

Reg # 618-97 PM-13 19 5  
US ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDES PROGRAMS  
REGISTRATION DIVISION (TS-767)  
WASHINGTON, DC 20460

EPA REGISTRATION NO.

618-97

DATE OF ISSUANCE

APR 1 1992

TERM OF ISSUANCE

EXPIRES APRIL 30, 1995

NAME OF PESTICIDE PRODUCT

ZEPHYR 0.15 EC  
Miticide/Insecticide

NOTICE OF PESTICIDE:  REGISTRATION  
 REREGISTRATION

(Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended)

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

MERCK & COMPANY, INC.  
MERCK SHARP & DOHME RESEARCH LABORATORIES  
HILLSBOROUGH ROAD  
THREE BRIDGES, NEW JERSEY 08887

331/5415474  
18/18

NOTE: Changes in labeling formula 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 U.S. 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.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this 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) since you agreed to:

- 1). Submit and/or cite all data or other material required for registration/reregistration of your product under FIFRA section 3(c)(5) or FIFRA section 4 when the Agency requires all registrants of similar products to submit such data.
- 2). Within 30-days of receipt of an EPA approved protocol for an aquatic mesocosm study (GRN 72-7) provide the Agency a written unconditional commitment to conduct the study through completion. For any modification of the protocol to be valid it must be agreed to by EPA within the above mentioned 30-day period.
- 3). Initiate the in-life phase of study on April 30, 1992,
- 4). Submit the first progress report by November 3, 1992, and the second progress report by August 21, 1993,
- 5). Submit the final study by October 31, 1994.

Note this study was originally due October 1991 and granted and extension to April 30, 1994 because of the delay by EPA

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

April 1, 1992

in responding to your waiver request. You are now requesting a six month extension for the submission of this study based upon the time needed by your contractor to format and finalize this voluminous report. We are granting the extension for this short period of time. Please note that we will grant no further extension for submission of this study.

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

a. Add the following minimum interval (between treatment) treatment statement to label, "Do not apply within 21 days of last treatment."

b. Revise the statement regarding the total amount of ai/acre/year to read, "Do not apply more than 32 fl oz per acre in any growing season".

c. In the environmental hazard section, revise the statement pertaining to wetlands to read as follows:

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark.

d. Add the statement, "Do not use this product east of the Mississippi River.

7). Submit product information (pounds or gallons produced) for this product for the fiscal year in which the use on cotton is conditionally registered, in accordance with FIFRA Section 29. The fiscal year begins October 1, and ends September 30.

This information is to be submitted to:

Environmental Protection Agency  
Registration Support Branch  
Registration Division (H7505C)  
401 M Street SW  
Washington, DC 20460

The conditional registration will be subject to an expiration date of April 30, 1995. Such expiration will occur automatically notwithstanding the fulfillment of any conditions set forth in this letter and expiration will not give rise to hearing rights pursuant to FIFRA Section 6(e). We are issuing this new conditional registration for this additional period of time to allow you sufficient time to conduct this study in accordance with the EPA approved protocol. We concluded that based upon your proposed label restrictions to reduce exposure including a reduction in the total seasonal amount of abamectin

active ingredient, continued use of avermectin for this period of time will not cause a significant increase in the risk of adverse effects to the environment. Upon completion of review of the mesocosm study and all other available data the Agency will decide whether this product could be registered under FIFRA Section 3(c)(5) or if other regulatory action is warranted.

As you know the current tolerances for avermectin B<sub>1</sub> and its delta-8,9-isomer are due to expire March 31, 1993. By a separate action, the tolerances authorizing residues of the subject product on cotton will be extended to April 30, 1996. After that date sale or distribution of food in interstate commerce containing any residues of the subject product will be a violation of the Federal Food Drug and Cosmetic Act.

**YOU SHOULD KNOW THAT IF YOU FAIL TO SATISFY ANY OTHER CONDITIONS IMPOSED ON THIS REGISTRATION, E.G., YOU FAIL TO SUBMIT THE REQUIRED DATA BY THE SPECIFIED DEADLINES, OR THE DATA SUBMITTED WERE NOT GENERATED IN ACCORDANCE WITH THE GOOD LABORATORY PRACTICE STANDARDS (40 CFR PART 160) AND/OR THE EPA APPROVED PROTOCOL, EPA MAY ISSUE A NOTICE TO CANCEL THIS REGISTRATION UNDER FIFRA SECTION 6(E).**

Submit five (5) copies of your final printed labeling before you release the product for shipment.

A stamped copy of the label has been enclosed for your records.

George T. LaRocca  
Product Manager (15)  
Insecticide-Rodenticide Branch  
Registration Division (H7505C)

Enclosure:

475

**Restricted Use Pesticide**  
Toxic to Fish, Mollusks, and Aquatic Organisms  
For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

APPROVED  
BY THE OFFICE OF  
THE EPA LABORER

APR 1 1992

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the uses and registered under EPA Reg. No. 613-9-

# Zephyr<sup>®</sup> 0.15 EC

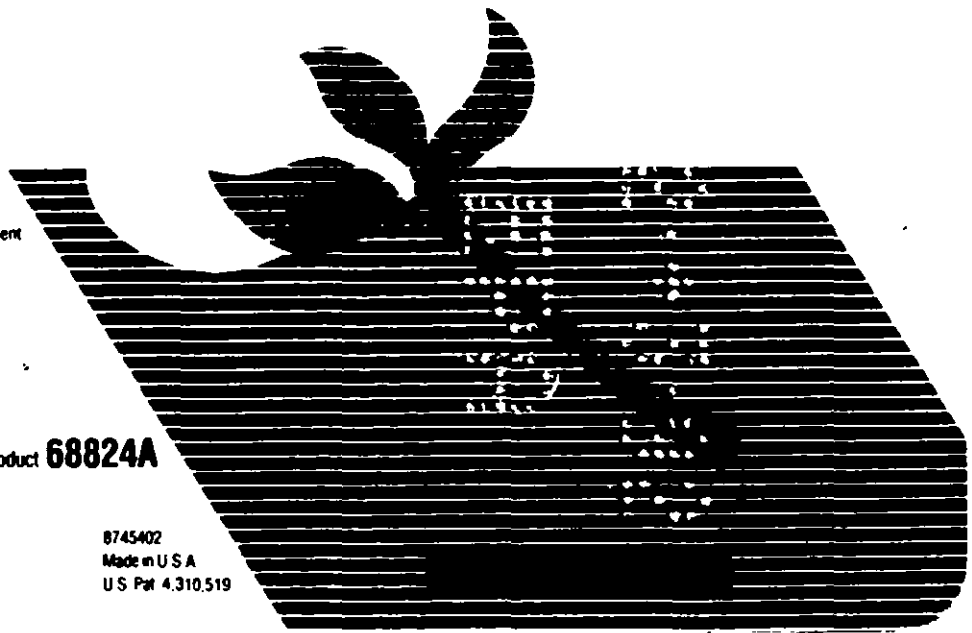
**miticide/insecticide**

**ACTIVE INGREDIENT**  
Avermectin B<sub>1</sub> [A mixture of avermectins containing ≥ 80% avermectin B<sub>1a</sub> (5-O-demethyl avermectin A<sub>1a</sub>) and ≤ 20% avermectin B<sub>1b</sub> (5-O-demethyl-25-de (1-methylpropyl)-25-(1-methylethyl) avermectin A<sub>1a</sub>)] 1.9%  
**INERT INGREDIENTS** 98.1%  
\* 1 gallon contains 0.15 pound avermectin B<sub>1</sub>

**KEEP OUT OF REACH OF CHILDREN**  
**WARNING**

PRECAUCION AL USUARIO: Si usted no lee ingles, no use este producto hasta que la etiqueta haya sido explicada ampliamente

See Back Label for Additional Precautionary Statements and Statement of Practical Treatment



EPA EST NO 39578 TX-1  
EPA REG NO 618 87

**MSDAGVET**



Division of MERCK & CO., INC.  
Rahway, New Jersey 07065, U.S.A.  
ZEPHYR REG TM MERCK & CO., INC.

FOR LOT NUMBER SEE BOTTOM OF BOTTLE ▼

Product **68824A**

8745402  
Made in U.S.A.  
U.S. Pat. 4,310,519

TERM OF ISSUANCE  
EXPIRES APRIL 30, 1995

NAME OF PESTICIDE PRODUCT  
**ZEPHYR 0.15 EC**  
Miticide/Insecticide

NOTICE OF PESTICIDE:  REGISTRATION  
 REREGISTRATION

(Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended)

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

**MERCK & COMPANY, INC.**  
**MERCK SHARP & DOHME RESEARCH LABORATORIES**  
**HILLSBOROUGH ROAD**

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**  
**WARNING**

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if inhaled or absorbed through the skin. Do not breathe spray mist. Avoid contact with skin. May be fatal if swallowed. Wear protective clothing including long sleeve shirt, long trousers, rubber gloves, and goggles or face shield when mixing and loading. During spray application, wear long sleeve shirt, long trousers, and rubber gloves. Remove any contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling, before eating, drinking or using tobacco. Do not apply this product in such a manner as to directly or through drift expose workers or other persons. The area being treated must be vacated by unprotected persons.

**STATEMENT OF PRACTICAL TREATMENT**

**If inhaled:** Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

**If swallowed:** Call a physician or Poison Control Center immediately. Drink one or two glasses of water and induce vomiting by gently touching the back of the throat with finger. Repeat until vomit fluid is clear. Do not induce vomiting or give anything by mouth to an unconscious person.

**If on skin:** Remove contaminated clothing and wash affected areas with soap and water. Get medical attention if irritation persists.

**If in eyes:** Flush eyes with plenty of water. Call a physician immediately. Recommendations for Medical Treatment for Avermectin B<sub>1</sub> Acute Toxicity. Early signs of intoxication include mydriasis (dilated pupils), ataxia (unsteadiness) and muscle tremors. Toxicity following accidental ingestion of the concentrate can be minimized by inducing vomiting within one half hour of exposure.

If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels) as indicated by clinical signs, symptoms and measurements.

In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since avermectin B<sub>1</sub> is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic avermectin B<sub>1</sub> exposure.

For emergency information, call Merck & Co., Inc. (215) 661-7300 during business hours (8:30 am to 4:30 pm EST) or (215) 661-5000 after hours or weekends.

**ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish and wildlife. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not apply when weather conditions favor drift from target areas. Do not contaminate water when disposing of equipment, wash water, or rinsate.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

**REENTRY STATEMENT**

Do not reenter treated areas until sprays have dried.

**PHYSICAL/CHEMICAL HAZARDS**

Do not use or store near heat or open flame.

**DIRECTIONS FOR USE**

It is a violation of Federal (U.S.A.) law to use this product in a manner inconsistent with its labeling.

**COTTON:** ZEPHYR® 0.15 EC is an emulsifiable concentrate containing 0.15 lb avermectin B<sub>1</sub> per gallon which, when mixed with water according to the Directions for Use, will control Spider mites (twospotted, carmine, Pacific and Strawberry) on cotton.

8745502

For control of spider mites on cotton, mix with water and apply at the rates given in the following table:

Spider Mites	Fluid Ounces Per Acre
Twospotted	8 - 16
Carmine	
Pacific	
Strawberry	

Use 8 - 16 fl oz ZEPHYR per acre depending on size of the plant and density of the foliage. Apply with ground sprayers or aerially by fixed-wing aircraft or helicopter in a minimum of 5 gallons of water per acre to provide thorough coverage. Begin application when mites are first noticed and repeat if necessary.

**USE RESTRICTIONS**

- Do not apply more than 48 fl oz ZEPHYR per acre per year.
- Do not apply within 20 days of harvest.
- Do not graze or feed cotton foliage.
- Do not apply this product through any type of irrigation system.

**STORAGE AND DISPOSAL**

**Storage:** Store in a tightly closed container in a cool, dry place.  
**Prohibitions:** Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.  
**Pesticide Disposal:** Pesticide spray mixture or rinsate that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticides or buried in a safe place away from water supplies. Improper disposal of excess pesticide spray mixture or rinsate is a violation of Federal (U.S.A.) law. If these wastes cannot be disposed of by the 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) and dispose in an incinerator or landfill approved for pesticide containers.

**CONDITIONS OF SALE AND WARRANTY**

Notice of Warranty: The Directions for Use of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with 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 MSD AGVET or the Seller. Treatment may not be effective if tolerant strains of spider mites develop. Use of alternate treatments should be considered if treatment with ZEPHYR proves ineffective. All such risks of use shall be assumed by the buyer.

MSD AGVET warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the Directions for Use subject to the inherent risks referred to above. Buyer assumes all risks of use or handling which are at variance in any way with the Directions hereon. MSD AGVET makes no other express or implied warranty of Fitness or Merchantability or any other express or implied warranty. In no case shall MSD AGVET or the Seller be liable for consequential, special or indirect damages resulting from the use or handling of this product. MSD AGVET and the Seller offer this product and the buyer and user accept it, subject to the foregoing Notice of Warranty which may be varied only by agreement in writing signed by a duly authorized representative of MSD AGVET.

**BEST AVAILABLE COPY**

SIGNATURE OF APPROVING OFFICIAL