



Reregistration Eligibility Decision (RED)

S-Kinoprene



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 S-Kinoprene which includes the active ingredient 2-propynyl-2E, 4E-3,7,11-trimethyl-2-4-dodecadienoate. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, 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 this product for reregistration. It may also include requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

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

If you have questions regarding the specific labeling requirements or wish to meet with the Agency, please contact the Biopesticides and Pollution Prevention Division Representative Beverly Sjoblad at (703) 308-8376.

Sincerely yours,

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

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

3. **APPLICATION FOR REREGISTRATION OR “8-MONTH RESPONSE”**--**You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**
 - a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it “Application for Reregistration.” Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

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

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

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

S-KINOPRENE

LIST D

CASE 4117

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

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KINOPRENE 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
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
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

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
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 has completed its comprehensive reassessment of the required target data and the use patterns of the currently registered product containing S-Kinoprene (Shaughnessy Number 107502, Case No. 4117). Kinoprene was registered in 1975, and the S-isomers will be the only active ingredient discussed in this document. Case 4117 also consists of R-S Hydroprene (Shaughnessy Number 488300), and R-S Kinoprene (Shaughnessy Number 107501) which are no longer being supported by the registrant. Products containing S-Kinoprene will be eligible for reregistration upon the publication of this document.

S-Kinoprene is a biochemical pesticide which is chemically synthesized and used as an insect juvenile hormone analog on indoor non-food/non-feed crops, including ornamental plants grown in greenhouses and interiorscapes. S-Kinoprene, applied at a low rate, inhibits normal insect growth during the molting process causing morphogenic, ovicidal, and sterilization effects. When applied at a higher rate, S-Kinoprene kills the adult populations of insects such as aphids, whiteflies, mealybugs, fungus gnats, and armored scales. Since S-Kinoprene is used on non-food/non-feed crops, a food tolerance establishment/exemption is not an issue.

The Agency believes that this use pattern does not present unreasonable risks to humans, including infants and children, or to the environment, due to the low mammalian toxicity, lack of dietary exposure, and low application rate. Also, the indoor use pattern eliminates the potential for exposure to birds, fish, aquatic organisms, plants, and non-target insects.

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 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, but FQPA does not obligate the Agency to consider the factors set forth in the new section 408 of the FFDCA when making decisions under FIFRA with respect to pesticides that do not have any food uses. However, the FQPA did not amend any of the existing reregistration deadlines in section 4 of FIFRA.

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 is likely to include an examination of whether the same or a similar safety standard should apply to non-food pesticide applications. Such a standard might include exposure of infants and children to the pesticide(s), cumulative effects on infants and children from this pesticide and other substances that have a common mechanism of toxicity, and aggregate exposure of the population and major subgroups of the population to the pesticide and related substances. The Agency has not yet determined with finality how it will make such decisions. 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 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 consider itself free to pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of S-Kinoprene. The document consists of six sections. Section I is the introduction. Section II describes S-Kinoprene, 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 S-Kinoprene. Section V discusses the reregistration requirements for S-Kinoprene. 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:** S-Kinoprene
- **Chemical Name:** 2-propynyl-(2E,4E)-3,7,11-trimethyl-2-4-dodecadienoate
- **Chemical Family:** Trimethyldodecadienoates
- **CAS Registry Number:** 65733-20-2
- **OPP Chemical Code:** 107502
- **Empirical Formula:** C₁₈H₂₈O₂
- **Trade and Other Names:** Enstar® II (formerly Enstar® 5E)
- **Basic Manufacturer:** Sandoz Agro, Inc. (formerly Zoecon Corporation)
1300 E. Touhy Ave.
Plaines, IL 60018

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. Details of these uses and application methods of S-Kinoprene are in Appendix A.

Type of Pesticide: Biochemical pesticide, a synthetic insect growth regulator analog

Use Sites: Greenhouse indoor non-food crops: Ornamental plants (nonflowering, herbaceous, shade trees, woody shrubs and vines)

Target Pests: Aphids, whiteflies, mealybugs, fungus gnats, and armored scales.

Formulation Types Registered:

The technical grade active ingredient (TGAI) consists of 89% synthetic S-Kinoprene and 11% related impurities. The only end-use product, Enstar®II (EPA Reg. No. 55947-82) consists of 65.1% TGAI and 34.9% inert ingredients.

Method and Rates of Application:

Preventative program (before insect populations reach damaging levels): Enstar®II should be mixed at a rate of 5 ounces per 100 gallons of water per 15,000-20,000 square feet, and sprayed to runoff every two weeks.

Curative program (for an existing population of adult insects): Two applications, seven days apart, of Enstar®II to runoff at the rate of 10 ounces per 100 gallons of water per 15,000-20,000 square feet. Two weeks later, the preventive program should be implemented and the mixture should be sprayed to runoff every two weeks.

For fungus gnat and root mealybug control: To control larval and adult fungus gnats, Enstar®II must be applied at 5 ounce per 100 gallons of water; complete coverage of soil is essential for fungus gnat control.

When infestations of root mealybugs are observed the entire pot containing the infested plant should be drenched by submersion in a solution of ½ ounce per 5 gallons of water.

Type of Treatment: Soil drench; Spray (indoor use only)

Equipment: Sprayer (conventional, Electro Static Spraying System®, Puls-fog®)

Timing: Interiorscapes; potted; prebloom

Use Practice Limitations: Do not use Enstar®II through any type of irrigation system.

C. Estimated Usage of Pesticide

The average annual estimated use is 1,000 pounds of active ingredient applied to 3,200 acres of ornamental plants in greenhouses and interiorscapes with 70% total usage in the States of California and Texas.

D. Data Requirements

Data requested in the Data Call-In for S-Kinoprene dated September 30, 1993, includes studies on toxicology, i.e., a standard battery of genotoxicity tests. These data were required to support the uses listed in the Data Call-In. All mammalian toxicology data are available. All product chemistry data are adequately satisfied. In light of the current indoor use pattern, the Agency will not impose any environmental fate requirements for reregistration of the currently registered products containing S-Kinoprene. All the ecological effects data requirements for S-Kinoprene have been adequately fulfilled. No additional data are required.

E. Regulatory History

Kinoprene was registered in the United States in 1975 under the trade name Enstar®5E, and renamed Enstar®II, (EPA Reg. No. 55947-82) for use as an insecticide on indoor non-food/non-feed crops grown in greenhouses and nurseries. A Data Call-In was issued on September 30, 1993 to Sandoz Agro, Inc., the registrant for S-Kinoprene, requiring additional toxicity data to satisfy the genotoxicity requirement. Case No. 4117 also consists of R-S Hydroprene (488300), and R-S Kinoprene (107501) which are no longer supported by the registrant. S-Hydroprene (128988) was registered in 1986. This decision includes a comprehensive reassessment of the required target data and the use patterns of the currently registered product.

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.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

1. Chemistry Assessment

All product chemistry data requirements for S-Kinoprene technical grade active ingredient and the end-use product Enstar®II are satisfied. These data will support a Reregistration Eligibility Decision (RED).

a. Product Identify and Mode of Action

S-Kinoprene [2-propynyl-(2E, 4E)-3,7,11-trimethyl-2-4-dodecadienoate] is a chemically synthesized insect juvenile hormone analog. When S-Kinoprene is applied at a low rate, normal insect growth is inhibited during the molting process causing morphogenic, ovicidal, and sterilization effects. S-Kinoprene applied at a higher rate, kills the adult insects.

b. Tolerance Exemption and Food/Non-Food Use

S-Kinoprene is an insecticide used on indoor non-food/non-feed crops and ornamental plants grown in greenhouses and nurseries. Therefore, a tolerance establishment/exemption is not an issue for these current uses.

c. Physical and Chemical Property Assessment

The analytical method used to determine S-Kinoprene is gas-liquid chromatogram (GLC) utilizing a flame ionization detector (FID).

Structural Formulation: $\text{CH}_3\text{CH}(\text{CH}_3)(\text{CH}_2)_3\text{CH}(\text{CH}_3)\text{CH}_2\text{CH}=\text{CHC}(\text{CH}_3)=\text{CHCO}_2\text{CH}_2\text{C}\equiv\text{CH}$

Empirical Formulation: $\text{C}_{18}\text{H}_{28}\text{O}_2$

Molecular Weight: 276

CAS Registry No.: 65733-20-2

The generic data requirements for physical and chemical characteristics of the technical grade active ingredient containing 89% S-Kinoprene are summarized in Table 1.

Table 1.

Physical and Chemical Properties of S-Kinoprene		
Guideline No. 151B-17	Results	MRID No.
Color	Clear amber	41591503
Physical state	Oily liquid	41591503
Odor	Mild fruity	41591503
Boiling point	134°C at 0.1 mm Hg	41591503
Density, specific gravity	0.918 at 25°C	41591503

Physical and Chemical Properties of S-Kinoprene		
Guideline No. 151B-17	Results	MRID No.
Solubility	Insoluble in water; 0.211 ppm at 25 ^o C and soluble in most organic compounds	41898904
Vapor pressure	7.19 x 10 ⁻⁶ mmHg at 20 ^o C	Merck Index Eleventh Edition
Dissociation constant	*N/A	41591503
Octanol/water partition coefficient (K _{ow})	2.38 X 10 ⁵ at 25 ^o C	41898904
pH	*N/A	41591503
Stability	Stable	41591503

*Not applicable because S-Kinoprene is insoluble in water.

B. Human Health Assessment

All mammalian toxicology data requirements have been submitted and adequately satisfy the requirements as set forth in 40 CFR 158.690 for biochemical pesticides for non-food/non-feed use. The mammalian toxicology data base includes acute toxicity studies, and a battery of genotoxicity studies. Based on the use sites, use patterns, application method, use rates, low exposure, and lack of significant toxicological concerns, as demonstrated in the submitted toxicology studies, the potential risks, if any, to humans are considered negligible.

1. Toxicology Assessment

Adequate mammalian toxicology data are available to support reregistration of the active ingredient S-Kinoprene.

a. Acute Toxicity

All acute mammalian toxicology studies have been submitted and adequately satisfy the requirements for non-food/non-feed use. The following toxicology studies were submitted to support the reregistration of the active ingredient S-Kinoprene as summarized in Table 2.

Table 2.

Guideline No.	Study	Results	Category	MRID No.
152B-10	Acute Oral LD50 (rat)	>6.8 g/kg*	IV	41591509
152B-11	Acute Dermal LD ₅₀ (rat)	>2 g/kg	III	41591510
152B-12	Acute Inhalation LD ₅₀ (rat)	>5.36 mg/l**	IV	41591501
152B-13	Primary Eye Irritation (rabbit)	Slight to moderate irritation ***	III	41591507
152B-14	Primary Dermal Irritation (rabbit)	Moderate irritation (Draize)	III	41591513
152B-15	Dermal Sensitization (guinea pigs)	Not a dermal sensitizer	N/A	47009035

* Males and females combined

** Greater than 4.78 mg/L when adjusted for purity

*** A single dose of undiluted test material produced slight to moderate conjunctival irritation in three (3) treated eyes at 1 hr post-treatment which persisted for 48 to 72 hrs. The cornea and iris of all rabbits appeared normal throughout the course of the study.

b. Mutagenicity

Mutagenicity studies have been submitted and adequately satisfy the requirements as set forth in 40 CFR 158.690. No additional data and/or information will be required. The following studies were submitted to support the registration of the active ingredient (Table 3).

Table 3.

Mutagenicity Studies - Ames Assay			
Guideline No.	Study	Results	MRID No.
152B-17	Ames Assay*	Not mutagenic	41591514
	Unscheduled DNA Synthesis (UDS)	Did not initiate UDS	43015201
	<i>In vivo</i> Mammalian Cytogenetics	Not mutagenic	43015202

* The test substance, S-Kinoprene, was not mutagenic, and caused no cytotoxicity or did not increase in mutant colonies of the five *Salmonella typhimurium* tester strains at any dose with or without metabolic activation.

c. Subchronic Assessment

A 90-day feeding study is not required because the non-food/non-feed uses do not require a tolerance or exemption from tolerance; and the uses are not likely to result in repeated human exposure by the oral route. Likewise, the 90-day dermal and inhalation toxicity studies are not required because the use pattern does not result in a long-term inhalation exposure at concentrations that are likely to be toxic, and there is no purposeful application to human skin, nor is

prolonged dermal exposure likely. A developmental toxicity study is not required because the use pattern of S-Kinoprene is not reasonably expected to result in significant exposure to pregnant women. The immunotoxicity study can be waived because of lack of significant exposure, and because of the lack of significant toxicological effects in the submitted acute toxicity studies with S-Kinoprene.

d. Exposure Assessment

(1) Non-dietary/Dietary Exposure

The uses of S-Kinoprene do not require a tolerance or an exemption from tolerance, and dietary exposure from the uses of S-Kinoprene is unlikely. Acute exposure from the proposed greenhouse and indoor use sites may occur, but would be very low because of the low application rates. The average annual estimate use is 1,000 pounds of active ingredient applied to 3,200 acres of ornamental plants in interiorscapes and greenhouses with 70% total usage in the States of California and Texas.

(2) Occupational and Residential

Based on the application methods, the potential for dermal, eye, and inhalation exposures to S-Kinoprene for pesticide handlers and applicators exist. Because of the lack of significant mammalian toxicity, worker exposure data (i.e., occupational exposure data) to the active ingredient are not required at this time. However, due to the primary eye irritation response (Toxicity Category III) the Agency will require the appropriate Signal Word (Caution) and Statements of Precaution (Causes slight eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling).

Based on the use sites, use patterns, application method, and use rates, the potential exposure to humans, including infants and children, is negligible.

2. Human Risk Assessment

a. Non-Dietary/Dietary Risk

The potential risks to humans, including infants and children from non-dietary routes are considered negligible based on the lack of significant toxicological concerns low application rates, and minimal exposure.

Although the potential for dermal, eye, and inhalation exposures to the pesticide for pesticide handlers and applicators exist, risk characterization is unnecessary because of the low dermal and inhalation toxicity, coupled with low exposure. In addition, there are no incident reports of adverse effects from exposure.

C. Environmental Assessment

All ecological toxicity and environmental fate data requirements have been adequately satisfied according to the guidelines set forth in 40 CFR 158.690 for biochemical pesticides for non-food/non-feed use.

1. Ecological Toxicity Data

In the Phase IV review of S-Kinoprene, the Ecological Effects Branch (EEB), Environmental Fate and Effects Division (EFED), waived all non-target data requirements because “Based on the use patterns, exposure to non-target organisms is expected to be non-existent or negligible.” (March 30, 1993 Memorandum from Anthony F. Maciorowski to Bruce Sidwell). An aquatic invertebrate toxicity study involving *Daphnia* (Table 4) recently has been submitted under FIFRA 6(a)2. All data requirements for S-Kinoprene have been adequately fulfilled; no additional studies are required for these uses.

Table 4.

Non-target Toxicity Studies - Tier I Guideline Requirements for S-Kinoprene			
Guideline No.	Study	Results	MRID
154B-9	Invertebrate Toxicity - <i>Daphnia Magna</i>	EC ₅₀ = 102 µg/L; highly toxic; test material = 89.6%	42756300

2. Environmental Fate

In the Phase IV review of S-Kinoprene, the Environmental Fate and Groundwater Branch (EFGWB) in the Environmental Fate and Effects

Division, did not require any Environmental Fate data for S-Kinoprene based on the use-patterns and low application rates (May 15, 1993 Memorandum from E. Brinson Conerly-Parks to Bruce Sidwell). Currently, Environmental Fate data are not required for biochemical pesticides unless effects in Tier I non-target studies indicate fate studies would be needed (40 CFR 185.690).

3. Exposure and Risk Characterization

S-Kinoprene was considered “highly toxic” to *Daphnia Magna* (Table 4). However, water insoluble material like S-Kinoprene might cause adverse effects to *Daphnia* based on the inherent design of the toxicity study (Guideline 154B-9). Since the use of S-Kinoprene is limited to greenhouses and interiorscapes and such use patterns are not expected to pose a significant risk to aquatic invertebrates, environmental fate studies will not be required. Rather, any potential effects will be further mitigated by including label language “do not contaminate water, food or feed by storage or disposal.”

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 (technical grade active ingredient) data required to support reregistration of products containing S-Kinoprene 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 S-Kinoprene. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of S-Kinoprene, 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 S-Kinoprene and to determine that S-Kinoprene can be used without resulting in unreasonable adverse effects to humans, including infants and children, and the environment. The Agency therefore finds that all products containing S-Kinoprene as the active ingredient are eligible for reregistration for these (non-food/non-feed) use patterns. 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 S-Kinoprene 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 S-Kinoprene, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the technical grade active ingredient S-Kinoprene, the Agency has sufficient information on the health effects of S-Kinoprene and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that S-Kinoprene products, labeled and used as specified in this document will not pose unreasonable risks or adverse effects to humans, including infants and children, or the environment. Therefore, the Agency concludes that products containing S-Kinoprene for all non-food/non-feed uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that certain uses of S-Kinoprene are eligible for reregistration.

Greenhouse Non-food Crop: Ornamental plants (non-flowering, herbaceous, shade trees, woody shrubs and vines)

C. Regulatory Position

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

1. Tolerance Reassessment

S-Kinoprene is used on indoor non-food/non-feed crops and ornamental plants grown in greenhouses and interiorscapes. Therefore, a food tolerance establishment/exemption is not required for these current uses.

2. Endangered Species Statement

The Agency has no concerns about the exposure of threatened and endangered species to S-Kinoprene since it is used on non-food/non-feed indoor greenhouses and nurseries.

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, interiorscapes, 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 those notices.

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

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

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

b. Precautionary Labeling

The Agency has examined the toxicological data base for S-Kinoprene and concluded that the current precautionary labeling (i.e. Signal Word, **WARNING**) needs to be amended to read “**CAUTION**” insofar as the toxicological data falls within category III and IV.

c. Application Rate

It is the Agency's position, that the labeling for the pesticide products containing S-Kinoprene complies with the current pesticide labeling requirements.

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 S-Kinoprene for the above eligible uses has been reviewed and determined to be substantially complete.

2. Labeling Requirements for Manufacturing-Use Products

Not Applicable; there are currently no manufacturing use products 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.

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 data base supporting the reregistration of Enstar®II, containing S-Kinoprene is substantially complete and no additional product specific data is being required at this time.

2. Labeling Requirements for End-Use Products

Worker Protection Standard: Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, “Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 93-11, “Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA’s labeling regulations for worker protection statements (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 those notices.

Restricted-Entry Interval (REI): The Agency has determined that the interim **REI** of 12 hours, may in certain circumstances, be reduced to 4 hours for pesticides with low acute mammalian toxicities (i.e. products with acute mammalian toxicities in Categories III and IV), such as the case of S-Kinoprene. However, the current **REI** for Epcot Center is labeled for 12 hours.

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.

Storage and Disposal: Current labeling is acceptable insofar as non-food use pattern. Current label reads, do not contaminate water, food or feed by storage or disposal.

Updated Labeling and Other 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, the rate of application (dosage), and maximum application rate. **Insofar as use pattern, current labeling is acceptable.**

The registrant must submit five (5) copies of the updated labeling and the updated Confidential Statement of Formula for each registered product.

C. Existing Stocks

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

The Agency has determined that registrants may distribute and sell S-Kinoprene 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

GUIDE TO APPENDIX B

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

REQUIREMENT	USE PATTERN	CITATION(S)
<u>PRODUCT CHEMISTRY</u>		
151B-10	Product Chemistry	IM 41898901, 41591501
151B-11	Manufacturing Process	IM 41898902
151B-12	Discussion of Formation of Unintentional Ingredients	IM 41898902
151B-13	Analysis of Samples	IM 41898903
151B-15	Certification of Limits	IM 41898903
151B-16	Analytical Method	IM 41898903
151B-17	Color	IM 41591503
151B-17	Physical State	IM 41591503
151B-17	Odor	IM 41591503
151B-17	Boiling Point	IM 41591503
151B-17	Density	IM 41591503
151B-17	Solubility	IM 41898904
151B-17	Vapor Pressure	IM Merck Index/Eleventh Edition
151B-17	Dissociation Constant	IM 41591503
151B-17	Octanol/Water Partition	IM 41898904
151B-17	pH	IM 41591503
151B-17	Stability	IM 41591503

Data Supporting Guideline Requirements for the Reregistration of S-Kinoprene

REQUIREMENT		USE PATTERN	CITATION(S)
151B-17	Storage Stability	IM	41591503
151B-17	Flammability	IM	41591503
151B-17	Viscosity	IM	41591503
 <u>ECOLOGICAL EFFECTS</u>			
154B-9	Invertebrate Toxicity - <i>Daphnia magna</i>	IM	42756300
 <u>TOXICOLOGY</u>			
152B-10	Acute Oral Toxicity - Rat	IM	41591509
152B-11	Acute Dermal Toxicity - Rabbit/Rat	IM	41591510
152B-12	Acute Inhalation Toxicity - Rat	IM	41591501
152B-13	Primary Eye Irritation - Rabbit	IM	41591507
152B-14	Primary Dermal Irritation - Rabbit	IM	41591513
152B-15	Gene Mutation (Ames Test)	IM	41591504, 43015201, 43015202

GUIDE TO APPENDIX C

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a “study.” In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting “studies” generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or “MRID number.” This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit “Accession Number” which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
 - a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
 - b. **Document date.** The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission date. The date of the earliest known submission appears immediately following the word “received.”
 - (2) Administrative number. The next element immediately following the word “under” is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol “CDL,” which stands for “Company Data Library.” This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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MRID

CITATION

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- 41591501 Sandoz Crop Protection Corp. (1990) Product Identity and Disclosure of Ingredients: ENSTAR II Insect Growth Regulator: Lab Project Number: 8790. Unpublished study. 7 p.
- 41591503 Sandoz Crop Protection Corp. (1989) Physical and Chemical Properties of S-Kinoprene Technical and S-ENSTAR: Lab Project Number: 432043. Unpublished study. 160 p.
- 41591504 Kynoch, S.; Denton, S.; Healing, G. (1989) Acute Oral Toxicity to Rats of S-ENSTAR 5E: Lab Project Number: 9081D/SNC 78/AC. Unpublished study prepared by Huntingdon Research Ctr. 26 p.
- 41591507 Liggett, M. (1989) Irritant Effects on the Rabbit Eye of S-ENSTAR 5 E: Lab Project Number: 9051D/SNC81/SE. Unpublished study prepared by Huntingdon Research Ctr. 12 p.
- 41591509 Kynoch, S.; Denton, S.; Healing, G. (1990) Acute Oral Toxicity to Rats of S-Kinoprene Technical (SAN 847): Lab Project Number: 901 29D/SNC 78/AC. Unpublished study prepared by Huntingdon Research Ctr. 25 p.
- 41591510 Kynoch, S.; Denton, S.; Healing, G. (1989) Acute Dermal Toxicity to Rats of S-Kinoprene Technical (SAN 847): Lab Project Number: 891497D/SNC 79/AC. Unpublished study prepared by Huntingdon Research Ctr. 18 p.
- 41591513 Liggett, M. (1989) Irritant Effects on Rabbit Skin of S-Kinoprene Technical (SAN 847): Lab Project Number: 9048D/SNC 80/SE. Unpublished study prepared by Huntingdon Research Ctr. 9 p.
- 41898901 Sandoz Crop Protection Corp. (1991) S-Kinoprene Technical Active Ingredient Product Identity and Disclosure of Ingredients: Lab Project Number: 52291. Unpublished study. 15 p.
- 41898902 Baer, T. (1991) Manufacturing Process Description and Discussion of the Formation of Unintentional Ingredients for S-Kinoprene/Enstar II: Lab Project Number: 591A. Unpublished study prepared by Sandoz Crop Protection Corp. 110 p.
- 41898903 Sandoz Crop Protection Corp. (1991) Purity Determination of ZR-777 (Kinoprene): Lab Project Number: 51491. Unpublished study. 13 p.
- 41898904 Yu, C. (1991) S-Kinoprene: Determination of n-Octanol/Water Partition Coefficient: Lab Project Number: 440065: RPT. NO. 3: RPT. NO. 1. Unpublished study prepared by Sandoz Crop Protection Corp. 38 p.

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MRID	CITATION
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|----------|---|
| 42756300 | Sandoz Agro, Inc. (1993) Submission of Toxicity Data in Support of FIFRA 6(a)(2) Requirements for S-Kinoprene. Transmittal of 1 Study. |
| 43015201 | McKeon, M. (1990) Mutagenicity Test on S-Kinoprene Technical in the in vitro Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay: Final Report: Lab Project Number: 12227/0/447. Unpublished study prepared by Hazleton Labs America, Inc. 23 p. |
| 43015202 | Ivett, J. (1990) Mutagenicity Test on S-Kinoprene Technical in vivo Mouse Micronucleus Assay: Final Report: Lab Project Number: 12227/0/455. Unpublished study prepared by Hazleton Labs America, Inc. 24 p. |

The following is a list of available documents for S-Kinoprene that may 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 Beverly Sjoblad at (703)-308-8376.

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 S-Kinoprene.

The following documents are part of the Administrative Record for S-Kinoprene and may be 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