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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

To: Jim Downing, Regulatory Action Leader
Biopesticides and Pollution Prevention Division, 7511C

From: Robyn Rose, Entomologist Robyn Rose 9/1/00
Biopesticides and Pollution Prevention Division, 7511C

Peer Review: Russell Jones, Ph.D., Biologist
Biopesticides and Pollution Prevention Division, 7511C

Product: OFF! Botanicals 2; EPA Reg. No. 4822-LRL; Barcode No. D265371; Case No. 065963; Submission No. S578450.

Formulation: OFF! Botanicals 2 contains 10% Eucalupta™ (p-Menthane-3,8-diol) and 90% other ingredients.

Action/Study Type: Review of efficacy (product performance) data in support of registration; MRID No. 450766-01.

Public Health Pests: No-see-ums (Culicoides sp.), black flies (Simulium sp.) and mosquitoes (Culicidae).

Label Claims: "Keeps bugs OFF!." "Protects your entire family from annoying mosquitoes, (black flies, gnats, no-see-ums and chiggers) (for up to two hours)." "Repels mosquitoes, (black flies, gnats, no-see-ums and chiggers)."

Classification: Supplemental to submitting information listed under conclusions.

Conclusions:

1. Mosquitoes were not repelled for two hours. Therefore, a reapplication time of no more than one and a half hours must be indicated for mosquitoes under the directions for use. Two additional studies, in environmentally distinct habitats, showing two or more hours of repellency are needed to claim a two hour reapplication time. It is also preferred if a test is conducted on a non-*Aedes* species.

2. Since SCJ has not shown that OFF! Botanical 2 will repel mosquitoes for two hours, each

insect and its duration of repellency may be listed separately on the label. If listing each insect is not preferred, two additional mosquito field tests are needed (see conclusion #1 above).

3. An additional sand fly and black fly field test in a second location are needed to verify duration of repellency. Tests from this submission were conducted in the same area as the original submission.

4. Since no studies were submitted for gnats, no-see-ums, and chiggers, they should not be listed on the label. In addition, the generic term "biting flies" should not be listed on the label. Acceptable product performance tests should be submitted to the Agency for each insect vector listed on the label.

5. In future tests, the duration of repellency should be based upon a 95% reduction in bites rather than the first confirmed bite test (FCB). Evaluating data based upon the FCB is not preferred by the Agency because bites may be disregarded if a second bite is not received within 30 minutes. In addition, the April, 2000 SAP that evaluated the proposed Agency guidelines for testing the efficacy of insect repellents recommended basing the duration of repellency on a 95% reduction in bites.

Background:

In support of registering OFF! Botanical 2 (EPA Reg. No. 48220-LRL) as an insect repellent, S.C. Johnson & Son, Inc. (SCJ) has submitted product performance (efficacy) data to the Agency. SCJ claims that OFF! Botanical (referred to as Uick-3 in submission) is effective at repelling gnats (commonly called no-see-ums)(*Culicoides* spp.), biting flies (black flies) (*Simulium* spp.) and mosquitoes (*Culicidae*) for up to two hours. Field test were conducted to verify the efficacy of OFF! Botanical-2.

SCJ previously submitted efficacy data to the Agency for this registration. In a memo dated June 29, 1999 from Russell Jones to Jim Downing, it was concluded that "[t]he submitted product performance (efficacy) studies for black flies (*Simulium* spp.) and biting gnats (*Culicoides* spp.) are supplemental and do not support registration of the end-use product. To upgrade the product performance studies to acceptable, the registrant must submit one additional field test for black flies and one additional field test for biting gnats. No additional field studies are required for mosquitoes (*Aedes* spp. and *Mansonia* spp.)."

DATA EVALUATION REPORT

STUDY TYPE:	Product performance of OFF! Botanical 2 against mosquitoes, no-see-ums, and black flies.
MRID NO.:	450766-01
SPONSOR:	S.C. Johnson & Son, Inc.
TEST MATERIAL:	Uick-3 (10% p-menthane 3,8 diol), SCJW Formula No. 15028R21
TESTING FACILITY:	S.C. Johnson & Son, Inc., 1525 Howe St., Racine, WI 53403-2236
AUTHOR:	Raymond E. Verwey, Research Scientist
REPORT DATE:	November, 1999

Study Summary

Title: Determining Repellency of Uick-3 (10% p-menthane 3,8 diol) Against Biting Gnats (commonly called no-see-ums) (Culicoides spp), Biting Flies (Black Flies) (Simulium spp.) and Mosquitoes (Culicoidae) in the Field.

Objective: "To evaluate Uick-3 (p-menthane 3,8 diol) on human skin for its ability to repel biting gnats (commonly called no-see-ums)(*Culicoides* spp.), biting flies (black flies) (*Simulium* spp.) and mosquitoes (*Culicidae*). This information is for use in substantiating the claim that this product repels biting gnats (commonly called no-see-ums)(*Culicoides* spp.), biting flies (black flies) (*Simulium* spp.) and mosquitoes (*Culicidae*).

Methods:
Field tests were conducted to evaluate the efficacy of OFF! Botanical 2 at repelling gnats (commonly called no-see-ums)(*Culicoides* spp.), biting flies (black flies) (*Simulium* spp.) and mosquitoes (*Culicidae*). Black flies (82% *Simulium venustum* and 18% *Prosimulium mixtum*) were evaluated near Copper Harbor, MI; mosquitoes (*Aedes taeniorhynchus*) were tested in Naples, FL; additional mosquitoes (73% *Aedes vexans*, 20% *Aedes cinereus*, and 7% *Aedes dorsalis*) were tested in Winnipeg, Canada.

The procedure followed in this test, with some exceptions, was ENT-REP-002: Method for Field Testing Insect Repellents o Human Test Subjects Against Mosquitoes, Black Flies, Sand Gnats and Deer Flies. Uick-3 was applied to lower legs and forearms of test subjects at a rate of 1.0 g / 645 cm^2. Each test consisted of four test subjects with three limbs treated. A total of six arms and six legs (12 replicates) were evaluated in each test. Test subjects cleaned the treated area with 70% ethanol and ivory soap prior to applying Uick-3. During the test, subjects wore Khaki shirt and pants, a hat, a head net, and white gloves.

The treated are of test subjects were continuously exposed to the biting insects. The test was terminated for each test subject once two bites were received within 30 minutes (first confirmed bite; FCB). Mean time to FCB, significance, and deviations were calculated.

Results:

Table 1. Mean duration of repellency of Uick-3 in the field

Sample	No. Reps	Test Insect	Protection Time (min.)
Uick-3	12	Sand Gnats	163 (SD 30)
Uick-3	12	Black Flies	341 (SD 80)
Uick-3	12	Mosquitoes (FL)	99 (SD 0.72)
Uick-3	12	Mosquitoes (CA)	84 (SD 39)

Table 2. Weather information and landing rates per minute

Test Insect	Date	Temp °C	RH%	Wind m/s	Cloud Cover	Full Body Landing (rates/min)	Single Limb landing (rates/min)
Sand Gnat	3/29/99	22.3-25.5	63.5-77.4	0.0-0.8	clear	104-288	2-27
Black Fly	6/7/99	19.6-30.4	47.0-80.1	NA	clear	24-208	0-19
Salt Marsh Mosquito	4/29/99	25.5-32.7	28.6-73.9	0.0	clear	48-480	6-27
Woodland Mosquito	7/20/99	27.0-30.4	60.1-71.9	NA	partly cloudy	24-88	5-12

Conclusions:

According to the data presented by SCJ, sand gnats are repelled by Uick-3 for 163 minutes, black flies for 341 minutes, and mosquitoes for an average of 91.5 minutes.