

264-718

05/03/2005

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

EPA Reg. Number:

264-718

Date of

May 3, 2005

Term of Issuance:

Conditional

Name of Pesticide Product:

Spiromesifen Technical

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Karen Shearer
Bayer Crop Science
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(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product when the Agency requires all registrants of similar products to submit such data.
2. Make the following label changes before you release the product for shipment:
 - a. Revise the EPA Registration Number to read, "EPA Reg. No. 264-718."
3. Submit studies to support the following data gaps. Each study must be submitted to the Agency within the time frame indicated measured from the effective date of this registration.
 - a. Preliminary analysis (Guideline 830.1700).
Repeat the preliminary analysis on commercial scale production and revise the Confidential Statement of Formula if differences are found from pilot production. Due within 12 months.
 - b. Storage Stability (Guideline 860.1380).
The commodities analyzed in the Field Accumulation in Rotational Crops studies were held for a maximum of 671 days (22 months) prior to extraction. Freezer storage stability data are available for a wide variety of crop matrices for 10.5 to 14.5 months with no indication of residue decline. Additional storage stability data are thus required to validate these intervals. Due within 18 months.

(continued on next page)

Signature of Approving Official:

Thomas C. Harris, Biologist
Insecticide-Rodenticide Branch
Registration Division (7504C)

Date:

May 3, 2005

- c. Avian Reproduction Study using Bobwhite Quail and Mallard Duck (Guideline 850.2300).
These studies should be repeated to establish a no observed effect concentration. Due within **24** months.
- d. Chironomid Sediment Toxicity Test (Draft Guideline 850.1790; part 2).
This is required since there is uncertainty regarding the toxicity of spiromesifen to sediment-dwelling invertebrates where the overlying water has been spiked rather than the sediment. Due within **24** months.
- e. Chronic Field Test for Pollinators (Guideline 850.3040).
Requirement based on chemical similarity to spiroticlofen which has demonstrated chronic effects on bee populations by affecting larval stages. Due within **24** months.

4. Submit two copies of the revised final printed label for the record before you release the product for shipment.

If any of 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.

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

Spiromesifen Technical

An Insecticide for Formulating Use Only

ACTIVE INGREDIENT: Spiromesifen:

2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate 96.99%

INERT INGREDIENTS: 3.01%

TOTAL: 100%

EPA Reg. No. 264-TRI

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 SWALLOWED:	<ul style="list-style-type: none">• Immediately call a poison control center or doctor 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 15-20 minutes.• Call a poison control center or doctor for treatment advice.
For <u>MEDICAL</u> 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: No specific antidote is available. Treat patient symptomatically.	

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin, or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

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).

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.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

MAY - 3 2005

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

264-718

000264-00TRI.20050419-Spiromesifen Technical.pdf EPA received 5/2/05

DIRECTIONS FOR USE

It is a violation of Federal 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:

- I. The following uses
 - A. Terrestrial Food and Feed Crops
 1. Brassica leafy vegetables (Crop Groups 5)
 2. Cotton
 3. Field Corn
 4. Cucurbit Vegetables (Crop Group 9)
 5. Fruiting Vegetables (except Cucurbits) (Crop Group 8)
 6. Leafy Greens Vegetables (Crop Subgroup 4A)
 7. Tuberos and Corn Vegetables (Crop Subgroup 1C)
 8. Strawberry
 - B. Greenhouse Non-Food Crop
 1. Ornamentals (shrubs, trees, flowers and foliage plants) in greenhouses, shade houses and nurseries.
 - C. Terrestrial Non-Food Crop
 1. Ornamentals (shrubs, trees, flowers and foliage plants) in outdoor landscapes.
- 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.

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.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. 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 container (or equivalent). Then offer container for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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.

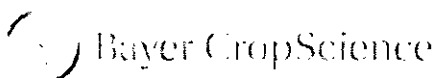
By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

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.

NET CONTENTS:



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