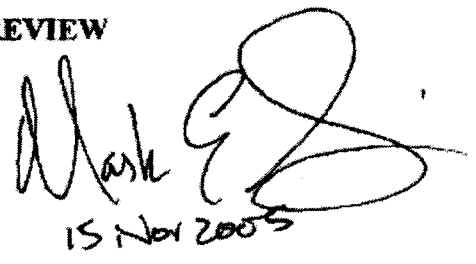


PRODUCT PERFORMANCE / EFFICACY REVIEW

Mark Suarez, Entomologist - IB



DATE: 15 November 2005

EPA REG. NUMBER: 79652-1

PRODUCT NAME: Miltrol

REGISTRANT: Marinize Products, Inc.

PM: Velma Noble, PM31

REVIEWER: Jacqueline Campbell-McFarlane

DECISION #: 358283

DP BARCODE: 320751

ACTION: A57

ACTIVE INGREDIENT(S): 107401, 1-Octadecanadium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride.....0.5%

TYPE: Trimethoxysilyl quats, Antimicrobial

OPPTS GUIDELINE(S): 810.1000
810.3000
810.3500 (as applicable)

MRID: 46579201

GLP ?: No.

SITES: Indoor Residential

PESTS: Dust Mites

STUDY APPLICATION RATE: 0.5%, 2.5%, and 5.0%, until wet

LABEL APPLICATION RATE: 0.5% until moist

STUDY SUMMARIES:

MRID 46579201. Loder, E.R. 2005. *Final Report. Efficacy of Organosilaine On the Acute Mortality of American Dust Mites.* 32pp.

The data provided examined the efficaciousness of 3-(trimethoxy) dimethylpropyloctadecyl ammonium chloride, a Trimethoxysilyl Quat, when applied at varying concentrations to mattress ticking, against American dust mites (*Dermatophagoides farinae*). Two studies were conducted in Petri dishes in the laboratory, under controlled conditions. Data were not provided for analysis from the first trial. The second trial was similar in design to the description of the first, with additional replication. (Only data from the second trial were submitted in support of the amendment.) Twenty female dust mites were placed into Petri dishes with treated mattress ticking and some food. Samples were examined daily (for 6 days) for mortality.

The results of the trials (see Table 1) are difficult to interpret due to the large control mortality observed (mean of 60% on day 6). Abbott's formula has been applied to the mean mortality data for each treatment in an effort to account for the decline in the control populations. The 5.0% solution of Miltrol resulted in greater than 90% mortality of the dust mites after 6 days of exposure to treated mattress ticking. However, the lower 95% CI brings the 6 day 5% solution efficacy to 91.39% dust mite mortality. This level of mortality is marginally acceptable. The lower concentration solutions resulted in markedly less dust mite mortality. The 0.5% formulation, similar to the formulation that is the subject of this registration action, never demonstrated greater than 40% dust mite mortality, after correction for control mortality.

| Corrected Mean % Mortality | | | | | | |
|----------------------------|------------|------------|------------|------------|------------|------------|
| Treatment | Day | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 |
| 5.00% | 64.38 (74) | 75.00 (83) | 77.42 (86) | 83.05 (90) | 82.00 (91) | 92.50 (97) |
| 1.50% | 26.03 (46) | 50.00 (66) | 51.81 (70) | 52.64 (72) | 52.00 (76) | 55.00 (82) |
| 0.50% | 17.81 (40) | 35.29 (60) | 37.10 (61) | 40.66 (65) | 35.00 (68) | 37.50 (75) |
| Control | 27 | 32 | 38 | 41 | 50 | 60 |

TABLE 1. Mean mortality of dust mites when exposed to mattress ticking treated with Miltrol. Mean % mortalities were corrected by application of Abbott's formula to the data. Numbers in parentheses are the mean percent mortalities observed.

ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS

The desired amendment, which would add claims that the product "kills dust mites", is not supported by the data submitted. The 0.5% trimethoxysilyl quat tested did not demonstrate the level of efficacy ($\geq 90\%$) required to include dust mites on the label.

Recommendations:

1. Remove all references to dust mites from the label.
2. The registrant may submit or cite data to support a "kill dust mites" claim in a subsequent label amendment. Product specific data would be highly preferable.