



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

EPA Reg. Number:
264-830

Date of Issuance:
JUN 30 2005

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:
Spirodiclofen Technical

Name and Address of Registrant (include ZIP Code):

Bayer Cropscience
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(c)(7)(A) 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. Add the phrase "EPA Registration Number 264-830".

(continued)

Signature of Approving Official:

Rita Kumar

Date:

6-30-2005

b. On page 2, under Storage and Disposal, Pesticide Disposal, revise the second sentence as follows: "Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of federal Law."

3. Within 24 months from the date of this Notice, submit the following data. These data requirements must be fulfilled in accordance with applicable provisions of the Good Laboratory Practice, as laid out in the Code of Federal Regulation (CFR) Volume 40, Part 160, and submitted in the format described in Pesticide Registration (PR) Notice 86-5:

Product Chemistry

1. Provide details of the commercial scale production process for the TGAI/MUP for the facility located in Germany.
2. Provide the 5-batch analysis for TGAI/MUP batches produced on a commercial scale. Submit a revised basic formulation based on the 5-batches produced on a commercial scale.

Residue Chemistry

Submit apple (juice) and grape (juice) processing studies which monitor for residue of spirodiclofen, BAJ 2510, 3-OH-enol, and 4-OH-enol.

Toxicology

1. In the developmental neurotoxicity study, provide additional morphometric analyses of the caudate putamen, parietal cortex, hippocampal gyrus, and dentate gyrus at the mid and low doses are required for both sexes.
2. A 28-day inhalation toxicity study is required as a condition of registration. However, based on the low volatility and low inhalation toxicity (Category IV) of spirodiclofen and inhalation MOEs of at least 1000 for the proposed uses, spirodiclofen qualifies for a waiver of the 28-day inhalation toxicity study for the proposed uses. **The requirement for the 28-day inhalation toxicity study is waived for this action only.** If in the future, requests for new uses or formulations are submitted that may result in a significant change in either the toxicity profile or exposure scenarios, we will reconsider this data requirement.

Environmental Fate and Effects

The following acute toxicity tests on the TGAI must be repeated:

- Freshwater Fish Acute Toxicity Study using Bluegill Sunfish (Guideline §72-1a)
- Freshwater Fish Acute Toxicity Study using Rainbow trout (Guideline §72-1a)
- Freshwater Invertebrate Toxicity Study using Daphnia magna (Guideline 72-2a)
- Estuarine/Marine Acute Toxicity using Sheepshead Minnow (Guideline 72-3a)
- Estuarine/Marine Acute Toxicity using Mysid Shrimp (Guideline 72-3b)

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The new test should attempt to use a teflon-lined test apparatus or better equilibrate the exposure system such that there are fewer sorption sites available for spiroticlofen. Additionally, greater effort should be expended to examine alternative co-solvents.

4. Submit production information (gallons produced) for this product for the fiscal year in which this use 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:

Registration Support Branch
Registration Division (7505C)
U.S. Environmental Protection Agency
401 M Street SW
Washington D.C. 20460

7. Submit two (2) copies of your final printed labeling 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(a). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Sincerely,



Rita Kumar
Senior Regulatory Specialist
Insecticide Rodenticide Branch
Registration Division (7505C)

Enclosure

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Spirodiclofen Technical

An insecticide for formulating use only.

ACTIVE INGREDIENT:

Spirodiclofen: 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutanoate 97.8%

INERT INGREDIENTS: 2.2%

100.0%

EPA Reg. No. 264-IGN

EPA Est. No.3125-MO-1

STOP - Read the label before use
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 SWALLOWED:	<ul style="list-style-type: none"> • 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 to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.

In case of emergency call toll free the Bayer Emergency Response Telephone No. 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: No specific antidote is available. Treat patient symptomatically.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Prolonged or frequent repeated skin contact may cause allergic reactions in some individuals. Washing hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco will reduce exposure. Removing and washing contaminated clothing before reuse may reduce exposure.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Formulators and handlers must wear long sleeved shirt and long pants, socks and shoes, and chemical resistant gloves (such as natural rubber, selection category A).

ACCEPTED
with COMMENTS
In EPA Letter Dated
JUN 30 2005

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

264-830

ENVIRONMENTAL HAZARDS

This pesticide is toxic to 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 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 labeling.

Only for formulation into an insecticide for:

- I. The following uses
 - A. Terrestrial Food and Feed Crops
 1. Citrus Fruits (Crop Group 10)
 2. Pome Fruits (Crop Group 11)
 3. Stone Fruits (Crop Group 12)
 4. Tree Nuts (Crop Group 14)
 5. Grapes
- II. Uses for which US EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- III. Uses for experimental purposes that are in compliance with US EPA requirements.

Labeling for products formulated from this product must conform to that which is currently registered with the U.S. Environmental Protection Agency. For specific information on federally registered uses contact Bayer Corporation. Any variance from the federally registered labeling for products containing SPIRODICLOFEN insecticide will have to be supported by data provided by the formulator.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If container is leaking, invert to prevent leakage. If the container is leaking or material is spilled for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose of as directed for pesticides below. In spill or leak incidents, keep unauthorized people away. You may contact the Bayer Emergency Response Team for decontamination procedures or any other assistance that may be necessary. The Bayer Emergency Response Telephone No. is (800) 334-7577, or contact Chemtrec at (800) 424-9300.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, 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: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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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.

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IMPORTANT: READ BEFORE USE

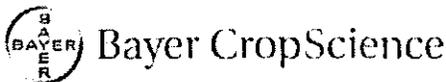
Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

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

Spirodiclofen Technical (PENDING) Submitted 05/13/02, Resubmitted 06/15/05.