

IRB PRODUCT PERFORMANCE REVIEW

PM: 10

05-06-92

65233-R  
TREG  
Primavera Products  
Hauppauge, NY 11788

D: 177483  
MRID: U.A.

FORMULATION

Oil of Citronella.....0.25%

Lotion

INTRODUCTION

Application for new registration. See prior review of 4/3/92. Note change in declaration of active ingredients. New declaration indicates 5X the citronella previously declared. Citronella has prior registrations for topical human repellents.

USES

Label claims are for repellency of "insects" and deer ticks.

SUBMITTED DATA

A. All data from Scott Carroll, Davis CA. Submission of addenda for previously reviewed studies and one new arena study on ticks. None of the data in this submission have been assigned MRIDs.

1. Mosquito Repellency. See prior review for MRID 421513-11. Study sites were Plantation Key FL and Bolivar PT. Texas. In both studies the TREG dose was 0.125 fl oz. Deet standard applied was not measured but was a uniform spray to one forearm. The other forearm served as the untreated control. Subjects walked or sat. 2 subjects. Round robin (compounds switched) design. Other details provided. Results:

Species	Site	Treatment	First Confirmed Bite	Total Bites/ 2 hrs.
Aedes sollicitans	TX	Treo	23 min.	3
		DW OFF	>120	0
		Untreated	1	105
Culex salinarius	FL	Treo	>120	1
		DW OFF	65	2
		Untreated	7	45
Anoph. albimanus	FL	Treo	>120	0
		DW OFF	>120	0
		Untreated	5	10
Aedes aegypti	FL	Treo	>120	1
		DW OFF	>120	1
		Untreated	7	12

2. Additional data for Mosquitoes. See MRID 421513-12. Salt Lake City, UT. 0.125 fl.oz. Treo. 3 second spray of Deep Woods OFF. 2 subjects. Some studies with 2 extra subjects using Avon Skin so Soft and Rescue 10% citronella. Round robin design. Results of 4 separate days of trials:

Species	Trial	Treatment	First Confirmed Bite	Total Bites/ 2 hrs.
Aedes dorsalis	1	Treo	47	3
		Cutters?	>120	1
		UTC	<1	90
Culex tarsalis	1	Treo	55	2
		Cutters?	>120	1
		UTC	1	50
Aedes dorsalis	2	Treo	23	2
		Cutters?	>120	0
		Avon SSS	3	9
		Rescue	12	6
		UTC	<1	50
Culex tarsalis	2	Treo	>120	0
		Cutters?	>120	1
		UTC	<1	50

Species	Trial	Treatment	First Confirmed Bite	Total Bites/ 2 hrs.
Aedes dorsalis	3	Treo	50	2
		Cutters?	>120	0
		UTC	<1	85
Culex tarsalis	3	Treo	52 (3rd)	3
		Cutters?	>120	0
		UTC	<1	85
Aedes dorsalis	4	Treo	60	2
		Cutters	>120	0
		UTC	2	32
Culex tarsalis	4	Treo	45	2
		Cutters	>120	0
		Avon SSS	5	8
		Rescue	14	5
		UTC	2	25

3. Deer Tick Flag Study. See MRID 421513-13. The 2x2 flags were treated with 0.5 fl oz treo or a 6 second spray of tick garde. 15 hours of flagging.

4. New study. White sock arena test for ticks. 4/12/92. 1.2 meter diameter wading pools. 0.25 fl.oz. treo or a 4 second spray of deep woods off. 50 Ixodes pacificus per pool. Ticks climbing socks were removed and replaced. Half hour duration per trial. 4 volunteers, socks rotated between trials for a total of 2 hours exposure time. Socks were then aged for 65 hours in towels and the study repeated. Finally, a bare foot study was used. 0.125 fl.oz. treo or 2 second spray deep woods off. After one half hour, feet were bathed and the study repeated with the alternate foot treated. Results:

Trial	Treatment	Number Climbing in 2 hours
Freshly treated	Treo	0
	Deep Woods Off	0
	Untreated	40
65 hours aged	Treo	3
	Deep Woods Off	4
	Untreated	38
Bare Feet	Treo	1
	Deep Woods Off	2
	Untreated	39

## CONCLUSIONS

1. Mosquitoes. All trials used very few subjects, and the duration of the trial was not sufficient to provide information relative to the minimum protection time specified in the guidelines (3 hours). It should be noted that this time was specified in 1982, and many products have reduced their Deet concentrations since that time. Also, ethyl hexanediol is no longer manufactured for this purpose.

For the 12 trials in the submitted data, Texas, Florida, and Utah are represented. Species represented were Aedes sollicitans, Culex salinarius, Anopheles albimanus, A. dorsalis, C. tarsalis, and A. aegypti. The absence of anophelines is noted. Taken as a group, the mean protection time for Treo was 69.6 minutes +/- 37 minutes. For registered deet formulations the mean protection time was greater than 120 minutes in 11 of 12 studies. The 10% citronella product was used in only 2 trials and had an average protection time of 13 minutes. While we do not find Rescue listed as a registered product in the REFS system (it may be a distributor product), there are two 10% citronella products registered and TREO is certainly superior to a 10% citronella product in the study submitted.

The submitted data are acceptable to support a claim for repelling mosquitoes. It should be qualified by statements of "for up to one hour.", and "reapply when effectiveness diminishes".

2. Ticks. There are three pertinent tick studies submitted. A laboratory study on Ixodes dammini indicates the inherent repellent properties of the formulation, and a potential superiority to deet. A flagging study for the same tick in Massachusetts showed that both Treo and Deet were 100% effective in repelling deer ticks, although only 20 ticks were collected on untreated flags in 15 hours of flagging. An arena study on Ixodes pacificus indicated good repellency for Treo (96% overall raw, 89% adjusted), slightly less for deet (95% raw, 77% adjusted). Most importantly, Treo worked well both on clothing and on bare skin. No data on other species of ticks were submitted.

The data are sufficient to support a claim for repelling deer ticks. No duration claim is necessary or appropriate (for this or other such repellent. A general tick repellent claim is not acceptable at this time. To support such a claim, data for other representative ticks, such as Dermacentor variabilis and Amblyomma americanum.

#### LABELING

1. In addition to the statements mentioned above, the following label comments are offered.
  - a. As before, "deet free" and "r-11 free" are unacceptable label statements as implied safety claims.
  - b. General references to repelling insects and ticks should be replaced by specific claims.

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