7760-34

10/25/2007

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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Ms. Karie E. Mavian Senior Regulatory Affairs Manger Cheminova Inc. 1700 Route 23, Suite 300 Wayne, NJ 07470

OCT 2 5 2007

Fyfanon ULV Mosquito EPA Reg. No. 67760-34 Application Dated January 25, 2006

Dear Ms. Mavian:

Subject:

The labeling amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, As Amended (FIFRA), is acceptable, provided that you submit the item listed below and one copy of your final printed label incorporating the following corrections before you release the product for shipment.

1. Reinstate the personal protective clothing and washing instructions that appear on the registered label for the product. These are as follows: long-sleeved shirt and long pants, shoes plus socks and chemical resistant gloves, such as barrier laminate, butyl rubber, nitrile rubber or viton. Follow manufacturer's instructions for cleaning and maintaining PPE. If no instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

2. Reinstate the user safety recommendations as they appear on the registered label for the product. These are as follows: Users should wash hands before eating, drinking, and chewing gum, using tobacco or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

3. Add the statement "Do not apply more than 0.23 lb active ingredient/A/day. This statement will be in agreement with that specified in the malathion RED.

4. Since the aquatic use restriction labeling cited below conflicts with the added environmental hazards statements set forth in PR Notice 2005-1, it needs to be removed. Please refer to a discussion of the adult mosquito use pattern under issue number two in the Notice.

"Note for aquatic uses: Broadcast use only over intermittently flooded areas. Application may not be made around bodies of water where fish or shellfish are grown and/or harvested commercially" 5. Correct the text pertaining to the 90% droplet size under aerial application on the third page from "smaller than 100 microns" to "smaller than 80 microns." This will be consistent with that cited in the RED.

6. Since the subject product label is intended only for the public health mosquito control use and only for uses under the scope of PR Notice 2005-1, all claims for use against "flies" are to be removed. The use restrictions and limitations added to the product label pursuant to the PR Notice would not necessarily be applicable for a product label bearing a general fly claim.

7. Correct the second sentence in the second paragraph on the fourth page (No label rates should be exceeded.) from advisory language to mandatory language so that the sentence reads somewhat as follows: "Label rates must not be exceeded." or "Do not exceed any label rates."

8. Correct the warranty and disclaimer statements as cited below to avoid misleading and/or overly broad statements. Refer to the Agency document entitled Guidance on Warranty Statements dated October 17, 2006. This document is located on the Agency's website at <u>http://www.epa.gov/pesticides/regulating/labels/warranty.pdf</u>

a. Add the text "to the extent consistent with applicable law" to the beginning of the first sentence of the second, third and fourth paragraphs under the Disclaimer heading on the last page.

b. Correct "should' to "must" in the second sentence of the first paragraph.

9. Submit your request for the removal of the non-mosquito uses from the subject registration. Identify each of the removed uses in your request.

A stamped copy of the label is enclosed for your records.

Sincerely,

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Marilyn A. Mautz Biologist Insecticide-Rodenticide Branch Registration Division (7504P)

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ACCEPTED with COMENTS in FP/ etter Dated: Under the Federal Insecticide, Fungicide, and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No. 67760-34

Fyfanon[®] ULV Mosquito ULTRA LOW VOLUME CONCENTRATE INSECTICIDE

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 INGREDIENT:	<i>.</i> .
*Malathion	
INERT INGREDIENTS:	
TOTAL:	
* O.O-dimethyl phosphorodithioate of diethyl mercaptosuccinate	

KEEP OUT OF REACH OF CHILDREN CAUTION

SEE BOOKLET FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND USE DIRECTIONS

EPA Reg. No. 67760-34

EPA Est. No. 4787-DN-1 **NET CONTENTS:**

Cheminova, Inc. 1700 Route 23 Wayne, NJ 07470 Product of Denmark

IN CASE OF A MEDICAL EMERGENCY INVOLVING THIS PRODUCT, CALL TOLL FREE, DAY OR NIGHT, 1-866-303-6950

	FIRST AID	
Thi	s product is an organophosphate and is a cholinesterase inhibitor.	
IF SWALLOWED:	Call a poison control center or doctor immediately for treatment advice.	
	Have person sip a glass of water if able to swallow.	
	Do not induce vomiting unless told to do so by a poison control center or c	loctor.
	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 res	piration,
	preferably by mouth-to-mouth, if possible.	1004
	Call a poison control center or doctor for further treatment advice.	
IF ON SKIN		υ (φοροι
OR CLOTHING:	Take off contaminated clothing.	φζεςιι σ
	Rinse skin immediately with plenty of water for 15-20 minutes.	ι
	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.	ະ .
	Remove contact lenses, if present, after the first 5 minutes, then continue	rinsing eye
	Call a poison control center or doctor for treatment advice.	co
Have the product c	ontainer or label with you when calling a poison control center or döctor, or	going for
treatment. You may	y also contact 1-866-303-6950 for emergency medical treatment information	n. ເວັດເປັ
NOTE TO PHYSIC antidotal.	IAN- This product is a cholinesterase inhibitor. Treat symptomatically. Atrop	

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful by swallowing, inhalation or skin contact. Avoid contact with skin. Avoid breathing spray mist. Do not contaminate food or feed products.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish, aquatic invertebrates, and aquatic life stages of amphibians. Runoff from treated areas or deposition of spray droplets into a body of water may be hazardous to aquatic organisms.

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.

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 if bees are 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 recovery effort.

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 washwaters.

PHYSICAL OR CHEMICAL HAZARDS

Before using, read the directions contained in this labeling for the proper methods and procedures which must be followed to achieve effective insect control and avoid permanent damage to automobile and other paint finishes.

STORAGE AND DISPOSAL

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

STORAGE: Fyfanon ULV Mosquito should be stored at temperatures not exceeding 25° C (77° F). It should never be heated above 55° C (131° F), and also local heating above this temperature should be avoided.

PESTICIDE DISPOSAL: Pesticide, spray mixture, or rinse water that cannot be used according to label instructions may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Returnable/refillable: Return to manufacturer for refilling. Disposable: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any "" requirements specific to your State or tribe, consult the agency responsible for pesticide regulation of the second state of the second st

MOSQUITO CONTROL

MOSQUITO CONTROL IN POPULATED AND RURAL AREAS

Do not re-treat a site more than 3 times in any one week when mosquitoes are swarming, or biting. More frequent treatments 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 efforts exponentiate to provide the state on the over intermittently flooded areas. Application may not

be made around bodies of water where fish or shellfish are grown and/or harvested commercially.

AERIAL APPLICATION

Adult mosquito control over cities, towns, and other areas where automobiles, trailers, trucks, and pleasure boats are present: Apply 2.6 to 3.0 fluid ounces of Fyfanon ULV Mosquito per acre. Apply only when weather conditions are favorable. Wind and rising air currents may cause undesirable spray drift and reduce insect control.

Spray equipment must be adjusted so that the volume or mass median diameter produced is less than 50 microns (Dv 0.5 < 50 um) and that 90% of the spray is contained in droplets smaller than 100 microns (Dv 0.9 < 100 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.

IMPORTANT: IN AREAS WHERE AUTOMOBILES, TRAILERS, TRUCKS AND PLEASURE BOATS ARE PRESENT, undiluted spray droplets of Fyfanon ULV Mosquito will permanently damage vehicle paint finishes unless the aircraft used for the ultra low volume application meets all of the specifications listed under **AERIAL APPLICATION**.

GROUND APPLICATION

Spray equipment must be adjusted so that the volume or mass median diameter is less than 17 microns (Dv 0.5 < 17 um) and that 90% of the spray is contained in droplets smaller than 32 microns (Dv 0.9 < 32 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.

Thermal Aerosols or Fogs

For control of adult mosquitoes with thermal aerosols or fogs, apply Fyfanon ULV Mosquito at the rate of 6 - 8 oz. actual / gallon (3.9 - 5.2 gallons Fyfanon ULV Mosquito in 100 gallons finished solution*) by ground equipment delivering 40 gallons per hour at a vehicle speed of 5 miles per hour to treat a swath width of 300 - 400 feet.

*There is a great variation in the chemical composition of fuel oils which may be used as thermal fog solvents. These differences may cause sludge and/or affect the solubility of the Fyfanon ULV Mosquito.

Nonthermal Aerosols

Adult Mosquito Control - Control of adult mosquitoes over a 300-foot swath can be obtained with nonthermal aerosols of Fyfanon ULV Mosquito using the following rates at the indicated vehicle speeds:

Vehicle Speed – Miles per Hour	Flow Rate of Fyfanon - Fl. oz./Min.	Maximum Flow - Rate per Hour
5	1.0 to 2.1	1 galloຍິດແລະ
10	2.0 to 4.3	:::::2;gallons
15	3.0 to 6.3	۲۰۰۰ ۲۰۰۶ Stgalloris
20	4.0 to 8.6	۰۰: ۲۰۰ (Gallons

Adult Mosquitoes and Flies on Rangeland, Pasture, and Other Uncultivated Non-Agricultural Areas (Wastelands, Roadsides)

Apply Fyfanon ULV Mosquito at the rate of 2 to 4 fluid ounces per acre for control of both adult mosquitoes and flies. Application may be made via ground or aerial equipment. No more than 3 applications should be made to a site in any one week when mosquitoes or flies are swarming or biting. More frequent treatments 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.

For enhanced knock-down effects against mosquitoes and flies, Fyfanon ULV Mosquito can be mixed with a synergized pyrethrin emulsifiable concentrate (6% pyrethrin + 60% PBO) in accordance with the most restrictive of label limitations and precautions indicated on both this and the tank-mixed product. No label rates should be exceeded. This product may not be mixed with any product bearing a label which specifically prohibits such mixing. Prior to tank mixing large quantities mix a small amount in a glass jar to verify that the products are physically compatible.

A tank mix of these may be prepared as follows:

Component	Rapid knock-down	Improved knock-down
Fyfanon ULV Mosquito	107 fl. oz.	117 fl. oz.
Synergized pyrethrin (6%/ 60%)	21 fl. oz.	11 fl. oz.

Depending upon your operational needs for knock-down, the amount of synergized pyrethrin can be reduced or adjusted. Application rates of Fyfanon ULV Mosquito and droplet distribution requirements remain the same as for Fyfanon ULV Mosquito used alone.

OPERATING EQUIPMENT

Each nonthermal aerosol generator used for dispersal of Fyfanon ULV Mosquito to control adult mosquitoes must have minimum capability of producing the droplet spectrum described under **GROUND APPLICATION**. The initial determination of droplet size is made after the unit is installed in a vehicle and prior to its use in mosquito control operations. The unit should be rechecked as frequently as necessary to insure that proper droplet size is maintained for each operation. Determination of droplet size every two months is usually sufficient if the unit has been maintained in good operating condition. Equipment manufacturer's instructions setting forth cleaning and maintenance of the unit must be followed. The unit must be inspected before each operation to correct any leaks or obstructions in the spray system; to detect whether the nozzle, hoses, or other parts are worn and need replacement; to insure that the flow meter is properly calibrated and to determine that the pressure recommended by the manufacturer is being maintained.

Flow Rate	- Must be regulated by accurate flow meter - Not greater than 1 gallon per hour at 5 mph; 2 gallons per hour at 10 mph; 3 gallons per hour at 15 mph, or 4 gallons per hour at 20 mph		
Nozzle Direction	- Rear of the vehicle		(L L
	- Upward at an angle of 45° or more		ι, τ. τ. τ. τ. τ.
Vehicle Speed	- Not greater than 20 mph	٤ (r دي <i>٤</i>	515 S
•	- Shut off spray equipment when vehicle is stopped		ι ι ι ι

IMPORTANT: Spray droplets of undiluted Fyfanon ULV Mosquito will permanently damage automobile paint unless all the conditions described and recommended in this label are met. If accidental exposure does occur, the vehicle should be washed at once.

DISCLAIMER

The label instructions for the 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, automobile paint damage, 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 Cheminova. All such risks shall be assumed by the user.

Cheminova warrants only that the material contained herein conforms to the chemical description on the label and is reasonably fit for the use therein described when used in accordance with the directions for use subject to the risks referred to above.

Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values or any other special or indirect damages.

CHEMINOVA makes no other express or implied warranty of FITNESS or MERCHANTABILITY. The sale of this product does not include a license under any patent owned by Cheminova.

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