

PM03

100-897

9/25/98

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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11/31

Note to file: citations allowing the 12 hour (instead of 24 hour) REI are attached

September 25, 1998

Dr. Robert E. M. Wurz,  
Novartis Crop Protection, Inc.  
P.O. Box 18300  
Greensboro, NC 27419-8300

Subject: Zephyr® 0.15 EC  
EPA Reg. No. 100-897  
Amendment of label to change % a.i. to 2%, as requested by EPA  
Your letter dated August 24, 1998

Dear Dr. Wurz:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. Please note that items 1 - 3 must be made for your products of identical or similar formulation. These changes are from the USEPA Label Review Manual, 2<sup>nd</sup> Edition.

1. Please place the phrase "Restricted Use Pesticide" under the heading "Directions for Use" (40 C156.10 (I)(2)(ii). Please note that this is in addition to the RUP statement at the top of the label's front panel.
2. Please change the "Hazards to Humans and Domestic Animals" statement to read the following:

**WARNING**

May be fatal if swallowed. Causes substantial but temporary eye injury. Wear protective eyewear (goggles or face shield). Do not get in eyes, on skin or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated

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clothing and wash clothing before reuse. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Harmful if inhaled. Avoid breathing spray mist.

- Under your "Statement of Practical Treatment" heading, please change your eye treatment statement to read the following:

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

- Based on the restricted use classification due to toxicity to fish and aquatic organisms, we recommend incorporation of the following spray drift precautions. Please note that this label language is considered interim. As you know, the Spray Drift Taskforce is developing more prescriptive guidance for agricultural pesticides in general to minimize off-gassed drift. This language may appear anywhere under your "Use Restrictions" heading. Once this guidance is finalized, the following language may be modified:

**OBSERVE THE FOLLOWING PRECAUTIONS WHEN SPRAYING IN THE VICINITY OF AQUATIC AREAS SUCH AS LAKES; RESERVOIRS; RIVERS; PERMANENT STREAMS, MARSHES OR NATURAL PONDS; ESTUARIES AND COMMERCIAL FISH FARM PONDS.**

Do not apply by ground within 25 feet, or by air within 150 feet of lakes; reservoirs; rivers; permanent streams, marshes or natural ponds; estuaries and commercial fish farm ponds.

For aerial applications, the spray boom should be mounted on the aircraft so as to minimize drift caused by wing tip vortices. The minimum practical boom length should be used, and must not exceed 75% of the wing span or rotor diameter.

Use the largest droplet size consistent with pest control. Formation of very small droplets may be minimized by appropriate nozzle selection, by orienting nozzles away from the air stream as much as possible and by avoiding excessive spray boom pressure.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Spray should be released at the lowest possible height consistent with good pest control and flight safety. Applications more than 10 feet above the crop canopy should be avoided.

Make aerial or ground applications when wind velocity favors on-target product deposition (approximately 3 to 10 mph). Do not apply when wind velocity exceeds 15 mph. Avoid applications when wind gusts approach 15 mph.

Risk of exposure to sensitive aquatic areas can be reduced by avoiding applications when the wind direction is toward the aquatic area.

Do not cultivate within 10 feet of the aquatic area as to allow growth of a vegetative filter strip.

Low humidity and high temperatures increase the evaporation rate of spray droplets and therefore the likelihood of spray drift to aquatic areas. Avoid spraying during conditions of low humidity and/or high temperature.

Do not make aerial or ground applications during temperature inversions. Inversions are characterized by stable air and increasing temperatures with height above the ground. Mist or fog may indicate the presence of an inversion in humid areas. The applicator may detect the presence of an inversion by producing smoke and observing a smoke layer near the ground surface.

Please submit two (2) copies of your final printed labeling before you release the product for shipment. A stamped copy of the label is enclosed for your records. If you have any questions regarding this action, please contact Tracy Keigwin of my team at (703) 305-6605.

Sincerely,

*Tracy Lynn Keigwin*

George T. LaRocca  
Team 3  
Insecticide Branch  
Registration Division (7505C)

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robert.wurz@cp.novartis.com on 09/17/98 11:17:47 AM



To: ksigwin.tracy  
cc:  
Subject: Avermectin citations

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43850126 Norton, J.; Dunbar, D.; Wehner, T. (1993) Combined Avermectin Strawberry Foliar Dislodgeable Residue/Strawberry Harvester Exposure Study: Lab Project Number: 618-0936-92849: 001-90-6001R: 2849. Unpublished study prepared by Plant Sciences, Inc., Analytical Development Corp. and Merck Research Labs. 2256 p.

00164163 Jenkins, J., compiler (1986) Foliar Dislodgeable Residue Data in Support of the Use of Avermectin B1 0.15 EC on Citrus in the USA: (ANR-001-86-2). Unpublished compilation prepared by Merck Sharp & Dohme Research Laboratories in cooperation with Analytical Bio-Chemistry Laboratories, Inc. 338 p.

40870919 Crouch, L. (1988) Comparative Degradation of Avermectin B1a in Cotton Leaf, Citrus Fruit, Celery, and in vitro: Laboratory Project ID 618-PMES-R1. Unpublished study prepared by Merck Sharp & Dohme Research Laboratories. 47 p.

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**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® 0.15EC

MITICIDE/INSECTICIDE

Active Ingredient:

Abamectin (CAS No. 65195-56-4 and 65195-55-3) .....	2.0%*
Other Ingredients: .....	98.0%
<b>Total:</b>	<b>100.0%</b>

\*1 gal. contains 0.15 lb. abamectin

EPA Reg. No. 100-897

EPA Est. 39578-TX-001

**KEEP OUT OF REACH OF CHILDREN.**

**WARNING/AVISO**

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.)

See additional precautionary statements and directions for use inside booklet.

NCP 897A-L1B 0898

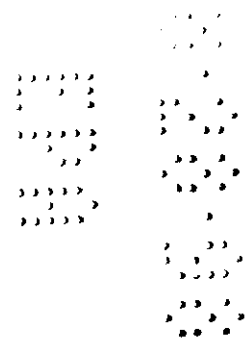
2.5 GALLONS  
U.S. STANDARD MEASURE

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated**

**SEP 25 1998**

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

100-897





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**DIRECTIONS FOR USE**

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It is a violation of federal law to use this product in a manner inconsistent with its labeling.

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 agricultural 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 of this product that are covered by the Worker Protection Standard.

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
- Chemical-resistant headgear for overhead exposure

**FAILURE TO FOLLOW DIRECTIONS AND PRECAUTIONS ON THIS LABEL MAY RESULT IN CROP INJURY, POOR PEST CONTROL, AND/OR ILLEGAL RESIDUES.**

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### COTTON

Zephyr 0.15EC is an emulsifiable concentrate containing 0.15 lb. abamectin per gal. which, when mixed with water according to the Directions for Use, will control spider mites (two-spotted, 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:

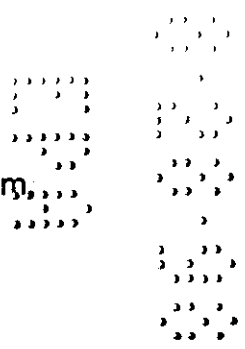
Spider Mites	Fluid Ounces Per Acre	
	Mid-season/Lay-by	Early Season
Two-spotted Carmine Pacific Strawberry	8-16	4-6

Use 8-16 fl. oz. of 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 gals. 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, apply when cotton is under 10 inches in height. Apply at a rate of 4-6 fl. oz. of Zephyr per acre by ground equipment only. Do not use less than 4 fl. oz./A.

#### Use Restrictions

- Do not apply more than 32 fl. oz. or more than 2 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.





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**STORAGE AND DISPOSAL**

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**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 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) and dispose of in an incinerator or landfill approved for pesticide containers.

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes. In the event of a major spill, fire, or other emergency, call 1-800-888-8372, day or night.

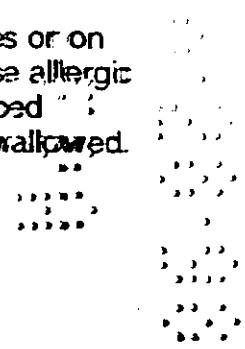
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**PRECAUTIONARY STATEMENTS**

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**Hazards to Humans and Domestic Animals****WARNING**

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals. Harmful if inhaled or absorbed through the skin. Do not breathe spray mist. May be fatal if swallowed. Avoid contact with skin.



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### 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
- Protective eyewear
- Chemical-resistant headgear for overhead exposure.
- 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.

#### 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 1 or 2 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

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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 Abamectin Acute**

**Toxicity:** Early signs of intoxication include mydriasis (dilated pupils), ataxia (unsteadiness), and muscle tremors. Toxicity follows accidental ingestion of the concentrate and 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 abamectin 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 abamectin exposure.

**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.

**Physical or Chemical Hazards**

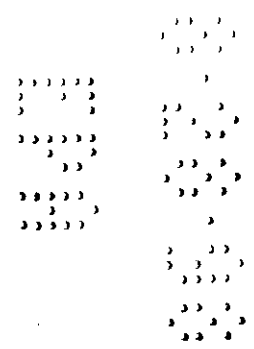
Do not use or store near heat or open flame.

Zephyr® trademark of Novartis  
U.S. Patent No. 4,310,519

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Novartis Crop Protection, Inc.  
Greensboro, North Carolina 27419  
NCP 897A-L1A 1297

[QUARKZEPHYR/N-ZEPHYR] - ccg - 8/19/98



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(BASE LABEL)

**RESTRICTED USE PESTICIDE**

**TOXIC TO FISH, MAMMALS, AND AQUATIC ORGANISMS**

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Other Ingredients:

98.0%

Total:

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\*1 gal. contains 0.15 lb. abamectin

EPA Reg. No. 100-897

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**KEEP OUT OF REACH OF CHILDREN.**

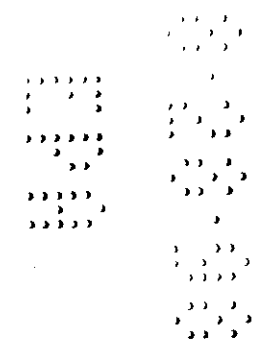
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See directions for use in attached booklet.

**2.5 GALLONS**

**U.S. STANDARD MEASURE**



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**AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to supplemental labeling under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

**Hazards to Humans and Domestic Animals**

**WARNING**

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals. Harmful if inhaled or absorbed through the skin. Do not breathe spray mist. May be fatal if swallowed. Avoid contact with skin.

Refer to **Statement of Practical Treatment** section in attached booklet for additional precautionary statements.

**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.

**Physical or Chemical Hazards**

Do not use or store near heat or open flame.

Zephyr® trademark of Novartis

