

IRB PRODUCT PERFORMANCE REVIEW

PM: 10

03-12-93

65233-1  
Treo  
Primavera Products

MRID: NA  
DP: D188029

FORMULATION

Oil of Citronella.....0.05%

RTU Lotion

INTRODUCTION

Application for amended registration. Request to remove label qualifiers regarding duration of effectiveness for mosquitoes. See prior reviews of 5/4 and 12/18/92.

USES

See label copy. Applicant wishes to delete label restriction stating up to 1 hour repellency, and wishes to add the claim long lasting protection.

SUBMITTED DATA

1. Scott Carroll, Davis, CA. Original MRID 425072-02. No MRID on the additional information faxed in from Washington DC attorneys. Field tests in Sutter County, CA. Culex tarsalis and Anopheles freeborni. Deep Woods Off positive control. Calves of subjects treated with either 5cc of TREO or 3 Second Spray of Off. Other leg untreated. The first confirmed bite for all controls is stated to be less than 3 min.

4 subjects. 1 trial using all 4 individuals. 12 additional trials using 2 individuals. Round-robin trade-off of test materials. See attached table of results. Overall summary as follows:

## Protection Times- First Confirmed Bite

<u>Subject</u>	<u>An. freeborni</u>		<u>C. tarsalis</u>	
	<u>Treo</u>	<u>DW Off</u>	<u>Treo</u>	<u>DW Off</u>
A	101	93	95	126
B	110	122	119	99
C	94	101	121	104
D	103	109	130	132
Average	102	106	116	115

Data in previous reviews encompass 11 trials in TX, FL, and UT. These trials utilized Treo applied at 0.125 oz. (3.5 cc) to forearms. The present study utilized 5cc of product per calf. The amount of material used is 40% more, but calves are usually larger than forearms. We cannot equate the doses on a mg/cm<sup>2</sup> basis. The average protection time in the previous 11 studies was 1.2 hours. The average protection time in the current submission was about 1.8 hours.

CONCLUSIONS

1. The data indicate that the product will last longer if more is applied to the skin. We would have no objection to removal of the duration statement with the following additional wording, or something similar to it:

"For longer lasting protection apply a heavier initial dose of Treo to exposed skin"

Phil Hutton

Minutes to first confirmed Bite  
af treo

ct treo

subject

subject

date	a	b	c	d
8-16	74	144	107	82
8-18	133	119		
8-21	94	43		
8-22			36	110
8-27	121	167		
8-28			117	78
8-31	90	61		
9-1	82	101		
9-2			79	99
9-6			75	82
9-7	111	138		
9-11			126	100
9-15			118	168
avg	101	110	94	103
overall	102			

date	a	b	c	d
8-16	77	156	190	135
8-18	121	68		
8-21	88	110		
8-22			140	117
8-27	98	106		
8-28			140	149
8-31	38	178		
9-1	134	148		
9-2			104	137
9-6			115	101
9-7	112	67		
9-11			39	141
9-15				
avg	95	119	121	130
overall	116			

af DWO

ct DWO

subject

subject

date	a	b	c	d
8-16	80	76	135	93
8-18	38	116		
8-21	185	160		
8-22			51	127
8-27	82	98		
8-28			106	111
8-31	101	162		
9-1	69	114		
9-2			134	102
9-6			96	108
9-7	93	128		
9-11			87	147
9-15			97	78
avg	93	122	101	109
overall	106			

date	a	b	c	d
8-16	119	98	41	130
8-18	76	41		
8-21	127	126		
8-22			115	100
8-27	137	93		
8-28			82	66
8-31	165	105		
9-1	84	134		
9-2			103	129
9-6			157	195
9-7	172	96		
9-11			125	169
9-15	insufficient populations			
avg	126	99	104	132
overall	115			