United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA 738-R-96-009
June 1996

Reregistration Eligibility Decision (RED)

Furanone

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 Furanone which includes the active ingredients dihydro-5-pentyl-2(3H)-furanone and dihydro-5-heptyl-2(3H)-furanone. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative, Emily Mitchell at (703) 308-8583. Address any questions on required generic data to the Planning and Reregistration Division representative, Emily Mitchell at (703) 308-8583.

Sincerely yours,

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

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

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

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

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

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

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

Furanone

LIST C

CASE 3138

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

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FURANONE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

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William Gross	Biological Analysis Branch
Thomas C. Harris	Biological Analysis Branch

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John Redden	Risk Characterization and Analysis Branch
Linnea Hansen	Toxicology Branch I
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Emily Mitchell	Planning and Reregistration Branch
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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System

GLOSSARY OF TERMS AND ABBREVIATIONS

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

EXECUTIVE SUMMARY

This Reregistration Eligibility Decision Document (RED) addresses the reregistration eligibility of two active ingredients: dihydro-5-pentyl-2(3H)-furanone and dihydro-5-heptyl-2(3H)-furanone (also known as gamma-nonalactone and gamma-undecalactone, respectively). Both of these active ingredients are also referred to by the common name furanone. Products containing furanones are registered for use as insecticides, repellents, mammal repellents and mosquito larvicides.

The Agency first registered a product containing furanone in 1983 for use as a cat repellent. Later, the Agency registered six additional products as insect toxicants, including use as a mosquito larvicide, or repellents. At present, there are seven furanone products, which are all registered as mixtures with the active ingredient, limonene (Case 3083). The Agency issued a Reregistered Eligibility Decision (RED) on limonene in September 1994. One of the seven products also contains a third active ingredient, Aliphatic Petroleum Hydrocarbons.

The Agency has determined that all uses of furanone products, labeled and used as specified in the RED, will not pose unreasonable risks to humans or the environment and, therefore, are eligible for reregistration.

Acute toxicity tests to assess both human toxicity and toxicity to non-target organisms were conducted on a formulated product containing : .024% dihydro-5-pentyl-2(3H)-furanone, .049% dihydro-5-heptyl-2(3H)-furanone, and 4.015% limonene. No toxicity data are available on the technical.

Acute oral, dermal, and inhalation toxicity studies indicate low acute toxicity (Category IV). Likewise, eye and dermal irritation studies also classified the formulated product in Category IV. The product also is not a skin sensitizer. Data from the open literature on each of the two compounds considered, the furanones, indicate low toxicity.

Acute toxicity data indicate that the formulated product is practically non-toxic to birds (oral, subacute dietary), mammals, and freshwater fish. The product is slightly toxic to freshwater invertebrates.

The furanones, when used in mosquito larvicides, are applied directly to water (residential and large scale public health use.) The public health larvicidal use of furanones applied at 4.10 lbs/A to 6 inches of water results in exceedances of the level of concern for freshwater invertebrates. The LOC for endangered species is exceeded when the product is applied at 1.64 lbs/A in water 6 inches deep or less, or when it is applied at 4.10 lbs/A in water 1 foot deep or less. This assessment is based on testing done on a formulated product and tells little about the actual toxicity of the furanones as active ingredients. Chronic invertebrate toxicity data (life cycle test with a freshwater invertebrate) and basic environmental fate data

would improve the Agency's understanding and assessment of the potential risk posed by the use of the furanones in mosquito larvicides.

The annual volume of products containing furanones that are used as mosquito larvicides is low and the percentage of furanone in the products is also low. The low volume used and low percent of furanone support the conclusion that widespread adverse impacts are not likely to result from the mosquito larvicide use if continued at the amounts currently produced and used (volume and percent furanone in the product). The Agency, in this RED document, is imposing a production limit on furanone for use in mosquito larvicide of 150 gallons per year. Should the volume produced and used and/or the percent of furanone in the product significantly increase, the Agency may impose additional data requirements to understand and assess potential risks.

It should be recognized that the risk posed to aquatic invertebrates is common to most, if not all, products for this use. It is the nature of mosquito larvicides to be harmful to aquatic invertebrates because the target species is itself an aquatic invertebrate. The mosquito larvicide product containing furanones would cause less harm to aquatic ecosystems than many other products because its risk is limited to aquatic invertebrates, whereas others pose a risk to fish and birds as well.

Before reregistering the products containing furanone, 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.

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 furanone. The document consists of six sections. Section I is the introduction. Section II describes furanone, 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 furanone . Section V discusses the reregistration requirements for furanone . Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Furanone
- **Chemical Name:** Dihydro-5-pentyl-2(3H)-furanone
- **Alternate Name:** gamma-nonalactone
- **CAS Registry Number:** 104-61-0
- **OPP Chemical Code:** 122301
- **Empirical Formula:** $C_9H_{16}O_2$
- **Trade and Other Names:** Doo-Not
- **Basic Manufacturer:** Rod Products Company

- **Common Name:** Furanone
- **Chemical Name:** Dihydro-5-heptyl-2(3H)-furanone
- **Alternate Name:** gamma-undecalactone
- **CAS Registry Number:** 104-67-6
- **OPP Chemical Code:** 122302
- **Empirical Formula:** $C_{11}H_{20}O_2$
- **Trade and Other Names:** Doo-Not
- **Basic Manufacturer:** Rod Products Company

B. Use Profile

The following is information on the currently registered uses for furanone. A detailed table of eligible uses as well as the methods, application rates, and use restrictions is included in Appendix A.

For: **dihydro-5-pentyl-2(3H) furanone**
For: **dihydro-5-heptyl-2(3H) furanone**

Type of Pesticide: Insecticide/repellent, mammal repellent, mosquito larvicide

Currently registered products, containing these chemicals, have the following uses:

1) dog and cat repellent;
2) fly, cockroach and ant killer;
3) insect repellent;
4) insect repellent strip;
5) insect repellent tablecloth; and
6) mosquito larvicide (contains mineral oil).

Use Sites: Terrestrial Non-Food & Outdoor Residential

Target Pests: cats, dogs, house flies, cockroaches, ants, biting flies, mosquito adults and larvae

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

Percentage of the three AIs in all formulations

Active Ingredient	Weight Percentage in formulations
d-Limonene	4.015%
gamma-Undecalactone	0.049%
gamma-Nonalactone	0.024%

There are no formulations that contain the furanones alone.

Method and Rates of Application:

Equipment - Hand, pre-moistened applicator puffs, aerosol sprayers, non-aerosol hand pumped sprayers, hydraulic ground sprayers, aircraft, compressed air sprayers and knapsack.

Method and Rate - Furanone may be applied by the use of impregnated table cloths, premoistened applicator puffs, aersol sprayers, non-aerosol hand pumped sprayer, knapsack sprayers, and the granules may be applied by hand by sprinkling from the bag.

Some product labels do not provide adequate information to calculate rates; however, for those that can be calculated they are as follows:
granules are applied at rates of 0.002 lb ai/1000 square feet, and for the emulsifiable concentrate for mosquito larvae control, the rates range from 0.0393 to 0.0984 lb ai/acre.

Timing - Product labels do not give specific timing of application of this product. The language reads: "when needed."

Use Practice Limitations: Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles. Avoid application to man-made surfaces sensitive to mineral oils.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of **furanone**. 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.

Estimated Typical Annual Usage of Furanone (Dihydro-5-pentyl-2(3H)-furanone and 5-Heptyldihydro-2(3H)-furanone)

	Site Available (000)	Site Treated		Lbs a.i. Applied
		(000)	(%)	
Drainage systems	na	na	<1	na
Eating establ incl servg areas	na	na	<1	na
Flooded areas, intermittent	na	na	<1	na
Food marktg/storg/distr facils	na	na	<1	na
Food proc/hndl/stor plts/areas	na	na	<1	na
Garbage dumps/manure	na	na	<1	na
Households, indoor/outdoor	90,000H	<90H	<1	<10
Human body/hair/clothg/footwr	250,000P	<250P	<1	<10
Lakes/ponds/impounded water	na	na	<1	na
Ornam herbaceous plants/lawns	30,000A	<30A	<1	<10
Ornam ponds/fountains/aquaria	na	na	<1	na
Paved areas	na	na	<1	na
Recreation areas	na	na	<1	na
Refuse/solid waste containers	na	na	<1	na
Swamps/marshes/bogs/stdg water	na	na	<1	na
Wide area/gen indr/outdr trtmt	na	na	<1	na
TOTAL	na	na	na	<40

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na = not available or not applicable
H = households
P = persons
A = acres

Note - Some sites overlap.

Sources --
- Kline & Co., Consumer Markets for Pesticides & Fertilizers, 1990 Update.
- Kline & Co., Professional Markets for Pesticides & Fertilizers, Year 1: 1990 & 1992.
- Research Triangle Institute, National Home & Garden Pesticide Use Survey, 1992.

In the table, "site available" refers to the quantity of a site that potentially could be treated with pesticides: for example, all 90 million households (indoor, outdoor or both), the entire population of about 250 million people (with potential treatments to themselves and/or their clothing or footwear) and 30 million acres of lawns and herbaceous ornamentals. Usage data is sparce, but indicates that typically furanone is used on less than one percent of the total households, less than one percent of the total population and less than one percent of the total lawn and herbaceous ornamental acreage. Although data are lacking for other labeled sites, their treatments with furanone are also likely to be less than one percent per site. For example,

probably considerably less than one percent of available recreation areas, however measured, are treated with furanone.

D. Data Requirements

Data requested in the Phase IV Data Call-In Notice(s) for **furanone** (dihydro-5-pentyl-2(3H)-furanone and dihydro-5-heptyl-2(3H)-furanone) include studies on **product chemistry and environmental fate**. These data were required to support the uses listed in the Phase IV Data Call-In Notice(s), dated July 27, 1992. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

The Agency first registered a product containing furanone in 1983 for use as a dog and cat repellent. Later, the Agency registered six additional products as insect toxicants, including use as a mosquito larvicide, or repellents. At present, there are seven furanone products, which are all registered as mixtures with the active ingredient, limonene (Case 3083). The Agency issued a Reregistration Eligibility Decision (RED) on limonene in September 1994. One of the seven products also contains a third active ingredient, Aliphatic Petroleum Hydrocarbons.

The compounds dihydro-5-heptyl-2(3H)-furanone (also known as gamma-undecalactone) and dihydro-5-pentyl-2(3H)-furanone (also known as gamma-nonalactone) are compounds that appear on the 'GRAS' ("generally recognized as safe") list of the Expert Panel of the Flavoring Extract Manufacturers' Association of the United States (FEMA). These same compounds are not on the FDA 'GRAS' list, but are approved as food additives by the FDA.

III. SCIENCE ASSESSMENT

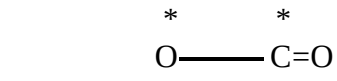
A. Physical Chemistry Assessment

The following physical/chemical property information was extracted from MRID No. 240229307 (Product Chemistry) and is supplied as background material, and from two monographs in Food and Cosmetics Toxicology (FD Cosmet Toxicol Vol. 12, 889 and 921 1975).

The data for the active ingredients were extracted from the Food Chemicals Codex as set forth on pages 456, 457, 844, 845, 553 and 554. The first active, dihydro-5-heptyl-2(3H)-furanone, is referred to as Undecanoic acid, 4-hydroxy, gamma-lactone by the registrant. The active ingredient product name is **gamma-Undecalactone**. The second active dihydro-5-pentyl-2(3H)-furanone (on submitted material this active ingredient is

referred to as: 2(3H)-furanone dihydro-5-pentyl; MW=156.25) is synonymous to **gamma-Nonalactone** (active ingredient product name).

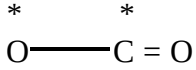
dihydro-5-heptyl-2(3H)-furanone Properties

- M.W. - 184.31
- Color - colorless to yellow
- Odor - strong fruity odor suggestive of peach
- Melting point - liquid, not applicable
- Solubility - 60% alcohol in water - 20% soluble
  70% alcohol in water - 33% soluble
  Insoluble in water
- Stability - stable under all normal conditions
- Octanol/water partition coefficient - not available
- Physical state - liquid
- Density - 0.942 - 0.945
- Vapor Pressure - not available
- pH - not available
- Structural Formula: 

Extracted from Food and Cosmetics Toxicology Volume 13, 921, 1975.

dihydro-5-pentyl-2(3H) furanone Properties

- M.W. - 156.25
- Color - colorless to yellow
- Odor - strong odor suggestive of coconut
- Melting point - liquid, not applicable
- Solubility - 50% alcohol in water - 20% soluble
  60% alcohol in water - 33% soluble
  Insoluble in water
- Stability - stable under all normal conditions
- Octanol/water partition coefficient - not available
- Physical state - liquid
- Density - 0.958 - 0.966
- Boiling point - 243°C
- Vapor Pressure - not available
- pH - not available
- Structural Formula: $CH_3(CH_2)_4\ CH\ CH_2CH_2$



Extracted from Food and Cosmetics Toxicology Volume 13, 889, 1975.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on furanones is adequate to support reregistration eligibility for dihydro-5-pentyl-2(3H)-furanone (PC CODE: 122301 synonymous to gamma-Nonalactone) and dihydro-5-heptyl-2(3H)-furanone (PC CODE: 122302 synonymous to gamma-Undecalactone).

a. Acute Toxicity

ACUTE TOXICITY DATA FOR FURANONES

ACUTE TOXICITY DATA

TEST	RESULTS	CATEGORY
Oral LD50--rat, Monogram Animal Repellent #100(Limonene) [1]	LD50 > 5 gm/kg	IV
Dermal LD50--rabbit, Monogram Animal Repellent #100(Limonene)[1]	LD50 of dry formulation > 5 gm/kg	IV
Inhalation LC50--rat, Monogram Animal Repellent #100(Limonene)[1]	LC50 > 5 mg/l, using particle size of 297 microns or less.	IV
Eye irritation--rabbit, Monogram Animal Repellent #100(Limonene)[1]	PIS - Washed = 0.0. PIS - Unwashed = 0.0	IV
Dermal irritation--rabbit, Monogram Animal Repellent #100(Limonene)[1]	PIS = 0.0 Primary Irritation Score	IV
Dermal sensitization--Guinea pig, Monogram Animal Repellent #100(Limonene)[1]	No sensitization using draize technique	----

1: At this time there are no products that contai n Furanones as the sole active ingredient. All formulations containing furanones also contain limonene.

It should be noted that only acute studies on formulations were conducted to support the reregistration of gamma-Undecalactone and gamma-Nonalactone. There are no toxicity data available on the technical. Toxicity data on the two compounds which comprise the furanones are available from the open literature and are discussed below:

The following was extracted from two monographs that appeared in Food and Cosmetics Toxicology (FD. Cosmet. Toxicol. Vol. 12, pp 889 and 921, 1975).

gamma Nonalactone:

"The acute oral LD_{50} in rats and guinea pigs was reported as 9.78 and 3.44 g/kg, respectively (Jenner, Hagan, Taylor, Cook & Fitzhugh, 1964). The acute oral LD_{50} in rats was reported as 6.6 g/kg (5.8-7.4 g/kg) (Moreno, 1972a). The acute dermal LD_{50} in rabbits exceeded 5 g/kg (Moreno, 1972b)."

Based on this information the toxicity category established in both rat studies, for nonalactone, would be IV for acute oral toxicity. The toxicity category based on the guinea pig acute oral LD_{50} study would be III for nonalactone.

"Nonalactone applied full strength to intact or abraded rabbit skin for 24 hr under occlusion was slightly irritating (Moreno, 1973b). Tested at 10% in petrolatum. It produced no irritation after a 48 hr closed-patch test on human subjects (Kligman, 1972). A maximization test (Kligman, 1966: Kligman & Epstein, 1975) was carried out on 25 volunteers. The material was tested at a concentration of 10% in petrolatum and produced no sensitization reactions (Kligman, 1972)."

gamma Undecalactone:

"The acute oral LD_{50} in rats was reported as 18.5 g/kg (Jenner, Hagan, Taylor, Cook & Fitzhugh. 1964). Fatty infiltration of liver parenchymal cells occurred in rats fed 13-115 mg gamma-undecalactone for 5-9 days (Shillinger, 1950)."

"Gamma-Undecalactone tested at 2% in petrolatum produced no irritation after a 48-hr closed-patch test on human subjects (Kligman, 1971). A maximization test (Kligman, 1966; Kligman & Epstein, 1975) was carried out on 25 volunteers. The material was tested at a concentration of 2% in petrolatum and produced no sensitization reactions (Kligman, 1971)."

The acute oral LD_{50} in rats for undecalactone would be classified as toxicity category IV. The studies on undecalactone are classified as **Supplementary** as they are from the open literature.

However, they offer valuable information for the evaluation of the toxicity of the furanones because these data indicate that the two compounds that make up the furanones are of low acute toxicity.

b. Subchronic Toxicity

In an open literature study (Fd Cosmet. Toxicol. Vol. 3, pp. 563-569. Pergamon Press 1965) gamma-Undecalactone and gamma-Nonalactone were two of 23 flavoring compounds that were examined in subchronic feeding studies.

Fifteen female FDRL and fifteen male FDRL rats were fed the following for 90 days: females were fed 14.6 mg/kg body weight/day gamma-undecalactone and 62.8 mg/kg body weight/day gamma-nonalactone; males were fed 16.5 and 72.5 mg/kg body weight/day gamma-undecalactone and gamma-nonalactone, respectively.

Body weight, food consumption, haematological and blood chemical determinations were made on 8 rats of each sex after 6 weeks of dosing, and in all rats at 12 weeks. The study was terminated after 90 days and the rats were necropsied. Liver and kidney weights were recorded for all rats. The following organs from half the animals in each group were taken for histological examinations: liver, kidneys, stomach, small and large intestines, spleen, pancreas, heart, lungs, bone marrow, muscle, brain, spinal cord, bladder, adrenals, thyroid, pituitary, gonads, salivary glands, and lymph nodes.

The study authors conclusions are presented below and the Agency agrees with their assessment:

> "No significant gross pathological change was observed at autopsy in any rats...Several of the animals in the groups receiving the lactones (L,M,N)....show various degrees of mild thyroid hyperplasia but this observation was also noted in the corresponding control groups and is not uncommon finding in these laboratories."
>
> "90-Day feeding studies in groups of rats receiving dietary doses of any of 23 different flavouring matters at levels corresponding to at least 100 times the maximum estimated human dietary levels, revealed no evidence of adverse toxic effects."

Since this is an open literature study it must be core graded **Supplementary**. However, it supplies useful information in evaluating the potential hazard of the furanones in that compounds making up the

furanones did not demonstrate a hazard following subchronic oral administration.

c. Chronic toxicity

The following was extracted from two monographs that appeared in Food and Cosmetics Toxicology (FD. Cosmet. Toxicol. Vol. 12, pp 889 and 921, 1975).

Nonalactone:

> "...In another study 0.1-0.5% fed to groups of 20 male and female rats in the diet for 2 yr produced no effects (Bar & Griepentrog. 1967)."

Undecalactone:

> "...Groups of 20 male and 20 female rats were fed diets containing 0.1 or 0.5% gamma-undecalacone for 2 yr without any specific adverse effects (Bar & Griepentrog. 1967)."

These studies are classified as **Supplementary** as they appear in the open literature. However, they offer valuable information for the determination of the toxicity of the furanones in that the compounds making up the furanones did not demonstrate a hazard following chronic oral exposure.

d. Carcinogenicity

No effects were observed in a 2 year rat study where rats were administered 0.10% to 0.5% furanones in their diet (Bar. F. U. Griepentrog. F. (1967)).

e. Other Toxic Endpoints

The Agency has determined that a 90-day dermal toxicity (safety) study would be required for a product that may result in prolonged human dermal exposure through repeated skin applications. The Agency has decided to waive the requirement for the 90-day dermal toxicity for the furanones based on the following : a combination of low exposure to furanones in the product; comparable concentrations of tanols in this product to those already used in cosmetic products (lotions, detergents,

perfumes); naturally occurring compound and absence of toxicity in the toxicology studies (notwithstanding limited data). Also, although not a FDA GRAS chemical, furanone is approved by FDA as a food additive and exposures to low concentrations are considered safe.

f. Reference Dose

There are no registered food uses for the furanones. The Agency's Peer Review Committee has not considered the furanones. The Joint FAO/WHO Expert Committee on Food Additives established an unconditional ADI of 0-1.25 mg/kg for undecalactone and nonalactone.

2. Exposure Assessment

a. Occupational and Residential

For the following reasons the Agency has no concerns for occupational or residential exposure to the furanones: 1) the acute battery for the furanones indicate toxicity category IV; and 2) the furanones are only in formulations containing limonene and the percentage in formulations is less than 1%.

However, there is a concern that repeated high dose dermal exposure to limonene may cause dermal sensitization based on a two week preliminary study for a rat 90 day dermal toxicity study. The data demonstrated that dermally applied technical limonene at 500, 1000, or 1500 mg/kg/day produced excessive dermal irritation after 1-3 days of dermal application. No overt treatment related systemic toxicity or clinical signs were observed.

Since these effects occur after repeated high dose administration of limonene, for purposes of reregistration, the following from the Limonene RED applies to the tanol derivatives:

> "The primary toxicological 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."

Thus, since the most noted dermal effect would be self limiting dermal irritation resulting from the limonene and not the furanones, the Agency does not anticipate occupational or residential risks of concern from exposure to the furanones.

3. Risk Assessment

a. Occupational and Residential

For the reasons discussed above, the Agency does not anticipate occupational or residential risks of concern from exposure to the furanones. However, as the furanones are only in formulations containing limonene, the following from the limonene RED applies to the furanones:

> "Human exposure may occur during 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. Toxicological 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 therefore self-limiting. Ocular irritation may also occur if products are accidently placed in the eye and not washed away."
>
> "Additional precautionary statements on label are required to reduce adverse effects."

C. Environmental Assessment

1. Ecological Toxicity Data

The term "furanones" will be used to refer to the two related chemicals covered by this RED: dihydro-5-pentyl-2(3H)-furanone and 5-heptyldihydro-2(3H)-furanone. All of the formulated products containing these furanones also contain a third active ingredient, limonene. All of the toxicity data for furanones are for one formulated product, Doo-Not Dog & Cat Repellent (Reg. No. 45987-1), containing the three active ingredients in the following concentrations:

PC Code	Name	% A.I.
122301	Dihydro-5-pentyl-2(3H)-furanone	0.024%
122302	5-heptyldihydro-2(3H)-furanone	0.049%
079701	Limonene	4.015%

The other registered formulations containing furanones contain the same set of active ingredients as Doo-Not in identical concentrations, although Rodspray Mosquito Larvicide (Reg. No. 45987-6) also contains 22.94% white mineral oil as a fourth active ingredient.

There are adequate data to assess the hazard of the formulated product Doo-Not, as well as other products that contain furanones in identical concentrations as Doo-Not and have low-volume minor uses. Only the six basic studies are required for these use patterns because they are expected to result in low exposure to the environment. The mosquito larvicide use is exceptional in that it may result in relatively large exposures to aquatic habitats. An additional chronic aquatic invertebrate study on the technical grade of the active ingredient is needed to clarify the Agency's understanding and assessment of the potential risk posed by the use of furanone as a mosquito larvicide.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

To establish the toxicity of furanones to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail). Data that have been submitted for these three tests have been with a formulated product, not the technical grade material. The following tables show the results of these tests.

Avian Acute Oral Toxicity Findings					
Species	**% A.I.** [a]	**LD_{50} mg/kg**	**MRID No. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Northern Bobwhite	4.015% 079701 0.024% 122301 0.049% 122302	> 2000	109340 Bottoms, J. (1982)	The formulated product is practically nontoxic	Yes, for the formulated product Doo-Not Dog Repellent

[a] Active ingredients are listed by their Shaughnessey numbers.

Avian Subacute Dietary Toxicity Findings					
Species	**% A.I.**[a]	**LC_{50} ppm**	**MRID No. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Northern Bobwhite	4.015% 079701 0.024% 122301 0.049% 122302	>5000	109342 Bottoms, J. (1982)	The formulated product is practically nontoxic	Yes, for the formulated product Doo-Not Dog Repellent
Mallard	4.015% 079701 0.024% 122301 0.049% 122302	>5000	109341 Bottoms, J. (1982)	The formulated product is practically nontoxic	Yes, for the formulated product Doo-Not Dog Repellent

[a] Active ingredients are listed by their Shaughnessey numbers.

These results indicate that the formulated product Doo-Not Dog Repellent is practically nontoxic to avian species on an acute oral and subacute dietary basis (MRID 109340-109341). However, since this product contains only a small percent of active ingredient, it cannot be inferred from these results that furanones are practically nontoxic. If the furanones caused all of the toxicity of the formulated product, an estimated acute oral LD_{50} of the furanones for avian species would be >1.46 mg ai/kg, and an estimated subacute dietary LC_{50} would be >3.65 ppm ai. These results tell little about the actual toxicity of the furanones as active ingredients. Furanones may fall into any of five toxicity classifications.

(2) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics.

The oral rat LD_{50} for Doo-Not Dog & Cat Repellent (Reg. No. 45987-1) is >5 g/kg (Accession No. 245190). This result indicates that this formulated product is practically nontoxic, but it tells little about the toxicity of furanones as active ingredients. If all of the toxicity of the formulated product was caused by the furanones, an estimated acute oral LD_{50} of the furanones for avian species would be >3.65 mg ai/kg. Furanones thus may fall into any of five toxicity classifications.

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

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 the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish). Data that have been submitted for these two tests have been with a formulated product, not the technical grade material. The following table shows the results of these tests.

Freshwater Fish Acute Toxicity Findings

Species	% A.I.[a]	LC_{50} ppm a.i.	MRID No.	Toxicity Category	Fulfills Guideline Requirement
Rainbow trout	4.015% 079701 0.024% 122301 0.049% 122302	569[b]	109343	The formulated product is practically nontoxic	Supplemental, for the formulated product Doo-Not Dog Repellent
Fathead minnow	4.015% 079701 0.024% 122301 0.049% 122302	1490[b]	109344	The formulated product is practically nontoxic	Supplemental, for the formulated product Doo-Not Dog Repellent

[a] Active ingredients are listed by their Shaughnessey numbers.
[b] Result is based on the moving average method.

The results of the 96-hour acute toxicity studies indicate that the formulated product is practically nontoxic to fish (MRID 109343-109344). However, since this product contains only a small percent of active ingredient, it cannot be concluded from these results that furanones are practically nontoxic to fish. Assuming that all of the toxicity of the formulated product was caused by the furanones, the estimated acute LC_{50} of the furanones is >0.42 ppm a.i. for the rainbow trout and >1.1 ppm a.i. for the fathead minnow. These results tell little about the toxicity of the furanones as active ingredients. Furanones could fall into any

toxicity classification except very highly toxic. (MRID No. 109343)

Because the tests were conducted with formulated product rather than technical grade active ingredients, they do not fulfill the guideline requirements for furanones. However, these data are considered adequate for assessing the risk of the use of the Doo-Not product. They may also be adequate for other low-use products that contain furanones in identical concentrations.

(2) Freshwater Invertebrates

The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. Data that have been submitted for a test with *Daphnia magna* have been with a formulated product, not the technical grade material. The table below gives the results of these tests.

Freshwater Invertebrate Toxicity Findings

Species	% A.I.[a]	EC_{50} (ppm)	MRID NO. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Daphnia magna	4.015% 079701 0.024% 122301 0.049% 122302	17[b]	109345 Bottoms, J. (1982)	The formulated product is slightly toxic	Supplemental, for formulated product Doo-Not Dog Repellent

[a] Active ingredients are listed by their Shaughnessey numbers.

[b] Result is based on the moving average method.

There is sufficient information to characterize the formulated product containing furanones as slightly toxic to aquatic invertebrates (MRID 109345). However, since this product contains only a small percent of active ingredient, it cannot be inferred from these results that furanones are slightly toxic to freshwater invertebrates. Assuming that all of the toxicity of the formulated product was caused by the furanones, the estimated acute LC_{50} of the furanones is >0.012 ppm a.i. for *Daphnia magna*. These results probably overestimate the toxicity of furanone because much of the toxicity of the formulated product could be the result of the other active ingredient, limonene, or of inert ingredients. These results tell little about the actual toxicity of the furanones as active ingredients. Furanones may fall into any of five toxicity classifications (MRID 109345).

Because the tests were conducted with formulated product rather than technical grade active ingredients, they do not fulfill the guideline requirements for furanones. However, these data are considered adequate for assessing the risk of the use of the Doo-Not product. They may also be adequate for other low-use products that contain furanones in identical concentrations.

A life-cycle test with a freshwater invertebrate (guideline 72-4b) is needed for the mosquito larvicide use of furanones because it involves direct application to water and because some of the acute risk quotients for freshwater invertebrates are greater than 0.01. This guideline requirement is not fulfilled.

2. Environmental Fate Assessment

Environmental fate data are not required to support low-volume outdoor residential uses for the furanones. Environmental fate data generally are required to support aquatic nonfood uses. To complete an ecological risk assessment for the mosquito larvicide use, the Agency needs the following data to assess the dissipation of the furanones in the environment:

161-1, Hydrolysis
161-2, Photodegradation in Water
162-3, Anaerobic Aquatic Metabolism
162-4, Aerobic Aquatic Metabolism
163-1, Leaching/Adsorption-Desorption
164-2, Aquatic Field Dissipation

A quantitative environmental fate assessment for the furanones cannot be made at this time because no environmental fate data have been submitted for review. However, the furanones are classified as lactones, and some open literature data are available on physiochemical properties of lactones and their possible effect on the environment.

Lactones are cyclic esters that can be synthesized by acidification of alpha-hydroxy acids. Detoxification mechanisms of lactones can be accomplished through base-catalyzed hydrolysis or microbial-mediated degradation of reactive groups. De-esterification may be catalyzed by metal ions, enzymes, and nucleophilic attack. The reported data indicate lactones may not be stable in alkaline environments.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC): The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine if an LOC has been exceeded, a risk quotient must be derived and compared to the LOCs. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration (EEC), by an appropriate toxicity test effect level, e.g. the LC_{50}. The acute effect levels typically are:

- EC_{25} (terrestrial plants),
- EC_{50} (aquatic plants and invertebrates),
- LC_{50} (fish and birds), and
- LD_{50} (birds and mammals)

The chronic test results are the:

-NOEL (or NOEC) for avian and mammal reproduction studies, and either the NOEL for chronic aquatic studies, or the Maximum Allowable Toxicant Concentration (MATC), which is the geometric mean of the NOEL and the LOEL (or LOEC) for chronic aquatic studies.

When the risk quotient exceeds the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented along with the corresponding LOCs.

Levels of Concern (LOC) and associated Risk Presumption

Mammals, Birds		
IF THE	LOC	PRESUMPTION
acute RQ>	0.5	High acute risk
acute RQ>	0.2	Risk that may be mitigated through restricted use
acute RQ>	0.1	Endangered species may be affected acutely
chronic RQ>	1	Chronic risk, endangered species may be affected chronically,
Fish, Aquatic invertebrates		
IF THE	LOC	PRESUMPTION
acute RQ>	0.5	High acute risk
acute RQ>	0.1	Risk that may be mitigated through restricted use
acute RQ>	0.05	Endangered species may be affected acutely

Mammals, Birds		
chronic RQ>	1	Chronic risk, endangered species may be affected chronically
Plants		
IF THE	LOC	PRESUMPTION
RQ>	1	High risk
RQ>	1	Endangered plants may be affected
Currently, no separate criteria for restricted use or chronic effects for plants exist.		

4. Exposure and Risk to Nontarget Terrestrial Animals

a. Birds

Birds may ingest granules of the product Doo-Not. They may also be exposed by other routes, such as dermal exposure when walking on top of granules. The number of lethal doses (LD_{50}s) that are available on one square foot immediately after application is normally used to assess the risk from such exposure. However, the available toxicity data are inadequate for this approach because definitive LD_{50} values are not available.

The only acceptable study on acute effects to birds used the formulated product Doo-Not. This study determined only that the LD_{50} is something greater than 2000 mg/kg. This information is inadequate to assess quantitatively the risk of Doo-Not to birds.

Although the risk of furanones to avian species cannot be quantified, several factors indicate that the risk is small. First, there was no mortality or signs of toxicity to birds that received the relatively high dose of 2000 mg/kg. Birds would need to consume more than 2000 mg/kg of this product before toxic effects may be expected. This is a relatively large quantity of granules for a bird to consume. Second, Doo-Not is labeled for use on lawns and ornamental turf around homes. It is likely to be applied only to small isolated areas. Any risk to birds that may result would be small in terms of area exposed and number of birds affected. Third, the formulation repels mammals and insects, and thus is probably somewhat repellent to birds as well. In conclusion, it is reasonable to assume that normal use of this product would not cause sufficient exposure to birds to result in any significant ecological damage.

Birds also could be exposed to furanones if they drink from bodies of water treated with Rodspray Mosquito Larvicide (Reg. No. 45987-6). The EECs in water immediately following application of the mosquito larvicide are not greater than 3.01 ppm (see section 3.a.2). In avian dietary toxicity tests with Doo-Not, a product that contains the same concentrations of furanones as the mosquito larvicide, the dietary LC_{50} for

both the bobwhite and mallard were greater than 5000 ppm. While there is uncertainty associated with comparing the toxicity of different formulated products and using a dietary toxicity test to assess the risk from drinking contaminated water, the huge difference (>1000 fold) between the EEC and the concentrations that may cause effects is large enough to safely presume minimal risk from this type of exposure.

Other products that contain furanones are expected to result in negligible exposure to birds. The Rodspray Fly, Cockroach, & Ant Killer (Reg. No. 45987-2) is sold in a pump-spray bottle and is designed for application to very small areas indoors and outdoor premises of domestic dwellings. Homeowners would not be likely to use this product on wildlife food. The other products are used as insect repellents and would not result in exposure to birds.

b. Mammals

Mammals may be exposed to furanones by consuming the granular product Doo-Not Dog & Cat Repellent (Reg. No. 45987-1) and by exposure to residues of the liquid product Rodspray Fly, Cockroach, & Ant Killer (Reg. No. 45987-2). An acute oral toxicity study with Doo-Not showed that no mortality occurred at doses as great as 5000 mg/kg. The fly, cockroach, & ant killer product has the same concentration of furanones as Doo-Not. Because of this apparent lack of toxicity of the formulated products containing furanone, and because these formulations repel mammals, it is anticipated that mammals will not be exposed to large enough quantities to cause any significant ecological damage. The EECs of the formulated product Rodspray mosquito larvicide are not expected to exceed 3.01 ppm. This concentration is too small to cause any appreciable risk to mammals that may drink treated water. The use pattern of other products should not lead to any appreciable exposure to mammals. Thus, the currently registered products containing furanones pose minimal risk to wild mammals.

c. Insects

None of the products containing furanones are used in a manner that is expected to cause any appreciable exposure to honey bees.

5. Exposure and Risk to Nontarget Aquatic Animals

With the exception of Rodspray Mosquito Larvicide (Reg. No. 45987-6), all registered products containing furanones should pose very little exposure to

aquatic organisms when used as directed. These products, which are for domestic use only, are used to repel dogs and cats, repel insects from human skin, and kill household insect pests. The dog and cat repellent use and insecticide use are for spot treatment of very small areas around homes, such as compost piles and garbage pails. Considering that the toxicities of these formulations are at most only slightly toxic to aquatic organisms, the risk they pose to aquatic organisms is minute. The potential of exposure to aquatic organisms is much greater with the mosquito larvacide use because it is applied directly to bodies of water. Furthermore, it is registered for public use as well as household use, and thus may be applied to much larger areas than the other products. The risk that the mosquito larvacide use poses to aquatic organisms is discussed in detail below.

Expected Aquatic Concentrations: The toxicity of furanones to aquatic organisms is not known. However, data on the formulated product Doo-Not (Reg. No. 45987-1) indicate that it is practically nontoxic to freshwater fish and slightly toxic to freshwater invertebrates. This formulated product contains the same concentration of furanones as the mosquito larvicide (0.024% dihydro-5-pentyl-2(3H)-furanone and 0.049% 5-heptyldihydro-2(3H)-furanone). Therefore, aquatic risk will be assessed by comparing the expected environmental exposure to the larvicide formulated product to the toxicity of the Doo-Not formulated product. This risk assessment approach is less than ideal because the larvicide contains an additional active ingredient, mineral oil, as well as different inert ingredients than Doo-Not.

The following table summarizes the EECs for the mosquito larvicide.

ESTIMATED ENVIRONMENTAL CONCENTRATIONS (EECs)					
Use Type	Application Method	Application Rate	Initial EEC (ppm)		
			6 inches	1 foot	6 feet
Mosquito Larvicide, Domestic Use	Pour-on	1.64 lb/A (2 gal/A)	1.200	0.603	0.100
Mosquito Larvicide, Public Health Use	Spray	4.10 lb/A (5 gal/A)	3.010	1.510	0.251

6. Freshwater Fish

The following table summarizes the risk quotients (EEC/LC_{50}) for freshwater fish.

Risk Quotients (RQ) for Freshwater Fish				
Crop/application rate	Species	Acute Risk Quotient		
		6 inches	1 foot	6 feet
Mosquito Larvicide, Domestic Use, 1.64 lb/A	Rainbow trout Fathead minnow	0.0021 0.00081	0.0011 0.00040	0.00018 0.000067
Mosquito Larvicide, Public Health Use, 4.10 lb/A	Rainbow trout Fathead minnow	0.0053 0.0020	0.0027 0.0010	0.00044 0.00017

None of the acute RQs listed above exceed any of the LOCs. Therefore, use of the mosquito larvicide containing furanones is presumed to pose low acute risk to freshwater fish and to cause no appreciable acute effects to endangered species.

As stated previously, use of the other formulated products containing furanones are expected to result in very little exposure to aquatic habitats, much less than the mosquito larvacide use described above. Since the mosquito larvacide is presumed to pose low acute risk to freshwater fish, the other uses are also presumed to pose low acute risk.

a. Freshwater Invertebrates

The following table summarizes the risk quotients (EEC/LC_{50}) for freshwater invertebrates.

Risk Quotients (RQ) for Freshwater Invertebrates

Crop/application rate	Species	Acute Risk Quotient		
		6 inches	1 foot	6 feet
Mosquito Larvicide, Domestic Use, 1.64 lb/A	*Daphnia magna*	0.071	0.035	0.0059
Mosquito Larvicide, Public Health Use, 4.10 lb/A	*Daphnia magna*	0.18	0.089	0.015

None of the acute RQ's listed above exceed the LOC for high acute risk. The acute level of concern for which restricted use may be appropriate (0.1) are not exceeded for either use of the larvicide when the depth of the water is 1 foot or greater. However, public health use of the larvicide at the rate of 4.10 lbs/A (5 gal/A) exceeds this LOC when applied to 6 inches of water.

The level of concern for endangered species is also exceeded when the product is applied at 1.64 lb/A (2 gal/A) in water 6 inches deep or less, or when it is applied at 4.10 lb/A (5 gal/A) in water 1 foot deep or less. These risk quotients are plausible, since mosquito larvicides are often applied to shallow, stagnant water.

The risk quotients also suggest that some risk could be posed to the aquatic stages of amphibians (e.g. tadpoles), although the extrapolation of risk from aquatic invertebrates to amphibian larvae is highly uncertain.

It should be recognized that the risk posed to aquatic invertebrates would be shared with most, if not all, products for this use. It is the nature of mosquito larvicides to be harmful to aquatic invertebrates because the target species is itself an aquatic invertebrate. The mosquito larvicide containing furanone would cause less harm to aquatic ecosystems than many other products because its risk is limited to aquatic invertebrates, whereas others pose a risk to fish and birds as well.

Persistence of furanones in water or repeated applications of the product could cause chronic exposure to furanones. A chronic freshwater invertebrate toxicity study is needed to complete the aquatic risk assessment.

As stated previously, use of the other formulated products containing furanones is expected to result in very little exposure to aquatic habitats, much less than the mosquito larvicide use described above. A high-risk scenario would be if 1% of the formulated product applied to a 1-acre lot runs off into a 1-acre pond. This scenario would result in aquatic exposures approximately 100 times smaller than those for the mosquito larvicide use. Since the mosquito larvicide generally is presumed to pose low acute risk (except for the extreme case of application to 6 inches of water), the other uses are also presumed to pose low acute risk.

b. Endangered Species

When the Endangered Species Protection Program becomes final, limitations in the use of furanones may be required to protect endangered and threatened species. These limitations have not been defined and may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service may be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants would be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

Use of the mosquito larvicide containing furanones (Reg. No. 45987-6) may have harmful effects on endangered species of aquatic invertebrates. The level of concern for endangered species are exceeded when the product is applied at 1.64 lb/A (2 gal/A) in water 6 inches deep or less, or when it is applied at 4.10 lb/A (5 gal/A) in water 1 foot deep or less. In general, mosquito larvicide of any kind should not be applied to stagnant or slow-flowing bodies of water that provide habitat for endangered aquatic invertebrates. The two primary types of habitats that are of concern are vernal pools in California and water that drains into caves. The California state-initiative plan will protect species in vernal pools. No federal protection is therefore required for these species as long as the state-initiative plan continues to be implemented. Use of this mosquito larvicide should be restricted around caves that harbor endemic populations of endangered crayfish, shrimp, or other aquatic invertebrates.

Other than the possible effect of the mosquito larvicide to endangered aquatic invertebrates, the use of products containing furanones should not cause effects to endangered species.

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 data required to support reregistration of products containing furanone as 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 furanone. Appendix B identifies the data requirements that the Agency reviewed as part of its determination of reregistration eligibility of furanone 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 furanone and to determine that furanone can be used without resulting in unreasonable adverse effects to humans and the environment provided the the production cap is not exceeded. The Agency therefore finds that all products containing furanone as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of furanone 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 furanone, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the furanone active ingredients, the Agency has sufficient information on the health effects of furanone and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that furanone products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore,

the Agency concludes that all uses of products containing furanone are eligible for reregistration.

2. Eligible and Ineligible Uses

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

C. Regulatory Position

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

1. Mosquito Larvicide Use-Production Limit

The furanones, when used as mosquito larvicides, are applied directly to water (residential and large scale public health use.) The public health larvicidal use of furanones applied at 4.10 lbs/A to 6 inches of water results in exceedances of the level of concern for freshwater invertebrates. The LOC for endangered species is exceeded when the product is applied at 1.64 lb/A in water 6 inches deep or less, or when it is applied at 4.10 lb/A in water 1 foot deep or less. This assessment is based on testing done on a formulated product and tells little about the actual toxicity of the furanones as active ingredients. Chronic invertebrate toxicity data (life cycle test with a freshwater invertebrate) and basic environmental fate data would improve the Agency's understanding and assessment of the potential risk posed by the use the of furanones in mosquito larvicides.

The volume of furanone products used annually as mosquito larvicides is low and the percentage of furanones in the product is also low. The low volume and low percent furanones support the conclusion that widespread adverse impacts are not likely to result from the mosquito larvicide use if continued at the amounts currently produced and used (volume and percent furanone in product). The Agency, in this RED document, is imposing a production limit on furanone for use in a mosquito larvicide of 150 gallons furanone per year. Should the volume produced and used and/or the percent of furanone in the product significantly increase, the Agency may impose additional data requirements to understand and assess potential risks.

It should be recognized that the risk posed to aquatic invertebrates is common to most, if not all, products for this use. It is the nature of mosquito larvicides to be harmful to aquatic invertebrates because the target species is itself an aquatic invertebrate. The mosquito larvicide product containing furanones would cause less harm to aquatic ecosystems than many other products because its

risk is limited to aquatic invertebrates, whereas others pose a risk to fish and birds as well.

2. Endangered Species Statement

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses.

In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of furanone for the above eligible uses has been reviewed and determined to be substantially complete.

Environmental fate and chronic invertebrate toxicity data are not available and are needed to complete the assessment of risks posed by the use of the furanones as mosquito larvicides. However, the Agency is not requiring these data as long as the product of furanone for this use does not exceed 150 gallons per year. Should the volume produced and used and/or the percent of active ingredient in the product significantly increase, the Agency may impose additional data requirements to understand and assess potential risks.

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 pesticide 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 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 support of such use(s)."

Effluent Discharge Labeling Statements

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

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

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA' s labeling regulations for worker protection statements (4 0 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person.

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

Effluent Discharge Labeling Statements

Refer to subsection A. above for labeling requirements for effluent discharge.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this 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 [add chemical names here] 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

Case 3138[Tanol derivs.] Chemical 122301[Dihydro-5-pentyl-2(3H)-furanone]

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 cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	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													
DRAINAGE SYSTEMS				Use Group: AQUATIC NON-FOOD INDUSTRIAL									
Water treatment (surface), When needed, By hand	EC*RTU	NA	3.936E-04 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		
Insecticidal strip, When needed, Not applicable	IMPR	NA			*	NS	NS	NS	NS	3	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		
Insecticidal strip, When needed, Not applicable	IMPR	NA		UC	*	NS	NS	NS	NS	3	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	.0024 lb 1K sq.ft		*	NS	NS	NS	NS	AN	NS		

APPENDIX A REPORT

Case 3138[Tanol derivs.] Chemical 122301[Dihydro-5-pentyl-2(3H)-furanone]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
HUMAN BODY/CLOTHING WHILE BEING WORN (INSECT CONTROL)				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	
ORNAMENTAL HERBACEOUS PLANTS				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL									
Sprinkle, When needed, Not on label	G	NA	.0024 lb 1K 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	.0024 lb 1K 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*RTU	NA	3.936E-04 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	.0024 lb 1K sq.ft		*	NS	NS		NS	NS	AN	NS	
SWAMPS/MARSHES/WETLANDS/STAGNANT WATER				Use Group: AQUATIC NON-FOOD OUTDOOR									
Water treatment (surface), When needed, By hand	EC*RTU	NA	3.936E-04 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	9.840E-04 lb A		*	NS	NS		NS	NS	14	NS	

APPENDIX A REPORT

Case 3138[Tanol derivs.] Chemical 122301[Dihydro-5-pentyl-2(3H)-furanone]

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LEGEND

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

HEADER ABBREVIATIONS

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

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

EC	: EMULSIFIABLE CONCENTRATE
G	: GRANULAR
IMPR	: IMPREGNATED MATERIAL
RTU	: LIQUID-READY TO USE
xx*RTU	: Form xx with LIQUID-READY TO USE

ABBREVIATIONS

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

APPLICATION RATE

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

APPENDIX A REPORT

Case 3138[Tanol derivs.] Chemical 122302[5-Heptyldihydro-2(3H)-furanone]

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)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations 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											
DRAINAGE SYSTEMS				Use Group: AQUATIC NON-FOOD INDUSTRIAL							
Water treatment (surface), When needed, By hand	EC*RTU	NA	8.036E-04 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
Insecticidal strip, When needed, Not applicable	IMPR	NA			*	NS	NS	NS	NS	3	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
Insecticidal strip, When needed, Not applicable	IMPR	NA		UC	*	NS	NS	NS	NS	3	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	.0049 lb 1K sq.ft		*	NS	NS	NS	NS	AN	NS

APPENDIX A REPORT

Case 3138[Tanol derivs.] Chemical 122302[5-Heptyldihydro-2(3H)-furanone]

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 Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
HUMAN BODY/CLOTHING WHILE BEING WORN (INSECT CONTROL)				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		
ORNAMENTAL HERBACEOUS PLANTS				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL									
Sprinkle, When needed, Not on label	G	NA	.0049 lb 1K 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	.0049 lb 1K 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*RTU	NA	8.036E-04 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	.0049 lb 1K sq.ft		*	NS	NS	NS	NS	AN	NS		
SWAMPS/MARSHES/WETLANDS/STAGNANT WATER				Use Group: AQUATIC NON-FOOD OUTDOOR									
Water treatment (surface), When needed, By hand	EC*RTU	NA	8.036E-04 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	.002009 lb A		*	NS	NS	NS	NS	14	NS		

APPENDIX A REPORT

Case 3138[Tanol derivs.] Chemical 122302[5-Heptyldihydro-2(3H)-furanone]
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LEGEND
444444

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

HEADER ABBREVIATIONS

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

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

EC	: EMULSIFIABLE CONCENTRATE
G	: GRANULAR
IMPR	: IMPREGNATED MATERIAL
RTU	: LIQUID-READY TO USE
xx*RTU	: Form xx with LIQUID-READY TO USE

ABBREVIATIONS

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

APPLICATION RATE

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

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Furanone covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Furanone 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 Furanone 122301

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ALL	00077001
61-2A	Start. Mat. & Mnfg. Process	ALL	00077001
61-2B	Formation of Impurities	ALL	00077001
62-1	Preliminary Analysis		
62-2	Certification of limits	ALL	00077001
62-3	Analytical Method	ALL	00077001
63-2	Color	ALL	00077001
63-3	Physical State	ALL	00077001
63-4	Odor	ALL	00077001
63-5	Melting Point	ALL	00077001
63-6	Boiling Point	ALL	00077001
63-7	Density	ALL	00077001
63-8	Solubility	ALL	00077001
63-9	Vapor Pressure	ALL	00077001
63-12	pH	ALL	00077001
63-13	Stability	ALL	00077001
63-14	Oxidizing/Reducing Action	ALL	00077001
63-15	Flammability	ALL	00077001
63-16	Explodability	ALL	00077001

Data Supporting Guideline Requirements for the Reregistration of Furanone 122301

REQUIREMENT		USE PATTERN	CITATION(S)
63-17	Storage stability	ALL	00077001
63-18	Viscosity	ALL	00077001
63-19	Miscibility	ALL	00077001
63-20	Corrosion characteristics	ALL	00077001
63-21	Dielectric breakdown volt	ALL	00077001
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	ALL	00109340
71-2A	Avian Dietary - Quail	ALL	00109342
72-1B	Fish Toxicity Bluegill - TEP	ALL	00109344
72-1C	Fish Toxicity Rainbow Trout	ALL	00077001, 00109343 & 00109344
72-1D	Fish Toxicity Rainbow Trout- TEP	ALL	00077001 & 00109343
72-2A	Invertebrate Toxicity	ALL	00077001 & 00109345
72-2B	Invertebrate Toxicity - TEP	ALL	00109345
72-4B	Life Cycle Invertebrate	EG	DATA GAP
81-1	Acute Oral Toxicity - Rat	ALL	00109339
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL	00109339
81-3	Acute Inhalation Toxicity - Rat	ALL	00109339
81-4	Primary Eye Irritation - Rabbit	ALL	00109339
81-5	Primary Dermal Irritation - Rabbit	ALL	00109339

Data Supporting Guideline Requirements for the Reregistration of Furanone 122301

REQUIREMENT		USE PATTERN	CITATION(S)
81-6	**Dermal Sensitization - Guinea Pig**	**ALL**	**00109339**
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**	**ALL**	**00077001**
161-1	**Hydrolysis**	**EG**	**DATA GAP**
161-2	**Photodegradation - Water**	**EG**	**DATA GAP**
161-4	**Photodegradation - Air**	**EG**	**Reserved**
162-3	**Anaerobic Aquatic Metabolism**	**EG**	**DATA GAP**
162-4	**Aerobic Aquatic Metabolism**	**EG**	**DATA GAP**
163-1	**Leaching/Adsorption/Desorption**	**EG**	**DATA GAP**
164-1	**Terrestrial Field Dissipation**	**EG**	**Reserved**
164-2	**Aquatic Field Dissipation**	**EG**	**DATA GAP**

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Furanone 122302

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-2A	Start. Mat. & Mnfg. Process	ALL	00077001
62-1	Preliminary Analysis	ALL	00077001
62-3	Analytical Method	ALL	00077001
63-2	Color	ALL	00077001
63-3	Physical State	ALL	00077001
63-6	Boiling Point	ALL	00077001
63-7	Density	ALL	00077001
63-8	Solubility	ALL	00077001
63-9	Vapor Pressure	ALL	00077001
63-10	Dissociation Constant	ALL	00077001
63-11	Octanol/Water Partition	ALL	00077001
63-12	pH	ALL	00077001
63-15	Flammability	ALL	00077001
63-17	Storage stability	ALL	00077001
63-18	Viscosity	ALL	00077001
63-19	Miscibility	ALL	00077001
63-20	Corrosion characteristics	ALL	00077001

Data Supporting Guideline Requirements for the Reregistration of Furanone 122302

REQUIREMENT		USE PATTERN	CITATION(S)
63-21	**Dielectric breakdown volt**	**ALL**	**00077001**
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	**ALL**	**00109340**
71-2A	**Avian Dietary - Quail**	**ALL**	**00077001**
71-2B	**Avian Dietary - Duck**	**ALL**	**00077001 & 00109341**
72-1A	**Fish Toxicity Bluegill**	**ALL**	**00077001 & 00109344**
72-1B	**Fish Toxicity Bluegill - TEP**	**ALL**	**00109344**
72-1C	**Fish Toxicity Rainbow Trout**	**ALL**	**00077001 & 00109343**
72-1D	**Fish Toxicity Rainbow Trout- TEP**	**ALL**	**00109343**
72-2A	**Invertebrate Toxicity**	**ALL**	**00109345**
72-2B	**Invertebrate Toxicity - TEP**	**ALL**	**00109345**
72-4B	**Life Cycle Invertebrate**	**EG**	**DATA GAP**
81-1	**Acute Oral Toxicity - Rat**	**ALL**	**00109339**
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	**ALL**	**00077001 & 00109339**
81-3	**Acute Inhalation Toxicity - Rat**	**ALL**	**00109339**
81-4	**Primary Eye Irritation - Rabbit**	**ALL**	**00109339**
81-5	**Primary Dermal Irritation - Rabbit**	**ALL**	**00109339**
81-6	**Dermal Sensitization - Guinea Pig**	**ALL**	**00077001 & 00109339**
160-5	**Chemical Identity**	**ALL**	**00077001**
161-1	**Hydrolysis**	**EG**	**DATA GAP**

Data Supporting Guideline Requirements for the Reregistration of Furanone 122302

REQUIREMENT		USE PATTERN	CITATION(S)
161-2	**Photodegradation - Water**	**EG**	**DATA GAP**
161-4	**Photodegradation - Air**	**EG**	**Reserved**
162-3	**Anaerobic Aquatic Metabolism**	**EG**	**DATA GAP**
162-4	**Aerobic Aquatic Metabolism**	**EG**	**DATA GAP**
163-1	**Leaching/Adsorption/Desorption**	**EG**	**DATA GAP**
164-1	**Terrestrial Field Dissipation**	**EG**	**Reserved**
164-2	**Aquatic Field Dissipation**	**EG**	**DATA GAP**

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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MRID	CITATION
00077001	Monogram Industries, Incorporated (19??) Product Chemistry. (Unpublished study received May 5, 1981 under 45987-1; CDL: 245189-A)
40543600	Rod Products Company (1988) Submission of Efficacy Data on Doo-Not (EPA Reg. No. 45987-1). Transmittal of 1 study.
40543601	Rod, R. (1987) Doo-Not Test Procedure TP-109B: Efficacy Tests with Cats. Unpublished study prepared by Connie's Kitty Castle. 13 p.
41864500	Rod Products Co. (1991) Submission of Products Chemistry Data to Support the Application for Amended Registration of RodSpray Fly , Cockroach, and Ant Killer Spray. Transmittal of 1 Study.
41864501	Rod, R. (1991) Subpart C-Product Chemistry Data. Unpublished study prepared by Rod Products Co. 58 p.
42380700	Rod Products Comp. (1992) Submission of Product Chemistry Data in Support of Registration for Fly, Cockroach, and Ant Killer. Transmittal of 1 study.
42380701	Rod, R. (1991) Subpart C--Product Chemistry Data Requirements: Unpublished study prepared by Rod Products Co. 58 p.
42678100	Rod Products Co. (1993) Submission of product chemistry, toxicity, and efficacy data to support Rodspray registration. Transmittal of 4 studies.
42678101	Rod, R. (1993) Subpart C: Product Chemistry: Rodspray Mosquito Larvicide. Unpublished study prepared by Rod Products Co. 15 p.
42678102	Rod, R. (1993) Subpart D: Data Requirements Tables-Rodspray Mosquito Larvicide. Unpublished study prepared by Rod Products Co. 10 p.
42678103	Rod, R. (1993) Efficacy Study: Rodspray Mosquito Larvicide. Unpublished study prepared by Rod Products Co. 23 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.

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MRID	CITATION
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.
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.
43355000	Rod Products Co. (1994) Submission of Product Chemistry Data in Support of Application for Registration of Rodspray IndoorOutdoor Crawling & Flying Insect Killer. Transmittal of 1 Study.
43355001	Rod, R. (1994) Product Chemistry Data Requirements (Rodspray Indoor-Outdoor Crawling & Flying Insect Killer). Unpublished study prepared by Rod Products Co. 68 p.
93207000	Rod Products Company (1990) Reregistration Phase 3 Response: Furanone, dihydro-5-pentyl(8CI,9CI).
93207001	Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00077001 and Related MRIDs 00077002, 00077003. (Product Identity: Doo-Not). 8 p.
93207002	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.
93207003	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.
93207004	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.

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93207005	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.
93207006	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.
93207007	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.
93207008	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. 9 p.
93207009	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. 9 p.
93207010	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. 9 p.
93207011	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. 9 p.
93207012	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. 10 p.
93207013	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. 9 p.
93207999	Rod Products Company (1990) Reregistration Phase 3 Response: Furanone, dihydro-5-pentyl(8CI,9CI). Correspondence and Supporting Material.

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93208000 Rod Products Company (1990) Reregistration Phase 3 Response: Furanone,5-heptyldihydro-.

93208001 Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00077001 and Related MRIDs 00077002, 00077003. (Product Identity: Doo-Not). 8 p.

93208002 Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00109340. Acute Avian Oral Toxicity: No-Go Dog Repellent: Quail: ABSL No. 18766. Prepared by Applied Biological Sciences Laboratory, Inc. 11 p.

93208003 Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00109342. Acute Avian Diet. Toxicity: No-Go Dog Repellent: Quail: ABSL No. 18866. Prepared by Applied Biological Sciences Laboratory, Inc. 12 p.

93208004 Rod, R. (1990) Rod Products Company Phase 3 Summary of MRID 00109341. Acute Avian Diet. Toxicity: No-Go Dog Repellent: Duck: ABSL No. 18866. Prepared by Applied Biological Sciences Laboratory, Inc. 12 p.

93208005 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.

93208006 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.

93208007 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.

93208008 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. 9 p.

93208009 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. 9 p.

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93208010	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. 9 p.
93208011	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. 9 p.
93208012	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. 10 p.
93208013	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. 9 p.
93208999	Rod Products Company (1990) Reregistration Phase 3 Response: Furanone,5-heptyldihydro-. Correspondence and Supporting Material.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachment 1 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(s). 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 4; or,

2. why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant'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, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 4).

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 five 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:

Attachment 1	-	Data Call-In Chemical Status Sheet
Attachment 2	-	Data Call-In Response Form
Attachment 3	-	Requirements Status And Registrant's Response Form
Attachment 4	-	List Of All Registrants Sent This Data Call-In Notice

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 ingredient(s).

SECTION II. DATA REQUIRED BY THIS NOTICE

A. DATA REQUIRED

The data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

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 (tel: 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 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 160.3(a)(6)].

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

A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice 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.

B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose 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 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.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Attachment 2) and the Requirements Status and Registrant's Response Form (Attachment 3). The Data Call-In Response Form must be submitted as part of every response to this Notice. 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 Registrant'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 identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient(s) 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 the Data Call-In Response Form. If you choose this option, this is the only form 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.

2. 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 Registrant's Response Form, 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 on the Requirements Status and Registrant's Response Form. 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 and Emergency Response Branch, Registration Division, (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, must bear an amended label.

3. 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(s) if the active ingredient(s) in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient(s). 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:

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

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

c. 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 product specific data.

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 the requirements or are no longer in compliance with this

Data Call-In Notice, the Agency will consider that both they and you are not in 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.

4. Satisfying the Data Requirements of this Notice - There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and option 6b and 7 on the Data Call-In Response Form. If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

5. Request for Data Waivers. Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 on 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.

C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), 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 --

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. A 90-day progress report must be submitted for all studies. 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 requirement(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 your 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. 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 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 burdens 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 will normally 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(7) " *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(7), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also 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 are usually 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 a 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 should also 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.

D. REQUESTS FOR DATA WAIVERS

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 inapplicable and do not apply to your product.

1. Low Volume/Minor Use Waiver -- Option 8 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 as low volume pesticides only those active ingredient(s) 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(s) 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(s) 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(s) 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:

a. Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), 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.

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

c. Total direct production cost of product(s) containing the active ingredient(s) 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.

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

e. 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.

f. 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.

g. For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient(s), direct production costs of product(s) containing the active ingredient(s) (following the parameters in item c above), indirect production costs of product(s)

containing the active ingredient(s) (following the parameters in item d above), and costs of data development pertaining to the active ingredient(s).

h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), 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(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

(1) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient(s) 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.

2. Request for Waiver of Data --Option 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 corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also 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 do not apply 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.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

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:

   a. 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 Registrant's Response Form; or,

b. fulfill the commitment to develop and submit the data as required by this Notice; or,

c. 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.

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.

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 Federal Insecticide, Fungicide, and Rodenticide 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 would generally 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 must also 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(s) for which the Agency has particular risk concerns will be determined on 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 listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Attachment 2) and a completed Requirements Status and Registrant's Response Form (Attachment 3) and any other documents required by this Notice, and should be submitted to the contact person identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form 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,

Lois Rossi, Division Director
Special Review
and Reregistration Division

Attachment 1. Chemical Status Sheets

FURANONE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Furanone. 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 Furanone Generic Data Call In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Furanone are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Furanone are needed. These data are needed to fully complete the reregistration of all eligible Furanone 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 Mitchell at (703) 308-8583.

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

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

SPECIFIC INSTRUCTIONS FOR THE GENERIC DATA CALL-IN RESPONSE FORM

This Form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1-4 will 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.

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 suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, 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

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the ease number, ease name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. 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. Cheek 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. You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily cancelled.

Item 6a. Check this item if this data call-in is for generic data as indicated in Item 3 and if 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. Check this Item if the data call-in is a generic data call-in 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.

Item 7a. Check this item if this call-in if a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is an end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 8. 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. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM

Generic Data

This form is designed to be used for registrants to respond to call-in- for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

Public reporting burden for this collection of information is estimated to average 30 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 suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, 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

Item 1. This item identifies your company name, number, and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be

submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:

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 crop
J.	Forestry
K.	Residential
L.	Indoor food
M.	Indoor non-food
N.	Indoor medical
O.	Indoor residential

Item 7. This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows.

EP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP _ *	Typical End-Use Product, Percent Active Ingredient Specified

TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI	Technical Grade Active Ingredient
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
MET	Metabolites
IMP	Impurities
DEGR	Degradates

*See: guideline comment

Item 8. This item identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date **of your** receipt of the Data Call-In Notice.

Item 9. Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

1. (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocol and progress reports required in item 5 above.

2. (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-ln Notice.

3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

5. (Upgrading a Study) I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

6. (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. I am providing the Agency's classification of the study.

7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Item 10. This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

Attachment 4. List of Registrant(s) sent this DCI (Insert)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific 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 6; or

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

3. Why you believe EPA should not require your submission of product specific 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, Data Call-In Response Form, as well as 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 03-31-96).

This Notice is divided into six sections and six 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 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional 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 Attachment 3, Requirements Status and Registrant's Response Form, within the time frames 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 (tel: 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 160.3(a)(6)].

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

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for 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

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 chose 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. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. 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 must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). 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 Registrant'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.

1. 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 the Data Call-In Response Form. If you choose this option, this is the only form 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.

2. 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 of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on 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.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 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 -- 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.

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. 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 -- 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. 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 -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. 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 your 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 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 burdens 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 will normally 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(j) " '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(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also 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 are usually 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 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 should also 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 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.

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, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

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 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.

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:

    a. 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 Registrant's Response Form;

    b. fulfill the commitment to develop and submit the data as required by this Notice; or

    c. 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 would generally 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 must also 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 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 (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for 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 Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms and the Confidential Statement of Formula Form

FURANONE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Furanone. 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 Furanone 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 Furanone are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Furanone 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 Furanone products.

INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

Emily 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: **Furanone**

INSTRUCTIONS FOR COMPLETING THE **DATA CALL-IN RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **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.

Item 7a. 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**." 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. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

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

This page is replaced with the Part A section from the PSDCI module.

INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the

agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "**Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed "**Certification With**

Respect To Data Compensation Requirements" form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this 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 P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

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

This page is replaced with part B page 1 from the PSDCI module.

This page is replaced with part B page 2 from the PSDCI module.

This page is replaced with part B page 3 from the PSDCI module.

This page is replaced with part B page 4 from the PSDCI module.

No tox batching for this case

Attachment 5. List of Registrant(s) sent this DCI (Insert)

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.

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	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. 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

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

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

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-233, 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 reregistratiion 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)(F) 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)(F) 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 section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

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

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Emily Mitchell at (703)-308-8583.

1. PR Notice 86-5.

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

3. A full copy of this RED document.

4. A copy of the fact sheet for Furanone.

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

1.Health and Environmental Effects Science Chapters.

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

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

1. The Label Review Manual.

2. EPA Acceptance Criteria