

10/25/2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

10/25/04

Carolyn Brinkley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419re: Zephyr 0.15EC Miticide/Insecticide, EPA Reg. # 100-897
revised CSF and label submitted 6/25/04
conditionally accepted with comments

Dear Ms. Brinkley:

On 10/23/03 Syngenta submitted a new basic confidential statement of formula (CSF) (dated 7/31/03) for the above product. The purpose was to remove an ingredient which triggered certain label language when used in California. Syngenta submitted both new product chemistry and new acute toxicity studies to support this change. EPA provided Syngenta with initial comments on 5/18/04. Corrections were required to both the CSF and label. Syngenta submitted corrections on 6/25/04.

CSF

The Agency has reviewed your submission for a revised Confidential Statement of Formula (CSF). The Confidential Statement of Formula dated **6/14/04** for the **basic formulation** is acceptable. Revised ingredients were found to be similar to previous ingredients. The ingredient percentages and limits comply with PR Notice 91-2.

The basic Confidential Statement of Formula has been added to your file as part of the record. This replaces all previous versions.

Labeling

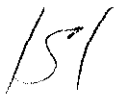
The revised labeling reference to above, submitted in connection with the registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is accepted provided you incorporate the changes required by the Agency as listed below.

Topic	Action required
Precautionary Statements PPE - applicators/handlers	CHANGE the following personal protective equipment for applicators and other handlers back to that on your previously accepted label: 1) change "long-sleeved shirt and long pants" to "coveralls over short-sleeved shirt and short pants" 2) change "shoes plus socks" to "chemical resistant footwear plus socks"

Submit two (2) copies of your final printed labeling incorporating the above changes prior to releasing your product for shipment. If the above provisions 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 bearing the amended labeling constitutes acceptance of these conditions.

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

Sincerely yours,



Thomas C. Harris
Biologist
Insecticide Rodenticide Branch
Registration Division (7505C)
Harris.Thomas@epa.gov
(703) 308-9423

enclosure

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 ¹	2.0%*
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Other Ingredients:	98.0%
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Total:	100.0%
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Contains petroleum distillate.

¹CAS No. 65195-56-4 and No. 65195-55-3

*1 gal. contains 0.15 lb. abamectin

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 in booklet.

EPA Reg. No. 100-897

EPA Est. XXXX

SCP 897A-L(draft)

2.5 gallons
Net Contents

ACCEPTED
with COMMENTS
In EPA Letter Dated:
OCT 25 2004
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
100-897

FIRST AID	
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 eye. • Call a poison control center or doctor for treatment advice.
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 swallowed	<ul style="list-style-type: none"> • Immediately call poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give any liquid to the person. • Do not give anything by mouth to an unconscious person.
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 by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
NOTE TO PHYSICIAN	
<p>Contains petroleum distillate. Vomiting may cause an aspiration pneumonia hazard. Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Toxicity following accidental ingestion of this product can be minimized by early administration of chemical adsorbents (e.g., activated charcoal).</p> <p>If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parental fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.</p> <p>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.</p>	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	
HOT LINE NUMBER	
<p>For 24-Hour Medical Emergency Assistance (Human or Animal) Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call 1-800-888-8372</p>	

PRECAUTIONARY STATEMENTS

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

Causes substantial but temporary eye injury. Harmful if absorbed through skin or if swallowed. Do not get in eyes, or on clothing. Remove and wash contaminated clothing before reuse. Avoid contact with skin. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals.

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:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves – EPA chemical-resistance category B (e.g., barrier laminate or butyl rubber ≥ 14 mils)
- Shoes plus socks
- Protective eyewear (goggles, face shield, or safety glasses)
- 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 thoroughly with soap and water after handling and 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.

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.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and Buyer and User assume the risk of any such use. SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall SYNGENTA or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

Restricted Use Pesticide

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 – EPA chemical-resistance category B (e.g., barrier laminate or butyl rubber ≥ 14 mils)
- Chemical-resistant footwear plus socks
- Protective eyewear

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

GENERAL INFORMATION

Use Restrictions

- Do not apply more than 32 fl. oz. or more than 2 applications of Zephyr/A 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.

Spray Drift Precautions

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 ft., or by air within 150 ft. 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.

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

Make aerial or ground applications when wind velocity favors on-target product deposition (approximately 3-10 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 ft. 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.

CROP USE DIRECTIONS

Cotton

Zephyr 0.15EC is an emulsifiable concentrate containing 0.15 lb. abamectin/gal. 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	Fl. oz./A	
	Mid-season/Lay-by	Early Season
Twospotted Carmine Pacific Strawberry	8-16	4-6

Use 8-16 fl. oz. of Zephyr/A 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/A 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/A by ground equipment only. Do not use less than 4 fl. oz./A.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

Storage

Store in a tightly closed container in a cool, dry place.

Pesticide Disposal

Pesticide wastes are toxic. 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). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures allowed by state and local authorities.

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.

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<p>For non-emergency (e.g. current product information) call Syngenta Crop Protection at 1-800-334-9481.</p>
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Syngenta Crop Protection, Inc.
Greensboro, North Carolina 27409
www.syngenta-us.com

SCP 897A-L(draft)

ZEP 0.15EC 897A L(draft) - lg - 6-24-04 000100-00897.20040624.pdf

(CONTAINER LABEL)

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 ¹	2.0%*
<u>Other Ingredients:</u>	<u>98.0%</u>
Total:	100.0%

Contains petroleum distillate.

¹CAS No. 65195-56-4 and No. 65195-55-3

*1 gal. contains 0.15 lb. abamectin

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 directions for use in booklet.

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.

EPA Est. XXXX

SCP 897A-L(draft)

2.5 gallons
Net Contents**PRECAUTIONARY STATEMENTS****Hazards to Humans and Domestic Animals****WARNING/AVISO**

Causes substantial but temporary eye injury. Harmful if absorbed through skin or if swallowed. Do not get in eyes, or on clothing. Remove and wash contaminated clothing before reuse. Avoid contact with skin. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals

FIRST AID	
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 eye. • Call a poison control center or doctor for treatment advice.
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 swallowed	<ul style="list-style-type: none"> • Immediately call poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give any liquid to the person. • Do not give anything by mouth to an unconscious person.
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 by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.

<p style="text-align: center;">NOTE TO PHYSICIAN</p> <p>Contains petroleum distillate. Vomiting may cause an aspiration pneumonia hazard. Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Toxicity following accidental ingestion of this product can be minimized by early administration of chemical adsorbents (e.g., activated charcoal).</p> <p>If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parental fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.</p> <p>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.</p>
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>
<p style="text-align: center;">HOT LINE NUMBER</p> <p style="text-align: center;">For 24-Hour Medical Emergency Assistance (Human or Animal) Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call 1-800-888-8372</p>

Refer to booklet for PPE.

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.

Container Disposal

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other procedures allowed by state and local authorities.

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.

Do not apply this product through any type of irrigation system.

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Syngenta Crop Protection, Inc.
Greensboro, North Carolina 27409
www.syngenta-us.com

SCP 897A-L(draft)
ZEP 0.15EC 897A L(draft) - lg - 6-24-04 000100-00897.20040624.pdf

Chron

1/31/02 – Notif -added Prop. 65 language

9/26/02 - Accepted – Revised First Aid per PR Notice 2001-1; revised glove statement in PPE and AG USE box to reflect category B language. Per EPA letter-moved “Spray Drift” to Direction for Use section, revised base label language

6-24-04-Draft- Revised per EPA letters of 5/18/04 and Memorandum of 3/5/05. Deleted head gear requirement. Revised pesticide and container disposal and moved Storage and Disposal section to end of label.