

4

Product Performance Review
By
Kevin J. Sweeney, Senior Entomologist

Date: August 15, 2006

Dec: 364404 DP: 326996

PM: Richard Gebken, PM 10

EPA File Symbol: 806-GR
31

Product Name:

Avon Skin So Soft SSS Bug Guard Plus Picaridin Insect Repellent Spray

Active ingredients: 10% Picaridin

Formulation: RTU Pump Spray

Use pattern/sites: Human skin

Request: New product that repels mosquitoes, biting midges (no-seeums), sand flies, and gnats.

OPPTS Guideline: 810.3300 (Studies incorrectly refer to 810.3400)

The following GLP field studies were submitted to support the subject product registration:

MRID 46751905 Evaluation of the Efficacy of a Personal Repellent Against Mosquitoes

MRID 46751906 Evaluation of the Efficacy of a Personal Repellent Against Mosquitoes

MRID 46751907 Evaluation of the Efficacy of a Personal Repellent Against Biting Midges

Science Reviews of the Submitted Studies

These studies were also the subject to an ethics review by John Carley.

Note: These studies are the same as previously reviewed MRIDs for 806-GN

MRID 46751905 Evaluation of the Efficacy of a Personal Repellent Against Mosquitoes

The subject product formulation was identified as 1004024-010(B) in this study.

Location: The study was conducted in the coastal plain of Georgia, USA. The site was located at the Savannah Canal Museum and Nature Center Site in Savannah, GA. Site selection was based upon prevailing populations of mosquitoes landing at the rate of 1 to 10 per minute on 250 square cm of exposed skin. Recording sites were rotated during the day as biting pressure changed. The mosquito species prevalent across these sites was *Psorophora ferox*. Other species includes *Aedes* and *Ochlerotatus* spp.

Study design:

Fifteen subjects served as test subjects and two subjects served as negative control subjects. Two subjects were alternates in the event subjects leave the test. A positive control was not tested.

The repellent formulation application was made by a syringe to an exposed forearm and lower leg at a volume of 0.47 ml/250 sq. cm. (treatment rate of 1.67 mg/cm²). The rest of the subject was covered with clothing. Shoes were treated with a permethrin-based repellent to prevent tick bites. Treatment was made early enough to allow peak mosquito biting activity to coincide with the eight hour exposure period. The treated subjects were exposed continuously until the First Confirmed Bite (FCB). Negative control subjects exposed an untreated leg for five minutes every hour to determine if an adequate biting rate existed at a site. The test lasted for eight hours.

Results: The repellent was effective for 8 hours on all 30 limbs tested. The repellent did not fail on any of the treated subjects during the eight-hour exposure period. Biting pressure was adequate throughout the testing period, averaging 12.6 to 14.7 bites throughout the study.

Conclusion: The data supports a claim of "Repels mosquitoes for up to 8 hours".

MRID 46752006 Evaluation of the Efficacy of a Personal Repellent Against Mosquitoes

The subject product formulation was identified as 1004024-010(B) in this study.

Location: The study was conducted in the State of Maine, USA. The site was located at Butter Field Island, Lake Niatous, Maine. Site selection was based upon prevailing populations of mosquitoes landing at the rate of 1 to 10 per minute on 250 sq cm of exposed skin. Recording sites were rotated during the day as biting pressure changed. The mosquito species prevalent across these sites was *Ochlerotatus intrudens*.

Study design:

Ten subjects served as test subjects and two subjects served as negative control subjects. Two subjects were alternates in the event subjects leave the test. A positive control was not tested.

The repellent formulation application was made by a syringe to an exposed forearm and an exposed lower leg on each subject at the rate of 0.47 ml/250 sq. cm. (treatment rate of 1.67 mg/cm²). Treatment was made early enough to allow peak mosquito biting activity to coincide with the eight hour exposure period. The rest of the subject was covered with clothing. Shoes were treated with a permethrin-based repellent to prevent tick bites. The treated subjects were exposed continuously until the First Confirmed Bite (FCB). Negative control subjects exposed an untreated leg for five minutes every hour to determine if an adequate biting rate existed at a site. The test lasted for up to eight hours.

Results: The average repellency time based upon the FCB bite test was 7 hrs and 54 minutes with a standard deviation of ± 24 minutes. The repellent was effective for up to eight hours on 19/20 limbs tested. On the forearm of one subject, the repellent failed at 6 hours and 11 minutes. Biting pressure was adequate throughout the testing period, averaging 35 to 37 bites throughout the study.

Conclusion: The results support a label claim of "Repels mosquitoes for up to 8 hours".

MRID 46752007 Evaluation of the Efficacy of a Personal Repellent Against Biting Midges

The subject product formulation was identified as 1004024-010(B) in this study.

Location: The study was conducted in the coastal plain of Florida, USA. The sites were located at Conifer Lake in Pine Island, Florida. Site selection was based upon prevailing populations of biting midges landing at the rate of 1 to 5 per minute. Recording sites were rotated during the day as biting pressure changed. The biting midge species prevalent across these sites was *Culicodes furens* (poey). Some *Culicodes barbosi* (Wirth and Blanton) were also collected.

Study design:

Ten subjects served as test subjects and two subjects served as negative control subjects. Two subjects were alternates in the event subjects leave the test. A positive control was not tested.

Each subject was treated up to eight hours before exposure to midges in order to test the repellent at the time of peak biting midge activity. The repellent formulation was applied with a syringe to the exposed forearm at the volume of approximately 0.47 ml/250 sq. cm. to yield 1.67 mg/cm². The rest of the subject was covered with clothing. Shoes were treated with a permethrin-based repellent to prevent tick bites. The treated subjects were exposed continuously until the First Confirmed Bite (FCB). Negative control subjects exposed an untreated arm for five minutes every hour to determine if an adequate biting rate existed at a site. The test lasted for up to eight hours. Testing was conducted on two consecutive evenings.

Results: The repellent was effective for up to eight hours (one subject) against the *Culicoides* biting midge species. Repellency duration averaged 4 hours and 18 minutes to 7 hours and 18 minutes with the average of both sessions equal to 5 hours and 48 minutes \pm 55 minutes. Biting pressure was adequate throughout the testing period.

Conclusion: The data support a label claim of "Repels biting midges for up to 6 hours".

Entomologist's Recommendations:

1. **The subject studies are acceptable and support the following repellency duration label claims :**
 - a. **"Repels mosquitoes for up to 8 hours." Reapply after 8 hours**
 - b. **"Repels biting midges (no-seeums) for up to 6 hours." The registrant requested a reapplication interval of 5 hours and this reapplication interval is acceptable.**
2. **Data should be submitted or cited to support the claim for sand flies and gnats (black flies) or these pests should be removed from the label.**
3. **Please explain how the extended duration and time-release technology is supported.**
4. **Please remove all references to an invisible, hidden, or unseen barriers for protection.**
5. **The claim for repelling WNV vectors is not supported by the submitted data. Please cite or submit additional data with WNV vectors or remove this claim. The mosquitoes tested in these studies are not WNV vectors. Species from the genera *Culex* should be tested. Testing should also be conducted against *Aedes albopictus*.**
6. **Remove the claim that skin-so-soft is an antidote to mosquitoes. This is an unsupported medical claim.**



13544

R160531

Chemical Name: Picaridin

PC Code: 070705

HED File Code: 512500 RD Efficacy Reviews Skin applied Insect Repellents

Memo Date: 8/15/2006

File ID: DPD326996

Accession #: 000-00-0125

HED Records Reference Center

7/15/2008