

8329-11

11/08/2007

1/6



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

**OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES**

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

NOV 8 2007

Subject: Label Revisions Pursuant to PR Notice 2005-1
Malathion E-5
EPA Reg. No. 8329-11
Application Dated September 19, 2005

Dear Ms. Larson:

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 one copy of your final printed label incorporating the following corrections before you release the product for shipment.

1. As the added limitations and restrictions pertain only to the public health mosquito use under the scope of PR Notice 2005-1, the ambiguous label claim "small flying insects" is to be removed.

2. Remove the non-ULV application for treatment of shrubbery and vegetation. Such an application does not fall under the scope of the PR Notice 2005-1. Consequently use restrictions and limitations for such a use would differ from those specified in the Notice.

3. Reinstate the text "Contains petroleum distillates" in the vicinity of the ingredient statement as it appears on the registered label for the product.

4. Correct the first sentence in the Note to Physician section from "This product may cause cholinesterase inhibition." to "This product contains a cholinesterase inhibitor."

5. Add the following personal protective clothing and washing instructions at the end of the precautionary statements section: long sleeved shirt and long pants, shoes plus socks and chemical resistant gloves such as barrier laminate, 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.

6. Add the following user safety recommendations: 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.

7. Make the changes cited below in the Environmental Hazards section.

a. Correct the text in the third sentence from "of applied material beyond the body of water" to read as follows: "of applied material away from the water".

b. Remove the added phrase appearing at the end of the section ("or for focal control (such as residential yards, parks, campgrounds, etc.) of day biting mosquitoes."

8. Relocate the second sentence under the Directions for Use to a location within the Environmental Hazards section as the third sentence. Refer to item 3 in PR Notice 2005-1.

9. Make the corrections cited below to the third paragraph under the Directions for Use section.

a. Add the number and frequency of applications at the beginning of the paragraph such as that cited below. Refer to item 7 of PR Notice 2005-1.

Do not re-treat more than 3 times in any one week when mosquitoes are swarming or biting.

b. Correct the maximum application rate per site to read as follows. Do not apply more than 0.23 lb a.i./A/day. This would be consistent with the maximum amount for mosquito control specified in the malathion RED dated July 2006.

10. Correct the 90% size droplet for aerial applications from "smaller than 100" to "smaller than 80". This change would bring it into compliance with that specified in the malathion RED.

11. Remove the last sentence under Aerial Application on the last page (Aerial applications should only be made when recommended by public health officials

3/6

and trained personnel of mosquito abatement districts and other mosquito control programs). Such a statement is not consistent with the user limitations specified in PR Notice 2005-1 for wide-area adult mosquito control. The correct statement appears on the front panel of your label. Please refer to item number one of the Notice.

12. Clarify the text specifying the amounts of malathion so that it reads as follows: "amounts of active ingredient (a.i.) malathion".

13. 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 <http://www.epa.gov/pesticides/regulating/labels/warranty.pdf>

Add the text "to the extent consistent with applicable law" to the beginning of the first sentence of the paragraph headed "Notice" appearing on the last page of the label.

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

Sincerely,



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

ACCEPTED
 with COMMENTS 4/6
 in EPA Letter Dated:
 NOV 8 2007
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act,
 As amended, for the pesticide
 Registered under EPA Reg. No.
8329-11

DRAFT LABELING

MALATHION E-5

For Use Outdoors to Control Adult Mosquitoes and Small Flying Insects in Populated and Rural Areas. 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	
Malathion*	57.00%
Other Ingredients	43.00%
	100.00%
* (0,0-dimethyl phosphorodithioate of diethyl mercaptosuccinate)	
Contains 5 pounds per gallon of Malathion	

CAUTION
KEEP OUT OF REACH OF CHILDREN

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

EPA Reg. No.: 8329-11
 EPA Est. No.: 8329-IL-01

NET CONTENTS: _____
 LOT NO.: _____

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 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.
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.
NOTE TO PHYSICIAN: This product may cause cholinesterase inhibition. Atropine is antidotal. 2-PAM may be effective as an adjunct to atropine. This product contains petroleum distillate. Vomiting may cause aspiration pneumonia.	

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Caution. Harmful if swallowed, inhaled or absorbed through skin. Avoid breathing spray mist. Avoid contact with skin, eyes or clothing. 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 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 fish, aquatic invertebrates, and aquatic life stages of amphibians. 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 beyond the body of 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, or for focal control (such as residential yards, parks, campgrounds, etc.) of day biting mosquitoes.

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.

Before using, read the directions contained in this label 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.

Do not treat a site with more than 0.1875 pounds of malathion per acre in a twenty-four hour period. Do not exceed 3.0 pounds of malathion per acre in any site in any 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-based application: Spray equipment must be adjusted so that the volume median diameter (VMD) is between 8 and 30 microns ($8 \leq D_v 0.5 \leq 30 \text{ um}$) 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 Application: Spray equipment must be adjusted so that the volume median diameter produced is less than 60 microns ($D_v 0.5 < 60 \text{ um}$) and that 90% of the spray is contained in droplets smaller than 100 microns ($D_v 0.9 < 100 \text{ um}$). 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 APPLICATION

Apply MALATHION E-5 through standard ULV cold aerosol or non-thermal aerosol (cold fog) generators diluted or undiluted at a flow rate of 3.7 to 8.0 fluid ounces MALATHION E-5 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 0.024 to 0.051 pounds of malathion per acre. Vary flow rate according to vegetation density and mosquito population. Use higher flow rate in heavy vegetation or when populations are high.

6/6

Malathion pounds/acre	Application Rates Fl. oz./Min.				Fl. oz. MALTHION E-5 per acre
	5 MPH	10 MPH	15 MPH	20 MPH	
0.051	4.0	8.0	12.0	16.0	1.32
0.024	1.8	3.7	5.4	7.4	0.60

MALATHION E-5 may also be applied as a 2% fog, aerosol or space spray by diluting 1 to 28 parts with water, fuel oil, diesel oil, mineral oil, or other suitable solvent for a 2% spray. Treat shrubbery and vegetation where mosquitoes may rest. Shrubby and vegetation around stagnant pools, marsh areas, ponds, and shore lines may be treated. Avoid applying oil based spray to ornamental plants.

AERIAL APPLICATION

MALTHION E-5 may be applied undiluted a rate of 4.15 to 4.80 fluid ounces MALTHION E-5 per acre by fixed wing or rotary aircraft equipped with suitable ULV application equipment. These rates are equivalent to 0.1621 to 0.1875 pounds of malathion per acre. MALATHION E-5 may also be diluted with water or a suitable oil and applied by aerial ULV equipment at rates up to 4.8 fluid ounces of MALATHION E-5 per acre. Dilute in sufficient water or oil to give good coverage. Aerial application should be made at an altitude below 300 feet. Do not apply when ground wind speeds exceed 10 MPH. Aerial applications shall only be made when recommended by public health officials and trained personnel of mosquito abatement districts and other mosquito control programs.

STORAGE & DISPOSAL

DO NOT STORE IN ANY PREMISE OCCUPIED BY HUMANS OR ANIMALS.

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

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 procedures approved by state and local authorities.

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

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

NOTICE: 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.