

264-588

03/15/2002

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg Number
264-588

Date of
March 15, 2002

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

Term of Issuance
Conditional

Name of Pesticide Product:
Acetamiprid Technical

Name and Address of Registrant (include ZIP Code):
**Aventis CropSciences
P.O.Box 12014
2 T.W. Alexander Drive
Research Triangle Park, NC 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 sec. 3(a)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 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. 264-588".**
3. You must address the data deficiencies listed on pages 2-3 within the specified time limit.

A copy of the label stamped "accepted with comments" is enclosed for your records.

Signature of Approving Official:
**Akiva Abramovitch, Ph.D.
Chemist
Insecticide-Rodenticide Branch
Registration Division (7505C)**

Date: **March 15, 2002**

Notice of Registration continued
EPA Reg. No. 264-588

1) Submit the following RESIDUE CHEMISTRY data:

- Storage stability data for rotational crops (2 years to submit).
- Radiovalidation data for IM-2-1-amide in ruminant muscle (6 months to submit).

2) Submit the following ENVIRONMENTAL FATE and EFFECTS data:

Avian Reproduction (850.2300). The value of repeating the avian reproduction studies with the northern bobwhite and the mallard is high. Major deficiencies with both studies made the results unreliable. Furthermore, the NOAEL was not determined for the northern bobwhite because chick body weight was significantly reduced at all treatment levels. While the tentative chronic avian risk assessment yielded risk quotients that were only slightly below the LOC for some uses. Changes in the NOAEL therefore may change the conclusions of the chronic risk assessment for birds. Data must be submitted within 1 year.

Acute Aquatic Invertebrate LC₅₀ (850.1010). The acute toxicity test conducted with the water flea was classified as supplemental because the test water used was too hard, which may have effected the toxicity of the test compound. More importantly, however, evidence suggest that the water flea may be an insensitive species to chloronicotinyl insecticides such as acetamiprid. The mode of action of these insecticides is highly selective and exhibit unusually large variability among species. We suspect that some other species of freshwater species, in particular freshwater insects, would exhibit much greater toxicity to acetamiprid than does the water flea. In order to better quantify the risk to freshwater invertebrates, we are requesting that this test be repeated with two additional test species, a freshwater amphipod and a freshwater insect (a stonefly, mayfly, or midge). This testing also will provide information on which types of threatened and endangered aquatic invertebrates are sensitive to acetamiprid and require special protective measures. Data must be submitted within 1 year.

Freshwater Fish Early Life-Stage (850.1400). This study was classified as supplemental because information on physiological and behavioral observations were lacking from the study report. This study may be upgraded to core without repeating the study if this information is provided. The value of this information is moderate. Data must be submitted within 6 months

Toxicity of Foliar Residue to the Honey Bee (850.3030). This study is required because the acute contact LD₅₀ of acetamiprid to the honey bee is less than 11 µg/bee. Data from this study would assist with labeling to protect bees since it would provide information on how long after application residues of acetamiprid will remain toxic to bees. The value of these data are high. Since this tier 2 study will provide sufficient information for assessing the toxicity of acetamiprid to bees, the tier 1 acute contact LD₅₀ study (850.3020) does not need to be repeated. Data must be submitted within 1 year.

Tier II Phytotoxicity, Seedling Emergence (850.4225). The seedling emergence portion of the study is supplemental because plant dry weights were not measured. Based on the current available data, however, the risk of acetamiprid causing seedling emergence effects to nontarget plants is expected to be minor. Also, based on results for lettuce, vegetative vigor effects are predicted to pose a greater risk to nontarget plants than seedling emergence effects. Therefore, we **do not** require that the seedling emergence portion of this test be repeated or upgraded.

Tier II Phytotoxicity, Vegetative Vigor (850.4250). The results of this study for lettuce is inconsistent with the results of the other none test species. Furthermore, unusual responses for some endpoints and observed problems

with the control plants make the results for lettuce questionable. The value of repeating this study with lettuce is high. Since the vegetative vigor effects observed in lettuce were far more sensitive than effects observed in other species, the terrestrial plant risk assessment was based upon these questionable data, which makes the plant risk assessment very uncertain. Any change in the results for lettuce would result in a change in the risk quotients and could change the risk conclusions for terrestrial plants. Any change also could change the determination of risk for threatened and endangered plants. The tier II vegetative vigor study does not need to be repeated for species other than lettuce. Data must be submitted on lettuce within 1 year.

Acute Earthworm LC₅₀. The PMRA has classified this study as invalid and is requiring that it be repeated for registration of acetamiprid in Canada. The USEPA does not have a test guideline for acute toxicity testing with the earthworm. However, we feel that this study would provide us with useful information for risk assessment and therefore request that it be submitted to the USEPA as well as to the PMRA when it is completed. Data should be submitted when available to PMRA.

The data gaps are listed in the following table:

Guideline	Study Type	Test Species	Acceptability
850.2300	Avian reproduction	Northern bobwhite, Mallard	Supplemental, major deficiencies in study-may change chronic risk to birds
850.1010	Aquatic invertebrate acute LC ₅₀	Water flea	Supplemental, more sensitive species needed
850.1400	Fish early life-stage	Fathead minnow	Supplemental, may be upgraded with additional data
850.3030	Honey bee, toxicity of residues on foliage	Honey bee	Invalid, important to establish label mitigations to protect bees
850.4250	Vegetative vigor, tier II	Corn, oat, onion, perennial ryegrass, cabbage, cucumber, lettuce, soybean, tomato, and turnip	Supplemental for lettuce, core for all other test species

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.

5. Submit production information (pounds or gallons produced) for this product for the fiscal year in which the technicals are conditionally registered, in accordance with FIFRA sec. 29. The fiscal year begins October 1 and ends September 30. The production information must be submitted to the Agency no later than November 15, following the end of the preceding fiscal year. This information must be submitted to:

Registration Support Branch
Registration Division (7505C)

1200 Pennsylvania AVE, NW
Washington, DC 20460

Notice of Registration continued
EPA Reg. No. 264-588

6. Submit one copy of the final printed label` 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 sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Enclosure: Stamped copy of label

ACETAMIPRID Technical

For Manufacturing Use Only

ACTIVE INGREDIENT:

Acetamiprid, (E)-N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamide 99.5%

INERT INGREDIENTS:..... 0.5%

EPA Reg. No. 264-XXX

Est. No. 8033-JP-2

KEEP OUT OF REACH OF CHILDREN WARNING

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

For PRODUCT USE Information Call 1-888-AVENTIS (1-888-283-684)

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

FIRST AID

MAR 15 2002

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. 	<p>Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. <u>264-588</u></p>
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 INHALED:	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice. 	
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: There is no specific antidote. All treatment should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS WARNING

May be fatal if swallowed, absorbed through the skin or inhaled. Causes eye injury. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Wear protective clothing and rubber gloves. Remove contaminated clothing and wash clothing before reuse. Do not breathe dust. Wear a mask or pesticide respirator jointly approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health.

SYMPTOMS OF POISONING: In severe cases of overexposure by oral ingestion, lethargy, muscle tremors, and, in extreme cases, possibly convulsions, may occur.

ENVIRONMENTAL HAZARDS

This product is toxic to birds, fish, and aquatic 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 law to use this product in a manner inconsistent with its labeling.
Read entire label before using this product.

Only for formulation into an insecticide for (1) the following uses: Cotton, Leafy Vegetables, Cole Crops, Fruiting Vegetables (except cucurbits), Citrus Fruits, Pome Fruits, Grapes, Ornamentals and Flowering Plants (grown outdoors and in greenhouses, shadehouses and lathhouses) (2) Uses for which USEPA 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 USEPA requirements.

STORAGE AND DISPOSAL

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

STORAGE

Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide 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.

In case of spill, clean up spillage using shovels and avoiding skin contact. Carefully scoop up loose material and place it in appropriate containers so as to avoid dust generation. Ensure adequate decontamination of tools and equipment following cleanup.

CONTAINER DISPOSAL

Completely empty container into manufacturing equipment. Triple rinse container (or equivalent). Then offer container for recycling or reconditioning or puncture and dispose of in a sanitary landfill. Or as an alternative, if allowed by government regulations, dispose of container by burning or incineration. If container is burned, stay out of smoke.

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 Aventis CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: AVENTIS 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 Aventis CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. AVENTIS 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 AVENTIS CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

Aventis CropScience USA LP
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Research Triangle Park, North Carolina 27709

Acetamiprid Technical (PENDING) Submitted 9/2/98, Resubmitted 3/15/02.

