EFFICACY REVIEW
by Mark Suarez, Entomologist - IB

Mark E. Suarez
19 August 2005

DATE:	19 August 2005
EPA REG. NUMBER:	806-EO
PRODUCT NAME:	Avon Skin-so-soft SSS Bug Guard Frontier Insect Repellent Spray
REGISTRANT:	Avon Products, Inc.
RM: **REVIEWER:**	Richard Gebken, PM10 Joseph Tavano
DECISION: **DP BARCODE:**	352099 313324
ACTION:	R31
ACTIVE INGREDIENT(S):	PC 070705 ~~070795~~, KBR 3023.....10.0%
TYPE:	Topical Aerosol Spray
OPPTS GUIDELINE(S):	810.1000 810.3000 810.3400
MRID:	~~46429508~~ ~~46429509~~ ~~46429510~~ ~~46429511~~ ~~46447102~~
GLP ?:	Yes
SITE(S):	Human Skin
PESTS(S):	Mosquitoes, Black Flies, Biting Midges,Ticks
STUDY APPLICATION RATE:	1.67 mg/cm^2 (equivalent to 1g/600 cm^2)
LABEL APPLICATION RATE:	1 g/600 cm^2

STUDY SUMMARY(IES):

MRID 446429508. The submitted study evaluated the efficacy of the subject formulation against mosquitoes in the field (LakeNicatous, ME). The predominant species of mosquito collected was *Ochlerotatus* intrudens. Bite pressure was marginal, but adequate for the purposes of confirming mosquito activity. All test subjects (n=9) exhibited >8 hours protection exposed, treated arms and legs.

MRID 446429509. The submitted study evaluated the efficacy of the subject formulation against mosquitoes in the field (Collier State Park, FL). The predominant species was *Ochlerotatus taeniorhynchus*. Bite pressure throughout the test was high (40.9-42.2 landings/5 minutes at each observation interval); this pressure is adequate for the purposes of this study. The duration of protection provided was approximately 6 hours (95% Lower Confidence Limit). The results of this study are presented below in Table 1.

	Time (Hours:Minutes)		
	1st Bite	*1st Confirmed Bite*	*Mean Duration of Protection*
Mean	5:42	6:50	
Standard Error	0:23	0:20	
95% Confidence Interval	--	0:45	6:05

Table 1. Mean time of protection offered from mosquitoes in the field (FL).

MRID 446429510. The submitted study evaluated the efficacy of the subject formulation against black flies, *Simulium aureum* and *Prosimulium multidentatum*, in the field (Nicatous Lodge, ME). Bite pressure throughout both tests was adequate for the purposes of this study. The duration of protection provided was approximately 2 ¾ hours (95% Lower Confidence Limit). The results of this study are presented below in Table 2.

	Time (Hours:Minutes)		
	1st Landing	*1st Confirmed Landing*	*Mean Duration of Protection*
Mean	3:43	4:02	
Standard Error	0:41	0:43	
95% Confidence Interval		1:15	2:47

Table 2. Mean time of protection offered from black flies in the field (ME).

MRID 446429511. The submitted study evaluated the efficacy of the subject formulation against biting midges, *Culicoides furens* and *Culicoides barbosai*, in the field (Pine Island, FL). Bite pressure during the period of midge activity was acceptable during both tests was adequate for the purposes of this study. Midges were active for only a portion of the study period. In order to enhance the length of the claim against biting midges, study participants were treated prior to midge activity and waited for midge activity to begin approximately 6 hours post-treatment. The duration of protection

provided was approximately 7 ½ hours (95% Lower Confidence Limit). The results of this study are presented below in Table 3.

	Time (Hours:Minutes)		
	1st Bite	*1st Confirmed Bite*	*Mean Duration of Protection*
Mean	6:54	7:46	
Standard Error	0:25	0:08	
95% Confidence Interval		0:14	7:32

Table 3. Mean time of protection offered from biting midges in the field (FL).

MRID 446447102. The submitted study evaluated the efficacy of the subject formulation against deer tick, *Ixodes scapularis*, nymphs. The results exhibited a high degree of variability between test subjects (n=10). In one instance, 100% repellency was noted through 1 hour only. For another test subject 100% repellency was observed through 8 hours. Although the results were variable (see Table 4) a mean duration of repellency of 5.5 hours was observed (Mean±CI_{95} = 5.5±1.617); however, the product was efficacious 98.43% of the time through 7 hours.

	% Repellency (hours after Treatment)											
	1	*2*	*3*	*4*	*4.5*	*5*	*5.5*	*6*	*6.5*	*7*	*7.5*	*8*
Mean	100	99.18	98.51	100	98.41	97.47	97.4	98.5	99.25	98.43	91.26	89.42
SEM	0.00	0.82	1.49	0.00	1.59	1.75	1.34	1.00	0.75	1.05	7.05	4.61

Table 4. Efficaciousness of Avon Skin-So-Soft against nymphal *Ixodes scapularis* in the laboratory.

ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS:

The data generally support claims against nymphal ticks and biting flies (mosquitoes, black flies, and midges). The GLP field data submitted support time specific tick claims of up to hours, mosquito claims of up to 6 hours, black fly protection of up to 3 hours, and biting midge protection of up to 7 ½ hours. The registrant has requested a number of marketing claims. These are addresses individually below.

Recommendations:

1. Repels insects that may carry West Nile Virus and Lyme Disease.
   - This claim is not acceptable at this time. Submit or cite data showing efficaciousness of the product for at least one additional and primary vector of West Vile virus for claims of protection (*Aedes albopictus* preferred).

2. Repels mosquitoes and deer ticks up to 7 hours.
   - This claim is not acceptable at this time. The data submitted support a claim for repellency up to 6 hours for mosquitoes and up to 7 hours for ticks.

3. Repels mosquitoes that may carry West Nile Virus up to 7 hours.
   - This claim is not acceptable at this time. Submit or cite data showing efficaciousness of the product for at least one additional and primary vector of West Vile virus for claims of protection (*Aedes albopictus* preferred).
   - This claim is not acceptable at this time. The data submitted support a claim for repellency up to 6 hours for mosquitoes.

4. Repels deer ticks that may carry Lyme Disease up to 7 hours.
   - This claim is acceptable.

5. Repels mosquitoes that may carry West Nile Virus.
   - This claim is not acceptable at this time. Submit or cite data showing efficaciousness of the product for at least one additional and primary vector of West Vile virus for claims of protection (*Aedes albopictus* preferred).

6. Repels deer ticks that may carry Lyme Disease.
   - This claim is acceptable.

Enclosure
000806-000EO-ER