United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-94-034
September 1994

Reregistration Eligibility Decision (RED)

Limonene

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 Limonene which includes the active ingredient limonene.

The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this[these] chemical[s], 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 ingredient(s) 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 are due 90 days from the date of this letter. The second set of required responses are 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 Special Review and Reregistration Division representative Franklin Gee at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Emily Mitchell at (703) 308-8583.

Sincerely yours,

Louis P. True, Jr., Director
Special Review and
Reregistration Division

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, another DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); 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 data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. 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 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

LIMONENE

LIST C

CASE 3083

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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LIMONENE REREGISTRATION ELIGIBILITY DECISION TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
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
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GLC	Gas Liquid Chromatography
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

GLOSSARY OF TERMS AND ABBREVIATIONS

	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
LOEL	Lowest Observed Effect Level
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.
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MOE	Margin Of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAM	Pesticide Analytical Method
PPE	Personal Protective Equipment

GLOSSARY OF TERMS AND ABBREVIATIONS

ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TMRC	Theoretical Maximum Residue Contribution
TLC	Thin Layer Chromatography
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Agency has determined that the uses of limonene as currently registered will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration. The Agency is requiring additional confirmatory data for the 90-Day Dermal Toxicity Study.

Before reregistering the products containing limonene, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

Limonene is a naturally occurring chemical which is used in many food products, for its characteristic lemon-like flavor and odor. The Food and Drug Administration lists limonene as a Generally Recognized as Safe (GRAS) food additive/flavoring and fragrance additive (soap,perfume).

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 limonene. The document consists of six sections. Section I is the introduction. Section II describes limonene, 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 limonene. Section V discusses the reregistration requirements for limonene. 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 is covered by this Reregistration Eligibility Document:

€ **Common Name:** Limonene

€ **Chemical Name:** 1-methyl-4-(1-methylethenyl)cyclohexene

€ **CAS Registry Number:** 138-86-3

€ **OPP Chemical Code:** 079701

€ **Empirical Formula:** $C_{10}H_{16}$

€ **Trade and Other Names:** d-limonene

€ **Basic Manufacturer(s):** Pet Chemicals
Rod Products

B. Use Profile

The following is information on the current registered uses with an overview of use sites and application methods. A detailed table of these use patterns of **limonene** is provided in Appendix A.

For **Limonene**:

Type of Pesticide: Insecticide; repellent

Use Sites: Terrestrial Food & Feed Crop - compost and manure

Indoor Residential - cats and dogs repellent spray and shampoo, pet living/sleeping quarters, household/domestic dwellings, indoor premises, and human body/clothing while being worn

Outdoor Residential - household/domestic dwellings, outdoor premises

Terrestrial Non-Food & Outdoor Residential - ornamental herbaceous plants, ornamental lawns and turf, paved and recreational areas

Aquatic Non-Food Residential - fountains, ponds and pools

Aquatic Non-Food Industrial - drainage systems

Aquatic Non-Food Outdoor - swamps/marshes/wetlands/stagnant water

Target Pests: flying insects, flies, ants, cockroaches and/or mosquito larvae, fleas, ticks, dogs, and cats

Formulation Types Registered:
Emulsifiable concentrate
Granular
Impregnated Material
Pressurized Liquid
Liquid - Ready to use

Method and Rates of Application:

Equipment - By hand

Method and Rate - Sprinkle

Household/Domestic Dwellings Outdoor Premises
.4015 lb AI/1000 sq. ft.
Ornamental Herbaceous Plants
.4015 lb AI/1000 sq. ft.
Ornamental Lawns and Turf
.4015 lb AI/1000 sq. ft.
Paved Areas (Private Roads/Sidewalks)
.4015 lb AI/1000 sq. ft.
Aquatic Sites (Drainage systems, ornamental ponds, swamps/marshes/wetlands/stagnant water)
.549 lb AI/A

Timing - When Needed

Use Practice Limitations:

Labels prohibit use on weanling kittens and caution against use of undiluted product.

C. Estimated Usage of Pesticide

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

The table below summarizes the pesticides use by site.

Annual U.S. Usage Estimates for Limonene

Site	- Units/Area/Volume - Available	Treated	Percent Treated	Quantity Applied
Drainage systems	NA	NA	NA	NA
Eating establ, serv'g areas	NA	NA	NA	NA
Garbage dumps	NA	NA	NA	NA
Households, indoor (*,#)	84,600 kHH	780 kHH	< 5%	4,300 kPA
dogs, cats & kennels (*, +)	< 84,600 kHH	< 780 kHH	< 10%	< 4,300 kPA
Households, outdoor (*,@)	66,800 kHH	0 kHH	< 1%	0 kPA
driveways & patios (*,@)	< 66,800 kHH	0 kHH	< 1%	0 kPA
lawns & ornamentals (*,@)	66,800 kHH	0 kHH	< 1%	0 kPA
Intermittently flooded areas	NA	NA	NA	NA
Lakes, ponds, impounded water	NA	NA	NA	NA
Manure	NA	NA	NA	NA
Orn'tal ponds, fountains, etc	NA	NA	NA	NA
Recreation areas, tables	NA	NA	NA	NA
Swamps, marshes, bogs, etc	NA	NA	NA	NA
Total - CA only	NA	NA	NA	15-35 kLB
TOTAL - U.S.	NA	NA	NA	NA

(*) Given usage includes applications by household members themselves but excludes those by pest control/lawn care companies and, therefore, may understate total site usage. Households covered are those occupying primary residences (except in AK and HI and excluding institutions, group quarters and military and Indian reservations).

(#) Given usage consists of indoor household treatment (including in garages, sheds, greenhouses and kennels) to control flying insects, flies, ants and/or cockroaches and household treatment of dogs and cats to control fleas and ticks.

(+) Dogs, cats and kennels included in "households, indoor".

(@) Given usage consists of outdoor household treatment to control dogs, cats, flying insects, flies, ants, cockroaches and/or mosquito larvae. Availability of household outdoors, including lawns and ornamentals, for treatment by household members assumed equal to the number of households with private lawns.

kHH = (household units) X 1000
kLB = (lbs. a.i.) X 1000
kPA = (product-applications) X 1000

SOURCES:
- CA EPA, Pesticides Sold in California, 1988, 1989 and 1990
- Research Triangle Instit., National Home & Garden Pesticide Use Survey, 1992
- US EPA, information, reports and proprietary sources

D. Regulatory History

Limonene was registered in the United States as an insecticide by the United States Department of Agriculture in 1958. Subsequently, limonene was first registered as an antimicrobial in 1971, and as a dog and cat repellent in 1983.

Limonene is an active ingredient in 15 currently registered products. These products are ready-to-use solutions, emulsifiable concentrates, granular, or impregnated material formulations. The products are used for pet flea and tick control, as an insecticide spray, as an outdoor dog and cat repellent, as a fly repellent tablecloth, as an insect repellent for use on humans, and as a mosquito larvicide.

On May 4, 1988, the Agency announced (53 FR 15989) that it no longer considered limonene to be an active ingredient if used in antimicrobial products. For these products the Agency considered limonene to function as as inert ingredient (i.e. odorants, perfumes). See 40 CFR 153.139(a).

In April 1994, limonene was granted an exemption from the requirement of a tolerance when it is an inert ingredient used as a solvent or fragrance in pesticide formulations (40 CFR 180.1001(c), (e)).

The Food and Drug Administration lists limonene as a Generally Recognized as Safe (GRAS) (21 CFR 182.60) food additive/flavoring and fragrance additive (soap, perfume).

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Limonene occurs naturally in fruits (especially citrus fruits, vegetables, meats, and spices). As an additive it is found in a variety of foods and beverages. It is listed by FDA as Generally Recognized As Safe (GRAS) under Title 21 of the Code of Federal Regulations (21 CFR 182.60). Limonene is also used as an inert ingredient in pesticide formulations.

Limonene ranges in color from clear to light yellow with a mild citrus-type odor. It is insoluble in water but soluble in mineral oils, fixed oils, alcohols and ether, and very slightly soluble in glycerin.

B. Human Health and Environmental Assessment

Adequate toxicological and environmental effects data on limonene are available to support reregistration eligibility.

The Agency determined that limonene meets the criteria for a category of pesticide active ingredients for which a reduced set of generic data requirements are appropriate for registration. Products in this category may be exempt from the generic data requirements for toxicology, residue chemistry, human exposure, ecological effects, and environmental fate on the active ingredient. In considering limonene for reregistration eligibility, the Agency believes that it is an active ingredient that meets the criterion for the following reasons:

1. Limonene has been established as an inert and has been granted an exemption from the requirement of a tolerance when used as an inert in solvents or fragrances in antimicrobial pesticide formulations. Limonene, a naturally occurring chemical, is found in high concentration in citrus fruits and spices and is generally regarded as safe by FDA. It is widely used as a flavoring and/or frangrance additive in foods, soaps, and perfumes.

2. Adverse effects from exposure are sufficiently well known and documented in the literature. Use of the substance for pesticidal purposes does not require additional data; additional testing of the pesticide active ingredient would not be expected to provide any additional information.

3. The 90-day dermal toxicity study is required to support registration of an insect repellent formulation to be directly applied to humans dermally, and is to be tested using the formulation, not technical limonene active ingredient alone. The study will be designed as a safety study. Because the systemic toxicity is not anticipated, the requirement of a 90-day dermal toxicity study is considered confirmatory.

4. A review of the available toxicity data indicates that adequate information is available to characterize risks to humans and animals.

5. Limonene is not mutagenic or a developmental toxicant. The primary toxicological concerns, dermal irritation in human and adverse effects in a small percentage of domestic animals, will require precautionary statements on labels of products. Systemic toxicity in humans is not expected to occur from pesticide uses since dermal irritation, which occurs at high doses leads to self-discontinuation of product use.

An assessment of the data used in determining the reregistration eligibility of limonene is detailed below.

1. Toxicology Assessment

Adequate animal toxicological data on limonene are available and will support reregistration eligibility.

Toxicology data on limonene reviewed here includes a 1992 National Toxicology Program (NTP) 2-year cancer bioassay including shorter-term oral toxicity tests and a comprehensive literature review, a developmental toxicity study in rat, a 2-week preliminary study conducted for a 90-day dermal toxicity study in rat and the U.S. EPA Risk Assessment Forum document entitled "$Alpha_{2u}$-Globulin: Association with Chemically Induced Renal Toxicity and Neoplasia in the Male Rat".

a. Acute Toxicity

The oral toxicity of limonene is relatively low. An oral lethal dose for humans has been estimated at 1 oz. - 1 pint. Limonene has been administered therapeutically to humans at doses of 20 g to dissolve gallstones. Systemic toxicity from dermal exposure is anticipated to be lower than oral toxicity because dermal penetration is expected to be less than 100% and since local dermal irritation would occur at high exposure levels, causing discontinuation of exposure.

b. Subchronic Toxicity

In the NTP study, toxicity of limonene administered by gavage in corn oil was assessed in CD rats and in B6C3F1 mice in 16-day, 13-week and 2-year studies. In the 16-day study, no effects were observed in males at or below 825 mg/kg/day or in females at or below 1,650 mg/kg/day. Decreased body weights were observed in males at 1,650 mg/kg/day and in females at 3,300 mg/kg/day. Deaths occurred at 3,300 and 6,600 mg/kg/day among both males and females.

In the 13-week study, no effects were observed in females at or below 600 mg/kg/day. At 1,200 and 2,400 mg/kg/day clinical signs (lethargy, salivation) were observed in males and females. Decreased body weight was observed in males at 1,200 mg/kg/day and females at 2,400 mg/kg/day. Lacrimation, rough coat and lethargy were noted at 1,200 mg/kg/day. Nephropathy related to $alpha_{2u}$-globin accumulation was observed in male rats at all doses (150 mg/kg/day above). Mortality was increased in males and females at 2,400 mg/kg/day (highest dose tested).

c. Chronic toxicity

In the 2-year study, male rats were given 75 or 150 mg/kg/day and females 300 or 600 mg/kg/day limonene. At 150 mg/kg/day males had slightly decreased body weight but at both doses developed $alpha_{2u}$-globulin nephrotoxicity and renal adenoma/adenocarcinoma. Females showed no effects at 300 mg/kg/day but at 600 mg/kg/day had slightly decreased body weight and increased mortality.

Mice given limonene at the same doses in the 16-day and 13-week studies also showed limited evidence of toxicity at high doses, although some body weight decrease in males was observed at all doses. Mice were given 250 or 500 mg/kg/day (males) or 500 or 1000 mg/kg/day (females) in the 2-year study. Females at 1000 mg/kg/day had decreased body weight. No treatment-related nephropathy or renal adenomas/carcinomas were observed in either sex in the 2-year study.

d. Mutagenicity and Carcinogenicity

Limonene is not mutagenic in numerous assays. Renal adenomas/carcinomas in male rats administered limonene for 2 years (NTP study) are considered to be related to $alpha_{2u}$-globulin-induced nephropathy and therefore are not considered relevant to human risk assessment (Risk Assessment Forum document on $alpha_{2u}$-globulin nephropathy).

e. Developmental Toxicity

Limonene is not a developmental toxicant. Delayed ossification in bone development may be observed at high doses that also cause maternal toxicity. Several developmental toxicity studies were cited in the literature review of the NTP study. No developmental effects were observed in rabbits administered limonene up to 1,000 mg/kg; 6/21 maternal animals died and decreased body weight was observed. At 250 mg/kg no maternal or developmental toxicity was observed. Pregnant rats given 2,869 mg/kg limonene during days 9-15 of gestation showed decreased body weight gain. Delayed ossification was seen in fetuses at this dose, presumably secondary to maternal effects. A study in mice (2,363 mg/kg during days 7-12 of gestation) also showed decreased maternal body weight gain with increased incidence of abnormal bone formation in fetuses. However, the dose administered in these two studies far exceeded limit doses.

In the rat developmental toxicity study submitted to the Agency in 1992, a NOEL of 250 mg/kg/day for maternal and developmental toxicity was determined. Small decrements in maternal body weight gain were observed at 500 and 1000 mg/kg/day and excess salivation at 1000 mg/kg/day. Slight but statistically significant and dose-dependent increases in the number of liters and

fetuses with 14 ribs instead of 13 were observed at 500 and 1000 mg/kg/day. These effects are considered variations in skeletal formation, were not accompanied by other effects, are secondary to maternal toxicity and do not represent a concern for developmental toxicity of limonene.

f. Other Toxic Endpoints

Limonene is a known dermal irritant when applied at high concentrations and may cause dermal sensitization. The 2-week preliminary study for the rat 90-day dermal toxicity study submitted as 6(a)(2) data showed that dermally-applied technical limonene at 500, 1,000 or 1,500 mg/kg/day produced excessive dermal irritation, usually after 1-3 days of application. No overt treatment-related systemic toxicity or clinical signs were observed.

The 90-day dermal safety study on the formulation of the newly registered product (Registration Number 045987-G) is required because the product use may result in prolonged human dermal exposure through repeated skin applications. The safety study on the formulated product is also needed because of the combination of ingredients in the formulation. This will ensure the combination in the formulation does not cause unexpected effects.

Another report cited in that submission indicated that doses of pine oil blend (a mix of terpenes including limonene) up to 226 mg/kg/day did not produce dermal irritation or systemic toxicity in rats after a 90-day exposure.

2. Exposure Assessment

a. Occupational and Residential

The primary toxicologic concerns for humans are dermal irritation and/or sensitization from dermal exposure at high concentrations. Systemic toxicity is not expected to occur from pesticide uses since dermal irritation, which occurs at high doses, results in self-discontinuation of product use.

The primary toxicologic concerns for domestic animals are adverse reactions in a small percentage of animals, cats in particular, exposed to limonene in flea and tick spray, shampoo or dip products.

An animal safety study in cats on a flea dip indicated that a small percentage of cats may develop transient symptoms when treated according to label instructions and that kittens/young cats are more sensitive. Labels contain Precautionary Statements indicating the potential for dermal irritation, sensitivity of some animals to treatment, prohibiting use on weanling kittens and cautioning against use of undiluted product.

Symptoms of limonene toxicity may include hypothermia, tremors, ataxia and excess salivation. Agitation and vocalization may also occur. Irritation of the skin, particularly around the scrotum, has been reported and ocular irritation may occur if eyes are accidentally exposed.

3. Risk Assessment

a. Occupational and Residential

Human exposure may occur during application of pet flea products, application of pet flea products, application of animal repellent granules or insect spray, or use of impregnated tablecloths. The tablecloth product containing limonene to repel insects was exempted from tolerances. Toxicologic concerns for humans from exposure to limonene are dermal irritation and sensitization. Systemic toxicity is not anticipated to occur at doses below the threshold for dermal irritation. Exposure to limonene would be discontinued if dermal irritation occurred and is therefore self-limiting. Ocular irritation may also occur if products are accidentally placed in the eye and not washed away.

Limonene is an active ingredient in several registered shampoo, dip and spray products applied dermally to domestic animals to control fleas and ticks. Most sprays and shampoos contain 5% limonene; dip concentrates (32-78%) are diluted prior to use to less than 1% limonene. Adverse reactions in domestic animals, particularly cats from exposure to limonene have been reported following exposure to flea control products.

Additional precautionary statements on label are required to reduce adverse effects.

C. Environmental Assessment

1. Environmental Fate

a. Environmental Chemistry, Fate and Transport

The Agency is relying on data available in the literature to assess the environmental fate of limonene for its current uses.

b. Environmental Fate Assessment

Limonene [1-methyl-4-(1-methylethenyl)cyclohexene] is classified as a terpene. It contains a carbon skeleton made up of isoprene units joined in a head-to-tail way. The chemical is insoluble in water. Because limonene does not have

functional groups for hydrolysis, and its cyclohexene ring and ethylene group are known to be resistent to hydrolysis, the compound is expected to be stable in water.

2. Ecological Effects

a. Ecological Effects Data

(1) Terrestrial Data

Terrestrial Animal Data

In order to establish the toxicity of limonene to birds, the following tests would ordinarily be required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard duck or bobwhite quail); two subacute dietary studies (LC_{50}) tests on one species of waterfowl (preferably the mallard duck) and one upland game-bird species (preferably the bobwhite quail). However, because the present use patterns of limonene were deemed low volume, the requirement for a dietary test with a waterfowl species has been waived.

The data submitted for limonene includes studies on both technical and formulated product. Because the first products registered were basically indoor-use applications for controlling ticks and fleas on dogs and cats, acute oral testing was not required for technical limonene. When the first of two products with outdoor uses was proposed for registration, it was concluded that any additional testing should be done using the formulated product, which contains other active ingredients and inerts that may be more toxic than limonene.

Avian Acute Toxicity

The single-dose study submitted for the formulated product is summarized below.

Species	%ai[1]	LD50 (mg/kg)	Conclusions
Bobwhite quail	4.015	> 2000	Practically Nontoxic

[1]the formulated product tested also contains two furanones (0.073%) as active ingredients

These results indicate that the formulated product is practically nontoxic to bobwhite quail. The guideline requirement for the avian acute oral LD_{50} is fulfilled. (MRID #00146988)

Avian Subacute Dietary Toxicity

The acute dietary toxicity study submitted for the technical product is summarized below.

Species	%ai	LC50 (ppm)	Conclusions
Bobwhite quail	92	> 5620	Practically Nontoxic

The data indicate that technical limonene is practically nontoxic to bobwhite quail on a dietary basis. The guideline requirement for a dietary toxicity test with bobwhite quail is satisfied.

The acute dietary toxicity studies submitted for a formulated limonene product are summarized below.

Species	%ai[1]	LC50 (ppm)	Conclusions
Bobwhite quail	4.015	> 5000	Practically Nontoxic
Mallard	4.015	> 5000	Practically Nontoxic

[1]the formulated product tested also contains two furanones (0.073%) as active ingredients

The data indicate that the formulated product is practically nontoxic to the bobwhite quail and mallard duck on a dietary basis. The requirements for dietary toxicity tests are satisfied. (MRID #s 00109342, 00109341)

(2) Aquatic Data

Freshwater Fish Toxicity

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a coldwater species (preferably rainbow trout) and the other a warmwater species (preferably bluegill sunfish). For the same reasons noted for the terrestrial tests, some testing was conducted on the formulated product rather than the technical.

The acute toxicity data for fish are summarized below for technical limonene.

Species	%ai	LC50 (ppm)	Conclusions
Rainbow trout	92	80	Slightly Toxic

The data indicate that technical limonene is slightly toxic to freshwater fish. The guideline requirements for acute toxicity testing with a coldwater fish are fulfilled. (MRID #00146085)

The acute toxicity data for fish are summarized below for the formulated product.

Species	%ai[1]	LC50 (ppm)	Conclusions
Rainbow trout	4.015	569-737	Practically Nontoxic
Fathead minnow	4.015	1490	Practically Nontoxic

[1]the formulated product tested also contains two furanones (0.073%) as active ingredients

These data indicate that the formulated limonene product is practically non-toxic to freshwater fish. The requirements for testing with freshwater fish are satisfied. (MRID #s 00109343, 00109344)

Freshwater Invertebrate Toxicity

In order to establish the toxicity of a pesticide to freshwater aquatic invertebrates, the minimum data required on the technical grade of the active ingredient is one acute toxicity study. The preferred test species is first instar Daphnia magna or early instar amphipods, stoneflies, or mayflies.

The useful aquatic invertebrate toxicity data for technical limonene are summarized below.

Species	%ai	LC50 (ppm)	Conclusions
Daphnia magna	92	39	Slightly Toxic

These data indicate that technical limonene is slightly toxic to freshwater invertebrates. The guideline requirement for an acute toxicity study with a freshwater invertebrate is satisfied. (MRID #00146085)

The aquatic invertebrate toxicity data for the formulated product are summarized below.

Species	%ai[1]	LC50 (ppm)	Conclusions
Daphnia magna	4.015	17-20	Slightly Toxic

[1]the formulated product tested also contains two furanones (0.073%) as active ingredients

These data indicate that the formulated product is slightly toxic to freshwater invertebrates. The requirement for acute toxicity studies with freshwater invertebrates is satisfied. (MRID #00109345)

b. Ecological Effects Risk Assessment

Risk to Terrestrial Animals

Avian Acute Oral and Subacute Dietary Effects

Limonene has not been quantitatively assessed. However, based on the lack of toxicity of limonene to birds, little risk is anticipated.

Potential risk to birds might occur from ingestion of granules spread on lawns, driveways, and sidewalks; or from consumption of contaminated insects around sprayed manure heaps, compost piles, garbage pails, and dumpsters.

"The Agency is unable to calculate an acute risk quotinent for birds, because toxicity test effect levels are unknown. The acceptable avian acute oral study demonstrated an LD_{50} greater than 2,000 mg/kg for the formulated product. The Agency's Guidelines for Avian Acute Oral testing specify that a study may demonstrate that the actual LD_{50} is greater than 2,000 mg/kg, in lieu of demonstrating an actual LD_{50}. Because the submitted study tested up to the maximum 2,000 mg/kg level and no indications of toxicity were noted, the Agency has determined it is reasonable to assume that the regulatory levels of concern for acute effects will not be exceeded."

The risk to birds from possible consumption of contaminated insects around the outdoor sites where insects are sprayed cannot be quantitatively assessed. Directions for use on the label for EPA Registration No. 45987-2 include spraying "to wet" crawling ants, roaches, and flying insects; thoroughly spraying ant trails on sidewalks, paths, and buildings, repeating the treatment a second time if ants reappear a few days later; and liberally spraying and thoroughly wetting manure heaps, compost piles, and insect-attracting garbage pails and dumpsters. Insects (e.g., flies, beetles, larva) contaminated by such spraying might be consumed by a variety of birds. However, based on the lack of toxicity of limonene to birds, little risk is anticipated.

Mammalian Acute Effects

The acute oral LD_{50} value for the rat is greater than 5000 mg/kg, which classifies it as practically nontoxic. Because granular limonene is registered as a mammalian repellent and is practically nontoxic, it is not anticipated that granules would be consumed in sufficient quantities to be a risk to mammals.

Risk to Aquatic Animals

Mosquito Larvicide Use

The LOC for freshwater invertebrates was exceeded (risk quotient = 1.5) for the mosquito larvicide use. However, the end-use product is expected to dissipate rapidly, by break up of the oily film. Thus, due to the likely short duration of the effect, there is not a major ecological concern.

Direct Application to Water

The mosquito larvicide product is applied directly to water where breeding mosquitos are likely to be. Potential risk to aquatic organisms is estimated by the EEC/LC_{50} (or EC_{50}). This is the risk quotient (RQ). The Level of Concern (LOC) for this endpoint is a risk quotient greater than or equal to 0.5 for nonendangered species and 0.05 for endangered species.

The EEC is calculated below. It is based on the maximum direct application to water, which is 5 gallons per acre. For this

use a six inch water body scenario is used since mosquito breeding areas are likely to be in shallow water.

EEC = 34.15 lbs x 734 ppb
(where 34.15 = max. appl. rate in lbs product/acre which equals 5 gal/acre x 6.83 lbs/gal and 734 ppb = EEC for a direct application of 1 lb. to 6 inches of water) = 25 ppm)

The aquatic organisms of concern in this case, based on the toxicity of the formulated product to daphnids, are aquatic invertebrates with a formulated product EC_{50} of 17-20 ppm. The risk quotient for these organisms is 25/17 = 1.5, which exceeds the level of concern. However, due to the nature of the product and the likely short duration of the effect, there is not a major ecological concern.

Other (Non-larvicide) Uses

Minimal risks to nonendangered and endangered aquatic species are expected from runoff into ponded waters 6-feet deep from applications of the granular product.

Ground Application

Runoff of limonene into water bodies could present a potential risk to aquatic organisms. Runoff of pesticide from ground applications was estimated by multiplying the maximum application rate (lbs ai/acre) by the percent runoff (based on solubility) from a 10-acre drainage basin into a 1-acre water body. Because solubility data are unavailable for limonene the maximum pesticide runoff, which is 5%, was assumed. Based on these assumptions the maximum aquatic concentration of limonene is 0.5 ppm for a 6-ft. deep water body, as calculated below.

Expected Aquatic Residues

[maximum application rate = 17.5 lbs ai/acre]
Runoff = maximum application rate (lbs ai/acre) x
% runoff x 10-acre drainage basin
= 17.5 lbs ai/acre x 0.05[1] x 10 acres
= 8.75 lbs ai

EEC = runoff (lbs ai) x EEC (ppb) of a 1 lb ai/acre direct application for a 6-ft. deep pond[2]
= 8.75 x 61 ppb for 6-ft. deep pond
= 0.533 ppm

[1]runoff is assumed to be 5%
[2]from Urban and Cook (1986)

Potential risk to aquatic organisms is estimated by the EEC/LC_{50} (or EC_{50}). This is the risk quotient (RQ). The Level of Concern (LOC) for this endpoint is a risk quotient greater than or equal to 0.5 for nonendangered species and 0.05 for endangered species. The risk quotients are shown in the table below.

Aquatic organism	**EEC (ppm)**	**RQ (EEC/ LC50[1])**
Fish	0.5	0.006
Invertebrates		0.03

[1]the EC_{50} value is used for invertebrates

Based on these values, minimal risks to nonendangered and endangered aquatic species are expected from runoff into ponded waters 6-feet deep from applications of the granular product.

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 (i.e. active ingredient specific) data required to support reregistration of products containing limonene 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 limonene. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of limonene, 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 limonene and to determine that limonene can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing limonene 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 and the data identified in Appendix B. Although the Agency has found that all uses of limonene 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 limonene, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients limonene, the Agency has sufficient information on the health effects of limonene and on its potential for causing adverse effects in fish and wildlife and the environment. Therefore, the Agency concludes that products containing limonene for all uses are eligible for reregistration.

The Agency has determined that limonene products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of limonene are eligible for reregistration.

B. Regulatory Position

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

C. Tolerance Reassessment

In April 1994, limonene was granted an exemption from the requirement of a tolerance when it is an inert ingredient used as a solvent or fragrance in pesticide formulations [cite Federal Register citation; i.e., 40 CFR §180.1001 (c), (e)].

V. ACTIONS REQUIRED BY 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 limonene for the above eligible uses has been reviewed and determined to be substantially complete. However, additional confirmatory data is needed for the 90-Day Dermal Toxicity study to fulfill the data requirements.

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions For Use:

"Only for formulation into an _____[fill blank with Insecticide, Herbicide or the applicable term which describes the type of pesticides use(s)] for the following use(s): _____(fill blank only with those uses that are being supported by MP registrant)."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

(a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s)."

(b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s)."

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 product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

Worker Protection Standard

To the Agency's knowledge, at this time all registered uses of limonene are outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The Agency will not establish entry restrictions at this time for limonene end-use products.

The labeling language for the end-use products:

(a) End-Use Products (except the mosquito larvicide use)
Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

(b) End-Use Products (mosquito larvicide use)
Do not contaminate water when disposing of equipment washwater or rinsate. Consult with your State Agency in charge of fish and game before applying to public waters to determine if a permit is needed.

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10and other applicable notices.

3. Additional Label Requirements

Although the toxicology of limonene has been adequately characterized and toxicity is generally relatively low, adverse effects may occasionally occur in pets exposed to limonene flea/tick dips, shampoos and sprays. Labels contain precautionary statements regarding sensitivity among some individual animals, dermal/ocular irritation, use on kittens or nursing mothers and warning against using undiluted product. Although the labels provide appropriate information, the Agency requires the following changes to strengthen the language and further reduce risk of adverse effects:

- Add: Applicators of flea and tick dip (concentrates), spray or shampoo products are to use protective gloves to reduce the risk of dermal irritation or dermal sensitization.

- Add: Flea dip concentrates may harm animals when used at greater strength than specified on the label.

- Change the age for product use on kittens/puppies to several months or a year.

- Change the statement: "Use with care on nursing animals" to "Do not use on nursing animals or any animal which is in poor health".

- Provide a list of symptoms, which may occur when animals are sensitive to the product, to the precautionary statement "individual animals may may be more sensitive to the product".

4. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (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 limonene 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. Table of Use Patterns Subject to Reregistration

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 cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES													
COMPOST/COMPOST PILES				Use Group: TERRESTRIAL FOOD+FEED CROP									
Compost treatment., When needed., Pump spray bottle.	RTU	NA		UC	*	NS	NS	NS	NS	NS	NS		
MANURE				Use Group: TERRESTRIAL FOOD+FEED CROP									
Spray., When needed., Pump spray bottle.	RTU	NA		UC	*	NS	NS	NS	NS	NS	NS		
NON-FOOD/NON-FEED													
CATS (ADULTS/KITTENS)				Use Group: INDOOR RESIDENTIAL									
Animal treatment (spray)., Not on label., Aerosol can.	PRL	NA		UC	*	NS	NS	NS	NS	2	NS		
Animal treatment (spray)., When needed., Aerosol can.	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
Animal treatment (spray)., When needed., Pump spray bottle.	RTU	NA		UC	*	NS	NS	NS	NS	2	NS		
Dip treatment., When needed., Not on label.	EC	NA		UC	*	NS	NS	NS	NS	AN	NS		
	EC	NA		UC	*	NS	NS	NS	NS	NS	NS		
Shampoo., When needed., By hand.	RTU	NA		UC	*	NS	NS	NS	NS	AN	NS		
	RTU	NA		UC	*	NS	NS	NS	NS	NS	NS		
Sponge-on., When needed., Sponge.	EC	NA		UC	*	NS	NS	NS	NS	AN	NS		
	EC	NA		UC	*	NS	NS	NS	NS	NS	NS		
Sprinkle., When needed., Not on label.	EC	NA		UC	*	NS	NS	NS	NS	AN	NS		
	EC	NA		UC	*	NS	NS	NS	NS	NS	NS		
DOGS/CANINES (ADULTS/PUPPIES)				Use Group: INDOOR RESIDENTIAL									
Animal treatment (spray)., Not on label., Aerosol can.	PRL	NA		UC	*	NS	NS	NS	NS	2	NS		
Animal treatment (spray)., When needed., Aerosol can.	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		
Animal treatment (spray)., When needed., Pump spray bottle.	RTU	NA		UC	*	NS	NS	NS	NS	2	NS		

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 cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
DOGS/CANINES (ADULTS/PUPPIES) (con't)				Use Group: INDOOR RESIDENTIAL (con't)									
Dip treatment., When needed., Not on label.	EC	NA		UC	*	NS	NS	NS	NS	AN	NS		
	EC	NA		UC	*	NS	NS	NS	NS	NS	NS		
Shampoo., When needed., By hand.	RTU	NA		UC	*	NS	NS	NS	NS	AN	NS		
	RTU	NA		UC	*	NS	NS	NS	NS	NS	NS		
Sponge-on., When needed., Sponge.	EC	NA		UC	*	NS	NS	NS	NS	AN	NS		
	EC	NA		UC	*	NS	NS	NS	NS	NS	NS		
Sprinkle., When needed., Not on label.	EC	NA		UC	*	NS	NS	NS	NS	AN	NS		
	EC	NA		UC	*	NS	NS	NS	NS	NS	NS		
DRAINAGE SYSTEMS				Use Group: AQUATIC NON-FOOD INDUSTRIAL									
Water treatment (surface)., When needed., By hand.	EC	NA	.549 lb A	*	NS	NS	NS	NS	NS	NS			
HOUSEHOLD/DOMESTIC DWELLINGS INDOOR PREMISES				Use Group: INDOOR RESIDENTIAL									
Indoor general surface treatment., When needed., Pump spray bottle.	RTU	NA		UC	*	NS	NS	NS	NS	NS	NS		
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES				Use Group: OUTDOOR RESIDENTIAL									
Impregnated covering., When needed., By hand.	IMPR	NA		UC	*	NS	NS	NS	NS	NS	NS		
Outdoor general surface spray., When needed., Pump spray bottle.	RTU	NA		UC	*	NS	NS	NS	NS	NS	NS		
Sprinkle., When needed., Not on label.	G	NA	4.015E-04 lb sq.ft	*	NS	NS	NS	NS	AN	NS			
HUMAN BODY/CLOTHING WHILE BEING WORN (INSECT CONTROL)				Use Group: INDOOR RESIDENTIAL									
Clothing treatment., When needed., Sprayer.	RTU	NA		UC	*	NS	NS	NS	NS	0.12	NS		
Skin contact treatment., When needed., By hand.	RTU	NA		UC	*	NS	NS	NS	NS	0.12	NS		
Spray., When needed., Hand held sprayer.	RTU	NA		UC	*	NS	NS	NS	NS	0.12	NS		

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. Dose	Max. # Apps @ Max. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
ORNAMENTAL HERBACEOUS PLANTS				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL							
Sprinkle., When needed., Not on label.	G	NA	4.015E-04 lb sq.ft	*	NS	NS	NS	NS	AN	NS	
ORNAMENTAL LAWNS AND TURF				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL							
Sprinkle., When needed., Not on label.	G	NA	4.015E-04 lb sq.ft	*	NS	NS	NS	NS	AN	NS	
ORNAMENTAL PONDS/AQUARIA				Use Group: AQUATIC NON-FOOD RESIDENTIAL							
Water treatment (surface)., When needed., By hand.	EC	NA	.549 lb A	*	NS	NS	NS	NS	NS	NS	
PAVED AREAS (PRIVATE ROADS/SIDEWALKS)				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL							
Sprinkle., When needed., Not on label.	G	NA	4.015E-04 lb sq.ft	*	NS	NS	NS	NS	AN	NS	
PET LIVING/SLEEPING QUARTERS				Use Group: INDOOR RESIDENTIAL							
Animal bedding/litter treatment., Not on label., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	NS	NS	
Animal bedding/litter treatment., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS	
Animal bedding/litter treatment., When needed., Pump spray bottle.	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	
RECREATIONAL AREAS				Use Group: TERRESTRIAL NON-FOOD CROP							
Impregnated covering., When needed., By hand.	IMPR	NA	UC	*	NS	NS	NS	NS	NS	NS	
SWAMPS/MARSHES/WETLANDS/STAGNANT WATER				Use Group: AQUATIC NON-FOOD OUTDOOR							
Water treatment (surface)., When needed., By hand.	EC	NA	.549 lb A	*	NS	NS	NS	NS	NS	NS	
WIDE AREA/GENERAL OUTDOOR TREATMENT (PUBLIC HEALTH USE)				Use Group: TERRESTRIAL NON-FOOD CROP							
Spray., When needed., Sprayer.	EC	NA	1.373 lb A	*	NS	NS	NS	NS	14	NS	

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 cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes

USES ELIGIBLE FOR REREGISTRATION

NOT SPECIFIED

€€€

LEGEND

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)

Restr. Entry Interv (days) : Restricted Entry Interval (days)

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

EC : EMULSIFIABLE CONCENTRATE
G : GRANULAR
IMPR : IMPREGNATED MATERIAL
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
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

APPENDIX B. Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Limonene covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Limonene 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 LIMONENE

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ALL	41962101
61-2A	Start. Mat. & Mnfg. Process		
61-2B	Formation of Impurities		
62-1	Preliminary Analysis		
62-2	Certification of limits		
62-3	Analytical Method	ALL	41962101
63-2	Color	ALL	41962101
63-3	Physical State	ALL	41962101
63-4	Odor	ALL	41962101
63-5	Melting Point	ALL	N/A
63-6	Boiling Point	ALL	41962101
63-7	Density	ALL	41962101
63-8	Solubility	ALL	41962101
63-9	Vapor Pressure	ALL	41962101
63-10	Dissociation Constant	ALL	
63-11	Octanol/Water Partition	ALL	
63-12	pH	ALL	WAIVED
63-13	Stability	ALL	43107701, 41962101
63-14	Oxidizing/Reducing Action		

Data Supporting Guideline Requirements for the Reregistration of LIMONENE

REQUIREMENT		USE PATTERN	CITATION(S)
63-15	Flammability		
63-16	Explodability		
63-17	Storage stability		
63-18	Viscosity		
63-19	Miscibility		
63-20	Corrosion characteristics		
63-21	Dielectric breakdown volt		
64-1	Submittal of Samples		
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	ALL	00109340
71-1B	Acute Avian Oral - Quail/Duck TEP		
71-2A	Avian Dietary - Quail	ALL	WAIVED
71-2B	Avian Dietary - Duck		
71-3	Wild Mammal Toxicity		
71-4A	Avian Reproduction - Quail		
71-4B	Avian Reproduction - Duck		
71-5A	Simulated Field Study		
71-5B	Actual Field Study		
72-1A	Fish Toxicity Bluegill	ALL	WAIVED
72-1B	Fish Toxicity Bluegill - TEP		

Data Supporting Guideline Requirements for the Reregistration of LIMONENE

REQUIREMENT		USE PATTERN	CITATION(S)
72-1C	Fish Toxicity Rainbow Trout		
72-1D	Fish Toxicity Rainbow Trout- TEP	ALL	WAIVED
72-2A	Invertebrate Toxicity		
72-2B	Invertebrate Toxicity - TEP		
72-3A	Estuarine/Marine Toxicity - Fish		
72-3B	Estuarine/Marine Toxicity - Mollusk		
72-3C	Estuarine/Marine Toxicity - Shrimp		
72-3D	Estuarine/Marine Toxicity Fish- TEP		
72-3E	Estuarine/Marine Toxicity Mollusk - TEP		
72-3F	Estuarine/Marine Toxicity Shrimp - TEP		
72-4A	Early Life Stage Fish		
72-4B	Life Cycle Invertebrate		
72-5	Life Cycle Fish		
72-6	Aquatic Organism Accumulation		
72-7A	Simulated Field - Aquatic Organisms		
72-7B	Actual Field - Aquatic Organisms		
122-1A	Seed Germination/Seedling Emergence		

REQUIREMENT		USE PATTERN	CITATION(S)
122-1B	Vegetative Vigor		
122-2	Aquatic Plant Growth		
123-1A	Seed Germination/Seedling Emergence		
123-1B	Vegetative Vigor		
123-2	Aquatic Plant Growth		
124-1	Terrestrial Field		
124-2	Aquatic Field		
141-1	Honey Bee Acute Contact		
141-2	Honey Bee Residue on Foliage		
141-5	Field Test for Pollinators		
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat		
81-2	Acute Dermal Toxicity - Rabbit/Rat		
81-3	Acute Inhalation Toxicity - Rat		
81-4	Primary Eye Irritation - Rabbit		
81-5	Primary Dermal Irritation - Rabbit		
81-6	Dermal Sensitization - Guinea Pig		
81-7	Acute Delayed Neurotoxicity - Hen	ALL	N/A
82-1A	90-Day Feeding - Rodent		
82-1B	90-Day Feeding - Non-rodent		

Data Supporting Guideline Requirements for the Reregistration of LIMONENE

REQUIREMENT		USE PATTERN	CITATION(S)
82-2	21-Day Dermal - Rabbit/Rat		
82-3	90-Day Dermal - Rodent	ALL	DATA GAP
82-4	90-Day Inhalation - Rat		
82-5A	90-Day Neurotoxicity - Hen		
82-5B	90-Day Neurotoxicity - Mammal		
83-1A	Chronic Feeding Toxicity - Rodent		
83-1B	Chronic Feeding Toxicity - Non-Rodent		
83-2A	Oncogenicity - Rat		
83-2B	Oncogenicity - Mouse		
83-2B	Oncogenicity - Mouse		
83-3A	Developmental Toxicity - Rat	ALL	42316301
83-3B	Developmental Toxicity - Rabbit		
83-4	2-Generation Reproduction - Rat		
84-2A	Gene Mutation (Ames Test)		
84-2B	Structural Chromosomal Aberration		
84-4	Other Genotoxic Effects		
85-1	General Metabolism		
85-2	Dermal Penetration		
86-1	Domestic Animal Safety		

REQUIREMENT		USE PATTERN	CITATION(S)
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	Foliar Residue Dissipation		
132-1B	Soil Residue Dissipation		
133-3	Dermal Passive Dosimetry Exposure		
133-4	Inhalation Passive Dosimetry Exposure		
231	Estimation of Dermal Exposure at Outdoor Sites		
232	Estimation of Inhalation Exposure at Outdoor Sites		
233	Estimation of Dermal Exposure at Indoor Sites		
234	Estimation of Inhalation Exposure at Indoor Sites		
ENVIRONMENTAL FATE			
160-5	Chemical Identity		
161-1	Hydrolysis	ALL	WAIVED
161-2	Photodegradation - Water		
161-3	Photodegradation - Soil		
161-4	Photodegradation - Air		
162-1	Aerobic Soil Metabolism	ALL	WAIVED
162-2	Anaerobic Soil Metabolism		

Data Supporting Guideline Requirements for the Reregistration of LIMONENE

REQUIREMENT		USE PATTERN	CITATION(S)
162-3	Anaerobic Aquatic Metabolism		
162-4	Aerobic Aquatic Metabolism		
163-1	Leaching/Adsorption/Desorption	ALL	WAIVED
163-2	Volatility - Lab		
163-3	Volatility - Field		
164-1	Terrestrial Field Dissipation	ALL	WAIVED
164-2	Aquatic Field Dissipation		
164-3	Forest Field Dissipation		
164-5	Long Term Soil Dissipation		
165-1	Confined Rotational Crop		
165-2	Field Rotational Crop		
165-3	Accumulation - Irrigated Crop		
165-4	Bioaccumulation in Fish		
165-5	Bioaccumulation - Aquatic NonTarget		
166-1	Ground Water - Small Prospective		
166-2	Ground Water - Small Retrospective		
166-3	Ground Water - Irrigated Retrospective		
201-1	Droplet Size Spectrum		
202-1	Drift Field Evaluation		

Data Supporting Guideline Requirements for the Reregistration of LIMONENE

REQUIREMENT		USE PATTERN	CITATION(S)
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants		
171-4B	Nature of Residue - Livestock		
171-4C	Residue Analytical Method - Plants		
171-4D	Residue Analytical Method - Animal		
171-4E	Storage Stability		
171-4F	Magnitude of Residues - Potable H2O		
171-4G	Magnitude of Residues in Fish		
171-4H	Magnitude of Residues - Irrigated Crop		
171-4I	Magnitude of Residues - Food Handling		
171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg		
171-4K	Crop Field Trials		
171-4L	Processed Food		
171-5	Reduction of Residues		
171-6	Proposed Tolerance		
171-7	Support for Tolerance		
171-13	Analtyical Reference Standard		

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Limonene

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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00042305 Purdue Frederick Company (1975) Primary Dermal Irritation in Albino Rabbits: Project # MB 79-3580. (Unpublished study received Sep 8, 1980 under 10279-7; CDL:243192-B)

00042306 Napp Laboratories, Limited (1980) A Summary of the Experience of the NAPP Pharmaceutical Group in the Manufacture and Marketing of Prioderm(R) Lotion. (Unpublished study received Sep 8, 1980 under 10279-7; submitted by Purdue Frederick Co., Norwalk, Conn.; CDL:243192-C)

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00042311 Purdue Frederick Company (19??) General Chemistry: Prioderm Lotion. (Unpublished study received Sep 8, 1980 under 10279-7; CDL:243192-J)

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00043010 Hercules Powder Company, Incorporated (1962) Hercules(R) Pine Oils: Yarmor(R) 302, 302W, 317, 350, F, and Herco(R): Summary of Toxicological Investigations. Wilmington, Del.: Hercules. (Bulletin T-103; also ~ In ~ unpublished submission received May 2, 1962 under unknown admin. no.; CDL:104228-A)

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00054054 Organic Chemicals (1974) Toxicity Tests: Terpene Alcohols. (Unpublished study received May 19, 1976 under 13648-7; CDL: 230193-A)

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	received May 19, 1976 under 13648-7; submitted by Organic Chemicals, Div. of SCM Corp., Jacksonville, Fla.; CDL:230193-B)
00063204	B.G. Davis (19??) Limonene: 1-Methyl-A-(1-methylethenyl) cyclohexene; P-Mentha-1, B-diene. (Unpublished study received Jun 12, 1976 under 41989-EX-1; CDL:234091-A)
00063205	Young, J.A.; Doyle, R.L. (1974) Acute Toxicity and Irritation Studies of Mac's Citrus Base Waterless Hand Cleaner: Report No. 74053-21. (Unpublished study received Jun 12, 1978 under 41989EX-1; prepared by Hill Top Testing Services, Inc., submitted by B.G. Davis, Titusville, Fla.; CDL:234091-B)
00063206	Young, J.A.; Doyle, R.L. (1974) Primary Skin and Acute Eye Irritation Studies of 15% Emul, WHC, 35% Citrus Oil, 50% H2O, 8.9 and PAD # 1: Report No. 74-131-21. (Unpublished study received Jun 12, 1976 under 41989-EX-1; prepared by American Biomedical Corp., submitted by B.G. Davis, Titusville, Fla.; CDL:234091-C)
00076995	Berlin, C.H.; Lesonsky, R.L. (1980) Dermal Toxicity on Rabbits: Test Report No. 1-2-27836-1. (Unpublished study received May 5, 1981 under 45987-1; prepared by Bio-Technics Laboratories, Inc., submitted by Monogram Industries, Inc., Santa Monica, Calif.; CDL:245190-A)
00076996	Berlin, C.H. (1980) Acute Oral Toxicity: Test Report No. 1-2-278362. (Unpublished study received May 5, 1981 under 45987-1; prepared by Bio-Technics Laboratories, Inc., submitted by Monogram Industries, Inc., Santa Monica, Calif.; CDL:245190-B)
00076997	Berlin, C.H. (1980) Primary Eye Irritation: Test Report No. 1-227836-3. (Unpublished study received May 5, 1981 under 45987-1; prepared by Bio-Technics Laboratories, Inc., submitted by Monogram Industries, Inc., Santa Monica, Calif.; CDL:245190-C)
00076998	Berlin, C.H. (1980) Acute Inhalation Toxicity: Test Report No. 12-27836-4. (Unpublished study received May 5, 1981 under 459871; prepared by Bio-Technics, Inc., submitted by Monogram Industries, Inc., Santa Monica, Calif.; CDL:245190-D)

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00077000	Berlin, C.H. (1980) Guinea Pig Sensitization: Test Report No. 1-227836-6. (Unpublished study received May 5, 1981 under 459871; prepared by Bio-Technics Laboratories, Inc., submitted by Monogram Industries, Inc., Santa Monica, Calif.; CDL:245190-F)
00077001	Monogram Industries, Incorporated (19??) Product Chemistry. (Unpublished study received May 5, 1981 under 45987-1; CDL: 245189-A)
00077002	Meuly, W.C., inventor; Rhodia, Inc., assignee (1975) Process for repelling dogs and cats from a selected area or from each other using gamma-N-alkyl-gamma-butyrolactones and delta-Nalkyl-delta-valerolactones. U.S. patent 3,923,997. Dec 2. 8 p. U.S. Cl. 424/279; 424/45; Int. C1.2 A0IN 9/28. (Published study; CDL:245188-A)
00077003	Monogram Industries, Incorporated (1978?) Environmental Chemistry. (Unpublished study received May 5, 1981 under 45987-1; CDL: 245187-A)
00094682	Young, S.M. (19??) D'limonene: Fema #2633. (Unpublished study received Jan 29, 1982 under 4758-141; prepared by Citrus & Allied Essences Ltd., submitted by Pet Chemicals, Inc., Miami Springs, Fla.; CDL:246738-A)
00094683	Ting, S.V.; Newhall, W.F. (1965) The Occurrence of a natural antioxident in citrus fruit. Journal of Food Science 30(1):57-63. (Also ~ In ~ unpublished submission received Jan 29, 1982 under 4758-141; submitted by Pet Chemicals, Inc., Miami Springs, Fla.; CDL:246738-B)
00094685	Cerven, D.R.; Moreno, O.M.; Altenbach, E.J. (1982) Oral Toxicity in Albino Rats: Project No. MB 81-5736 A. (Unpublished study received Jan 29, 1982 under 4758-141; prepared by MB Research Laboratories, Inc., submitted by Pet Chemicals, Inc., Miami Springs, Fla.; CDL:246739-A)
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00094688	Weatherby, S.E.; Moreno, O.M.; Altenbach, E.J. (1982) Eye Irritation in Rabbits: Project No. MB 81-5736 D. (Unpublished study received Jan 29, 1982 under 4758-141; prepared by MB Research Laboratories, Inc., submitted by Pet Chemicals, Inc., Miami Springs, Fla.; CDL:246739-D)
00094689	Cerven, D.R.; Moreno, O.M.; Altenbach, E.J. (1982) Guinea Pig Sensitization: Project No. MB 81-5736 F. (Unpublished study received Jan 29, 1982 under 4758-141; prepared by MB Research Laboratories, Inc., submitted by Pet Chemicals, Inc., Miami Springs, Fla.; CDL:246739-E)
00094690	Tansy, M.F. (1981) Letter sent to Oscar M. Moreno dated Dec 29, 1981: Inhalation toxicology report on compound 81-5736. (Unpublished study received Jan 29, 1982 under 4758-141; prepared by MB Research Laboratories, Inc., submitted by Pet Chemicals, Inc., Miami Springs, Fla.; CDL:246739-F)
00094691	Boyd, W.E. (1982) Efficacy Study of Citrus Shampoo on Fleas. (Unpublished study, including letter dated Jan 17, 1982 from L.A. Bernstein to Claire Ulanoff, received Jan 29, 1982 under 4758-141; prepared by Boyd & Doty D.V.M. Chartered, submitted by Pet Chemicals, Inc., Miami Springs, Fla.; CDL:246740-A)
00097972	Whitmire Research Laboratories, Incorporated (1981) Efficacy Data in Support of Application for Amended Registration for Whitmire Wasp-stopper III. (Compilation; unpublished study received Jul 19, 1980 under 499-215; CDL:247107-A)
00100789	Pet Chemicals, Inc. (1982) Efficacy of Citrex Dip. (Compilation; unpublished study received Apr 30, 1982 under 4758-142; CDL:247444-A)

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00100791	Cerven, D.; Moreno, O.; Altenbach, E. (1982) Acute Dermal Toxicity in Albino Rabbits: Citrex Flea and Tick Dip: Project No. MB 82-5844 B. (Unpublished study received Apr 30, 1982 under 4758-142; prepared by MB Research Laboratories, Inc., submitted by Pet Chemicals, Inc., Miami Springs, FL; CDL:247445-B)
00100792	Weatherby, S.; Moreno, O.; Altenbach, E. (1982) Primary Dermal Irritation in Albino Rabbits: Citrex Flea and Tick Dip: Project No. MB 82-5844 C. (Unpublished study received Apr 30, 1982 under 4758-142; prepared by MB Research Laboratories, Inc., submitted by Pet Chemicals, Inc., Miami Springs, FL; CDL: 247445-C)
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00117513	Moreno, O.; Cerven, D.; Altenbach, E. (1982) Oral Toxicity in Albino Rats: Citrus Pump Spray, Code #B-001: Project No. MB 826184 A. (Unpublished study received Sep 23, 1982 under 4758143; prepared by MB Research Laboratories, Inc., submitted by Pet Chemicals, Inc., Miami Springs, FL; CDL:248704-A)
00117514	Weatherby, S.; Moreno, O.; Altenbach, E. (1982) Eye Irritation in Rabbits: Citrus Pump Spray: Project No. MB 82-6184 D. (Unpublished study received Sep 23, 1982 under 4758-143; prepared by MB Research Laboratories, Inc., submitted by Pet Chemicals, Inc., Miami Springs, FL; CDL:248705-A)

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00117516	Cerven, D.; Moreno, O.; Altenbach, E. (1982) Acute Dermal Toxicity in Albino Rabbits: Citrus Pump Spray: Project No. MB 826184 B. (Unpublished study received Sep 23, 1982 under 4758143; prepared by MB Research Laboratories, Inc., submitted by Pet Chemicals, Inc., Miami Springs, FL; CDL:248707-A)
00117517	Yenser, B.; Moreno, O.; Altenbach, E. (1982) Guinea Pig Sensitization: Citrus Pump Spray: Project No. MB 82-6184 F. (Unpublished study received Sep 23, 1982 under 4758-143; prepared by MB Research Laboratories, Inc., submitted by Pet Chemicals, Inc., Miami Springs, FL; CDL:248708-A)
00117518	Rosenfeld, G. (1982) Acute Inhalation Toxicity Study in Rats: Citrus Pump Spray: Study #0574C. (Unpublished study received Sep 23, 1982 under 4758-143; prepared by Cosmopolitan Safety Evaluation, Inc., submitted by Pet Chemicals, Inc., Miami Springs, FL; CDL:248709-A)
00118424	Rosenfeld, G.; Robbins, G. (1982) Primary Eye Irritation Study in Rabbits: Citrus Pump Spray: Study #0605D. (Unpublished study received Nov 23, 1982 under 4758-145; prepared by Cosmopolitan Safety Evaluation, Inc., submitted by Pet Chemical, Inc., Miami Springs, FL; CDL:248894-A)
00121537	Greif, M. (1973) Toxicity Study on Lemon-Sol Disinfectant-cleaner. (Unpublished study received Jan 3, 1974 under 1730-31; prepared by Clinical Research Services, submitted by American Cyanamid Co., Consumer Products Research Div., Wayne, NJ; CDL: 240008-A)
00121936	Green, L. (1971) Toxicity Studies for Lemon Sol (CPD) 165-141: Study #39-71. (Unpublished study received Nov 29, 1971 under 1730-31; prepared by Bio-Toxicology Laboratories, submitted by American Cyanamid Co., Consumer Products Research Div., Wayne, NJ; CDL:006589-A)

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	Certified Limits: Lab Project Number: 00355-001. Unpublished study prepared by Case Consulting Laboratories, Inc. 17 p.
42392902	Anthony, C. (1992) D-Limonene: Physical and Chemical Properties: Lab Project Number: 00355-001. Unpublished study prepared by Case Consulting Laboratories, Inc. 46 p.
42392903	Harrison, E. (1992) Product Identity and Composition: Australian Luxury Shampoo for Dogs: Unpublished study. 107 p.
42392904	Harrison, E. (1992) Australian Luxury Shampoo for Dogs: Analysis and Certification of Product Ingredients. Unpublished study. 11 p.
42392905	Anthony, C. (1992) Dog Shampoo Physical and Chemical Properties: Lab Project Number: 00355-001. Unpublished study prepared by Case Consulting Laboratories, Inc. 46 p.
42392906	Cerven, D. (1992) Single Dose Oral Toxicity in Rats/LD50 in Rats: Australian Luxury Dog Shampoo, Formula DS (CTF)-R1: Lab Project Number: MB 91-1103 A. Unpublished study prepared by MB Research Laboratories, Inc. 9 p.
42392907	Cerven, D. (1992) Acute Dermal Toxicity in Rabbits/LD50 in Rabbits: Australian Luxury Dog Shampoo, Formula DS (CTF)-R1: Lab Project Number: MB 91-1103 B. Unpublished study prepared by MB Research Laboratories, Inc. 14 p.
42392908	Werley, M. (1992) Inhalation Toxicity in Rats: Australian Luxury Dog Shampoo, Formula DS (CTF)-R1: Lab Project Number: MB 91-1103 E. Unpublished study prepared by MB Research Laboratories, Inc. 33 p.
42392909	Cerven, D. (1992) Primary Eye Irritation and/or Corrosion in Rabbits: Australian Luxury Dog Shampoo, Formula DS (CTF)-R1: Lab Project Number: MB 91-1103. Unpublished study prepared by MB Research Laboratories, Inc. 11 p.
42392910	Cerven, D. (1992) Primary Eye Irritation and/or Corrosion in Rabbits: Australian Luxury Dog Shampoo, Formula DS (CTF)R-4: Lab Project Number: MB 92-1484 D. Unpublished study prepared by MB Research

MRID	CITATION
	Laboratories, Inc. 11 p.
42392911	Cerven, D. (1992) Primary Dermal Irritation in Albino Rabbits: Australian Luxury Dog Shampoo, Formula DS (CTF)-R1: Lab Project Number: MB 91-1103 C. Unpublished study prepared by MB Research Laboratories, Inc. 10 p.
42392912	Cerven, D. (1992) Delayed Contact Dermal Sensitization Buehler Method: Australian Luxury Dog Shampoo, Formula DS (CTF)-R1: Lab Project Number: MB 91-1103 F. Unpublished study prepared by MB Research Laboratories, Inc. 18 p.
42392913	Cerven, D. (1992) Single Dose Oral Toxicity in Rats/LD50 in Rats: Sunkist Premium Orange Terpene (Limonene) #6098: Lab Project Number: MB 91-1104 A. Unpublished study prepared by MB Research Laboratories, Inc. 11 p.
42392914	Cerven, D. (1992) Acute Dermal Toxicity in Rabbits/LD50 in Rabbits: Sunkist Premium Orange Terpene (Limonene) #6098: Lab Project Number: MB 91-1104 B. Unpublished study prepared by MB Research Laboratories, Inc. 12 p.
42392915	Cerven, D. (1992) Primary Eye Irritation and/or Corrosion in Rabbits: Sunkist Premium Orange Terpene (Limonene) #6098: Lab Project Number: MB 91-1104 D. Unpublished study prepared by MB Research Laboratories, Inc. 11 p.
42392916	Cerven, D. (1992) Primary Dermal Irritation in Albino Rabbits: Sunkist Premium Orange Terpene (Limonene) #6098: Lab Project Number: MB 91-1104 C. Unpublished study prepared by MB Research Laboratories, Inc. 10 p.
42392917	Cerven, D. (1992) Delayed Contact Dermal Sensitization Buehler Method: Sunkist Premium Orange Terpene (Limonene) #6098: Lab Project Number: MB 91-1104 F. Unpublished study prepared by MB Research Laboratories, Inc. 18 p.

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MRID	CITATION
42626200	Rod Products Co. (1993) Submission of product chemistry and efficacy data in support of the registration of Bugchaser Insect Repellent Tablecloth. Transmittal of 3 studies.
42626201	Rod, R. (1993) Product Chemistry: Bugchaser Insect Repellent Outdoor Tablecloth. Unpublished study prepared by Rod Products Co. 14 p.
42626202	Rod, R. (1993) Data Requirements Tables (Subpart D): Bugchaser Insect Repellent Strip & Bugchaser Insect Repellent Outdoor Tablecloth. Unpublished study prepared by Rod Products Co. 8 p.
42626203	Rod, R. (1992) Efficacy Studies: Insect Repellents/Feeding Depressants. Unpublished study prepared by Rod Products Co. 11 p.
42626300	Rod Products Co. (1993) Submission of product chemistry and efficacy data in support of the registration of Bugchaser Insect Repellent Strip. Transmittal of 3 studies.
42626301	Rod, R. (1993) Product Chemistry: Bugchaser Insect Repellent Strip. Unpublished study prepared by Rod Products Co. 14 p.
42626302	Rod, R. (1993) Data Requirements Tables (Subpart D): Bugchaser Insect Repellent Strip & Bugchaser Insect Repellent Outdoor Tablecloth. Unpublished study prepared by Rod Products Co. 8 p.
42626303	Rod, R. (1992) Efficacy Studies: Insect Repellents/Feeding Depressants. Unpublished study prepared by Rod Products Co. 7 p.
42678104	Kuhn, J. (1993) Rodspray: Acute Dermal Toxicity Study in Rabbits: Lab Project Number: 9684-92. Unpublished study prepared by Stillmeadow, Inc. 11 p.
42694200	Mr. Christal's (1993) Submission of toxicity data in support of the Limonene reregistration. Transmittal of 1 study.
42694201	Jameson, C. (1983) NTP Technical Report on the Toxicology and Carcinogenesis Studies of d-Limonene in F344/N Rats and B6C3F Mice. Prepared by Mr. Christal's Inc.; available from the National Institutes of Health, Public Health Service, NIH Publication No. 90-2802. 168 p.

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42726600	Mr. Christal's Inc. (1993) Submission of Product Chemistry and Toxicity Data in Support of Registration Australian Luxury Shampoo for Dogs. Transmittal of 5 Studies.
42726601	Cervin, D. (1993) Delayed Contact Dermal Sensitization Test (Buehler Method): Australian Luxury Dog Shampoo, Formula DS (CTF)-R1: Amended Final Report: Lab Project Number: MB 91-1104 F. Unpublished study prepared by MB Research Laboratories, Inc. 18 p.
42726602	Cervin, D. (1993) Delayed Contact Dermal Sensitization Test (Buehler Method): Sunkist Premium Orange Terpene (Limonene): Amended Final Report: Lab Project Number: MB 91-1103 F. Unpublished study prepared by MB Research Laboratories, Inc. 18 p.
42726603	Moreno, M. (1993) Inhalation Toxicity in Rats: Australian Luxury Dog Shampoo, formula DS (CTF)-R1: Amended Final Report: Lab Project Number: MB 91-1103 E. Unpublished study prepared by MB Research Laboratories, Inc. 33 p.
42726604	Anthony, C. (1993) Mr. Christal's Australian Luxury Dog Shampoo: Physical and Chemical Properties: Lab Project Number: 00425-001. Unpublished study prepared by Case Consulting Laboratories, Inc. 15 p.
42726605	Harrison, E. (1993) Addendum to MRID# 42392903: Mr. Christal's Australian Luxury Shampoo for Dogs: Beginning Materials and Discussion of Impurity Formation. Unpublished study prepared by Mr. Christal's. 19 p.
42864100	Rod Products Co. (1993) Submission of efficacy data in support of registration for Bugchaser Insect Repellent Strip. Transmittal of 1 study.
42864101	Rod, R. (1993) Efficacy Studies: Various Rodspray Products. Unpublished study prepared by Rod Products Co. 14 p.
43011900	Applied Biochemists, Inc. (1993) Submission of Product Chemistry and Acute Toxicology Data in Support of Pond and Lake Algaecide Product Clearigate. Transmittal of 7 studies.

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43011901	Anthony, C. (1993) Enhanced Cutrine: Physical and Chemical Properties: Lab Project Number: 00408-001. Unpublished study prepared by Case Consulting Labs, Inc. 39 p.
43011902	Anthony, C. (1993) Enhanced Cutrine: Storage Stability: Lab Project Number: 00428-001. Unpublished study prepared by Case Consulting Labs, Inc. 21 p.
43011903	Shapiro, R. (1993) EPA Acute Dermal Toxicity--Defined LD50 (in Rabbits of Enhanced Cutrine): Lab Project Number: T-1964. Unpublished study prepared by Product Safety Labs. 23 p.
43011904	Shapiro, R. (1993) EPA Acute Inhalation--Defined LC50 (in Rats of Enhanced Cutrine): Lab Project Number: T-1966. Unpublished study prepared by Product Safety Labs. 40 p.
43011905	Shapiro, R. (1993) EPA Primary Dermal Irritation Test (in Rabbits of Enhanced Cutrine): Lab Project Number: T-1963. Unpublished study prepared by Product Safety Labs. 17 p.
43011906	Shapiro, R. (1993) EPA Guinea Pig Sensitization Test (Buehler) (of Enhanced Cutrine): Lab Project Number: T-1965. Unpublished study prepared by Product Safety Labs. 23 p.
43011907	Kierkowski, D. (1993) Product Chemistry Series 61 (of Cleargate): Lab Project Number. Unpublished study prepared by Applied Biochemists, Inc. 9 p.
43013700	Rod Products Co. (1993) Submission of Efficacy Data in Support of Application for Registration of BUGCHASER Insect Repellent Strip. Transmittal of 1 Study.
43013701	Vargo, A. (1993) Efficacy Study: Bugchaser Wrist Band Insect Repellent Strip. Unpublished study prepared by American Samoa Community College. 5 p.
43107700	Speer Products, Inc. (1994) Submittal of Product Chemistry Data in Support of Reregistration of Limonene. Transmittal of 1 study.
43107701	Rondon, C. (1994) Stability of d-Limonene Technical: Final Report: Lab Project Number: 93-6411-11. Unpublished study prepared by Arctech, Inc. 44 p.

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43117000	Speer Products (1994) Submission of toxicology data in support of FIFRA 6(a)(2) requirements for d-limonene. Transmittal of 1 study.
43117001	Lewis, E. (1994) Letter Sent to R. Mountfort dated January 21, 1994: (Dermal Irritation and Ulceration in 2-week Dermal Range Finding Test: d-Limonene). Prepared by Pazianos Associates for Speer Products, Inc. 37 p.
43182700	Mr. Christal's, Inc. (1994) Submittal of Skin Sensitization Data in Support of Registration of Christal's Australian Luxury Shampoo for Dogs. Transmittal of 2 studies.
43182701	Chmura, P. (1994) Delayed Contact Dermal Sensitization Test (Buehler Method): Australian Dog Shampoo, DS (CTF) R-5, Lot #ALS-54, 5.07% Limonene: Lab Project Number: MB 93-3128 F. Unpublished study prepared by MB Research Laboratories, Inc. 24 p.
43182702	Chmura, P. (1994) Delayed Contact Dermal Sensitization Test (Buehler Method): Sunkist Essential Oils, Premium Orange Terpenes, Lot #61983, 98.55% Limonene: Lab Project Number: MB 93-3290 F. Unpublished study prepared by MB Research Laboratories, Inc. 23 p.
93136000	Pazianos Associates (1990) Reregistration Phase 3 Response: Limonene.
93136001	Damico, J. (1990) Pazianos Associates Phase 3 Summary of MRID 00150435 and Related MRIDs 00152930. D-Limonene Product Chemistry Data. 12 p.
93136002	Damico, J. (1990) Pazianos Associates Phase 3 Summary of MRID 00150435. D-Limonene Product Chemistry Data: Chemical and Physical Properties. 5 p.
93136003	Smith, F. (1990) Pazianos Associates Phase 3 Summary of MRID 00146988. A Dietary LC50 Study in the Bobwhite with d-Limonene. Prepared by Wildlife International, Ltd. 6 p.
93136004	Smith, F. (1990) Pazianos Associates Phase 3 Summary of MRID 00146085. A 96-hour Static Bioassay in Rainbow Trout with d-Limonene. Prepared by Environmental & Toxicological Consultants, Inc. 6 p.

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93136005	Smith, F. (1990) Pazianos Associates Phase 3 Summary of MRID 00146085. A 48-hour Static Bioassay in Daphnia magna with d-Limonene. Prepared by Environmental & Toxicological Consultants, Inc. 6 p.
93136006	Smith, F. (1990) Pazianos Associates Phase 3 Summary of MRID 00150437. Acute Oral Toxicity Study in Rats: d-Limonene. Prepared by Cosmopolitan Safety Evaluation, Inc. 6 p.
93136007	Smith, F. (1990) Pazianos Associates Phase 3 Summary of MRID 00150436. Acute Dermal Toxicity in the Rabbit: d-Limonene. Prepared by Cosmopolitan Safety Evaluation, Inc. 6 p.
93136008	Smith, F. (1990) Pazianos Associates Phase 3 Summary of MRID 00150433. Acute Inhalation Toxicity in the Rat: d-Limonene. Prepared by Cosmopolitan Safety Evaluation, Inc. 5 p.
93136009	Smith, F. (1990) Pazianos Associates Phase 3 Summary of MRID 00150431. Primary Eye Irritation Study in Rabbits: d-Limonene. Prepared by Cosmopolitan Safety Evaluation, Inc. 5 p.
93136010	Smith, F. (1990) Pazianos Associates Phase 3 Summary of MRID 00150432. Primary Dermal Irritation Study in Rabbits: d-Limonene. Prepared by Cosmopolitan Safety Evaluation, Inc. 6 p.
93136011	Smith, F. (1990) Pazianos Associates Phase 3 Summary of MRID 00150434. Dermal Sensitization in the Guinea Pig: d-Limonene. Prepared by Cosmopolitan Safety Evaluation, Inc. 5 p.
93136999	Pazianos Associates (1990) Reregistration Phase 3 Response: Limonene. Correspondence and Supporting Material.
93137000	Rod Products Company (1990) Reregistration Phase 3 Response: Limonene.
93137001	Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00077001 and Related MRIDs 00077002, 00077003. (Product Identity: Doo-Not). 7 p.

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93137002	Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00109340. Acute Avian Oral: Quail: No-Go Dog Repellent: ABSL No. 18766. Prepared by Applied Biological Sciences Laboratory, Inc. 11 p.
93137003	Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00109342. Acute Avian Diet.: Quail: No-Go Dog Repellent: ABSL No. 18866. Prepared by Applied Biological Sciences Laboratory, Inc. 12 p.
93137004	Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00109341. Acute Avian Diet.: Duck: No-Go Dog Repellent: ABSL No. 18866. Prepared by Applied Biological Sciences Laboratory, Inc. 12 p.
93137005	Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00109344. Fish Toxicity Fathead Minnows: No-Go Dog Repellent: ABSL No. 18766. Prepared by Applied Biological Sciences Laboratory, Inc. 11 p.
93137006	Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00109343. Fish Toxicity Rainbow Trout: No-Go Dog Repellent: ABSL No. 18766. Prepared by Applied Biological Sciences Laboratories, Inc. 11 p.
93137007	Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00109345. Invertebrate Toxicity: No-Go Dog Repellent: ABSL No. 18766. Prepared by Applied Biological Sciences Laboratories, Inc. 11 p.
93137008	Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00109339. Acute Oral Toxicity Rat: Monogram Animal Repellant No. 100: Test Report No. 1-2-27836-2. Prepared by Bio-Technics Laboratories, Inc. 8 p.
93137009	Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00109339. Acute Dermal Toxicity Rabbit…Monogram Animal Repellant No. 100: Test Report No. 1-2-27836-1. Prepared by Bio-Technics Laboratories, Inc. 8 p.
93137010	Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00109339. Acute Inhalation Toxicity Rat: Monogram Animal Repellant No. 100: Test Report No. 1-2-27836-4. Prepared by Bio-Technics Laboratories, Inc. 8 p.

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MRID	CITATION
93137011	Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00109339. Primary Eye Irritation Rabbit: Monogram Animal Repellant No. 100: Test Report No. 1-2-27836-3. Prepared by Bio-Technics Laboratories, Inc. 8 p.
93137012	Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00109339. Primary Dermal Irritation: Monogram Animal Repellant No. 100: Test Report No. 1-2-27836-5. Prepared by Bio-Technics Laboratories, Inc. 9 p.
93137013	Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00109339. Dermal Sensitization: Monogram Animal Repellant No. 100: Test Report No. 1-2-27836-6. Prepared by Bio-Technics Laboratories, Inc. 8 p.
93137999	Rod Products Company (1990) Reregistration Phase 3 Response: Limonene. Correspondence and Supporting Material.
93280000	Mr. Cristal's (1993) Reregistration Phase 3 Response: d-Limonene.
93280999	Mr. Cristal's (1993) Reregistration Phase 3 Response: d-Limonene. Correspondence and Supporting Material.

APPENDIX D. List of Available Related Documents

The following is a list of available documents related to Limonene. It's purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for Limonene and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Limonene RED Fact Sheet

4. PR Notice 86-5 (included in this appendix)

5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement

APPENDIX E. PR Notices 86-5 and 91-2

PR Notice 86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 86-5

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS
AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the

entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

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G. Special Requirements for Submitting Data to the Docket 10

A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.

- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an

application for an EUP should be subdivided into sections A, B, C,... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, ...250 of 250).

- Include a company name or mark and study number on each page of the study, e g , Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product

produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE**. An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI

claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d)(1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit

disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- € Do not include frayed or torn pages.
- € Do not include carbon copies, or copies in other than black ink.
- € Make sure that photocopies are clear, complete, and fully readable.
- € Do not include oversize computer printouts or fold-out pages.
- € Do not bind any documents with glue or binding tapes.
- € Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided ln three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- € Remove the "Supplemental Statement of Data Confidentiality Claims".
- € Remove the "Confidential Attachment".
- € Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- € Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.

/S/

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

†Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

†Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

Vol n Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____ _____
Name Signature

Company Name _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

Page 1 of X
(X is the total number of pages in the study)

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____Typed Name_____ Date:_____

_____Title_____ _____Signature_____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____Typed Name_____ Date:_____

_____Title_____ Signature _____

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information in voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
6	14	Identity of Inert Ingredient	§10(d)(C)
28	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PAGES(S): are attached immediately behind this page

PAGES	REASON FOR THE DELETION	FIFRA REFERENCE
35-41.	Description of product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

```
This study meets the requirements for 40 CFR Part 160

      Submitter _____________________________________________________

      Sponsor   _____________________________________________________
```

Example 2.

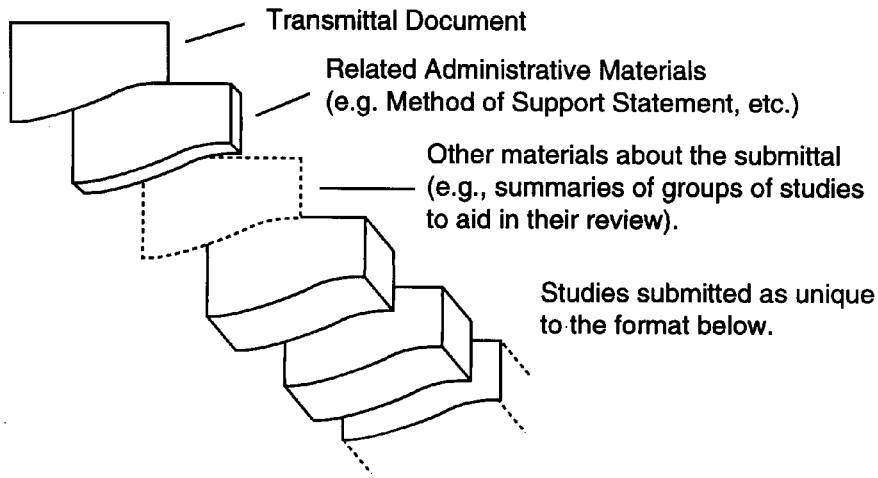
```
This study does not meet the requirements of 40 CFR Part 160, and
differs in the following ways:

1._____________________________________________

2._____________________________________________

3._____________________________________________

      Submitter_____________________________________

      Sponsor_______________________________________

      Study Director_______________________________
```

Example 3.

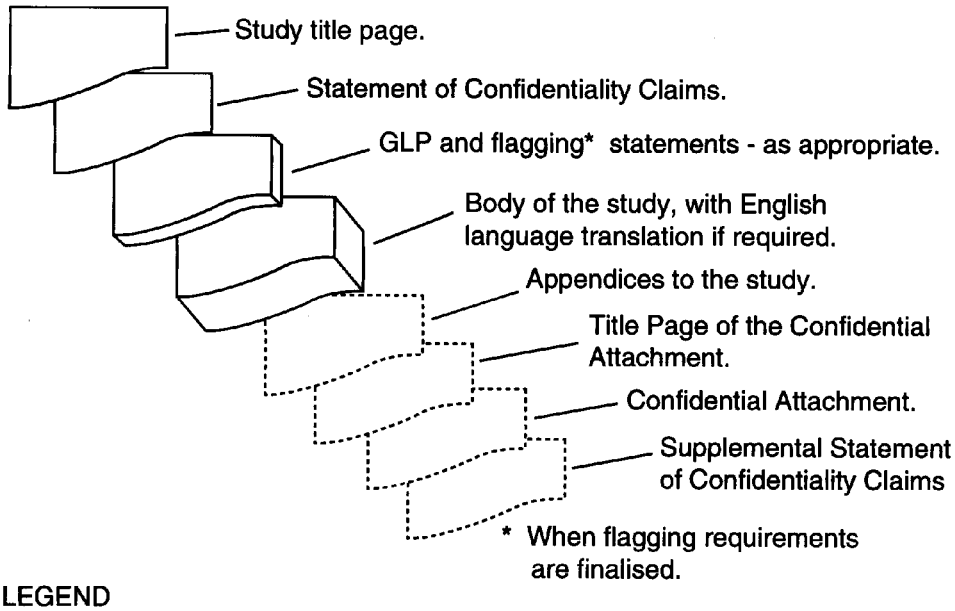
```
The submitter of this study was neither the sponsor of this study nor
conducted it, and does not know whether it has been conducted in
accordance with 40 CFR Part 160.

      Submitter_____________________________________________________
```

ATTACHMENT 7.

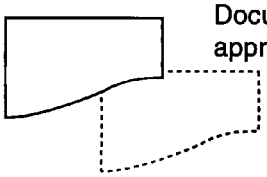
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



Documents which must be submitted as appropriate to meet established requirements.

Documents submitted at submitter's option.

PR Notice 91-2

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual

product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section l0(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE,"** all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be **set based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient StatementS must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 308-7031.

/s/
Anne E. Lindsay, Director
Registration Division (H-7505C)

APPENDIX F. Combined Generic and Product Specific Data Call-In

GENERIC AND PRODUCT SPECIFIC
DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 7; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Reqistrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-96).

This Notice is divided into six sections and seven Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I	-	Why You are Receiving this Notice
Section II	-	Data Required by this Notice
Section III	-	Compliance with Requirements of this Notice
Section IV	-	Consequences of Failure to Comply with this Notice
Section V	-	Registrants' Obligation to Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries and Responses to this Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet

2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredients.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (Telephone number: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific

Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice, which are contained in Section IV-C.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Reqistrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Reqistrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations

of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data Requirements

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Reqistrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on both the Generic and Product Specific Data Call-In Response Forms. If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

b. Satisfying the Product Specific Data Requirements of this Notice.

There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Reqistrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40

CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant normally will be subject to initiation of suspension proceedings, unless you commit to submit, and do submit, the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly Met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3 'Raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been

transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must certify at the time of submitting the existing study that such GLP information is available for post May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5. Upgrading a Study

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option also should be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally, your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria, as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core-minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option, you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time-frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data

jointly (Cost Sharing)

(3) I have made offers to cost-share (Offers to Cost Share)

(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)

(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)

(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the

pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   i. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Reqistrant's Response Form.

   ii. Fulfill the commitment to develop and submit the data as required by this Notice; or

   iii. Otherwise take appropriate steps to meet the requirements stated in this Notice,

   unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1) EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2) EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3) EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding generally would not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You also must explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due, unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3-year study is scheduled to be submitted, all progress

reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice must include completed Data Call-In Response Forms (Attachment 2)and completed Requirements Status and Registrant's Response Forms (Attachment 3), for both (generic and product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Louis P. True, Jr., Acting Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

Attachment 1. Chemical Status Sheets

Limonene DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing Limonene.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Limonene. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this Limonene Generic Data CallIn (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Limonene are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Limonene are needed. These data are needed to fully complete the reregistration of all eligible Limonene products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Emily H. Mitchell at (703) 308-8583.

All responses to this Notice for the generic data requirements should be submitted to:

Emily H. Mitchell, Chemical Review Manager
Planning and Reregistration
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Limonene

LIMONENE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing Limonene.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Limonene. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this Limonene Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Limonene are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Limonene are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible Limonene products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Limonene, please contact Emily H. Mitchell at (703) 308-8583.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Franklin Gee at (703) 308-8008. (703) 308-8583.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Emily H. Mitchell
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **Limonene**

Attachment 2. Combined Generic and Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions

Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of data call-in (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form**. **BOTH** "Data Call-In Response" forms must be completed.

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 1.**ON BOTH FORMS**: This item identifies your company name, number and address.

Item 2.**ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3.**ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4.**ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5.**ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a.**ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b.**ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a.**ON THE PRODUCT SPECIFIC DATA FORM:** For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b.For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

Item 8.**ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9.**ON BOTH FORMS:** Enter the date of signature.

Item 10.**ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11.**ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Attachment 3. Generic and Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions

Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of data call-in (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form**. **BOTH** "Data Call-In Response" forms must be completed.

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 1.**ON BOTH FORMS**: This item identifies your company name, number and address.

Item 2.**ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3.**ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4.**ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5.**ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a.**ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b.**ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a.**ON THE PRODUCT SPECIFIC DATA FORM:** For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b.For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

Item 8.**ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9.**ON BOTH FORMS:** Enter the date of signature.

Item 10.**ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11.**ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

EPA'S BATCHING OF PRODUCTS CONTAINING D-LIMONENE AS THE ACTIVE INGREDIENT FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient d-limonene (1-Methyl-4-(1-methylethenyl) cyclohexene) the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table 1 displays the batch for the active ingredient d-limonene.

Table 1.

Batch	Registration Number	% Active Ingredients	Form
1	4758-153	d-limonene … 0.920% linalool … 0.925% piperonyl butoxide … 0.500% propylene glycol … 10.000%	non-aerosol spray
	11715-243	d-limonene … 0.920% linalool … 0.925% piperonyl butoxide … 0.500% propylene glycol … 10.000%	non-aerosol spray

Table 2 lists those products the Agency was unable to batch. These products were either considered not to be similar to other products for purposes of acute toxicity or the Agency lacked sufficient information for decision making. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Table 2.

Unbatched Products		
Reg. No.	% Active Ingredient	Form
4758-141	d-limonene … 5.00	liquid
4758-142	d-limonene … 32.00	liquid
4758-143	d-limonene … 9.20 pyrethrins … 0.05 piperonyl butoxide … 0.25	liquid
4758-144	d-limonene … 78.20	liquid
4758-145	d-limonene … 5.00	liquid
Table 2 (continued)		
4758-146	d-limonene … 5.00	aerosol
4758-149	d-limonene … 92.00	liquid
45987-1	d-limonene … 4.015 dihydro-5-pentyl-2(3H) furanone … 0.024 dihydro-5-heptyl-2(3H) furanone … 0.049	granular
45987-2	d-limonene … 4.015 dihydro-5-pentyl-2(3H) furanone … 0.024 dihydro-5-heptyl-2(3H) furanone … 0.049	liquid
45987-5	d-limonene … 4.015 dihydro-5-pentyl-2(3H) furanone … 0.024 dihydro-5-heptyl-2(3H) furanone … 0.049	vinyl sheet
62012-1	d-limonene … 5.00	liquid

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Name of technical material tested (include product name and trade name, if appropriate).

2.____ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.

3.____ Name and upper certified limit for each impurity or each group of impurities present at $>$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at $<$ 0.1%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.
- ____ EPA Registration Number if registered;
  for other beginning materials, the following:
- ____ Name and address of manufacturer or supplier.
- ____ Brand name, trade name or commercial designation.
- ____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____Description of manufacturing process.
- ____ Statement of whether batch or continuous process.
- ____ Relative amounts of beginning materials and order in which they are added.
- ____ Description of equipment.
- ____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
- ____ Statement of whether process involves intended chemical reactions.
- ____ Flow chart with chemical equations for each intended chemical reaction.
- ____ Duration of each step of process.
- ____ Description of purification procedures.
- ____ Description of measures taken to assure quality of final product.

9.____ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1.____ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at > 0.1%.
2.____ Degree of accountability or closure > ca 98%.
3.____ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.].
4.____ Complete and detailed description of each step in analytical method used to analyze above samples.
5.____ Statement of precision and accuracy of analytical method used to analyze above samples.
6.____ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at > 0.1% and for certain toxicologically significant impurities at < 0.1% along with explanation of how limit determined.
9.____ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10.____ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color
____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State
____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25° C

63-4 Odor
____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point
____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point
____ Reported in °C
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity
____ Measured at about 20-25° C
____ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility
____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25° C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure
____ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant
____ Experimental method described
____ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient
____ Measured at about 20-25° C
____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
____ Data supporting reported value provided

63-12 pH
____ Measured at about 20-25° C
____ Measured following dilution or dispersion in distilled water

63-13 Stability
____ Sensitivity to metal ions and metal determined
____ Stability at normal and elevated temperatures
____ Sensitivity to sunlight determined

SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ At least 5 young adult rats/sex/group.
3.____ Dosing, single oral may be administered over 24 hrs.
4.*___ Vehicle control if other than water.
5.____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6.____ Individual observations at least once a day.
7.____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8.____ Individual daily observations.
9.____ Individual body weights.
10.____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc).
2._____ At least 5 animals/sex/group.
3.*____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4._____ Dosing, single dermal.
5._____ Dosing duration at least 24 hours.
6.*____ Vehicle control, only if toxicity of vehicle is unknown.
7._____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8._____ Application site clipped or shaved at least 24 hours before dosing.
9._____ Application site at least 10% of body surface area.
10._____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11._____ Individual observations at least once a day.
12._____ Observation period to last at least 14 days.
13._____ Individual body weights.
14._____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 µm or less).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22° C (±2°), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11.___ Individual observations at least once a day.
12.___ Observation period to last at least 14 days.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult rabbits.
4.____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.____ Solid or granular test material ground to a fine dust.
7.____ Eyes not washed for at least 24 hours.
8.____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.*___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult animals.
4.____ Dosing, single dermal.
5.____ Dosing duration 4 hours.
6.____ Application site shaved or clipped at least 24 hours prior to dosing.
7.____ Application site approximately 6 cm^2.
8.____ Application site covered with a gauze patch held in place with nonirritating tape.
9.____ Material removed, washed with water, without trauma to application site.
10.___ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.*__ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of <2 or >11.5.
3.___ One of the following methods is utilized:
_____ Freund's complete adjuvant test
_____ Guinea pig maximization test
_____ Split adjuvant technique
_____ Buehler test
_____ Open epicutaneous test
_____ Mauer optimization test
_____ Footpad technique in guinea pig.
4.___ Complete description of test.
5.*___ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an * are supplemental and may not be required for every study.

Attachment 6. List of All Registrants Sent This Data Call-In (insert) Notice

Attachment 7. Cost Share Data Compensation Forms, Confidential Statement of Formula Form and Instructions

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	b. Lower Limit	15. Purpose in Formulation

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

EPA	United States Environmental Protection Agency Washington, DC 20460 **CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA**	Form Approved OMB No. 2070-0106 2070-0057 Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)

   [ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form."

3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-90)

APPENDIX G. FACT SHEET

United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA-738-F-94-030
September 1994

R.E.D. FACTS

Limonene

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 3083, limonene.

Use Profile

Limonene is a naturally occurring chemical which is used in many food products, soaps and perfumes for its lemon-like flavor and odor. Limonene also is a registered active ingredient in 15 pesticide products used as insecticides, insect repellents, and dog and cat repellents.

Pesticide products containing limonene are used for flea and tick control on pets, as an insecticide spray, an outdoor dog and cat repellent, a fly repellent tablecloth, a mosquito larvicide, and an insect repellent for use on humans. Formulations include ready-to-use solutions, emulsifiable concentrates, granulars and impregnated material. Limonene is applied by hand as needed, both indoors and outdoors. Use practice limitations include a label prohibition against use on weanling kittens and a caution against use of undiluted product.

Regulatory History

Limonene was first registered as a insecticide in the U.S. in 1958. It was registered as an antimicrobial in 1971, and as a dog and cat repellent in 1983. In May 1988, EPA announced that limonene is considered an inert rather than an active ingredient when used in antimicrobial products (please see 40 CFR 153.139(a)). In April 1994, limonene was granted an exemption from the requirement of a tolerance (or maximum residue limit) when it is an inert ingredient used as a solvent or fragrance in pesticide formulations (please see 40 CFR 180.1001(c), (e)). The Food and Drug Administration (FDA) lists limonene as Generally Recognized as Safe (GRAS) as a food additive or flavoring and a fragrance additive (please see 21 CFR 182.60). Currently, 15 limonene pesticide products are registered.

Human Health Assessment

Limonene is among those pesticide active ingredients for which a reduced set of generic data requirements is appropriate for registration or reregistration. Limonene is naturally occurring, has been established as an inert, is exempt from the requirement of a tolerance, and is recognized as safe by FDA. Its effects are well known and documented in scientific literature; additional testing would not likely provide any new findings. Adequate information is available to characterize its risks to humans and animals.

Toxicity

Limonene is of relatively low acute toxicity taken orally. It is a dermal irritant when applied at high concentrations and may cause dermal sensitization. A 90-day dermal toxicity study using the formulated product is required as confirmatory data to support reregistration of the insect repellent that is to be applied directly to human skin.

A subchronic study by the National Toxicology Program (NTP) using rats and mice resulted in decreased body weights, kidney disease and mortality at the highest dose tested. A chronic toxicity study by NTP using rats resulted in decreased body weight, kidney disease and kidney tumors, which occurred due to a species-specific mechanism. Limonene is not considered a human carcinogen, a developmental toxicant or mutagenic.

Dietary Exposure

Limonene occurs naturally in citrus and other fruits, vegetables, meats and spices. It also is used in a variety of foods and beverages (as well as in soaps and perfumes) to add lemon-like flavor and aroma. FDA considers limonene Generally Recognized as Safe (GRAS) as a food additive or flavoring, and as a fragrance additive. EPA has granted limonene an exemption from the requirement of a tolerance when it is used as an inert ingredient in pesticide formulations, and when used as an insect repellent tablecloth.

As a pesticide active ingredient, limonene is not registered for food or feed crop uses and is not expected to result in dietary exposure.

Occupational and Residential Exposure

People and pets may be exposed to limonene during and after application in household settings. Human exposure may occur during application of pet flea products, animal repellent granules or insecticide sprays, or during use of insect repellent impregnated tablecloths. Toxicologic concerns for humans from these exposures include skin irritation and sensitization. Ocular irritation also may occur if limonene products accidentally enter the eye and are not washed away.

Limonene is used in several shampoo, dip and spray products applied dermally to domestic animals to control fleas and ticks. Adverse reactions have been reported in a small percentage of animals, especially cats, following exposure to limonene products. Kittens and young cats seem to be most sensitive. Product labels bear precautionary statements warning of the potential for dermal irritation, prohibiting use on weanling kittens, and cautioning against use of undiluted product on pets.

Human Risk Assessment

Dietary exposure to limonene is not a concern. Limonene occurs naturally in foods, is used as a flavoring agent, is generally recognized as safe by FDA, and has only one food-related pesticide use (as an insect repellent impregnating tablecloths) that EPA has exempted from tolerance requirements.

People may be exposed to limonene when applying flea and tick control shampoos, dips or sprays to their pets, when applying animal repellent granules or insecticide sprays, or when using impregnated tablecloths. Skin irritation and sensitization or eye irritation may occur from these uses. In addition, adverse reactions may occur in some pets, especially cats, treated with the flea and tick control products. Additional precautionary statements are required on limonene product labeling to reduce the potential for adverse effects among users and treated pets.

Environmental Assessment

Environmental Fate

Limonene is insoluble and is expected to be stable in water.

Ecological Effects

Technical limonene is practically nontoxic to birds on a subacute dietary basis, and is slightly toxic to freshwater fish and invertebrates on an acute basis. The formulated product is practically nontoxic to birds on an acute and subacute dietary basis. It is practically nontoxic to freshwater fish and slightly toxic to freshwater invertebrates on an acute basis. Based on acute toxicity data using rats, limonene is practically nontoxic to mammals.

Ecological Effects Risk Assessment

Potential risk to birds might occur from ingesting limonene granules spread on lawns, sidewalks or driveways, or from consuming insects contaminated with limonene. However, based on the lack of toxicity of limonene to birds, little risk is anticipated.

Similarly, mammals are not likely to ingest a sufficient quantity of limonene granules to be at risk, particularly since limonene is practically nontoxic to mammals.

The mosquito larvicide use of limonene produces an oily film that is expected to dissipate rapidly, posing no major ecological concern for freshwater invertebrates or other aquatic species. Minimal risks to aquatic species, including endangered aquatic species, are expected from runoff into pond water from applications of the granular product.

Additional Data Required

EPA is requiring a 90-day dermal toxicity study for the recently registered limonene personal insect repellent product, to confirm its regulatory assessments and conclusions. The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs) and revised labeling for reregistration.

Product Labeling Changes Required

All limonene end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

Environmental Hazard Statements

End-use products with the mosquito larvicide use must bear the following statement:

> "Do not contaminate water when disposing of equipment washwater or rinsate. Consult with your State Agency in charge of fish and game before applying to public waters to determine if a permit is needed."

End-use products without the mosquito larvicide use must bear the following statement:

> "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment washwater or rinsate."

Precautionary Statements

To reduce the risk of adverse effects which occasionally occur in pets exposed to limonene flea and tick control products, and to reduce risks of skin irritation/ sensitization to product users, the following strengthened statements are required on labels of products intended for use on domestic animals:

Add: "Applicators of flea and tick dip (concentrates), spray or shampoo products are to use protective gloves to reduce the risk of dermal irritation or dermal sensitization."

Add: "Flea dip concentrates may harm animals when used at greater strength than specified on the label."

Change the age for product use on kittens/puppies to several months or a year.

Change the statement, "Use with care on nursing animals," to "Do not use on nursing animals or any animal which is in poor health."

Provide a list of symptoms which may occur when animals are sensitive to the product, to the precautionary statement, "Individual animals may be more sensitive to the product."

Regulatory Conclusion

The use of currently registered pesticide products containing limonene in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

These limonene products will be reregistered once the required confirmatory data, product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for limonene during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Following the comment period, the limonene RED document will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the limonene RED, or reregistration of individual products containing limonene, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 6:00 pm Central Time, Monday through Friday.