Product Performance Data Evaluation Review

By Kevin Sweeney, Senior Entomologist

11/20/2009

Date: November 20, 2009

PM: Richard Gebken, PM 10

Product Name: No Fly Zone Treated Fabric

EPA Reg. No. 83588-1

Action Code: R350

Due date: December 13, 2009

Dec: 399886

DP: 371727

Registrant: International Textile Group, Inc.

GLP? No

This is a resubmission with bioassays to support product performance. The original submission had permethrin residue data but no efficacy data were submitted to support label claims after 110 washes. The registrant submitted a response that addressed the efficacy study results and the durability study supporting their argument that treated and untreated fabrics can be washed together. The registrant argues that if 92% of the permethrin content in the fabric is retained after 110 washes, the treated garment can be washed with untreated clothing. This would enable a family to wash treated and untreated garments together.

Submitted Study:

MRID47871301 Amended Final Report: Bioassay for insecticidal activity of treated fabric samples against adult mosquitoes by Gary Benzon, Benzon Research, Inc. on September 22, 2009.

Purpose: To determine if the permethrin content in washed and unwashed fabric is bio-available to knockdown mosquitoes in laboratory assays. Permethrin is a toxicant that can cause knockdown and mortality following exposure. This assay does not

Materials and Methods:

Test species: *Aedes aegypti.* They were non-blooded females 5-15 days old.

Test chambers: The test chamber was a polystyrene Petri dish measuring 15 x 140 mm. A hole was drilled in the middle of each plate to accommodate the transfer of mosquitoes into the dish.

Fabric swatches: Fabric swatches were 15 cm (6 in) squares. Treated and untreated swatches were provided.

Procedure: The Petri dish lid was laid on the lab table surface. A fabric swatch was laid inside and over the lid. The bottom of Petri dish was laid on top to obtain a snug fit. Some of the fabric swatch hung over the side. Mosquitoes (10-20) were aspirated into the dish. A piece of tape was placed over the hole. The procedure was repeated for treated and untreated swatches. Exposure intervals of 2, 15 and 30 minutes were used. After this time the plate was held vertically, tapped on the fabric side, and the fabric swatch was slowly removed. Any remaining threads were removed with fine forceps. The number of injured mosquitoes was recorded. This number was subtracted from the total in the plate.

Mosquitoes remained in the dishes and knockdown was recorded at 15 and 60 minutes post-exposure. Plates were inverted at each counting period. If a mosquito could not right itself after plate inversion, was moribund or not moving, it was counted as knocked down. Knocked down mosquitoes also included individuals not capable of coordinated flight. After the knockdown counts are completed, mosquitoes were frozen and the total recorded.

Treatments. Sample 1 consisted of poly-nylon "FS15899-Original", which was unwashed. Sample 2 was poly-nylon "FS15899-110x", which was laundered 110 times. Sample 3 was poly-cotton "BDU-Original", which was unwashed. Sample 4 was a poly-cotton "BDU-110x", which was laundered 110 times. All unwashed treated fabrics contained 0.52% permethrin w/w. The exact composition of the sample fibers and the denier were not reported. Lot numbers were not reported in this study. It is unclear if these samples were the same ones analyzed for permethrin content in MRID47570001, which was previously reviewed. In that MRID the registrant submitted residue data on

the poly-nylon fabric but there appears to be no residue data on the poly-cotton fabric that was also tested in this study.

Replication. Each sample exposure time was replicated once. N = the number of mosquitoes tested in the Petri dish.

Results:

"Exposure" refers to the time interval where the treated fabric was present in the Petri dish for mosquitoes to contact. "Post-exposure" refers to the time mosquitoes spent in the Petri after the treated fabric was removed. BDU = "Battle Dress Uniform".

2 minutes exposure
FS 15899-Original: 0% KD at 15 mins and 60 mins post-exposure
FS-15899-110x: 0% KD at 15 mins and 15.4 % at 60 mins post-exposure
BDU-Original: 20% KD at 15 mins and 73.3% at 60 mins post-exposure
BDU-110x: 8.3% KD at 15 mins and 25% KD at 60 mins post-exposure.

15 minutes exposure
FS 15899-Original: 50% KD at 15 mins and 70% KD at 60 mins post-exposure
FS 15899-110x: 44.4% KD at 15 mins and 55.6% KD at 60 mins post-exposure
BDU-Original: 100% KD at 15 mins and 100% KD at 60 mins post-exposure
BDU-110x: 75% KD at 15 mins and 100% KD at 60 mins post-exposure

30 minutes exposure
FS 15899-Original: 76.5% KD at 15 mins and 100% KD at 60 mins post-exposure
FS-15899-110x: 91.7% KD at 15 mins and 100% KD at 60 mins post-exposure
BDU-Original: 100% KD at 15 mins and 100% KD at 60 mins post-exposure
BDU-110x: 78.6% at 15 mins and 100% at 60 mins post-exposure

Control mortality (15 mosquitoes) was 0% in the study

Conclusion:

KD should exceed $\geq$ 80% to be considered effective.

- The product did not effectively knockdown mosquitoes after the 2-minute exposure period for any of the tested samples.
- The FS-15899 original and 110x samples had $\geq$ 80% knockdown of mosquitoes only after a 30-minute exposure tests.
- The BDU-original provided 100% knockdown following the 15-minute and 30-minute exposure tests.
- The BDU-110x sample provided 100% knockdown at the 60-minute post-exposure count in the 15 minutes and 30 minutes exposure tests.

Entomologist's Recommendation:

1. The amendment for 110 washes should not be approved based on the submitted data. The results of the submitted bioassay indicate that the permethrin is not readily bio-available. Long periods of exposure to the treated fabrics were required to achieve knockdown of mosquitoes.
    a. I suggest the registrant cite other data and make an offer to pay to get a 70 wash claim. Alternatively, they may request an extension and conduct another bioassay with the treated fabrics to see if the fabric is efficacious through 0, 25, 50, 70, 80, 90, 100, 110 washes. Permethrin residue data are needed for fabric samples used in the bioassays unless the registrant can demonstrate why data on one fabric type should satisfy the requirement on multiple fabrics. Lot numbers should be identified. Testing should be done with mosquitoes and ticks. A meeting should be scheduled in late December or early January to finalize the protocol.
    b. The BDU samples outperformed the FS-15899 sample suggesting that the poly-cotton blend provides better efficacy against mosquitoes than the poly-nylon blend based on the data provided. Residue data were only submitted for the poly-nylon blend.
2. In response to the permethrin PDCI I suggest the registrant prepare a protocol for efficacy testing with human subjects to test their label claims of repellency for all pests through 110 washes. The registrant should refer to the EPA Human Studies Review Board web site in order to prepare an efficacy study with human subjects and meet with the Agency to discuss it. The protocol will need to describe a study that adheres to Good Laboratory Practices (GLP) while meeting the requirements of the EPA Human Subject Testing Rule.