Product Performance Review
By
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Date: Augu: 15, 2006

Dec: 36440- DP: 326996

PM: Richar Gebken, PM 10

EPA File Sy bol: 806-GR

Product Nar :
Avon Skin S Soft SSS Bug Guard Plus Picaridin Insect Repellent Spray

Active ingre ents: 10% Picaridin

Formulation RTU Pump Spray

Use pattern/ es: Human skin

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

OPPTS Gui line: 810.3300 (Studies incorrectly refer to 810.3400)

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

MRID 4675 005 Evaluation of the Efficacy of a Personal Repellent Against Mosquitoes

MRID 4675 006 Evaluation of the Efficacy of a Personal Repellent Against Mosquitoes

MRID 4675 007 Evaluation of the Efficacy of a Personal Repellent Against Biting Midges

Science Reviews of the Submitted Studies

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

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

MRID 46751 05 Evaluation of the Efficacy of a Personal Repellent Against Mosquitoes

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

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

Study desigr
Fifteen subje ; served as test subjects and two subjects served as negative control subjects. Tw subjects were alternates in the event subjects leave the test. A positive control was n tested.

The repellent ormulation application was made by a syringe to an exposed forearm and lower leg at a olume of 0.47 ml/250 sq. cm. (treatment rate of 1.67 mg/cm^2). The rest of the subject w covered with clothing. Shoes were treated with a permethrin-based repellent to p vent tick bites. Treatment was made early enough to allow peak mosquito biting activit o coincide with the eight hour exposure period. The treated subjects were exposed cont uously until the First Confirmed Bite (FCB). Negative control subjects exposed an u reated leg for five minutes every hour to determine if an adequate biting rate existed a i site. The test lasted for eight hours.

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

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

MRID 4675 06 Evaluation of the Efficacy of a Personal Repellent Against Mosquitoes

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

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

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

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

Results: Th verage repellency time based upon the FCB bite test was 7 hrs and 54 minutes witl standard deviation of ± 24 minutes. The repellent was effective for up to eight hours 19/20 limbs tested. On the forearm of one subject, the repellent failed at 6 hours and 1 ninutes. Biting pressure was adequate throughout the testing period, averaging 3 o 37 bites throughout the study.

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

MRID 4675 007 Evaluation of the Efficacy of a Personal Repellent Against Biting Midges

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

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

Study desig
Ten subjects erved as test subjects and two subjects served as negative control subjects. Two subject vere 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 syring to the exposed forearm at the volume of approximately 0.47 ml/250 sq. cm. to yield 67 mg/cm^2. The rest of the subject was covered with clothing. Shoes were treated with permethrin-based repellent to prevent tick bites. The treated subjects were exposed con nuously until the First Confirmed Bite (FCB). Negative control subjects exposed an t treated arm for five minutes every hour to determine if an adequate biting rate existed a site. The test lasted for up to eight hours. Testing was conducted on two consecutive enings.

Results: The epellent was effective for up to eight hours (one subject) against the *Culicoides* b ng midge species. Repellency duration averaged 4 hours and 18 minutes to 7 hours and minutes with the average of both sessions equal to 5 hours and 48 minutes ±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".

Entomologis s Recommendations:

1. **The bject studies are acceptable and support the following repellency dura on 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 ould 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. **Pleas explain how the extended duration and time-release technology is supp ted.**
4. **Pleas remove all references to an invisible, hidden, or unseen barriers for prote ion.**
5. **The im for repelling WNV vectors is not supported by the submitted data. Pleas cite or submit additional data with WNV vectors or remove this claim. The squitoes tested in these studies are not WNV vectors. Species from the gene *Culex* should be tested. Testing should also be conducted against *Aede* *lbopictus*.**
6. **Rem e the claim that skin-so-soft is an antidote to mosquitoes. This is an unsu orted medical claim.**