

US EPA ARCHIVE DOCUMENT



Reregistration Eligibility Decision (RED) Nuranone



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 nuranone which includes the active ingredient nuranone. 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 are due 90 days from the date of this letter. The second set of required responses are due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Biopesticides and Pollution Prevention Division representative Anne R. Leslie at (703) 308-8727. Address any questions on required generic data to the Biopesticides and Pollution Prevention Division representative, Anne R. Leslie.

Sincerely yours,

Janet Andersen, Director
Biopesticides and Pollution
Prevention Division

Enclosures

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

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

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

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

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

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

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified

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

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

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

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

By U.S. Mail:

Document Processing Desk (**RED-BPPD**)
Office of Pesticide Programs (7501W)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk (**RED-BPPD**)
Office of Pesticide Programs (7501W)
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

Nuranone

LIST D

CASE 4113

TABLE OF CONTENTS

NURANONE REREGISTRATION ELIGIBILITY DECISION TEAM	i
EXECUTIVE SUMMARY	iv
I. INTRODUCTION	1
II. CASE OVERVIEW	2
A. Chemical Overview	2
B. Use Profile	2
C. Estimated Usage of Pesticide	4
D. Regulatory History	4
III. SCIENCE ASSESSMENT	5
A. Physical and Chemical Properties Assessment	5
B. Human Risk Assessment	6
1. Toxicology Assessment	6
a. Acute Toxicity	6
b. Mutagenicity	7
2. Exposure Assessment	7
a. Dietary Exposure	7
b. Occupational and Residential Exposure	7
3. Risk Assessment	8
C. Environmental Risk Assessment	8
1. Ecological Toxicity Data	8
2. Environmental Fate Data	8
IV. RISK MANAGEMENT AND REREGISTRATION DECISION	9
A. Determination of Eligibility	9
1. Eligibility Decision	9
2. Eligible and Ineligible Uses	10
B. Regulatory Position	10
1. Tolerance Reassessment	10
2. Endangered Species Statement	10
3. Labeling Rationale	11
V. ACTIONS REQUIRED OF REGISTRANTS	12
A. Manufacturing-Use Products	12
1. Additional Generic Data Requirements	12
2. Labeling Requirements for Manufacturing-Use Products	13

B.	End-Use Products	13
1.	Additional Product-Specific Data Requirements	13
2.	Labeling Requirements for End-Use Products	13
3.	Existing Stocks	14
VI.	APPENDICES	16
APPENDIX A.	Table of Use Patterns Subject to Reregistration	17
APPENDIX B.	Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision	20
APPENDIX C.	Citations Considered to be Part of the Data Base Supporting the Reregistration of Nuranone	23
APPENDIX D.	List of Available Related Documents	27

NURANONE REREGISTRATION ELIGIBILITY DECISION TEAM

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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 ₁₀	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
NOEL	No Observed Effect Level

GLOSSARY OF TERMS AND ABBREVIATIONS

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
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 © 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

The U.S. Environmental Protection Agency (hereafter referred to as the "Agency" or "EPA") has completed its reregistration assessment of the available information on the pesticide active ingredient nuranone. Nuranone is the sex pheromone of the female Japanese beetle, *Popillia japonica* (Newman), and is used as a lure for male Japanese beetles in conjunction with a floral lure to attract female Japanese beetles.

The Agency considers that nuranone, when used around a crop is a non-food use because it is placed in traps rather than applied to the crop. The Agency has determined that the uses of nuranone in dispensers, as currently registered, will not cause unreasonable risk to humans or the environment, and these uses are eligible for reregistration. The Agency is requiring a new or revised Confidential Statement of Formula (CSF) and an amended label for each product, but additional generic or specific product chemistry studies are not required for the technical grade active ingredient (TGAI).

Data requested in the **September, 1993 Data Call-In for nuranone includes product chemistry, toxicology, and some ecological effects data.** The Agency has received data in all categories except for the ecological effects studies.

Prior to reregistration of the end-use products containing nuranone, the **specific data, revised Confidential Statements of Formula and revised labels are to be submitted within eight months of the issuance of this document. These data include product chemistry for each registration.** After review of these data and any revised labels and upon finding them acceptable in accordance with Section 3(c)(5) of Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Agency will reregister a product. **Those products which contain other active ingredients will be eligible for reregistration only if the other active ingredients are registered.**

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

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

- **Common Name:** nuranone
- **Chemical Name:** (R,Z)-5-(1-decenyl)dihydro-2(3H)-furanone
- **Chemical Family:** furanone
- **CAS Registry Number:** 64726-91-6
- **Case No.:** 4113
- **OPP Chemical Code:** 116501
- **Empirical Formula:** C₁₄H₂₄O₂
- **Trade and Other Names:** JAPONILURE, Furanone
- **Basic Manufacturer:** Nitto Denko, Osaka, Japan;
ACE, Allentown, PA

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. This information is current as of 6/16/95. A detailed table of these uses of nuranone is in Appendix A.

Type of Pesticide for Single Active Ingredient:

BIOCHEMICAL (PHEROMONE, ATTRACTANT)

Additional Type of Pesticide for Multiple Active Ingredient:

FLORAL LURE

Mode of Action:

Attracts adult beetles to a trap (a bag); these beetles can then be killed by physical or mechanical means. The traps are multiple active ingredient products that contain a floral lure in a separate dispenser.

Use sites:**TERRESTRIAL NON-FOOD CROP:**

Registrants need to specify type of orchards, fruit trees, vegetables and soils

- * AGRICULTURAL CROPS/SOILS
- * DECIDUOUS FRUIT TREES
- * GRAPES

TERRESTRIAL NON-FOOD + OUTDOOR RESIDENTIAL

- * ORNAMENTAL AND/OR SHADE TREES
- * ORNAMENTAL HERBACEOUS PLANTS
- * ORNAMENTAL NONFLOWERING PLANTS
- * ORNAMENTAL WOODY SHRUBS AND VINES

Target Pests for Single Active Ingredient:

Popillia japonica (Newman), Japanese beetle

Types/Formulations Registered:

END USE PRODUCT

IMPREGNATED MATERIAL 0.13 to 0.47% a.i. per dispenser

Types of Treatment: Attractant treatment (beetles are attracted into trap where they may die or be killed mechanically.)

Equipment: Package applicator (trap)

Timing: Summer (when foliage is present)

Use Limitations: None.

Methods and Maximum Rates of Application:

As an attractant, package traps are placed to allow a maximum application rate of 3.53×10^{-5} pounds active ingredient per acre or 2.204×10^{-7} pounds active ingredient per one foot interval. See Appendix A for other rates.

C. Estimated Usage of Pesticide

Nuranone is registered for grapes, all fruits and vegetables, and orchards, as well as ornamental trees, shrubs and herbaceous plants. Use of this product on agricultural or food crops is considered a non-food use because the product is placed in traps rather than applied to the crop. A review of in-house proprietary and non-proprietary usage data from 1990-1992 confirms that nuranone is not used directly on any of the food crop sites.

The Agency examined available data to support in-house estimates that the usage of nuranone is not likely to exceed 500 lbs. a.i. per year.

D. Regulatory History

Nuranone was registered in the United States in **1979** for use as an insect attractant for Japanese beetles.

There are currently five nuranone products with an active registration. All products contain in one dispenser, technical grade nuranone, (R,Z)-5-(1-Decenyl)dihydro-2-(3H)-furanone, and in a separate dispenser, a floral lure consisting of varying amounts of eugenol, geraniol, and 2-phenylethyl propionate.

Because nuranone is an insect pheromone, and is used in a trap, the Agency granted reduced data requirements appropriate for a biochemical pesticide, for the original registration. A Data Call-In was issued in **September, 1993** for **nuranone** requiring additional **product chemistry, toxicology, and ecological effects** data to assess the potential for toxicity as a result of exposure to this compound.

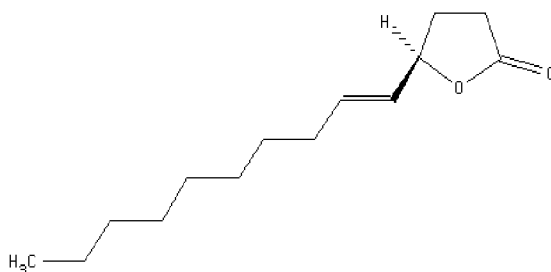
Data on product chemistry and toxicology were received. The Agency has since waived the requirement for the remaining generic studies.

This Reregistration Eligibility Decision reflects an assessment of all data and other available information before the Agency.

III. SCIENCE ASSESSMENT

A. Physical and Chemical Properties Assessment

Nuranone, R,A-5(1-decenyl)-dihydro-2(3H)-furanone is a pheromone, a sex attractant naturally produced by the female Japanese beetle to attract the male. The structural formula is:



Nuranone

Empirical Formula: $C_{14}H_{24}O_2$
Molecular Weight: 224
CAS Registry No.: 64726-91-6
Shaughnessy No.: 116501

Below are physical chemistry characteristics of technical nuranone:

<u>Guideline Reference Number</u>	<u>Characteristics</u>	<u>Results</u>	<u>MRID #</u>
151B-17(a)	Color	Clear (colorless)	425071-03
151B-17(b)	Physical State	Oily liquid	425071-03
151B-17 [©]	Odor	No characteristic odor; Slightly organic odor	425071-03
151B-17(d)	Melting Point	Not applicable	CA416144-01
151B-17(e)	Boiling Point	135-136 °C @0.25-0.30 mmHg; 110 °C @ 0.005 mmHg	425071-01-C 416144-03
151B-17(f)	Density	0.904 g/L 0.9387 g/L @ 25°C	416144-03 425010-02

<u>Guideline Reference Number</u>	<u>Characteristics</u>	<u>Results</u>	<u>MRID #</u>
151B-17(g)	Solubility	Insoluble in water; soluble in aliphatic and aromatic hydrocarbons. Solubility in water @ 25°C < 0.01 %	416144-03 425010-02
151B-17(h)	Vapor Pressure	Very low	416144-03
	Dissociation Constant	Not applicable	416144-03
151B-17(l)	pH	7.6	425010-02
151B-17(j)	Stability	Stable to heat and light	416144-03
151B-17(k)	Flammability	Flash Point > 200 °C	416144-03; Ca416144-01
151B-17(l)	Storage Stability	Stable to heat (at 50°C for 30 days); and light (48 hours in sun)	425010-02
151B-17(o)	Corrosion Characteristics	Not Corrosive	416144-03
151B-17(p)	Octanol/Water Partition Coefficient	1.00	416144-03

B. Human Risk Assessment

1. Toxicology Assessment

Adequate mammalian toxicology data on nuranone are available for uses of nuranone in a trap, and will support a Reregistration Eligibility Decision (RED).

a. Acute Toxicity

Certain acute mammalian toxicity studies are required under 40 CFR 158.690. The following table summarizes the data requirements and data received (studies were performed on the TGAI):

Guideline No.	Study	Result	Category	MRID #
152B-10	Acute oral toxicity (rat)	Data waiver request	(Waived)	N/A
152B-11	Acute dermal toxicity (rabbit)	Data waiver request	(Waived)	N/A
152B-12	Acute Inhalation (rat)	> 1.35 mg/L aerosol to rats	III	50879, 50880
152B-13	Primary eye irritation	Data waiver request	(Waived)	N/A
152B-14	Primary dermal irritation	Data waiver request	(Waived)	N/A
152B-15	Hypersensitivity incidents	Will report	To be reported	N/A

b. Mutagenicity

Guideline No. 152B-17, Mutagenicity (Ames Assay). A study, MRID # 50881 was submitted but not reviewed. The study reported negative results. The data requirement was waived.

c. Incident Data

No incidents have been reported since the initial registration in 1979.

2. Exposure Assessment

a. Dietary Exposure

Since there are no food uses of nuranone, dietary exposure is not expected.

b. Occupational and Residential Exposure

Human exposure is limited to the inhalation route since the product is only available in the controlled-release dispenser. Exposure will be limited if label instructions are followed. The release rate from the trap (0.0005 mg/hr/dispenser) is comparable to the release from the female Japanese beetle in the environment at peak pest infestations. Based on low exposure and lack of significant toxicological concerns by the inhalation

route, occupational exposure studies are not triggered. The studies submitted for inhalation toxicology on the technical grade active ingredient (MRID# 50879 and 50880) used a dosage that resulted in a rating of Toxicology Category III. Based on a release rate of 0.005mg/hr from the end-use product, the Agency has placed inhalation toxicity in Toxicology Category IV (>20 mg/L).

3. Risk Assessment

a. Dietary Risk

Nuranone has no food uses and therefore a dietary risk is not expected.

b. Additional Risk Characterization

The only route of exposure is inhalation, but risk characterization is inappropriate at this time because of the low exposure, the categorization of inhalation risk as Toxicology Category IV, and the lack of incident reports since 1979. Therefore no additional information and/or toxicology data are required. In the event that the technology for manufacturing and/or synthesizing the compound and/or the use pattern changes such as to increase the likelihood of exposure, the Agency may reevaluate the need for toxicology testing on the technical grade material.

C. Environmental Risk Assessment

1. Ecological Toxicity Data

Effects to nontarget organisms are not expected because of the specific mode of action of nuranone as a Japanese beetle pheromone. Because nuranone is enclosed in a plastic dispenser within the trap, no exposure to birds, fish, or aquatic organisms is expected. Pheromones in traps are exempted from FIFRA regulation under 40 CFR §152.25 (b), and therefore the data requirements for ecological toxicity testing have been waived.

2. Environmental Fate Data

Environmental fate Tier II studies for biochemicals are not imposed unless adverse effects are observed in Tier I Environmental Expression testing with fish and wildlife. The Agency will not impose any environmental fate requirements for reregistration of the current registered products containing nuranone in dispensers.

3. Environmental Risk Assessment

No more data are required because nuranone is specific only for Japanese beetles. It has a non-toxic mode of action, and with a lack of exposure to non-target organisms, no unreasonable adverse effects are expected.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing nuranone 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 nuranone. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of nuranone, 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 nuranone and to determine that nuranone can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing nuranone 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 nuranone 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 nuranone, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

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

unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing nuranone in traps, all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of nuranone in traps are eligible for reregistration.

B. Regulatory Position

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

1. Tolerance Reassessment

The Agency has determined that nuranone, as a pheromone in a trap, is a non-food use, and therefore is exempt from tolerance requirements.

2. Endangered Species Statement

The Agency has no concerns about the exposure of threatened and endangered species to nuranone because it is specific to Japanese beetles and enclosed in a trap.

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 modifications or a generic product label statement, requiring users to consult county-specific bulletins. These bulletins would provide information about specific use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses.

The Agency plans to publish a description of the Endangered Species Program in the Federal Register in the future. 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.

3. Labeling Rationale

a. 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 (40 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 these 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.

b. Precautionary Labeling

The Agency has reexamined the toxicological data base for nuranone and concluded that the current precautionary labeling (i.e. Signal Word, Statement of Practical Treatment, and other label statements associated with mitigating risks) adequately mitigate the risks associated with the use of this pheromone.

c. Application Rate

In order to remain in compliance with FIFRA, it is the Agency's position that the labeling of the currently registered pesticide product containing nuranone must comply with the Agency's current pesticide labeling requirements. The Agency has determined that labeling must be changed to give a specific maximum application rate and specific directions for replacement. Application directions such as:

"TRAP SHOULD BE SET OUT AT FIRST SIGHTING OF JAPANESE BEETLES. PLACE TRAPS DOWNWIND OF PLANTINGS. HANG TRAPS IN SUNNY AREAS WITH FINS 3-5 FEET ABOVE THE GROUND. PLACE TRAPS 20-30 FEET FROM PLANTINGS AS THEY WILL ATTRACT BEETLES TO THE FOLIAGE IF PLACED CLOSER. SET TRAPS 10 FEET APART FOR HEAVY INFESTATIONS, 30 FEET APART FOR LIGHT. WHEN BOTTOM IS FULL OF BEETLES, DISPOSE OF TRAP."

are considered too general. Because no upper limit is given, excessive application of the product may occur. A maximum application rate and frequency of replacing pheromone must be given.

The Agency has also determined that use sites must be described on the labeling in order to reflect the plant groups to be protected. Several labels have no use site specified, and these labels will be conditionally eligible. They will become eligible when revised labels specifying use site are approved by the Agency.

d. Spray Drift Advisory

This is not applicable to nuranone, because it is in dispensers and not applied directly to crops.

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 nuranone for the above eligible uses has been reviewed and determined to be substantially complete. Therefore, there are no further generic data requirements being imposed at this time.

2. Labeling Requirements for Manufacturing-Use Products

There are currently no manufacturing use products (MP) registered. However, in the event that a registrant wishes to register a MP in the future, to be in compliance with FIFRA, manufacturing use product labeling must 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 a pheromone dispenser for the following use: as an attractant in a trap."

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

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

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Agency is only requiring a new Confidential Statement of Formula (EPA Form 8570-4) and amended labeling as additional product specific data on the currently registered product. No other additional data are required at this time.

2. Labeling Requirements for End-Use Products

Worker Protection Standard

According to Pesticide Regulation (PR) Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)", WPS does not apply to

attractants used in insect traps. Therefore, nuranone is exempt from WPS labeling requirements.

Maximum Application Rate

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and described in the Pesticide Reregistration Handbook. As stated in Section IV, the Agency has determined that labeling must be changed to give a specific maximum application rate.

Storage and Disposal

In conformity with nuranone's non-food use, labels should read "Do not contaminate water, food, or feed by storage or disposal."

Other Labeling Requirements

Registrants must specify on labeling the complete directions for use for each use pattern: site of application, type of application, timing of application, equipment used for application, and the rate of application (dosage).

3. 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 nuranone 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

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. # Apps	Max. Dose [(AI unless noted otherwise)/A]	Min. Restr. Interv (days)	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION									
NON-FOOD/NON-FEED									
AGRICULTURAL CROPS/SOILS (UNSPECIFIED)									
Use Group: TERRESTRIAL NON-FOOD CROP									
Attractant treatment., Foliar., Not applicable.	IMPR	NA	2.205E-07 lb ft interval	* NS	NS	NS	NS	NS	NS
DECIDUOUS FRUIT TREES (UNSPECIFIED)									
Use Group: TERRESTRIAL NON-FOOD CROP									
Attractant treatment., Foliar., Package applicator.	IMPR	NA	1.764E-05 lb A	* NS	NS	NS	NS	84	NS
Attractant treatment., Summer., Package applicator.	IMPR	NA	3.527E-05 lb A	* NS	NS	NS	NS	84	NS
GRAPES									
Use Group: TERRESTRIAL NON-FOOD CROP									
Attractant treatment., Summer., Package applicator.	IMPR	NA	3.527E-05 lb A	* NS	NS	NS	NS	84	NS
ORCHARDS (UNSPECIFIED)									
Use Group: TERRESTRIAL NON-FOOD CROP									
Attractant treatment., Foliar., Not applicable.	IMPR	NA	2.205E-07 lb ft interval	* NS	NS	NS	NS	NS	NS
Attractant treatment., Foliar., Package applicator.	IMPR	NA	1.764E-05 lb A	* NS	NS	NS	NS	84	NS
Attractant treatment., Summer., Package applicator.	IMPR	NA	3.527E-05 lb A	* NS	NS	NS	NS	84	NS
ORNAMENTAL AND/OR SHADE TREES									
Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL									
Attractant treatment., Foliar., Not applicable.	IMPR	NA	2.205E-07 lb ft interval	* NS	NS	NS	NS	NS	NS
Attractant treatment., Foliar., Package applicator.	IMPR	NA	1.764E-05 lb A	* NS	NS	NS	NS	84	NS
Attractant treatment., Summer., Package applicator.	IMPR	NA	3.527E-05 lb A	* NS	NS	NS	NS	84	NS
ORNAMENTAL HERBACEOUS PLANTS									
Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL									
Attractant treatment., Foliar., Not applicable.	IMPR	NA	2.205E-07 lb ft interval	* NS	NS	NS	NS	NS	NS

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Rate (AI Tex. /crop /year cycle)	Max. # Apps @ Max. Rate /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

ORNAMENTAL HERBACEOUS PLANTS (con't) Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL (con't)

Attractant treatment., Foliar., Package applicator.	IMPR	NA	1.764E-05	lb A	* NS	NS	NS	NS	84	NS
Attractant treatment., Summer., Package applicator.	IMPR	NA	3.527E-05	lb A	* NS	NS	NS	NS	84	NS

ORNAMENTAL NONFLOWERING PLANTS Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL

Attractant treatment., Foliar., Package applicator.	IMPR	NA	1.764E-05	lb A	* NS	NS	NS	NS	84	NS
Attractant treatment., Summer., Package applicator.	IMPR	NA	3.527E-05	lb A	* NS	NS	NS	NS	84	NS

ORNAMENTAL WOODY SHRUBS AND VINES Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL

Attractant treatment., Foliar., Not applicable.	IMPR	NA	2.205E-07	UC lb ft interval	* NS	NS	NS	NS	NS	NS
Attractant treatment., Foliar., Package applicator.	IMPR	NA	1.764E-05	lb A	* NS	NS	NS	NS	84	NS
Attractant treatment., Summer., Package applicator.	IMPR	NA	3.527E-05	lb A	* NS	NS	NS	NS	84	NS

VEGETABLES (UNSPECIFIED) Use Group: TERRESTRIAL NON-FOOD CROP

Attractant treatment., Foliar., Not applicable.	IMPR	NA	2.205E-07	UC lb ft interval	* NS	NS	NS	NS	NS	NS
Attractant treatment., Foliar., Package applicator.	IMPR	NA	1.764E-05	lb A	* NS	NS	NS	NS	84	NS
Attractant treatment., Summer., Package applicator.	IMPR	NA	3.527E-05	lb A	* NS	NS	NS	NS	84	NS

USES CONDITIONALLY ELIGIBLE FOR REREGISTRATION

NOT SPECIFIED

SITE NOT SPECIFIED Use Group: USE GROUP FOR SITE 00000

Attractant treatment., Foliar., Not applicable.	IMPR	NA		UC	* NS	NS	NS	NS	NS	NS
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LEGEND

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless : Minimum dose for a single application to a single site. System calculated. Microbial claims only.
noted otherwise)
Max. Appl. Rate (AI unless : Maximum dose for a single application to a single site. System calculated.
noted otherwise)
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 : Maximum dose applied to a site over a single crop cycle or year. System calculated.
noted otherwise)/A]
Min. Interv (days) : Minimum Interval between Applications (days)
Restr. Entry Interv (days) : Restricted Entry Interval (days)
PRD Report Date : LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products
registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have
data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

IMPR : IMPREGNATED MATERIAL

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 nuranone covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to nuranone 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 Nuranone

REQUIREMENT		USE PATTERN	MRID #	CITATION(S)
PRODUCT CHEMISTRY				
151B-10	Product Identity	ALL	82161, 86978, 416144-01, CA416144-01, 425071-02C, 430693-01C	
151B-11	Manufacturing Process	ALL	50873, 71692, CA416144-01, CA425071-01,	
151B-12	Discussion of formation of unintentional ingredients	ALL	416144-01	
151B-13	Analysis of samples	ALL	50874, 86978, 416144-02-C, 425071-02C, 425010-01	
151B-15	Certification of limits	ALL	CA416144-01, 425010-01, 425071-02C, 430693-01C	
151B-16	Analytical Methods	ALL	416144-02C, 425010-01, 425010-02, 425071-02C, 430693-01C	
151B-17(a)	Color	ALL	CA416144-01, 416144-03, 425010-02, 425071-03, 430693-01	
151B-17(b)	Physical State	ALL	416144-03, 425010-02, 425071-03, 430693-01, 430693-01C	
151B-17 [©]	Odor	ALL	CA416144-01, 416144-03, 425010-02, 425071-03, 430693-01, 430693-01C	
151B-17(d)	Melting Point	ALL		N/A
151B-17(e)	Boiling Point	ALL	CA416144-01, 416144-03, 425071-01-C, 430693-01	

Data Supporting Guideline Requirements for the Reregistration of Nuranone

REQUIREMENT		USE PATTERN	MRID #	CITATION(S)
151B-17(f)	Density	ALL		416144-03, 425010-02, 425071-02, 430693-01C,
151B-17(g)	Solubility	ALL		416144-03, 425010-02, 430693-01, 430693-01C
151B-17(h)	Vapor Pressure	ALL		416144-03
151B-17(p)	Octanol/Water Partition	ALL		416144-03
151B-17(I)	pH	ALL		425010-02
151B-17(j)	Stability	ALL	CA416144-01, 416144-03,	425010-02
151B-17(k)	Flammability	ALL	CA416144-01, 416144-03,	430693-01, 430693-01C
151B-17(l)	Storage stability	ALL		416144-03, 425010-02
151B-17(m)	Viscosity	ALL		N/A
151B-17(n)	Miscibility	ALL		416144-03
151B-17(o)	Corrosion characteristics	ALL		416144-03
ECOLOGICAL EFFECTS				
154B-6	Avian Acute Oral-Quail	ALL		WAIVED
154B-8(a)	Fish Toxicity-rainbow trout	ALL		WAIVED
154B-9	Invertebrate Toxicity	ALL		WAIVED
TOXICOLOGY				
152B-10	Acute Oral Toxicity - Rat	ALL		WAIVED
152B-11	Acute Dermal Toxicity	ALL		WAIVED
152B-12	Acute Inhalation Toxicity - Rat	ALL		50879, 50880
152B-13	Primary Eye Irritation - Rabbit	ALL		WAIVED
152B-14	Primary Dermal Irritation - Rabbit	ALL		WAIVED
152B-16	Hypersensitivity	ALL	RESERVED (MUST BE REPORTED)	
152B-17	Gene Mutation (Ames Test)	ALL		WAIVED

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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CITATION

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| 00050879 | Kane, L.E.; Gallo, M.A.; Weinberg, M.S.; et al. (1979) Evaluation of 38-RD-114: Japanese Beetle Pheromone: Acute Inhalation Toxicity (Rat): Snell Project # 3095. (Unpublished study received Aug 14, 1980 under 562-21; prepared by Booz, Allen & Hamilton, Inc., submitted by J.T. Baker Chemical Co., Phillipsburg, N.J.; CDL:243068-G) |
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- 43069301 Metzger, W. (1993) Nuranone: Product Identity and Certification of Limits. Unpublished study prepared by United Industries, Inc. 26 p.

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

1. Health and Environmental Effects Science Chapters
2. Detailed Label Usage Information System (LUIS) Report
3. Nuranone RED Fact Sheet
4. PR Notice 86-5 (included in this appendix)
5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement