United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA-738-R-96-003
September 1995

# Reregistration Eligibility Decision (RED)

# Starlicide (3-chloro-p-toluidine hydrochloride)

**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 active ingredient 3-chloro-p-toluidine hydrochloride, or starlicide. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Edward Setren at (703) 308-8166. Address any questions on required generic data to the Special Review and Reregistration Division representative Mark Wilhite at (703)308-8586.

Sincerely yours,

Lois Rossi, Division Director
Special Review
and Reregistration Division

Enclosures

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

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

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

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

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

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

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

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must

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

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

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

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

**By U.S. Mail:**

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

**By express:**

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

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

# REREGISTRATION ELIGIBILITY DECISION

## 3-Chloro-p-toluidine hydrochloride
## (Starlicide)

## LIST B

## CASE 2610

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

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**STARLICIDE**
**REREGISTRATION ELIGIBILITY DECISION TEAM**

**Office of Pesticide Programs:**

Biological and Economic Analysis Division

| | |
|---|---|
| Steve Jarboe | Biological Analysis Branch |
| Richard Peacock | Biological Analysis Branch |
| Joe Hogue | Economic Analysis Branch |

Environmental Fate and Effects Division

| | |
|---|---|
| Sharlene Matten | Science Analysis and Coordination Staff |
| Dana Spatz | Environmental Fate and Groundwater Branch |
| Bill Erickson | Ecological Effects Branch |

Health Effects Division

| | |
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| Tom Myers | Risk Characterization and Analysis Branch |
| Felicia Fort | Reregistration Support Chemistry Branch |
| John Leahy | Occupational and Residential Exposure Branch |
| Irving Mauer | Toxicology Branch I |

Registration Division

| | |
|---|---|
| Dan Peacock | Insecticide-Rodenticide Branch |
| Bill Jacobs | Insecticide-Rodenticide Branch |
| Mark Perry | Registration Support Branch |

Special Review and Reregistration Division

| | |
|---|---|
| Mark Wilhite | Accelerated Reregistration Branch |
| Bruce Sidwell | Accelerated Reregistration Branch |

# GLOSSARY OF TERMS AND ABBREVIATIONS

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

# GLOSSARY OF TERMS AND ABBREVIATIONS

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

## EXECUTIVE SUMMARY

As required under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended in 1988, the U.S. Environmental Protection Agency has completed its reregistration eligibility decision for the pesticide active ingredient starlicide, or 3-chloro-p-toluidine hydrochloride. This decision includes a comprehensive reassessment of the required target data base and use patterns of currently registered products. The Agency compared its risk assessment to current science and regulatory policies. Where appropriate, it has imposed changes to the terms for continued registration in order to reduce human health and environmental risks.

The Agency has determined that the uses of starlicide as currently labeled on products and specified in this Reregistration Eligibility Decision document will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration. However, the Agency is requiring new measures and use restrictions to mitigate risks to non-target organisms.

### Use Patterns

Starlicide is an avicide used to control ravens, starlings, crows, pigeons, cowbirds, grackles, blackbirds, magpies, and certain gull species. It is slow-acting and highly toxic to target species, with death occurring 1-3 days after ingestion. Use sites vary by species but include livestock and poultry feedlots, buildings and fenced noncrop areas, Federal and State wildlife refuges and protected areas, gull colonies in coastal areas, and bird staging areas and roosting sites.

### Human Health Assessment

From its review of the target database, the Agency concluded that starlicide is moderately acutely toxic when administered orally and dermally. It is corrosive to eyes and skin and is a mild to moderate dermal sensitizer. Although an acute inhalation study was not required, based on its acute toxicity properties, starlicide is assumed to be highly toxic on an acute inhalation basis. Starlicide is not a carcinogen and was negative in the three required mutagenicity assays.

Starlicide is not directly applied to food or feed crops or commodities, but is used in some areas where food or feed crops could be grown. Therefore, for broadcast applications, registrants will be required to delete such sites and include prohibitions against grazing animals or growing crops for 365 days on areas treated with starlicide baits. With these changes, no dietary exposure is expected. Since it is used in relatively small amounts, and all products except one are currently classified as restricted use, exposure to mixers and applicators is expected to be low.

### Environmental Risk Assessment

Starlicide is very highly toxic to birds and freshwater invertebrates, and moderately toxic to freshwater fish. Starlicide does not hydrolyze, but does photodegrade in water, which, based on available data, appears to be its primary route of dissipation in the environment. It also binds

to organic matter in soils. However, the Agency cannot perform a comprehensive environmental fate assessment for this chemical due to inadequacies associated with the aerobic metabolism and leaching studies. The Agency is not requiring additional environmental fate data because minimal environmental impact is expected due to the limited use of this chemical and because it is used as a bait.

Based on toxicity and exposure estimates, starlicide poses a high acute primary risk to nonendangered and endangered birds. Acute risk to both endangered aquatic invertebrates and endangered small mammals also exists.

Risk Mitigation Measures

The Agency is requiring risk reduction measures to mitigate mixer/loader and ecological risk. These include lowering the application rates on all broadcast applications, which are currently as high as 0.5 lb a.i./A, to 0.1 lb a.i./A, requiring prebaiting to ensure rapid bait acceptance by target species, and restricting the use of treated baits to at least 50 ft. from bodies of water. In addition, because of its potential high risk to non-target mammals and birds, the only remaining starlicide end-use product which is currently classified for general use, is being changed to restricted use. The Agency is also requiring a respirator for mixers/loaders of packages containing one pound or more of starlicide concentrate, because of its presumed high acute inhalation toxicity.

Additional ecological toxicity data to assess risk to freshwater invertebrates or marine/estuarine species are not required because the prescribed risk mitigation measures will reduce the likelihood that starlicide or its degradates will be available for runoff.

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

## I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of 3-chloro-p-toluidine hydrochloride, hereafter referred to as starlicide. The document consists of six sections. Section I is the introduction. Section II describes starlicide, 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 starlicide. Section V discusses the requirements for its reregistration. 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 Names:** Starlicide, DRC-1339
- **Chemical Name:** 3-Chloro-p-toluidine hydrochloride
- **CAS Registry Number:** 7745-89-3
- **OPP Chemical Code:** 009901
- **Empirical Formula:** $C_7H_9Cl_2N$
- **Basic Manufacturer:** PM Resources Inc.

### B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of current uses of starlicide is in Appendix A.

**Type of Pesticide:** POISON, SINGLE DOSE (Avicide)

**Use Sites:**

TERRESTRIAL FOOD CROP[1]

Bird Staging Areas (Including broadcast applications in cut hay fields, grassy areas, orchards, stubble fields)

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[1] Although there are uses currently on starlicide labels which may result in use in areas where food or feed crops are grown, these uses must be deleted or modified, as specified in this document. After these uses are removed from labels, there will no longer be food/feed uses for starlicide.

Bird Staging Areas in Rice Growing Areas (Including broadcast applications in areas under blackbird flight lines near roosts, which are fallow stubble fields, harvested hay fields, open grassy areas and pastures)

TERRESTRIAL NON-FOOD CROP

Bird Nesting Areas (In coastal nesting areas of certain gulls within predation range of important nesting colonies of colonial nesting birds)

Bird Roosting or Loafing Areas (Including bridges, buildings, electrical power stations, electrical towers, flat roof tops, fenced areas, industrial sites)

Bird Staging Areas (Including bare ground noncrop areas, cut hay fields (in bait dispensers), grassy noncrop areas, near night time roosting sites, orchards (nonbearing or in bait dispensers), roadsides, roads (unused gravel or dirt), trails, open areas, rooftops, industrial and commercial structures, stubble fields (in bait dispensers) and secured parking areas)

Bird Staging Areas in Rice Growing Areas (includes areas under blackbird flight lines near roosts, which are fallow stubble fields (in bait dispensers), harvested hay fields (in bait dispensers), open grassy or bare-ground noncrop areas, roadsides, ungrazed pastures (in bait dispensers) and other noncrop areas

Citrus Fruits (Bait box application only; confined to 5 counties in Texas)

FEEDLOT GROUP (non/food/feed areas only)

Beef cattle , dairy cattle, poultry, livestock and swine feedlots
Fodder/Silage Bags (bags must be unbroken)

Poultry Operations (outside of pens, buildings or range areas)
Rangeland and pastureland areas where birds feed on newborn livestock (uneaten bait and dead birds must be removed)

Refuges or other areas where pest birds prey upon protected species.

Sunflowers (Decoy fields)

**Target Pests:**

Black-billed Magpies, Blackbirds (unspecified), Boat-tailed Grackles, Brewer's Blackbirds, Brown-headed Cowbirds, Common Crows, Common Grackles, Common Ravens, Great Black-backed Gulls, Great-tailed Grackles, Herring Gulls,

Pigeons, Red-wing Blackbirds, Rusty Blackbirds, Ring-billed Gulls, Starlings, Tri-colored Blackbirds, Yellow-headed Blackbirds and White-necked Ravens.

**Types/Formulations Registered:**

| | |
|---|---|
| Technical Grade Active Ingredient | |
| Solid | 97.0000% |
| End Use Product | |
| Bait/Solid | 00.1000% |
| Soluble Concentrate/ | |
| Solid | 98.0000% |

**Methods and Rates of Application:**

Types of Treatment: Bait application.

Equipment: Aircraft.; Bait box.; By hand.; Glove.; Ground.; Scoop.

Timing: See Appendix A

**Use Practice Limitations:**

See Appendix A

## C. Estimated Usage of Pesticide

Approximately 110 pounds of starlicide active ingredient is applied annually in the United States. It is applied entirely to non-crop areas for control of bird pests. Starlicide is applied by treated bait, and treatments are preceded by a non-treated "pre-bait" to determine the presence of non-target species. Typically, about 85-90 percent of the applications are ground applications with a broadcast spreader, with nearly all of the rest being aerial broadcast applications.

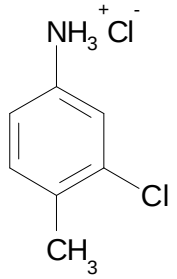
## D. Regulatory History

The first product containing starlicide was registered in 1967. Currently, there are 15 product registrations; 7 Federal and 8 state.

## III. SCIENCE ASSESSMENT

### A. Physical Chemistry Assessment

The physical/chemical characteristics, including the molecular structure, of starlicide are described below.




Molecular weight: 141.6

Starlicide is a granular, gray-colored powder with a mothball-like odor. It has a melting point of 220-230°C and a density of 0.44 g/mL. Its solubility in water is 91 g/L at 30°C, vapor pressure is $1.408 \times 10^{-2}$ Pascals at 25°C and the pH is 2.67. Starlicide is stable at normal temperatures.

### B. Human Health Assessment

#### 1. Toxicology Assessment

The toxicological data base on starlicide is adequate and will support reregistration eligibility.

##### a. Acute Toxicity

Acute toxicity studies performed using 95-98% technical grade starlicide have been submitted and adequately satisfy the Agency's requirements for reregistration. The table below summarizes the values and categories for each reviewed study.

| Acute Toxicity Values | | | |
|---|---|---|---|
| **Study** | **Results** | **Category** | **MRID No.** |
| Acute Oral $LD_{50}$ rat | males 350 mg/kg<br>females 302 mg/kg | II | 41632101 |
| Acute Dermal $LD_{50}$ rabbit | > 2000 mg/kg | III | 41632102 |
| Acute Inhalation[a] | not required | I | N/A |
| Eye Irritation rabbit[b] | corrosive | I | 41632103 |
| Dermal Irritation rabbit[b] | corrosive | I | 41632104 |
| Dermal Sensitization guinea pig[b] | mild to moderate sensitizer | - | 42201101 |

a An acute inhalation study was not required for starlicide since the technical material is incorporated in small amounts into various baits. Based on the severely irritating properties observed in the ocular and dermal irritation studies, starlicide has been placed in toxicity category I for acute inhalation.

b This study is a requirement for manufacturing-use and end-use products (40 CFR Section 158). For starlicide data have been generated on the TGAI and are presented here for informational purposes.

From an acute oral toxicity study with rats, the $LD_{50}$ was estimated to be 350 mg/kg for males and 302 mg/kg for females (MRID 41632101). An acute dermal toxicity study with rabbits estimated the $LD_{50}$ to be greater than 2000 mg/kg (MRID 41632102).

Starlicide is considered to be corrosive, both dermally and ocularly, when administered to rabbits (MRIDs 41632103 and 41632104).

A guinea pig dermal sensitization study conducted by the modified Buehler method demonstrated that starlicide was a mild to moderate sensitizer (MRID 42201101).

### b. Subchronic Toxicity

Based on the very low volume used and the restricted use nature of its application, the Agency does not believe the potential exists for significant exposure of production workers or applicators to starlicide. Therefore, a subchronic toxicity study is not required.

### c. Chronic toxicity and Oncogenicity

While not required due to starlicide's current use patterns, the Agency thought it noteworthy to mention a study conducted by the National Cancer Institute. This study conducted with rats and mice indicates that starlicide is not oncogenic, since the administration of the free base (3-chloro-p-toluidine) for 78 weeks to rats and mice produced only body weight depression at 3,629 ppm, the highest dose treated. There were no other clinical signs or induced tumors noted (MRID 40408814).

### d. Developmental Toxicity

Based on the use characteristics of this active ingredient, the Agency does not believe the potential exists for repeat oral, dermal or inhalation exposures to production workers or applicators. Therefore, a developmental toxicity study is not required.

### e. Mutagenicity

An Ames Assay with Salmonella strains TA1535, TA1537, TA1538, TA98, and TA100 was conducted. Starlicide was negative for inducing reverse gene mutation at the histidine locus when tested at levels up to 2,500 $\mu$g/plate with and without metabolic activation (MRID 41605301). Starlicide was also negative for inducing forward mutation at the HPRT locus of Chinese hamster ovary (CHO) cells exposed *in vitro* with and without metabolic activation to cytotoxic/precipitating doses up to 600 $\mu$g/mL (MRID 41605303).

In an *in vitro* chromosomal aberration test in CHO cells, starlicide was positive in a dose-related manner for structural aberrations in S9-activated cultures when exposed to moderately cytotoxic doses of 250 or 350 $\mu$g/mL. However, starlicide was negative in the absence of metabolic activation when exposed to cytotoxic doses up to 350 $\mu$g/mL (MRID 41605302).

## 2. Exposure Assessment

### a. Dietary Exposure

The Agency considers the uses of starlicide to be non-food. Therefore, residue chemistry data or tolerances are not required, and a dietary exposure assessment is not needed. However, for broadcast applications, the registrants must drop certain sites (orchards and grasslands) and include a 365 day prohibition on grazing animals and growing crops on lands treated with starlicide baits, for the Agency to consider these uses of starlicide to be nonfood.

### b. Occupational and Residential

Several factors affect occupational exposure. Starlicide concentrate is a restricted use pesticide to be handled only by (or under the direct supervision of) certified applicators. One end-use product (EPA Reg. No. 67517-8), containing 0.1% active ingredient intended for use in cattle and poultry feeding lots, is currently classified for general use, but is now

being classified as restricted use, as described in this document. Starlicide concentrate is packaged in one gram, one ounce, and one pound quantities. The concentrate is dissolved in water or edible oil, and the solution is then poured over the bait material and allowed to air dry at ambient temperatures. Egg baits are produced by injecting the solution into eggs with a hypodermic needle. There are no residential uses registered for starlicide.

In addition, approximately 85 to 90% of the applications are ground applications where 1-2 acres are treated on foot by the applicator with a broadcast spreader. Nearly all of the remaining percentage is applied aerially or by using mechanical ground equipment when more than a few acres are treated. Because starlicide is relatively unstable, particularly in sunlight, starlicide is usually mixed and applied the same day.

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators) during use or to persons entering treated sites after application is complete. Starlicide and its uses meet these criteria as explained below.

Handler (Mixer/Loader/Applicator) Exposures

The Agency expects that for handlers mixing starlicide concentrate from 1 gram and 1 ounce packages, the potential for respiratory exposure is negligible because the small size of the containers means that a very small amount of starlicide is available to result in inhalation exposure by becoming airborne or through volatilization. However, the Agency is concerned about potential respiratory exposure to handlers mixing starlicide concentrate in the 1 lb. quantity. This concern is based on starlicide's acute inhalation toxicity (category I), its relatively high vapor pressure ($1.4 \times 10^{-2}$ Pa at 25°C), and the potential for greater quantities of the powdered starlicide concentrate to become airborne or to volatilize while handling the 1-pound package, measuring the concentrate, or mixing the powdered concentrate with water or edible oil under field conditions.

Post-Application Exposure

The Agency has determined that there is potential for only minimal exposure to persons entering treated sites after application, such as re-entering poultry and livestock areas where the bait has been applied. While the toxicity triggers for requiring post-application exposure data are met, the Agency sees no need to require these data due to the presumed low level of exposure.

### 3. Risk Assessment

#### a. Dietary

The Agency considers the uses of starlicide to be nonfood, and thus a dietary risk assessment is not needed.

#### b. Occupational and Residential

In most cases small volumes of starlicide are handled and exposure is expected to be minimal. When large volumes are handled, such as packages containing one pound or more of concentrate, the Agency believes that there may be a risk of inhalation toxicity to mixers/loaders. A respirator would minimize inhalation exposure and risk to these workers. Based on this reasoning, the Agency concludes that a quantified worker risk assessment is not necessary. Also, for reasons stated above for post application scenarios, a risk assessment was not conducted.

## C. Environmental Assessment

### 1. Ecological Toxicity Data

The Agency has adequate data to characterize the primary toxicity of starlicide to nontarget terrestrial organisms.

#### a. Toxicity to Terrestrial Animals

##### (1) Birds - Acute and Subacute

In order to establish the toxicity of starlicide to birds, the following tests are required using technical-grade material: an avian single-dose oral ($LD_{50}$) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies ($LC_{50}$) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail). These studies have been conducted and reviewed. The Agency's conclusions follow.

| Avian Acute Oral Toxicity Findings | | | | |
|---|---|---|---|---|
| **Species** | **% A.I.** | **$LD_{50}$ (mg/kg)** | **MRID No.** | **Toxicity Category** |
| Northern Bobwhite Quail | 97.1 | 2.9 | 41760503 | very highly toxic |
| Mallard Duck | 97.1 | 105 | 41760502 | moderately toxic |

| Avian Subacute Dietary Toxicity Findings | | | | |
|---|---|---|---|---|
| **Species** | **% A.I.** | **$LC_{50}$ (ppm)** | **MRID No.** | **Toxicity Category** |
| Northern Bobwhite Quail | 98 | 14.1 | 42671802 | very highly toxic |
| Mallard Duck | 98 | 322 | 42671801 | highly toxic |

As would be expected given starlicide's pesticidal qualities, results of the above studies indicate that starlicide is moderately to very highly toxic to avian species on an acute oral and subacute dietary basis. The guideline requirements are fulfilled. (MRID 41760502, 41760503, 42671801, 42671802)

### (2) Birds - Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Because starlicide is acutely toxic to birds, chronic exposure is unlikely. Therefore, avian reproduction testing is not required.

### (3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. Data from an acute oral $LD_{50}$ study on rats (MRID 41632101), previously mentioned in section III.B., suggest that technical starlicide is moderately toxic to small mammals on an acute oral basis ($LD_{50}$ was 350 mg/kg for males and 302 mg/kg for females).

### (4) Insects

A honey bee acute contact $LD_{50}$ study is required if the proposed use will result in honey bee exposure. Because starlicide

applications are not likely to result in exposure to honey bees, data are not required.

### b. Toxicity to Aquatic Animals

#### (1) Freshwater Fish

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two acute toxicity studies. One study should use a cold-water species (preferably the rainbow trout), and the other should use a warm-water species (preferably the bluegill sunfish).

The results of the 96-hour acute toxicity studies indicate that starlicide is moderately toxic to cold- and warm-water fish. The guideline requirements are fulfilled. (MRID 41767501, 41767502)

| Freshwater Fish Acute Toxicity Findings | | | | |
|---|---|---|---|---|
| **Species** | **% A.I.** | **$LC_{50}$ (ppm)** | **MRID No.** | **Toxicity Category** |
| Rainbow trout | 96.3 | 9.7 | 41767502 | moderately toxic |
| Bluegill sunfish | 96.3 | 10.5 | 41767501 | moderately toxic |

#### (2) Freshwater Invertebrates

The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate acute toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

There is sufficient information to characterize starlicide as very highly acutely toxic to aquatic invertebrates. The guideline requirement is fulfilled. (MRID 41783701)

| Freshwater Invertebrate Toxicity Findings | | | | |
|---|---|---|---|---|
| **Species** | **% A.I.** | **$EC_{50}$ (ppm)** | **MRID NO.** | **Toxicity Category** |
| *Daphnia magna* | 96.3 | 0.07 | 41783701 | very highly toxic |

Because starlicide may be transported to water from application sites, and because the $EC_{50}$, the exposure at which 50% of the exposed organisms exhibit the evaluated effect, is less than 1 ppm and the EEC in water is greater than 0.01 of the acute $EC_{50}$,

data from an aquatic invertebrate life cycle study are generally required. However, if prebaiting is required to insure rapid acceptance of treated bait, little toxicant would likely be available for run-off. Also, a restriction of application of treated baits to at least 50 feet from water would lessen exposure to aquatic organisms. Therefore, if prebaiting and distance restrictions are required for all products, the value of the additional data is considered to be low.

**(3) Estuarine and Marine Animals**

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. Because of the use site and application methods of the starlicide product registered for use to control gulls (EPA Reg. No. 56228-17), exposure of starlicide to marine/estuarine organisms is possible. However, because of the limited use of this product, the value of the additional information is considered to be low.

**c. Toxicity to Plants**

**(1) Terrestrial and Aquatic**

Terrestrial and aquatic plant testing (seedling emergence and vegetative vigor) is required for herbicides which have terrestrial non-food/feed or aquatic non-food (except residential) use patterns and which have endangered or threatened plant species associated with the site of application. Because starlicide is not a herbicide, plant testing is not required.

**2. Environmental Fate**

The environmental fate data requirements are fulfilled for hydrolysis, photodegradation in water, and bioaccumulation in fish, but are unfulfilled for aerobic soil metabolism, unaged leaching-adsorption/desorption and aged leaching studies. Because of the deficiencies in these key studies, a comprehensive environmental fate and transport assessment cannot be made at this time. Based on the available information, a tentative environmental data assessment has been made. Due to the lack of sound data, the soil metabolism and mobility of starlicide are not well understood. However, the environmental impact from starlicide is expected to be minimal because the use is limited and it is applied in bait.

**a. Environmental Fate Assessment**

Starlicide is highly soluble in water (91 g/L) and has a relatively high vapor pressure. It has an estimated $pK_a$ of 3.9 for protonation of the amine group; consequently, in soils at pH values >4.8, over 90% of the starlicide will be in the free amine form, and in soils below pH 3, the ammonium ion form of starlicide will be the major species.

Based on the acceptable studies received to date, starlicide does not degrade through hydrolysis in sterile water at pH's 5, 7, or 9, but does photodegrade in water with a half-life of approximately 16 hours. The major degradate was identified as 3-hydroxy-p-toluidine (HPT). Starlicide accumulates only slightly in bluegill sunfish with bioconcentration factors (BCF's) in the range of 33x to 150x. Therefore, the primary route of dissipation, based on the acceptable data, is photolysis in water.

Because the loam soil chosen to conduct the aerobic soil metabolism study was very high in organic matter content (8.2%) and therefore not representative of all the use sites, the data generated were of limited value. Starlicide apparently binds to organic matter and in this study, a major portion was bound almost immediately after treatment.

A similar situation applies to the aged column leaching study, which was also conducted with the loam soil with an organic matter content of 8.2%. Because binding is often correlated with soil organic matter content, the use of this high organic soil likely resulted in a limited characterization of the mobility of aged starlicide residues. In addition, the study did not adequately address the mobility of the primary soil degradate, N-acetyl-3-chloro-4-methylaniline, nor did it address the major degradate found in the photodegradation in water study, 3-hydroxy-p-toluidine (HPT), and therefore, did not satisfy the major objective of the data requirement.

Concerning the adsorption/desorption data requirement for parent starlicide, only preliminary studies were conducted. Definitive batch equilibrium studies were not performed. It was reported that equilibrium ("as indicated by a constant value of the concentration of starlicide in the supernatant") was not reached in the adsorption phase of the 2-3 day preliminary experiment. However, based on the kinetics data provided in the study, the Agency believes that equilibrium was nearly achieved after approximately 48-72 hours.

## b. Environmental Fate and Transport

### (1) Degradation

#### (a) Hydrolysis

Starlicide, (3-chloro-p-toluidine hydrochloride; purity 98.14%), at 20.94 $\mu$g/mL, did not hydrolyze during 30 days of incubation in aqueous buffer solutions that had been adjusted to pH 5, 7, and 9 and incubated in the dark at 25 $\pm$ 1°C. In the pH 5 solutions, starlicide averaged 100-101% of the applied through 139 hours post-treatment, 97.1-98.7% at 331 through 546 hours, and 94.6-96.6% at 643 and 715 hours. In the pH 7 and 9 solutions, starlicide averaged 97.9-101 and 98.4-101% of the applied, respectively, throughout the 30-day incubation period. During the study, material balances ranged from 93.1 to 103% of the applied. This study fulfills the hydrolysis data requirement. Starlicide does not degrade in water through hydrolysis at environmentally significant pH's. (MRID 41760501)

#### (b) Photodegradation in Water

Starlicide (purity 99.1%), photodegraded with a half-life of approximately 16 hours in an aqueous buffer solution (0.001 M phosphate; pH 7) that was continuously irradiated for 30 hours using a Pyrex glass-filtered, 300-watt xenon lamp. Starlicide decreased from an average concentration of 1.07 ppm immediately post-treatment to 0.82 ppm after 6 hours, 0.58 ppm after 12 hours, 0.43 ppm after 18 hours, and 0.30 ppm after 30 hours of irradiation. The maximum half-lives of starlicide in sterile buffer solution, calculated from the quantum yield, were estimated to be 6.3 hours under summer sunlight conditions, 16 hours under fall sunlight, 41 hours under winter sunlight, and 9.2 hours under spring sunlight. Starlicide was stable in the dark control, averaging 1.07 ppm immediately post-treatment, 1.01 ppm at 18 hours, and 1.03 ppm at 24 hours.

Ring-labeled [U-$^{14}$C]starlicide (radiochemical purity $>$98%), at 6.2 ppm, photodegraded with an observed half-life of $>$18 hours in aqueous buffer solutions irradiated under similar conditions for 18 hours. [$^{14}$C]starlicide

decreased from 100% of the applied radioactivity immediately post-treatment to 80.8-81.1% after 6 hours, 70.4-71.8% after 12 hours, and 57.2% after 18 hours of irradiation. One [$^{14}$C]degradate, 3-hydroxy-p-toluidine (HPT), was identified in the irradiated solution. [$^{14}$C]HPT increased from 0% of the applied immediately post-treatment to 20.4-20.7% after 6 hours, 32.2-35.1% after 12 hours, and 46.8% after 18 hours of irradiation. Material balances ranged from 100 to 107% of the applied radioactivity.

This study fulfills the photodegradation in water data requirement. Starlicide photodegraded with a half-life of approximately 16 hours in an aqueous buffer solution that was continuously irradiated for 30 hours using a filtered xenon lamp. One degradate, 3-hydroxy-p-toluidine (HPT), was identified. (MRID 42838801)

**(2) Mobility**

**(a) Aerobic Soil Metabolism**

The soil chosen for this study was not the recommended sandy loam or silt loam, but a loam soil high in organic matter content (8.2%). Starlicide apparently binds strongly to organic matter and in this study, a major portion was bound almost immediately after treatment. By day two, as much as 70.6% of the applied radioactivity was considered bound. The soil half-life calculated by the registrant (25.3 hours), is therefore more indicative of soil binding than starlicide's potential to degrade under aerobic conditions. This was further demonstrated by a preliminary study in which the study author, based on the similar half-lives of starlicide in nonsterile and sterile (autoclaved) soil, attributed the "initial rate loss" to the binding of starlicide to the soil rather than to degradation resulting from metabolism of starlicide. While some degradation did occur, (i.e., small amounts of N-acetyl-3-chloro-p-toluidine (ACPTH) were identified through 96 hours and up to 12.8% of the total radioactivity after 99 days was identified as $^{14}CO_2$), it was clear that the disappearance of starlicide was due primarily to its binding to the soil.

Starlicide (3-chloro-p-toluidine hydrochloride) dissipated with a calculated half-life of 25.3 hours in loam soil that was incubated in the dark at approximately 22²C and 68% of field moisture capacity for 99 days. The only degradate identified, N-acetyl-3-chloro-p-toluidine (ACPTH), was at a maximum at one day post-treatment and exhibited a pattern of dissipation similar to that of starlicide. The dissipation of starlicide could be attributed primarily to soil binding.

This study does not satisfy the aerobic soil metabolism data requirement, but does provide supplemental information. In order to understand the nature and extent of microbial degradation of starlicide in soil, an additional aerobic soil metabolism study with either a sandy loam or silt loam and an organic matter content of less than 2% would be needed. (MRID 43284501)

**(b) Adsorption/Desorption**

The study submitted also does not satisfy the unaged adsorption/desorption data requirement, but provides supplemental information. Definitive batch equilibrium studies were not conducted. It was reported that equilibrium (as indicated by a constant value of the concentration of starlicide in the supernatant) was not reached in the adsorption phase of the 2-3 day preliminary experiment, therefore, a definitive experiment was not conducted. However, based on the kinetics data, the Agency believes that equilibrium was nearly achieved after approximately 48-72 hours.

Preliminary Kd's, based on the "non-GLP" kinetics study at a single concentration, were 69, 3.7, 7.0, 3.7, and 8.8 for the loam soil, two sandy loams, a silty clay, and a clay sediment, respectively.

In order to better assess the mobility of unaged starlicide, a soil column leaching study or preferably, a batch equilibrium study that provides Freundlich Kd's would be required. (MRID 43284502)

### (c) Aged Leaching

This study provides supplemental information concerning the mobility of aged starlicide in a soil high in organic matter content. However, the study does not adequately address the mobility of the major degradates, N-acetyl-3-chloro-4-methylaniline and 3-hydroxy-p-toluidine (HPT), and therefore, does not satisfy the major objective of the data requirement. In addition, the soil chosen for this study was not representative of all the potential use areas with respect to percent organic matter. Because binding is often correlated with soil organic matter content, the use of this high organic soil likely resulted in a limited characterization of mobility.

Aged (24 hours) starlicide residues were not mobile in 45 cm columns of loam soil that were leached with 450-600 ml of a 0.01 M calcium sulfate solution. Prior to leaching, each column was topped with loam soil that had been treated with starlicide (3-chloro-p-toluidine hydrochloride) and aged under aerobic conditions for 24 hours. In the soil columns, 84.3-95.3% of the applied radioactivity remained in the upper 6 cm of soil and 1.7-2.5% was isolated in the column leachates. The degradate N-acetyl-3-chloro-4-methylaniline was isolated in only the upper 6 cm of the soil column and amounted to approximately 1.3% of the applied.

This study does not satisfy the aged leaching data requirement, but does provide supplemental information. Additional studies would be required to characterize the mobility of N-acetyl-3-chloro-4-methylaniline and HPT in various soils. (MRID 43284503)

## (3) Accumulation

### (a) Accumulation in Fish

Starlicide residues accumulated only slightly in bluegill sunfish exposed to starlicide hydrochloride at 0.1 mg/L for 28 days under flow-through conditions. Average calculated bioconcentration factors were 33x, 150x, and 88x for edible tissues (muscle), nonedible tissues (carcass and viscera), and whole fish, respectively. Maximum mean

concentrations of starlicide residues were 3.6 mg/kg in the edible tissues after 14 days of exposure, 17 mg/kg in the nonedible tissues after 28 days, and 9.3 mg/kg in the whole fish after 28 days. One major degradate, N-acetyl-3-chloro-4-methylaniline, was identified from fish (all tissue substrates) collected after 28 days of exposure. Depuration was relatively slow; after 28 days of depuration, 54.3% of the accumulated [$^{14}$C]residues were eliminated from the edible tissues, 64.1% from the nonedible tissues, and 63.4% from the whole fish.

This study fulfills the fish accumulation data requirement. Starlicide only slightly accumulates in bluegill sunfish. Accumulated residues depurate somewhat slowly. (MRID 43069801)

## 3. Exposure and Risk Characterization

### a. Ecological Exposure and Risk Characterization

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

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

When the risk quotient is greater than or equal to the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented along with the corresponding LOC's.

**Levels of Concern (LOC) and associated Risk Presumption**

**Mammals, Birds**

| IF THE | LOC | PRESUMPTION |
|---|---|---|
| acute RQ $\geq$ | 0.5 | High acute risk |
| acute RQ $\geq$ | 0.2 | Risk that may be mitigated through restricted use |
| acute RQ $\geq$ | 0.1 | Endangered species may be affected acutely |

**Fish, Aquatic invertebrates**

| IF THE | LOC | PRESUMPTION |
|---|---|---|
| acute RQ $\geq$ | 0.5 | High acute risk |
| acute RQ $\geq$ | 0.1 | Risk that may be mitigated through restricted use |
| acute RQ $\geq$ | 0.05 | Endangered species may be affected acutely |

**(1) Exposure and Risk to Nontarget Terrestrial Animals**

Nontarget birds and mammals may be at risk from either primary or secondary exposure to starlicide. A primary hazard occurs if an animal eats treated bait. Secondary hazard occurs if a predator or scavenger eats a target or nontarget animal that has fed on treated bait.

**(a) Birds**

**Primary risks:** RQs for a broadcast food bait are based on the number of $LD_{50}$s applied per square foot and are determined as follows:

$RQ = LD_{50}/ft^2 = mg\ ai/ft^2 \div (LD_{50})(body\ wt, kg)$

where $mg\ ai/ft^2 = (lb\ ai/acre)(453{,}590\ mg/lb) \div 43{,}560\ ft^2/acre$

RQs, which are equal to $LD_{50}/ft^2$, for maximum applications in staging areas (i.e., stubble fields, cut hay fields, orchards, roadsides, grassy areas, bare ground), sunflower fields, feedlots, and rooftops and fenced noncrop areas are tabulated below for four bird species for which body

weights and $LD_{50}$ values are available. These species are presumed to represent all bird species that might consume starlicide-treated bait. Body weights used in the calculations were obtained from Kenaga (1973) and Dunning (1984). $LD_{50}$ values for the mourning dove (3.1 mg/kg) and red-winged blackbird (2.4 mg/kg) were obtained from information submitted to the Agency by the USDA/APHIS/Denver Wildlife Research Center (DWRC) in 1991 to support starlicide products (EPA Reg. Nos. 56228-10 and -17).

| Estimated Risk Quotients (RQs) for birds | | | |
|---|---|---|---|
| **Species (body weight)** | **Application rate (lb ai/acre)** | **Est. no. $LD_{50}$s/$ft^2$** | **LOC[1]** |
| Mallard (1082 g) | 0.5[2] | 0.05 | HR $\geq$ 0.5<br>RU $\geq$ 0.2<br>ES $\geq$ 0.1 |
| | 0.125[3] | 0.01 | |
| Bobwhite quail (178 g) | 0.5 | **10.1** | |
| | 0.125 | **2.5** | |
| | 0.09[4] | **1.8** | |
| | 0.05[5] | **1.0** | |
| | 0.04[6] | **0.8** | |
| Mourning dove (100 g) | 0.5 | **16.8** | |
| | 0.125 | **4.2** | |
| | 0.09 | **3.0** | |
| | 0.05 | **1.7** | |
| | 0.04 | **1.3** | |
| Red-winged blackbird (53 g) | 0.5 | **40.9** | |
| | 0.125 | **10.2** | |
| | 0.09 | **7.4** | |
| | 0.05 | **4.1** | |
| | 0.04 | **3.3** | |

[1]LOCs: HR=high risk; RU=restricted use; ES=endangered species
[2]staging areas (LA)
[3]staging areas (IN,KY,TN,TX)
[4]staging areas; feedlots (concentrate); sunflower fields (ND)
[5]rooftops and fenced noncrop areas; feedlots (0.1% pellets)
[6]staging areas (TX)

Based on the number of $LD_{50}$s/$ft^2$ for the bobwhite quail, mourning dove, and red-winged blackbird, and because starlicide is a very highly toxic acute avicide, high acute risk is presumed for granivorous birds that consume starlicide treated baits. This

presumption of high acute risk to birds is supported by adverse effects information submitted by the DWRC in 1991, which indicates that primary poisoning of some nontarget birds is likely during many starlicide baiting operations. Although RQs cannot be determined for raptors and avian scavengers that might consume meat or egg baits, or nontarget species that might eat bread/margarine baits intended for gulls, acute high risk is presumed, because such baits are designed to be lethal to target bird species.

**Birds - Secondary Risks:** The Agency does not have data to assess secondary risks to birds, although some indications of risk can be made from information previously submitted by the DWRC. The information includes summaries of published and unpublished laboratory and field studies with starlicide. Studies have included the metabolism of starlicide in target species, effects of feeding starlicide killed birds to captive predator or scavenging species, and carcass searches conducted in conjunction with efficacy field tests.

According to the DWRC, orally ingested starlicide is absorbed rapidly in the gut and converted into three major metabolites: N-(3-chloro-4-methylphenyl)acetamide (CAT), 4-acetylamino-2-chlorobenzoic acid (CPTC), and 4-amino-2-chlorobenzoic acid (CPTD). CAT is similar in toxicity to starlicide, whereas CPTC and CPTD have not shown any signs of toxicity in rats at 4800 mg/kg or in red-winged blackbirds at 316 mg/kg. Target species that ingest starlicide will die after 1-3 days, with death resulting from a build-up of uric acid. According to Cunningham et al. (1979), less than 10% of the 3.16-100 mg/kg of starlicide administered to starlings was retained in the body 30 minutes after treatment. Whole body residues of starlicide or CAT at death were 1-2 ppm, independent of dosage level or time to death. Metabolism in mammals is reported to be similar to that in birds but is slower.

The following starlicide $LD_{50}$ values to raptors and avian scavengers have been reported by the DWRC:

| Acute Oral Toxicity to Avian Raptors and Scavengers | |
|---|---|
| **Species** | **$LD_{50}$ (mg/kg)** |
| American crow (*Corvus brachyrhynchos*) | 1.3 |
| Barn owl (*Tyto alba*) | 4.2 |
| Black-billed magpie (*Pica pica*) | 10 |
| Common raven (*Corvus corax*) | 13.3 |
| Marsh hawk (*Circus cyaneus*) | 100 |
| Golden eagle (*Aquila chrysaetos*) | >100 |
| American kestrel (*Falco sparverius*) | 178 |
| Cooper's hawk (*Accipiter cooperii*) | 562 |

Laboratory studies with hawks and American kestrels indicated no adverse effects when they were fed starlings poisoned with 1% starlicide-treated baits. Two kestrels survived eating 11 and 60 poisoned starlings over 24 and 141 days, respectively. Two Cooper's hawks ate 191 and 222 starlings with no observable adverse effects. Three marsh hawks ate 100, 191, and 222 starlings over 75-104 days and survived with no apparent detrimental effects. The $LD_{50}$ values tabulated above suggest, however, that other avian predators and scavengers (e.g., crows, ravens, owls, magpies) are acutely more sensitive to starlicide than are hawks and kestrels.

Numerous efficacy field trials have been conducted for blackbird control in staging areas. Other studies conducted on blackbirds in feedlots, ravens preying on young livestock, pigeons on structures, and gulls on islands provide additional information. Many of these studies reported the nontarget species observed, including predators and scavengers, their potential exposure to starlicide, and conducted carcass searches for nontarget species.

DWRC previously submitted the following summarized information from more than 70 field and operational reports:

> **Feedlots:** From 22 references regarding the use of starlicide in feedlots, the following birds were observed feeding on dead or dying birds: great-horned owl, marsh hawk, red-tailed hawk, short-eared owl, and magpie. The number of birds involved was not indicated. American

kestrels were reported in the area of one operation but were not observed feeding on dead or dying birds.

**Urban pigeons:** From 12 studies, the following species were observed feeding on dead or dying birds: gull, crow.

**Staging areas:** From 16 studies, the following observations were made: owls were in the area of operation, but none were known to have fed on dead or dying birds.

**Livestock depredations:** From 22 studies, no predator or scavenging avian species reported in the area was known to have been impacted by secondary poisoning.

**Gulls on breeding islands:** A number of studies conducted from 1969-73 notes that the only nontarget kill was a crow that apparently ingested a treated bait. No instances of scavenger or predatory birds consuming treated gulls were observed.

The available information on the metabolism of starlicide in target birds, feeding trials with captive hawks and kestrels, and observations made in many efficacy field trials indicates that some avian predators and scavengers will eat poisoned birds. Because starlicide is slow-acting and intoxicated birds may die some distance from the treatment site, carcasses from secondary poisoning could be overlooked during searches for nontarget kills. However, there are no indications that diurnal birds of prey (hawks, kestrels, eagles) are at significant risk. Information regarding secondary risks to more highly sensitive species (e.g., owls, ravens, crows, magpies) is lacking.

High acute primary risk to non-target bird populations exists for all registered uses of starlicide. This presumption of risk is supported by the above risk quotients, as well as the adverse effects and incident reports submitted to the Agency. Lowering the maximum application rates and prebaiting would decrease the high acute risk to non-target birds especially for bird control in "staging areas".

**(b) Mammals**

**Primary risks:** Starlicide baits are most likely attractive to a variety of rodents and other small mammals

because of the kinds of food (e.g., cracked and whole grains, raisins, pellets, bread, french fries, meat, eggs) used to make baits. RQs, based on the number of $LD_{50}s/ft^2$, were calculated as for birds. They are tabulated below for the highest application rates used to control birds in staging areas, where small mammals would be expected to be present and encounter baits. RQs are calculated for three rodent species for which toxicity values are available. The acute oral $LD_{50}$ value of 330 mg/kg for the laboratory rat was obtained from data submitted to the Agency to evaluate potential human hazards from starlicide. $LD_{50}$ values of 960 mg/kg for the laboratory mouse and 1800 mg/kg for the deer mouse were obtained from data previously submitted by the DWRC.

| Estimated Risk Quotients (RQs) for small mammals | | | |
|---|---|---|---|
| **Species (weight)** | **Applicati-on rate (lb ai/acre)** | **Est. no. $LD_{50}s/ft^2$** | **LOC[1]** |
| Lab. rat (300 g) | 0.5[2] | 0.05 | HR $\geq$ 0.5<br>RU $\geq$ 0.2<br>ES $\geq$ 0.1 |
| Lab. mouse (35 g) | 0.5 | **0.15** | |
| | 0.125[3] | 0.04 | |
| Deer mouse (20 g) | 0.5 | **0.14** | |
| | 0.125 | 0.04 | |

[1] LOCs:HR=high risk; RU=restricted use;ES=endangered species

[2] staging areas (state of LA)

[3] staging areas (states of IN,KY,TN,TX)

Based on these values, high acute risk to small mammals is not presumed for applications of starlicide baits. Risk to endangered small mammals is presumed from an application of 0.5 lb ai/acre in staging areas in Louisiana. Applications of 0.125 lb ai/acre or less do not exceed any LOC. Although RQs cannot be determined for egg and meat baits used to control ravens, crows, and/or magpies on rangeland, pastureland, or refuges, the Agency presumes that any carnivorous mammal (e.g., fox, skunk, weasel) eating such bait is at high risk.

Lowering the maximum application rates and prebaiting would decrease the high acute risk to small mammals, especially those exposed to starlicide in bird control "staging areas".

**Secondary risks:** Little information on secondary risks to mammals is available. Coyote and grey fox have been observed feeding on dead or dying birds, but the fate of those animals is not known. $LD_{50}$ values for the coyote and dog exceed 100 mg/kg, indicating that starlicide is not highly toxic to canids.

### (2) Exposure and Risk to Nontarget Aquatic Animals

**Expected Aquatic Concentrations:** Peak generic EEC values in ponded water are tabulated below for various application rates of starlicide used in staging areas and sunflower fields where runoff might occur. EEC values are based on the Agency's Generic Estimated Exposure Concentration (GENEEC) computer modeling program, and determined by application rate and method, number of annual applications, the application interval, and the available environmental fate data (solubility, hydrolysis, soil aerobic half-life, photolysis). The program estimates runoff from a 10-hectare field into a 1-hectare, 2-meter deep pond.

| Estimated Ponded Residues (ppb) | | | | | | |
|---|---|---|---|---|---|---|
| **Application rate (lb ai/acre)** | **No. applications** | **Applic-ation interval (days)** | **Peak EEC (ppb)** | **Fish RQ ($EEC/LC_{50}$)** | **Inverte-brate RQ ($EEC/EC_{50}$)** | **LOC** |
| 0.5[1] | 5* | 5* | 28.98 | 0.003 | **0.41** | HR $\geq$ 0.5<br>RU $\geq$ 0.1<br>ES $\geq$ 0.05 |
| 0.125 | 2[2]<br>5[3] | 5* | 7.24<br>7.25 | 0.0007 | **0.10** | |
| 0.09[4] | 5* | 7 | 5.09 | 0.0005 | **0.07** | |
| 0.04[5] | 4 | 5* | 2.32 | 0.0002 | 0.03 | |

* assumed; not specified on product label
1 staging areas (LA)
2 staging areas (TN)
3 staging areas (IN,KY,TN,TX)
4 staging areas; sunflower fields (ND)
5 staging areas (TX)

### (a) Freshwater Fish

As indicated in the tabulations above, freshwater fish LOCs have not been exceeded for any maximum application of starlicide bait. Therefore, the Agency presumes no undue risks to freshwater fish from registered uses of starlicide.

### (b) Freshwater Invertebrates

Based on the RQ values tabulated for freshwater invertebrates, high acute risk to aquatic invertebrates is not presumed. However, assuming maximum application rates, the endangered-species LOC is exceeded for multiple applications of 0.09 lb ai/acre or more. Therefore, acute risk to endangered aquatic invertebrates is presumed. Data are not currently available to assess chronic risk. However if prebaiting is required to ensure rapid acceptance of bait, little toxicant is likely to be available for runoff.

### (c) Endangered Species

Applications of starlicide are apt to pose a risk to endangered/threatened birds and small mammals that would be attracted to the various food baits registered for control of pest birds. Endangered aquatic invertebrates may also be adversely affected if runoff occurs from applications in staging areas and decoy sunflower fields.

## IV. RISK MANAGEMENT AND REREGISTRATION DECISION

### 1. 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 starlicide as an ingredient. 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 starlicide. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of starlicide, 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 starlicide products and to determine that starlicide, as labeled and specified in this document, can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing starlicide as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

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

## 2. Eligibility Decision

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

## 3. Eligible and Ineligible Uses

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

## 4. Regulatory Position and Risk Mitigation Measures

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

### a. Restricted Use Classification

Currently, all starlicide products are classified for restricted use with the exception of one. The restricted use classification is necessary to address the potential for harm to applicators and because products are applied to various baits and placed in a variety of areas where exposure to endangered or other non-target species could occur.

A ready-to-use 0.1% formulation, which is used in unoccupied cattle and poultry feeding structures, is the only remaining end-use product currently classified for general use. Because of the potential for adverse effects to non-target organisms which could result from the use of this product, the Agency is reclassifying it as restricted use.

**(1) Endangered Species Statement**

The Agency has concerns about the exposure of threatened and endangered animal species to starlicide as discussed above in the science assessment chapter.

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use modifications or a generic product label statement, requiring users to consult county-specific bulletins. These bulletins would provide information about specific use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses.

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

**(2) Lower Application Rates**

Acute primary risks to birds occurs at all application rates of starlicide. Decreasing application rates would decrease risks. However, the Agency is aware that application rates for nationally registered products were established from numerous efficacy tests and thus likely could not be decreased for those products without an unacceptable drop in efficacy.

However, for bird control in "staging areas", for which 8 SLN (special local needs) registrations exist, application rates vary among states and even between labels within states (i.e., TN, TX). The proposed maximum application rate on a recently registered DWRC product (EPA Reg. No. 56228-30) for staging areas is 0.09 lb ai/acre. The rate in Louisiana (LA930020) is much higher (0.5 lb ai/acre) for the same use. Rates in TX, KY, and IN (0.125 lb ai/acre) also exceed that for the new product. Reducing application rates of the SLNs to conform to that of the nationwide product

would help reduce risks in those states. Therefore the Agency, after consultations with USDA, is requiring the application rates for all product registrations not to exceed 0.1 lbs a.i./acre, which is the maximum rate of the Federal product registrations.

**(3) Prebaiting**

Currently, the various product labels differ somewhat in their requirements for prebaiting. Some labels require prebaiting, whereas others only indicate that it "may be necessary". The Agency believes that prebaiting should be required for all starlicide products. Prebaiting enables applicators to determine the best locations and time of day to apply bait and to identify the food base most acceptable to the target species. Successful prebaiting helps ensure rapid acceptance of treated bait by the target species, resulting in less bait being exposed to nontarget birds and mammals and less potential runoff into water bodies if a rainfall event occurs.

Prebaiting also allows for the identification of at least some nontarget species, particularly birds, feeding on the prebait, although nocturnal mammals may be overlooked. If the applicator determines that a nontarget species problem is likely (e.g., more than just the occasional nontarget sparrow or two would be exposed), treated bait should not be applied prior to consultation with appropriate wildlife authorities.

Other mitigation measures include baiting at another location where nontarget problems are not likely; baiting at a different time of day; or switching to a different food base that is less attractive to the nontarget species present.

**(4) Buffer Zone Restriction**

Because of the risk posed to aquatic organisms, particularly aquatic invertebrates, the Agency is requiring that treated starlicide baits be applied at least 50 feet from water. This "buffer zone" will lessen the possibility of starlicide residues contaminating nearby bodies of water where aquatic invertebrates may live.

**(5) Personal Protective Equipment Controls for Handlers**

Due to its concern for the safety of mixer/loaders of large quantities of starlicide, the Agency is requiring that, in addition to

the current PPE on starlicide labels (gloves and goggles for starlicide concentrate products), the requirement for a respiratory protection device for mixers/loaders be added to the labeling of all packages containing one pound or more of starlicide concentrate. The respiratory protection statement shall specify either a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval prefix number TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval prefix number 14G).

Additional PPE requirements may be imposed by the Agency at the time of the product reregistration based upon the acute toxicity of individual products.

#### (6) Additional Data Requirements

As discussed in the Environmental Assessment portion (III.C.) of this document, there are deficiencies in information which do not allow the Agency to do a complete environmental fate profile for starlicide, as well as assess the risk to non-target freshwater invertebrates and marine and estuarine organisms. However, because of the small amount of starlicide used each year in the United States (approximately 110 lbs.), the restricted use classification of starlicide products, required prebaiting, new lower use rates, and the new requirement of application of baits at a distance of at least 50 feet from water, the Agency is not requiring any additional environmental fate or ecotoxicity data at this time.

## 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 starlicide for the above eligible uses has been reviewed and determined to be complete.

#### 2. Labeling Requirements for End-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 avicide for use in certain bird feeding, roosting, staging and nesting areas, livestock feedlots, rangelands, pasturelands, refuges and decoy sunflower fields. "

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)."

## B. End-Use Products

### 1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

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

## 2. Labeling Requirements for End-Use Products

### a. Restricted Use Pesticide Statement

All end-use Starlicide products have been classified as "Restricted". Therefore, the following text must appear at the top of the Front Panel:

**Restricted Use Pesticide**

> "Due to Acute Hazards to Humans, Nontarget Animals and Aquatic Invertebrates, and the Need for Highly Specialized Applicator Training
>
> "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicators' certification."
>
> "For use only by U.S. Department of Agriculture personnel trained in bird control or persons under their direct supervision."

For EPA Reg. No. 67517-8 only, the last sentence may be modified to:

> "For use only by personnel specifically trained in bird control or persons under their direct supervision."

### b. Personal Protective Equipment Statement

For end-use products containing 98% active ingredient and packaged in containers of one (1) pound or more of product, add the following section to the "Hazards to Humans and Domestic Animals":

> "Personal Protective Equipment
> Handlers who mix packages containing 1 lb or more of this product must wear:
> Coveralls over long-sleeved shirt & pants
> Water-proof gloves
> Chemical-resistant footwear plus socks
> Protective eyewear
> Respirator with either an organic vapor-removing cartridge witha prefilter approved for pesticides (MSHA/NIOSH approval prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number TC-14G)"

After the Agency receives the results of the required acute toxicity testing for the 98% concentrate and 0.1% formulation end-use products, it will inform the registrants of any additional WPS requirements, such as "Entry Restrictions" for the 98% or 1% formulas.

**c. Skin Sensitization Statement:**

Because starlicide is classified as a skin sensitizer, the Agency is requiring the following statement to be located in the "Hazards to Humans and Domestic Animals" section of the Precautionary Statements on the labeling of all end-use products containing starlicide:

> "This product may cause skin sensitization reactions in some people."

**d. Use Directions (Food Uses)**

Currently, there are several sites on the label that are food use sites. Therefore, registrants with such sites must do the following:

1. Remove sites such as "fruit trees and grassland" for broadcast application.

2. For sites such as "cut hay fields" and "stubble fields", add the following restriction in the use directions:

   Do not graze animals or grow crops on treated areas for 365 days.

**e. Prebaiting**

To insure rapid acceptance of treated baits by target species, prebaiting will be required for all end-use products unless the registrant provides an acceptable rationale to the Agency why pre-baiting should be optional or not required.

**f. Buffer Zone**

To lessen the risk to aquatic invertebrates, add the following statement to the "USE RESTRICTIONS" section of the use directions:

Do not apply treated baits within 50 feet of water.

**g. Broadcast Rates Above 0.1 lb/acre**

Broadcast rates cannot exceed 0.1 lb. A.I. per acre. Registrants of non-complying products must modify their mixing directions so that rates do not exceed the above figure.

**h. Dilution of Treated Baits with Untreated Material**

If the label provides for the dilution of treated bait with untreated material, the registrant must state the minimum, mandatory dilution rate, as follows:

> Dilute treated bait with similar untreated material at a rate of at least 1 part treated material to [insert number] parts untreated material.

**i. Use of Similar Units in Bait Formulas**

Currently, calculation of bait concentrations and use rates are overly difficult because directions for mixing baits are presented inconsistently in English and Metric units, some of which are by volume and some by weight. To simplify calculations, insure that each ingredient includes the amount 1) in English measure and 2) by weight. Other measures may be used for the convenience of persons mixing baits.

**j. Other Labeling Statements Required**

The following restrictions must also appear on all starlicide end-use product labels:

<u>Entry restrictions:</u>

> "Keep persons other than authorized handlers, as well as pets and livestock, away from the bait at all times."

Placement in labeling -- Add the entry restriction to the labels of all end-use products in a section in the Directions For Use with the heading: "Entry Restrictions:"

Application Restrictions:

> "Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application."

User Safety Requirements:

> "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are provided for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations:

> "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
>
> "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
>
> "Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing."

**3. Existing Stocks**

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

The Agency has determined that registrants may distribute and sell starlicide products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

# VI. APPENDICES

| SITE Application Type, Application Timing, Application Equipment ) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only) | Form(s) | Min. Appl. Rate (AI unless noted otherwise) | Max. Appl. Rate (AI unless noted otherwise) | Soil Tex. Max. Dose | Max. # Apps @ Max. Rate /crop cycle | /year | Max. Dose [(AI unless noted otherwise)/A] /crop cycle | /year | Min. Interv (days) | Restr. Entry Interv [day(s)] | Geographic Limitations Allowed | Disallowed | Use Limitations Codes |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| USES ELIGIBLE FOR REREGISTRATION | | | | | | | | | | | | | |
| FOOD/FEED USES[2] | | | | | | | | | | | | | |
| BIRD STAGING AREAS (Including broadcast applications in cut hay fields, grassy areas, orchards, stubble fields) | | | | Use Group: Terrestrial FOOD-FEED CROP | | | | | | | | | |
| | | | | | | | Geo.013: Do not use within 1/2 mile of peregrine falcon aeries. | | | | | | |
| Bait application., Daytime., Not on label. | SC/S | NA | .245 lb A | * | NS | NS | NS | NS | NS | NS | TX | 013 | C20, CAS |
| | | | | | | | Geo.013: See above | | | | | | |
| Bait application., When needed., Aircraft. | SC/S | NA | .0392 lb A | * | 2 | NS | NS | NS | NS | NS | TX | | C20, CAS, G01(365), H01(365) |
| | SC/S | NA | .0882 lb A | * | NS | NS | NS | NS | NS | NS | | | C20, C92, CAG, CEA, G01(365), H01(365) |
| Bait application., When needed., Glove. | SC/S | NA | .0882 lb A | * | NS | NS | NS | NS | NS | NS | ND | | C20, CAB, CAG, CAT, CEA, G01(365), H01(365) |
| | SC/S | NA | .002178 lb 1K sq.ft | * | NS | NS | NS | NS | NS | NS | | | C20, C92, CAG, CEA, G01(365), H01(365) |
| | SC/S | NA | .003267 lb 1K sq.ft | * | NS | NS | NS | NS | NS | NS | TN | | C20, C92, CAG, CAS, CAT, CEA |
| Bait application., When needed., Ground. | SC/S | NA | .0882 lb A | * | NS | NS | NS | NS | NS | NS | | G01(365), | C20, C92, CAG, CEA, H01(365) |
| Bait application., When needed., Not on label. | SC/S | NA | .02744 lb A | * | NS | NS | NS | NS | NS | NS | IN | | C20, CAB, CAG, CAT, CEA |
| BIRD STAGING AREAS IN RICE GROWING AREAS (Including broadcast applications in areas under blackbird flight lines near roosts, which are fallow stubble fields, harvested hay fields, open grassy areas and pastures) | | | | Use Group: Terrestrial FOOD_FEED CROP | | | | | | | | | |
| Bait application., Postemergence., Aircraft. | SC/S | NA | .49 lb A | * | NS | NS | NS | NS | NS | NS | 013 | | CAT |
| | | | | | | | Geo.013: Apply only in LA in Wards 1 and 3 of Evangeline Parish and a portion of Vermillion Parish. | | | | | | |

2 Although there are uses currently on Starlicide labels which may result in use in areas re food or feed crops are grown, these uses must be deleted or modified, as specified in this document. After these uses are removed from the labels, there will no longer be food/feed uses for this pesticide.

| SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only) | Form(s) | Min. Appl. Rate (AI unless noted otherwise) | Max. Appl. Rate (AI unless noted otherwise) | Soil Tex. @ Max. Dose | Max. # Apps /crop cycle | Max. Rate /year | Max. Dose [(AI unless noted otherwise)/A] /crop cycle | Max. Dose [(AI unless noted otherwise)/A] /year | Min. Interv (days) | Restr. Entry Interv [day(s)] | Geographic Limitations Allowed | Geographic Limitations Disallowed | Use Limitations Codes |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| USES ELIGIBLE FOR REREGISTRATION | | | | | | | | | | | | | |
| FOOD/FEED USES | | | | | | | | | | | | | |
| BIRD STAGING AREAS IN RICE GROWING AREAS - continued | | | | | | | | | | | | | |
| Bait application., Postemergence., Ground. | SC/S | NA | .49 lb A | * | NS | NS | NS | NS | NS | NS | 013 | | CAT |
| | | | Geo.013: See above | | | | | | | | | | |
| Bait application., When needed., Aircraft. | SC/S | NA | .0392 lb A | * | 2 | NS | NS | NS | NS | NS | TX | | C20, CAS, G01(365), H01(365) |
| Bait application., When needed., Ground. | SC/S | NA | .0392 lb A | * | 2 | NS | NS | NS | NS | NS | TX | | C20, CAS, G01(365), H01(365) |
| USES ELIGIBLE FOR REREGISTRATION | | | | | | | | | | | | | |
| NON-FOOD/FEED | | | | | | | | | | | | | |
| BEEF CATTLE FEEDLOTS (Non-food/feed areas only) | | | Use Group: TERRESTRIAL NONFOOD CROP | | | | | | | | | | |
| Bait application., Early morning., Bait box. | SC/S | NA | UC | * | NS | NS | NS | NS | NS | NS | | | C20, CAB, CAG, CEA |
| Bait application., Early morning., By hand. | SC/S | NA | .07742 lb A | * | NS | NS | NS | NS | NS | NS | | | C20, CAB, CAG, CEA |
| BIRD NESTING AREAS (In coastal nesting areas of certain gulls within predation range of important nesting colonies of colonial nesting birds) | | | Use Group: TERRESTRIAL NONFOOD CROP | | | | | | | | | | |
| Bait application., March 1 to June 30., Glove. | SC/S | NA | 2.377E-04 lb bird | * | 10 | NS | NS | NS | NS | NS | 013 | | C20, C92, CAG, CEA, GE3 |
| | | | | | Geo.013: For coastal breeding areas or colonies within predation radius of important nesting areas or colonies of protected birds. | | | | | | | | |
| Bait application., March 1 to June 30., Scoop. | SC/S | NA | 2.377E-04 lb bird | * | 10 | NS | NS | NS | NS | NS | 013 | | C20, C92, CAG, CEA, GE3 |
| | | | | | Geo.013: See above | | | | | | | | |
| BIRD ROOSTING OR LOAFING AREAS (Including bridges, buildings, electrical power stations, electrical towers, flat roof tops, fences areas and industrial sites) | | | Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | | | | |
| Bait application., When needed., Bait box. | SC/S | NA | .01764 lb bait station | * | NS | NS | NS | NS | NS | NS | | | C20, C92, CAG, CEA, G01(365), H01(365) |
| | SC/S | NA | .0931 lb A | * | NS | NS | NS | NS | NS | NS | | PR, 013 | C20, C92, CAG, CEA |
| | | | | | Geo.013: Do not apply within 1/2 mile of peregrine falcon aeries at times of the yr. that falcons are present. | | | | | | | | |
| | SC/S | NA | .0098 lb bait station | * | NS | NS | NS | NS | NS | NS | IL | | CAB, CAG, CAS, CAT, CEA |

| SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only) | Form(s) | Min. Appl. Rate (AI unless noted otherwise) | Max. Appl. Rate (AI unless noted otherwise) | Soil Tex. | Max. # Apps @ Max. Rate /crop cycle | /year | Max. Dose [(AI unless noted otherwise)/A] /crop cycle | /year | Min. Interv (days) | Restr. Entry Interv [day(s)] | Geographic Limitations Allowed | Disallowed | Use Limitations Codes |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| USES ELIGIBLE FOR REREGISTRATION | | | | | | | | | | | | | |
| NON-FOOD/FEED USES | | | | | | | | | | | | | |
| BIRD ROOSTING OR LOAFING AREAS -continued | SC/S | NA | .0098 lb bait station | * | NS | NS | NS | NS | NS | NS | IN | | C20, CAB, CAG, CAT, CEA |
| | SC/S | NA | .02205 lb bait station | * | NS | NS | NS | NS | NS | NS | KY | | C20, CAB, CAG, CAT, CEA, G88 |
| Bait application., When needed., Scoop. | SC/S | NA | .0931 lb A | * | NS | NS | NS | NS | NS | NS | PR, 013 | | C20, C92, CAG, CEA |
| | | | | | Geo.013: Do not apply within 1/2 mile of peregrine falcon aeries at times of the yr. that birds are present. | | | | | | | | |
| BIRD STAGING AREAS (Including bare ground noncrop areas, cut hay fields (in bait dispensers), grassy noncrop areas, near night time roosting sites, nonbearing orchards, orchards (in bait dispensers), roadsides, roads (unused gravel or dirt), trails, open areas, rooftops, industrial and commercial structures, stubble fields (in bait dispensers) and other noncrop areas) | Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | | | | | | |
| Bait Application., When needed., Bait box | SC/S | NA | .0098 lb bait station | * | NS | NS | NS | NS | NS | NS | IN | | C20, CAB, CAG, CAT, CEA |
| | SC/S | NA | .02205 lb bait station | * | NS | NS | NS | NS | NS | NS | KY | | C20, CAB, CAG, CAT, CEA, G88 |
| | SC/S | NA | .03022 lb bait station | * | NS | NS | NS | NS | NS | NS | TN | | C20, C92, CAG, CAS, CAT, CEA |
| Bait application., When needed., Glove. | SC/S | NA | .0882 lb A | * | NS | NS | NS | NS | NS | NS | ND | | C20, CAB, CAG, CAT, CEA, G01(365), H01(365) |
| | SC/S | NA | .002178 lb 1K sq.ft | * | NS | NS | NS | NS | NS | NS | | | C20, C92, CAG, CEA, G01(365), H01(365) |
| | SC/S | NA | .003267 lb 1K sq.ft | * | NS | NS | NS | NS | NS | NS | TN | | C20, C92, CAG, CAS, CAT, CEA |
| Bait application., When needed., Ground. | SC/S | NA | .0882 lb A | * | NS | NS | NS | NS | NS | NS | | | C20, C92, CAG, CEA, G01(365), H01(365) |
| Bait application., When needed., Not on label. | SC/S | NA | .02744 lb A | * | NS | NS | NS | NS | NS | NS | IN | | C20, CAB, CAG, CAT, CEA |
| | SC/S | NA | .05513 lb A | * | NS | NS | NS | NS | NS | NS | KY | | C20, CAB, CAG, CAT, CEA, G88 |

| SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only) | Form(s) | Min. Appl. Rate (AI unless noted otherwise) | Max. Appl. Rate (AI unless noted otherwise) | Soil Tex. @ Max. Dose | Max. # Apps /crop cycle | Max. Rate /year | Max. Dose [(AI unless noted otherwise)/A] /crop | /year | Min. Interv (days) | Restr. Entry Interv [day(s)] | Geographic Limitations Allowed | Disallowed | Use Limitations Codes |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| USES ELIGIBLE FOR REREGISTRATION | | | | | | | | | | | | | |
| NON-FOOD/FEED USES | | | | | | | | | | | | | |
| BIRD STAGING AREAS IN RICE GROWING AREAS (Including broadcast applications in areas under blackbird flight lines near roosts, which are follow stubble fields (in bait dispensers), harvested hay fields (in bait dispensers), open grassy areas or bare-ground noncrop areas, roadsides, ungrazed pastures (in bait dispensers) and other noncrop areas. | | | | Use Group: TERRESTRIAL NON_FOOD | | | | | | | | | |
| Bait application., Postemergence., Aircraft. | SC/S | NA | .49 lb A | * | NS | NS | NS | NS | NS | NS | 013 | | CAT |
| | | | Geo.013: Apply only in LA in Wards 1 and 3 of Evangeline Parish and a portion of Vermillion Parish. | | | | | | | | | | |
| Bait application., Postemergence., Ground. | SC/S | NA | .49 lb A | * | NS | NS | NS | NS | NS | NS | 013 | | CAT |
| | | | Geo.013: See above | | | | | | | | | | |
| Bait application., When needed., Aircraft. | SC/S | NA | .0392 lb A | * | 2 | NS | NS | NS | NS | NS | TX | | C20, CAS, G01(365), H01(365) |
| Bait application., When needed., Ground. | SC/S | NA | .0392 lb A | * | 2 | NS | NS | NS | NS | NS | TX | | C20, CAS, G01(365), |
| CITRUS FRUITS (Bait box application only) | | | | Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | | | |
| Bait application., Daytime., Bait box. | SC/S | NA | .245 lb A | * | NS | NS | NS | NS | NS | NS | 013 | 013 | C20, CAS |
| | | | Geo.013: Do not use within 1/2 mile of peregrine falcon aeries. Apply in TX in Cameron, Hidalgo, Kenedy, Starr and Willacy Counties. | | | | | | | | | | |
| DAIRY CATTLE FEEDLOTS (nonfood-feed areas) | | | | Use Group: TERRESTRIAL NON-FOOD | | | | | | | | | |
| Bait application., Early morning., Bait box. | SC/S | NA | UC | * | NS | NS | NS | NS | NS | NS | | | C20, CAB, CAG, CEA |
| Bait application., Early morning., By hand. | SC/S | NA | .07742 lb A | * | NS | NS | NS | NS | NS | NS | | | C20, CAB, CAG, CEA |
| FODDER/SILAGE BAGS (bags must be unbroken) | | | | Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | | | |
| Bait Application., Not on label, Bait box | SC/S | NA | 1.296E-04 lb sq.ft | * | NS | NS | NS | NS | NS | NS | | | C20, CAB, CAG, CEA |
| Bait Application., Not on label, By hand | SC/S | NA | 6.482E-04 lb 1k sq.ft | | NS | NS | NS | NS | NS | NS | | | C20, CAB, CAG, CEA |
| LIVESTOCK FEEDLOTS (in areas not accessable to livestock) | | | | Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | | | |
| Bait application., Early morning., Bait box. | B/S | NA | .05 lb A | * | NS | NS | NS | NS | NS | NS | | | CAC, CEA |
| Bait application., Early morning., By hand. | B/S | NA | .05 lb A | * | NS | NS | NS | NS | NS | NS | | | CAC, CEA |

| SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only) | Form(s) | Min. Appl. Rate (AI unless noted otherwise) | Max. Appl. Rate (AI unless noted otherwise) | Soil Tex. @ Max. Dose | Max. # Apps /crop cycle | Max. # Apps /year | Max. Rate unless noted otherwise)/A] /crop cycle | Max. Rate unless noted otherwise)/A] /year | Min. Interv (days) | Restr. Entry Interv [day(s)] | Geographic Limitations Allowed | Geographic Limitations Disallowed | Use Limitations Codes |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| USES ELIGIBLE FOR REREGISTRATION | | | | | | | | | | | | | |
| NON-FOOD/FEED USES | | | | | | | | | | | | | |
| POULTRY FEEDLOTS (nonfood-feed areas) | | | | Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | | | |
| Bait application., Early morning, Bait Box | SC/S | NA | | UC | * | NS | NS | NS | NS | NS | NS | | C20, CAB, CAG, Box |
| Bait application., Early morning., By hand | SC/S | NA | .07742 lb A | | * | NS | NS | NS | NS | NS | NS | | C20, CAB, CAG, CEA |
| POULTRY OPERATIONS (outside of pens, buildings or range areas) | | | | Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | | | |
| Bait application., Early morning., By hand. | B/S | NA | .05 lb A | | * | NS | NS | NS | NS | NS | NS | | CAC, CEA |
| Bait application., Early morning., Bait box. | B/S | NA | .05 lb A | | * | NS | NS | NS | NS | NS | NS | | CAC, CEA |
| RANGELAND PASTURELAND AREAS WHERE BIRDS FEED ON NEWBORN LIVESTOCK (uneaten bait and dead birds must be removed) | | | | Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | | | |
| Bait application., When needed., By hand. | SC/S | NA | 6.482E-04 lb 1K sq.ft | | * | NS | NS | NS | NS | NS | NS | | C20, CAB, CAG, CEA |
| REFUGES OR OTHER AREAS WHERE PEST BIRDS PREY UPON PROTECTED SPECIES | | | | Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | | | |
| Bait application., When needed., By hand. | SC/S | NA | 6.482E-04 lb 1K sq.ft | | * | NS | NS | NS | NS | NS | NS | | C20, CAB, CAG, CEA |
| Bait Application., Not on label, Bait box | SC/S | NA | 1.296E-04 lb sq.ft | | * | NS | NS | NS | NS | NS | NS | | C20, CAB, CAG, CEA |
| Bait Application., Not on label, By hand | SC/S | NA | 6.482E-04 lb 1k sq.ft | | NS | NS | NS | NS | NS | NS | NS | | C20, CAB, CAG, CEA |
| SWINE FEEDLOTS (nonfood-feed areas) | | | | Use Group: TERRESTRIAL NON-FOOD CROP | | | | | | | | | |
| Bait application., Early morning., Bait box. | SC/S | NA | | UC | * | NS | NS | NS | NS | NS | NS | | C20, CAB, CAG, CEA |
| Bait application., Early morning., By hand. | SC/S | NA | .07742 lb A | | * | NS | NS | NS | NS | NS | NS | | C20, CAB, CAG, CEA |
| SUNFLOWER (Decoy Fields) | | | | Use Group: TERRESTRIAL FOOD+FEED CROP | | | | | | | | | |
| Bait application., When needed., Glove. | SC/S | NA | .0882 lb A | | * | NS | NS | NS | NS | 7 | NS | ND | C20, CAB, CAG, CAT, CEA, G01(365), |

LEGEND

HEADER ABBREVIATIONS

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

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

| | |
|---|---|
| B/S | BAIT/SOLID |
| SC/S | SOLUBLE CONCENTRATE/SOLID |

ABBREVIATIONS

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

APPLICATION RATE

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

USE LIMITATIONS CODES

C20 : Endangered species restriction.
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
CAB : Keep out of lakes, streams, ponds, tidal marshes, and estuaries.
CAC : Keep out of lakes, streams, and ponds.
CAG : Do not apply where runoff is likely to occur.
CAS : Do not contaminate food or feed.
CAT : Do not place in locations accessible to children, pets or domestic animals.
CEA : Do not expose to areas accessible to waterfowl, poultry, and other non-target birds.
G01 : __ day(s) pregrazing interval.
G88 : Do not graze or feed forage.
GE3 : Do not use for food or feed.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
013 : Other
IL : Illinois
IN : Indiana
KY : Kentucky
ND : North Dakota
PR : Puerto Rico
TN : Tennessee
TX : Texas

## GUIDE TO APPENDIX B

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

| REQUIREMENT | | USE PATTERN | CITATION(S) |
|---|---|---|---|
| **PRODUCT CHEMISTRY** | | | |
| **61-1** | **Chemical Identity** | ALL | 43708001 |
| **61-2A** | **Start. Mat. & Mnfg. Process** | ALL | 43437301 |
| **61-2B** | **Formation of Impurities** | ALL | 43708001 |
| **62-1** | **Preliminary Analysis** | ALL | 43708001 |
| **62-2** | **Certification of limits** | ALL | 43708001 |
| **62-3** | **Analytical Method** | ALL | 43708001 |
| **63-2** | **Color** | ALL | 41609301 |
| **63-3** | **Physical State** | ALL | 41609301 |
| **63-4** | **Odor** | ALL | 41609301 |
| **63-5** | **Melting Point** | ALL | 41609301 |
| **63-6** | **Boiling Point** | ALL | WAIVED |
| **63-7** | **Density** | ALL | 41609301 |
| **63-8** | **Solubility** | ALL | 41609301 |
| **63-9** | **Vapor Pressure** | ALL | 42114501 |
| **63-10** | **Dissociation Constant** | ALL | 41609301 |
| **63-11** | **Octanol/Water Partition** | ALL | 42225702 |
| **63-12** | **pH** | ALL | 42225703 |
| **63-13** | **Stability** | ALL | 41609301 |
| **63-17** | **Storage stability** | ALL | 43437301 |

# Data Supporting Guideline Requirements for the Reregistration of Starlicide

| REQUIREMENT | | USE PATTERN | CITATION(S) |
|---|---|---|---|
| **ECOLOGICAL EFFECTS** | | | |
| **71-1A** | **Acute Avian Oral - Quail/Duck** | ABC | 41760502, 41760503 |
| **71-2A** | **Avian Dietary - Quail** | ABC | 42671802 |
| **71-2B** | **Avian Dietary - Duck** | ABC | 42671801 |
| **72-1A** | **Fish Toxicity Bluegill** | ABC | 41767501 |
| **72-1C** | **Fish Toxicity Rainbow Trout** | ABC | 417667502 |
| **72-2A** | **Invertebrate Toxicity** | ABC | 41783701 |
| **TOXICOLOGY** | | | |
| **81-1** | **Acute Oral Toxicity - Rat** | ABC | 41632101 |
| **81-2** | **Acute Dermal Toxicity - Rabbit/Rat** | ABC | 41632102 |
| **81-3** | **Acute Inhalation Toxicity - Rat** | ABC | WAIVED |
| **81-4** | **Primary Eye Irritation - Rabbit** | ABC | 41632103 |
| **81-5** | **Primary Dermal Irritation - Rabbit** | ABC | 41632104 |
| **81-6** | **Dermal Sensitization - Guinea Pig** | ABC | 42201101 |
| **84-2A** | **Gene Mutation (Ames Test)** | ABC | 41605301 |
| **84-2B** | **Structural Chromosomal Aberration** | ABC | 41605302 |
| **84-4** | **Other Genotoxic Effects** | ABC | 41605302 |
| **OCCUPATIONAL EXPOSURE** | | | |
| **No occupational exposure data were required.** | | | |

## Data Supporting Guideline Requirements for the Reregistration of Starlicide

| REQUIREMENT | | USE PATTERN | CITATION(S) |
|---|---|---|---|
| **ENVIRONMENTAL FATE** | | | |
| **161-1** | **Hydrolysis** | ABC | 41760501 |
| **161-2** | **Photodegradation - Water** | ABC | 42838801 |
| **162-1** | **Aerobic Soil Metabolism** | ABC | 43284501 |
| **163-1** | **Leaching/Adsorption/Desorption** | ABC | 43284502, 43284503 |
| **165-4** | **Bioaccumulation in Fish** | ABC | 43069801 |

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

# DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).

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

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

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

## SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

## SECTION II. DATA REQUIRED BY THIS NOTICE

### II-A. DATA REQUIRED

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

### II-B. SCHEDULE FOR SUBMISSION OF DATA

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

## II-C. TESTING PROTOCOL

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

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

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

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

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

# SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

## III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

## III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

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

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

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

## III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the

request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

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

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as

well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

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

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

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

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

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both

available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

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

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

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

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

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

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

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

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

## III-D REQUESTS FOR DATA WAIVERS

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

## IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

## IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

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

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

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

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

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

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

## IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

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

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

## SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

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

## STARLICIDE PRODUCT SPECIFIC DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Edward Setren at (703) 308-8166.

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

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

RE: **Starlicide**

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

Item 1-4. Already completed by EPA.

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

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

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

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

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

**REMOVE THIS PAGE AND INSERT PART A OF THE PRODUCT SPECIFIC DCI HERE**

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

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

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

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

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

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

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

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

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

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy

data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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

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

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID

or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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

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

Items 10-13. Self-explanatory.

**NOTE**: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you

have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

REMOVE THIS PAGE AND INSERT PART B PAGE 1 OF THE PSDCI

REMOVE THIS PAGE AND INSERT PART B PAGE 2 OF THE PSDCI

REMOVE THIS PAGE AND INSERT PART B PAGE 3 OF THE PSDCI

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## EPA'S BATCHING OF STARLICIDE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

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

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to

Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Sixteen products were found which contain starlicide as the active ingredient. The products have been placed into one batch in accordance with the active and inert ingredients, type of formulation and current labeling. Table 1 identifies the products in the batch and the "no batch" product.

**Table 1**

| | EPA Reg. No. | % Active Ingredient | Formulation Type |
|---|---|---|---|
| No Batch | 67517-8 | 0.1 | Solid |
| Batch 1 | 56228-10 | 98.0 | Solid |
| | 56228-17 | 98.0 | Solid |
| | 56228-28 | 98.0 | Solid |
| | 56228-29 | 98.0 | Solid |
| | 56228-30 | 98.0 | Solid |
| | 67517-7 | 97.0 | Solid |
| | IL89000600 | 98.0 | Solid |
| | IN90000300 | 98.0 | Solid |
| | KY89000300 | 98.0 | Solid |
| | LA93002000 | 98.0 | Solid |
| | ND92000100 | 98.0 | Solid |
| | TN89000500 | 98.0 | Solid |
| | TN94000600 | 98.0 | Solid |
| | TX89000100 | 98.0 | Solid |
| | TX94001200 | 98.0 | Solid |

**Attachment 4. List of All Registrants Sent This Data Call-In Notice (insert)**

## Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA

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

# Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

| EPA USE ONLY | 10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)* | 11. Supplier Name & Address | 12. EPA Reg. No. | 13. Each Component in Formulation a. Amount | 13. b. % by Weight | 14. Certified Limits % by Weight a. Upper Limit | 14. b. Lower Limit | 15. Purpose in Formulation |
|---|---|---|---|---|---|---|---|---|
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| | | | | | | | | |
| 16. Typed Name of Approving Official | | | | 17. Total Weight | 100% | | | |

| 18. Signature of Approving Official | 19. Title | 20. Phone No. *(Include Area Code)* | 21. Date |
|---|---|---|---|
| | | | |

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

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

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

**Please fill in blanks below.**

| Company Name | Company Number |
|---|---|
| Product Name | EPA Reg. No. |

I Certify that:

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

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

| Name of Firm(s) | Date of Offer |
|---|---|
| | |

Certification:

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

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

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

**United States Environmental Protection Agency**
**Washington, DC 20460**

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

## CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS



**Please fill in blanks below.**

| Company Name | Company Number |
|---|---|
| | |

| Product Name | EPA Reg. No. |
|---|---|
| | |

**I Certify that:**

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

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

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

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

| Signature | Date |
|---|---|
| | |

Name and Title (Please Type or Print)

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

| Signature | Date |
|---|---|
| | |

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

The following is a list of available documents for Starlicide 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 Edward Setren at (703)-308-8166.

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 Starlicide.

The following documents are part of the Administrative Record for Starlicide 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