

US EPA ARCHIVE DOCUMENT

EFFICACY STUDY REVIEW

by Kevin J. Sweeney, Entomologist - IB

Kevin J. Sweeney
6/2/04

To: Joe Tavano

Date: June 2, 2004

EPA Reg. or File No.: 4822-167

Product Name: OFF! Insect Repellent Formula V

Registrant: S.C. Johnson & Son, Inc.

PM: Richard Gebken, Acting PM 10

Dec No. 328966

4822167

DP: 295674

GLP: yes

Chemical: DEET

OPPTS Guideline 810.3300

Formulation: RTU 25% DEET spray-on

Request: review efficacy data to support 8 hour repellency claim and WNV/disease related claims.

Studies Submitted: **MRID: 45922801 Determining Repellency of OFF! 4822-167 Against Mosquitoes (Culicidae) in the Field by S.C. Johnson**

This study was conducted in the field to determine the effectiveness of the subject product against mosquitoes. The study was conducted in Australia and the study location and test species were previously approved by Kevin Sweeney prior to initiation. The study was conducted in Australia due to concerns about exposure to West Nile virus in the U.S. Multiple field habitats were tested with a variety of test species present including those from the genera *Culex* and *Ochlerotatus*. Mosquito exposure began at 6.5 hours post-treatment and data were recorded at 8, 9, and 10 hours. There were 30 replicates for the First Bite Test and % repellency tests. Biting pressure in the control replicates was acceptable - averaging about 1 bite per minute. 1.0 g of product was applied/600sq.cm of skin surface.

The study was conducted in accordance with GLP requirements and the data reported as MEDIAN and Mean Time to First Bite and 95% or greater repellency. Currently, the EPA is using the Time to First Bite or Time to First Confirmed Bite as the regulatory standard. However, future guidance could include a 95% repellency test and this study was designed to address both tests.

Entomologist Comments and Recommendations:

1. The study is acceptable in accordance with OPPTS Guideline 810.3300.
2. The study results support a claim of eight hours repellency against mosquitoes based on the first bit test results.
3. The additional new claims are acceptable except for "from/against mosquitoes... that carry diseases." I also believe that some of the other disease claims are not appropriate for the U.S. including Murray Valley, Cache Valley, Rift Valley Fever, Barmah Forest Disease, and Ross River Fever given the lack of explanation regarding the supporting data in light of such claims. The WNV claims are acceptable.
4. Likewise, the tick claims are also rather broad for the U.S. including European Tick-borne Encephalitis.
5. Likewise for black flies transmitting Onchocerciasis.