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



OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

4/8/05

Carolyn Brinkley Syngenta Crop Protection, Inc. PO Box 18300 Greensboro, NC 27419

re:

Zephyr 0.15 EC Miticide/Insecticide, EPA Reg. # 100-897 revised basic CSF (dated 9/10/04), acute toxicology, and label submitted 10/18/04 CSF accepted; data gaps acute toxicology acceptable for regulatory purposes label accepted with comments

Dear Ms. Brinkley:

CSF

On 10/18/04 Syngenta submitted a new basic confidential statement of formula (CSF) (dated 9/10/04) for the above product. This formula will be used globally for this product. The percent active ingredient dropped from 2.0% to 1.84% (although due to a change in density the quantity remains 0.15 lb a.i./gallon).

The Confidential Statement of Formula dated **9/10/04** for the **basic formulation** is acceptable. Enclosed please find a copy of the 3/14/05 review by DRate. 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 replaces all previous versions.

Studies must be submitted within 18 months to support the following data gaps: one year storage stability (830.6317) corrosion characteristics (830.6320)

acute toxicology

Given the change in formula, a new set of acute toxicology studies was submitted. A copy of the 11/24/04 review by EMcAndrew is enclosed. The results of the acute toxicology studies are as follows:

acute oral toxicity
acute dermal toxicity
acute inhalation toxicity
primary eye irritation
primary skin irritation
dermal sensitization
signal word

III *
IV
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CAUTION

^{*} acute oral study unacceptable but satisfactory for regulatory purposes as Category III.



labeling

Given the changes in the acute toxicology, new labeling (mainly reflecting changes in precautionary statements) was submitted 10/18/04.

The revised labeling reference to above, submitted in connection with the registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided you make the following changes.

Directions for Use Agricultural Use Requirements	Replace current text with the following:	
early entry PPE	 "- 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" 	

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

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.

Sincerely yours,

Thomas C. Harris

Biologist

Insecticide Rodenticide Branch Registration Division (7505C)

Harris.Thomas@epa.gov

(703) 308-9423

enclosures

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

¹(CAS No. 65195-56-4 and 65195-55-3) Contains petroleum distillate *1 gal. contains 0.15 lb. abamectin

KEEP OUT OF REACH OF CHILDREN. CAUTION

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-897

EPA Est. XXXX

SCP 897A-M(DRAFT global formula 10-14-04)

Net Contents

ACCEPTED with COMMENTS In EPA Letter Dated:

APR - 8 2005

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

FIRST AID		
If swallowed	 Immediately call a poison control center or doctor for treatment advice. Do not give any liquid to the person Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. 	
If in eyes	 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 inhaled	 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. 	
If on skin or clothing	 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. 	

NOTE TO PHYSICIAN

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).

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.

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.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.



HOT LINE NUMBER

For 24-Hour Medical Emergency Assistance (Human or Animal)
Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident)
Call
1-800-888-8372

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Harmful if absorbed through skin, inhaled or swallowed. Causes moderate eye irritation. Avoid breathing spray mist. Avoid contact with skin, eyes, or clothing. Washing hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco will reduce exposure. Removing and washing contaminated clothing before reuse may reduce exposure.

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 C 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 C (e.g., barrier laminate, butyl rubber ≥14 mils, nitrile rubber ≥14 mils, neoprene rubber ≥14 mils, polyvinyl chloride (PVC) ≥14 mils or viton ≥14 mils)
- Shoes plus socks
- Chemical-resistant apron when cleaning equipment, mixing, or loading.

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.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d), the handler PPE requirements may be reduced or modified as specified in the WPS.

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 clothing 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.

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 restrictedentry 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 0.15EC 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:

	FI. oz./A		
Spider Mites	Mid-season/Lay-by	Early Season	
Twospotted Carmine Pacific	8-16	4-6	
Strawberry			

Use 8-16 fl. oz. of Zephyr 0.15 EC/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 0.15 EC/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

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Disposal

Triple rinse (or equivalent). Then offer for recycling or reconditiong, or puncture and dispose of in 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.

Zephyr® and the Syngenta logo are trademarks of a Syngenta Group Company U.S. Patent No. 4,310,519

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For non-emergency (e.g. current product information) call Syngenta Crop Protection at 1-800-334-9481.

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

SCP 897A-M(DRAFT global formula10-14-04)

ZEP 0.15EC 897A-M(DRAFT global formula 10-14-04)-lg-10-14-04 000100-00897.20041014.globalformula.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:

 Abamectin¹
 1.84%*

 Other Ingredients:
 98.16%

 Total:
 100.00%

¹(CAS No. 65195-56-4 and 65195-55-3) Contains petroleum distillate *1 gal. contains 0.15 lb. abamectin

KEEP OUT OF REACH OF CHILDREN.

CAUTION

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 Reg. No. 100-897

EPA Est. XXXX

SCP 897A-M(DRAFT global formula10-14-04)

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PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Harmful if absorbed through skin, inhaled or swallowed. Causes moderate eye irritation. Avoid breathing spray mist. Avoid contact with skin, eyes, or clothing. Washing hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco will reduce exposure. Removing and washing contaminated clothing before reuse may reduce exposure.

	FIRST AID		
If swallowed	 Immediately call a poison control center or doctor for treatment advice. Do not give any liquid to the person. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. 		
If in eyes	 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 inhaled	 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. 		
lf on skin or clothing	 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. 		

NOTE TO PHYSICIAN

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).

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.

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.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

HOT LINE NUMBER

For 24-Hour Medical Emergency Assistance (Human or Animal)
Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident)
Call

1-800-888-8372

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.

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.

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

Zephyr® and the Syngenta logo are trademarks of a Syngenta Group Company

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