UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case Oil of citronella which includes the active ingredient Oil of citronella. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the reregistration representative for the Biopesticides and Pollution Prevention Division, Richard King at (703) 308-8052.

Sincerely yours,

Janet Andersen, Director
Biopesticide and Pollution
Prevention Division (7501W)

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**.

You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

Oil of Citronella

LIST C

CASE 3105

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
BIOPESTICIDES AND POLLUTION
PREVENTION DIVISION

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OIL OF CITRONELLA REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
μg/L	Micrograms per liter
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Environmental Protection Agency has completed an assessment of the potential human health and environmental risks associated with the pesticidal uses oil of citronella.

Oil of citronella is a biopesticide (biochemical) with a non-toxic mode of action. It is registered as an animal repellent and as an insect repellent/feeding depressant. Oil of citronella is the volatile oil obtained from the steam distillation of freshly cut or partially dried grasses, (*Cymbopogon nardus* (Rendal) and *Cymbopogon winterianus* (Jowitt)). Two varieties of the citronella oil exist commercially -- "Ceylon type" (derived from *C. nardus*) and "Java type" derived from *C. winterianus*).

This reregistration eligibility document includes a comprehensive reassessment of the required data for all of the use patterns of currently registered products containing oil of citronella, which do not meet the exemption criteria listed below.

On February 28, 1996 the Agency issued a rule under the provisions of FIFRA Section 25(b) exempting certain pesticides, including oil of citronella, from regulation. In order to be exempt from regulation, products containing oil of citronella must meet the following criteria:

1. Products must contain <u>only</u> inert ingredients listed in the most current List 4A. [The most current List 4A may be obtained by writing to Registration Support Branch (4A Inert List), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street SW, Washington, DC 20460].

2. Products must bear labeling identifying the name and percentage (by weight) of each active ingredient and the name of each inert ingredient.

3. Products must not bear label claims either to control or mitigate microorganisms that pose a threat to human health, including but not limited to disease transmitting bacteria or virus, or claims to control insects or rodents carrying specific diseases, including but not limited to ticks that carry Lyme disease.

4. Products must not include any false and misleading labeling statements, including those listed in 40 CFR 156.10(a)(5)(i) through (viii).

A number of currently registered oil of citronella products do not qualify for the 25(b) exemption, because they contain inert ingredients which are not on the List 4A (refer to #1 above). Therefore, the Agency is issuing a reregistration decision for oil of citronella.

Before reregistering the products containing oil of citronella (*i.e.*, those which do not meet the criteria stipulated in the exemption above), the Agency is requiring that a revised Confidential

Statement of Formula (CSF) and revised product labeling statements relating to dermal sensitization and product performance (maintenance of efficacy) be submitted within eight months of the issuance of this document. After reviewing this information and finding it acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products that contain oil of citronella in combination with other active ingredients will be eligible for reregistration only when the other active ingredient(s) are determined eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of oil of citronella. The document consists of six sections. Section I is the introduction. Section II describes oil of citronella, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for oil of citronella. Section V discusses the reregistration requirements for oil of citronella. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient(s) are covered by this Reregistration Eligibility Decision:

- **Common Name:** Oil of citronella "Ceylon type", and oil of citronella "Java type".

- **Chemical Name:** Oil of citronella -- An essential oil made up of more than 80 compounds of closely related terpenic hydrocarbons, alcohols, and aldehydes.

- **CAS Registry Number:** 8000-29-1

- **OPP Chemical Code:** 021901

- **Basic Manufacturers:**

American Candle Company Inc.	Bug Master Products
Candle Corp. of America	Cardinal Laboratories Inc.
Empire Manufacturing Co.	Farnam Companies
Fiebing Chemical Company	Flintlock Ltd
General Wax & Candle Co.	Kameyama U.S.A., Inc.
L.R. Wilson Enterprises	Lamplight Farms Inc.
Natural Research People Inc.	P.J. Maxwell Co. Inc.
Perycut-Chemie AG	Plantabbs Corp.
Primavera Laboratories Inc.	Quantum Inc.
S.C. Johnson & Sons Inc.	Tender Corporation

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these uses of oil of citronella is in Appendix A.

For oil of citronella:

Type of Pesticide: Biochemical -- insect and animal repellent

Use Sites: **Indoor nonfood:** Animal treatment -- horse-show/race/special, ponies.

Indoor residential: Human body/clothing while being worn (insect control); skin contact treatment; animal treatment (flea collar).

Outdoor residential: Household/domestic dwellings outdoor premise use.

Terrestrial non-food + outdoor residential: Ornamental and/or shade trees: ornamental herbaceous plants; ornamental woody shrubs and vines.

Target Pests: biting midges, biting flies, black flies, bugs, cats, deer flies, deer ticks, dogs, face flies, fleas, flies, flying insects, gnats, horn flies, horse flies, house flies, insects, mosquitoes, "no-see-ums", stable flies.

Formulation Types Registered: Liquid-ready to use, impregnated material, pelleted/tableted, impregnated collar/tag.

Method and Rates of Application:

Types of treatment: Hand-held sprayer, cloth wipe-on, candle, cartridge, rub-on, scent-post application, sprinkle by hand, flea collar.

Method and Rate - Refer to Appendix A.

Timing - As needed.

Use Practice Limitations: None.

C. Estimated Usage of Pesticide

This section summarizes the amounts of citronella estimated for the pesticide uses of oil of citronella. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Based on pesticide survey usage information for the years 1991 through 1992, annual citronella domestic usage ranged approximately from 33,000 to 48,000 pounds active ingredient (a.i.) for four sites (domestic dwelling; ornamentals and dumps; human face, skin, and clothing; and manufacturing). Oil

of citronella is an insect repellent with its largest markets, in terms of total pounds active ingredient, allocated to human face, skin, and clothing (56% to 74%); domestic dwelling [outdoor] (22% to 41%); and ornamentals and dumps (1.5% to 2.0%). The balance is for manufacturing use.

TABLE I: Oil of citronella usage analysis

Site	Annual Amount (lbs. ai)	Product formulation
Domestic dwelling (outdoor)	7,084 - 19,690	Insect repellent candles
Ornamentals and dumps	676 - 744	Twist-ons and pellets
Human face, skin, and clothing	24,500 - 27,500	Insect repellent sprays and lotions
Manufacturing use	350 - 400	oil of citronella
Total	33,000 - 48,000	All of the above

D. Data Requirements

In Phase 4 of the Reregistration process, data gaps for oil of citronella were identified and a DCI was issued in September, 1992 for studies on product chemistry and mammalian toxicity. These data were required to support the currently registered uses of oil of citronella. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

The insect repellent, oil of citronella was initially registered in the United States in 1948 as McKesson's® oil of citronella (EPA Reg. No. 385-32) for human applications (body, hair, clothing, and footwear while being worn) to repel gnats (adult) and mosquitoes (adult). Oil of citronella is a biochemical pesticide which has a non-toxic mode of action. It is registered as an insect repellent (feeding inhibitor) and as an animal repellent.

Product performance guidelines (efficacy standards) for pesticides used as insect repellents were first published in the Pesticide Assessment Guidelines, Subdivision G, Product Performance in October 1982. The Guidelines required efficacy testing for all pesticides that were used to control microbes or other pests that impact public health. For mosquito repellents, these guidelines state, products "must generally provide a minimum of 2 -3 hours protection time based upon first confirmed bite field tests, depending upon biting pressure evidenced in the testing. If the product provides longer protection times, then this may be stated on the label." For ticks, fleas and mites, the products must provide

100% control of the pest infestation through a killing or repelling action when tested under simulated or actual conditions. Or, the product must provide the protection time (in hours) which is justified by the supporting data and appears on the label. For ticks, fleas and mosquitoes, the minimum acceptable protection time is one hour, when using first confirmed bite methodology, or sock testing.

After these standards were published in 1982, the Agency became aware of medical incidents implicating other active ingredients (e.g., DEET). In an effort to encourage the registration of other less toxic active ingredients for repelling insects, the Agency relaxed the 2-3 hour standard. Because citronella products protected humans from mosquito, tick and flee bites for at least one hour, and they provided a relatively non-toxic alternative, the Agency adopted one hour as a new standard. In the interest of public safety, the Agency will only consider products eligible for registration if they are efficacious for at least one hour and the user is provided instructions on how to maintain effective protection.

On February 28, 1996, the Agency issued a rule exempting certain pesticide active ingredients, including oil of citronella, from regulation under FIFRA. In order to be eligible for this exemption (under FIFRA Section 25(b)), the oil of citronella products must meet all of the criteria listed below:

1. The product must only contain active ingredients listed in the FIFRA 25(b) Exemption.

2. The product must only contain inert ingredients listed in the most current List 4A. [This list is updated periodically and is publish in the Federal Register. The most current list may be obtained by writing to the Registration Support Branch (4A Inert List), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460].

3. The product must bear a label identifying the name and percentage (by weight) of each active ingredient and the name of each inert ingredient.

4. The product must not bear claims either to control or mitigate microorganisms that pose a threat to human health, including but not limited to, disease transmitting bacteria or viruses, or claims to control insects, rodents carrying specific diseases, including, but not limited to, ticks that carry Lyme disease.

5. The product must not include any false and misleading labeling statements, including those listed in 40 CFR 156.10 (a)(5)(i) through (viii).

Citronella products that do not meet the criteria listed above, must comply with the provisions of reregistration set forth in this RED.

During Phase 4 of Reregistration, the database for oil of citronella was evaluated and determined to be inadequate in satisfying certain requirements for biochemical pesticides, which include certain insect and animal repellents. The following were identified as outstanding data gaps and a DCI was issued in September 1992:

	Guideline No.	Study
Product Chemistry:		
	151B-10	Product Identity
	151B-11	Manufacturing Process
	151B-12	Discussion of formation of unintentional ingredients
	151B-13	Analysis of samples
	151B-15	Certification of limits
	151B-16	Analytical methods
	151B-17(a-p)	Physical/Chemical properties
Mammalian Toxicity:		
	152B-10	Acute oral toxicity
	152B-11	Acute dermal toxicity
	152B-12	Acute inhalation toxicity
	152B-13	Primary eye irritation
	152B-14	Primary dermal irritation
	152B-15	Dermal sensitization
	152B-16	Hypersensitivity
	152B-17	Mutagenicity battery
	152B-18	Immunotoxicity
	152B-21	90-Day dermal - rat
	152B-22	90-Day inhalation -rat
	152B-23	Teratogenicity

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Oil of citronella is obtained from the steam distillation of the freshly cut or partially dried cultivated grasses, *C. nardus* and *C. winterianus*. Oil of citronella is an essential oil made up of more than 80 compounds of closely related terpenic hydrocarbons, alcohols, and aldehydes. Two varieties of citronella oil exist commercially -- "Ceylon type" (extracted from *C. nardus*) and "Java type" (extracted from *C. winterianus*). The "Java type oil" is produced in larger quantities and is characterized by

containing higher concentrations of (the aldehyde) citronellal than the "Ceylon type oil". "Java type oil" contains not less than 35% citronellal versus 7-15% citronellal for the "Ceylon type oil". However, based on available product chemistry data, the Agency has concluded that oil of citronella is a single substance and that "Java oil" and the "Ceylon oil" are "substantially similar" compounds. The product chemistry data base for oil of citronella is adequate and satisfies the requirements set forth in 40 CFR 158.690 -- Biochemical Pest Control Agents (Table II: MRID 41785703)

TABLE II: Physical and chemical characteristics for oil of citronella (technical)

Guideline No. 151B-17	Characteristic/ Description
Color	Light yellow/yellowish brown
Physical state	Liquid
Odor	Sweet-floral/grassy/camphoraceous
Melting point	Not applicable
Boiling point	170ºC
Density	0.891 - 0.901 [@ 25ºC]
Solubility	Very soluble in water 20ºC
Vapor pressure (Major components)	Camphene 3.0/Limonene 1.4/Geraniol 0.02 Citronellal 0.23/Citronellol 0.015
Flammability	Flash point 170ºC (TCC)
Storage stability	Stable under normal conditions
Viscosity	Not known
Miscibility	Not to be diluted w/petroleum solvents
Corrosion characteristics	Non-corrosive
Octanol/Water Partition Coefficient	Very large, because of high solubility in octanol

B. Human Health Assessment

1. Toxicology Assessment

Adequate mammalian toxicology data on oil of citronella are available and will support a RED.

a. Mammalian Toxicity

Certain mammalian toxicity studies conducted with oil of citronella have been submitted to the Agency and adequately satisfy the requirements as set forth in 40 CFR 158.690 -- Biochemical Pest Control Agents. (See Table III).

TABLE III: Acute mammalian toxicity requirements for oil of citronella as technical grade active ingredient

Guideline	Test Material	Results	Toxicity Category	MRID No.
152B-10 Acute oral tox.(rat)	Citronella oil 100% (Ceylon)	LD 50 > 5000mg/kg	IV	41747402
	Citronella oil 100% (Java)	LD 50 > 4380mg/kg	III	43179401
152B-11 Acute dermal tox. (rabbit)	Citronella oil 100% (Ceylon)	LD 50 > 2000mg/kg	III	41747403
	Citronella oil 100% (Java)	LD 50 > 2000mg/kg	III	43167101
152B-12 Acute inhalation (rat)	Citronella oil 100% (Ceylon)	LC 50 > 5000 mg/kg	IV	41747404
	Citronella oil 100% (Java)	4 hr. exposure LC 50 > 3.1 mg/l	IV	43167102
152B-13 Primary eye irritation (rabbit)	Citronella oil 100% (Ceylon)	Irritation cleared in 72 hours	III	41747405
	Citronella oil 100% (Java)	Irritation cleared within 7 days or less	III	43167103
152B-14 Primary dermal irritation (rabbit)	Citronella oil 100% (Ceylon)	Irritation present at 21 days	II	41747406
	Citronella oil 100% (Java)	All irritation resolved by 48 hrs. Citronella mild irritant.	III	43167104
152B-15 Dermal sensitization (Guinea Pig)	Citronella oil 100% (Ceylon)	Sensitizer (Buehler Test)	Not applicable	41747407
	Citronella oil 100% (Java)	Non-sensitizer (Buehler Test)	Not applicable	43167105
152B-16 Hypersensitivity	All products	All incidents must be reported to the Agency		

In the evaluation of the toxicity data base for the reregistration eligibility decision for oil of citronella, the primary dermal irritation study (MRID 41747406) was re-evaluated. If solely based on the criterion of mild to slight irritation at 72 hours, the technical oil of citronella would be Toxicity Category IV. However, very slight to well defined erythema (and slight edema) persisted in one test animal (rabbit) until study termination, hence the Toxicity Category II designation.

The Agency has concluded that an overall Toxicity Category III designation with attendant labeling precautions for skin irritation for all products containing oil of citronella may be more appropriate than a Toxicity Category II designation, as suggested by the results of the acute battery conducted with the "Ceylon type" oil. This decision is based on the following factors: in the dermal irritation test conducted with "Ceylon type" oil, very slight to well defined erythema was noted until test termination (i.e., well defined erythema in one animal, while very slight erythema was noted in the other five test animals); in the dermal irritation study conducted with "Java type" oil, there was no irritation present in the six test animals at the 48 hours or 72 hours scoring points; and the results of the primary eye irritation studies conducted with both "Ceylon type" oil and "Java type" oil are similar (Toxicity Category III -- all irritation cleared within 7 days).

The dermal sensitization studies conducted with "Ceylon type" oil (MRID 41747407) and "Java type" oil (MRID 43167105) were re-evaluated as part of the RED. The "Ceylon type" oil was determined to be a sensitizer while the "Java type" oil was determined to be a non-sensitizer . Therefore, the Agency is requiring additional precautionary label language about dermal sensitization for end-use products formulated from "Ceylon type" oil. Refer to Section V for further information. However, it should be noted that this additional precautionary label language regarding dermal sensitization does not preclude the precautionary label language about irritations and rashes required by FDA for certain sunscreen products that are formulated from either "Java type" oil, or "Ceylon type" oil.

b. Mutagenicity

Oil of citronella was tested in a *Salmonella*/Mammalian Microsome Reverse Mutation Assay with a confirmatory assay (with and without S9 activation, MRID 417585701) was negative for inducing reverse gene mutation in various *Salmonella* test strains up to cytotoxic levels (1000 μg/plate/-S9 ; 3300 μg/plate/+S9).

An *in vitro* cytogenicity assay measuring chromosomal aberration frequencies in Chinese hamster ovary (CHO) cells (MRID 41785702) was conducted with oil of citronella. Test results were negative up to cytotoxic levels (75.5 μg/ml/-S9 ; 150 μg/ml/+S9).

An unscheduled DNA synthesis (UDS) study in rat hepatocytes (MRID 41747408) conducted with oil of citronella was negative for

increasing nuclear labeling (a measure of UDS) at moderate levels of cytotoxicity (30-50 μg/ml).

c. Subchronic Toxicity

The Agency has waived the requirement for a subchronic oral toxicity based on the lack of adverse effects observed in the acute oral toxicity study (MRID 41747402), and the currently registered non-food uses of oil of citronella.

d. Immunotoxicity, Developmental Toxicity, and 90-Day Dermal Toxicity, and 90-Day Inhalation Toxicity

The immunotoxicity (152B-18), 90-Day dermal toxicity (152B-21), and developmental toxicity 152B-23) guideline requirements for oil of citronella have been waived based on: (1) the submitted acute mammalian toxicology studies (MRIDs 41747402, 41747403, and 41747404), which show no significant adverse effects (Toxicity Categories III & IV) for various routes of exposure (i.e., oral, dermal, and inhalation); (2) negative results observed in the battery of mutagenicity studies (MRIDs 41785701, 41785702, and 417474408); (3) the current GRAS status of oil of citronella (21 CFR 182.2, 182.6, and 172.515); (4) no reports of hypersensitivity (FIFRA Section 6(a)(2)) of adverse effects following oral and dermal exposure; and (5) the rationales used to develop and support an exemption under Section 25(b).

The Agency has waived the requirements for 90-day inhalation toxicity based on the lack of significant adverse effects observed in the acute inhalation study (MRID 41747404), and long term use with no adverse effects reported.

2. Exposure Assessment

a. Occupational and Residential

Based on the application methods listed in the use directions on labels of currently registered oil of citronella products, the potential for oral, eye, dermal and inhalation exposure exists. However, the lack of significant acute mammalian toxicity does not trigger additional requirements for evaluation of exposure over that mitigated by the precautionary labeling statements currently proposed for certain products formulated from oil of citronella (refer to Section V).

C. Environmental Assessment

There are no outstanding data requirements. The available data is sufficient for the Agency to make an assessment of the environmental effects for the currently registered uses of oil of citronella.

1. Ecological Toxicity Data

All of the ecological effects data requirements have been adequately addressed. The candle, lotion, and indoor spray formulations of citronella pose minimal or nonexistent exposure situations for avian, aquatic, and nontarget species. While the ornamental and dump uses pose the greatest potential for exposure, these uses represent only two percent of the total use of oil of citronella. These data (Table IV), in light of the use patterns and estimated usage, indicate that adverse effects in avian, aquatic, or insect species are not likely.

Table IV: Environmental Expression - Tier I Guideline Requirements for oil of citronella

Guideline No.	Study	Results	MRID
154B-6	Avian acute oral (bobwhite quail)	LC_{50} > 2,250 mg/kg; practically non-toxic; NOEL = 1,350 mg/kg	41747409
154B-7	Avian subacute dietary	Waived because of low avian acute toxicity (MRID 41747409) and no mortality observed at upper test limits.	N/A
154B-8	Fish toxicity (rainbow trout)	LC_{50} > 17.3 mg/L (based on nominal concentration); slightly toxic. Minimal exposure to aquatic sources. Study will adequately fulfill data requirements for currently registered uses.	41747410
154B-9	Invertebrate toxicity (*Daphnia magna*)	EC_{50} > 26.4 mg/L (based on nominal concentration); slightly toxic. Minimal exposure to aquatic invertebrate species. Study will adequately fulfill data requirements for currently registered uses.	41747411
154B-10	Nontarget plants	Waived because exposure to nontarget plants will be minimal.	N/A
154B-11	Nontarget insects	Waived because exposure to nontarget insects will be minimal. Additionally, any exposure to nontargets should result in the insects being repelled.	N/A

2. Environmental Fate

Environmental fate studies are not required for biochemical pesticides unless adverse effects on nontarget species are observed as a result of acute testing (Tier I) for ecological effects. No adverse effects are suggested by the data as described in Table IV above.

D. Product Performance (Efficacy) Assessment

Because of numerous public inquires regarding the effectiveness (efficacy) of oil of citronella lotions, the Agency examined efficacy data associated with oil of citronella insect repellent lotion products and determined that product effectiveness diminishes rapidly over time; on the average, reasonable effectiveness (efficacy) lasts for 1 to 2 hours. Therefore inorder to maintain a reasonable degree of effectiveness, the Agency is requiring all oil of citronella products with label claims for repelling ticks and mosquitoes to bear a statement pertaining to the maintenance of effectiveness.

E. Other Considerations

On August 3, 1996, the Food Quality Protection Act (FQPA) was signed into law requiring EPA to consider new factors when making regulatory decisions regarding pesticide registration, reregistration, petitions for tolerances, and tolerance exemptions. The Agency must now consider specific factors relevant to children's exposure to pesticides. In this case these include: special sensitivity; aggregate exposure; cumulative effects; and endocrine disruption effects. Although the new standards in FQPA are clearly applicable to food use pesticides, the Agency believes that it is prudent to also apply a similar standard to actions involving non-food use pesticides, which may pose significant non-dietary risks to infants and children.

The principle uses of oil of citronella have been identified as insect repellent sprays and lotions with human applications. The Agency acknowledges that such uses may result in exposures for children. Based on the mammalian toxicity, oil of citronella (derived from "Ceylon type" oil) may cause dermal irritation and sensitization in some individuals. To reduce this risk, the Agency is requiring the labels of all products with dermal applications to include a special precautionary statement pertaining to dermal irritation and sensitization. It is the Agency's opinion that this proposed precautionary label language may also mitigate special sensitivity risks to children.

Oil of citronella has been in continuous use as an insect repellent with human applications for almost 50 years without any adverse incidents being reported to EPA. This

long use history without adverse incidents combined with the low acute mammalian toxicity indicates that oil of citronella is not likely to cause adverse effects resulting from aggregate exposures or cumulative effects. Further, the Agency is not aware of any evidence relevant to the possibility that oil of citronella may have endocrine disrupter effects, individually or in combination with another chemical.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic data required to support reregistration of products containing oil of citronella technical active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing oil of citronella. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of oil of citronella, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of oil of citronella and to determine that oil of citronella can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing oil of citronella as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of oil of citronella are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing oil of citronella, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients oil of citronella as non-food use, the Agency has sufficient information on the health effects of oil of

citronella and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that oil of citronella products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing oil of citronella for all non-food uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all currently registered uses of oil of citronella are eligible for reregistration. (Refer to Appendix A).

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for oil of citronella. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Tolerance Reassessment

Oil of citronella is a non-food use biochemical and therefore tolerance requirements are not applicable.

2. Labeling Rationale

Potential Risks for Dermal Irritation and Sensitivity

Oil of citronella formulated from "Ceylon type" oil has been determined to be a weak dermal sensitizer in guinea pigs (Buehler Test), while oil of citronella formulated from "Java type" oil is not (Refer to Section III). Under FIFRA, 40 CFR 156.10, products known to be dermal sensitizers are required to have precautionary labeling mitigating dermal sensitization risks. Thus, all products made from "Ceylon type" oil with directions for dermal applications must be labeled with the appropriate label precautions. Additionally, the FDA requires all products containing sunscreens to display specific label language pertaining to dermal irritation and dermal sensitivity (21 CFR 352.10). The net result is that all oil of citronella products containing sunscreens and those formulated from "Ceylon type" oil that have use directions for dermal applications must bear special precautionary labeling relating to dermal sensitization.

Potential Risks to Infants and Children

The FQPA significantly amended both FIFRA and FFDCA to permit increased protection for infants and children. Since the principal uses of Oil of citronella have been identified as insect repellent sprays and lotions, which may result in exposure for children,

the Agency is requiring special precautionary labeling relating to dermal sensitization and irritation for all product with use directions for dermal applications. Refer to Section V.

3. Product Performance (Efficacy) Reassessment

The Agency has an established policy, 40 CFR 158.640 -- Pesticide Assessment Guidelines, Subdivision G -- Product Performance, that the submission of efficacy data may be waived, unless the pesticide bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot be readily observed by the user including but not limited to, microorganisms infectious to man in any area of the inanimate environment. However, each registrant must ensure through testing that his products are efficacious when used in accordance with the label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide registered or proposed for registration/reregistration.

In this case, the registrants of all oil of citronella topical products with label claims to repel fleas, ticks and mosquitoes are required to either submit/cite product performance (efficacy) data, or delete label claims for repelling fleas, ticks and mosquitoes. Additional, all oil of citronella lotion products which bear claims for repelling fleas, ticks and mosquitoes must also have a statement pertaining to maintenance of effectiveness (efficacy). Refer to Section V (B)(2).

2

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of oil of citronella for the above eligible uses has been reviewed and determined to be substantially complete. At this time no additional data are being required. However, the Agency is requiring that a revised Confidential Statement of Formula (CSF) and revised product labeling be submitted within eight months of the issuance of this document for all products.

2. Labeling Requirements for Manufacturing-Use Products

At this time, no changes are required for the current precautionary labeling of manufacturing-use products containing oil of Citronella.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The database supporting the reregistration of the above eligible uses of oil of citronella is substantially complete and no additional product specific data is being required at this time. However, the Agency is requiring that a revised CSF and revised product labeling be submitted within 8 months of issuance of this document for all products.

2. Labeling Requirements for End-Use Products

Dermal Sensitivity:

Based on the results of the acute mammalian toxicity in Section III and the provisions of FQPA, the current precautionary statements on the labels of certain end-use products containing oil of citronella must be revised to include a special statement pertaining to dermal sensitivity listed in Table V.

TABLE V -- Precautionary label language for dermal sensitivity

Type of Formulation	Application	Precautionary Statement regarding Dermal Sensitivity
"Ceylon type" oil	Dermal	"Discontinue if irritation or rash appears. Prolonged or frequent skin contact may cause allergic reactions in some individuals. Use on children under 6 months of age only with the advice of a physician."
"Ceylon type" oil	Non-dermal	None required
"Java type" oil	Dermal, containing sunscreen ingredients*	"For external use only. Avoid contact with eyes. Discontinue if irritation or rash appears. Use on children under 6 months of age only with the advice of a physician."
"Java type" oil	Dermal, w/o sunscreen ingredients	"Discontinue if irritation or rash appears. Use on children under 6 months of age only with the advice of a physician."
"Java type" oil	Non-dermal	None required.

*Statements required by FDA (21 CFR 352.52 -- Labeling of sunscreen drug products).

Product Performance (Efficacy):

Based on the review of available product performance data, the Agency is requiring all oil of citronella products with label claims for repelling mosquitoes, fleas and ticks to have specific instructions pertaining to maintenance of effective repellent activity (i.e., protection time). The minimum acceptable protection time is one hour. The following statement pertaining to maintenance of repellent activity must appear in the direction for use.

"For maximum repellent effectiveness of this product, repeat applications at 1 hour intervals."

A label statement identical to the one listed above except with a protection time longer one hour may be permitted, provided it can be supported by product performance data showing an acceptable level of repellent activity. Refer to the Pesticide Assessment Guidelines, Subdivision G -- Product Performance for further information regarding acceptable levels of repellent activity.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this RED. Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell oil of citronella products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A REPORT

Case 3105 [Oil of citronella] Chemical 021901 [Oil of citronella]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED											
HORSES (SHOW/RACE/SPECIAL/PONIES)				Use Group: INDOOR NON-FOOD							
Animal treatment (spray), When needed, Sprayer	RTU	NA	UC	*	NS	NS	NS	NS	1	NS	
	RTU	NA	UC .001047 lb animal	*	NS	NS	NS	NS	AN	NS	
	RTU	NA	.001047 lb animal	*	NS	NS	NS	NS	AN	NS	C93, CAG, CAL
	RTU	NA	UC .001047 lb animal	*	NS	NS	NS	NS	NS	NS	
Animal treatment, When needed, Cloth	RTU	NA	UC	*	NS	NS	NS	NS	1	NS	
Enclosed premise treatment, When needed, Sprayer	RTU	NA	UC	*	NS	NS	NS	NS	AN	NS	
	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	
Wipe-on/wiper treatment, When needed, Cloth	RTU	NA	UC .001047 lb animal	*	NS	NS	NS	NS	AN	NS	
	RTU	NA	.001047 lb animal	*	NS	NS	NS	NS	AN	NS	C93, CAG, CAL
HOUSEHOLD/DOMESTIC DWELLINGS INDOOR PREMISES				Use Group: INDOOR RESIDENTIAL							
Premise treatment, Not on label, Not on label	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES				Use Group: OUTDOOR RESIDENTIAL							
Citronella candle, Not on label, By hand	IMPR	NA	UC	*	NS	NS	NS	NS	NS	NS	

APPENDIX A REPORT

Case 3105 [Oil of citronella] Chemical 021901 [Oil of citronella]

SITE Application Type, Application Timing, Application Equipment) & Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps Max. Rate /crop /year /crop cycle /year cycle	Max. Dose [(AI unless noted otherwise)/A]	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES (con't)				Use Group: OUTDOOR RESIDENTIAL (con't)							
Citronella candle, When needed, By hand	IMPR	NA		UC	* NS	NS	NS	NS	NS	NS	
Citronella cartridge, When needed, By hand	RTU	NA		UC	* NS	NS	NS	NS	NS	NS	
Outdoor treatment, Not on label, Package applicator	IMPR	NA		UC	* NS	NS	NS	NS	NS	NS	
Rub-on, When needed, By hand	IMPR	NA		UC	* NS	NS	NS	NS	NS	NS	
Scent post application, When needed, By hand	IMPR	NA		UC	* NS	NS	NS	NS	NS	NS	
Sprinkle, When needed, By hand	P/T	NA		UC	* NS	NS	NS	NS	10	NS	
HUMAN BODY/CLOTHING WHILE BEING WORN (INSECT CONTROL)				Use Group: INDOOR RESIDENTIAL							
Clothing treatment, Not on label, By hand	IMPR	NA		UC	* NS	NS	NS	NS	NS	NS	
Clothing treatment, When needed, Not on label	RTU	NA		UC	* NS	NS	NS	NS	AN	NS	
Clothing treatment, When needed, Sprayer	PRL	NA		UC	* NS	NS	NS	NS	AN	NS	
	RTU	NA		UC	* NS	NS	NS	NS	AN	NS	
Skin contact treatment, Not on label, By hand	IMPR	NA		UC	* NS	NS	NS	NS	NS	NS	
	RTU	NA		UC	* NS	NS	NS	NS	NS	NS	
Skin contact treatment, When needed, By hand	IMPR	NA		UC	* NS	NS	NS	NS	AN	NS	
	PRL	NA		UC	* NS	NS	NS	NS	AN	NS	
	RTU	NA		UC	* NS	NS	NS	NS	AN	NS	

APPENDIX A REPORT

Case 3105 [Oil of citronella] Chemical 021901 [Oil of citronella]

SITE Application Type, Application Timing, Application Equipment) & Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
HUMAN BODY/CLOTHING WHILE BEING WORN (INSECT CONTROL) (con't)				Use Group: INDOOR RESIDENTIAL (con't)								
Skin contact treatment, When needed, Not on label	RTU	NA		UC	*	NS	NS	NS	NS	AN	NS	
Skin contact treatment, When needed, Sprayer	RTU	NA		UC	*	NS	NS	NS	NS	AN	NS	
ORNAMENTAL AND/OR SHADE TREES				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL								
Scent post application, When needed, By hand	IMPR	NA		UC	*	NS	NS	NS	NS	NS	NS	
Sprinkle, When needed, By hand	P/T	NA		UC	*	NS	NS	NS	NS	10	NS	
ORNAMENTAL HERBACEOUS PLANTS				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL								
Scent post application, When needed, By hand	IMPR	NA		UC	*	NS	NS	NS	NS	NS	NS	
ORNAMENTAL LAWNS AND TURF				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL								
Sprinkle, When needed, By hand	P/T	NA		UC	*	NS	NS	NS	NS	10	NS	
ORNAMENTAL WOODY SHRUBS AND VINES				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL								
Scent post application, When needed, By hand	IMPR	NA		UC	*	NS	NS	NS	NS	NS	NS	
Sprinkle, When needed, By hand	P/T	NA		UC	*	NS	NS	NS	NS	10	NS	

APPENDIX A REPORT

Case 3105 [Oil of citronella] Chemical 021901 [Oil of citronella]
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LEGEND
444444

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Re-Entry Intv.	: Reentry Intervals
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

*	: Non-specific
C	: Coarse
M	: Medium
F	: Fine
O	: Others

FORMULATION CODES

IMPR	: IMPREGNATED MATERIAL
P/T	: PELLETED/TABLETED
PRL	: PRESSURIZED LIQUID
RTU	: LIQUID-READY TO USE

ABBREVIATIONS

AN	: As Needed
NA	: Not Applicable
NS	: Not Specified (on label)
UC	: Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC	: Dosage Can Not be Calculated
No Calc	: No Calculation can be made
W	: PPM calculated by weight
V	: PPM Calculated by volume
U	: Unknown whether PPM is given by weight or by volume
cwt	: Hundred Weight
nnE-xx	: nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

APPENDIX A REPORT

Case 3105 [Oil of citronella] Chemical 021901 [Oil of citronella]

USE LIMITATIONS CODES
C93 : Do not apply directly to water.
CAG : Do not apply where runoff is likely to occur.
CAL : Do not contaminate water, food or feed.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

UNIT DESCRIPTIONS
animal :
lb : pound

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Oil of Citronella covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Oil of Citronella in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Oil of Citronella

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
151B-10	**Chemical Identity**	All	41785703
151B-11	**Start. Mat. & Mnfg. Process**	All	41785703
151B-12	**Formation of Impurities**	All	41785703
151B-13	**Preliminary Analysis**	All	41785703
151B-15	**Certification of limits**	All	41785703
151B-17	**PHYSICAL AND CHEMICAL PROPERTIES:**		
(a)	**Color**	ALL	41785703
(b)	**Physical State**	ALL	41785703
(c)	**Odor**	ALL	41785703
(d)	**Melting Point**	ALL	41785703
(e)	**Boiling Point**	ALL	41785703
(f)	**Density**	ALL	41785703
(g)	**Solubility**	ALL	41785703
(h)	**Vapor Pressure**	ALL	41785703
(i)	**pH**	ALL	41785703
(j)	**Stability**	ALL	41785703
(k)	**Flammability**	ALL	41785703
(l)	**Storage stability**	ALL	41785703

Data Supporting Guideline Requirements for the Reregistration of Oil of Citronella

REQUIREMENT		USE PATTERN	CITATION(S)
(m)	**Viscosity**	ALL	41585703
(n)	**Miscibility**	ALL	41785703
(o)	**Corrosion characteristics**	ALL	41785703
TOXICOLOGY (Tier I)			
152B-10	**Acute Oral Toxicity**	All	41747402, 43179401
152B-11	**Acute Dermal Toxicity - Rabbit/Rat**	All	41747403, 43167101
152B-12	**Acute Inhalation Toxicity -Rabbit**	All	41747404, 43167102
152B-13	**Primary Eye Irritation -Rabbit**	All	41747405, 43167103
152B-14	**Primary Dermal Irritation -Rabbit**	All	41747405, 43167104
152B-15	**Dermal Sensitization - Guinea Pig**	All	41747407, 43167105
152B-16	**Hypersensitivity**	All	All incidents must be reported.
152B-17	**Microbial mutagenicity**	All	41785701, 41785702, 41747408
152B-18	**Immunotoxicity**	Waived	
152B-20	**90-Day Oral Toxicity**	Waived	
152B-21	**90-Day Dermal Toxicity**	Waived	
152B-23	**Develpomental Toxicity**	Waived	
ECOLOGICAL EFFECTS:			
154B-6	**Avian Acute Oral Toxicity**	All	**41747409**
154B-7	**Avian Subacute Dietary Toxicity**	Waived	
154B-8	**Fish Toxicity**	All	**41747410**

Data Supporting Guideline Requirements for the Reregistration of Oil of Citronella

REQUIREMENT		USE PATTERN	CITATION(S)
154B-9	**Invertebrate Toxicity**	All	**41747411**
154B-10	**Nontarget plants**	Waived	
154B-11	**Nontarget insects**	Waived	
ENVIRONMENTAL FATE:			
			All data requirements have been waived.
PRODUCT PERFORMANCE:			
156B-2	**Efficacy - Product Specific**	Mosquito and Tick	00001004, 00001005, 00001145, 00053315, 00059308, 00073787, 00073788, 00093884, 00107683, 00123621, 00134321, 41851601, 41851602, 41851603, 41851604, 42151311, 42151312, 42151313, 42151314, 42151315, 42504601, 42504602, 42507201, 42507202, 42649201, 42821501, 42649201, 42821501, 42821502, 42821503, 42890102, 42921302, 42921303, 43590401, 43725901, 43761601, 43902306, 44010101, 44167301, 44173201

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

   c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

   d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

      (1) Submission date. The date of the earliest known submission appears immediately following the word "received."

      (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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The following is a list of available documents for Oil of Citronella that my further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Richard King at (703)-308-8052.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for Oil of Citronella.

The following documents are part of the Administrative Record for Oil of Citronella and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1.Health and Environmental Effects Science Chapters.

2.Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria