



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

EPA Reg.
Number:

264-803

Date of Issuance:

JUL 16 2004

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Spiroxamine 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 (FIFRA).

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)(B) provided that you:

1. Submit and/or cite all data required for registration 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 change before you release the product for shipment: Revise the EPA Registration Number to read, "EPA Reg. No. 264-803."

3. As a condition of registration, submit the following data:

a. Guideline No. 860.1340 - Modify the confirmatory method to use more than single-ion monitoring or conduct an interference study. Due Date: July 31, 2005.

b. Guideline No. 860.1380 - Submit storage stability data for the hops trials which were conducted in Germany and storage stability data for bananas stored frozen for 6 months. Due Date: December 31, 2004.

c. Guideline No. 870.3800 - Two-Generation Reproduction Study - Rat. Additional data to clarify lactation indices and clinical signs of toxicity in the second generation in the submitted study. Note that if data is insufficient to upgrade study, a new two-generation reproduction study must be submitted with any future new uses. Due Date for additional data: September 30, 2004.

Cont.

Signature of Approving Official:

Mary J. Waller

Mary Waller, Product Manager 21
Fungicide Branch, Registration Division

Date:

7/16/04

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d. Guideline No. 8350.1230 - Adsorption/Desorption study with soils from hop-growing areas. Due Date: September 30, 2005

e. Guideline No. 72-1(a) - Freshwater Fish (Bluegill Sunfish) - Acute. Due Date: September 30, 2005.

f. Guideline No. 72-1(c) - Freshwater Fish Rainbow Trout -Acute. Due Date: September 30, 2005.

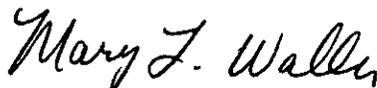
g. Guideline No. 123-2 - Aquatic Plant Growth (conducted at maximum seasonal use rate). Due Date: September 30, 2005.

4. Submit one copy of the revised final printed label before releasing the product for shipment.

If the conditions enumerated above 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. Please contact me on (703) 308-9354 if you have questions regarding this registration.

Sincerely,



Mary Waller
Product Manager 21
Fungicide Branch
Registration Division (7505C)

Enclosure 1) Stamped Label

Spiroxamine Technical Fungicide

For use in the manufacture of fungicides.

ACTIVE INGREDIENTS:

Spiroxamine,

8-(1,1-Dimethylethyl)-N-ethyl-N-propyl-1,4 dioxaspiro[4,5]decane-2-methanamine *.....97.2%

OTHER INGREDIENTS:.....2.8%

* Consists of two pesticidally active diastereomers, isomers A and B, at a ratio of 50.68 to 44.22.

TOTAL: 100.0%

EPA Reg. No. 264-ING

Est. No.

STOP – Read the label before use
KEEP OUT OF REACH OF CHILDREN
DANGER

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. • 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.
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: No specific antidote is available. Severe skin irritation and edema possible. Treat symptomatically. In case of poisoning, it is requested that Bayer CropScience also be notified. Telephone: 1-800-334-7577.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS DANGER

CORROSIVE. Causes skin burns. May be fatal if swallowed or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear coveralls over long-sleeved shirt and long pants, socks, chemical-resistant footwear, and gloves. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

ENVIRONMENTAL HAZARDS

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.
Read entire label before using this product.**

Detailed information on chemical and physical properties and other formulating recommendations for Spiroxamine Technical are available upon request from Bayer CropScience. Obtain and read this information before undertaking the formulation of Spiroxamine Technical in order to avoid formulation hazards and ensure a satisfactory finished product.

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 CropScience. Any variance from the federally registered labeling for products containing Spiroxamine Technical will have to be supported by data provided by the formulator.

Spiroxamine Technical fungicide is intended for formulation into end-use products for:

Terrestrial Food Crops: Hops

This product may be used to formulate products for any additional uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such uses.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Handle and open container in a manner as to prevent spillage. If the container is leaking or material spilled for any reason or cause, carefully sweep material into a pile. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Dispose of pesticide as directed below. In spill or leak incidents, keep unauthorized people away. You may contact the Bayer CropScience Emergency Response Team for decontamination procedures or any other assistance that may be necessary. The Bayer CropScience Emergency Response Telephone No. is 1-800-334-7577.

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

Do not use container in connection with food, feed, or drinking water. Completely empty container into the processing equipment. 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.

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:

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

JUL 16 2004

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

264-803



Bayer CropScience

**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)**