Study Title

TEST OF DERMAEGIS LIPODEET 302 PERSONAL INSECT REPELLENT
EPA Reg. # 82810-1

Data Requirement

OPPTS 810.3700

Author

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Study Initiation Date

November 7, 2007

Study Completion Date

November 27, 2007

Performing Laboratory

Carroll-Loye Biological Research
711 Oak Avenue
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Laboratory Project ID

SCI-001.4

Statement of No Confidentiality Claims

No Claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 10(d) (1) (A), (B), or (C).

Company: DermAegis, Inc.

Company Agent: Timothy H. Dickens, Ph. D.

Title: Authorized Agent

Date: December 7, 2007

Signature: Timothy H. Dickens

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GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

Study Compliance for the final report entitled Test of DermAegis LipoDEET 302 Personal Insect Repellent (Carroll-Loye Biological Research Report SCI-001.4) for Scientific Coordination, Inc., Rockville, MD.

This study meets the requirements of U.S. EPA Good Laboratory Practice Regulations; Pesticide Programs (40 CFR 160).

27 November 2007

Scott P. Carroll, Ph.D. Date
Study Director

Timothy H. Dickens 7 December 2007

Sponsor Date

Timothy H. Dickens 7 December 2007

Study Submitter Date

QUALITY ASSURANCE STATEMENT

Carroll-Loye Biological Research, GLP study for Scientific Coordination, Inc., Protocol Number SCI-001.4 Entitled "Test of Dermaegis LipoDEET 302 Personal Insect Repellent, EPA Reg. No. 82810-1" was inspected during various stages of the study. The data presented in the final report represent an accurate record of the raw data and the experimental findings. Records of results of facility inspections, study and final report audits are kept on file at Sierra Research Laboratories. The phases of the study inspected, dates and the findings were reported to management are as follows:

Phase Inspected	Date	Description
Protocol Review	07 November 2007	Protocol Review
Review Protocol Amendments	08 November 2007	Protocol Amendments (3) Review
In-Life Inspection And Audit	08 November 2007	Pre-treatment Dosemitry – Application of Test Substances to Test System, raw data audit (partial)
Letter to Management & Study Director	01 December 2007	Letter Sent to C-LBR Management & Study Director
Final Report Audit	02 December 2007	Final Report Audit and QAU Statement

William A. Donahue Jr. 02 December 2007

William A. Donahue, Jr., Ph.D. **Date**
Quality Assurance Unit

Information Summary

1) Objective

The objective of this study was to measure the Complete Protection Time afforded by the Test Material against mosquitoes in nature.

2) Protocol Reference

Carroll-Loye protocol SCI-001, 'Test of Personal Insect Repellents', as amended (Appendix 7a; includes sponsor signature). Protocol SCI-001 and its associated consent form were approved by the Independent Investigational Review Board Inc. (Appendix 7c).

3) Test Material
The Test Material is DermAegis LipoDEET 302 Insect Repellent, a registered topical insect repellent formulation in lotion delivery (EPA Reg. # 82810-1-58188). This product is a 30% DEET product with the DEET held in microscopic lipid spheres that inhibit evaporation to prolong efficacy, improve cosmetic properties, and reduce plasticizing action. There is no positive control or comparison article.

Table 1. Test Material and Comparison Article information.

Repellent	Description	Active ingredient
DermAegis LipoDEET 302 ('Ultra 30') Insect Repellent (EPA #82810-1) Lot # 27G	4 oz. lotion	30% DEET

4) Untreated Control
Untreated skin (hereinafter 'Untreated Control').

5) Deviations from the Protocol
Deviations from the protocol and their consequences are given in Appendix 7d.

Testing Materials and Methods

1) Test Sites and Dates

Dosimetry testing was conducted in the Arthropod Behavior Laboratory at Carroll-Loye Biological Research on November 7-8, 2007. Field tests of repellent efficacy were conducted in the field in Glenn and Butte Counties, California. Testing at Site 1, in Glenn County (10 November 2007), was in the understory beneath the canopy of tall native forest. Testing at Site 2, in Butte County (11 November 2007), was in a grassland habitat, with scattered shrubs and small trees, around a small lake. The two test sites represented different habitat types, which differed in the composition and relative abundance of foraging mosquito species present.

As specified in the amended protocol, a second DEET product was similarly tested at the same test sites on the same dates by an additional 10 test subjects. The results for that product are reported separately, in Carroll-Loye report SCI-001.5. There is substantial data sharing between that report and this report, including values from the untreated control subjects, data on environmental conditions, and data on mosquito community composition.

2) Environmental Conditions

Temperature, relative humidity, average wind speed over 1-min sample periods, and light intensity were recorded at approximately 1-hr intervals during efficacy testing.

3) Human Study Subjects

Ten human subjects were used in measurements of self-dosing behavior (dosimetry). Likewise, ten human subjects exposed the test material to mosquitoes for efficacy evaluation in each habitat. A sample size of ten subjects was chosen to give a reasonably large statistical population size while avoiding exposing too many individuals to the minor but present risks associated with exposure to biting arthropods. The subjects had the following attributes: they were18-55 years old, reported themselves to be in good physical condition and frequently active in rural outdoor settings, had not used repellents on the day prior to enrolling in the study, were not students or

employees of the Study Director, did not believe themselves to be allergic to mosquito bites, refrained from using alcoholic beverages or smoking beginning at 9 PM the night before, and during the test, and signed the IRB approved Informed Consent Form. Females were negative in pregnancy tests conducted immediately before dosimetry or, if they did not participate in dosimetry, immediately before they participated in efficacy testing, and stated that they were not lactating.

4) Mosquitoes

Mosquitoes were engaged as encountered in nature. Sites were chosen based on mosquito and virus surveillance data compiled weekly by the California State Department of Public Health. Note that a small proportion of mosquitoes evaded capture. At the time of testing, no mosquito pools or sentinel chicken flocks in either of the counties in which testing was conducted had been positive for West Nile Virus, Western Equine Encephalitis Virus, or St. Louis Encephalitis Virus for more than one month.

Mosquitoes that landed on the exposed limbs of control or treated subjects, were collected by subjects and technicians using mechanical aspirators. To expand the sample, some additional mosquitoes were aspirated from the surfaces of Tyvek suits worn by subjects. Collected mosquitoes were either pooled within genus by subject (if control), isolated individually (if treated subject), or pooled generically (if captured from area other than a test limb) and labeled by a technician, and held alive with sugar water nutriment until transported to the CLBR laboratory. There they were anaesthetized with chloroform, identified individually with a stereomicroscope by the Study Director.

5) Viral Assays

After being identified, individual or grouped mosquitoes were shifted into glass vials with glass beads for subsequent viral assays, and held at approximately -80°C. They were then hand-delivered cold to the University of California Center for Vector-borne disease for Taqman multiplex RT-PCR assays that screened for West Nile Virus, Western Equine Encephalitis Virus, and St. Louis Encephalitis Virus.

6) Dosage determination and margin of exposure

To determine dosage, we measured lower limb surface area for individual subjects based on the length and a set of four circumferences taken from each limb. The procedures, abstracted here, are detailed in the study protocol (Appendix 7a). Subjects completed a series of three self-application replicates to each forelimb. Before and after each application, a technician weighed the repellent container, on a traceably calibrated Sartorius GC 2502 (measurement increment 0.001 g, 500 g capacity). A mean dosage weight was calculated for each subject based on the weight decrement of the container. That difference, divided by the surface area of the treated limb, yielded a dosing rate of grams per square cm, and was calculated for two female and eight male subjects (subjects 6, 13, 14, 15, 24, 32, 38, 50, 63, 67). Subject dosing was measured only on arms, because pre-study reconnaissance of field sites indicated that the intensity of LIBes (Landings with Intent to Bite) was higher on arms than on legs, and consequently, subsequent efficacy studies were conducted with forearms only.

The grand mean of subject means was then used as the dosage rate for the efficacy testing. Those applications were made volumetrically, based on the limb surface areas of each subject and the specific gravity of LipoDEET 302 (0.976 g/ml). The mean dose for LipoDEET 302 was 1.16 g (348 mg DEET). For a 70 kg adult, that rate would be 4.97 mg/kg. Using EPA DEET RED value for acute dermal toxicity (rabbit) of 4280 mg/kg body weight, the margin of exposure (MOE) for a subject in this study would average 861. This MOE value was deemed sufficient to permit risking dermal exposure of the subjects to the repellent formulation during efficacy testing.

7) Test Material and its application

LipoDEET 302 was couriered to Carroll-Loye Biological Research and received on 30 May 2007, with Chain-of-Custody documented. It was stored at the Carroll-Loye Offices in a closed cabinet at room temperature (20-27°C).

Ten subjects tested the LipoDEET 302 in each of two habitats. In order that sufficient time would remain in the day for a long-duration test, the test

material was applied in the laboratory, in advance of travel to the test sites. Once treated, subjects were instructed to minimize abrasion of the treated skin during travel to the site. For studies at Site 1, repellent was applied to 5 females and 5 males. For studies at Site 2, repellent was applied to 4 females and 6 males.

Individual doses were prepared for each subject on the basis of the surface area of their forearm skin. Based on the results of the dosimetry analysis (see Results section, below), the dosing rate for LipoDEET 302 was 0.00224 ml/cm^2 of forearm skin surface.

Before repellent was applied, subjects washed their forearms carefully with a fragrance-free cleanser in tap water, rinsed them with tap water and then rinsed them again with 35% ethanol in water, and then dried them with clean towels. They then donned white Tyvek coveralls, rolling arms to permit application of the repellent. Repellent was then applied by technicians and experienced personnel, using 1 ml syringes (0.01 ml measurement increment) and two fingertips in a surgical glove, to spread the material as evenly as possible. For subjects with arms large enough to require doses exceeding 1 ml, the total dose was measured into, and dispensed, from two syringes.

The treatment allocation and dosing is given in Appendix 3.

8) Exposure to mosquitoes

All subjects wore head nets and surgical glove in addition to Tyvek coveralls, and each carried a mechanical aspirator. Treated subjects were partnered into groups of two. Each member of a partner pair was instructed to monitor their own exposed limb and that of their partner for mosquito landings during one-minute periods of exposure to mosquitoes (a “buddy system”). Exposures took place at 15-minute intervals, which began 150 min to 180 min after application (Appendix 4a). A technician advised subjects when the one-minute period began and ended. Subjects immediately removed any LIBing mosquitoes (Landing with Intent to Bite) from the exposed skin with a mechanical aspirator. All LIBes were reported to technical personnel who recorded the events by subject code and the clock time of exposure interval. At the end of each one-minute exposure period, subjects moved into a screen house.

Subjects immediately covered exposed skin with the protective garment if a LIBe followed another in the same or in either of the two previous exposure periods. Data recording personnel played an active role in monitoring the temporal pattern of LIBes to ensure proper protective responses.

Ambient LIBe pressure was measured by two experienced personnel on the same schedule as that for repellent exposure. These negative control subjects were attended by two assistants who use mechanical aspirators to quickly remove any LIBing mosquitoes. Both control subjects exposed a forearm. The controls protected their exposed arms as soon as LIBes occurred.

9) Data recording

A technician recorded LIBe data for each subject on a data sheet every 15 minutes, after each one-minute exposure.

10) Data Analyses

Dosimetry data were entered into an Excel 2004 (Macintosh) spreadsheet for calculations of surface area and dosing means. Those means were double-checked with a handheld calculator. Dosimetry analyses were based on subject means. Those, and other, descriptive statistics, were generated with the software 'SAS JMP' Version 5.0.1.2 (SAS Institute, Cary NC).

We calculated Complete Protection Time (CPT) as the interval between application and the First Confirmed LIBe. The First Confirmed LIBe was defined as the first LIBe followed by another LIBe within one-half hour, i.e., in either of the subsequent two exposure periods. This measure is identical to that of 'First Confirmed Bite', which was classically used in measures of repellency to biting insects, with the exception that our practices minimized the probability that a subject was actually bitten by a foraging mosquito. Complete Protection Time measured in this way gave a single duration value for each subject. Mean CPT was calculated across all 10 subjects, and is presented herein with standard deviation and 95% confidence interval information as well. Kaplan-Meier median CPT and a CPT survival plot were also generated.

Test Results

Dosimetry

Changes in container weight before versus after application indicated that individuals varied substantially in the amounts of the repellents that they applied (Table 2). Most individual subjects were reasonably consistent across limbs. The mean dosing rate was 0.00219 ± 0.00060 g/cm^2. The specific gravity of LipoDEET 302 (0.98) was divided into this mean weight value to provide rates in ml/ cm^2.

Table 2. LipoDEET 302 dosimetry mean (g/cm^2) from 10 subjects. [1]

Subject code no.	LipoDEET 302
6	0.00262
13	0.00196
14	0.00291
15	0.00190
24	0.00206
32	0.00154
38	0.00156
50	0.00214
63	0.00339
67	0.00185

[1]Each subject applied Lotion to each limb three times. Means for each limb were calculated, and those resulting two means averaged to provide the values tabulated.

The rates estimated from the dosimetry analysis resulted in a mean subject dose of 1.19 ± 0.20 ml, with the values varying among subjects depending on individual forearm surface area.

Environmental Conditions

Efficacy data were collected under suitable environmental conditions. At Site #1, temperature ranged from 13-15 °C, relative humidity from 86-98%, average wind speed from 0.0-1.7 mph and ambient light from 11-8820 lux. At Site #2, temperature ranged from 13-24 °C, relative humidity from 36-72%, average wind speed from 0.7-4.4 mph and ambient light from 5440-133,300 lux. Environmental data are given in Appendix 5.

Ambient LIBing Pressure

At each test site, the dual untreated control subjects experienced a minimum of 1 LIBe per exposure in almost all exposures (94-100%; see data sets, Appendix 1). While in most cases a value of '1' was used to indicate suitable mosquito activity, in 17% of the observation periods, values of '2' indicate that two foraging mosquitoes landed simultaneously.

Mosquito species present

LIBing mosquitoes were collected from the exposed limbs of treated and control subjects by aspiration. Some additional mosquitoes were also collected from Tyvek suits worn by subjects. The species *Aedes melanimon* was most abundant at both sites (Table 3 and Appendix 6). *Aedes vexans* was also common at Site #1, and three other *Aedes*, a *Culiseta* and *Culex tarsalis* were also present there. Site #2 had a lower diversity of mosquito species, but featured a different additional *Aedes* species (*Ae. stichticus*) and a different *Culex* species (*Cu. pipiens*).

For treated subjects, there were no LIBes at Site 1. At Site 2, there were nine such LIBes. Of these, five were captured, with three being *Ae. melanimon*, one *Ae. vexans* and one *Ae. increpitus*. From two subjects, 20 and 39, four LIBing mosquitoes were removed, but not successfully captured for further analysis.

LIBing mosquitoes collected from the controls may give a reasonable representation of the attacks rates of the mosquito species resident at each site. Those mosquitoes are identified and summed for each control at each Site in Table 4.

Table 3. Mosquito species collected during the repellent efficacy trials at each study site.

Species collected	No. of mosquitoes collected by species Site 1	No. of mosquitoes collected by species Site 2
Aedes melanimon	119	108
Aedes vexans	32	3
Aedes stichticus	0	6
Aedes increpitus	3	1
Aedes sierrensis	1	0
Aedes nigromaculis	1	0
Culiseta inornata	5	0
Culex tarsalis	4	0
Culex pipiens	0	3

Table 4. Mosquito species collected from the control subjects at each study site.

	No. of mosquitoes collected by species Site 1		No. of mosquitoes collected by species Site 2	
Species collected	Control 1	Control 2	Control 1	Control 2
Aedes melanimon	29	27	36	32
Aedes vexans	5	12	1	1
Aedes stichticus	0	0	0	6
Aedes nigromaculis	0	1	0	0
Culiseta inornata	5	0	0	0
Culex tarsalis	4	0	0	0
Culex pipiens	0	0	3	0

Viral Assays

Collected mosquitoes were assayed for diagnostic molecular evidence of the viral pathogens that cause West Nile Fever, Western Equine Encephalitis, and St. Louis Encephalitis. The assayed mosquitoes, in 22 separate samples, included single specimens collected from treated limbs (labeled with subject numbers) and pooled specimens from each control. None of the submitted specimens or pools was positive for any of the viruses (Appendix 6).

Influence of Test Material on Probability of LIBes

Mosquitoes were strongly affected by the LipoDEET 302, and alighted on subjects with intent to bite in only a small minority of exposures. Table 5 documents the CPT values and number of LIBes experienced for each subject. The raw data are given in Appendix 1.

Table 5. Efficacy: Complete Protection Times (CPTs[1]) in hr for LipoDEET 302, in descending order, and number of LIBes, by subject.

Site 1, Forest			Site 2, Grassy Lakeside		
Subject no.	CPT	LIBes[2]	Subject no.	CPT	LIBes
1	11.25	0	14	11.75	0
7	11.25	0	32	11.75	0
12	11.25	0	52	11.75	0
24	11.25	0	67	11.75	0
37	11.25	0	74	11.75	0
49	11.25	0	75	11.75	1
52	11.25	0	20	11.00	2
64	11.25	0	39	11.00	2
65	11.25	0	50	11.00	2
71	11.25	0	64	9.25	2

[1] Complete Protection Time, the hrs until the 'FCL' or First Confirmed LIBe ('Landing with Intent to Bite'), defined as the first LIBe followed by another within 30 min (i.e., in one of the subsequent two exposure periods).

[2] Including the confirming LIBe.

At Site 1, the forest, no subjects received LIBes. The mean CPT was 11.25 ± 0.0 hr (95% CI 11.25 -11.25). All exposures were ultimately censored before failure by the approach of darkness, which hindered accurate assessment of mosquito activity. Kaplan-Meier survival analysis was not conducted because the lack of variance in the data means that no additional information is to be gained. The mean CPT value clearly represents a minimum estimate.

At Site 2, the lakeside grassland, four of the ten subjects received confirming LIBes. The mean CPT was 11.28 ± 0.79 hr (95% CI 10.70-11.84 hr), with 0.9 ± 1.1 LIBes. Even though the time span of exposure intervals was the same on both test days (8.75 hr), the mean CPT was greater at Site 2 than at Site 1 because of the 30 min longer pre-exposure period (the time between application of the test material and the first exposure to mosquitoes) on the second test day. A Kaplan-Meier survival plot (Fig. 1) for the CPT values from Site 2 is given principally for illustrative purposes. One failure occurred 9.25 hr after application, and three others at 11 hr after application. Because a majority of subjects did not fail, but ceased exposure due to low light levels at dusk, as at Site 1, a median cannot be calculated.

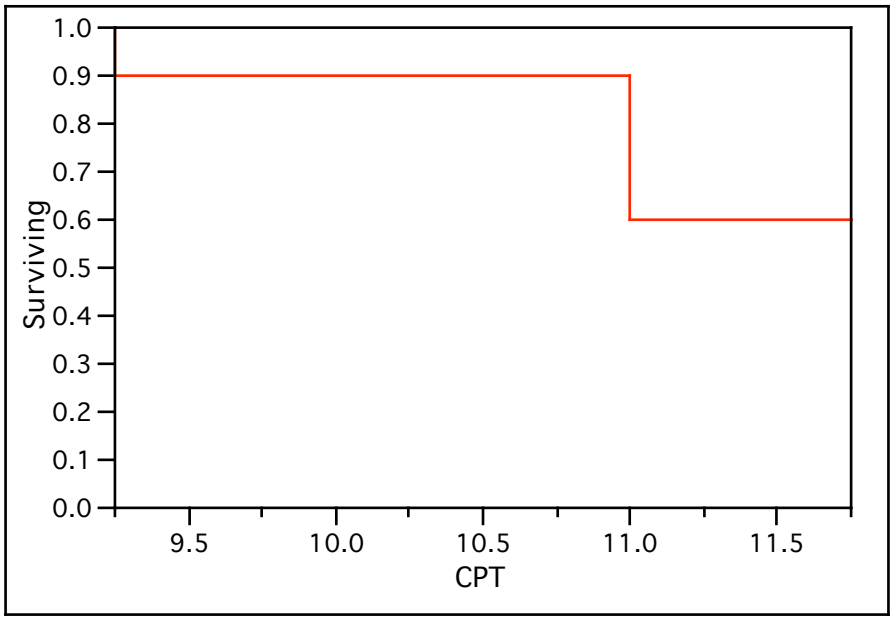

Figure 1. Site 2, survival plot of CPT for LipoDEET 302.

Summary and Conclusions

This mosquito repellent efficacy study was conducted for purposes of US/EPA registration. The test material was DermAegis LipoDeet Insect Repellent (LipoDEET 302), formulated with 30% DEET in liposomal capsules to extend duration and improve cosmetic properties. We conducted a study of dosimetry in advance of efficacy testing in order to estimate a typical consumer dosing behavior. The resulting average dosing rate was then used as the rate for all subjects in efficacy trials in two habitats in nature. Those habitats were grassy, open areas around a lake, and the understory of a dense, tall native forest. The results from the two control subjects showed that ambient biting pressure was sufficient at both sites on the respective test days.

LipoDEET 302 provided substantial and prolonged protection against foraging mosquito communities in two natural habitats. Mean Complete Protection Times (CPTs) in both sites were above 11 hours. Fifteen of the 20 total subjects concluded their periods of exposure due to the onset of darkness without experiencing any contact from mosquitoes on their treated limbs.

Nine mosquito species were attracted to the test subjects, representing the important public health and nuisance genera *Aedes*, *Culex* and *Culiseta*. One species of *Aedes* (*Ae. melanimon*) was most common at both sites, but the proportional composition of other species differed between the sites. Ambient biting pressure from the mosquito community was sufficient and consistent in both study habitats throughout each test day. *Aedes* species were responsible for all four of the failures observed.

In summary, Carroll-Loye study report SCI-001.4 shows that single doses of DermAegis LipoDeet Insect Repellent (LipoDEET 302, EPA Reg. #82810-1) gave an average of above 11 hr of Complete Protection against *Aedes, Culex* and *Culiseta* mosquito species. There were no landings on treated skin by *Culex tarsalis* or *Cu. pipiens*, suggesting that protection against these principal vectors of West Nile Virus in the US was excellent.

Appendix 1. Subject Tracking Spreadsheets

Research Subject Tracking Form

Study: SCI-001

Test Material: LipoDEET 302

Legend:
1 = November 7, 2007
2 = November 8, 2007
3 = November 9, 2007
4 = November 10, 2007
5 = November 11, 2007
na = Not Applicable

Subject Number	1	3	6	7	12	13	14	15	20	24	32	37	38	39	49	50	52	63	64	65	67	71	74	75
Subject Gender	F	M	M	F	M	M	M	M	F	M	M	F	F	F	F	F	M	M	M	F	M	M	M	F
MSD Sheet(s) Provided	3	3	2	3	2	1	2	2	3	1	1	3	1	3	1	2	3	2	2	1	1	3	2	2
Study Synopsis Provided	3	3	2	3	2	1	2	2	3	1	1	3	1	3	1	2	3	2	2	1	1	3	2	2
Experimental Subject Bill of Rights Completed	3	3	2	3	2	1	2	2	3	1	1	3	1	3	1	2	3	2	2	1	1	3	2	2
Pregnancy Test Advisory (Females)	3	na	na	3	na	na	na	na	3	na	na	3	1	3	1	2	na	na	na	1	na	na	na	2
Informed Consent Form Completed	3	3	2	3	2	1	2	2	3	1	1	3	1	3	1	2	3	2	2	1	1	3	2	2
Test Subject Contact Info Form Completed	3	3	2	3	2	1	2	2	3	1	1	3	1	3	1	2	3	2	2	1	1	3	2	2
Limb Measurements Completed	3	3	2	3	2	1	2	2	3	1	1	3	1	3	1	2	3	2	2	1	1	3	2	2
Dosimetry Completed	na	na	2	na	na	1	2	2	na	1	1	na	1	na	na	2	na	2	na	na	1	na	na	na
Arthropod Training Orientation Completed	3	3	na	3	2	na	2	2	3	1	1	3	na	3	1	2	3	2	2	1	1	3	2	2
Certified Negative Pregnancy Test	4	na	na	4	na	na	na	na	5	na	na	4	1	4	4	2	na	na	na	4	na	na	na	4
Repellent Efficacy Test Day 1	4	4	na	4	4	na	na	4	na	4	na	4	na	na	4	na	4	na	4	4	na	4	na	na
Repellent Efficacy Test Day 2	na	5	na	na	na	na	5	5	5	na	5	na	na	5	na	5	5	na	5	na	5	na	5	5

SCI-001_novLipoDEETSubTrack.xls

Research Subject Tracking Form

Study: SCI-001

Legend:
1 = November 7, 2007
2 = November 8, 2007
3 = November 9, 2007
4 = November 10, 2007
5 = November 11, 2007
na = Not Applicable

Duranon and LipoDEET Subjects Combined

Subject Number	1	3	6	7	12	13	14	15	20	24	32	37	38	39	48	49	50	52	53	59	63	64	65	66	67	71	73	74	75
Subject Gender	F	M	M	F	M	M	M	M	F	M	M	F	F	F	M	F	F	M	F	F	M	M	F	M	M	M	M	M	F
MSD Sheet(s) Provided	3	3	2	3	2	1	2	2	3	1	1	3	1	3	1	1	2	3	3	3	2	2	1	1	1	3	3	2	2
Study Synopsis Provided	3	3	2	3	2	1	2	2	3	1	1	3	1	3	1	1	2	3	3	3	2	2	1	1	1	3	3	2	2
Experimental Subject Bill of Rights Completed	3	3	2	3	2	1	2	2	3	1	1	3	1	3	1	1	2	3	3	3	2	2	1	1	1	3	3	2	2
Pregnancy Test Advisory (Females)	3	na	na	3	na	na	na	na	3	na	na	3	1	3	na	1	2	na	3	3	na	na	1	na	na	na	na	na	2
Informed Consent Form Completed	3	3	2	3	2	1	2	2	3	1	1	3	1	3	1	1	2	3	3	3	2	2	1	1	1	3	3	2	2
Test Subject Contact Info Form Completed	3	3	2	3	2	1	2	2	3	1	1	3	1	3	1	1	2	3	3	3	2	2	1	1	1	3	3	2	2
Limb Measurements Completed	3	3	2	3	2	1	2	2	3	1	1	3	1	3	1	1	2	3	3	3	2	2	1	1	1	3	3	2	2
Dosimetry Completed	na	na	2	na	na	1	2	2	na	1	1	na	1	na	na	na	2	na	na	na	2	na	na	na	1	na	na	na	na
Arthropod Training Orientation Completed	3	3	na	3	2	na	2	2	3	1	1	3	na	3	1	1	2	3	3	3	2	2	1	1	1	3	3	2	2
Certified Negative Pregnancy Test	4	na	na	4	na	na	na	na	5	na	na	4	1	4	na	4	2	na	4	4	na	na	4	na	na	na	na	na	4
Repellent Efficacy Test Day 1	4	4	na	4	4	na	4	4	na	4	na	4	na	4	4	4	4	4	4	4	na	4	4	na	4	4	4	4	4
Repellent Efficacy Test Day 2	5	5	na	na	5	na	5	5	5	5	5	na	na	5	5	5	5	5	5	na	na	5	5	5	5	5	5	5	5

Appendix 2. Dosimetry, Dosage and Treatment Allocation
Appendix 2a. Dosimetry Data Spreadsheet

Subject number	Sex	Limb	Limb Surface Area (sq cm)	LipoDEET 302 Lotion mass before	LipoDEET 302 Lotion mass after	LipoDEET 302 Total lotion applied (gm)	LipoDEET 302 Average lotion applied (gm)	LipoDEET 302 Average grams lotion /sq cm						
6	M	L arm	641	97.841	96.475	1.366	1.665	0.00260						
				96.475	94.738	1.737								
				94.738	92.845	1.893								
		R arm	647	92.845	91.281	1.564	1.701	0.00263						
				91.281	89.444	1.837								
				89.444	87.743	1.701								
13	M	L arm	563	119.012	117.754	1.258	1.160	0.00206						
				117.754	116.733	1.021								
				116.733	115.532	1.201								
		R arm	563	115.532	114.400	1.132	1.043	0.00185						
				114.400	113.420	0.980								
				113.420	112.402	1.018								
14	M	L arm	549	107.574	105.797	1.777	1.632	0.00297						
				105.797	104.100	1.697								
				104.100	102.678	1.422								
		R arm	566	102.678	101.133	1.545	1.607	0.00284						
				101.133	99.473	1.660								
				99.473	97.858	1.615								
15	M	L arm	494	121.661	120.686	0.975	0.972	0.00197						
				120.686	119.642	1.044								
				119.642	118.744	0.898								
		R arm	499	118.744	117.703	1.041	0.913	0.00183						
				117.703	116.670	1.033								
				116.670	116.006	0.664								
24	M	L arm	598	122.916	120.854	2.062	1.343	0.00225						
				120.854	119.813	1.041								
				119.813	118.888	0.925								
		R arm	595	118.888	117.589	1.299	1.106	0.00186						
				117.589	116.532	1.057								
				116.532	115.571	0.961								
32	M	L arm	569	109.681	108.917	0.764	1.233	0.00217						
				108.917	107.439	1.478								
				107.439	105.982	1.457								
		R arm	569	105.982	105.594	0.388	0.517	0.00091						
				105.594	105.055	0.539								
				105.055	104.432	0.623								

38	F	L arm	507	127.701	126.716	0.985	0.777	0.00153						
				126.716	126.133	0.583								
				126.133	125.369	0.764								
		R arm	518	125.369	124.693	0.676	0.817	0.00158						
				124.693	123.665	1.028								
				123.665	122.918	0.747								
50	F	L arm	407	114.957	114.459	0.498	0.779	0.00191						
				114.459	113.769	0.690								
				113.769	112.621	1.148								
		R arm	410	112.621	111.438	1.183	0.971	0.00237						
				111.438	110.706	0.732								
				110.706	109.709	0.997								
63	M	L arm	606	112.376	110.537	1.839	1.739	0.00287						
				110.537	109.133	1.404								
				109.133	107.159	1.974								
		R arm	612	107.159	104.855	2.304	2.390	0.00391						
				104.855	102.096	2.759								
				102.096	99.989	2.107								
67	M	L arm	532	104.430	103.549	0.881	0.954	0.00179						
				103.549	102.794	0.755								
				102.794	101.569	1.225								
		R arm	539	101.569	100.574	0.995	1.028	0.00191						
				100.574	99.540	1.034								
				99.540	98.484	1.056								
							LipoDEET	LipoDEET						
							302	302						
							Overall	Overall						
							average	average						
							grams	grams						
							lotion	lotion						
							/ arm	/ sq cm						
							1.217	0.00219						
							L arm	L arm						
							1.225	0.00221						
							R arm	R arm						
							1.209	0.00217						

Appendix 2b. Completed Dosimetry Data Capture Forms

Lotion Dosimetry Form

Study: SCI-001

Subject number: 6

Test article: Lipo Deet 302

Date: November 8, 2007

Data recorder name: W. K. Johnson

Data recorder signature: W K Johnson

Left Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	97.841	96.475
2	96.475	94.738
3	94.738	92.845

Right Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	92.845	91.281
2	91.281	89.444
3	89.444	87.743

Left Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Right Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Dosimetry form.xls

Lotion Dosimetry Form

Study: SCI 001

Date: November 7, 2007

Subject number: 13

Data recorder name: W. K. Johnson

Test article: LipoDeet 302

Data recorder signature: W K Johnson

Left Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	119.012	117.754
2	117.754	116.733
3	116.733	115.532

Right Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	115.532	114.400
2	114.400	113.420
3	113 420	112.402

Left Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Right Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Dosimetry form.xls

Lotion Dosimetry Form

Study: SCI 001

Date: November 8, 2007

Subject number: 14

Data recorder name: W.K. Johnson

Test article: LipoDeet 302

Data recorder signature: W K Johnson

Left Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	107.574	105.797
2	105.797	104.100
3	104.100	102.678

Right Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	102.678	101.133
2	101.133	99.473
3	99.473	97.858

Left Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Right Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Dosimetry form.xls

Lotion Dosimetry Form

Study: SCI 001

Date: November 8, 2007

Subject number: 15

Data recorder name: W. K. Johnson

Test article: Lipo Deet 302

Data recorder signature: W K Johnson

Left Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	121.661	120.686
2	120.686	119.642
3	119.642	118.744

Right Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	118.744	117.703
2	117.703	116.670
3	116.670	116.006

Left Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Right Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Dosimetry form.xls

Lotion Dosimetry Form

Study: SCI 001

Date: November 7, 2007

Subject number: 24

Data recorder name: W. K. Johnson

Test article: LipoDeet 302

Data recorder signature: W K Johnson

Left Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	122.916	120.854
2	120.854	119.813
3	119.813	118.888

Right Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	118.888	117.589
2	117.589	116.532
3	116.532	115.571

Left Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Right Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Dosimetry form.xls

Lotion Dosimetry Form

Study: SCI 001

Date: November 7, 2007

Subject number: 32

Data recorder name: W. K. Johnson

Test article: LipoDeet 302

Data recorder signature: WK [illegible]

Left Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	109.681	108.917
2	108.917	107.439
3	107.439	105.982

Right Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	105.982	105.594
2	105.594	105.055
3	105.055	104.432

Left Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Right Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Dosimetry form.xls

Lotion Dosimetry Form

Study: SCI 001

Date: November 7 2007

Subject number: 38

Data recorder name: W. K. Johnson

Test article: LipoDeet 302

Data recorder signature: WK Johnson

Left Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	127.701	126.716
2	126.716	126.133
3	126.133	125.369

Right Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	125.369	124.693
2	124.693	123.665
3	123.665	122.918

Left Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Right Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Dosimetry form.xls

Lotion Dosimetry Form

Study: SCI 001

Date: November 8, 2007

Subject number: 50

Data recorder name: W. K. Johnson

Test article: LipoDeet 302

Data recorder signature: WK Johnson

Left Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice	115.988	114.957

Right Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	114.957	114.459
2	114.459	113.769
3	113.769	112.621

Right Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	112.621	111.438
2	111.438	110.706
3	110.706	109.709

Left Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Right Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Dosimetry form.xls

Lotion Dosimetry Form

Study: SCI 001

Subject number: 63

Test article: LipoDeet 302

Date: November 8, 2007

Data recorder name: W. K. Johnson

Data recorder signature: WK Johnson

Left Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	112.376	110.537
2	110.537	109.133
3	109.133	107.159

Right Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	107.159	104.855
2	104.855	102.096
3	102.096	99.989

Left Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Right Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Dosimetry form.xls

Lotion Dosimetry Form

Study: SCI 001

Date: November 7, 2007

Subject number: 67

Data recorder name: W. K. Johnson

Test article: LipoDeet 302

Data recorder signature: W K Johnson

Left Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Arm Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	104.430	103.549
2	103.549	102.794
3	102.794	101.569

Right Arm Sampling		
Trial number	Mass before (g)	Mass after (g)
1	101.569	100.574
2	100.574	99.540
3	99.540	98.484

Left Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Right Leg Practice Application		
Trial number	Mass before (g)	Mass after (g)
Practice		

Left Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Right Leg Sampling		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Dosimetry form.xls

Appendix 2c. Completed Limb Measurement Forms

.

Limb Measurement Form

Study: SCI 001

Subject number: 1

Date: November 9, 2007

Data recorder name: W. K. Johnson

Data recorder signature: WK Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	23	7.7	19	22	27	27.	23.75	546
Right forearm	23	7.7	19	22	27	27.5	23.88	549
Left lower leg	33	11	23.5	29	38	38	32.13	1060
Right lower leg	33	11	23.5	29.5	38	38	32.25	1064

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form.xls

Limb Measurement Form

Study: SCI-001

Subject number: 3

Date: November 9, 2007

Data recorder name: W.K. Johnson

Data recorder signature: W K Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	29.5	9.8	18.5	20.5	26.5	28	23.38	690
Right forearm	29.5	9.8	18.5	20	26.5	28.5	23.38	690
Left lower leg	43	14.3	24	27.5	39.5	37.5	32.13	1381
Right lower leg	43	14.3	24.5	27.5	40	37.5	32.38	1392

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form.xls

Limb Measurement Form

Study: SCI-001

Subject number: 6

Date: November 8, 2007

Data recorder name: W. K. Johnson

Data recorder signature: W K Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	25.5	8.5	19.0	22	29	30.5	25.13	641
Right forearm	25.5	8.5	19.5	22	29	31	25.38	647
Left lower leg	35	11.7	23	28	39.5	36.5	31.75	1111
Right lower leg	35	11.7	23	28.5	39	36.5	31.75	1111

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form

Study: SCI-001

Subject number: 7

Date: November 9, 2007

Data recorder name: W. K Johnson

Data recorder signature: WK Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	22.5	7.5	16.5	19.5	24	26	21.5	484
Right forearm	22.5	7.5	17	20	24	26	21.75	489
Left lower leg	38	12.7	23	27.5	38	35	30.88	1173
Right lower leg	38	12.7	23	28	38	35	31	1178

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form.xls

Limb Measurement Form

Study: SCI 001

Subject number: 12

Date: November 8, 2007

Data recorder name: W. K. Johnson

Data recorder signature: W K John

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	23	7.7	17	23	28.5	27.5	24	552
Right forearm	23.5	7.8	17	23	28.5	28	24.13	567
Left lower leg	36	12	24.5	31.5	39	34	32.25	1161
Right lower leg	36	12	24.5	32	39.5	34	32.5	1170

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form.xls

Limb Measurement Form

Study: SCI-001

Subject number: 13

Date: November 7, 2007

Data recorder name: Scott Carroll

Data recorder signature: [signature]

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	25	8.3	16.5	20.5	26	27	22.5	563
Right forearm	25	8.3	16.5	20.5	26	27	22.5	563
Left lower leg	36	12	24.5	30.5	37.5	34	31.63	1139
Right lower leg	36	12	24.5	30.5	37.5	34	31.63	1139

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form

Study: SCI-001

Subject number: 14

Date: November 8, 2007

Data recorder name: W.K. Johnson

Data recorder signature: WKJohnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	26	8.7	16.5	17.5	24	26.5	21.13	549
Right forearm	26	8.7	17	18	25	27	21.75	566
Left lower leg	44	14.7	22	26.5	36	34.5	29.75	1309
Right lower leg	44	14.7	22	26	36	34	29.5	1298

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form.xls

Limb Measurement Form

Study: SCI-001

Subject number: 15

Date: November 8, 2007

Data recorder name: W.K. Johnson

Data recorder signature: wk Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	23.5	7.8	15.5	17.5	24	27	21	494
Right forearm	23.5	7.8	15.5	17.5	24.5	27.5	21.25	499
Left lower leg	39	13	22	25	33	31	27.75	1082
Right lower leg	39	13	22	25	33.5	31	27.88	1087

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form

Study: SCI-001

Subject number: 20

Date: November 9, 2007

Data recorder name: W. K. Johnson

Data recorder signature: W K John

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	20	6.7	14.5	18.5	22	24.5	19.88	398
Right forearm	20	6.7	14.5	19	22.5	24.5	20.13	403
Left lower leg	37	12.3	21	29.5	38	33	30.38	1124
Right lower leg	37	12.3	21.5	30	37.5	33.5	30.63	1133

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form.xls

Limb Measurement Form

Study: SCI-001

Subject number: 24

Date: November 7, 2007

Data recorder name: W. K. Johnson

Data recorder signature: WK Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	26	8.7	17	21	26.5	27.5	23	598
Right forearm	26	8.7	17	20.5	26.5	27.5	22.88	595
Left lower leg	42	14	24.5	30	38	33.5	31.5	1323
Right lower leg	42	14	24.5	29.5	38	33.5	31.38	1318

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form

Study: SCI-001

Subject number: 32

Date: November 7, 2007

Data recorder name: W. K. Johnson

Data recorder signature: W K Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	26	8.7	16.5	20.5	25	25.5	21.88	569
Right forearm	26	8.7	16.5	20.5	25	25.5	21.88	569
Left lower leg	44	14.7	24	27	36.5	31	29.63	1304
Right lower leg	44	14.7	24	27	37	31	29.75	1309

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form

Study: SCI-001

Subject number: 37

Date: November 9, 2007

Data recorder name: W. K. Johnson

Data recorder signature: W K Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	25.5	8.5	15	17.5	22	23	19.38	494
Right forearm	25.5	8.5	15	17.5	22.5	23.5	19.63	500
Left lower leg	39	13	21.5	26	32.5	30.5	27.63	1077
Right lower leg	39	13	21.5	26.5	33	30.5	27.88	1087

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form

Study: SCI-001

Subject number: 38

Date: November 7, 2007

Data recorder name: W. K Johnson

Data recorder signature: WK Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	24	8	16	18	24.5	26	21.13	507
Right forearm	24.5	8.2	16	18	24.5	26	21.13	518
Left lower leg	40	13.3	23	27	35	34.5	29.88	1195
Right lower leg	40	13.3	23	27	35	34.5	29.88	1195

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form

Study: SCI-001

Subject number: 39

Date: November 9, 2007

Data recorder name: W. K. Johnson

Data recorder signature: W K Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	25	8.3	14.5	17	20.5	22	18.5	463
Right forearm	25	8.3	15	17	21	22	18.75	469
Left lower leg	38	12.7	21	26	36	32	28.75	1093
Right lower leg	38	12.7	21	26	36	32.5	28.88	1097

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form.xls

Limb Measurement Form

Study: SCI-001

Subject number: 49

Date: November 7, 2007

Data recorder name: W. K. Johnson

Data recorder signature: w k Joh

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	21	7	16	20	25	25.5	21.63	454
Right forearm	21	7	16	20.5	25.5	26	22	462
Left lower leg	35	11.7	23.5	30.5	39	35.5	32.13	1124
Right lower leg	35	11.7	23.5	30.5	38.5	35	31.88	1116

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form

Study: SCI-001

Subject number: 50

Date: November 8, 2007

Data recorder name: W. K. Johnson

Data recorder signature: WK Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	22	7.3	14	16.5	20.5	23	18.5	407
Right forearm	22	7.3	14	16	21	23.5	18.63	410
Left lower leg	34	11.3	22.5	29	34	32	29.38	999
Right lower leg	34	11.3	22.5	29	34	32	29.38	999

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form.xls

Limb Measurement Form

Study: 52

Subject number: SCI - 001

Date: November 9, 2007

Data recorder name: W. K. Johnson

Data recorder signature: WK Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	26	8.7	18.5	23.5	29	29.5	25.13	653
Right forearm	26	8.7	19	24	29.5	30	25.63	666
Left lower leg	32	10.7	23	32.5	41	40	34.13	1092
Right lower leg	32	10.7	23.5	32	41	40.5	34.25	1096

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form

Study: SCI-001

Subject number: 63

Date: November 8, 2007

Data recorder name: W.K. Johnson

Data recorder signature: WK Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	25.5	8.5	17	20.5	28	29.5	23.75	606
Right forearm	25.5	8.5	17.5	20.5	28	30	24	612
Left lower leg	44	14.7	25	31.5	42	37	33.88	1491
Right lower leg	44	14.7	25	31.5	41.5	36.5	33.63	1480

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form

Study: SCI-001

Subject number: 64

Date: November 8, 2007

Data recorder name: W.K. Johnson

Data recorder signature: W K Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	22	7.3	17.5	22.5	29	28	24.25	534
Right forearm	22	7.3	17.5	23	29.5	28	24.5	539
Left lower leg	37	12.3	22.5	28	38	35	30.88	1142
Right lower leg	37	12.3	22.5	28	38	35	30.88	1142

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form.xls

Limb Measurement Form

Study: SCI-001

Subject number: 65

Date: November 7, 2007

Data recorder name: W. K. Johnson

Data recorder signature: W K Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	21	7	14.5	16.5	22	23.5	19.13	402
Right forearm	21	7	14.5	16.5	21.5	23.5	19	399
Left lower leg	38	12.7	21.5	29.5	37	33	30.25	1150
Right lower leg	38	12.7	21.5	29	37	33	30.13	1145

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form

Study: SCI-001

Subject number: 67

Date: November 7, 2007

Data recorder name: W. K. Johnson

Data recorder signature: W K Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	25.5	8.5	15	18	25	25.5	20.88	532
Right forearm	25.5	8.5	15	18.5	25	26	21.13	539
Left lower leg	40	13.3	24	27	36.5	33	30.13	1205
Right lower leg	40	13.3	24	26.5	36.5	33	30	1200

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form

Study: SCI-001

Subject number: 71

Date: November 9, 2007

Data recorder name: W. K. Johnson

Data recorder signature: W K Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	27.5	9.2	19.5	25.5	29.5	30.5	26.25	722
Right forearm	27.5	9.2	19.5	25.5	29	30.5	26.13	718
Left lower leg	42	14	26	35.5	46	41.5	37.25	1565
Right lower leg	42	14	26	35.5	46	41.5	37.25	1565

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form.xls

Limb Measurement Form

Study: SCI-001

Subject number: 74

Date: November 8, 2007

Data recorder name: W.K. Johnson

Data recorder signature: WK Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	25	8.3	18	21	25.5	27	22.88	572
Right forearm	25	8.3	18	21	26	27	23	575
Left lower leg	40	13.3	25	28	36	33	30.5	1220
Right lower leg	40	13.3	25	28.5	36	33	30.63	1225

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Limb Measurement Form

Study: SCI-001

Subject number: 75

Date: November 8, 2007

Data recorder name: W. K. Johnson

Data recorder signature: W K Johnson

Note: all measurements in cm

			Circumference					
Limb	**Length**	**Length/3[1]**	**Lower (A)**	**Lower-mid (B)**	**Upper-mid (C)**	**Upper (D)**	**Mean circumference[2]**	**Surface area[3]**
Left forearm	20	6.7	15	20	23	24	20.5	410
Right forearm	20	6.7	15	19.5	23	23.5	20.25	405
Left lower leg	38	12.7	21	27	38.5	35	30.38	1154
Right lower leg	38	12.7	21	27.5	39	35	30.63	1164

[1] For placing dosimeters in pump spray & aerosol studies. 'B' is 1/3 Length from 'A' (wrist/ankle), 'C' is 1/3 Length from 'B' & 'D' (elbow/knee crease).

[2] Sum of the four circumferences measured per limb, divided by 4.

[3] Product of mean circumference and length

Appendix 3. Treatment Allocation and Dosing

(Note: #63 was an alternate subject, not treated or exposed)

Repellent Application

Study: SCI-001 **Test Location:** Glenn County, California **Date:** November 10, 2007

Subject Name	Subject Number	Sex	Arm	Lower Arm Surface Area (sq cm)	Repellent Applied	Application Rate (mL of Repellent / sq cm of skin)	mL of Repellent Applied	Time of Application
	1	F	L	546	LipoDEET 302	0.00224	1.22	06:30
	7	F	L	484	LipoDEET 302	0.00224	1.08	06:30
	12	M	L	552	LipoDEET 302	0.00224	1.24	06:30
	14	M	L	549	Duranon	0.00189	1.04	06:30
	24	M	L	598	LipoDEET 302	0.00224	1.34	06:30
	37	F	L	494	LipoDEET 302	0.00224	1.11	06:30
	39	F	L	463	Duranon	0.00189	0.88	06:30
	48	M	L	523	Duranon	0.00189	0.99	06:30
	49	F	L	454	LipoDEET 302	0.00224	1.02	06:30
	50	F	L	407	Duranon	0.00189	0.77	06:30
	52	M	L	653	LipoDEET 302	0.00224	1.46	06:30
	53	F	L	468	Duranon	0.00189	0.88	06:30
	59	F	L	441	Duranon	0.00189	0.83	06:30
	63	M	L	606	Untreated	—	–	–
	64	M	L	534	LipoDEET 302	0.00224	1.20	06:30
	65	F	L	402	LipoDEET 302	0.00224	0.90	06:30
	67	M	L	532	Duranon	0.00189	1.01	06:30
	71	M	L	722	LipoDEET 302	0.00224	1.62	06:30
	73	M	L	653	Duranon	0.00189	1.23	06:30
	74	M	L	572	Duranon	0.00189	1.08	06:30
	75	F	L	410	Duranon	0.00189	0.77	06:30
(Control) #1	3	M	L	690	Untreated	-	-	–
(Control) #2	15	M	L	494	Untreated	-	-	–

[illegible]
November 10, 2007

Repellent Application

Study: SCI-001 **Test Location:** Butte County, California **November 11, 2007**

Subject Name	Subject Number	Sex	Arm	Lower Arm Surface Area (sq cm)	Repellent Applied	Application Rate (mL of Repellent / sq cm of skin)	mL of Repellent Applied	Time of Application
	1	F	R	549	Duranon	0.00189	1.04	06:00
	12	M	R	567	Duranon	0.00189	1.07	06:00
	14	M	R	566	LipoDEET 302	0.00224	1.27	06:00
	20	F	R	403	LipoDEET 302	0.00224	0.90	06:00
	24	M	R	595	Duranon	0.00189	1.12	06:00
	32	M	R	569	LipoDEET 302	0.00224	1.27	06:00
	39	F	R	469	LipoDEET 302	0.00224	1.05	06:00
	48	M	R	526	Duranon	0.00189	0.99	06:00
	49	F	R	462	Duranon	0.00189	0.87	06:00
	50	F	R	410	LipoDEET 302	0.00224	0.92	06:00
	52	M	R	666	LipoDEET 302	0.00224	1.49	06:00
	53	F	R	470	Duranon	0.00189	0.89	06:00
	63	M	R	612	untreated	—	—	—
	64	M	R	539	LipoDEET 302	0.00224	1.21	06:00
	65	F	R	399	Duranon	0.00189	0.75	06:00
	66	M	R	495	Duranon	0.00189	0.94	06:00
	67	M	R	539	LipoDEET 302	0.00224	1.21	06:00
	71	M	R	718	Duranon	0.00189	1.36	06:00
	73	M	R	653	Duranon	0.00189	1.23	06:00
	74	M	R	575	LipoDEET 302	0.00224	1.29	06:00
	75	F	R	405	LipoDEET 302	0.00224	0.91	06:00
(Control) #1	3	M	R	690	Untreated	-	-	-
(Control) #2	15	M	R	499	Untreated	-	-	-

W K Johnson
November 11, 2007

Appendix 4. Efficacy

Appendix 4a. Repellency data spreadsheet

Site	Date	Subject	Sex	Product	first exposure	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Glenn Co	Nov 10 2007	1	F	Lipodeet 302	150 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Glenn Co	Nov 10 2007	7	F	Lipodeet 302	150 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Glenn Co	Nov 10 2007	12	M	Lipodeet 302	150 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Glenn Co	Nov 10 2007	24	M	Lipodeet 302	150 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Glenn Co	Nov 10 2007	37	F	Lipodeet 302	150 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Glenn Co	Nov 10 2007	49	F	Lipodeet 302	150 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Glenn Co	Nov 10 2007	52	M	Lipodeet 302	150 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Glenn Co	Nov 10 2007	64	M	Lipodeet 302	150 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Glenn Co	Nov 10 2007	65	F	Lipodeet 302	150 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Glenn Co	Nov 10 2007	71	M	Lipodeet 302	150 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Butte Co	Nov 11 2007	14	M	Lipodeet 302	180 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Butte Co	Nov 11 2007	20	F	Lipodeet 302	180 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Butte Co	Nov 11 2007	32	M	Lipodeet 302	180 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Butte Co	Nov 11 2007	39	F	Lipodeet 302	180 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Butte Co	Nov 11 2007	50	F	Lipodeet 302	180 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Butte Co	Nov 11 2007	52	M	Lipodeet 302	180 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Butte Co	Nov 11 2007	64	M	Lipodeet 302	180 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Butte Co	Nov 11 2007	67	M	Lipodeet 302	180 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Butte Co	Nov 11 2007	74	M	Lipodeet 302	180 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Butte Co	Nov 11 2007	75	F	Lipodeet 302	180 min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

						20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
1						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
24						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
37						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
49						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
64						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
65						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
71						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20						0	0	0	0	0	0	0	0	0	0	0	0	0	2			
32						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
39						0	0	0	0	0	0	0	0	0	0	0	0	0	1	1		
50						0	0	0	0	0	0	0	0	0	0	0	0	0	2			
52						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
64						0	0	0	0	0	0	1	1									
67						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
74						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
75						0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Appendix 4b. Completed repellency data capture forms

Note that these forms show data for all products tested under general protocol SCI-001. The cases pertaining to the present report (SCI-001.4) are given by subject number in Appendices 1 and 3.

Incidence of LIBes at 15 Minute Intervals

Pg. 1 of 2

Study #: SCI-001

Date: November 10, 2007

Application time(s): 06:30

Time of first exposure: 09:00

Data recorder name and signature: W.K. Johnson
W K Johnson

LIBe recording code: 0=none, 1=1

15-min interval

	09:00	09:15	09:30	09:45	10:00	10:15	10:30	10:45	11:00	11:15	11:30	11:45	12:00	12:15	12:30	12:45	13:00	13:15	13:30	13:45	14:00	14:15	14:30	14:45	15:00	15:15	15:30	15:45
Subject #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
59	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
64	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
67	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
71	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
73	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
74	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3 Control 1	1	1	2	1	1	2	2	1	1	2	1	1	1	2	1	1	1	1	1	1	1	1	1	1	2	1	1	1
15 Control 2	0	1	1	0	1	1	1	1	1	1	2	1	2	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1

SCI-001

Incidence of LIBes at 15 Minute Intervals

Study #: SCI-001

Date: November 10, 2007

Application time(s): 06:30

Time of first exposure: 09:00

Data recorder name and signature: W. K. Johnson
WK Johnson

LIBe recording code: 0=none, 1=1

15-min interval

Subject #	29 (16:00)	30 (16:15)	31 (16:30)	32 (16:45)	33 (17:00)	34 (17:15)	35 (17:30)	36 (17:45)	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56
1	0	0	0	0	0	0	0	0																				
7	0	0	0	0	0	0	0	0																				
12	0	0	0	0	0	0	0	0																				
14	0	0	0	0	1	0	0	0																				
24	0	0	0	0	0	0	0	0																				
37	0	0	0	0	0	0	0	0																				
39	0	0	0	0	0	0	0	0																				
48	0	0	0	0	0	0	0	0																				
49	0	0	0	0	0	0	0	0																				
50	0	0	0	0	0	0	0	0																				
52	0	0	0	0	0	0	0	0																				
53	1	0	0	0	0	0	0	0																				
59	0	0	0	0	0	0	0	0																				
64	0	0	0	0	0	0	0	0																				
65	0	0	0	0	0	0	0	0																				
67	0	0	0	0	0	0	0	0																				
71	0	0	0	0	0	0	0	0																				
73	0	0	1	0	0	0	0	0																				
74	0	0	0	0	0	0	0	0																				
75	0	0	0	0	0	0	0	0																				
3 Control 1	0	2	1	2	1	1	2	2																				
15 Control 2	1	1	1	2	1	2	2	1																				

Incidence of LIBes at 15 Minute Intervals

Study #: SCI-001

Date: November 11, 2007

Application time(s): 06:00

Time of first exposure: 09:00

Data recorder name and signature: W. K. Johnson
WK Johnson

LIBe recording code: 0=none, 1=1

15-min interval

Subject #	1 (09:00)	2 (09:15)	3 (09:30)	4 (09:45)	5 (10:00)	6 (10:15)	7 (10:30)	8 (10:45)	9 (11:00)	10 (11:15)	11 (11:30)	12 (11:45)	13 (12:00)	14 (12:15)	15 (12:30)	16 (12:45)	17 (13:00)	18 (13:15)	19 (13:30)	20 (13:45)	21 (14:00)	22 (14:15)	23 (14:30)	24 (14:45)	25 (15:00)	26 (15:15)	27 (15:30)	28 (15:45)
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
32	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
64	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	—
65	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	—	—	—
66	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	—	—
67	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
71	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
73	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
74	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3 control 1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	2	1	1	1	1	1	2	1	1	1	1	1	1
15 control 2	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	2	1	1

Incidence of LIBes at 15 Minute Intervals

Study #: SCI-001

Date: November 11, 2007

Application time(s): 06:00

Time of first exposure: 09:00

Data recorder name and signature: W. K. Johnson
WK Johnson

LIBe recording code: 0=none, 1=1

15-min interval

	16:00	16:15	16:30	16:45	17:00	17:15	17:30	17:45																				
Subject #	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56
1	0	0	0	0	0	0	0	0																				
12	0	0	0	0	2	—	—	—																				
14	0	0	0	0	0	0	0	0																				
20	0	0	0	0	2	—	—	—																				
24	0	1	—	—	—	—	—	—																				
32	0	0	0	0	0	0	0	0																				
39	0	0	0	0	1	1	—	—																				
48	0	0	0	0	0	0	0	0																				
49	0	0	0	0	1	1	—	—																				
50	0	0	0	0	2	—	—	—																				
52	0	0	0	0	0	0	1	0																				
53	0	0	0	0	0	0	0	0																				
64	—	—	—	—	—	—	—	—																				
65	—	—	—	—	—	—	—	—																				
66	—	—	—	—	—	—	—	—																				
67	0	0	0	0	0	0	0	0																				
71	0	0	0	0	0	0	0	0																				
73	1	0	0	0	0	0	0	0																				
74	0	0	0	0	0	0	0	0																				
75	0	0	0	0	0	0	0	0																				
3 control 1	1	1	1	1	1	2	1	1																				
15 control 2	1	1	1	1	2	1	1	1																				

Appendix 5. Environmental records

Carroll-Loye Biological Research

711 Oak Avenue Davis, California 95616 Tel (530) 297-6080 Facsimile x6081

ENVIRONMENTAL CONDITIONS

Study: SCI-001
Date: November 10, 2007
Exact Locale: Howard Slough, Glenn County, California
Observer: W. K. Johnson

Time	Temp°C	% humidity	Wind mph/hr (1 min/av)	Lux	Sky	Other
09:00	14	86	0.7	699 [x10]	cloudy	mist
10:00	14	92	0.0	770 [x10]	cloudy	mist
11:00	15	98	0.1	822 [x10]	cloudy	mist
12:00	14	98	0.4	457 [x10]	cloudy	light rain *
13:00	13	98	0.4	554 [x10]	cloudy	mist
14:00	13	98	1.7	577 [x10]	cloudy	mist
15:00	14	98	0.2	422 [x10]	cloudy	light rain *
16:00	14	98	0.3	292 [x10]	cloudy	mist
17:00	13	98	0.5	11 [x1]	cloudy	mist

Additional comments: * little precipitation under trees

Observer signature: WK Johnson

Carroll-Loye Biological Research

711 Oak Avenue Davis, California 95616 Tel (530) 297-6080 Facsimile x6081

ENVIRONMENTAL CONDITIONS

Study: SCI-001
Date: November 11, 2007
Exact Locale: Gray Lodge, Butte County, California
Observer: W.K. Johnson

Time	Temp°C	% humidity	Wind mph/hr (1 min/av)	Lux	Sky	Other
09:00	19	52	4.4	520 [x100]	Clear	
10:00	20	49	2.1	679 [x100]	Clear	
11:00	22	47	2.7	712 [x100]	Clear	
12:00	23	36	2.0	944 [x100]	Clear	
13:00	23	37	2.2	1333 [x100]	Clear	
14:00	24	39	0.9	1312 [x100]	Clear	
15:00	20	45	1.1	1217 [x100]	Clear	Blustery
16:00	16	58	2.0	69 [x100]	Clear	
17:00	13	72	0.7	544 [x10]	Clear	

Additional comments:

Observer signature: W.K. Johnson

Appendix 6. Mosquito Identifications and Viral Assays

MOSQUITO POOLS SUBMITTED TO UCD 2007

LABORATORY OF SCOTT CARROLL

297-6080
spcarroll@ucdavis.edu

DATE RCVD UCD
11/15/07

DATE TESTED
11/20/07

Mosquito Pools from Scott P Carroll 2007									
							Multiplex RT-PCR		
Research	Pool no	Site	Subject	Date	Species	# in pool	WEE	SLE	WNV
CLBR	1	Glenn 1	3 Cntl	11/10/07	Cu. tarsalis	4	0	0	0
CLBR	2	Glenn 1	None	11/10/07	Ae. melanimon	35	0	0	0
CLBR	3	Glenn 1	None	11/10/07	Am25,Av15,Aincrep3, Asierr1	44	0	0	0
CLBR	4	Glenn 1	73	11/10/07	Ae. melanimon	1	0	0	0
CLBR	5	Glenn 1	14	11/10/07	Ae. melanimon	1	0	0	0
CLBR	6	Glenn 1	53	11/10/07	Ae. melanimon	1	0	0	0
CLBR	7	Glenn 1	15 Cntl	11/10/07	Am27,Av12,Anigro1	40	0	0	0
CLBR	8	Glenn 1	3 Cntl	11/10/07	Am29,Av5	34	0	0	0
CLBR	9	Glenn 1	3 Cntl	11/10/07	Culiseta inornata	5	0	0	0
CLBR	10	Butte 1	None	11/11/07	Ae. melanimon	26	0	0	0
CLBR	11	Butte 1	15 Cntl	11/11/07	Am32,Astich6, Av1	39	0	0	0
CLBR	12	Butte 1	3 Cntl	11/11/07	Am36, Av1	37	0	0	0
CLBR	13	Butte 1	65	11/11/07	Ae. melanimon	2	0	0	0
CLBR	14	Butte 1	66	11/11/07	Ae. melanimon	2	0	0	0
CLBR	15	Butte 1	73	11/11/07	Ae. melanimon	1	0	0	0
CLBR	16	Butte 1	64	11/11/07	A increp, Am	2	0	0	0
CLBR	17	Butte 1	24	11/11/07	Av, Am	2	0	0	0
CLBR	18	Butte 1	12	11/11/07	Ae. melanimon	2	0	0	0
CLBR	19	Butte 1	49	11/11/07	Ae. melanimon	2	0	0	0
CLBR	20	Butte 1	50	11/11/07	Ae. melanimon	2	0	0	0
CLBR	21	Butte 1	52	11/11/07	Ae. melanimon	1	0	0	0
CLBR	22	Butte 1	3 Cntl	11/11/07	Cu. pipiens	3	0	0	0

Appendix 7. Study Protocol SCI-001 and Informed Consent

Appendix 7a. Protocol SCI-001

Carroll-Loye Biological Research

711 Oak Avenue Davis, California 95616 Tel (530)297-6080 http://www.carroll-loye.com/

COVER PAGE

EFFICACY TEST PROTOCOL SCI-001

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TEST OF PERSONAL INSECT REPELLENTS

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Informed Consent documentation
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EFFICACY TEST PROTOCOL SCI-001

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1 TITLE: TEST OF PERSONAL INSECT REPELLENTS

2 PROTOCOL NUMBER:

SCI–001

3 SPONSOR:

Scientific Coordination, Inc.

3.1 Address:

4629 Cherry Valley Drive
Rockville, MD 20853

4 PROTOCOL OBJECTIVE:

4.1 Type of Protocol:

This protocol will indicate the specific methods to be used and direct the conduct of the Study SCI–001. The study will be conducted in the laboratory at the letterhead address and at locales in nature with mosquitoes.

5 STUDY OBJECTIVE, RATIONALE AND STANDARDS:

5.1 Objective of Research:

The objectives of this study are to test the mosquito repellent efficacy characteristics of the Test Materials, compare them to one another, and contrast the with a comparison article that is the US Military issue topical insect repellent. Note that efficacy will be measured as Complete Protection Time. Complete Protection Time, or CPT, is defined herein as the time between application of Test Material and the First Confirmed 'Lite with Intent to Bite.' A 'Lite with Intent to Bite', or 'LIBe', occurs when a mosquito alights on the treated test skin of a subject and extends its proboscis to the skin surface while ceasing locomotion. A 'First Confirmed LIBe' is that which is followed by another within 30 minutes. This work conducted pursuant to this protocol will be initiated by determining the amount of each of the repellents that subjects typically apply. Dosimetry will consist of a behavioral assay.

5.2 Rationale and Main Endpoint:

This study will test the efficacy of new formulations of DEET (N, N-diethyl-m-toluamide) that are intended to increase cosmetic quality for better user acceptance. US/EPA requires new repellent formulations to be registered, and some registrants must present efficacy data as part of the registration review. The rationale for this study is to provide those efficacy data, which have not been previously collected. DEET has been used worldwide for decades, but continued consumer concerns about it attributes, including poor cosmetic quality, appear to have limited its use even in situations in which its public health value is clear. Thus there is potential public value from the development and registration of more acceptably, DEET-based repellents.

Stability of the end-products will be tested in a different study.

The main endpoint of this study will be the conclusion of a mosquito repellent efficacy field test of three novel DEET-based topical repellent formulations, with the data set suitable for submission to US EPA for insect repellent registration purposes. The efficacy study will consist of two field trials. In each trial, each formulation, including the comparison article, will be tested by ten subjects, with two untreated control subjects. Initial dosage

determination ('dosimetry') will also be conducted with a total of 10 subjects per formulation, some of whom may then go on to participate in efficacy testing. Dosimetry will be conducted at the letterhead address. When 10 subjects have completed dosimetry for each formulation, including the comparison article, those data will be used to determine dosing for the efficacy testing.

5.3 Rationale for use of Human Subjects:

Human subjects are required because they represent the target system for the test materials, and sufficiently reliable models for repellency testing have not been developed. In addition, subjects will self-administer the test articles during dose determination. Ten subjects are required in order to reduce variation around the population means we will describe. The low toxicity of the test materials should mean that there is little incremental risk associated with increasing sample size.

5.4 Balance of Risks and Benefits:

The study-associated risks are of three types: exposure to the test materials themselves, exposure to biting arthropods, and possible exposure to vectors of arthropod-borne diseases. As described below, subject health and safety are unlikely to be impacted by any study-associated risks during or after the study.

The repellent active ingredient has a low acute and chronic risk profile, established both through experimentation and through long-term consumer use. The concentrations of the active ingredient in the product being tested are lower than those of many products currently EPA-registered and marketed in the US. Subjects with known allergic reactions to insect repellents and common cosmetics are excluded from participating. 'Repeat' exposures during dosimetry are all brief before the repellent is washed off, and likely total a much shorter duration of exposure than would a typical single consumer application. Risks associated with inhalation and ingestion would require gross intentional mishandling by subjects, a scenario that the study methods do not promote.

The risk of a skin reaction to a mosquito bite is reduced by excluding candidate subjects who are aware of having a history of such reaction. In addition, subjects will be trained to quickly remove any mosquitoes that attempt to bite them, before penetration or injection of saliva if possible. Moreover, a stopping rule instructs subjects to cover any treated skin immediately if more than one mosquito attempts to bite during any exposure period. Subjects will be exposing small areas of treated skin for only 4 minutes per hour. Other parts of the body will be protected with provided fabric. Subjects will be teamed with a partner for joint observation and experienced technical personnel will be present at all times to assist.

The US Centers for Disease Control estimates that about 1-in-5 people who become infected with West Nile virus will develop West Nile fever. Subjects are instructed to be alert for any flu-like symptoms (unusual tiredness or unusually severe headaches, body aches, fever, or a rash on the trunk of the body) for up to two weeks after the test. About 1-in-150 infected people will develop more serious symptoms, which will be described to the subjects. Most people (about 4 out of 5) who are infected with West Nile virus will not develop any type of illness.

In addition, the techniques employed to minimize exposure to mosquitoes and mosquito bites render the possibility of contracting a disease carried by mosquitoes very low. Field tests are being conducted in an area where such viruses have not been detected by county and state health or vector/mosquito control agencies for at least a month, so the risk is probably low that any individual mosquito present carries a disease. In each trial, only two experienced, qualified subjects (qualification criteria described in §9.1) will expose untreated limbs to monitor biting pressure, at the same infrequent, brief intervals as treated subjects, and with multiple assistants to remove any mosquitoes that lite with intent to bite.

In summary, the combination of technical precautions and natural factors means that the chances that any subject will contract West Nile fever or another disease from a mosquito bite are probably extremely small. There is probably no more risk to subjects than they would experience when engaged in normal outdoor activities

in a similar rural area at the same time of year. If at anytime during the study a subject suffers a skin reaction or feels ill, he or she is instructed to inform the Study Director (i.e., the 'Principal Investigator'), or anyone else who is also working to direct the study). Such subjects will be immediately withdrawn from testing and medical management will be implemented (§9.5). Subjects may also request access to standard first aid materials (such as bandages, antiseptics, and mild topical and oral antihistamines) and request qualified first aid assistance at any time. Epi-Pens will also be on-site in case of Type 1 (anaphylactic) allergic reaction. At least one qualified researcher will remain with the other test subjects if other researchers depart with an injured or ill subject. Subjects are clearly and repeatedly informed that they may remove themselves for any reason from the study at anytime, without penalty to their compensation.

Against the slight risks are balanced substantial and reasonably likely benefits. Insect-borne disease is of growing significance in the United States and around the world where U.S. citizens are active. Discomfort associated with nuisance biting restricts many work and pleasure activities. DEET-based repellents have been the only reliable personal protection for many decades. However, health, comfort and practical concerns about DEET have created a niche for new formulations with better consumer acceptance. Because EPA registration requires efficacy data, a test such as this one is the only path toward further product development and greater availability of superior DEET products to consumers in the United States. In addition, the US Military is seeking improved DEET formulations, and is limited in its consideration to EPA-registered products.

5.5 Standards Applied:

U. S. EPA Good Laboratory Practice Regulations (40 CFR 160); 40 CFR 26 subparts K and L; FIFRA § 12(a)(2)(P); California State EPA Department of Pesticide Regulation study monitoring (California Code of Regulations Title 3, Section 6710).

6 INVESTIGATIONAL AND TEST MATERIAL CONTROL:

6.1 Test Substance:

6.1.1 Description of the Test Materials

1. EPA Reg. # 82810-1- LipoDEET
   This is a 30% DEET formulation contained in cosmetic lipid spheres that inhibit evaporation to prolong duration of efficacy, improve feel, reduce plasticizing and reduce odor.
2. EPA Reg. # 50404-8- Coulston's Duranon Insect Repellent
   This is a controlled-release, low-odor formulation of 20% DEET.
3. EPA Reg. # 54287-8 - Associated Registrations - Insect Guard II
   This is a functionally synergistic formulation of 17.5% DEET synergized by N-octyl bicycloheptane dicarboximide (5%) and complemented by Di-n-propyl isocinchomeronate (2.5%) to repel flies.
4. EPA Reg. # 58007-1- 3M Ultrathon- 34.34% DEET.
   This polymer based lotion extends efficacy and reduces plasticizing caused by DEET. This is the comparison article and is the insect repellent used by the US Armed Forces.

Test Materials 1-3 are EPA registered insect repellents. Details of the test formulations are appended.

6.1.2 Trade Name:

TBD

6.1.3 Dosage Form:

Lotions applied to the skin.

6.1.4 Dose:

Determining dosage is a main objective of this study.

Dosage for repellency testing will be the mean of the subject means determined for each product in the dosimetry portion of this study. Dosage will be measured in weight and reported by weight and volume.

6.1.5 Manufacturing Site:

TBA

6.1.6 Test Material Storage During Study:

Prior to application, test materials will be stored indoors, at room temperature and away from direct sunlight or direct sources of moisture. Storage will be at Carroll-Loye Biological Research.

6.1.7 Test Material Safety:

EPA regulates use of inert ingredients (also termed “other” ingredients) by toxicology profiles in animal tests and by their inclusion in EPA lists of “approved” other ingredients. Ingredients on lists 4a or 4b are considered relatively safe for all uses. The ingredients in the proposed insect repellent formulations are mainly on lists 4a or 4b with a few ingredients on list 3 because of ocular irritation potential. EPA normally regulates the presence of materials on list 3 by labeling to avoid contact with eyes and to prohibit application by children. The other ingredients in the test formulations are commonly used in marketed products for application to human skin as components of cosmetic and drug formulations.

The insect repellent products proposed for testing have all been tested in animals for potential oral and dermal toxicity. The DEET active ingredient has an extensive toxicity data file, has been re-registered by EPA, and has a positive safety record in consumer use for nearly 50 years.

MSDS documentation is appended.

6.1.8 Test Material Composition and Stability:

The Test Material formulations are typical of topical cosmetics and insect repellent products marketed to consumers. They are produced under Good Manufacturing Practices (GMPs) with records available to EPA. They will be couriered to Carroll-Loye Biological Research, with Chain-of-Custody documented. After that time they will be stored at the Carroll-Loye Offices in a closed cabinet at room temperature (20-24°C). The composition and content of active ingredients in the products used for the proposed efficacy studies will be confirmed by analytical methods prior to and following human subject efficacy testing. Storage stability testing will also be conducted. The EPA has extensive experience with enforcing requirements for such tests based upon their history with similar products applied to humans and Scientific Coordination, Inc. intends to provide any requested information as appropriate to safety and efficacy issues.

6.2. Negative Control:

6.2.1 Description of the Negative Control

The negative control is untreated for both dosimetry and repellency assays.

6.2.2 Rationale for Employing a Negative Control

Repellent efficacy can only be measured in the presence of biting mosquitoes. In addition, the duration of repellency recorded is likely a function of the number of host-seeking mosquitoes active during the study. The US/EPA uses a standard minimum rate of mosquito attack on untreated subjects to insure that the repellents under study are sufficiently challenged to provide meaningful data. Traditionally, the measure rate is termed the ‘ambient biting

pressure'. We adopt that value, but use LIBes ('Lites with Intent to Bite') rather than bites. A mean study LIBe rate of ≥ 1 LIBe per untreated (negative control) lower leg or lower arm per 1 minute is required.

We take several precautions to minimize the probability that untreated control subjects receive any bites (see §§ 5.4, 8.2, 8.3.1, 8.4.1, 10.3.6). Recognizing that individual subjects differ in their inherent attractiveness to mosquitoes, US/EPA science reviewers have recommended that we use two untreated control subjects for this study in order to improve the likelihood of sampling ambient biting pressure in a representative fashion, while still exposing a very small number of untreated subjects to risks from foraging mosquitoes. Having separate untreated subjects also avoids the problem of interaction between treated and untreated limbs that may arise when subjects serve as their own simultaneous controls. In reviewing a similar protocol in May 2006, the California Department of Pesticide Regulation initially requested use of a single negative control, but compromised at two such subjects based on the position of the US/EPA. The prospect of receiving approval to use more untreated control subjects is probably small in this case.

There is no control in which each formulation matrix without the repellent active is tested. There is no a priori basis for anticipating significant repellent activity in the matrices, and the study objective is to examine efficacy of the end products. The question of whether there is interaction between matrix and active is external to that objective. Accordingly, the added risk of including additional subjects testing matrix-only formulations cannot be justified.

6.3 Comparison Article:

6.3.1 Description of the Comparison Article:

The Comparison Article is 3M Ultrathon. This is a 34.34% DEET insect repellent polymerized to reduce the rate of evaporation and thus extend duration of efficacy. It is the chief repellent used by the US Armed Forces.

6.3.2 Rationale for Employing a Comparison Article:

The US Armed forces have used Ultrathon as the principle insect repellent for deployed warfighters for almost two decades. Because of that, it is commonly regarded as the most effective insect repellent available. Yet for reasons similar to those experienced by other consumers, the military is actively seeking alternatives. These reasons include lack of cosmetic acceptance and problems with melting plastics. Because the DEET-based products to be tested under this protocol are expected to be superior to Ultrathon in these auxiliary performance categories, yet show excellent repellent efficacy, their repellency is most appropriately directly compared to Ultrathon. Indeed, the military is considering new DEET formulations for adoption, but will require efficacy comparisons in order to make further decisions.

6.4 Test Arthropod Species:

Testing will be conducted with all or some of wild *Aedes vexans*, *Aedes melanimon, Aedes taeniorhynchus, Culex tarsalis* and *Culex pipiens* mosquitoes, and possibly other mosquito species that occur in the same habitats. Mosquito specimens will be collected from untreated control subjects, and from the protective clothing of all subjects, during testing and identified in the laboratory using taxonomic keys and stereomicroscopy in the laboratory.

7 STUDY SCHEDULE:

7.1 Proposed Date of Initiation:

TBD, within one year of IRB approval.

7.2 Schedule of Events:

Test day	Date	Activities
-30– -2	TBD	Begin subject recruitment. Introduce subjects to test plan and procedures; explain compensation; review subject rights and consent forms; option to sign consent forms in order to participate; measure limb surface areas; determine individual dosage values.
1	TBD	Prepare individual dosages for application. Meet with subjects to review day plan and safety procedures. Travel to field site. Review safety and data collection procedures. Administer repellent, commence repellency data collection. Monitor subject safety, comfort, comportment, compliance with data collection protocol.

7.3 Proposed Date of Completion:

Experimental Completion Date (Test Day 1): TBD.
Final Report Completion Date: TBD.

8 STUDY DESIGN:

8.1 Treatment Groups:

For efficacy testing, there are three experimental groups, namely 1) a 'treated' group of subjects treated with the test products, of which there are three formulations, 2) comparison article group testing Ultrathon, and 3) an untreated ('negative') control group. The dosimetry study is an examination of dosing behavior. Hence, for dosimetry, all subjects are treated, and there is not an untreated control group.

8.2 Experimental Design:

The experiment will be treated as a partially randomized, experimenter and subject-blinded trial. However, control subjects will be chosen only from among individuals that are experienced in field biology or entomology. Whether arms, legs or both are tested at a given site will depend on the species of mosquitoes present and their behavior. That decision will be made by the Study Director based on visits to the field sites prior to data collection.

8.3 Randomization Procedures for Repellent Efficacy Testing:

8.3.1 Allocation of subjects to treatment groups:

Subjects will be assigned to the treatment (but not negative control) groups on the basis of a randomly assigned subject number. Subjects will be assigned a treatment based on their subject number and the treatment allocation table, which follows. Treatments will be balanced between arms and legs if both limbs are used. Negative control subjects will be selected exclusively from among experienced personnel. To be regarded as experienced personnel, a candidate subject must have an undergraduate (or higher) degree in life sciences, of be a vector control professional, or have participated in at least 5 Carroll-Loye repellent efficacy studies. In addition, that person must meet all of the other participation criteria listed in §§9.1.1.1 and 9.1.1.2.

8.3.2 Treatment allocation table:

Materials will be distributed among subjects as tabulated below. Two additional personnel will monitor ambient biting pressure with untreated limbs during in the test.

Subject	LipoDeet	Duranon	Bug Guard	Ultrathon
1	Left limb			
2	Right limb			
3	Left limb			
4	Right limb			

5	Left limb			
6	Right limb			
7	Left limb			
8	Right limb			
9	Left limb			
10	Right limb			
11		Left limb		
12		Right limb		
13		Left limb		
14		Right limb		
15		Left limb		
16		Right limb		
17		Left limb		
18		Right limb		
19		Left limb		
20		Right limb		
21			Left limb	
22			Right limb	
23			Left limb	
24			Right limb	
25			Left limb	
26			Right limb	
27			Left limb	
28			Right limb	
29			Left limb	
30			Right limb	
31				Left limb
32				Right limb
33				Left limb
34				Right limb
35				Left limb
36				Right limb
37				Left limb
38				Right limb
39				Left limb
40				Right limb

8.4. Conditional Boundaries or Limits of Study

8.4.1. Ambient 'Lite with intent to bite' Pressure:

A mean study LIBe ('Lite with Intent to Bite') rate of ≥ 1 LIBe per untreated (negative control) lower leg or lower arm per 1 minute is required. No more than 10% '0' values for individual exposure periods are permitted. Ambient LIBe pressure is measured from continuous exposure during 1-minute exposure periods commencing once every 15 minutes, beginning at the onset of data collection. Negative

control subjects are attended by two assistants who use mechanical aspirators to remove all mosquitoes that LIBe before biting commences.

8.5. Monitoring of Environmental Conditions During the Study

Records will be made of environmental conditions (temperature, relative humidity, wind speed, light intensity and precipitation (presence/absence and general rate/quality) at approximately one-hour intervals throughout the course of the field trial.

9 STUDY PROCEDURES:

9.1 Test Subjects:

9.1.1 Inclusion criteria, all subjects:

9.1.1.1	Age:	18-55 years
9.1.1.2	Sex:	Male/female
9.1.1.3	Race:	Any race
9.1.1.4	Written consent: (see 9.4, below)	
9.1.1.5	Language:	Speak and read English

9.1.2. Inclusion criteria specific to the two untreated subjects

9.1.2.1 To qualify for candidacy as a subject who exposes untreated skin, an individual must be regarded as competent to do so by the Principal Investigator, must have participated in at least five prior Carroll-Loye repellent efficacy trials, or have participated in at least three such trials and have at least two years of experience as a college life sciences major, or be professionally employed in vector control services.

9.1.3 Exclusion criteria, all subjects:

9.1.3.1 Known to be hypersensitive to mosquito bites or exhibiting hypersensitivity during test

9.1.3.2 Known to be sensitive or showing sensitivity to any of the test product ingredients, including DEET, after application.

9.1.3.3 Poor physical condition.

9.1.3.4 Unwilling to submit to brief query about personal condition.

9.1.3.5 Use of insect repellent within one day preceding the study.

9.1.3.6 Unwilling to refrain from use of perfumed products, alcoholic beverages or smoking after 9 PM the evening preceding the test and throughout the test.

9.1.3.7 Known to be pregnant or lactating. Pregnancy will be self-checked by each female volunteer on the morning of the repellent test using an OTC test kit provided by the Study Director. Results of each such test will be immediately verified by direct inspection by a female technician trained to make that assessment. Only volunteers scored as nonpregnant will be allowed to participate.

9.1.3.8 Inability to deliver the test materials to own left and right limbs.

9.1.3.9 Student or employee of the Study Director.

9.1.3.10 Do not regularly spend time in outdoor settings.

9.1.4 Number of Subjects and Rationale for Sample Sizes:

In efficacy testing, we will use 10 subjects per treatment and 2 untreated control subjects per field trial. Each subject is a replicate. In the dosimetry portion of the study, 10 subjects will be engaged to apply each repellent, including the comparison article.

The number of subjects is chosen as a compromise between several conflicting factors. In the absence of clear means of estimating the distribution of outcome values, it is difficult to predict an ideal sample size. From a strictly scientific standpoint an appropriate response under such

circumstances is to increase size, but ethical and economic considerations demand the opposite in the present study, particularly during the repellency phase.

The US/EPA has historically required a minimum of six subjects. Given that test repellents are nearly certain to exhibit greater than zero efficacy, and that testing is conducted under adequate ambient biting pressure, it is nearly certain that no untreated subjects will register fewer or later LIBes than any treated subjects. As a result, from the standpoint of statistical power, six treated and one untreated subject are sufficient to demonstrate a significant treatment effect at $P<0.05$. In the same vein, six is often regarded as a statistically sufficient sample for an observation subset because the increment in the confidence of means estimate begins to drop off sharply at that point. Notably, under the historical guidelines, there seem to have been few problems with EPA registering repellents that commonly fail to meet their labeled performance specification.

The main scientific risk of using a very small sample is that the probability of over-representing subjects inherently unattractive to mosquitoes is rather large. Note, however, that for US/EPA registration purposes, the test for mosquito repellency is conducted twice, once in each of two ecologically different habitats. In our experience, the subjects in one test normally do not participate in the other (due to large geographic distances between sites). In addition, two negative controls are used for a more robust baseline comparison. Those facts decrease the probability of such sampling error substantially.

However, further considerations indicate that a somewhat larger sample would be superior. Note that the draft EPA guidelines state that the response variable, ‘Time to First Confirmed Bite’ (or LIBe in this study) is calculated as the average duration for all treated subjects. There is no consideration of variation. In any given study, increasing the number of treated subjects to 10 will improve the probability of estimating the population mean accurately.

The 95% confidence interval computation is useful for assessing the certainty of a means estimate, and for normal probability density function that interval is ±1.96 standard error of the mean. The normal density function is part of the exponential family of density functions, and in this study we anticipate that the distribution of Times to First Confirmed LIBe will be truncated toward the origin. However, available mean and variance data on efficacy (e.g., Carroll, S., 2006, In Debboun et al. (eds.), *Insect Repellents*, CRC Press) indicate that no individual values will be near zero. Using the rule of thumb that a distribution in which the mean is greater than three standard deviations above zero may be regarded as effectively normal, it is sensible to compute and report the normal 95% confidence interval in this study.

Employing eight subjects in a cage test, Cilek et al. (J. Amer. Mosq. Control Assoc. 20: 299-304, 2004) recorded a mean protection time of approximately 180 minutes, with a standard error of about 15 minutes. Had their N been six, we can roughly predict that the 95% CI would be 148-212. At N=10, the estimate would be 155-205. At N= 20, the interval would be roughly 162-198. Evidently, adding the additional 10 subjects to reach an N of 20 shrinks the interval, in absolute terms, no more than did the addition of four subjects to increase the sample size from 6 to 10.

To summarize, adding subjects beyond six increases the precision of the means estimate only slowly. However, the individual and public health importance of avoiding inaccuracy in this study, coupled with the fact that data collection is only ‘replicated’ once (in a different habitat at that), argues for a prudent approach. To reduce the risk of over-representing atypically attractive subjects, as well the weight of the value obtained from any one subject, we regard 10 (rather than six) treated subjects as a better sample size for the repellency portion of the study.

9.1.5 Test Subject Recruitment:

9.1.5.1 Synopsis of Recruitment Process:

i) Source(s): Participants are recruited by verbal networking through our academic and personal communities of friends, neighbors and scientists in Davis, California. Individuals are recruited from the community specifically for each study. Studies are not conducted with individuals from particular employers or agencies. Those who will serve as untreated control subjects are limited to experienced technical personnel, who are screened with the same exclusion criteria as are other subjects, and have additional inclusion requirement.
ii) Initial Contact Method: Initial contact is through word-of-mouth and telephone contact with individuals in our Volunteer Data Base.
iii) Follow up Contact Method: Telephone interview, personal interview with the Study Director conducted at the Carroll-Loye Biological Research Offices.

9.1.5.2 Methods of Recruitment:

Our subjects are mainly University of California–Davis graduate and undergraduate students in life science programs with which the Principal Investigator is associated. Students in his laboratory who depend on him directly for employment or scholastically are not eligible to participate. Other subjects are science, education and health care professionals, and mosquito and vector control professionals.

We contact subjects who participated in previous Carroll-Loye repellent efficacy tests by selecting them from our Volunteer Database. At that time, interested individuals often ask if one or more of their lab mates or acquaintances may participate as well. All such potential participants are screened or re-screened for suitability for each test in a private, one-on-one conversation held at the office of the Study Director. The Exclusion Criteria (section 9.1.2) are exercised by asking each candidate to address them in the interview with the Study Director. It is explained that

pregnancy will be assessed directly on the test day. The Study Director encourages candidates to ask questions and ask for clarification at any time during the interview and in all activities that follow. To candidates that pass screening the Study Director describes the test purpose in plain language (in English), and the procedures and comportment to be followed are described in detail. Candidates are then asked if they would like to retire from consideration at that point. If they wish to remain in consideration, it is explained and emphasized that they may withdraw from the test at any time during the test without penalty to their compensation. This freedom is especially re-emphasized in cases in which considerable effort or expense has been required to include a subject (e.g., air travel to a distant site), to discourage the conception that that effort or expense creates any added obligation in the subject.

Candidates are given copies of the State of California Department of Pesticide Regulation 'Experimental Subjects' Bill of Rights' (Appendix 4) to read as the Study Director reads it aloud. They are also given a copy of the IRB-approved consent form to read as the Study Director reads it aloud. The amount and form of compensation is described. They are again encouraged to ask any questions they have about the test, which may include understanding its purpose more fully, understanding risks and discomforts more fully, and understanding treatment and compensation for injury more fully. While the majority of our subjects have worked with us on an occasional basis for a number of years, we encourage them to personally evaluate their interests and concerns about participation seriously each time. We ask them not to sign on immediately but to give the situation due consideration (normally at least one day, sometimes less for those who have participated in multiple prior studies). Because most of the volunteers are researchers and/or have advanced degrees in life sciences, we regard their motivations and decisions to participate as being unusually well considered and well informed. Accordingly, we normally accept their decisions to participate if they so choose following due consideration. Nonetheless, the Study

Director retains the final right to refuse participation to any candidate.

9.1.6 Identification method and records retention:

Subjects will initially be identified by first and last name, and assigned a unique number for purposes of this study. Individual data will be entered into the computer for retention and analysis with reference to individual number, not name. Records relating individual names to individual numbers will be retained separately. The Study Director will retain records indefinitely. Subjects may obtain their own records from the Study Director.

9.1.7 Enrollment of alternate subjects and its relation to individual privacy:

We will enroll three more subjects than are required to meet our sample size. All subjects will be informed during the Consent process that on the day of testing, a small number of subjects may be designated as alternates and sent away after being compensated for coming to the test site. Alternate subjects may return later to replace subjects that initiate testing but withdraw before useful data are generated. They also serve as insurance against any enrolled subjects who fail to appear.

The possibility that any subject may be designated as an alternate will assist in protecting the privacy of any subject that must withdraw in or near the presence of other subjects at the start of the test day (i.e., before treatment and testing begins), for reasons such as a positive pregnancy test result, or for any other personal circumstance to which possibly inappropriate attention might otherwise more readily be drawn. In the case of privacy concerns related to pregnancy detection, we regard this “indirect” approach as potentially as discrete and less likely to result in errors that would be the case if we were to employ, e.g., separate male and female Informed Consent Forms, with pregnancy only mentioned on the female form. The latter approach does not address loss of privacy among females, nor does it control the possibility of indiscrete revelation of pregnancy testing by females to males during the test or later,

and it also creates the risk of a female subject using the wrong form. Separate forms would also assume that we may fairly treat individual subjects unequally on the basis of postulated gender-based differences in the information the merit receiving in to arrive at their informed consent decision. The soundness of making such an assumption enters ethically complex grounds requiring an intricacy of analysis and breadth of treatment beyond the scope appropriate to the privacy concerns of the present study.

9.2 Blinding of Study:

9.2.1. Extent of the Blinding:

The types of Test Materials and their identities will be evident to subjects as they apply them during the dosimetry portion of the study. During the repellency portion of the study, subjects will be blinded to the exact treatments they receive although some may note differences between the lotions and the clear liquids in the repellency potion of the study. The Study Director will be blinded to the identity of individual treatments until the conclusion of data evaluation.

9.2.2 Blinding Methods:

The Test Materials as well as the Dosing & Administration and Data Capture forms will be coded by a researcher with respect to treatment, so that subjects and personnel recording data will not be aware of the treatments for which they are reporting. The Study Director will access the codes to identify the Test Materials in the Study Report after completing the data analysis.

9.3. Study Material Administration:

Study Materials will be administered to each subject by Carroll-Loye technicians. Test products will be applied volumetrically to the skin surface from a tuberculin (1 ml) syringe, and spread on the site as evenly as possible with two fingertips in a surgical glove,

using a light rubbing motion. Skin surfaces to be treated are first cleansed with water and a fragrance free detergent soap, rinsed with a 50% ethanol in water solution, and then towel dried.

9.4 Subject Consent:

Written subject consent is an inclusion criterion.

9.5 Stop Rule and Medical Management:

Specific adverse reactions in subjects to the test materials are not anticipated based on low acute and chronic toxicity, as well as the research design to minimize exposures, and the training of subjects to aspirate landing mosquitoes before they probe or bite. Because the products are topical, technical personnel will monitor, and subjects will self-monitor, for allergic and irritant skin reactions, particularly redness, edema, itching or pain, and report any such reactions to the Study Director. Any subject showing adverse skin reactions will immediately stop further participation. The treated skin will be gently washed with clean water and mild soap to remove the test product, and the area will be gently dried with a clean towel. The subject will be removed from further exposure to mosquitoes.

On the day of testing, a physician who has read the protocol and discussed the research with the Study Director will be on call. In unlikely event of a Type 1 allergic reaction (anaphylaxis), we will contact 9-1-1 by cellular or satellite telephone and cooperate as instructed with emergency personnel. We will be prepared to instruct emergency personnel on how to reach our site via multiple routes. In addition, we will personally transport affected persons to the nearest hospital if so advised by emergency personnel. There is sufficient redundancy in personnel that in such a case subjects remaining at the study site will still receive appropriate technical, scientific and safety guidance.

All subjects are asked to contact the Study Director and a physician of their own choice at any time should they develop a

rash (a delayed hypersensitivity reaction) within 48 hours of the conclusion of the test day.

The risk of mosquito-associated health risks is likewise regarded as very low due to the complementary precautions outlined herein. However, the Study Director will assess skin condition of affected subjects should any bites inadvertently occur during efficacy testing. In addition, subjects will be asked to make contact with Study Director at any time should they have health concerns relating to their participation in the efficacy testing.

As part of Medical Management, the Study Director will record all benign and adverse health observations.

9.6 Subject training for research with mosquitoes

Approximately one week to four days before repellent efficacy testing, subjects will be trained by technical personnel in handling mechanical aspirators and observing mosquitoes in the laboratory. Subjects will be shown how to turn on and manipulate the aspirator to capture mosquitoes by a technician who first demonstrates the following procedure, which subjects then emulate: Two laboratory-reared, disease-free female mosquitoes are released in a cage. A small area (less than one-half) of the forearm is uncovered and exposed in the cage, with no insect repellent applied. Subjects will learn how to watch approach and land on the arm, how to detect a mosquito's intention to bite, and how to quickly remove LIBing mosquitoes with the aspirator. A technician will be present to instruct and guide throughout; mosquitoes will not be exposed to more than one subject before being destroyed. This training will be documented. This 'hands-on' experience will assist subjects in collecting data accurately and handling mosquitoes safely during the repellent efficacy trial.

10 TEST VARIABLES AND THEIR MEASUREMENT:

10.1 Variables to be Measured:

Subject forearm and lower leg surface area.
Subject self-dosing behaviors.

Weight of test materials delivered to the surrogate skin (gauze) dosimeters.
Number of mosquito lites with intent to bite (LIBes) on the treated surface.

10.2 When Variable will be Assessed:

Dosage will be calculated on the basis of surface area of the lower limb skin that is treated. Measurements to calculate that surface area will be made on each subject in advance of application of the test materials.

Self-dosing behavior will be measured prior to Test Day 1.

In efficacy testing, subjects will record any 'lites with intent to bite' (LIBes) as they occur. Data are recorded in one-minute exposures at 15 minute intervals. The time at which the application of a treatment is completed is recorded as t_0 ('time zero'). The time between application of test materials and the initiation of exposure will be measured. Subjects will practice removing mosquitoes exhibiting LIBes before the field test.

10.3 Procedures for Assessing Variable:

10.3.1 Limb dimensions and surface area:

The term 'limb' refers to the forearm and the lower leg. The surface area of each limb is computed as the average of four evenly spaced circumferences (two peripheral, two central) of the forearm (elbow to wrist) or lower leg (back of knee to ankle) multiplied by the length of treatment area.

10.3.4. Dosimetry

The amount of lotion applied to limbs will be quantified in a series of three applications for each repellent. The amount applied is the weight difference in the dispensing tube before and after application.

The instructions are as follows:

"Put a new surgical glove on each hand. You will apply lotion to one arm only. The technician will tell you to which arm to apply. You will begin with an amount that you suppose is about one half of what you will need to achieve thorough and uniform coverage. After spreading that around the lower part of your arm, you will apply more as needed to the area closer to your elbow. Begin by gently squeezing lotion from a tube with the cap open directly onto the horizontally-held surface of the opposite arm. Hand the tube to the technician. Using the tips of the index and middle fingers, spread the lotion as evenly as possible on all surfaces of the lower arm. Do not spread it onto the hand. If you have sufficient lotion remaining, spread it evenly and thoroughly toward the elbow. Do not spread it beyond the elbow. If you need more lotion to achieve thorough and even coverage, make sure you have wiped all repellent from your fingertips onto the skin and ask the technician to hand you the tube. Apply as much additional as you think you need, as before, but to complete the coverage. If you decide that you have applied more repellent that you would normally use to achieve thorough and even coverage, immediately have the technician wash and dry the treated arm so that none of the repellent you have applied is visible on close inspection, and begin again. Likewise, be careful to avoid dropping any lotion off of the arm, and if this happens, begin again as you would if you applied too much.

After you have completed an application successfully, the technician will instruct you to wash and dry the treated arm so that none of the repellent you have applied is visible on close inspection, and reweigh the tube. You will continue until you have completed three successful applications to the arm. Then you will repeat the entire procedure above, but with a lower leg. You will complete this sequence of three arm applications, and three leg applications for each of the repellents being studied. For each repellent you will begin with a practice application to familiarize yourself with how it comes out of the tube, and how it covers and spreads on the skin."

10.3.5 Equipment Used to Assess the Dosimetry Variable:

Test material containers will be weighed before and after dispensing on a traceably calibrated Sartorius GC 2502 (measurement increment 0.001 g, 500 g capacity).

10.3.6. Repellency and LIBes:

Repellency is assessed in the field. Preparatory training of the subjects to recognize and remove mosquitoes that lite with intent to bite contributes to subject safety. Subject safety is also enhanced by brief periods of exposure at intervals. as well as careful dosing and application.

Subjects will have approximately one hour of training and practicing observing foraging mosquitoes and catching them from their own arms in a laboratory cage, using an aspirator. A researcher will first demonstrate the procedure using his or her own arms, and will be present to instruct and guide each subject throughout the exercise. Subjects will be shown how to place both arms in a screen cage and to turn on the aspirator using the switch on the handle. One mosquito will be released in the cage. A small area (less than one-half of the forearm) will be uncovered, with no insect repellent applied. Subjects will be instructed to carefully watch the mosquito as it flies in the cage. The subject will be instructed to carefully observe the mosquito as it lands on the skin, and to watch to see if its needle-like mouths are placed against the skin. Once a mosquito lands on the skin, places it mouth against the skin and stops walking, subjects will immediately attempt to catch the mosquito in the plastic nozzle of the mosquito catcher. They may practice as many times as they wish with additional mosquitoes, and the researcher will be certain that the use of the mosquito catcher is correct. After several captures of single mosquitoes, a maximum of two mosquitoes will be placed in the cage. Two LIBing mosquitoes may be readily captured after little practice. Two represents the maximum number of mosquitoes that may LIBe on limb before the exposure

stopping rule is reached (below), and so the exercise in the cage with two mosquitoes is highly appropriate.

The mosquitoes used for this training are *Aedes aegypti* reared in the laboratory and free from diseases. The source colony of *Aedes aegypti* was established from eggs collected in Northern Thailand in 2004. F_1 adults were tested by Vero cell (African green monkey kidney, *Cercopithecus aethiops*) plaque assay for possible transovarial infection of viruses. Typically, 20 females from subsequent generations are tested routinely, and no infection has been detected in the 2 years since this colony was established. Individual mosquitoes will not be used for more than one subject.

At the field site, the subjects and researchers will gather in an area without biting mosquitoes. Subjects are instructed not leave this area until guided by a researcher.

The technicians and other researchers who will assist subjects during the test will be introduced or reintroduced to the subjects. Subjects are instructed to call on them whenever they have questions. Each subject is given and must wear a head net, Tyvek coveralls, latex, nitrile or vinyl gloves in their size, and is given an aspirator to suck any mosquitoes that land on treated skin and attempt to bite (LIBes*)* once formal exposures begin. A researcher will remind subjects about how to identify LIBes and when and how to operate the aspirator. Subjects will be further instructed about protecting themselves from mosquito bites during the test, and reporting on a mosquito that lands on skin treated with repellent.

Before the repellent is applied, subjects will be guided to wash the lower arms and/or legs with mild, low fragrance soap, rinsing them with a spray of ethyl alcohol (mixed with an equal part of water), and then drying them with a clean towel. A technician will then apply insect repellents to their forearms or lower legs to give even, complete coverage of the skin. The amount of repellent to be applied to any limb will be calculated in advance for each subject. The dosing rate will be the product of the subject's limb surface area

multiplied by the grand mean (mean of subject means) rate calculated in the dosimetry data analysis for that test material. Each subject will therefore be dosed at the same rate within a given repellent even if their individual application rates differed from the grand mean.

Treated subjects will be partnered into groups of two. A researcher will then guide subjects into the area of the field site in which mosquitoes are active. Each member of a partner pair will watch their own exposed limbs and those of their partner for mosquitoes that land for one minute. A technician will advise subjects when the one-minute period begins and ends. Subjects will immediately remove any LIBing mosquitoes from the skin with repellent with the aspirator. They may also use the plastic nozzle of the aspirator or a finger to interrupt any mosquito even more quickly.

At the end of the one-minute exposure period, subjects take shelter in a shade/screenhouse nearby. Partners will assist one another in covering the treated skin with the sleeve of the protective garments. Each subject will report the number of mosquitoes that attempted to bite their own treated skin during that one-minute period when asked by a technician who will record it on a data sheet. For perspective, note that in a typical test of a reasonably effective repellent, dozens of ‘0’ LIBe values will be recorded for each ‘1’ or ‘2’. In other words, during most exposure periods subjects do not experience close contact with mosquitoes.

Stopping Rule: Subjects are instructed to immediately cover exposed skin with the protective mesh provided if more than one LIBe occurs in a one-minute exposure period. Similarly, if subject receive a LIBe and recall receiving another in either of the two previous exposure periods, they are to ask their data recording technician to verify that recollection from the data record. If verified, the subject is instructed to immediately cover the limb as above.

Ambient LIBe pressure will be measured by experienced, untreated personnel from continuous exposure of a single limb during 1-minute periods commencing once every 15 minutes, beginning at the onset of data collection. Such negative control subjects are attended by two assistants who use mechanical aspirators switched on throughout the period to remove all mosquitoes that LIBe before biting commences. If mosquitoes are too abundant to permit ready aspiration, the controls may protect the exposed limb as soon as a LIBe occurs.

10.3.7 Forms for Retention of Source Data:

Dosimety data will be recorded on data form for each test material formulation. 'Lite with intent to bite' (LIBe) data will be recorded on a repellency data form. Data forms are appended.

10.4 Study Facility:

Dosimetry data collection will take place in the main building and on the terrace of Carroll-Loye Biological Research.

11 DATA ANALYSIS:

11.1 Experimental Unit:

The individual subject will be the experimental unit.

11.2 Replicates per Treatment:

For dosimetry, there will be 10 treated subjects testing each of the three repellent formulations and the comparison article. For efficacy testing, there will be 10 subjects treated with each test material and two serving as untreated controls at each of two sites.

11.3 Statistical Methodology:

Statistics will be computed with the software 'SAS JMP' Version 5.0.1.2 (SAS Institute, Cary, NC).

11.3.1 Dosimetry:

Dosage will be calculated per square centimeter of skin. The amount of test material delivered to each arm in each trial will be calculated as the container weight before application minus the container weight after application.

The specific gravity of each test material will be measured and used to convert the dosage weight data to volumes for preparing individual subject doses volumetrically for dispensing from the tuberculin syringes.

Subject means and standard deviations will be calculated for all measures of weight changes.

We will statistically assess the strength of any individual subject differences in dosing with the test materials using Friedman two-way analysis of variance of subject dose means for each test material. We will use subject dose means for each test material to calculate dosing grand means (± SD) for each test material. Those means, expressed as repellent weight per unit skin surface area, will be used to determine individual subject doses in the field repellency test.

11.3.2. Repellency:

Field tests are conducted with large populations of arthropods. This permits the analysis of the replicates (data by subject) as independent values. The hypothesis that the test materials will significantly reduce the number of mosquitoes LIBing on treated versus untreated skin is not the focus of this study. The focus is to compute, for each test material, a reasonable estimate of mean and standard

deviation for the duration between application and sufficient repellency breakdown such that two mosquitoes LIBe on a subject within a half hour period. That pattern is here assessed at a resolution of 15 minutes. The untreated limbs serve to monitor whether the ambient biting pressure remains at or above the EPA standard.

Complete protection time (CPT) is measured as the length of time from initial application to the first confirmed LIBe. A confirmed LIBe is a LIBe followed by another LIBe within 30 minutes. For example, a LIBe at 90 minutes followed by another at 135 minutes is not confirmed, but a third LIBe at 150 minutes would confirm that at 135 minutes, giving a CPT of 135 minutes.

CPT measured in this way will yield a single time value for each subject. Mean CPT will be calculated across all 10 subjects per treatment, and will be presented with standard deviation and 95% confidence interval information as well. Ambient LIBing pressure as measured by untreated subjects will be presented tabulated by individual and exposure period. Mean LIBing pressure will be calculated as the number of LIBes received per untreated control subject and per period and span of exposure.

12 STUDY LOCATION(S):

Field sites are in or adjacent to the Central Valley of California, and the Florida Keys (depending on season). Test site information will be furnished to EPA once it is clear when testing will be permitted, since season influences the availability of test arthropods on both regional and local scales.

13 QUALITY ASSURANCE:

An independent, professional Quality Assurance Unit (QAU) will inspect the study. The QAU will report to the Study Director. Protocol Review and Comments must take place before data collection commences. In-Life Inspection must include observing the measurement and recording

of key variables by subjects and researchers. In addition, the Final Report will be audited for completeness and accuracy. A QAU Statement will address compliance and noncompliance or any omissions in auditing. Findings from the In-Life Inspection and the Final Report, as well as the QAU Statement will be transmitted to both the Study Director and to the Sponsor Monitor.

14 PERSONNEL:

14.1 Investigator (Study Director):

14.1.1 Address:

Dr. Scott Carroll
Carroll—Loye Biological Research
711 Oak Avenue
Davis, CA 95616

14.1.2 Telephone:

530-297-6080
530-297-6081 (Facsimile)

14.1.3 Training and experience of investigator:

CV on file with sponsor

14.2 Study Monitor:

Timothy H. Dickens, PhD.

14.2.1 Address:

Scientific Coordination, Inc.
4629 Cherry Valley Drive
Rockville, MD 20853

14.2.2 Telephone:

Phone: 301-570-4390

Fax: 301-570-5914

14.3 Quality Assurance Unit:

Dr. Jenella Loye

14.3.1 Address:

Carroll—Loye Biological Research
711 Oak Avenue
Davis, CA 95616

14.3.2 Telephone:

530-297-6080
530-297-6081 (Facsimile)

14.1.3 Training and experience of QAU:

CV on file with sponsor

15 AMENDMENTS AND DEVIATIONS TO THE PROTOCOL:

Protocol amendments or deviations will be reviewed by the Study Monitor and the Study Director. Any changes that may affect the health or safety of study participants must be approved the Study Director, the State of California Department of Pesticide Regulation, and the approving IRB. The amendments, deviations as well as any adverse events will be documented in the Study Director's final report. Documentation will include a description of the change, the reason for the change and the effect of the change on the conduct and outcome of the study.

16 PROTOCOL APPROVAL SIGNATURES:

29 December 2006

Scott P. Carroll, Ph.D.
Study Director

Date

Timothy Dickens, Ph.D.
President, Scientific Coordination, Inc.

29 December 2006

Appendix 1. Data recording forms.

Limb Measurement Form

Study **SCI-001**

Date:

Subject name: Data recorder name:

Subject number: Data recorder signature:

Limb Measurements	Left arm	Right arm	Left leg	Right leg
Length				
Lower (A)				
Lower-mid (B)				
Upper-mid (C)				
Upper (D)				

Lotion Data Form

Study **SCI-001**

Date:

Subject name:

Subject number:

Data recorder name:

Data recorder signature:

I. Practice Application		
A. Arm, Left or Right (circle 1)		
Trial number	Mass before (g)	Mass after (g)
1		

II. Lotion Sampling		
A. Arm, Left or Right (circle 1)		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

B. Leg, Left or Right (circle 1)		
Trial number	Mass before (g)	Mass after (g)
1		

B. Leg, Left or Right (circle 1)		
Trial number	Mass before (g)	Mass after (g)
1		
2		
3		

Study: SCI-001

Date:

Site:

Application Time:

Time of first exposure: **LIBe recording code: 0=none, 1=1**

Incidence of LIBes at 15-minute intervals

Subject code	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	71	18	19	20	21	22	23	24	25	26	27	28	29	30

Data collected by:

Data collector's signature:

Appendix 2. Subject training documents

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Test Reference: SCI-001

CLBR Training Manual

§1.c. Practicing and performing dosimetry with Lotion delivery systems

A. Goals of exercise

1. Determine your preferred practices for applying lotion repellents to your arms or arms and legs.
2. Assist technicians in measuring the amounts of such repellents that you apply when using your practices

B. General information

1. A technician will measure the surface area of your forearms and lower legs. He or she will introduce you to the repellents and their containers
2. You will work in the laboratory, practicing applying the repellents.
3. You will thoroughly wash your limbs with a gentle skin cleaner between each application of repellent.

C. Materials and equipment needed

1. Test materials
2. Latex or vinyl gloves (various sizes)
3. Temperature and humidity measuring devices
4. Written copy of the procedures for subjects to read
5. Flexible metric rule

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D. Practicing the methods and performing the measurements

Measuring arms and legs[1]:

Limb is used to refer to your forearm and your lower leg. A technician will measure the distance around your limbs at four evenly spaced places on the forearm (elbow to wrist) and lower leg (back of knee to ankle), and also length of those limbs.

Lotion sampling

The amount of lotion applied to limbs will be quantified in a series of three applications analogous to the Spray Sampling above. However, dosimeters are not required, nor are the extensive practice sessions. The amount applied is the weight difference in the dispensing tube before and after application.

The instructions are as follows:

"Put a new latex glove on each hand. You will apply lotion to one arm only. The technician will tell you to which arm to apply. You will begin with an amount that you suppose is about one half of what you will need to achieve thorough and uniform coverage. After spreading that around the lower part of your arm, you will apply more as needed to the area closer to your elbow. Begin by gently squeezing lotion from a tube with the cap open directly onto the horizontally-held surface of the opposite arm. Hand the tube to the technician. Using the tips of the index and middle fingers, spread the lotion as evenly as possible on all surfaces of the lower arm. Do not spread it onto the hand or beyond the marking on your wrist. If you have sufficient lotion left to spread it evenly and thoroughly toward the elbow, continue in the direction. Do not spread it beyond the elbow or past beyond the marking near the elbow. If you need more lotion to achieve thorough and even coverage, make sure you have wiped all repellent from your fingertips onto the skin and ask the technician to hand you the tube. Apply as much additional as you think you need, as before, but to complete the coverage. If you decide that you have applied more repellent that you would normally use to achieve thorough and even coverage, immediately have the technician wash and dry the treated arm

---

[1] **Limb dimensions and surface area (technical details):**
The term 'limb' refers to the forearm and [1]the lower leg. The surface area of each limb is computed as the average of four evenly spaced circumferences (two peripheral, two central) of the forearm (elbow to wrist) or lower leg (back of knee to ankle) multiplied by the length of treatment area. The locale along the limb at which each circumference is taken will be recorded (for later use to place dosimeters) as the distance in centimeters from the distal margin of the site of the most distal circumference site (i.e., at wrist or ankle).

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so that none of the repellent you have applied is visible on close inspection, and begin again. Likewise, be careful to avoid dropping any lotion off of the arm, and if this happens, begin again as you would if you applied too much.

After you have completed an application successfully, the technician will wash and dry the treated arm so that none of the repellent you have applied is visible on close inspection, and reweigh the tube. You will continue until you have completed three successful applications. Then you will repeat the entire procedure above, but with the lower leg."

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Test Reference: SCI-001

CLBR Training Manual

§1.a. Observing mosquito landings and learning mechanical aspiration

A. Goals of exercise

1. Learn to determine when a mosquito on your arm is about to bite.
2. Learn to use a "mechanical aspirator" to remove such a mosquito before it bites. Catch at least 10 mosquitoes.

B. General information

1. A technician will show you how to watch mosquitoes that land on you to see if they are about to bite. He or she will then show you how to remove mosquitoes. quickly with a handheld mosquito catching device called a mechanical aspirator
2. You will work with you arms in a screen cage about 1 foot square, with up to two mosquitoes in the cage at one time.
3. You may be bitten by a mosquito while learning to use the aspirator. The mosquitoes were reared in the laboratory and are free from disease.

C. Materials and equipment needed

1. Mosquito cage with entrance stocking
2. Latex or vinyl gloves (various sizes)
3. "Ace" bandage
4. Approximately 12 mature unfed adult female *Aedes aegypti* mosquitoes
5. Mechanical aspirator with charged batteries and collection tube

D. Learning the methods

Spend at least 15-30 minutes practicing observing and catching mosquitoes, working with one or two at a time. Aspirators resemble flashlights except that they have a small electric fan and suction tube rather than a light bulb. You will carry one with you during the field test of the repellent. Your trainer will first demonstrate the method of use and capture. The trainer will then cover your upper forearm with the bandage to protect that area from biting.

Put on gloves. Practice using the switch on the aspirator handle to turn it on, and insert the sucking tube into the cage through the elastic cloth. Then place your arm with the bandage into the cage. About half or your forearm will be uncovered, with no insect repellent. Carefully watch the mosquito as it flies in the cage. Once it lands on your skin, watch carefully to see if it stops walking and places its needle-like mouth against your skin. You may move your arms to get better views and access to the mosquito. Once you observe a mosquito mouth touching your skin, you will immediately attempt to catch the mosquito in the plastic nozzle of the mosquito catcher. You may practice as many times as you wish, with one and then two mosquitoes, and the researcher will be certain that your use of the mosquito catcher is correct.

1. Study subjects
    a. mosquitoes
        i. observing landings
        ii. mechanical aspiration
    (v. 1, 11 September 2006)

INFORMED CONSENT AUTHORIZATION TO PARTICIPATE AS A RESEARCH STUDY SUBJECT

Title of Study: (SCI-001) Test of Personal Insect Repellents

Principal Investigator: Scott P. Carroll, Ph.D.
Carroll-Loye Biological Research
711 Oak Avenue
Davis, CA 95616

Site of Investigation: _____
_____
_____

Telephone #: (530) 297-6080

Sponsor: Scientific Coordination, Inc.

Participant's Name: _____

You are being asked to participate in a research study. Your participation is voluntary. The information in this Informed Consent Form explains the study. You will receive a copy of this form, and you may take it home and think about it before making your decision. If you have any questions, or do not understand anything in this form, please ask the Principal Investigator to explain any words or information you do not clearly understand.

NATURE AND PURPOSE

Carroll-Loye Biological Research is conducting this research study in order to develop effective mosquito repellents. Many people are interested in having new and better insect repellents available to them. The insect repellents that we will study were developed with the popular insect repellent called 'DEET' formulated to be more pleasant and convenient to use. More studies are needed to determine how well such new insect repellents work.

The purpose of the study is to test how well new lotion insect repellent products work outdoors against mosquitoes. These four products, which are similar to some already being sold, have been formulated to be more cosmetically acceptable to users. The information gained from the study will assist in the development of these repellents for future commercial marketing. During the study we will first measure how much insect repellent subjects put on their own arms and legs in a visit to the study laboratory. On a later date, we will go to a field site to test the insect repellents against mosquitoes in nature. You may be asked to participate in one or both parts of the study.

Version : 1/2/07
Protocol: SCI-001

APPROVED BY
Independent IRB
Corrected 1/22/07
Signature — Date: 1/2/07

Initials: _____
Date: _____

The sponsor, Scientific Coordination, Inc. has contracted Carroll-Loye Biological Research to conduct the study. Scott Carroll, Ph.D., of Carroll-Loye Biological Research is the Principal Investigator in charge of the study.

SUBJECT SELECTION

You have been offered an opportunity to participate in this research study because you read and speak English, consider yourself to be in good physical condition and are 18-55 years of age. If you are a female of child bearing potential you cannot be pregnant or breastfeeding.

Up to about 40 volunteers will be enrolled in this field research study. A few more subjects will be enrolled than are needed in order to make up for anyone who is unexpectedly unable to participate once testing begins. If more subjects are present than are needed for any part of the test, you may be asked not to participate, but will instead be an 'alternate subject' who may be contacted to participate later if needed. If you are designated as an alternate subject, you will be compensated for your participation up to that point and for your inconvenience.

STUDY INTRODUCTION AND DURATION

Schedule of visits and time required to participate in the study

Activity	Visit 1 (1-21 days before the field test)	Visit 2
1. Orientation and Dosage visit	X	
2. Field study visit		X
Total time	2-3 hours	8-14 hours

You will be given a training manual and will have a chance to review it and to read along with the instructions.

Visit 1 for Orientation and determining Dosage

Within 21 days before the field study visit you will meet with a researcher to perform introductory activities for the repellent study. The researcher will also tell you more about what you will experience while participating and what is expected of you. You will work with a researcher to determine how much insect repellent you apply. Completing those measurements will take 1.5-2.0 hours.

You will also be shown how to use a handheld mosquito catching device called an aspirator. These devices resemble flashlights except that they have a small electric fan and suction tube rather than a light bulb. You will carry one of these devices with you during the field study. During this visit you will also practice removing mosquitoes from a small area of your arm with the aspirator. This training and practice will take about ½ to 1 hour.

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The total time for Visit 1 activities will be about 2-3 hours.

Visit 2 for the Field Test against Mosquitoes
The study will also require one visit to the site of the field study. The field site visit will most likely require approximately 10 hours of your time. However, it may require as few as 8 hours (including travel time) and as many as about 14 hours, depending on how long the repellents remain effective. Bathrooms are available, and meals, drinks and snacks will be provided. There is a small chance that weather conditions will require that the test be canceled or rescheduled. The Principal Investigator will inform you in a timely manner if that happens.

The Principal Investigator may also ask if you would like to participate in a second field test of these products, using the same procedures as in the first test, on a later date. You may refuse to participate in additional testing without penalty to your compensation.

STUDY PROCEDURES

Study Design

The study will test four different insect repellent lotions. You will be randomly (by chance) assigned to receive one product, so your chance of receiving any one product is one-in-four. You will not have a choice as to which repellent product you receive. If you participate on more than one day, you will receive a different product on different days. For each product assigned to you, you will have an amount typical of what people commonly use applied to your forearms or lower legs.

Two experienced subjects will also participate to record the activity of mosquitoes by exposing their own arms or legs without repellent applied. Experienced subjects are pre-qualified by the Principal Investigator, and designated before the field test begins. Unless you have been qualified in advance as an experienced subject and agreed to expose untreated skin, you will not be asked to expose untreated skin and should avoid doing so.

If you are a female, you will perform a pregnancy test using an Over the Counter (OTC) pregnancy kit in the morning prior to the start of each of the two study visits. The results of your test will be verified by a female technician that is qualified to make that determination. If you are pregnant, you will not be allowed to participate in the study. Information regarding your pregnancy test results will be kept in confidence.

Procedures

Visit 1
At the laboratory, a researcher will measure the length and circumference of your

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forearm and lower leg. If you are participating in this part of the study, you will then practice using the products to decide how you best like to apply them and how much you would apply to your forearm or lower leg in order to have thorough and even coverage. The researcher will answer any questions you have about the application. Once you have a method you are satisfied with, you will wash your arms and lower legs with soap and water and dry them with a towel. The researcher will then ask you to apply an amount of the lotion repellent product to your skin that you think gives complete and even coverage. We will use the amounts you apply in this part of the study to determine how much repellent people normally apply.

You will also spend 15-30 minutes practicing catching mosquitoes in a laboratory cage, using an aspirator. You will be shown how to place both arms in a screen cage and turn on the aspirator using the switch on the handle. Two mosquitoes will be released in the cage. A small area (less than ½ of your forearm) will be uncovered, with no insect repellent applied. You will carefully watch the mosquitoes as they fly in the cage. Once they land on your skin, you will watch carefully to see if their needle-like mouths are placed against your skin. A researcher will be present to instruct and guide you. You may carefully move your arms to get better views and access to the mosquitoes. Once you observe a mosquito mouth touching your skin, you will immediately attempt to catch the mosquito in the plastic nozzle of the mosquito catcher. The researcher will first demonstrate the procedure to you using his or her own arms. You may practice as many times as you wish, and the researcher will be certain that your use of the mosquito catcher is correct. The mosquitoes used for this training are reared in the laboratory and free from diseases.

Visit 2

At the field site, the subjects and researchers will gather in an area without biting mosquitoes. You should not leave this area until instructed by a researcher.

You will be given an aspirator to suck any mosquitoes that land on your treated skin and attempt to bite you once the test begins. A researcher will show you again how to operate it. You will also be introduced to the technicians and other researchers who will assist you during the test. You will be instructed to call on them whenever you have questions about using the aspirator, protecting yourself from a mosquito, or reporting on a mosquito that lands on skin treated with repellent.

Before the repellent is applied, a technician will guide you in washing the lower arms and legs with mild, low fragrance soap, rinsing them with a spray of ethyl alcohol (mixed with an equal part of water), and then drying them with a clean towel. A technician will then apply insect repellents to your forearms or lower legs to give even, complete coverage of the skin. The amount of repellent applied on

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any one arm or leg will be no more than about ¼ teaspoon. You will also be given protective material to prevent bites on other parts of your arms and legs, plus a head net.

During the field test you and the Investigator will not know which repellent you are using. The study is done this way because knowing which repellent you are using can change the results of the study. If you start having any side effects from the repellent, the investigators can find out what you are taking in order to help you. Please ask the investigator if you have any questions at all about this kind of study.

The Principal Investigator or one of his technicians will guide you into the area of the field site in which mosquitoes are active approximately 15 minutes after you have had the test repellents applied. You and a partner will watch your own exposed arms or legs and those of your partner for mosquitoes that land for one minute. A technician will let you know when the one-minute period begins and ends. If any mosquitoes land and attempt to bite the skin with repellent, you will remove them immediately with the mosquito catcher. If at any time you have difficulties using the mosquito catcher you should push the mosquito from your skin with the plastic nozzle of the catcher. You may also use your finger to brush any mosquito aside. If you brush a mosquito aside watch carefully because it may quickly return to your skin. You will report the number of mosquitoes that attempted to bite your own treated skin during the one-minute period when asked by a technician who will record it on a data sheet. At the end of the one-minute period you should immediately cover the skin with the protective mesh or clothing provided. Every 15 minutes a project leader will announce the beginning of the next one-minute period for testing the treated skin and watching for mosquitoes that might attempt to bite it. If more than one mosquito attempts to bite you on your treated skin in one of the one-minute periods, or if one mosquito attempts to bite in two of three consecutive exposure periods (that is, 15 or 30 minutes apart), you should cover the skin and not expose it again.

If you are one of the two untreated ("experienced") subjects, two technicians with aspirators will assist you in watching for and removing mosquitoes during each one-minute exposure, and in each exposure you should cover your limb with the protective fabric as soon as the first mosquito lands and attempts to bite, and keep it covered until the next exposure period, 15 minutes later.

RESTRICTIONS

- You must not be a student or employee of the Principal Investigator
- You must not be hypersensitive (allergic) to mosquito bites
- You must not be sensitive to any of the test product ingredients
- You must regularly spend time in outdoor settings
- You must not have used repellents within a day prior to the start of the study

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- You must be able to apply spray and lotion repellents to your left and right arms
- You must not use perfumed products after 9 PM the night before and throughout the tests
- You must refrain from smoking or alcoholic beverages after 9 PM the night before and throughout the tests
- You must wear specified protective clothing during mosquito testing

RISK/DISCOMFORTS

If at anytime you feel ill, inform the Principal Investigator (or anyone else who is also assisting to direct the study) immediately, and you will be taken to receive medical attention at the nearest hospital. You may also request access to standard first aid materials (such as bandages, antiseptics, and mild antihistamines) and request first aid assistance at any time. You may remove yourself for any reason from the study at anytime. At least one qualified researcher will remain with the other test subjects if other researchers depart with an injured or ill subject.

There is a small possibility that the repellents may cause skin, lung and eye irritation. Excessive inhalation can cause lung irritation, headache and dizziness. Swallowing the products may cause temporary stomach distress. You may obtain more information about the safety of the repellents by asking the Principal Investigator, and he will provide you with the official "Material Safety Data Sheets" which give safety details similar to those found on commercial product labels.

In addition, even if you have not had a serious skin reaction to a mosquito bite previously, it is possible that such a reaction could occur if you receive any bites during this study. Swelling, redness and itching near the site of the bite are all symptoms of an allergic reaction to a mosquito bite. You should inform the Principal Investigator or one of his technicians if you are having such a reaction. There will be a first aid kit at the field site with treatments to reduce allergic symptoms from bites. Inform the Principal investigator if you are allergic to any nonprescription medicines. At least one technician with current first aid training will be present during the field test.

In addition, there is a slight possibility that you will contract a disease carried by mosquitoes if you are bitten, such as West Nile virus or equine encephalitis. This test is being conducted in an area in which such viruses have not been detected by state health or mosquito control agencies for at least a month, so the risk is probably low that any individual mosquito that might bite you carries a disease. In addition, since you are wearing repellent and other protective measures, and are carefully watching for mosquitoes that land and try to bite, you are probably at no

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Date: _____

more risk than you would experience when engaged in normal outdoor activities in a similar rural area at the same time of year.

The US Centers for Disease Control estimates that about 1-in-5 people who become infected with West Nile Virus will develop West Nile fever. For up to two weeks after the test, be alert for any flu-like symptoms (unusual tiredness or unusually severe headaches, body aches, fever, or a rash on the trunk of the body). About 1-in-150 infected people will develop more serious symptoms including neck stiffness, stupor, disorientation and possibly coma and paralysis.

Most people (about 4 out of 5) who are infected with West Nile virus will not develop any type of illness. Since you will work to quickly remove mosquitoes before they have an opportunity to bite, and few of the mosquitoes present are likely to carry the virus, your chances of getting West Nile fever or another disease from a mosquito bite are probably extremely small.

If you experience any of the symptoms described above in the month following the field test you should contact a medical practitioner and inform the Principal Investigator.

PREGNANCY RISKS

The risks to the unborn are unknown and if you are a woman of childbearing potential, it is important that you do not participate in this study if you are, or if you think you may be pregnant, or are lactating. Pregnancy will be self-checked by each female volunteer on the morning of the repellent test using an OTC test kit provided by the Study Director. Results of each such test will be immediately verified by direct inspection by a female technician trained to make that assessment.

UNKNOWN / UNFORESEEABLE RISKS

In addition to the risks and discomforts listed above, there may be some unknown or infrequent and unforeseeable risks associated with the use of this product, including allergic reaction or interaction with a medication. You will be informed in a timely manner both verbally and in writing of any new information, findings or changes to the way the research will be performed that might influence your willingness to continue participation in this study.

RESEARCH RELATED INJURIES

If you are injured as a result of being in this study, a consulting physician who is aware of the study will be contacted immediately by telephone. Medical treatment will be available from a health care facility. Carroll-Loye Biological Research will cover the costs of such medical treatment that are not covered by your own insurance or by a third party. If necessary, Carroll-Loye Biological Research will transport you to receive medical attention and pay costs associated with the

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Date: _____

reasonable and appropriate treatment for any injuries incurred as a result of participation in the study. For further information about this, the research test subject should call the office of Carroll-Loye Biological Research (530) 297-6080.

You DO NOT waive your legal rights by signing this form.

TREATMENT ALTERNATIVE
Since this study is not intended to provide any therapeutic or other health-related benefit, your alternative is to not participate in this study.

BENEFITS
There are no immediate benefits to you from your participation. However, by serving as a participant you may assist in making new insect repellent products available to consumers

OFFER TO ANSWER ANY QUESTIONS ABOUT THIS STUDY
If you have any questions or problems during this study, or if you think that you may have experienced a research-related injury, you should contact Scott Carroll of Carroll-Loye Biological Research at (530) 297-6080 or (530) 902-8267.

If you have any questions regarding your rights as a research volunteer, please contact Kim Lerner, Chairman of the Independent Investigational Review Board, Inc. at toll free (877) 888-IIRB (4472) during regular working hours. The Independent Investigational Review Board is a committee established for the purpose of protecting the rights of volunteers in a research study.

COSTS AND REIMBURSEMENT
There will be no costs to you from participating in this study.

For participation in the study, each research study participant will receive a cash payment of $15 per hour. Payment will be made at the end of each visit or whenever you withdraw from the study. If you are designated as an 'alternate subject', you will be paid for the hours you spent being trained, plus you will receive a payment of $50 dollars to compensate for being inconvenienced by the administration of the study.

CONFIDENTIALITY
Carroll-Loye Biological Research will retain records of this study indefinitely. You may access you own records by contacting the Study Director. Representatives from the Sponsor, Scientific Coordination, Inc., the U.S. Environmental Protection Agency (EPA), the California Department of Pesticide Regulation, and the Independent Investigational Review Board, Inc. Review Board (an independent committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants) may have access to all non-personal information collected in this study. Because of the need to release information to

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Date: _____

these parties, absolute confidentiality cannot be guaranteed. Any information or reports published as a result of this study will not identify you by name, or any other personal identification.

STATEMENTS OF UNDERSTANDING

Right to withdraw or removal from study

I understand that I am free to withdraw from this study at any time, and I agree to inform the Principal Investigator immediately if I intend to withdraw. It is understood that my decision to participate in this study or to withdraw from this study will not influence the availability of my future medical care and will involve no penalty or loss of compensation to which I am otherwise entitled. I may withdraw from this study at any time.

I agree that the Principal Investigator in charge of the study can remove me from this study without my consent for any reason, including, but not limited to:

a. His/her judgment that any condition or circumstance may jeopardize my welfare or the integrity of the study.
b. My failure to follow the instructions of the investigator(s).
c. If the study is stopped by the sponsor and/or Principal Investigator participating in the study prior to completion.

Consent and signatures

I have read, in a language that I understand well, and understand the information which has been stated above. I have received satisfactory answers to all of the questions, which I have asked. I hereby voluntarily consent to take part in this study and to be a research study participant in this study. I do **not** waive my legal rights by signing this Informed Consent Form. I shall receive a copy of the signed Informed Consent Authorization.

_____	_____	_____
Date/Time	**Print** Subject Name	**Sign** Subject Name
_____	_____	_____
Date/Time	**Print** Carroll-Loye Biological Research Representative	**Sign** Carroll-Loye Biological Research Representative

Independent Investigational Review Board, Inc.
Approval: 11/7/06, Revised: 1/02/07

Version : 1/2/07
Protocol: SCI-001

APPROVED BY
Independent IRB
Corrected 1/22/07

Signature _____ Date 1/2/07

Initials: _____
Date: _____

Appendix 7b. Protocol Amendments

Carroll-Loye Biological Research

711 Oak Avenue Davis, California 95616 Tel (530)297-6080 http://www.carroll-loye.com/

2 November 2007

AMENDMENT TO PROTOCOL SCI-001

Introduction. This Amendment to reduce the scope of Protocol SCI-001 (previously amended) is here presented in descriptive narrative form rather than as text amending specific wording in protocol SCI-001. As will be evident, this approach is taken because altering the wording of the protocol to suit the purposes of this amendment would be intractably complex.

Synopsis. This amendment reduces the number of test articles in the study from three to two, and eliminates the comparison article. Thus eliminated are the article '34.34% LipoDEET' and the comparison article '3M Ultrathon- 34.34% DEET'. It also stipulates the collection of dosimetry and efficacy data for the remaining test articles, 'Coulston's Duranon' and 'LipoDeet 302' to replace the data collected for those test materials in July 2007. Instances and language in the Protocol (as previously amended) either describing or inferring the inclusion of the test article '34.34% LipoDEET' and the comparison article '3M Ultrathon- 34.34% DEET' are therefore stricken.

Rationale. During its meeting of October 25, 2007 the US/EPA Human Studies Review Board found our data submission for SCI-001 to be ethically disputable because we did not obtain IRB approval for Amendment #1b, which substituted the test article '34.34% LipoDEET' for another, 'Insect Guard II'. Due to this unforeseen regulatory development, the sponsor would like to economize by narrowing the scope of the study described in Protocol SCI-001 in a manner that does not in any way compromise its main objective, which is first and foremost test the products' repellent efficacy characteristics. That can best be accomplish by testing solely the articles 'Coulston's Duranon' and 'LipoDeet 302', for which the sponsor already holds registrations, but for which additional data are needed to improve labeling.

Impact on Subject Rights and Safety. The minor risks to which subjects are exposed through their participation will not differ, per unit time participating, from the unamended protocol.

Impact on Study Design. Other aspects of the study design will remain the same.

Scott P. Carroll, Ph.D., Study Director

Timothy H. Dickens, Ph.D., Sponsor Monitor

Carroll-Loye Biological Research

711 Oak Avenue Davis, California 95616 Tel (530)297-6080 http://www.carroll-loye.com/

2 July 2007

AMENDMENT TO PROTOCOL SCI-001

§6.1 Test Substance, which reads

6.1.1 Description of the Test Materials

1. EPA Reg. # 82810-1- LipoDEET
   This is a 30% DEET formulation contained in cosmetic lipid spheres that inhibit evaporation to prolong duration of efficacy, improve feel, reduce plasticizing and reduce odor.
2. EPA Reg. # 50404-8- Coulston's Duranon Insect Repellent
   This is a controlled-release, low-odor formulation of 20% DEET.
3. EPA Reg. # 54287-8 - Associated Registrations - Insect Guard II
   This is a functionally synergistic formulation of 17.5% DEET synergized by N-octyl bicycloheptane dicarboximide (5%) and complemented by Di-n-propyl isocinchomeronate (2.5%) to repel flies.
4. EPA Reg. # 58007-1- 3M Ultrathon- 34.34% DEET. This polymer based lotion extends efficacy and reduces plasticizing caused by DEET. This is the comparison article and is the insect repellent used by the US Armed Forces.

is amended by the replacement of the text for Test Material '3' to read:

3. 34.34% LipoDEET
   This is a 34.3% DEET formulation contained in cosmetic lipid spheres that inhibit evaporation to prolong duration of efficacy, improve feel, reduce plasticizing and reduce odor. It is included in this study to provide a comparison with 3M Ultrathon at the same concentration of DEET.

Scott P. Carroll, Study Director

Timothy Dickens, Ph.D.
President, Scientific Coordination, Inc.

Carroll-Loye Biological Research

711 Oak Avenue Davis, California 95616 Tel (530)297-6080 http://www.carroll-loye.com/

2 July 2007

AMENDMENT #1a TO PROTOCOL SCI-001

The following amendment adds viral screening of mosquitoes captured during the conduct of study SCI-001 to the protocol. This screening is added based on the decision of the US/EPA Human Studies Review Board to recommend such testing for insect repellent registration efficacy studies. That recommendation, first proffered in the April 18, 2007 Human Studies Review Board (HSRB) meeting, and formalized in the June 27, 2007 HSRB meeting, is now incorporated as a standard element in new Carroll-Loye repellent efficacy protocols. The procedure, with wording as follows, has received IRB, US EPA OPP, and HSRB approval in that context.

Here we add viral screening to approved, pending efficacy protocol SCI-001 in order to comply with the latest HSRB recommendations.

§10.3 Procedures for Assessing Variable, is amended by the addition of a new section:

> '§10.3.8 PCR Virus Assay: Mosquitoes collected while attempting to bite control and treated subjects will be held individually in vials labeled with site, subject number, date and time, and placed in portable coolers on dry ice. After identification under at Carroll-Loye (still on dry ice), they will then be hand-delivered cold to the University of California Center for Vector-borne disease. There we will run multiplex RT-PCR assays for West Nile Virus, Western Equine Encephalitis, and St. Louis Encephalitis. These three pathogens, while rare, are the most likely in the proposed study region to cause disease if vectored to a person by a mosquito bite. We anticipate screening 50-100 mosquitoes for the three viruses. The mosquitoes will be screened individually. The goal of this assay is not to measure the minimum infection rate (0.5/1000 is a common rate of epidemiologic interest, for which, e.g., 40 pools of 50 mosquitoes each is a standard sample). Instead, our goal is to determine whether any of our subjects have come into contact with a pathogen-bearing mosquito. Should any positive mosquitoes be detected, we will contact all subjects and remind them to be especially alert to flu-like symptoms and to take appropriate action if they experience them (as described in §5.4 and the Informed Consent Form).'

Scott P. Carroll, Study Director

Timothy Dickens, Ph.D.
President, Scientific Coordination, Inc.

Appendix 7c. IRB Approvals, Informed Consent Form

INDEPENDENT
INVESTIGATIONAL
REVIEW BOARD INC.
Your Advocate for Clinical Research Participants

Kim Lerner
Chairman

Anita McSharry, R.N.
President

DATE: November 06, 2007

TO: Scott P. Carroll, PhD
Principal Investigator

FROM: Kim Lerner, Chairman or
Anita McSharry, Vice-Chairman
Independent Investigational Review Board, Inc.

SUBJECT: Approval for Ongoing Research

PROTOCOL: (SCI-001) Test of Personal Insect Repellents

At the meeting held on November 06, 2007 the Independent Investigational Review Board, Inc. had an opportunity to review the Progress Report and the consent form (previously) in use for the above noted study. The information provided in the Study Progress Report is found to be consistent with the information on file. The Committee verified that all new information regarding changes to study procedures has now been reported and that there have been no changes to the risks to subjects. Utilizing this information, the Committee has conducted a risk-benefit assessment and is satisfied that the research can continue to be permitted as revised (see approval documentation of Amendment 1 C and revised informed consent form).

The research approval extends 11/7/2007 to 11/6/2008. If the study is completed prior to that time period, the Independent Investigational Review Board is to be advised of the completion of the study and the Investigator is to provide a final Progress Report. If there are any changes to the protocol (amendments), changes in risks to subjects, significant protocol deviations, or other unanticipated problems involving risks to the human subjects, the Investigator is to notify the IIRB as soon as possible. Serious adverse reactions must be reported in accordance with protocol requirements. The current Informed Consent Form is identified as Version 11/6/2007.

Thank you for your cooperation.

kl/ams/yc:

phone 954-327-0778 • fax 954-327-5778 • 6738 West Sunrise Blvd., Suite 102 • Plantation, FL 33313 • info@iirb.com (email) • www.iirb.com

INDEPENDENT
INVESTIGATIONAL
REVIEW BOARD INC.
Your Advocate for Clinical Research Participants

Kim Lerner
Chairman

Anita McSharry, R.N.
President

DATE: November 06, 2007

TO: Scott P. Carroll, PhD
Principal Investigator

FROM: Kim Lerner, Chairman or
Anita McSharry, Vice-Chairman
Independent Investigational Review Board, Inc.

SUBJECT: Amendment #1C dated 11/2/2007
- Revised Informed Consent Form (Ver. 11/6/2007)

PROTOCOL: SCI-001

At the meeting held on November 06, 2007 the Independent Investigational Review Board, Inc. had an opportunity to review Amendment #1C and the revised Informed Consent Form for the above noted research study. The Amendment #1C reduces the number of test articles in the study and stipulates the collection of dosimetry and efficacy data for the remaining articles. The Committee does not require that the Amendments dated 2 July 2007 be specifically renamed at this time and can be referred to as identified in Amendment #1C. In addition the Committee noted that the disclosure of the rational for conducting this additional testing is thoroughly addressed in the nature and purpose statement of the informed consent.

NOTE: The Committee noted that it was reported that the EPA HSRB strongly suggested that the data from the completed study would not be admissible for consideration by the EPA and therefore the research is being repeated. The Committee discussed the merits/necessity of the research being repeated based on the failure of the Principal Investigator to appropriately obtain IRB approval prior to implementing changes that did not affect subject's safety or scientific merit verses the unnecessary exposure of additional subjects to the test materials. The Committee agreed to permit the repetition of the study procedures because of the minimal risk of the exposure to test materials and the value and benefit that will be attained by EPA acceptance of the study findings.

Amendment #1C is unanimously approved as submitted. The revised Informed Consent Form is unanimously approved as submitted. The Informed Consent Form has been revised to accommodate the Amendment. The approved revised Informed Consent Form is identified as Version 11/6/2007 and stamped, "Approved 11/6/2007". All current subjects and future volunteers must sign the revised consent forms.

Thank you for your cooperation.
KL/AMS/yc:kl

phone 954-327-0778 • fax 954-327-5778 • 6738 West Sunrise Blvd., Suite 102 • Plantation, FL 33313 • info@iirb.com (email) • www.iirb.com

INDEPENDENT
INVESTIGATIONAL
REVIEW BOARD INC.
Your Advocate for Clinical Research Participants

Kim Lerner
Chairman

Anita McSharry, R.N.
President

DATE: October 30, 2007

TO: Scott P. Carroll, PhD
Principal Investigator

FROM: Kim Lerner, Chairman or
Anita McSharry, Vice-Chairman
Independent Investigational Review Board, Inc.

SUBJECT: Approval Amendment July 2, 2007 Sections 6.1.1 and 10.3
- Protocol Deviation Reporting

PROTOCOL: SCI-001

At the meeting held on October 30, 2007 the Independent Investigational Review Board, Inc. had an opportunity to review the Amendments to the above noted research study and protocol deviation reporting. The amendments add additional safety testing (virus assay of mosquitoes) and substitution of 34.3% Lipo DEET for Insect Guard II (as a better comparator article). The protocol deviation reports identify that these protocol amendments were implemented without prior approval by the IRB. The Committee noted that these protocol deviations did not compromise subject safety or the scientific merit of the study.

The Committee unanimously approved the protocol amendments and noted that the Principal Investigator reports full understanding of the requirements for submission to the IRB and the need for IRB approval of all changes to the way a research study will be conducted prior to implementation and will participate in additional continuing education related to human subject's protection. The IIRB will develop procedures for requiring that investigators have current training in human subject protection issues. No further action by the Principal Investigator is required at this time.

Thank you for your cooperation.

KL/AMS/yc:

phone 954-327-0778 • fax 954-327-5778 • 6738 West Sunrise Blvd., Suite 102 • Plantation, FL 33313 • info@iirb.com (email) • www.iirb.com

Appendix 7d. Deviations from the Protocol and their Consequences

Appendix 7d. Deviations from the protocol and their consequences

1. With the Study Director's consent, subjects did not always cover treated limbs between exposures when it was straightforward to avoid mosquitoes in the interim periods by entering the screen house.

   This deviation probably reduced abrasion of the Test Material by the coveralls, without significantly increasing the risk of biting from mosquitoes.

2. During dosimetry, the stipulated number of practice applications quickly proved excessive, and so was reduced from two to one or zero for most subjects. While more applications might have been appropriate for subjects wholly unfamiliar with applying lotion products to their own skin, all subjects regarded a single or no practice application as sufficient for familiarization purposes. This was especially true when subjects had already performed a number of dosimetry applications as part of the entire SCI-001 project. The number of subsequent applications per limb performed by each subject for actual dosimetry data collection remained at three.

   Subject exposure to the insect repellent was reduced, and the quality of the data set is not seriously affected.

3. To reduce the risk of artificially truncating data records as has occurred in prior efficacy tests, the Study Director scheduled treatment applications *before* subjects went to the field.

   Subjects were transported for 150-180 minutes before initial exposure, during which time they were instructed to remain vigilant about avoiding abrasion of their treated surfaces. Subjects were protected from LIBes until, at minimum, the twenty-second exposure after initiation. The prolonged delay in LIBes after initial exposure suggests that the data records accurately represent the temporal distribution of protection.

Submitted By:	Study Director	27 November 2007 Date
Acknowledged:	William A. Donahue Jr. Quality Assurance Representative	02 December 2007 Date
Acknowledged:	Timothy H. Dickens Sponsor's Representative	07 December 2007 Date

Appendix 7e. Correspondence with IRB

10/30/07

From: "Yesenia Crespo" <ycrespo@iirb.com>
To: <spcarroll@ucdavis.edu>
Subject: SCI-001

Dear Scott,
We the above mentioned study is up for renewal next week. We need for you to submit a progress report along with the documentation requested in it. This information has to be received by Friday 11/2. You may find the progress report on our web site at iirb.com. Please let me know if I can help you with anything.

Best Regards,

Yesenia Crespo

Independent Investigational Review Board INC.

10/30/07
Dear Yesenia,

We will renew this week.
Thanks!

Best,
Scott

11/2/07
From: Scott P Carroll [mailto:spcarroll@ucdavis.edu]
Sent: Friday, November 02, 2007 4:34 PM
To: Robert Roogow
Cc: Tim Dickens
Subject: Amendments to SCI-001

Hi Robert,

Last week as part of a deviations report for SCI-001, I included our amendments to include virus screening and to substitute a test material. I understand from a telephone conversation with Kim Lerner, Chair of IIRB that those amendments have been favorably reviewed and are currently in process administratively at IIRB.

Attached here is a **draft** of a further amendment to SCI-001, in which we request permission to gather replacement dosimetry and efficacy data on a subset of the test materials. It eliminates the test material substituted in the earlier amendment, and also eliminates the comparison article. The present amendment therefore interacts with that which specifies the substitution.

Another point in question: Given that we are seeking to replace data likely to be disallowed by EPA, to what extent and how should we inform subject of that fact. I have discussed this with Ms. Lerner, who is still thinking about it, and am attempting to reach appropriate personnel at US EPA on this point. One approach would be as follows: On the first page of the consent forms, we could add verbiage to the effect of

'Data for this study were originally collected in July 2007. More data are needed to complete this study due to an administrative error that took place then. At that time, the sponsor added a new test repellent to the study, for which the Study Director did not obtain proper approval. While regulatory authorities at the US Environmental Protection Agency have not suggested that participants were at risk due to that error, the data collected at that time are likely not acceptable for ethical reasons. Accordingly, your participation would serve to replace some of those data. The repellent formulation added in July is not being tested now.'

For clarity's sake, I propose that we henceforth refer to the three amendments 1 a-c, with 'Virus' as 1a, 'Add LipoDeet 3434' as 1b, and the attached draft as 1c. (Another approach would be Virus as 1, and the other amendments as 2a&b). None are currently labeled in either of these ways, however, and I am open to whatever works for you.

I will be in the field on Monday but reachable by telephone. I have copied this email to the sponsor monitor, Dr. Tim Dickens, whose final review and

signature will be needed on the final version of the draft amendment. Please copy the correspondence that follows to him as well.

Thank you very much,
Scott

11/2/07

From: "Robert Roogow" <rroogow@iirb.com>
To: "'Scott P Carroll'" <spcarroll@ucdavis.edu>
Cc: "'Tim Dickens'" <DickensTH@aol.com>
Subject: RE: Amendments to SCI-001

Hi Scott,

Kim told me briefly about the problems at hand but she did not tell me if she had reached a decision on her response to you. She will be in on Tuesday morning and I will contact you as soon as she arrives with any additional information. I think the best way to reference the amendments is 1a, 1b, and 1c. Please have that done on the final versions that you submit for review. As for notifying the new participants of the previous problems, just provide how you would like the consent to read and the Board will determine what if anything is required. Good luck in the field on Monday and have a good weekend.

Regards,
Robert Roogow, MS, CIM
Director of Operations
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778
<mailto:rroogow@iirb.com>rroogow@iirb.com

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Appendix 8. MSDS, Labels, and Supplementary Test Materials Information

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 27, 2006

Mr. Timothy H. Dickens, PhD.
Scientific Coordination, Inc.
4629 Cherry Valley Drive
Rockville, MD 20853

Subject: Submission of a label amendment with alternate advisory statements.
EPA Registration No. 54287-8
Product Name: INSECT GUARD II
Date of Submission: April 17, 2006

Dear Dr. Dickens;

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable subject to the comments listed below. Five copies of the finished labeling must be submitted prior to releasing the product for shipment.

1. Revise the marketing claim as follows: "Provides 95% or greater protection against mosquitoes for up to 4 hours"

A stamped copy of the draft label is enclosed for your records. Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you have any questions, you may contact Richard J. Gebken, at (703) 305-6701.

Sincerely,

Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7505C)

Enclosure

INSECT GUARD II

ACTIVE INGREDIENTS:

DEET	17.5 %
N-octyl bicycloheptene dicarboximide*	5.0 %
Di-n-propyl isocinchomeronate**	2.5 %
OTHER (INERT) INGREDIENTS	75.0 %
Total	100.0 %

*MGK 264, Insecticide Synergist
**MGK Repellent 326
MGK® - Registered trademark of McLaughlin Gormley King Co.

Keep Out of Reach of Children
WARNING
See back panel for additional precautionary statements.

NET CONTENTS: ____ oz.

Optional Marketing Claims

- Repels Mosquitoes, Chiggers, Ticks, Black Flies Also Deerflies, Gnats, Stable Flies and Fleas on Exposed Skin Surfaces
- Repels mosquitoes that may carry West Nile virus.
- Contains DEET to Repel Mosquitoes Plus R-326 to Repel Flies
- Lotion

Key
[Optional / Alternate text]
NOTE: The First Aid statement's grid format will be used if market label space permits; otherwise a paragraph format will be used.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **Read and follow all directions and precautions on this product label.**

Shake well before using.

Rub a thin uniform layer on exposed skin. Use just enough repellent to cover exposed skin, do not use under clothing. Avoid over-application. Do not apply near eyes and mouth and apply sparingly around ears. Do not apply to children's hands. Do not allow children to handle this product. When using on children, apply to your own hands and then put it on the child. (Instruct older children in the proper use of this product.) Do not apply over cuts, wounds or irritated skin.

After returning indoors, wash treated skin with soap and water. Wash treated clothing before wearing it again.

May damage certain synthetic fabrics; acetate, spandex, rayon and leather and plastics such as eyeglasses and watch crystals. [Will not damage cotton, wool, or nylon.][Do not apply on or near acetate, rayon, spandex, or other synthetics, furniture, plastics, watch crystals, leather and painted or varnished surfaces including automobiles.]

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry area away from heat or open flame.

DISPOSAL: If empty: do not reuse this container. Place in trash or offer for recycling if available. If partly filled: call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals -

WARNING: Causes substantial but temporary eye injury. Do not get in eyes. Due to irritating nature, may be harmful if swallowed. Use of this product may cause skin reactions in rare cases. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

If you suspect a reaction to this product:

- Discontinue use;
- Take off contaminated clothing;
- Rinse skin immediately with plenty of water for 15-20 minutes;
- Call a poison control center or doctor for treatment advice.

Have the product container with you when calling a poison control center or doctor, or going for treatment. For additional information in case of emergency call toll free 1-800-940-4464.

EPA Reg. No. 54287-8 EPA Est. No. 54287-FL-1

Associated Registrations
P.O. Box 188
Safety Harbor, FL 34695

[For product information call: 1-800-940-4464
Weekdays from 9-5 EST]

54287-8Amend.Final04-14-06

ACCEPTED
with COMMENTS
In EPA Letter Dated
SEP 27 2006
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.
54287-8

MATERIAL SAFETY DATA SHEET

Insect Guard II

1. Company Identification

Associated Registrations, Inc.
Safety Harbor FL 34695

Telephone Number: 800-356-7811
Fax Number: 727-725-1954
Emergency Telephone Number: 800-356-7811

Issue Date 5-Sep-06
Replaces Issue Date: 17-Aug-06

Manufacturer
Sawyer Products
Safety Harbor FL 34695

Product Description: Personal Insect Repellent
EPA Registration No.: 54287-8
Product Code: None Assigned

2. Composition/Information on Ingredients

Chemical Name	CAS Number	Percent
Deet	134-62-3	17.50
N-octyl bicycloheptene dicarboximide	113-48-4	5.00
Di-n-propyl isocinchomeronate	136-45-8	2.50
Inert Ingredients	Not Established	75.00

Ingredients not identified are proprietary or nonhazardous. Values are not product specifications.

3. Hazards Identification

Primary Route(s) of Entry
None Known
Eye Hazards: Not a primary eye irritant, but contact with eyes may cause mild, transient irritation.
Skin Hazards:: None Known
Ingestion Hazards: None Known
Inhalation Hazards: None Known

4. First Aid Measures

Eye
In case of contact, hold eyelids apart and immediately flush eyes with plenty of water for at least 15 minutes.
Remove contact lenses, if worn.
Call a medical officer, poison control center or doctor for further treatment advice.

Ingestion
If swallowed, consult a physician immediately.

Signs And Symptions Of Overexposure: Eye Contact: Redness, Swelling, Pain, Tearing, and Hazy Vision.
In rare occasions, children have had reactions characterized by diarrhea and vomiting from gross overexposure to deet, the active ingredient in this product.

5. Fire Fighting Measures

Flash Point: >200°F
Flash Point Method: TCC
Lower Explosive Limit: NE
Upper Explosive Limit: NE

Fire and Explosion Hazards
None Known

Extinguishing Media
In case of fire, use water spray, CO_2, Dry Chemical, or Foam

Fire Fighting Instructions
None Known

6. Accidental Release Measures

Soak up with absorbent, shovel into waste container, flush area with water.

7. Handling and Storage

Handling and Storage Precautions

Do not store over 160°F. Material may separate.

Handling Precautions

Avoid contact with eyes and lips.

Storage Precautions

Keep away from heat.

Work/Hygienic Practices

Follow Label Directions.

8. Exposure Controls/Personal Protection

Engineering Controls: None Known
Eye/Face Protection: None Known
Skin Protection: Non Known
Respiratory Protection: None normally required

9. Physical and Chemical Properties

Appearance: Peach Cream	Melting Point: Not applicable
Odor: Slighly sweet fragrance	Boiling Point: Not applicable
Specific Gravity: .99	% Low VOC: Not applicable
% Medium VOC: Not applicable	Solubility: Oil: NA Water: NA
Evaporation Rate: Not applicable	Shelf Life: 4 years

10. Stability and Reactivity

Stability: Stable
Hazardous Polymerization: Will not occur

Condition to Avoid (Stability)

Do not store when temperatures exceed 160° F. Exposure to temperatures above 160° F may cause material to separate.

Incompatible Materials

None Known

Hazardous Decomposition Products

None Known

Conditions to Avoid

None Known

11. Toxicological Information

No Data Available

12. Ecological Information

No Data Available

13. Disposal Considerations

Dispose of in accordance with all applicable Federal, State and Local regulations. Material collected with absorbent may be disposed of in a permitted landfill in accordance with Federal, State, and Local reulations.

14. Transport Information

U.S. Department of Transportation (DOT) information: Not considered hazardous by DOT Title 49 regulations. Proper Shippng Name: N/A. Hazard Class: N/A. Identification Number (UN or NA): NA Packing Group: N/A. International Transportion Reulations: ICAO/IATA Description: Not considered hazardous by IATA regulations for tranportation via air. IMO Description (IMDG Code): Not considered harardous by IMO Regulations for Transportation via vessel.

15. Regulatory Information

US Regulatory Information

This product is a pesticide and is exempt from the US Toxic Substances Control Act (TSCA) Chemical Substance Inventory

EPA Reg. No.: 54287-8

SARA Section 313 Notification

This product does not contain any ingredients regulated under Section 313 of the Emergency Planning and Community Right-To-Know Act of 1986 or 40 CFR 372

16. Other Information

Precautionary Label

WARNING: MAY BE HARMFUL IF SWALLOWED. MAY CAUSE EYE IRRITATION

Wash thoroughly after handling and before eating or smoking.

Disclaimer

The information contained herein is believed to be accurate whether originating with Associated Registrations or not. Associated Registrations provides no warranty either express or implied, and assumes no responsibility for the accuracy or completeness of the data. Recipients are advised to confirm any data, in advance of need, that it is current, applicable, and suitable to their circumstances.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 28, 2006

Mr. Timothy H. Dickens, PhD.
Scientific Coordination, Inc.
4629 Cherry Valley Drive
Rockville, MD 20853

Subject: Submission of a label amendment with alternate advisory statements.	
EPA Registration No.	**50404-8**
Product Name:	**Coulston's Duranon Insect Repellent**
Date of Submission:	**April 17, 2006**

Dear Dr. Dickens;

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable subject to the comments listed below. Five copies of the finished labeling must be submitted prior to releasing the product for shipment.

1. Revise the marketing claim as follows: "Provides 95% or greater protection against mosquitoes for up to 4 hours"
2. Modify the following marketing claim by removing the text shown in strikeout below:

   20% DEET IN A ~~NON-ALCOHOL~~
   CONTROLLED RELEASE FORMULA

   Statements or claims that express the absence of certain ingredients are misleading statements prohibited by the Agency's labeling regulation. These claims are examples of a true statement used in such a way as to give a false and misleading impression to the purchaser. Even though a claim expressing the absence of an ingredient is true, it could be misleading if it is used in a way to falsely suggest to the potential purchaser that the product is in some way less risky, better, or more desirable than a product containing the ingredient in question. Further, a product must not claim that it does not contain an ingredient if it never contained the substance in the first place.

3. Remove the following claim[1]:

   Contains DEET as recommended by the
   Centers for Disease Control
   www.cdc.gov/ncidod/dvbid/westnile/index.htm

[1] 40 CFR 156.10 (a)(5) in part states the following:
"(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 152.500, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations
in the labeling which constitute misbranding include:
(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;"

4. Remove the following claim:
   "Compatible with Sun Block"
   This non-pesticidal claim is potentially false and misleading about the safety of the product.

A stamped copy of the draft label is enclosed for your records. Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you have any questions, you may contact Richard J. Gebken, at (703) 305-6701.

Sincerely,

Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7505C)

Enclosure

Coulston's®
DURANON® INSECT REPELLENT

PROVIDES 95% OR GREATER PROTECTION
AGAINST
MOSQUITOES FOR 4 OR MORE HOURS

20% DEET IN A NON-ALCOHOL
CONTROLLED RELEASE FORMULA

INSECT REPELLENT● LOTION● REPELS
MOSQUITOES

ODORLESS AFTER APPLICATION
TIME RELEASE [DEET] FORMULA

LOW DEET ABSORPTION FORMULA

ODORLESS TIME-RELEASE FORMULA

Family Insect Repellent
Controlled Release Odorless
~~Double Protection – Use With Family Clothing Repellent~~

Contains DEET as recommended by the
Centers for Disease Control
www.cdc.gov/ncidod/dvbid/westnile/index.htm

Non-Greasy Compatible with Sun Block
Visit www.sawyer.com to Learn More Or Ask Your Doctor

ACTIVE INGREDIENTS:

DEET (CAS No. 134-62-3)	20.00%
OTHER INGREDIENTS	80.00%
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS
[SEE ADDITIONAL PRECAUTIONS ON BACK
PANEL]

Net Contents: oz

ACCEPTED
with COMMENTS
In EPA Letter Dated
SEP 28 2006
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 80404-8

This Coulston Controlled Release insect repellent uses the patented "Sub Micron Encapsulation" technology as developed by Coulston Products Inc. This process evens out the evaporation rate of DEET by encapsulating the DEET in a protein. Each application provides effective protection while at the same time limiting the skin's exposure to DEET thereby significantly reducing possible deet absorption.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

Avoid contact with eyes. Use of this product may cause skin reactions in rare cases. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash treated clothing before wearing it again. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID

If Swallowed	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If In Eyes	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, continue rinsing the eye. • Call a poison control center or doctor for treatment advice.
If you suspect a reaction to this product	• Discontinue use. • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. Questions ???: 800-940-4464 , Weekdays from 9-5 EST.	

NOTE: The First Aid statement's grid format will be used if market label space permits; otherwise a paragraph format will be used.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label. SHAKE WELL BEFORE USING.
Skin application: Squeeze into one hand, rub hands together and apply thoroughly in a thin layer to the forearms. Use additional lotion for upper arms. Repeat for other exposed areas. To apply to face, squeeze lotion into palm of hand and spread on face and neck. Do not apply near eyes and mouth. Apply sparingly around ears. Do not apply to children's hands. Do not apply over cuts, wounds or irritated skin. When using on children, apply to your own hands and then put it on the child. Do not allow children to handle this product. Use just enough repellent to cover exposed skin and/or clothing. Wipe excess from hands after applying. Do not use under clothing. Avoid over-application of this product. Frequent reapplication and saturation is unnecessary for effectiveness. After returning indoors wash treated skin with soap and water. May damage certain synthetic fabrics, acetate, spandex and rayon ~~nylon~~. [Will not damage cotton, wool, or nylon.][Do not apply on or near acetate, rayon, spandex, or other synthetics, furniture, plastics, watch crystals, leather and painted or varnished surfaces including automobiles.]

STORAGE AND DISPOSAL

Pesticide Storage: Store in a cool and dry place. Keep out of reach of children.
If empty: Do not reuse this container. Place in trash or offer for recycling if available. **If partly filled**: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 50404-8 EPA Est. No. 54287-FL-01
COULSTON PRODUCTS INC., BOX 30, EASTON, PA 18044-0030

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50404-8AmendRef-041706

[ ] Indicates Alternate Verbiage
<u>Underlined</u> denotes new verbiage.
~~Single strikethrough~~ denotes deleted/replaced verbiage

MATERIAL SAFETY DATA SHEET

Coulston Products Inc.
P.O. Box 30
Easton, PA 18044

Date-Issued: 08/31/1997
MSDS Ref. No: 01
Date-Revised: 05 sep 2006
Revision No: 03

DURANON INSECT REPELLENT

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: DURANON INSECT REPELLENT
PRODUCT DESCRIPTION: Personal Insect Repellent.
PRODUCT CODE: None Assigned EPA REGISTRATION NO.: 50404-8
MANUFACTURER: Coulston Products Incorporated
Product Stewardship: 1-800-940-4464
Customer Service: 1-800-940-4464
24 HR. EMERGENCY TELEPHONE NUMBERS
CHEMTREC U.S. and CANADA: (800) 424-9300
CHEMTREC All Other Areas: (703) 527-3887
Emergency Phone (888) 740-8712
COMMENTS:
For information regarding MEDICAL EMERGENCIES or PESTICIDE INCIDENTS, call the INTERNATIONALPOISON CENTER at 1-888-740-8712 24 hrs a day.

2. COMPOSITION / INFORMATION ON INGREDIENTS

	Wt.%	CAS#	ACGIH TLV
N,N-diethyl-m-Toluamide (DEET)	20	134-62-3	N/A

COMMENTS:
Ingredients not identified are proprietary or nonhazardous. Values are not product specifications.

3. HAZARDS IDENTIFICATION
EMERGENCY OVERVIEW
IMMEDIATE CONCERNS:
CAUTION: Avoid contact with eyes. Use of this product may cause skin reactions in rare cases. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash treated clothing before wearing it again. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet..
POTENTIAL HEALTH EFFECTS
EYES: May cause eye injury.
SKIN: Avoid contact with eyes and lips. May cause skin reaction in rare cases.
INGESTION: Harmful if swallowed.
INHALATION: Avoid breathing spray mist or using in an enclosed area.
CHRONIC: Not established

4. FIRST AID MEASURES
EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
INGESTION: If swallowed, call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
INHALATION: Remove affected person to fresh air. If breathing has stopped, administer artificial respiration and seek medical attention immediately.

If you suspect a reaction to this product:

Discontinue use; Take off contaminated clothing; Rinse skin immediately with plenty of water for 15-20 minutes; Call a poison control center or doctor for treatment advice.

MATERIAL SAFETY DATA SHEET

Coulston Products Inc.
P.O. Box 30
Easton, PA 18044

Date-Issued: 08/31/1997
MSDS Ref. No: 01
Date-Revised: 05 sep 2006
Revision No: 03

DURANON INSECT REPELLENT

5. FIRE FIGHTING MEASURES

FLASHPOINT AND METHOD: 170°F TCC
FLAMMABLE LIMITS: Lower: NE Upper: NE
AUTOIGNITION TEMPERATURE: NA
FIRE EXTINGUISHING MEDIA: CO_2, Foam or Dry Chemical
FIRE FIGHTING PROCEDURES:
Use a full-faced self-contained breathing apparatus along with full protective gear. Keep nearby containers and equipment cool with a water stream.

6. ACCIDENTAL RELEASE MEASURES

Wipe up with absorbent material. Wash small quantities away with soapy water. Prevent bulk quantities from entering open sewers and waterways.

Waste Disposal:

Dispose of all wastes in accordance with Federal, state and local regulations.

7. HANDLING AND STORAGE PRECAUTIONS

Do not store where temperature exceeds 130°F

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS:

Mechanical ventilation should be used when handling this product in enclosed spaces. Local exhaust ventilation may be necessary.

PERSONAL PROTECTIVE EQUIPMENT

EYES AND FACE: Wear OSHA-approved safety glasses, goggles or face shield.
SKIN: Wear chemically impervious gloves such as Neoprene or Nitrile and protective clothing.
RESPIRATORY: In absence of proper mechanical ventilation, wear a NIOSH approved organic vapor respirator.
PROTECTIVE CLOTHING: Wear chemically impervious gloves, such as neoprene or nitrile. Wear leather shoes and long pants and long sleeve shirt.
WORK HYGIENIC PRACTICES:
DO NOT SMOKE, EAT OR DRINK OR APPLY COSMETICS IN WORK AREA! Wash promptly if skin becomes contaminated. Wash at the end of each work shift and before eating, smoking and using the toilet.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:	Lotion
ODOR:	Slight (deet)
APPEARANCE:	Milky white
pH:	7.1 – 7.25
PERCENT VOLATILE:	Not Available
VAPOR DENSITY:	Not Available
BOILING POINT:	Not Available
FREEZING POINT:	Not Available
MELTING POINT:	Not Applicable
SOLUBILITY IN WATER:	Miscible
SPECIFIC GRAVITY:	0.98 (water=1) at 20°C
EVAPORATION RATE:	Not Available

MATERIAL SAFETY DATA SHEET

Coulston Products Inc.
P.O. Box 30
Easton, PA 18044

Date-Issued: 08/31/1997
MSDS Ref. No: 01
Date-Revised: 05 sep 2006
Revision No: 03

DURANON INSECT REPELLENT

10. STABILITY AND REACTIVITY
STABLE: YES HAZARDOUS POLYMERIZATION: NO
CONDITIONS TO AVOID: Temperatures above 130°F

11. TOXICOLOGICAL INFORMATION
GENERAL COMMENTS: No data available.
COMMENTS: None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as being carcinogens.

12. ECOLOGICAL INFORMATION
ECOTOXICOLOGICAL INFORMATION: None Available

13. DISPOSAL CONSIDERATIONS
Pesticide Storage: Store in a cool and dry place. Keep out of reach of children.
If empty: Do not reuse container. Place in trash or offer for recycling if available.
If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

14. TRANSPORT INFORMATION
DOT (DEPARTMENT OF TRANSPORTATION)
PROPER SHIPPING NAME: Consumer Commodity
PRIMARY HAZARD CLASS/DIVISION: ORM-D

15. REGULATORY INFORMATION
UNITED STATES
SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT)
311/312 HAZARD CATEGORIES:
FIRE: NO PRESSURE GENERATING: NO REACTIVITY: NO ACUTE: NO
313 REPORTABLE INGREDIENTS: None
302/304 EMERGENCY PLANNING
EMERGENCY PLAN: There are no SARA Title III Section 302 extremely hazardous substances present in this formulation. (40 CFR 355). There are no components that are subject to emergency requirements under CERCLA Section 103(a)(40 CFR 302.4) in this formulation.

TSCA (TOXIC SUBSTANCE CONTROL ACT)
TSCA STATUS: All chemical substances found in this product comply with the Toxic Substances Control ACT inventory reporting requirements.

MATERIAL SAFETY DATA SHEET

Coulston Products Inc.
P.O. Box 30
Easton, PA 18044

Date-Issued: 08/31/1997
MSDS Ref. No: 01
Date-Revised: 05 sep 2006
Revision No: 03

DURANON INSECT REPELLENT

16. OTHER INFORMATION
REVISION SUMMARY: Updated MSDS
HMIS CODES
FIRE: 0 HEALTH: 2 REACTIVITY: 0

HMIS RATINGS NOTES:
We assign HMIS ratings to this product based on the hazards of its ingredients(s). Since the customer is most aware of the applications and conditions of use, he must ensure that the proper personal protective equipment is provided consistent with the information contained in sections 7 and 8 of this MSDS.

COMMENTS:
The data contained herein is based on information currently available to Coulston Products Inc. and believed to be factual and the opinions expressed to be those of qualified experts; however, this data is not to be taken as a warranty or representation for which Coulston Products Inc. assumes legal responsibility.
MSDS Prepared by Scientific Coordination, Inc.

DermAegis LipoDEET Insect Repellent 302

Provides Protection Against Mosquitoes for Up to 4 Hours

30% DEET

Insect Repellent ● Lotion ● Repels Mosquitoes

Odorless After Application

Repels biting insects for up to 4 hours

Effective Unscented Protection From Mosquitoes, Gnats, No-See-Ums, Sand Flies, Biting Flies, Deer Flies, Stable Flies, Black, Flies, Ticks, Chiggers, Red Bugs and Fleas

Just the right protection around the home and backyard

Non-greasy ●Non Staining ●Resists Perspiration

ACTIVE INGREDIENTS:
DEET (CAS No. 134-62-3) …… 30.00%
OTHER INGREDIENTS ……..…… 70.00%
TOTAL: 100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents _____ oz..

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

Avoid contact with eyes. Use of this product may cause skin reactions in rare cases. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash treated clothing before wearing it again. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID

If Swallowed	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If In Eyes	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, continue rinsing the eye. • Call a poison control center or doctor for treatment advice.
If you suspect a reaction to this product	• Discontinue use. • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. Questions ???: 858-259-5659	

NOTE: The First Aid statement's grid format will be used if market label space permits; otherwise a paragraph format will be used.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label. SHAKE WELL BEFORE USING.
Skin application: Squeeze into one hand, rub hands together and apply thoroughly in a thin layer to the forearms. Use additional lotion for upper arms. Repeat for other exposed areas. To apply to face, squeeze lotion into palm of hand and spread on face and neck. Do not apply near eyes and mouth. Apply sparingly around ears. Do not apply to children's hands. Do not apply over cuts, wounds or irritated skin. When using on children, apply to your own hands and then put it on the child. Do not allow children to handle this product. Use just enough repellent to cover exposed skin and/or clothing. Wipe excess from hands after applying. Do not use under clothing. Avoid over-application of this product. Frequent reapplication and saturation is unnecessary for effectiveness. After returning indoors wash treated skin with soap and water. May damage certain synthetic fabrics, acetate, spandex and nylon. If you suspect a reaction to this product, discontinue use, wash treated skin, and call your local poison control center. If you go to a doctor, take this product with you.

STORAGE AND DISPOSAL

Pesticide Storage: Store in a cool and dry place. Keep out of reach of children.
If empty: Do not reuse this container. Place in trash or offer for recycling if available. **If partly filled**: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 82810-1 EPA Est. No. 54287-FL-01
DermAegis, Inc.
4747 Plummer Ct.
San Diego, CA 92130

102506LipoDEETCorrectedLABEL

MATERIAL SAFETY DATA SHEET

DermAegis, Inc.
5730 Clarendon Drive
Rockford, IL 61114

Date-Issued: 02/02/2005
MSDS Ref. No: 01
Date-Revised: 05 SEP 2006
Revision No: 02

LIPODEET INSECT REPELLENT FORMULA 302

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: LIPODEET INSECT REPELLENT FORMULA 302
PRODUCT DESCRIPTION: Personal Insect Repellent Lotion.
PRODUCT CODE: 302 EPA REGISTRATION NUMBER: 82810-1
MANUFACTURER: DermAegis, Incorporated
Product Stewardship: 815-877-2313
Customer Service: 815-877-2313
24 HR. EMERGENCY TELEPHONE NUMBERS
CHEMTREC U.S. and CANADA: 815-877-2313
CHEMTREC All Other Areas: (703) 527-3887
Emergency Phone 815-877-2313
COMMENTS:
For information regarding MEDICAL EMERGENCIES or PESTICIDE INCIDENTS, call the INTERNATIONALPOISON CENTER at 1-888-740-8712 24 hrs a day.

2. COMPOSITION / INFORMATION ON INGREDIENTS

	Wt.%	CAS#	ACGIH TLV
N,N-diethyl-m-Toluamide (DEET)	30	134-62-3	N/A
Phospholipid-containing membrane plus Other inert ingredients	~70	N/E	N/E

COMMENTS:
Ingredients not identified are proprietary or nonhazardous. Values are not product specifications.

3. HAZARDS IDENTIFICATION
EMERGENCY OVERVIEW
IMMEDIATE CONCERNS:
WARNING: Harmful if swallowed. May cause eye injury. Avoid contact with eyes and lips. May cause skin reaction in rare cases. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
POTENTIAL HEALTH EFFECTS
EYES: May cause eye injury.
SKIN: Avoid contact with eyes and lips. May cause skin reaction in rare cases.
INGESTION: Harmful if swallowed.
INHALATION: Avoid breathing spray mist or using in an enclosed area.
CHRONIC: Not established

4. FIRST AID MEASURES
EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
INGESTION: If swallowed, call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
INHALATION: Remove affected person to fresh air. If breathing has stopped, administer artificial respiration and seek medical attention immediately.

If you suspect a reaction to this product:

Discontinue use; Take off contaminated clothing; Rinse skin immediately with plenty of water for 15-20 minutes; Call a poison control center or doctor for treatment advice.

MATERIAL SAFETY DATA SHEET

DermAegis, Inc.
5730 Clarendon Drive
Rockford, IL 61114

Date-Issued: 02/02/2005
MSDS Ref. No: 01
Date-Revised: 05 SEP 2006
Revision No: 02

LIPODEET INSECT REPELLENT FORMULA 302

5. FIRE FIGHTING MEASURES

FLASHPOINT AND METHOD: N/E
FLAME EXTENSION: N/A
FLAMMABLE LIMITS: Lower: N/E Upper: N/E
AUTOIGNITION TEMPERATURE: N/E
FIRE EXTINGUISHING MEDIA: CO_2, Foam or Dry Chemical
FIRE FIGHTING PROCEDURES:
Use a full-faced self-contained breathing apparatus along with full protective gear. Keep nearby containers and equipment cool with a water stream.

6. ACCIDENTAL RELEASE MEASURES

Wipe up with absorbent material. Wash small quantities away with soapy water. Prevent bulk quantities from entering open sewers and waterways.

Waste Disposal:

Dispose of in accordance with local, state and Federal regulations. Do not incinerate empty container, dispose of properly.

7. HANDLING AND STORAGE PRECAUTIONS

Store in a cool and dry place. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS:

Mechanical ventilation should be used when handling this product in enclosed spaces. Local exhaust ventilation may be necessary.

PERSONAL PROTECTIVE EQUIPMENT

EYES AND FACE: Wear OSHA-approved safety glasses, goggles or face shield.
SKIN: Wear chemically impervious gloves such as Neoprene or Nitrile and protective clothing.
RESPIRATORY: In absence of proper mechanical ventilation, wear a NIOSH approved organic vapor respirator.
PROTECTIVE CLOTHING: Wear chemically impervious gloves, such as neoprene or nitrile. Wear leather shoes and long pants and long sleeve shirt.
WORK HYGIENIC PRACTICES:
DO NOT SMOKE, EAT OR DRINK OR APPLY COSMETICS IN WORK AREA! Wash promptly if skin becomes contaminated. Wash at the end of each work shift and before eating, smoking and using the toilet.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:	Lotion
ODOR:	Faint DEET
APPEARANCE:	Off white lotion
pH:	6.4
PERCENT VOLATILE:	N/A
VAPOR DENSITY:	N/A
BOILING POINT:	N/E
FREEZING POINT:	N/E
MELTING POINT:	N/E
SOLUBILITY IN WATER:	Fine suspension
SPECIFIC GRAVITY:	N/E
EVAPORATION RATE:	N/E

MATERIAL SAFETY DATA SHEET

DermAegis, Inc.
5730 Clarendon Drive
Rockford, IL 61114

Date-Issued: 02/02/2005
MSDS Ref. No: 01
Date-Revised: 05 SEP 2006
Revision No: 02

LIPODEET INSECT REPELLENT FORMULA 302

10. STABILITY AND REACTIVITY
STABLE: YES HAZARDOUS POLYMERIZATION: NO
CONDITIONS TO AVOID: Temperatures above 120°F

11. TOXICOLOGICAL INFORMATION
DERMAL SENSITIZATION: Not a sensitizer.
PRIMARY SKIN IRRITATION: Not a skin irritant.
DERMAL TOXICITY: Not a dermal toxicant.
ORAL TOXICITY: Not an oral toxicant.
EYE IRRITATION: Moderately irritating. Irritation cleared by day 14.
COMMENTS: None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as being carcinogens.

12. ECOLOGICAL INFORMATION
ECOTOXICOLOGICAL INFORMATION: None Available

13. DISPOSAL CONSIDERATIONS
DISPOSAL METHOD:
If empty: Do not reuse container. Place in trash or offer for recycling if available.
If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

14. TRANSPORT INFORMATION
DOT (DEPARTMENT OF TRANSPORTATION)
PROPER SHIPPING NAME: Consumer Commodity
PRIMARY HAZARD CLASS/DIVISION: ORM-D
OTHER SHIPPING INFORMATION: N/A

15. REGULATORY INFORMATION
UNITED STATES
SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT)
311/312 HAZARD CATEGORIES:
FIRE: NO PRESSURE GENERATING: NO REACTIVITY: NO ACUTE: NO
313 REPORTABLE INGREDIENTS: None
302/304 EMERGENCY PLANNING
EMERGENCY PLAN: There are no SARA Title III Section 302 extremely hazardous substances present in this formulation. (40 CFR 355). There are no components that are subject to emergency requirements under CERCLA Section 103(a)(40 CFR 302.4) in this formulation.

TSCA (TOXIC SUBSTANCE CONTROL ACT)
TSCA STATUS: All chemical substances found in this product comply with the Toxic Substances Control ACT inventory reporting requirements.

MATERIAL SAFETY DATA SHEET

DermAegis, Inc.
5730 Clarendon Drive
Rockford, IL 61114

Date-Issued: 02/02/2005
MSDS Ref. No: 01
Date-Revised: 05 SEP 2006
Revision No: 02

LIPODEET INSECT REPELLENT FORMULA 302

16. OTHER INFORMATION
REVISION SUMMARY: Updated MSDS
HMIS CODES
FIRE: 1 HEALTH: 2 REACTIVITY: 0

HMIS RATINGS NOTES:
We assign HMIS ratings to this product based on the hazards of its ingredients(s). Since the customer is most aware of the applications and conditions of use, he must ensure that the proper personal protective equipment is provided consistent with the information contained in sections 7 and 8 of this MSDS.

COMMENTS:
The data contained herein is based on information currently available to DermAegis, Inc. and believed to be factual and the opinions expressed to be those of qualified experts; however, this data is not to be taken as a warranty or representation for which DermAegis, Inc. assumes legal responsibility.
MSDS Prepared by Scientific Coordination, Inc.

N/A: Not Applicable
N/E: Not Established

U.S. ENVIRONMENTAL PROTECTION AGENCY **Office of Pesticide Programs** **Registration Division (7505P)** **1200 Pennsylvania Ave., N.W.** **Washington, D.C. 20460**	**EPA Reg. Number:** 82810-1	**Date of Issuance:** MAY 19 2006
NOTICE OF PESTICIDE: X Registration ___ Reregistration (under FIFRA, as amended)	**Term of Issuance:** Conditional	
	Name of Pesticide Product: LIPODEET 302	

Name and Address of Registrant (include ZIP Code) :

Dermaegis, Inc.
5730 Clarendon Drive
Rockford, IL 61114

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby conditionally registered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA §3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA §3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA §4.

2. Make the following label changes before you release the product for shipment:

   a. Revise the EPA Registration Number to read, "EPA Reg. No. 82810-1."

Continued on page 2

Signature of Approving Official: Ann Sibold for Richard Gebken, Product Manager (10) Insecticide Branch, Registration Division (7505P)	**Date:** MAY 19 2006

EPA Form 8570-6

a. Change the product signal word to "WARNING." The results of the primary eye irritation study submitted within the acute toxicity data six pack resulted in the classification of the formulation as a category II eye irritant.

b. The following statements are required on all end-use DEET products. Modify the directions for use presented on the label to incorporate the following statements:

   i. If you suspect a reaction to this product, discontinue use, wash treated skin, and call your local poison control center.
   ii. If you go to a doctor, take this product with you.

c. Remove or revise the following label claims as indicated below:
   i. Provides 95% or Greater Protection Against Mosquitoes for 4 or More Hours.
      - Revise to read "Provides Protection Against Mosquitoes for up to 4 Hours."
   ii. 30% DEET in a Non-Alcohol Formula.
      - Revise to read "30% DEET."
   iii. Repels biting insects for hours.
      - Revise to read "Repels biting insects for up to 4 hours."

4. Submit one copy of the revised final printed label for the record before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA §6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Sincerely,

Richard Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7505P)

Enclosures
Stamped Label

DermAegis LipoDEET Insect Repellent 302

Provides 95% or Greater Protection Against Mosquitoes for 4 or More Hours

30% DEET in a Non-Alcohol Formula

Insect Repellent ● Lotion ● Repels Mosquitoes

Odorless After Application

Repels biting insects for hours

Effective Unscented Protection From Mosquitoes, Gnats, No-See-Ums, Sand Flies, Biting Flies, Deer Flies, Stable Flies, Black, Flies, Ticks, Chiggers, Red Bugs and Fleas

Just the right protection around the home and backyard

Non-greasy ●Non Staining ●Resists Perspiration

ACTIVE INGREDIENTS:

DEET (CAS No. 134-62-3)	30.00%
OTHER INGREDIENTS	70.00%
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents _____ oz..

ACCEPTED with COMMENTS In EPA Letter Dated:

MAY 19 2006

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 82810-1

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

Avoid contact with eyes. Use of this product may cause skin reactions in rare cases. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash treated clothing before wearing it again. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID

If Swallowed	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If In Eyes	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, continue rinsing the eye. • Call a poison control center or doctor for treatment advice.
If you suspect a reaction to this product	• Discontinue use. • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. Questions ???: 858-259-5659	

NOTE: The First Aid statement's grid format will be used if market label space permits; otherwise a paragraph format will be used.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label. SHAKE WELL BEFORE USING.
Skin application: Squeeze into one hand, rub hands together and apply thoroughly in a thin layer to the forearms. Use additional lotion for upper arms. Repeat for other exposed areas. To apply to face, squeeze lotion into palm of hand and spread on face and neck. Do not apply near eyes and mouth. Apply sparingly around ears. Do not apply to children's hands. Do not apply over cuts, wounds or irritated skin. When using on children, apply to your own hands and then put it on the child. Do not allow children to handle this product. Use just enough repellent to cover exposed skin and/or clothing. Wipe excess from hands after applying. Do not use under clothing. Avoid over-application of this product. Frequent reapplication and saturation is unnecessary for effectiveness. After returning indoors wash treated skin with soap and water. May damage certain synthetic fabrics, acetate, spandex and nylon.

STORAGE AND DISPOSAL

Pesticide Storage: Store in a cool and dry place. Keep out of reach of children.
If empty: Do not reuse this container. Place in trash or offer for recycling if available. **If partly filled**: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 82810- EPA Est. No.

DermAegis, Inc.
4747 Plummer Ct.
San Diego, CA 92130

100705LipoDEETLABEL-01

Material Safety Data Sheet

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SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: ULTRATHON (tm) INSECT REPELLENT (lotion)
MANUFACTURER: 3M
DIVISION: Protective Materials & Consumer Specialties Division

ADDRESS: 3M Center
St. Paul, MN 55144-1000

EMERGENCY PHONE: 1-800-364-3577 or (651) 737-6501 (24 hours)

Issue Date: 12/14/2005
Supercedes Date: 12/14/2004

Document Group: 16-0613-6

Product Use:
Specific Use: INSECT REPELLANT

SECTION 2: INGREDIENTS

Ingredient	C.A.S. No.	% by Wt
WATER	7732-18-5	40 - 44
N,N-DIETHYL M-TOLUAMIDE	134-62-3	34 - 36
INERT INGREDIENTS	Mixture	24 - 26

SECTION 3: HAZARDS IDENTIFICATION

3.1 EMERGENCY OVERVIEW

Specific Physical Form: Viscous Lotion
Odor, Color, Grade: White with DEET odor.
General Physical Form: Liquid
Immediate health, physical, and environmental hazards: May cause severe eye irritation.

3.2 POTENTIAL HEALTH EFFECTS

Eye Contact:
Severe Eye Irritation: Signs/symptoms may include significant redness, swelling, pain, tearing, cloudy appearance of the cornea, and impaired vision.

Skin Contact:
Prolonged or repeated exposure may cause:
Mild Skin Irritation: Signs/symptoms may include localized redness, swelling, and itching.

Inhalation:
No health effects are expected.

Ingestion:
Ingestion may cause:
Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, nausea, diarrhea and vomiting.

SECTION 4: FIRST AID MEASURES

4.1 FIRST AID PROCEDURES

The following first aid recommendations are based on an assumption that appropriate personal and industrial hygiene practices are followed.

Eye Contact: Immediately flush eyes with large amounts of water for at least 15 minutes. Get immediate medical attention.

Skin Contact: Wash affected area with soap and water. If signs/symptoms develop, get medical attention.

Inhalation: No need for first aid is anticipated.

If Swallowed: Do not induce vomiting. Give victim two glasses of water. Never give anything by mouth to an unconscious person. Get medical attention.

4.2 NOTE TO PHYSICIANS

Probable mucosal damage may contraindicate the use of gastric lavage.

SECTION 5: FIRE FIGHTING MEASURES

5.1 FLAMMABLE PROPERTIES

Autoignition temperature	*No Data Available*
Flash Point	*Not Applicable*
Flammable Limits - LEL	*Not Applicable*
Flammable Limits - UEL	*Not Applicable*

5.2 EXTINGUISHING MEDIA
Non-combustible. Choose material suitable for surrounding fire.

5.3 PROTECTION OF FIRE FIGHTERS

Special Fire Fighting Procedures: Wear full protective equipment (Bunker Gear) and a self-contained breathing apparatus (SCBA).

Unusual Fire and Explosion Hazards: Not applicable.

Note: See STABILITY AND REACTIVITY (SECTION 10) for hazardous combustion and thermal decomposition information.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Accidental Release Measures: Observe precautions from other sections. Call 3M- HELPS line (1-800-364-3577) for more information on handling and managing the spill. Evacuate unprotected and untrained personnel from hazard area. The spill should be cleaned up by qualified personnel. Ventilate the area with fresh air. Contain spill. For larger spills, cover drains and build dikes to prevent entry into sewer systems or bodies of water. Working from around the edges of the spill inward, cover with bentonite, vermiculite, or commercially available inorganic absorbent material. Mix in sufficient absorbent until it appears dry. Collect as much of the spilled material as possible. Clean up residue with an appropriate solvent selected by a qualified and authorized person. Ventilate the area with fresh air. Read and follow safety precautions on the solvent label and MSDS. Place in a closed container approved for transportation by appropriate authorities. Dispose of collected material as soon as possible.

In the event of a release of this material, the user should determine if the release qualifies as reportable according to local, state, and federal regulations.

SECTION 7: HANDLING AND STORAGE

7.1 HANDLING
Avoid eye contact. Keep out of the reach of children. Wash hands thoroughly with soap and water after applying product.

7.2 STORAGE
Store under normal warehouse conditions.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 ENGINEERING CONTROLS
Not applicable.

8.2 PERSONAL PROTECTIVE EQUIPMENT (PPE)

8.2.1 Eye/Face Protection
Avoid eye contact.

8.2.2 Skin Protection
Gloves are not required. Do not use on synthetic fabrics, plastics, watch crystals, leather, painted, or varnished surfaces. After returning indoors, wash treated skin with soap and water. Wash treated clothing.

If irritation occurs, discontinue use.

8.2.3 Respiratory Protection
Not applicable.

8.2.4 Prevention of Swallowing
Wash hands thoroughly with soap and water after applying product.

8.3 EXPOSURE GUIDELINES

None Established

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specific Physical Form:	Viscous Lotion
Odor, Color, Grade:	White with DEET odor.
General Physical Form:	Liquid
Autoignition temperature	*No Data Available*
Flash Point	*Not Applicable*
Flammable Limits - LEL	*Not Applicable*
Flammable Limits - UEL	*Not Applicable*
Boiling point	>=95 ºF
Density	0.995 - 1.035 g/ml
Vapor Density	*Not Applicable*
Vapor Pressure	<=16 psia [@ 68 ºF]
Specific Gravity	0.995 - 1.035 [*Ref Std:* WATER=1]
Melting point	*No Data Available*
Solubility In Water	*Not Applicable*
Solubility in Water	Negligible
Evaporation rate	*No Data Available*
Volatile Organic Compounds	Approximately 0.19 g/l
Percent volatile	>=44.00 % weight
VOC Less H2O & Exempt Solvents	Approximately 38.16 g/l
Viscosity	150000 - 300,000 centipoise [*Test Method:* ASTM METHOD]

SECTION 10: STABILITY AND REACTIVITY

Stability: Stable.

Materials and Conditions to Avoid: None known

Hazardous Polymerization: Hazardous polymerization will not occur.

Hazardous Decomposition or By-Products

Substance	Condition
Carbon monoxide	During Combustion

Carbon dioxide	During Combustion
Oxides of Nitrogen	During Combustion

SECTION 11: TOXICOLOGICAL INFORMATION

Product-Based Toxicology Information:

Use of this product may cause skin reactions in rare cases.

Component-Based Toxicology Information:

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION

Not determined.

CHEMICAL FATE INFORMATION

Not determined.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal Method: Dispose of waste product in a permitted hazardous waste facility.
Dispose of empty product containers in a sanitary landfill.

EPA Hazardous Waste Number (RCRA): Not regulated

Since regulations vary, consult applicable regulations or authorities before disposal.

SECTION 14:TRANSPORT INFORMATION

ID Number(s):
70-0711-7347-3, 70-0711-7696-3, 70-1000-7054-2, 70-1000-7097-1, 70-1000-7404-9, 70-1000-8095-4, 70-1000-8287-7, 70-1000-9881-6, 70-1000-9888-1, 70-1000-9889-9, 70-2007-2649-8

Please contact the emergency numbers listed on the first page of the MSDS for Transportation Information for this material.

SECTION 15: REGULATORY INFORMATION

US FEDERAL REGULATIONS

Contact 3M for more information.

311/312 Hazard Categories:
Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No Immediate Hazard - Yes Delayed Hazard - No

FIFRA

Status	Registration Number
Registered	58007-1

STATE REGULATIONS
Contact 3M for more information.

CHEMICAL INVENTORIES
The components of this product are in compliance with the chemical notification requirements of TSCA.

Contact 3M for more information.

INTERNATIONAL REGULATIONS
Contact 3M for more information.

This MSDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.

SECTION 16: OTHER INFORMATION

NFPA Hazard Classification
Health: 2 **Flammability:** 0 **Reactivity:** 0 **Special Hazards:** None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

Revision Changes:
Copyright was modified.
Section 10: Hazardous decomposition or by-products table was modified.
Section 2: Ingredient table was modified.
Sections 3 and 9: Specific physical form information was modified.

Section 5: Flammable limits (UE) information was modified.
Section 5: Flammable limits (LEL) information was modified.
Section 9: Property description for optional properties was modified.
Section 9: Flammable limits (LEL) information was modified.
Section 9: Flammable limits (UEL) information was modified.
Section 4: Note to physicians heading was added.
Section 15: FIFRA heading was added.
Section 15: FIFRA information was added.
Section 4: Note to physicians was added.
Section 15: Inventories information was added.
Section 9: Solubility in water text was added.

DISCLAIMER: The information in this Material Safety Data Sheet (MSDS) is believed to be correct as of the date issued. 3M MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR COURSE OF PERFORMANCE OR USAGE OF TRADE. User is responsible for determining whether the 3M product is fit for a particular purpose and suitable for user's method of use or application. Given the variety of factors that can affect the use and application of a 3M product, some of which are uniquely within the user's knowledge and control, it is essential that the user evaluate the 3M product to determine whether it is fit for a particular purpose and suitable for user's method of use or application.

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3M MSDSs are available at www.3M.com

58007-1 04/08/2004 115

APR 8 2004

Susan M. Price
3M
3M Ctr., Bldg. 290-04-01
St. Paul, MN 55144-1000

Subject: Revised Label For:
3M Ultrathon Insect Repellent
Insect/Arthropod Insect Repellent Lotion
EPA Registration No. 58007-1
Application dated May 30, 2001

Dear Ms. Price

The proposed amendment to the registration for the product cited above under The Federal Insecticide, Fungicide And Rodenticide Act, as amended revising the label in response to the DEET RED is acceptable subject to the comments listed below:

1) Change the Precautionary Statements to read as follows:

Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes. Use of this product may cause skin reactions in rare cases. Wash treated clothing before wearing it again. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

2) Change the First Aid section to read:

IF IN EYES:

* Hold eye open and rinse slowly and gently with water for 15-20 minutes.
* Remove contact lenses, if present, after the first five minutes, then continue rinsing.
* Call a poison control center or doctor for treatment advice.

IF YOU SUSPECT A REACTION TO THIS PRODUCT:

* Discontinue use.
* Take off contaminated clothing.
* Rinse skin immediately with plenty of water for 15-20 minutes.
* Call a poison control center or doctor for treatment

2/5

advice.

HOT LINE NUMBER
In case of emergency call toll free(insert number). Have the product container or label with you when calling a poison control center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

3) Add a Storage And Disposal section to read:

PESTICIDE STORAGE: Store the product in a cool and dry place. Keep out of reach of children.
CONTAINER DISPOSAL:
IF EMPTY: Do not reuse this container. Place in trash or offer for recycling if available.
IF PARTLY FILLED: Call your local solid waste agency(or toll free number which meets the criteria in paragraph II.E of PR Notice 2001-6) for disposal instructions. Never place unused product down any indoor or outdoor drain.

4) Change the statement, ※READ ALL DIRECTIONS BEFORE USING THIS PRODUCT※, to read ※READ AND FOLLOW ALL DIRECTIONS AND PRECAUTIONS ON THIS PRODUCT LABEL.※.

5) Change the Ingredients Statement to read:

DEET.....34.34%
Other Ingredients 65.66%

6) Delete the statement, ※Used by the Military.※.

7) Delete the statement, ※Used by the military because of its effective, long lasting protection.※.

8) Delete the table which compares Product, Hours of Protection and DEET Levels.Comparison claims are not permitted.

9) The signal word, WARNING, must appear on a separate line directly below the statement, Keep Out Of Reach Of Children.

10) The following statements must be grouped together in the Directions for Use section under the Subheading, General Precautions and Restrictions.

※Do not apply near eyes and mouth.※
※Apply sparingly around ears.※
※Do not apply over cuts, wounds or irritated skin.※
※Do not allow children to handle this product.※

- Do not apply to children's hands.
- When using on children, apply to your own hands, and then put it on the child.
- Use just enough repellent to cover exposed skin and/or clothing.
- Do not use under clothing.
- Avoid over-application of this product.
- After returning indoors, wash treated skin with soap and water.

You may wish to propose alternate labeling for the military label.

This product is not being re-registered at this time. Product specific efficacy data will be required. Once the efficacy guidelines are in place, you will be notified of the efficacy requirements.

A stamped copy of the draft label is enclosed for your records. Submit two copies of the finished label revised in accordance with the comments listed above before the product is released for shipment under this amended label.

The Confidential Statement Of Formula(CSF) dated May 30, 2001 is acceptable and has been made a part of the file for this product.

Sincerely,

Joseph M. Tavano

Richard Gebken
Acting Product Manager 10
Insecticide Branch
Registration Division (7505C)

415

MASTER LABEL

INSECT/ARTHROPOD INSECT REPELLENT LOTION
ULTRATHON™ INSECT REPELLENT

UP TO 12 HOURS OF PROTECTION AGAINST MOSQUITOS
Advanced 3M Controlled Release Technology also repels ticks, biting flies, chiggers, gnats, and fleas. Tested in Central American jungles. Used by the Military.

Repels mosquitos, biting flies, chiggers, deer flies, fleas and stable flies. Also repels terrestrial leeches in tropical areas where pest occurs.

Provides 95% or greater protection against mosquitoes for 12 or more hours under normal use conditions.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
APR 8 2004
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 58007-1

ACTIVE INGREDIENTS:
DEET [N,N-diethyl-m-toluamide + Related Isomers] 34.34%
OTHER INGREDIENTS 65.66%

KEEP OUT OF REACH OF CHILDREN

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS **WARNING**:
For external use only. Causes eye irritation. Do not get in eyes or mouth. Do not apply to hands of young children. Do not apply over cuts, wounds, or irritated skin. When using on children, apply to your own hands and then apply to the child.

FIRST AID: If in eyes, flush with plenty of water. Get medical attention if irritation persists.

(Net contents)

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT.
Squeeze into hand and spread evenly in a thin layer. Use just enough repellent to cover all exposed skin. Do not use under clothing. Frequent reapplication and saturation is unnecessary for effectiveness. Avoid overexposure and contact with eyes and lips. After returning indoors, wash treated skin with soap and water. Wash treated clothing. Use of this product may cause skin reactions in rare cases. If you suspect that you or your child is reacting to this product, wash treated skin and call your local poison control center. If you go to a doctor, take this repellent with you. May damage some synthetic fabrics, plastics, and painted or varnished surfaces. Avoid smearing on plastic eyeglasses, goggles, watch crystals, etc. WILL NOT DAMAGE nylon, cotton, or wool fabrics.

(Insect/Arthropod Repellant Lotion - military label directions:)
Squeeze into one hand 2.5 ml of repellent, a strip equal in length and width to the diagram on the side of the tube. (2.5 ml. Strip Diagram on side of tube)Rub hands together and apply thoroughly in a thin layer to both forearms. Use additional lotion for upper arms. Repeat for other exposed areas. To apply to face, squeeze lotion into palm of hand and spread on face and heck. Avoid contact with eyes and lips. Repeat as necessary. Wipe hands after application.

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STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage and disposal.
Storage: Store the product in a cool and dry place away from heat.
Disposal: Do not reuse empty container. Wrap container and put in trash.

In case of emergency, call 651-737-8501 or 800-364-3577

Position UPC

EPA Reg. No. 58007-1
EPA Est. No. 50678-NJ-001

3M
3M Center,
St. Paul MN 55144-1000

Repels deer ticks that may carry Lyme disease.

Repels mosquitos that may carry the West Nile virus

Repels biting flies, ticks, chiggers, gnats and fleas.

Advanced 3M Controlled Release Technology provides a continuous shield of protection that lasts up to 12 hours against mosquitos .

This unique formula

- Creates an effective vapor barrier that repel mosquitos and biting insects
- Provides maximum protection hour after hour
- Tested for effectiveness in the Florida Everglades and Central American jungles
- Used by the military because of its effective, long lasting protection
- Resists rain, sweat, and water splashes
- No strong odor

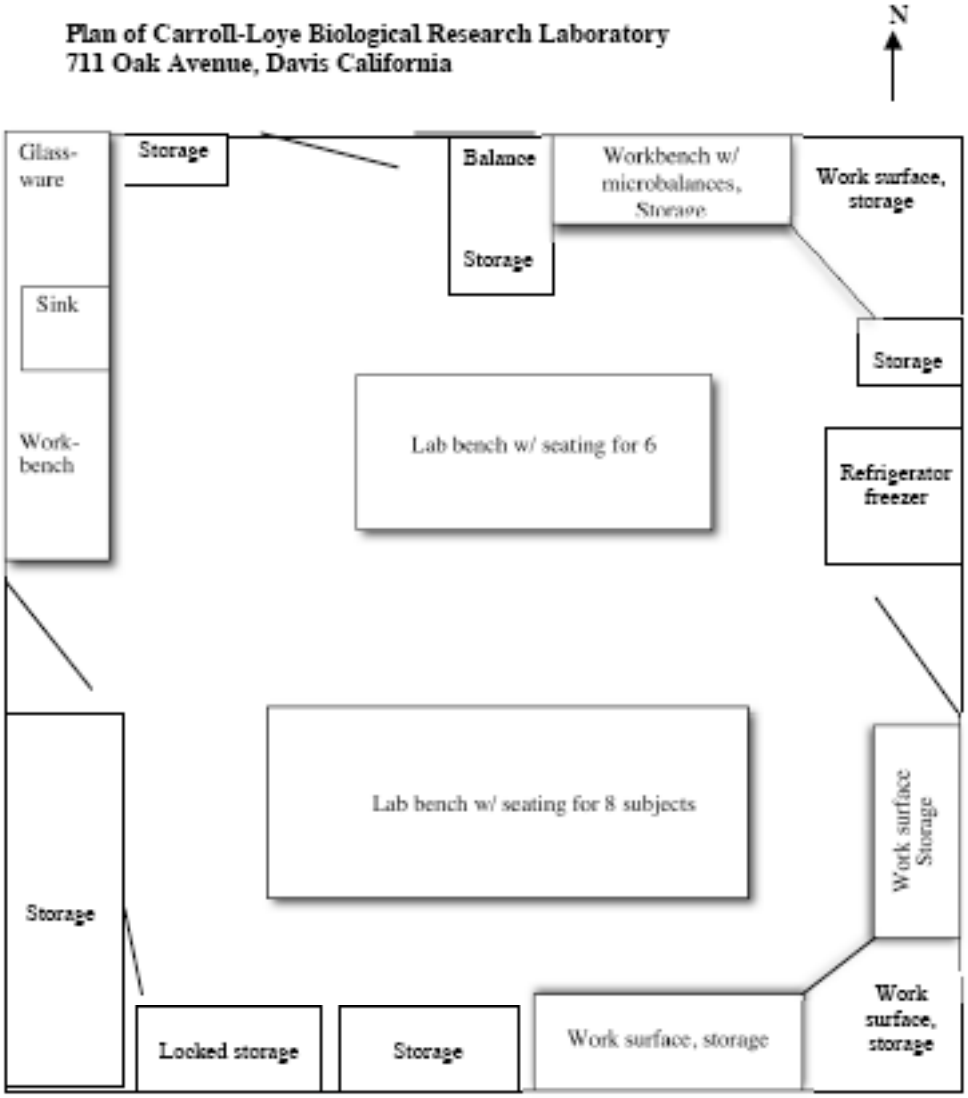
Controlled release formula allows 33.3% DEET to repel mosquitos up to 12 hours

Product	Hours of Protection*	DEET Levels
3M Ultrathon™ Insect Repellent	Up to 12 hours	33.3%
Most 100% DEET products	Up to 10 hours	100.0%
Most 60% or less DEET products	Up to 6 hours	60% or less

*as stated on 1992 package claims against mosquitos

Appendix 9. Physical plan of Carroll-Loye Biological Research Laboratory

Plan of Carroll-Loye Biological Research Laboratory
711 Oak Avenue, Davis California



Interior dimensions: 18.5' E-W, 20' N-S

Version 2, June 2006