgrade of the crop field residue trial studies.

g. For Guideline Requirement No. 860.1520 (Processed Food and Feed), as detailed on page 7 in the Summary of Analytical Chemistry and Residue Data document for Fluoxastrobin, submit, by no later than two years following the date of this letter, a new peanut processing study. The processing factor for peanut in the study that was submitted previously exceeded the theoretical concentration factor by a significant margin.

h. For Guideline Requirement No. 860.1650 (Submittal of Analytical Standards), as detailed on page 8 in the Summary of Analytical Chemistry and Residue Data document for Fluoxastrobin and page 2 of the Review of Bayer Response to ACB TMV Memo Re: Fluoxastrobin Enforcement Methods document, submit, by June 30, 2006, analytical reference standards for Fluoxastrobin, its Z-isomer, a Fluoxastrobin metabolite, several deuterated molecules related to Fluoxastrobin, and the isotopically labeled internal standard for the residue chemistry methods to the EPA National Pesticide Standards Repository.

i. For Guideline Requirement No. 860.1900 (Field Accumulation in Rotational Crops), as detailed on page 8 in the Summary of Analytical Chemistry and Residue Data document for Fluoxastrobin, submit, by June 30, 2006, additional, summary information concerning the weather conditions for the growing season for each field rotational crop residue study, including whether conditions were normal and/or whether any unusual condition(s) was observed. This information may allow upgrade of the field rotational crop residue studies.

j. For Guideline Requirement No. 860.1900 (Field Accumulation in Rotational Crops), as detailed on page 8 in the Summary of Analytical Chemistry and Residue Data document for Fluoxastrobin, submit, by June 30, 2006, soil characteristics data for each field rotational crop trial from which samples were analyzed. This information will support the field rotational crop studies.

k. For Guideline Requirement No. 860.1900 (Field Accumulation in Rotational Crops), as detailed on page 8 in the Summary of Analytical Chemistry and Residue Data document for Fluoxastrobin, explain, by June 30, 2006, why samples from one of the grass forage and hay rotational crop field trials appears to have been harvested more than one year after planting of the grass crop. If it was, explain the reason for the delay and why the study should be considered valid.

l. Submit, by June 30, 2006, one acute (10-day) sediment toxicity test, as described in the OPPTS 850.1735 and 850.1740 protocols. This study will reduce risk assessment uncertainties in regard to freshwater and estuarine/marine sediment dwelling organisms.

m. Submit, by June 30, 2006, one chronic (28-day) sediment toxicity test, as described in the OPPTS 850.1735 and 850.1740 protocols. This study will reduce risk assessment uncertainties in regard to freshwater and estuarine/marine sediment dwelling organisms.

n. If such data are available, submit, by June 30, 2006, upgrade data for the Anaerobic Aquatic Metabolism (Guideline Requirement Number (GRN) 162-3) and one of the Aerobic Aquatic Metabolism (GRN 162-4; MRID No. 458653-13) studies to show that following the addition of [^{14}C] Fluoxastrobin to the water layer, the [^{14}C] residues did not initially partition from the water layer to become adsorbed onto the glassware surface, as discussed on the fourth and fifth pages in the EFED Ecological Risk Assessment for Fluoxastrobin that is dated July 27, 2004.

o. If such data are available, upgrade the 96-hour Rainbow Trout acute toxicity study of the Fluoxastrobin degradate HEC 7180 (HEC 5725-carboxylic acid) by submitting (by September 30, 2006) documentation of HES 7180 solubility limits, including sample processing, under test conditions. This documentation should be based on data requirements specified in OPPTS Series 850.1000. Discussion of this requirement can be found on the second page of the Transmittal of Fluoxastrobin Ecotoxicity Data Reviews memorandum for Fluoxastrobin that is dated July 29, 2004.

p. If such data are available, upgrade the 96-hour Sheepshead Minnow acute toxicity study of technical Fluoxastrobin by submitting (by September 30, 2006) documentation of the limits of Fluoxastrobin solubility in seawater under test conditions. This documentation should be based on data requirements specified in OPPTS Series 850.1000. . Discussion of this requirement can be found on the second page of the Transmittal of Fluoxastrobin Ecotoxicity Data Reviews memorandum for Fluoxastrobin that is dated July 29, 2004.

4. Submit one copy of the revised final printed label for our records before you release the product for shipment.

If these conditions 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.

A stamped copy of the label is enclosed for your records.

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

Attachments

5/6

Fluoxastrobin Technical

FOR FORMULATION PURPOSES ONLY.

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

ACTIVE INGREDIENT: Fluoxastrobin: [(1*E*)-[2-[[6-(2-Chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy] phenyl] (5,6-dihydro-1,4,2-dioxazin-3-yl)methanone-O-methyloxime] **94.8%**

OTHER INGREDIENTS: **5.2%**

Total 100.0%

EPA Reg No. 264-TIT **EPA Est. No.**

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:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	• 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.
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.**	

PRECAUTIONARY STATEMENTS

HAZARDS 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. Remove and wash contaminated clothing before reuse. Avoid contact with eyes or clothing. Wear protective eye wear. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other public waters unless this product is specifically identified and addressed in an NPDES permit. 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 EPA.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
SEP 20 2005

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 264-787

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store in original container and keep tightly closed. Store in a cool dry place.

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

Empty containers should be triple rinsed. Do not reuse empty containers. Offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

DIRECTIONS FOR USE

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

This product may be used only for formulation into a fungicide for the uses listed below:

1. The following approved uses:
   - for control of certain diseases in peanuts, potato and tuber vegetables, fruiting vegetables, leafy vegetables (petioles subgroup)
   - for control of certain diseases in turf
   - for suppression of seed-borne disease as a seed treatment in potato, peanut and turf
2. Uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration and
3. Uses for experimental purposes that are in compliance with U.S. EPA requirements

This product may be used to formulate products for specific use(s) not listed on this label if the formulator, user group, or grower has complied with U.S. EPA requirements regarding the support of such use(s).

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.

NET CONTENTS:

Bayer CropScience

Bayer CropScience LP
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1-866-99BAYER (1-866-992-2937)
http://www.bayercropscienceus.com

Fluoxastrobin Technical (PENDING) Submitted 1/31/03, Resubmitted 03/11/05, Resubmitted 08/03/05, Resubmitted 09/09/05