

**EFFICACY REVIEW**

**Ortho Malathion 50 Insect Spray**

Date: 04/2/03

EPA Reg. No.: 239-739

Case Number: 008843

DP Barcode: D287875 and D288446

Pest: Mosquito Adults

Formulation: Premise

Chemical: Malathion.....50%

Shaughnessy Number: 057701

Purpose: Request is to review efficacy data to support label claims for control of mosquitoes which may transmit West Nile Virus.

MRID 45829601 V. Pedibhotla 1999. Evaluation Ortho Malathion 50 Insect Spray (EPA Reg. No. 239-739) Against Three Species of Mosquitoes. Insect Control and Research, Inc. Baltimore, MD, Laboratory Project ID 256-0030.

45850101 R. Soufi 2003. Evaluation of Malathion 50 Insect Spray (EPA Reg. No. 239-739) Against Southern House Mosquito, *Culex quinquefasciatus*. Insect Control and Research, Inc. Baltimore, MD, Laboratory Project ID 069-0034.

GLP: Non-GLP submission

Branch Supervisor: Meredith Laws, Branch Chief

Team Reviewer: Marilyn Mautz

Efficacy Reviewer: Joanne S. Edwards, Entomologist

Joanne S. Edwards  
4/2/03

## BACKGROUND:

The product ORTHO Malathion 50 Insect Spray, EPA Reg. No. 239-739, is registered for use to control adult mosquitoes. The label directions state to apply the product as a coarse spray to and around lower foundation of houses, patios and garbage cans; under porches and shrubbery; along fences; to firewood piles; and to other infested areas. The application rate for outside residual mosquito control is nine tablespoons (4 ½ fl oz) per gallon of water.

The registrant, Scotts, is requesting approval of the following label claims:

- **Controls (or kills) mosquitoes that (or which) may transmit West Nile Virus.**
- **Mosquito-B-Gon products have been proven to kill species of mosquitoes known to carry West Nile Virus. However, as with all insect controls, Mosquito-B-Gon products do not achieve 100% control of insects.**
- **Product does not provide 100% control.**

The registrant submitted two packages of data (MRID 45829601 and 45850101) to support the proposed label claims.

## REVIEW OF DATA:

- 45829601 V. Pedibhotla. 1999. Evaluation Ortho Malathion 50 Insect Spray (EPA Reg. No. 239-739) Against Three Species of Mosquitoes. Insect Control and Research, Inc. Baltimore, MD, Laboratory Project ID 256-0030.
- 45850101 R. Soufi. 2003. Evaluation Ortho Malathion 50 Insect Spray (EPA Reg. No. 239-739) Against Southern House Mosquito, *Culex quinquefasciatus*. Insect Control and Research, Inc. Baltimore, MD, Laboratory Project ID 069-0034.

These tests were designed to determine knockdown and the time to knockdown of four species of mosquitoes: *Aedes aegypti*, *Anopheles albimanus*, *Culex pipiens* and *Culex quinquefasciatus*. The test design was a randomized complete block with 10 replicates per treatment (with an exception that there were only 7 replicates for *A. albimanus*). Each replicate consisted of 10 adult female mosquitoes placed in a cardboard cylinder (3 inch diameter by 2 inch length), screened at both ends.

A B&G tank sprayer was used to apply the Ortho 50% Malathion 50 Plus at 1 TBS per gallon. The sprays were applied to a line of cages, with one continuous spray swath at an application rate of 6.2 ml/ft<sup>2</sup>. The sprayer was held approximately 8 inches above the cages.

Knockdown counts were taken at 5, 15 and 60 minutes post-application, and mortality counts were taken at 24 hours post-application. Knockdown was defined as "inability to fly". Untreated controls (10 replicates) were utilized.

To obtain mean knockdown values, the mortality counts were converted to percentages and then arcsine averaged. For 24-hr mortality counts, the counts were converted to percentages, and then the values were arcsine averaged to obtain mean mortality values. Where mortality was observed in the controls, Abbott's formula was used to correct for it.

Results are shown in the table below:

Percentage (%) Knockdown

Species	5 minutes	15 minutes	60 minutes	24 hours (Mortality)
<i>Aedes aegypti</i>	0.4	16	100	100
<i>Anopheles albimanus</i>	5.7	3.2	98	100
<i>Culex pipiens</i>	0.4	1.2	96	100
<i>Culex quinquefasciatus</i>	53	83	100	100

The results show biological activity of the product; >95% control was achieved by one hour.

#### RECOMMENDATIONS:

The submitted laboratory data demonstrate biological activity of the test product against the four species of mosquitoes tested.

The decision as to whether or not to allow the proposed claim being sought (which I consider a "marketing" type claim) is a management decision, and is not under the peruse of this efficacy review.

The label already bears claims for control of adult mosquitoes. It could be assumed that there are adequate laboratory and field testing data available to support this product, as well as other EPA-registered mosquitocides and mosquito repellents. Therefore, if a decision is made to allow such a claim for this product, then such claims should be allowed for other registered products with mosquito control/repellency claims (and for that matter, also pending products that have adequate supporting efficacy data).

In regards to the types of data needed to support a mosquitocide or mosquito repellent, the registrant is referred to the Product Performance Guidelines **810.3400** Mosquito, Black Fly, and Biting Midge (Sand Fly) treatments and **810.3700** Insect Repellents for Human Skin and Outdoor

Premises in public draft (also see Fradin and Fay 2002. Comparative Efficacy of Insect Repellants Against Mosquito Bites. New England Journal of Medicine Volume 347:13-18).

In the case of this particular malathion product, the submitted laboratory data are deemed adequate to demonstrate intrinsic toxicity against various species of mosquitoes. According to the Centers for Disease Control and Prevention ([www.cdc.gov](http://www.cdc.gov)) the number of mosquito species known to vector West Nile Virus is quite large, and now stands at over thirty-five species.

No field testing data were submitted for this product. Field testing is required to demonstrate knock-down/residual efficacy under actual use conditions and should be submitted for this product. [Note: I am aware historical data is available for ULV applications; it may also be available for this 50% formulation.]

#### Labeling Issues:

- The label bears a claim for "residual" control of mosquitoes, but no time period is specified. A time period needs to be specified, and the supporting data needs to reflect that time interval.

- if a RD decision is made to allow this marketing claim, then a suggestion is that the statement "Mosquito-B-Gon products have been proven to kill species of mosquitoes known to carry West Nile Virus" should be reworded to read "Mosquito-B-Gon **controls (or kills)** kill species of mosquitoes **that (or which)** **may** carry West Nile Virus".