

8329-34

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

January 3, 2007

Ms. Karen J. Larson
Regulatory Affairs Manager
Clarke Mosquito Control Products, Inc.
159 North Garden Avenue
Roselle, IL 60172

Dear Ms. Larson,

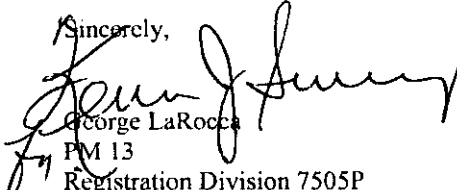
Subject: Agency Initiated Action – Product Labeling
Biomist 4 + 12 ULV
EPA Reg. No. 8329-34
Application dated December 28, 2006

The labeling referred to above, submitted in connection with registration under the Federal, Insecticide, Fungicide and Rodenticide Act, is acceptable provided you:

1. Remove the term "All-Temperature" from the statement "An All-Temperature, Quick Knockdown, Low Odor..." on page 1 of the label.
2. Move the following statements from the Environmental Hazards section to the Directions for Use section: "Do not contaminate food or feed products. Do not allow spray treatment to drift onto pastureland, cropland, poultry ranges, or water supplies." Revise the statements to read as follows: "Do not contaminate food or feed products. Do not allow spray treatments to drift onto pastureland, cropland, poultry ranges or potable water supplies. Do not use on crops for food storage or pasture. In treatment of corrals, feed lots, swine lots, and zoos, cover any exposed drinking water, drinking water fountains and animal feed before application."

Please note that the availability of EPA's reregistration eligibility document (RED) for products containing permethrin was published in the FR on June 28, 2006 (Vol.71 No.124 pg. 36788). Additional data or labeling changes may be required for products containing permethrin.

A stamped copy of the label is enclosed for your records. Submit two copies of the final printed label before releasing the product for shipment. If you any questions, please do not hesitate to contact Kevin Sweeney at (703) 305-5063. Thank you for your cooperation in this matter.

Sincerely,

George LaRocca
PM 13
Registration Division 7505P
Insecticides Branch

Enclosure

ACCEPTED
with COMMENTS
In EPA Letter Dated

JAN 03 2007
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 8329-34

DRAFT LABELING

BIOMIST® 4+12 ULV

An All Temperature, Quick Knockdown, Low Odor, Non-Corrosive, Synthetic Pyrethroid for Control of Adult Mosquitoes in Outdoor Residential and Recreational Areas. Also For Use Against Biting and Non-Biting Midges and Blackflies.

For use only by federal, state, tribal or local government officials responsible for public health or vector control, or by persons certified in the appropriate category or otherwise authorized by the state or tribal lead pesticide regulatory agency to perform adult mosquito control applications, or by persons under their direct supervision.

Active Ingredients	
Permethrin (3-Phenoxyphenyl) methyl (+/-) cis, trans-3-(2,2-dichlorethenyl)-2,2-dimethyl cyclopropanecarboxylate	4.00%
Piperonyl Butoxide, Technical *	12.00%
Other Ingredients **	84.00%
	100.00%
Contains 0.3 pounds of Permethrin and 0.9 pounds of Piperonyl Butoxide per gallon.	
* Equivalent to 80% (butylcarbityl)(6-propylpiperonyl) ether and 20% related compounds.	
** Contains petroleum distillate	

**CAUTION
KEEP OUT OF REACH OF CHILDREN**

FIRST AID	
Have product container or label with you when calling a poison control center or doctor, or going for treatment. For Medical Emergencies, call the International Poison Control Center at 1-800-214-7753.	
IF SWALLOWED:	Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a 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:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth. 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.
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 the eye. Call a poison control center or doctor for treatment advice.
NOTE TO PHYSICIAN: Product contains a petroleum distillate. Gastric lavage is indicated if material was taken internally. Vomiting may cause aspiration pneumonia.	

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

Caution. Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes or clothing. Avoid breathing of mist. May cause contact sensitization following repeated contact with skin in susceptible individuals.

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to aquatic organisms, including fish and aquatic invertebrates. Runoff from treated areas or deposition of spray droplets into a body of water may be hazardous to fish and aquatic invertebrates. Do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes or estuaries), except when necessary to target areas where adult mosquitoes are present, and weather conditions will facilitate movement of applied material away from the water in order to minimize incidental deposition into the water body. Do not contaminate bodies of water when disposing of equipment rinsate or wash waters.

This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area, except when applications are made to prevent or control a threat to public and/or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes, or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recover effort.

Do not contaminate food or feed products. Do not allow spray treatment to drift on pastureland, cropland, poultry ranges or water supplies.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame. Flashpoint minimum of 170°F.

DIRECTIONS FOR USE

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

Before making the first application in a season, it is advisable to consult with the state or tribal agency with primary responsibility for pesticide regulation to determine if other regulatory requirements exist.

BIOMIST® 4+12 ULV is recommended for application as an ultra low volume (ULV) nonthermal aerosol (cold fog) to control adult mosquitoes in residential and recreational areas where these insects are a problem. For best results treat when mosquitoes are most active and weather conditions are conducive to keeping the spray cloud close to the ground. An inversion of air temperatures and a light breeze is preferable. Application in calm air conditions is to be avoided. Apply only when ground wind speed is greater than 1 mph. Air temperatures should be greater than 50 °F when conducting all types of applications.

Do not treat a site with more than 0.007 pounds of permethrin per acre in a twenty-four hour period. Do not apply more than 0.18 pounds of permethrin per acre per year. More frequent applications may be made to prevent or control a threat to public and/or animal health determined by a state, tribal, or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort.

SPRAY DROPLET SIZE DETERMINATION

Ground Equipment: Spray equipment must be adjusted so that the volume median diameter (VMD) is 8 to 30 microns ($8 \leq D_v \leq 30 \text{ um}$) and that 90% of the spray is contained in droplets smaller than 50 microns ($D_v 0.9 < 50 \text{ um}$). Directions from the equipment manufacturer or vendor, pesticide registrant, or a test facility using a laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated.

Aerial Equipment: Spray equipment must be adjusted so that the volume median diameter produced is less than 60 microns ($D_v 0.9 < 60 \text{ um}$) and that 90% of the spray is contained in droplets smaller than 115 microns ($D_v 0.9 < 115 \text{ um}$). The effects of flight speed and, for non-rotary nozzles, nozzle angle on the droplet size spectrum must be

considered. Directions from the equipment manufacturer or vendor, pesticide registrant, or a test facility using a wind tunnel and laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated.

GROUND ULV APPLICATION

Apply BIOMIST® 4+12 ULV through standard ULV cold aerosol or non-thermal aerosol (Cold Fog) generators undiluted at a flow rate of 4.5 to 18.0 fluid ounces per minute at an average vehicle speed of 10 mph. If a different vehicle speed is used, adjust rate accordingly. These rates are equivalent to 0.0017 to 0.007 pounds of permethrin and 0.005 to 0.021 pounds of piperonyl butoxide per acre. An accurate flow meter must be used to ensure the proper flow rate.

Vary flow rate according to vegetation density and mosquito population. Use higher flow rate in heavy vegetation or when populations are high.

Permethrin/PBO pounds/acre	Application Rates Fl. oz./Min.			Fl.oz. BIOMIST® 4+12 ULV per acre
	5 MPH	10 MPH	15 MPH	
0.007 / 0.021	9.0	18.0	27.0	3.0
0.0035 / 0.0105	4.5	9.0	13.5	1.5
0.00175 / 0.00525	2.25	4.5	6.75	0.75

For proper application, mount the applicator so that the nozzle is at least 4 ½ feet above ground level and directed out the back of the vehicle. Failure to follow the above directions may result in reduced effectiveness.

AERIAL APPLICATION

BIOMIST® 4+12 ULV may be applied undiluted at rates up to 3.0 fluid ounces BIOMIST® 4+12 ULV per acre by fixed wing or rotary aircraft equipped with suitable ULV application equipment. Aerial application shall be made at altitudes ranging from 75 to 300 feet. Aerial applications shall only be made when recommended by public health officials and trained personnel of mosquito abatement districts and other mosquito control programs.

IN FLORIDA: Do not apply by aircraft except in emergency situations and with the approval of the Florida Department of Agriculture & Consumer Services.

STORAGE & DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE AND SPILL PROCEDURES: Store upright at room temperature. Avoid exposure to extreme temperatures. In case of spill or leakage, soak up with an absorbent material such as sand, sawdust, earth, fuller's earth, etc. Dispose of with chemical waste.

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

CONTAINER DISPOSAL: Triple rinse (or equivalent) then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other approved state and local procedures.

CONTAINERS ONE GALLON AND SMALLER: Do not reuse container. Wrap containers in several layers of newspaper and discard in trash.

CONTAINERS LARGER THAN ONE GALLON: Metal Containers – Triple rinse or equivalent. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Plastic Containers – Triple rinse or equivalent. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

IN CASE OF MEDICAL EMERGENCY,
CALL THE INTERNATIONAL POISON CONTROL CENTER
1-800-214-7753
IN CASE OF TRANSPORTATION EMERGENCY,
CALL INFO-TRAC 1-800-553-5053

Manufactured By
CLARKE MOSQUITO CONTROL PRODUCTS, INC.
159 N. GARDEN AVENUE
ROSELLE, ILLINOIS 60172

EPA Reg. No.: 8329-34
EPA Est. No.: _____

NET CONTENTS: _____
LOT NO.: _____

FOR MORE INFORMATION CALL: 1-800-323-5727

NOTICE: To the extent provided by law, seller makes no warranty, expressed or implied concerning the use of this product other than as indicated on the label. Buyer assumes all risk of use and/or handling of this material when use and/or handling is contrary to label instructions.