EFFICACY STUDY REVIEW

by Kevin J. Sweeney, Entomologist - IB

12/2/04

To: Joseph Tavano

Date: December 2, 2004

EPA Reg. No.: 121-IO and ON

Product Name: 121-IO Cutter Insect Repellent 7K
121-ON Cutter Insect repellent 5KT

Registrant: Spectrum - Division of United Industries Corporation

PM: Richard Gebken, Acting PM 10

Dec #: 339450

DP : 301344

Chemical: picaridin - repellent (also known as KBR 3023)

121-IO 7% picaridin pump spray
121-ON 5% picaridin towelette

OPPTS Guideline 810.33

Action: review efficacy data in support of the subject products. Registrant will bridge down from the 7% to the 5% picaridin product. Registrant submitted non-GLP laboratory efficacy studies and cited the supplier's data for the technical product. The products were tested and they include a fragrance. The supplier's data was collected without a fragrance.

Studies Submitted:

MRID 46184810 Efficacy of Cutter Repellent 7K against laboratory raised *Aedes aegypti* mosquitoes by Jacob Morris, United Industries.

Method: 0.2 grams of product are applied to 30 square centimeters of skin on the arm of the test subject. This would be equivalent to 4.0 g of product per 600 square centimeters. It is probably not possible for an arm to hold this much material. It is possible this is typographical error and that the protocol should have read apply the arm from wrist to elbow - 30 cm in length, which is the typical application scenario for testing repellents. A 7% registered DEET product (121-76)

was used as a positive control. Pre-test landing rates were used to demonstrate mosquito attraction to the test subject and biting pressure. Test cages contained 500 female mosquitoes. There was adequate replication.

Evaluation: FCB determined by 3 minute exposures every 30 minutes until there is a confirmed bite as described in OPPTS Guideline 810.33.

Results: FCB of 4.5 to 6.5 hours supports label claim of 4 hours. The subject products outperformed the 7% DEET product.

MRID 46184811 Evaluation of Mosquito Repellents KSC-23-77, KSC-23-79, and KSC 23-81 compared to Cutter All Family Insect Repellent toward the Southern house mosquito, *Culex quinquefasciatus* by Reed Kirkland, Bio Research Laboratories, Fresno, CA.

Protocol: The protocol as described by Hageman, A.G. 1974 with revision by R.E. Verwey 1997 (SC Johnson & Sons) was used. Approximate 1g of product was applied at the rate of 600 square centimeters of arm surface. Approximate 0.8 to 0.9 g of product was actually applied to each test subject arm from wrist to elbow. This is a typical dose for a skin applied insect repellent. Biting pressure was established as was the attractiveness of each of the four test subjects. Negative and positive (a 6% DEET formulation; 7% DEET Cutter All Family Insect repellent EPA Reg No 121-76; and a 12% DEET formulation) controls were used.

Evaluation: FCB bite was used as described in OPPTS Guideline 810.33.

Results: The subject 7% picaridin product performed better than all the DEET formulations with an average repellency time of 7 hours. These data support the product label claim of four hours.

Entomologist's Comments:

1. The data support the label claims for duration of repellency provided that:

a. the registrant submit an explanation or correction to Test Method 6A as it appears that it would required a large amount of repellent to be applied.

b. the registrants agrees to conduct a field study with both subject product in accordance with GLP and will submit the protocol to EPA for approval before the test begins. These data are due by January 2, 2006.

c. the registrant submit or cite product specific data for ticks, stable flies (biting flies), ceratopogonid midges (no-see-ums); black flies (gnats); and fleas. Laboratory studies can be conducted for the ticks (black-legged; Lone Star; and American Dog Tick); stable flies, and fleas. Field studies are to be done for black flies and ceratopogonid midges. All data are to be collected under full GLP.

2. 121-IO Label: The repellency claims are acceptable. However, remove the following marketing claims:

#7; #8; 14; 16; and 20.

3. 121-ON label. Repellency claims are acceptable. However, remove the following marketing claims:

#7; 8; 14; 16; and 20.