COVER PAGE

EFFICACY TEST PROTOCOL SCI-001

TEST OF PERSONAL INSECT REPELLENTS

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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 objective of this study is to test the repellent characteristics of the Test Materials against mosquitoes, with efficacy 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, with 10 treated subjects in each trial testing each formulation, and two untreated subjects in each trial. Ion addition, the current US Military repellent (the DEET-based 'Ultrathon') will be used a comparison article. Initial dosage determination ('dosimetry') will be conducted with 10 subjects, 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, those data will be used to determine dosing for the efficacy.

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. Only experienced professionals (the Study Director and/or other qualified researchers) 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.

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 positive control 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.

6.4 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 consumer, 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 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. In dosimetry testing, all subjects are treated.

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.

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

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 data collection.

9 STUDY PROCEDURES:

9.1 Test Subjects:

9.1.1 Inclusion criteria:

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 Exclusion criteria:

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

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

9.1.2.3 Poor physical condition.

9.1.2.4 Unwilling to submit to brief query about personal condition.

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

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

9.1.2.7 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.

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

9.1.2.9 Student or employee of the Study Director.

9.1.2.10 Do not regularly spend time in outdoor settings.

9.1.3 Number of Subjects and Rationale for Sample Sizes:

We will use 10 subjects per treatment and 2 untreated control subjects in efficacy testing. Each subject is a replicate. In the dosimetry portion of the study, 10 subjects will be engaged. For the Comparison Article, we propose to initially test six subjects, with the possibility of enrolling up to 10 if initial analyses indicate that greater statistical power would assist in resolving important ambiguities.

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.

9.1.4 Test Subject Recruitment:

9.1.4.1 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.
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.

9.1.4.2 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.

9.1.5 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.

9.1.6 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 '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. 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. 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 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 a lower leg."

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 move away from the area with mosquito activity. 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 positive control. For repellency testing, there will be 10 subjects treated with each test repellent and two serving as untreated controls for repellency testing 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 the technical personnel serving as untreated controls 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:

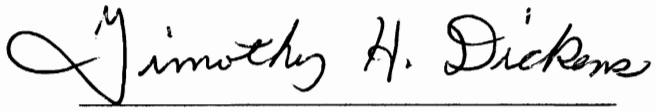
Protocol amendments or deviations will be reviewed by the Study Monitor and the Study Director. Any changes that may affect the health or safety of study participants must be approved the Study Director, the State of California Department of Pesticide Regulation, and the approving IRB. The amendments, 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:

3 November 2006

Scott P. Carroll, Ph.D.
Study Director

Date



3 November 2006

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

Date

Appendix 1. Sample data recording forms.

C-L Field Record Mosq 8 hr

Test #	Note:			Test #	Note:			Test #	Note:			Test #	Note:		
Mosquitoes				Mosquitoes				Mosquitoes				Mosquitoes			
Name:				Name:				Name:				Name:			
Time appld:				Time appld:				Time appld:				Time appld:			
Time exposed:				Time exposed:				Time exposed:				Time exposed:			
LIMB:		Left Arm		LIMB:		Right Arm		LIMB:		Left Leg		LIMB:		Right Leg	
Min	Bites*	Min	Bites*	Min	Bites*	Min	Bites*	Min	Bites*	Min	Bites*	Min	Bites*	Min	Bites*
5		245		5		245		5		245		5		245	
10		250		10		250		10		250		10		250	
15		255		15		255		15		255		15		255	
20		260		20		260		20		260		20		260	
25		265		25		265		25		265		25		265	
30		270		30		270		30		270		30		270	
35		275		35		275		35		275		35		275	
40		280		40		280		40		280		40		280	
45		285		45		285		45		285		45		285	
50		290		50		290		50		290		50		290	
55		295		55		295		55		295		55		295	
60		300		60		300		60		300		60		300	
65		305		65		305		65		305		65		305	
70		310		70		310		70		310		70		310	
75		315		75		315		75		315		75		315	
80		320		80		320		80		320		80		320	
85		325		85		325		85		325		85		325	
90		330		90		330		90		330		90		330	
95		335		95		335		95		335		95		335	
100		340		100		340		100		340		100		340	
105		345		105		345		105		345		105		345	
110		350		110		350		110		350		110		350	
115		355		115		355		115		355		115		355	
120		360		120		360		120		360		120		360	
125		365		125		365		125		365		125		365	
130		370		130		370		130		370		130		370	
135		375		135		375		135		375		135		375	
140		380		140		380		140		380		140		380	
145		385		145		385		145		385		145		385	
150		390		150		390		150		390		150		390	
155		395		155		395		155		395		155		395	
160		400		160		400		160		400		160		400	
165		405		165		405		165		405		165		405	
170		410		170		410		170		410		170		410	
175		415		175		415		175		415		175		415	
180		420		180		420		180		420		180		420	
185		425		185		425		185		425		185		425	
190		430		190		430		190		430		190		430	
195		435		195		435		195		435		195		435	
200		440		200		440		200		440		200		440	
205		445		205		445		205		445		205		445	
210		450		210		450		210		450		210		450	
215		455		215		455		215		455		215		455	
220		460		220		460		220		460		220		460	
225		465		225		465		225		465		225		465	
230		470		230		470		230		470		230		470	
235		475		235		475		235		475		235		475	
240		480		240		480		240		480		240		480	
Subject signature:				Subject signature:				Subject signature:				Subject signature:			
*Measured as 'ites with intent to bite'															

Page 1

Lotion Application

Subject name: Subject number

Date:

A. Left arm

Trial no.	Mass before	Mass after
1		
2		
3		

B. Right arm

Trial no.	Mass before	Mass after
1		
2		
3		

Appendix 2. IRB Approval Letter and Informed Consent Form

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

Kim Lerner
Chairman

Anita McSharry, R.N.
President

DATE: November 07, 2006

TO: Scott P. Carroll, PhD
Principal Investigator

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

SUBJECT: Approval Clinical Research Protocol dated: 11/2/2006
- Informed Consent Form (Ver. 11/7/2006)
- Site Questionnaire
- The Experimental Subject's Bill of Rights

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

The Independent Investigational Review Board, Inc. is an institutional review Committee structured in compliance with the regulations of the Food and Drug Administration contained in the Code of Federal Regulations (2ICFR 50 and 56) and is in compliance with the International Conference of Harmonization (ICH) Good Clinical Practice (GCP) guidelines for IRB/IECs.

At the meeting held on November 07, 2006, the Committee reviewed and unanimously approved the Research Protocol, the Investigator(s), Informed Consent Form, and The Experimental Subject's Bill of Rights for the above noted research study. The Site Questionnaire was reviewed and unanimously accepted.

The Informed Consent Form is unanimously approved as submitted. The approved Informed Consent Form is identified as Version 11/7/2006 and stamped, "Approved 11/7/2006". The Informed Consent Form contains all regulatory required consent elements. The Experimental Subject's Bill of Rights is stamped "Approved 11/7/2006".

The study has been approved for a 12 month period. At the end of this time, you are required to provide the Independent Investigational Review Board with a written progress report and completed Informed Consent Form for this research and obtain approval for continuing the research. Changes to the protocol or use of non-approved recruitment materials cannot be initiated without IIRB review and approval.

In the event of any serious adverse reactions, significant deviations from the protocol or problems in the research, written notice to the Independent Investigational Review Board is required. Please provide this reporting to the above-noted address so that appropriate follow-up will be initiated.

Thank you for your cooperation.

kl/ams/je:rr

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

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 three 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 you put on your own arms and legs in a visit to the study laboratory, and train you to use a mechanical mosquito catcher. On a later date, we will go to a field site to test the insect repellents against mosquitoes in nature.

APPROVED BY
Independent IRB
Signature 11/7/06 Date

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 go to the laboratory and 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

APPROVED BY
Independent IRB
Signature
11/7/06
Date

Initials: _____
Date: _____

removing mosquitoes from a small area of your arm with the aspirator. This training and practice will take about ½ to 1 hour.

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.

STUDY PROCEDURES

Study Design

The study will test three different insect repellent products, namely a lotion, a pump spray and an aerosol spray. You will be randomly (by chance) assigned to receive one or two of the three products, so your chance of receiving any one of them is one-in-three or two-in-three. You will not have a choice as to which repellent product or products you receive. For each product assigned to you, you will have an amount typical of what people commonly use applied to your forearms or lower legs. Experienced personnel will also be present to record the activity of mosquitoes by exposing their own arms or legs without repellent applied. However, 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 forearm and lower leg. 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 place three small

Initials: _____
Date: _____

"bracelets" made of medical gauze around your arm or leg. You will then spray that area, including the bracelets, with a repellent, and a technician will remove the gauze and weigh it to determine how much spray has clung to its surface. Similarly, we will 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 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.

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Independent IRB
Signature 11/7/06 Date

Initials: _____
Date: _____

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 on a data sheet 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.

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
- 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

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Date: _____

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.

The spray repellents contain alcohol and are flammable. 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 of 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 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.

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Initials: _____
Date: _____

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 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.

APPROVED BY
Independent IRB
Signature 11/7/06 Date

Initials: _____
Date: _____

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, EMD Chemicals, 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 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

APPROVED BY
Independent IRB
Signature 11/7/06 Date

Initials: _____
Date: _____

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	Scott Carroll **Print** Carroll-Loye Biological Research Representative	**Sign** Carroll-Loye Biological Research Representative

Independent Investigational Review Board, Inc.
Approval: 11/7/06

APPROVED BY
Independent IRB
Signature 11/7/06 Date

Initials: _____
Date: _____

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the study.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the study may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of a signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

_____ _____

Signature of Subject Date

_____ _____

Signature of Witness Date

Appendix 5. Test Material Labels and MSDS

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

Efficacy Study SCI-001

MATERIAL SAFETY DATA SHEET

Insect Guard II

1. Company Identification

Associated Registrations, Inc. Safety Harbor FL 34695	Manufacturer Sawyer Products Safety Harbor FL 34695
Telephone Number: 800-356-7811 Fax Number: 727-725-1954 Emergency Telephone Number: 800-356-7811	Product Description: Personal Insect Repellent EPA Registration No.: 54287-8 Product Code: None Assigned
Issue Date 5-Sep-06 Replaces Issue Date: 17-Aug-06	

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, CO2, 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 ~~4~~ 24

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. 30404-8

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

® Reg'd TM &™ - Trademarks of Coulston Products Inc.
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

Efficacy Study SCI-001

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

NOTICE OF PESTICIDE:
X Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
82810-1	MAY 19 2006

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:

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

Efficacy Study SCI-001

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

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

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

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,

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

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.

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