United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-99-003
March 1999

EPA

Reregistration Eligibility Decision (RED)

Virelure ((Z)-11-hexadecenal)

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7501W) | EPA-738-F-99-033 March 1999

EPA **R.E.D. FACTS**

Virelure

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

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

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 4118, virelure.

Use Profile

Virelure is an insect pheromone that attracts male artichoke plume moths. They are either attracted to a trap, where they become entrapped and die, or the release of the pheromone from a dispenser disrupts their mating activity. The mode of action is non-toxic.

A manufacturing-use product and two end-use products are presently registered for virelure. End-use products are twist-ties that are distributed throughout the affected area.

Because of its containment, virelure's use sites are considered terrestrial non-food. The artichoke plume moth is only a pest of artichokes; therefore, virelure would be used in areas where artichokes are grown.

Regulatory History

Virelure was first registered as a pesticide in the U.S. in 1981. In 1989, there were three registered end-use products and two registered manufacturing-use products. As of 1996, one manufacturing-use product and two end-use products were registered; all other products were canceled for non-payment of maintenance fees. Data on product chemistry were received in response to a Data Call-In in 1993.

Human Health Assessment

Toxicity

Adequate mammalian toxicology data on virelure are available for its use in a solid-matrix dispenser and will support a Reregistration Eligibility Decision (RED). Oral and inhalation toxicology indicate that virelure is practically nontoxic by these routes. Studies submitted for eye and dermal irritation resulted in a classification of Toxicology Category III.

Dietary Exposure

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

Human Risk Assessment

Based on the use pattern, the potential for dermal and eye exposures to pesticide handlers exists but is expected to be negligible. Residential exposure is not expected based on the use pattern.

Environmental Assessment

Adequate data are available to satisfy adverse risk concerns to nontarget organisms. Virelure is practically nontoxic to terrestrial animals. Virelure is highly toxic to freshwater invertebrates and creates an oily surface film on water that may adversely affect organisms that utilize the water surface. Based on its uses, studies for non-target plants are not required.

Based on the use pattern, the potential for exposure to non-target organisms is not expected.

Additional Data Required

The generic database supporting the reregistration of virelure 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.

Product Labeling Changes Required

The labels of all registered pesticide products containing virelure must comply with EPA's current pesticide product labeling requirements. In addition:

NPDES Statement - Manufacturing-use product labels must contain the following NPDES statement: "Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority.

For guidance contact your State Water Board or Regional Office of the EPA."

Precautionary Statement - The following statement should appear under the "Precautionary Statement" heading on the label: "Causes slight eye and dermal irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling."

Environmental Hazard - The following statement should appear under the "Environmental Hazards" heading on the label: "This product is highly toxic to aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters."

Non-Food Use - In conformity with virelure's non-food use, labels should contain the statement: "Do not contaminate water, food or feed by storage or disposal."

Regulatory Conclusion

Based on the review of the generic data for the active ingredients virelure, the Agency has sufficient information on the health effects of virelure and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that virelure products, labeled and used as specified in the Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that, for products containing virelure in twist-tie dispensers, all uses are eligible for reregistration.

For More Information

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

Electronic copies of the RED and this fact sheet 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*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

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

For more information about EPA's pesticide reregistration program, the virelure RED, or reregistration of individual products containing virelure, please contact Robyn Rose (703) 308-9581 or the Biopesticides and Pollution Prevention Division (7511WC), OPP, US EPA, Washington, DC 20460, telephone

703-308-8712.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact Robyn Rose (703) 308-9581 or the Biopesticides and Pollution Prevention Division (7511C), OPP, US EPA, Washington, DC 20460, telephone (703) 308-8712.

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 revised reregistration eligibility review and decisions on the pesticide chemical case virelure which includes the active ingredient (Z)-11-hexadecenal. 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.

Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 3, 1996, amending portions of both pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should be noted that in continuing to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. Rather, these early determinations will be made on a case-by case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

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 Robyn Rose(703) 308-9581.

Sincerely yours,

Janet L. Andersen, Ph.D, Director
Biopesticides and Pollution Prevention Division

Enclosures

REREGISTRATION ELIGIBILITY DECISION DOCUMENT

Virelure

LIST D

CASE 4118

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

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Virelure Reregistration Eligibility Decision Document
(Case 4118
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GLOSSARY OF TERMS AND ABBREVIATIONS

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

MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
ug/L	Micrograms per liter
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 an assessment of the potential human health risk and environmental risks associated with the pesticidal use of the lepidopteran pheromone, (Z)-11-hexadecenal or virelure.

Virelure is a naturally occurring lepidopteran pheromone with a non-toxic mode of action. Virelure is used in agriculture as a sex attractant, disrupting the mating activity of the male artichoke plume moth. Because virelure is a naturally occurring lepidopteran pheromone with a non-toxic mode of action, it is classified as a biopesticide (biochemical).

The Agency has determined that the use of virelure, as currently registered (a pheromone attractant and mating disruptor) for use in artichoke fields, will not cause unreasonable risk to humans or the environment when used in accordance with label directions. An exemption from the requirements of tolerance has been established at 40CFR 180.1153 for lepidopteran pheromones that are naturally occurring compounds, or identical or substantially similar synthetic compounds, designated by an unbranched aliphatic chain (between 9 and 18 carbons) ending in an alcohol, aldehyde or acetate functional group and containing up to 3 double bonds in the aliphatic backbone. This exemption pertains to only those situations when the pheromone is applied to growing crops at a rate not to exceed 150 grams active ingredient/acre/year in accordance with good agricultural practices.

Although human health and ecological risk assessments indicated that virelure is generally non-toxic and exposures are unlikely, the Agency, after a comprehensive reassessment of the toxicology data base, has concluded that a potential for eye and dermal irritation does exist, and thus, will be requiring additional precautionary labeling addressing this issue. The Agency also notes that in laboratory testing situations, virelure may create an oily film on water that could adversely affect certain aquatic invertebrates; therefore, EPA will require special precautionary labeling statements warning against contamination of water bodies.

Before reregistering the products containing virelure, the Agency is requiring that a revised Confidential Statement of Formula (CSF) and revised product labeling be submitted within eight months of issuance of this document. After reviewing this information and finding it acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister these products. Those products containing virelure in combination with 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.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the FIFRA, 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amended the FFDCA by establishing a new safety standard for the establishment of tolerances. The FQPA did not, however, amend any of the existing reregistration deadlines in section 4 of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of virelure. The document consists of six sections. Section I is the introduction. Section II describes virelure, 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 virelure . Section V discusses the reregistration requirements for virelure. 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:** Virelure
- **Chemical Name:** (Z)-11-hexadecenal
- **Chemical Class:** Lepidopteran pheromone
- **CAS Registry Number:** 53939-28-9
- **OPP Chemical Code:** 120001
- **Case Number:** 4118
- **Empirical Formula:** $C_{16}H_{30}O$
- **Trade and Other Names:**
  1. AgriSense Technical Pheromone Z-11®
  2. APM-ROPE™
- **Basic Manufacturer:**
  1. Thermo Triology Corporation
     9145 Guilford Rd., Suite 175
     Columbia, MD 21046
  2. Mitsubishi International Corporation
     520 Madison Ave
     New York, NY 10022

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A summary of the currently-registered use of virelure is contained in Appendix A.

Type of Pesticide for Single Active Ingredient:

Biochemical (pheromone, attractant)

Mode of Action:

Virelure is an insect pheromone that attracts male adult artichoke plume moths. They are either attracted to a trap, where they become entrapped and die, or the release of the pheromone from a dispenser disrupts their mating activity. The mode of action is non-toxic.

Use Sites:

Terrestrial non-food crops: artichokes

Target Pest:

Platyptilia carduidactyla, artichoke plume moth

Formulation Types Registered:

In addition to the manufacturing-use product, one end-use product containing virelure is registered. The currently registered end-use product is applied via a dispenser twist-tied to the inside of an artichoke stalk.

Method and Maximum Rates of Application:

The end-use dispenser products are applied at rates of 400 APM-ROPE dispensers per acre. Pheromones are generally applied at rates below 150 grams per acre per year.

Equipment:

Individual dispensers (traps or twist-ties)

Timing:

Apply after planting; either immediately before moths emerge or after an insecticide treatment to eradicate existing moth infestations.

Use Practice Limitations:

Do not apply directly to water or wetlands

C. Estimated Usage of Pesticide

The usage would not likely exceed 500 lbs. a.i. per year.

D. Regulatory History

Virelure was first registered in the United States in 1981. In 1989, there were three registered end-use products and two registered manufacturing-use products. All of these end-use products contained (Z)-11-hexadecenal, and one also contained (Z)-9-tetradecenal. Both pheromones were previously included in this reregistration case. In 1991, all of the end-use products and one of the manufacturing-use products were canceled for non-payment of maintenance fees. April 10, 1997, BIOSYS Corporation (company number 67250) transferred the registration of virelure to Thermo Triology (company number 70051). As of the publication of this document two products were registered: one manufacturing-use product containing (Z)-11-hexadecenal (AgriSense® Technical Pheromone Z-11; EPA Registration Number 70051-32; Registered September 23,1985), and one end-use product (APM-ROPE™; EPA Registration Number 50675-8; Registered February 8, 1996). No registrations remain for (Z)-9-tetradecenal; thus, only (Z)-11-hexadecenal is covered in this document.

In 1993, a Data Call-In was issued for virelure. Data on product chemistry were received in response to the Data Call-In. The Agency has subsequently reduced data requirements for pheromones such as virelure, and the remaining guideline studies have been satisfied.

A number of actions have been taken by the Agency to provide regulatory relief for pheromones. In February of 1993, the Agency published in the Federal Register, a final rule exempting inert materials in polymeric matrix dispensers from the requirement of a tolerance (58 FR 64493, Inert ingredients of semiochemical dispensers; tolerance exemption). An exemption from the requirement of a tolerance for inert ingredients of semiochemical dispensers was subsequently published in 40 CFR 180.1122)

In March of 1994, the Agency published in the Federal Register, a final rule exempting from the requirement of a tolerance, residues of arthropod pheromones resulting from the use of these substances in retrievably-sized polymeric matrix dispensers with an annual application limitation of 150 grams active ingredient per acre for pest control in or on all raw agricultural commodities (59 FR 14757, Arthropod Pheromones Tolerance Exemption). An exemption from the requirement of a tolerance for arthropod pheromones was subsequently published in 40 CFR 180.1124).

On August 18, 1995, a notice was published by the Agency in the Federal Register regarding an exemption from the requirement for a food tolerance for certain lepidopteran pheromones when used at 150 grams active ingredient per annum (60 FR 45060). An exemption from the requirement of a tolerance for Lepidopteran pheromones was subsequently published in 40CFR 180.1153.

The Agency also published, on February 21, 1996, in the Federal Register an

exemption from the requirement for a food tolerance for inert materials of polymeric dispensers for pheromones (61 FR 6550). An exemption from the requirement of a tolerance for acrylate polymers and copolymers was subsequently published in 40 CFR 180.1162

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. EPA is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in depth analysis of the new safety standard and how it should be applied to both food and non-food pesticide applications. However, in light of the unaffected statutory deadlines with respect to reregistration, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

This Reregistration Eligibility Decision Document reflects a comprehensive assessment of all data and other available information presently before the Agency.

III. SCIENCE ASSESSMENT

E. Physical Chemistry Assessment

1. Product Identity and Mode of Action

Virelure is a sex attractant pheromone produced by female artichoke plume moths to attract the males. The analytical method used to identify (Z)-11-hexadecenal is gas chromatography (GC).

Structural Formula:	$CH_3(CH_2)_3CH=CH(CH_2)_9CHO$
Empirical Formula:	$C_{16}H_{30}O$
Molecular Weight:	238.42
CAS Registry No.:	53939-28-9

The physical and chemical characteristics of the technical grade active ingredient containing 94% virelure are summarized below:

Guideline Reference Number	*Characteristic*	*Result (MRID No. 420364-01)*
151B-17(a)	Color	Colorless
151B-17(b)	Physical state	Liquid
151B-17(c)	Odor	Waxy odor
151B-17(d)	Melting point	Not required, because TGAI is a liquid
151B-17(e)	Boiling point	120-126°C
151B-17(f)	Density, specific gravity	0.849 at 20°C
151B-17(g)	Solubility	Insoluble in water 0.2 ppm at 25 °C; soluble in most organic solvents
151B-17(h)	Vapor pressure	1.2×10^{-3} mm Hg
	Dissociation constant	Not applicable, because the TGAI is not soluble in water
	Octanol/water partition coefficient	$> 1.0 \times 10^4$ k_{ow}
151B-17(I)	pH	Not applicable, because the TGAI is not soluble in water
151B-17(j)	Stability	Stable under normal storage without sunlight

2. Tolerance Exemption Food/Non-Food Use

Virelure is a pheromone sex attractant that is not applied directly to artichokes; rather, virelure is impregnated onto polymeric dispensers and/or fibers which are ultimately twist-tied to the stalk of an artichoke plant. This compound belongs to the class of lepidopteran pheromones which are exempted from the requirement of a tolerance when used at application rates of less than 150 grams of active ingredient per acre per season in or on all raw agricultural commodities (40 CFR 180.1153). Additionally, an exemption from the requirement of a tolerance has been established for (Z)-11-hexadecenal (virelure) when used as a sex attractant on artichoke plants to control the artichoke plume moth in 40 CFR 180.1069; but this exemption is expected to be revoked due to the existence of the exemption in 40 CFR 180.1153.

F. Human Health Assessment

1. Toxicology Assessment

Adequate mammalian toxicology data are available on virelure and will support a Reregistration Eligibility Decision.

a. Acute Toxicity

In the evaluation of the toxicology data base for a reregistration eligibility decision for virelure, the Agency reevaluated the primary eye irritation studies (MRID No. 41693204 and 40757204) and primary dermal irritation study (MRID No. 41693205) and concluded that additional precautionary label statements are necessary to adequately mitigate these risks. Refer to Section V.

All acute mammalian toxicology studies have been submitted and adequately satisfy the requirements as set forth in 40 CFR 158.690. The following toxicology studies were submitted to support the registration of the active ingredient:

Guideline Reference Number	*Study*	*Results*	*Category*	*MRID Number(s)*
152B-10	Acute Oral LD_{50} (rat)	> 5 g/kg	IV	41693201, 00096677, 40757202
152B-11	Acute Dermal LD_{50} (rabbit)	> 2 g/kg	III	41693202, 00096677, 40757201
152B-12	Acute Inhalation LD_{50} (rat)	> 5 mg/L	IV	41693203, 40757203

Guideline Reference Number	*Study*	*Results*	*Category*	*MRID Number(s)*
152B-13*	Primary Eye Irritation (rabbit)	None to slight irritation	III	41693204, 40757204
152B-14*	Primary Dermal Irritation (rabbit)	Slight to moderate irritation	III	41693205
152B-15*	Dermal Sensitization	Dermal sensitizer	N/A	40757206
152B-16*	Hypersensitivity	All incidents must be reported to the Agency	N/A	N/A

*Not required for TGAI

b. Mutagenicity

Mutagenicity studies have been submitted and satisfy the requirements as set forth in 40 CFR 158.690. Based on the negative results observed in the Ames assay test, and due to the known metabolism of long-chain aldehydes, all other mutagenicity studies were waived. The following studies were submitted to support the initial registration of the active ingredient (Z)-11-hexadecenal:

Guideline Reference Number	*Study*	*Results*	*MRID Number*
152B-17	Ames Assay	Not mutagenic	00085716, 00082638

c. Additional Toxicity Information

Data from subchronic toxicology studies that evaluate compounds similar in structure to the lepidopteran pheromones have been published in the scientific literature (Daughtrey *et al.* 1990. Subchronic toxicity evaluation of tridecyl acetate in rats. *Fundam. Appl. Toxicol.* 14: 104-112). Tridecyl acetate is structurally similar to virelure in that it is a long-chain hydrocarbon having carbon numbers predominantly in the range of C_{10} through C_{14}. The data and/or information submitted included compounds that were from six- to sixteen- carbon unbranched alcohols, acetates and aldehydes. The Agency's analysis of these compounds indicate that there were no significant signs of toxicity in rats other than those expected with longer-term exposure to high doses of a hydrocarbon. The findings were indicative of an overall low degree of systemic toxicity following subchronic oral administration of tridecyl acetate at doses up to 1 g/kg body weight. In

addition, for most of the hematology parameters there were no statistically significant differences between control and treated groups. Similarly, there were no significant differences from control for the majority of measured serum chemistry values. It should be noted that no significant acute toxicity effects were observed with the primary alcohols, acetates or aldehydes evaluated. Based on these test results, an exemption from tolerance (40 CFR 180.1153), low application rates (<150 g/a.i./acre/year), and nominal potential exposure, the Agency has waived data requirements for immunotoxicity. No additional information and/or data will be required for virelure based on the use pattern.

2. Exposure Assessment

a. Dietary Exposure

An exemption from the requirements of a tolerance has been established for residues of arthropod pheromones when used in retrievable-sized polymeric matrix dispensers in or on the raw agricultural commodities when applied to growing crops at a rate not to exceed 150 g/a.i./acre/year in accordance with good agricultural practices (see 40 CFR § 180.1124). The exemption was extended to broadcast applications for lepidopteran pheromones on August 31, 1995 (60 FR 45060). The Agency was unable to make a no-unreasonable-adverse effects finding for other arthropod pheromone pesticides for use on food crops. However, based on the data and/or information submitted to support the registration of straight chained lepidopteran pheromones, the Agency concluded that the potential for such residues is not a dietary hazard. This conclusion was based on: the lack of Sec. 6(a)(2) incident reports; the low acute mammalian toxicity observed in the lepidopteran pheromones registered to date; the known metabolism of long chain aldehydes; low application rates; and nominal human exposure subsequent to application due to volatilization.

Further, this compound is not applied directly to the artichoke plants nor is it taken up or metabolized by artichoke plants, rather it is incorporated into dispensers or as a microencapsulated material. Therefore, dietary exposure to this compound is expected to be minimal. Consequently, the Agency has determined that, when used in accordance with good agricultural practices, a food tolerance for the defined subset of lepidopteran pheromones, which includes virelure, is not necessary to protect the public health. Therefore, the Agency established an exemption from the requirement of a tolerance for this group of active pesticidal ingredients when used at less than 150 g/a.i./acre/year (40 CFR 180.1153)

b. Occupational and Residential Exposure

Based on the use pattern, the potential for dermal, eye, and inhalation exposures to pesticide handlers exists but is expected to be negligible. Because of the lack of mammalian toxicity, as demonstrated in the battery of acute toxicity studies and a related subchronic toxicity study, worker exposure data to the active ingredient are not required. However, due to the potential for dermal and eye irritation, the Agency will require appropriate signal word and precautionary statements to mitigate any potential risk discussed in Section V. Residential exposure to virelure is not expected based on the use pattern.

c. Residential, School, and Daycare Exposure

No indoor residential, school, or daycare uses currently appear on the label. The potential of significant exposure to children other than from dietary exposure is anticipated to be considerably less than that used in exposing experimental animals in tests. While accidental nondietary exposure to children could occur, any resulting health risks are expected to be minimal based on low mammalian toxicity, nominal exposure due to high volatility of the compound, and a history of safe use.

3. Human Risk Assessment

The potential risks to humans are considered negligible based on the lack of significant toxicological concerns, as demonstrated in the Agency's evaluation of the mammalian toxicology studies, low application rates, low exposure subsequent to application due to volatilization, and known metabolism of long-chain aldehydes. In the event that the technology for manufacturing and/or synthesizing the compound and/or use pattern changes such as to increase the likelihood of exposure, the Agency will continue to evaluate the need for additional toxicology testing on the technical grade material.

4. Drinking Water and Risk Characterization

No significant exposure is expected from an accumulation of virelure in the aquatic environment due to the application method (dispensers) and precautionary label language; "Do not apply directly to water or wetlands." Based on the available studies used in EPA's assessment of environmental risk, the Agency does not anticipate exposure to residues of virelure in drinking water. Also, the aforementioned label language mitigates against exposure through drinking water.

5. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

The Agency has concluded that the potential for pheromone residues is not a dietary hazard to the general population, including infants and children. This decision was based on: low acute and subchronic mammalian toxicity, known metabolism of similar compounds, and the history of safe use of similar lepidopteran pheromones. Also, for food uses of pheromones, the toxicity and residue data have allowed for the conclusion that an exemption from the requirement of a tolerance is appropriate and adequate to protect human health, including that of infants and children.

6. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

(Z)-11-hexadecenal (virelure) technical pheromones are synthetic compounds which mimic naturally occurring substances of insect origin with a non-toxic mode of action to target pests. The low oral, dermal and inhalation toxicity is demonstrated by the data summarized above. Based on this information, the Agency has concluded that aggregate exposure to such lepidopteran pheromones as (Z)-11-hexadecenal technical pheromones over a lifetime will not pose appreciable risks to human health. Moreover, the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of virelure. The Agency concludes that there is reasonable certainty of no harm to infants and children from aggregate exposure to residues of (Z)-11-hexadecenal technical pheromone.

7. Cumulative Effects

The Agency has considered available information on the cumulative effects of such residues and other substances that might have a common mechanism of toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. Since there is no significant toxicity for Lepidopteran active pheromones, the Agency concluded that there won't be any cumulative effects.

G. Environmental Assessment

Virelure meets current eligibility requirements for reregistration. There are no outstanding data gaps. There is sufficient background and intended use information regarding this particular class of lepidopteran pheromones to satisfy adverse risk concerns to nontarget organisms.

1. Ecological Toxicity Data

All of the ecological effects data requirements for virelure have been adequately fulfilled. These data indicate that virelure is not likely to cause adverse effects in nontarget avian, fish, plant, and insect species.

Since virelure has been determined to be highly toxic to aquatic invertebrates (Daphnia- MRID No. 41693207) and may form an oily surface film on water (MRID No. 41693206), the Agency has concluded that special precautionary label language will be required to mitigate risks to aquatic invertebrate species. Refer to Section V.

The following ecological data on nontarget organisms was submitted to support the registration of virelure:

Guideline No.	*Study*	*Results*	*MRID*
154B-6	Avian acute oral	Virelure did not demonstrate toxicity when administered orally to bobwhite quail (*Colinus virginianus*) under reported study conditions	417181-01
154B-7	Avian acute dietary	Virelure was practically nontoxic to bobwhite quail (*Colinus virginianus*) when administered in the diet for five days	417181-02
154B-8	Fish Toxicity-Rainbow Trout	The virelure is practically nontoxic to rainbow trout (*Salmo gairdneri*) under reported study conditions, at and above its solubility limit of 0.2 mg/L. Beyond the solubility limit, the compound forms an oily surface film that may likely affect organisms that utilize the water surface.	416932-06
154B-9	Invertebrate toxicity	Virelure was determined highly toxic to *Daphnia* under conditions of the reported flow-through study. The LC_{50} was based on nominal concentrations and, as a result, is probably invalid. The actual LC_{50} may have been between 0.58 mg/L and the 0.20 mg/L solubility limit of the test compound. Also, the pheromone forms an oily film potentially capable of affecting interfacial tensions at the water surface upon which various arachnids and insects depend.	416932-07
154B-10	Nontarget Plants	Based on the intended use of the virelure, data or studies for non-target terrestrial or aquatic plants are not required at this time for reregistration.	
154B-11	Nontarget Insects	Virelure's biological activity is highly specific to the artichoke plume moth and as such is considered practically nontoxic to other insects. Accordingly, no data or studies concerning nontarget insects are required at this time for reregistration.	

2. Environmental Fate

Environmental fate studies are not required for biochemical pesticides unless adverse effects on nontarget species are observed as a result of acute testing for ecological effects (Tier I). No adverse effects are suggested by the data as described in the table above. Because no adverse effects were observed in Tier I testing on fish and wildlife, there are no Environmental Fate Data Requirements for the reregistration of virelure.

3. Exposure and Risk Characterization

a. Exposure and Risk to Nontarget Terrestrial Animals

Because no adverse effects were observed in Tier I testing on wildlife, there is little to no risk of adverse effects on terrestrial animals. Virelure is impregnated in a solid matrix dispenser and is slowly released by volatilization, limiting its transport and resultant exposure. This dispensing system is generally accepted as posing minimal to no exposure risk to birds or terrestrial mammals.

b. Exposure and Risk to Nontarget Aquatic Animals

Virelure was determined highly toxic to *Daphnia* and practically nontoxic to freshwater fish. Based on the intended use of the virelure, exposure to aquatic animals is not expected. Moreover it is the Agency's opinion that risks to aquatic species will be adequately mitigated by special precautionary product labeling. Refer to Section V.

c. Exposure and Risk to Nontarget Plants

Based on the intended use of virelure, studies for nontarget terrestrial or aquatic plants are not required for reregistration at this time.

d. Exposure and Risk to Endangered Species

Virelure has a nontoxic mode of action specific to the artichoke plume moth. There are no endangered species concerns in an agricultural (intensive) system. Furthermore, there is limited national acreage affected, as artichokes are a minor crop.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

H. 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 virelure active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of products containing virelure for non-food use. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of virelure, 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 virelure and to determine that virelure can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that products containing virelure as the active ingredients are eligible for reregistration for non-food use. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the 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 virelure 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 virelure, 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 in virelure, the Agency has sufficient information on the health effects of virelure and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that products containing virelure, when 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 virelure for non-food use are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that virelure, when used as a sex attractant on artichoke plants to control the artichoke plume moth, is eligible for reregistration. No other uses of virelure are eligible for reregistration.

I. Regulatory Position

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

1. Food Quality Protection Act Considerations

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amended the FFDCA by establishing a new safety standard for the establishment of tolerances. The FQPA did not, however, amend any of the existing reregistration deadlines in section 4.

In determining whether a tolerance meets the new safety standard, section 408(b)(2)(C) directs EPA to consider information concerning the exposure of infants and children to pesticides in food, available information concerning the susceptibility of infants and children to pesticide residues in food, and available information concerning cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity. Section 408(b)(2)(D) establishes factors that the Agency must consider in determining whether the safety standard is met; these factors include the consideration of available information on the cumulative effects of the pesticide for which a tolerance is sought as well as other substances that have a common mechanism of toxicity and consideration of available information on the aggregate exposure levels of the population and of major subgroups of the population to the pesticide and related substances.

EPA is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in depth analysis of the new safety standard and how it should be applied to both food and non-food pesticide applications. However, in light of the unaffected statutory deadlines with respect to reregistration, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early, case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rule-making that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will consider itself free to pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

2. Tolerance Reassessment

Lepidopteran pheromones are exempt from the requirements of a tolerance under 40 CFR 180.1153.

3. 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 and have available voluntary county-specific bulletins. 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.

4. Labeling Rationale

The Agency has reexamined the toxicological database for virelure and concluded that the current Signal Word (Caution) and Statement of Practical Treatment are appropriate. However, due to the primary eye and dermal irritation response, the Agency will require a revised Precautionary Statement to mitigate this risk.

The Agency has also reexamined the ecological database for virelure and concluded the since virelure is toxic to *Daphnia* and forms an oily film on the surface of water that is capable of adversely affecting certain aquatic organisms, label language will be required to prevent application to water, effluent discharges to water bodies, or contamination of water during equipment cleaning. Refer to Section V.

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.

J. Manufacturing-Use Products

1. Additional Generic Data Requirements

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

According to guideline 151B-15, an updated and current CSF including Certification of Limits must be submitted to the Agency.

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 insecticide contained within a solid matrix dispenser."

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)."

Manufacturing use product labels must also contain the following NPDES statement: "Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

K. 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.

According to guideline 151B-15, an updated and current CSF including Certification of Limits must be submitted to the Agency.

2. Labeling Requirements for End-Use Products

Precautionary Statement

To mitigate the risk of eye and skin irritation, the following statement must appear under the Precautionary Statement: "Causes slight eye and dermal irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling."

Environmental Hazards

To mitigate exposures to freshwater invertebrates, precautionary label language for products containing virelure must include the following statement under the "Environmental Hazards" heading: "This product is highly toxic to aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters."

Worker Protection Standard

According to Pesticide Regulation (PR) Notice 93-7, "Labeling Revision Required by the Worker Protection Standard (WPS)," WPS does not apply to attractants used in insect traps. Since virelure is expected to be used in a solid matrix device, it is exempt from WPS labeling requirements.

Storage and Disposal

In conformity with virelure's use, labels must read "Do not contaminate water, food, or feed by storage or disposal."

VI. APPENDICES

APPENDIX A. Use Pattern Subject To Reregistration

The manufacturing-use product (AgriSense® Technical Pheromone Z-11) is registered to be used only for manufacturing or formulating registered biochemical pesticide products or devices. The end-use product (APM-ROPE™) is currently labeled to contain 7.04% (Z)-11-hexadecenal. The APM-ROPE™ is to be applied as a twist-tie dispenser loosely attached around the inside of the stalk of the artichoke plant either immediately before moths emerge or after an insecticide treatment to eradicate existing moth infestations at a rate of at least 400 per acre.

APPENDIX B. Citations Considered to be Part of the Data Base Supporting the Reregistration of Virelure

GUIDE TO APPENDIX B

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

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
151B-10	Product Identity	ALL	42036401
151B-11	Manufacturing Process	ALL	42036401
151B-12	Discussion of Formation of Unintentional Impurities	ALL	42036401
151B-13	Analysis of Samples	ALL	42036401
151B-15	Certification of limits	ALL	42036401
151B-16	Analytical Method	ALL	42036401
151B-17(a)	Color	ALL	42036401
151B-17(b)	Physical State	ALL	42036401
151B-17(c)	Odor	ALL	42036401
151B-17(d)	Melting Point	ALL	42036401
151B-17(e)	Boiling Point	ALL	42036401
151B-17(f)	Density	ALL	42036401
151B-17(g)	Solubility	ALL	42036401
151B-17(h)	Vapor Pressure	ALL	42036401
	Dissociation Constant	ALL	42036401
151B-17(p)	Octanol/Water Partition	ALL	42036401
151B-17(I)	pH	ALL	42036401
151B-17(j)	Stability	ALL	42036401

Data Supporting Guideline Requirements for the Reregistration of Virelure

REQUIREMENT		USE PATTERN	CITATION(S)
151B-17(k)	Flammability	Not required	
151B-17(l)	Storage stability	Not required	
151B-17(m)	Viscosity	Not required	
151B-17(n)	Miscibility	Not required	
151B-17(o)	Corrosion characteristics	Not required	
ECOLOGICAL EFFECTS			
154B-6	Acute Avian Oral - Quail	ALL	41718101
	Avian Dietary - Quail	ALL	41718102
154B-8(a)	Fish Toxicity Rainbow Trout	ALL	41693206
154B-9	Invertebrate Toxicity	ALL	41693207
TOXICOLOGY			
152B-10	Acute Oral Toxicity - Rat	ALL	41693201, 00096677, 40757202
152B-11	Acute Dermal Toxicity - Rabbit	ALL	41693202, 00096677, 40757201
152B-12	Acute Inhalation Toxicity - Rat	ALL	41693203, 40757203
152B-13	Primary Eye Irritation - Rabbit	ALL	41693204, 40757204
152B-14	Primary Dermal Irritation - Rabbit	ALL	41693205
152B-15	Dermal Sensitization - Guinea Pig	ALL	40757206
152B-16	Hypersensitivity		All incidents must be reported to the Agency
152B-17	Gene Mutation (Ames Test)	ALL	00085716, 00082638

BIBLIOGRAPHY

MRID	CITATION
00082638	Jagannath, D.R.; Goode, S. (1980) Mutagenicity Evaluation of Heliothis--2 Component ... in the Ames Salmonella/Microsome Plate Test: LBI Project No. 20988; Genetics Assay No. 5194. (Unpublished study received Feb 13, 1981 under 36638-EX-4; prepared by Litton Bionetics, Inc., submitted by Conrel, an Albany International Co., Needham Heights, Mass.; CDL:099916-E)
00085716	Jagannath, D.R.; Goode, S. (1980) Mutagenicity Evaluation of Heliothis--2 Component: 94.1% Z-11-hexadecenal, 5.9% Z-9-tetradecenal plus 1% Banox 20BA in the Ames Salmonella/Microsome Plate Test: LBI Project No. 20988. Final rept. (Unpublished study received Aug 7, 1981 under 36638-10; prepared by Litton Bionetics, Inc., submitted by Conrel, an Albany International Co., Needham Heights, Mass.; CDL:245801-G)
00096677	Herculite Products, Incorporated. (1982). Chemical Study of Hercon (R) Disrupt (R) /Artichoke Plume Moth. (Compilation; unpublished study received March 17, 1982 under 8730-34; CDL: 070717-A.
40757201	Hathorn, S. (1988) (Z)-11-Hexadecenal (APM-ROPE): Acute Dermal Toxicity Studies in Rats. Unpublished study prepared by Hazleton Labs America, Inc. 20 p.
40757202	Hathorn, S. (1988) (Z)-11-Hexadecenal (APM-ROPE): Acute Oral Toxicity Studies in Rats. Unpublished study prepared by Hazleton Labs America, Inc. 13 p.
40757203	Hathorn, S. (1988) (Z)-11-Hexadecenal (APM-ROPE): Acute Inhalation Toxicity Studies in Rats -- LC50 (4 Hour Exposure). Unpublished study prepared by Hazleton Labs America, Inc. 51 p.
40757204	Hathorn, S. (1988) (Z)-11-Hexadecenal (APM-ROPE): Primary Eye Irritation Study in Rabbits. Unpublished study prepared by Hazleton Labs America, Inc. 21 p.
40757206	Hathorn, S. (1988) (Z)-11-Hexadecenal (APM-ROPE): Guinea Pig Maximization Test. Unpublished study prepared by Hazleton Labs America, Inc. 33 p.

41693201 Glaza, S. (1989) Acute Oral Toxicity Study of Z-11 Hexadecenal in Rats: Final Report: Lab Project Number: HLA 81102696. Unpublished study prepared by Hazleton Labs America, Inc. 31 p.

41693202 Glaza, S. (1989) Acute Dermal Toxicity Study of Z-11 Hexadecenal in Rabbits: Final Report: Lab Project Number: HLA 81102697. Unpublished study prepared by Hazleton Labs America, Inc. 34 p.

41693203 Terrill, J. (1989) Acute Inhalation Toxicity Study with Technical Pheromone Z-11 in the Rat: Final Report: Lab Project Number: 652-226. Unpublished study prepared by Hazleton Labs America, Inc. 40 p.

41693204 Glaza, S. (1990) Primary Eye Irritation Study of Z-11-Hexadecenal in Rabbits: Final Report: Lab Project Number: HLA 81102698. Unpublished study prepared by Hazleton Labs America, Inc. 36 p.

41693205 Glaza, S. (1989) Primary Dermal Irritation Study of Z-11 Hexadecenal in Rabbits: Final Report: Lab Project Number: HLA 81102699. Unpublished study prepared by Hazleton Labs America, Inc. 27 p.

41693206 Bowman, J. (1989) Acute Toxicity of Technical Pheromone Z-11 to Rainbow Trout (Salmo gairdneri): Lab Project Number: 37088. Unpublished study prepared by Analytical Bio-Chemistry Labs, Inc. 67 p.

41693207 Burgess, D. (1989) Acute Flow-Through Toxicity of Technical Pheromone Z-11 to Daphnia magna: Final Report: Lab Project Number: 37089. Unpublished study prepared by Analytical Bio-Chemistry Labs, Inc. 71 p.

41718101 Grimes, J.; Jaber, M. (1988) Technical Pheromone Z-11: An Acute Oral Toxicity Study with the Bobwhite: Final Report: Lab Project No. 251-104. Unpublished study prepared by Wildlife International Ltd. 18 p.

41718102 Grimes, J.; Jaber, M. (1988) Technical Pheromone Z-11: A Dietary LC50 Study with the Bobwhite: Lab Project Number: 251-103. Unpublished study prepared by Wildlife International Ltd. 17 p.

42036401 Kirsch, P. (1991) Product Chemistry: Isomate-191 Pheromone. Unpublished study prepared by Biocontrol Ltd. 143 p.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Laura Sallmen Smith at (703) 308-8716.

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

Robyn Rose, Entomologist

Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Virelure

The following is a list of available documents for virelure 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 Robyn Rose at (703)-308-9581.

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 virelure.

The following documents are part of the Administrative Record for virelure 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