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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 22 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Patricia A. Sheehy
MERCK 7 CO. INC.
THREE BRIDGES, NJ 08887

Subject: Label Amendment Submission of 08/26/93 in Response to PR Notice 93-7
EPA Reg. No. 618-97
ZEPHYR 0.15 EC

Dear Registrant:

The labeling cited above and submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is accepted subject to the comments reflected on the enclosed sheet. A copy of your proposed labeling stamped "ACCEPTED WITH COMMENTS" is enclosed.

WHAT THIS ACCEPTANCE MEANS:

Based on your certification, the Agency has accepted the labeling changes that are necessary to comply with the Worker Protection Standard (WPS) labeling requirements of 40 CFR part 156, subpart K, described in PR Notices 93-7 and 93-11. Any other labeling changes submitted in connection with this amendment application but not directly related to compliance with the WPS have not been reviewed or accepted by the Agency. If you wish to make such changes, you must submit a separate amendment application proposing them. If your product is currently suspended, the acceptance of this labeling amendment does not affect the suspension in any way.

WHAT YOU NEED TO DO NEXT:

By the next label printing make all the specified changes to your labeling. Send to EPA one (1) copy of the final printed labeling:

- BEFORE selling or distributing any product bearing the final printed labeling
- AND
- WITHIN one year from date of this acceptance.



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

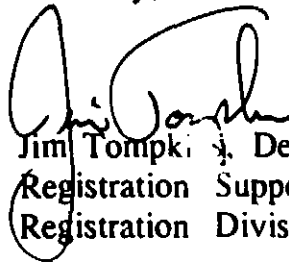
Submit the final printed labeling via the U.S. Postal Service to:

Document Processing Desk (FIN-LABEL)
Office of Pesticide Programs (7505C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460-0001

Hand or courier deliveries of final printed labeling may be made to:

Document Processing Desk (FIN-LABEL)
Office of Pesticide Programs
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Sincerely,



Jim Tompkins, Deputy Chief
Registration Support Branch
Registration Division (7505W)

Attachment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division

Patricia A. Sheehy
MERCK & CO INC
BOX 450
THREE BRIDGES NJ 08887

Comment for: EPA Reg Nr.618-97
ZEPHYR 0.15 EC

The following specific comments pertain to your WPS
labeling submission concerning the product
cited above:

You have incorrect wording in the first paragraph in the
Agricultural Use Requirements box on your proposed label.
That paragraph must contain the exact wording of the
paragraph shown as "2" in Section F on Part 2 of the Product
Worksheet in Supplement Three-A to PR Notice 93-7.

~~Delete the crossed-out statements on your proposed label.
They are redundant statements or phrases.~~

disregard

BEST AVAILABLE COPY

ACCEPTED
with COMMENTS
In EPA Letter Dated

MAR 22 1994
Under the Federal Insecticide-
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
628-97

Please refer to attached page for
language to be included on revised
labeling as indicated by number.

Restricted Use Pesticide
Toxic to Fish, Mammals, 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.

Zephyr[®] 0.15 EC

miticide/insecticide

ACTIVE INGREDIENT
Avermectin B₁ [A mixture of
avermectins containing ≥ 80%
avermectin B_{1a} (5-O-demethyl
avermectin A_{1a}) and ≤ 20%
avermectin B_{1b} (5-O-demethyl-25-de
(1-methylpropyl)-25-(1-methylethyl)
avermectin A_{1a})]..... 1.9%
INERT INGREDIENTS..... 98.1%
* 1 gallon contains 0.15 pound avermectin B₁

**KEEP OUT OF
REACH OF CHILDREN
WARNING ADD 1**

ADD 2 → **PRECAUTIONAL STATEMENT**—See back label for additional precautionary statements and statement of practical treatment.

EPA EST NO 30873-TX-1
EPA REG NO 610-97



Merck & Co., Inc.
Rahway, New Jersey 07065-0912, U.S.A.
ZEPHYR REG TM MERCK & CO., INC.
FOR LOT NUMBER SEE BOTTOM OF BOTTLE

Product **68824A**

8771801
Made in USA
U.S. Pat 4,310,519

BEST AVAILABLE COPY

Please refer to attached page for language to be included on revised labeling as indicated by number.

ZEPHYR® 0.15 EC

Product 68824A

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS WARNING

ADD 3

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. May be fatal if swallowed. Avoid contact with skin. ~~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.~~

delete

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, 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, 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, exposure.

For 24-hour emergency information, call (908) 750-2380

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. 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.~~

delete

PHYSICAL/CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

ADD 4

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, per gallon which, when mixed with water according to the Directions for Use, will control Spider mites (twospotted, carmine, Pacific and Strawberry) on cotton.

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	
	Mid season/Lay-by	Early Season (California only)
Twospotted Carmine Pacific Strawberry	8 - 16	4 - 6

Use 8 - 16 fl oz ZEPHYR per acre depending on size of the plant and density of the foliage. Apply with ground sprayers or aeriately 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.

For use on early season cotton within the state of California, apply prior to June 15 on cotton under 10 inches in height. Apply at a rate of 4 - 6 fl oz ZEPHYR per acre by ground equipment only.

USE RESTRICTIONS

- Do not apply more than 32 fl oz or more than two applications of ZEPHYR per acre in any growing season.
- Do not apply within 21 days of last treatment
- Do not apply this product east of the Mississippi River.
- 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.

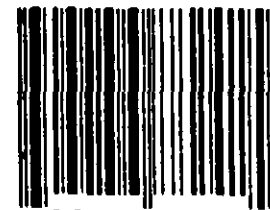
Pesticide Disposal: Pesticide spray mixture or rinsate that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticides or buried in a safe place away from water supplies. Improper disposal of excess pesticide spray mixture or rinsate is a violation of Federal (U.S.A.) law. If these wastes cannot be disposed of by the user 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 MERCK 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.

MERCK 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. Buyer's exclusive remedy shall be refund or replacement of any product found by MERCK to be defective. MERCK makes no other express or implied warranty of Fitness or Merchantability or any other express or implied warranty. In no case shall MERCK or the Seller be liable for consequential, special or indirect damages resulting from the use or handling of this product, regardless of the legal theory asserted, including negligence and/or strict liability. MERCK 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 MERCK.



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retain stet

1. **AVISO**
2. Si Usted no entiende la etiqueta, busque a alguien para que se la explique a Usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)
3. **Personal Protective Equipment:**
Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category B on an EPA chemical-resistance category selection chart. Applicators and other handlers must wear coveralls worn over short-sleeved shirt and short pants, chemical-resistant gloves (such as barrier laminate or butyl rubber), chemical-resistant footwear plus socks, and protective eyewear. Wear chemical-resistant headgear for overhead exposure. Wear chemical-resistant apron when cleaning equipment, mixing, or loading. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove clothes immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

4. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses that are covered by the Worker Protection Standard.

missing word

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is: coveralls over short-sleeved shirt and short pants, chemical-resistant gloves (such as barrier laminate or butyl rubber), chemical-resistant footwear plus socks, protective eyewear, and chemical-resistant headgear for overhead exposure.

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*Reply 2
618-97*