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United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-95-003
March 1995

Reregistration Eligibility Decision (RED)

Linuron

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case linuron which includes the active ingredient 3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative C.P. Moran at (703) 308-8590. Address any questions on required generic data to the Special Review and Reregistration Division representative Karen Jones at (703) 308-8047.

Sincerely yours,

Peter Caulkins, Acting Director
Special Review
and Reregistration Division

Enclosures

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

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

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

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

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

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

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

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

batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

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

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

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

By U.S. Mail:

Document Processing Desk **(RED-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.

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REREGISTRATION ELIGIBILITY DECISION

LINURON

LIST A

CASE 0047

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

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LINURON REREGISTRATION ELIGIBILITY DECISION TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
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
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized As Safe as designated by FDA

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GLOSSARY OF TERMS AND ABBREVIATIONS

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
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
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MOE	Margin Of Exposure

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GLOSSARY OF TERMS AND ABBREVIATIONS

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PPE	Personal Protective Equipment
ppb	Parts Per Billion
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

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GLOSSARY OF TERMS AND ABBREVIATIONS

TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TMRC	Theoretical Maximum Residue Contribution
TLC	Thin Layer Chromatography
WP	Wettable Powder
WPS	Worker Protection Standard

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EXECUTIVE SUMMARY

Reregistration Decision

This Reregistration Eligibility Decision document (RED) addresses the reregistration eligibility of the pesticide linuron, 3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea.

Based on the reviews of the generic data for the active ingredient linuron, the Agency has reviewed information on the health effects of linuron and on its potential for causing adverse effects in fish and wildlife and the environment. Based on this information, the Agency concludes that products containing linuron for most registered uses are eligible for reregistration. However, the Agency is unable to make a reregistration decision for certain uses. Because of the lack of key generic data, the Agency cannot complete an assessment on the use of linuron on cotton, potato, non-cropland (rights-of-way), and sweet corn. At this time, the Agency is unable to make a reregistration eligibility decision on the use of linuron on potatoes because under current policies a tolerance under Section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) is needed for this use, but such a tolerance may be barred by the Delaney clause in Section 409.

The Agency has further determined based on information currently available that the remaining uses of linuron, as currently registered, will not cause unreasonable risk to humans and the environment. However, the Agency is concerned with the potential for postapplication/reentry exposure to workers and handlers (mixers/loaders/applicators) exposure. In order to reduce the postapplication/reentry exposure risks, the Agency is establishing a 24 hour REI, requiring postapplication/reentry exposure data, and requiring minimum handler personal protective equipment (PPE) for all end-use products containing linuron. The 24 hour REI is only for those uses in the scope of the Worker Protection Standards.

Linuron exceeds the Levels of Concern (LOCs) for ecological effects and groundwater quality. The Agency is requiring additional ecological effects data, which include plant and chronic aquatic studies needed to confirm the risk assessment for all uses of linuron. In addition, the Agency has some moderate concerns for potential risks of linuron to surface water source supply systems.

Following discussions with the technical registrant, E.I. DuPont de Nemours and Company, Inc., several risk mitigation measures were agreed upon. These measures include the following:

- prohibiting the aerial uses of linuron
- prohibiting the use on sand or loamy sand soils
- prohibiting the use on soils of <1% organic matter

- voluntarily cancelling the high application rate uses such as Hybrid poplar and Non-Cropland uses (Rights-of-way)
- reducing the maximum use rate for soybeans (to 1.0 lb ai/A), field corn (to 0.75 lb ai/A), potatoes (to 1.5 lbs ai/A), asparagus (to 2.0 lbs ai/A)
- limiting soybeans, field corn, potatoes to 1 application per year (pre-emergent use only) and limit asparagus to 3 applications per year
- adding a ground water label advisory
- adding a surface water label advisory

DuPont's risk mitigation measures would substantially reduce the amount of linuron entering the environment. However, exposure does not get below all acute and chronic LOCs. For example, using the new proposed rate for soybean use of 1 lb ai/A to determine the expected environmental concentration, small mammals remain at risk from acute and chronic effects to linuron and birds still potentially remain at risk to chronic effects. Reduction of the application rates for soybeans and asparagus may also improve the MOEs for handlers.

The main technical producer for linuron, DuPont, has agreed to voluntarily cancel the Hybrid poplar and non-cropland (rights-of-way) uses of linuron as a risk mitigation measure. DuPont has already voluntarily cancelled the cotton use. At this time, the Agency is unable to make a reregistration eligibility decision for the linuron use on cotton, rights-of-way, and sweet corn because there is a lack of data to support these uses. Registrants are required to either amend their product labels deleting these uses or submit the outstanding data to support the cotton, rights-of-way, and sweet corn uses.

Background Information

Linuron [3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea] is a substituted urea herbicide registered for use on asparagus, carrots, celery, corn (field and sweet), cottonseed (DuPont has voluntarily dropped use), parsley, parsnips, potatoes, sorghum, soybeans, and wheat (winter). Linuron is registered for application preplant, preemergence, postemergence, or post-transplant using ground equipment. The registered modes of application are band treatment, directed spray, or broadcast spray. The end-use formulations of linuron include wettable powder (50% a.i.), flowable concentrate (40.6% a.i.), water dispersible granules (50% a.i.), and liquid suspensions. There are currently 23 end-use products and 5 technical products registered for linuron.

Linuron was initially registered as a pesticide in 1966. Technical linuron is currently being produced in the United States by E.I. DuPont de Nemours and Company, Inc., Griffin Corporation, and Drexel Chemical Company. A Registration Standard for Linuron was issued in June 1984 (NTIS# PB85-149011). The Registration Standard summarized available data supporting the registrations of products containing linuron. The Registration Standard also required the submission of product chemistry, residue chemistry, toxicology, ecological

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effects and environmental fate studies. In 1984, the Agency initiated a Special Review because linuron exceeded the oncogenicity risk criteria. The Agency was concerned about applicator exposure and dermal penetration. The Special Review was concluded in 1988 and in the Federal Register (dated 6/26/90), the Agency revised the toxicological classification of linuron from a quantifiable Group C carcinogen to an unquantifiable Group C carcinogen.

DuPont is no longer supporting the cotton use. Reregistration support from end-use registrants or amendment of their labels deleting the cotton use is required. This document addresses the cotton use because this use currently exists on end-use product labels.

A Data Call-In (DCI) was issued in May 1986 for linuron requiring product chemistry, chronic toxicity, processing and cooking studies. In September 1990, a second DCI was issued requiring additional data on ecological effects, phytotoxicity and residue chemistry. Most recently, in November 1993, a DCI was issued requiring cropfield trials replacement data for studies generated by Craven Laboratories. This RED reflects a reassessment of all data which were submitted in response to the Registration Standard and the subsequent DCIs.

Supporting Rationales for Reregistration Decision

- **Product Chemistry**

All of the registrants of linuron products must confirm the sources of linuron used for their products. Registrants are also required to submit the product chemistry data for the linuron technical products, and either certify that the suppliers of the starting materials and the manufacturing process for the linuron TGAIs and MPs have not changed since the last comprehensive product chemistry review or submit a complete updated product chemistry data package.

- **Health Effects**

Linuron is classified as Category III for acute oral and dermal toxicity, Category III for acute inhalation toxicity, Category III for primary eye irritation, and Category IV for skin irritation. Linuron is also a nonsensitizer. The Agency classified linuron as a Group C carcinogen based upon testicular effects in the rat (interstitial cell hyperplasia and adenomas) from a two-year feeding study. Quantification of risk by unit risk is not recommended.

The Reference Dose (RfD) is 0.008 mg/kg/day based on a one-year feeding study in dogs in which a No Observed Effect Level (NOEL) of 0.77 mg/kg/day was demonstrated. An uncertainty factor of 100 was used to account for inter-species extrapolation and intra-species variability. Chronic dietary exposure to the general population is expected to be 2% of the Reference Dose. Of the standard subgroups routinely analyzed by the Dietary Risk Evaluation System (DRES), the two subgroups with the highest exposures are non-nursing

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infants less than 1 year old, with expected exposures of 6% of the RfD, and children 1 through 6 years old, with expected exposures 4% of the RfD.

Acute, high-end, exposure to females 13 years of age or older (DRES approximation of women of childbearing age) on any given day is expected to result in a MOE of 1667 for developmental toxicity.

The qualitative nature of linuron residue in plants, ruminants, and poultry is adequately understood. The Agency is requiring residue data to establish tolerances for corn aspirated grain fractions (grain dust). Field trial data are required for asparagus; sorghum, forage and hay; soybeans forage and hay; sweet corn; and wheat forage as replacement for Craven data and to confirm tolerances established on limited data for these crops. There are sufficient data to indicate that significant linuron residue declines are not expected to occur in oilseeds/nuts, leafy vegetables, root vegetables, and non-oily grains over short to intermediate storage intervals. A cotton processing study is also required.

Food additive tolerances are needed for potato chips and granules, and feed additive tolerances are needed for wet and dry peel waste. However, such tolerances may be barred by the Delaney clause of the FFDCA, which provides that a food additive regulation may not be established for a pesticide which induces cancer in man or animals. The Agency is unable to make a reregistration eligibility decision as to this use because EPA is currently evaluating legal challenges to its policies related to the coordination of actions under Section 409's Delaney clause and FFDCA section 408 and FIFRA. But in the event that the Agency allows the use of linuron on potatoes, additional data to upgrade an existing potato processing study will be required. Furthermore, the established linuron tolerances for corn, popcorn, forage and fodder; barley, oats, and rye forage, grain, hay and straw will be revoked since there are no registered uses of linuron on these commodities. A tolerance reassessment is also included in this document.

- **Occupational and Residential Exposure**

Margins of Exposure (MOE's) for linuron were calculated for all occupational exposure scenarios for which data were available. Margins of exposure (MOE's) for certain mixer/loader scenarios are below 100 for both short-term and intermediate-term exposure. Particularly low are those MOE's for mixer/loaders supporting the aerial applications. For those scenarios, MOE's are below 100 for intermediate-term exposure, even with the use of closed mixing/loading systems.

Most applications of linuron are made early in the season, before reentry tasks are likely, or applications are made to crops that are mechanically harvested. The notable exception is asparagus where applications of linuron are made between asparagus cuttings. Because asparagus harvesting occurs over a long period of time, the use of both the short-term and the intermediate-term end-points are appropriate for addressing

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postapplication/reentry exposure. The task specific MOE's for asparagus reentry workers: 1) 1000 for short term exposure; and 2) 100 for intermediate exposure.

The Agency is requiring a restricted-entry interval (REI) of 24 hours for uses within the scope of the WPS. For crops such as celery and carrots, where intermediate exposure is likely, the 24 hour REI is required until worker exposure data [132-1a Foliar Dislodgeable Residues (carrots and celery), 132-1b Soil Dislodgeable Residues (carrots and celery), 133-3 Dermal Exposure (carrots and celery), and 133-4 Inhalation Exposure (carrots and celery)] are submitted by the registrant and evaluated by the Agency.

Due to the short-term and intermediate-term endpoints based on maternal and developmental concerns, the Agency is requiring minimum handler personal protective equipment requirements for any end-use product containing linuron. Products containing linuron may contain more stringent PPE, but in no case may they require less stringent PPE than the following: coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant apron.

- **Environmental Fate**

The environmental data base of only parent linuron is essentially complete. Linuron appears to be moderately persistent and relatively immobile. Increased mobility of linuron may occur under specific environmental conditions such as coarse textured soils and soils with low organic matter levels. However, information on the persistence, mobility and dissipation pathways of several primary degradates of linuron is not currently available; therefore, the environmental fate assessment is considered incomplete and tentative. Additional data are required on leaching/adsorption and desorption to assess the mobility of the primary degradates of linuron; and field dissipation to assess the rates of dissipation of parent linuron and its primary degradates.

Linuron exceeds the Level of Concern (LOC) for groundwater quality. Linuron exhibits some of the properties and characteristics associated with chemicals that have been detected in groundwater. Based on its persistence and possible mobility under certain environmental conditions, linuron may have an impact on ground water quality. Furthermore, the Agency has some moderate concerns for potential risks of linuron to surface water source drinking water supply systems.

- **Ecological Effects**

Levels of concern from linuron use have been exceeded for acute effects to birds, mammals, fish, aquatic invertebrates, aquatic plants and endangered species. Risk to terrestrial plants cannot be assessed due to the lack of adequate data. High risk to terrestrial plants is likely, based on the herbicidal properties of linuron. In addition, levels of concern

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for chronic effects have been exceeded for birds and mammals. Chronic effects to fish cannot be fully evaluated since a NOEL was not determined. Chronic effects to aquatic invertebrates cannot be evaluated due to inconsistencies between acute and chronic testing. The Agency is requiring additional ecological effects data, which include plant and chronic aquatic studies, needed to complete the ecological effects risk assessment for linuron.

In summary, based on the information currently available to the Agency, all uses of linuron are eligible for reregistration, with the exception of cotton, potato, non-cropland (rights-of-way), and sweet corn. The Agency is unable to make a reregistration eligibility decision for the use of linuron on cotton, non-cropland (rights-of-way), and sweet corn until additional data are submitted and reviewed. **Also, the Agency is unable to make a reregistration decision for the potato use of linuron until a decision on Delaney is made regarding EPA's coordination policy.** Furthermore, the Agency is requiring that additional confirmatory data be submitted to fulfill the generic data requirements for reregistration of linuron.

Starting Materials and Manufacturing Process

Foliar Dislodgeable Residues (Carrots/Celery)
Soil Dislodgeable Residues (Carrots/Celery)
Dermal Exposure (Carrots/Celery)
Inhalation Exposure (Carrots/Celery)

Cropfield Trials - Asparagus; Corn Aspirated Fractions (Grain Dust); Sorghum, Forage and Fodder; and Wheat, Forage
Cropfield Trials - Soybeans Forage and Hay - required due to change in Agency policy on grazing restrictions

Acute Avian Dietary Toxicity w/TGAI - Quail and Duck
Acute Aquatic Invertebrate Toxicity
Fish Early Life Stage - both Rainbow Trout and Sheepshead Minnow
Aquatic Invertebrate Life Cycle - Mysid shrimp
Leaching/Adsorption/Desorption
Terrestrial Field Dissipation

In order to support the use of linuron on cotton and sweet corn, the following residue data are required:

Cottonseed processing study
Cropfield trials - sweet corn

In order to support the use of linuron on non-cropland (rights-of-way) uses, the following data are required:

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Acute Marine/Estuarine (TEP) - Sheepshead Minnow using DF Formulation for Rights-of-Ways

Certain data are not part of the target database for linuron, but are also required:

Seed germination/seedling emergence - 10 species
Vegetative vigor - 10 species
Aquatic plant growth - 4 additional species

Before reregistering the products containing linuron, 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 for all products containing linuron. The product specific data include product chemistry for each registration and acute toxicity testing. After reviewing all 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. However, those products which bear uses of this or any other active ingredients which have not been determined to be eligible for reregistration will be reregistered only when such uses and active ingredients are determined to be eligible for reregistration.

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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 linuron. The document consists of six sections. Section I is the introduction. Section II describes linuron, 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 linuron. Section V discusses the reregistration requirements for linuron. 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.

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II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Linuron
- **Chemical Name:** Linuron [3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea]
- **Chemical Family:** Substituted urea
- **CAS Registry Number:** 330-55-2
- **OPP Chemical Code:** 035506
- **Empirical Formula:** $C_9H_{10}Cl_2N_2O_2$
- **Trade and Other Names:** Lorox®, Lorox Plus®, Gemini®, Linex®, Linuron 4L®
- **Basic U.S. Manufacturers:** E.I. DuPont DeNemours Company, Inc., Griffin Corporation, and Drexel Chemical Company

B. Use Profile

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

For linuron:

Type of Pesticide: Herbicide

Mechanism of Action: Photosynthesis inhibitor (Hill reaction)

Use Sites: Terrestrial Food Crop: asparagus, carrots, celery

Terrestrial Food + Feed Crop: corn (field and sweet), cotton, parsnips, potatoes, soybeans, and wheat.

Terrestrial Non-Food and Feed Crop: ornamental bulb production (Calla lily, daffodil, Dutch iris, tulip), non-cropland (roadsides, fencerows, etc.),

Forestry: hybrid poplar plantations (pulpwood source)

Target Pests: Preemergence application: Florida beggarweed, carpetweed, chickweed, common dayflower, Florida pussley, galinsoga, lambsquarters, mustards, nettleleaf goosefoot, pigweeds, purslane, wild radish, common ragweed, Pennsylvania smartweed, barnyardgrass, canarygrass, crabgrass, foxtails, goosegrass, fall panicum.

Postemergence application: the above **PLUS**: annual morningglory, cocklebur, dog fennel, fiddleneck, groundsel, knawel, prickly sida, sesbania, sicklepod, velvetleaf, wild buckwheat, annual ryegrass, broadleaf signalgrass, rattail fescue, Texas panicum; **NOT** galinsoga, chickweed, common ragweed, wild radish

Formulation Types Registered:

Single Active Ingredient (AI) Products
95% flake (technical)
92% flake (technical)
50% wettable powder
50% dispersible granules
50% liquid concentrate
41% liquid concentrate

Multiple Active Ingredient (AI) Products
56.9% linuron + chlorimuron
30.8% linuron + atrazine

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Current Method and Rates of Application:

ASPARAGUS (CA, MI, MN, NC, OR, WA)

Direct seeded/newly planted crowns, applied by ground boom: **Preemergence**, **1-2 lb ai/A**, using band of activated charcoal over seed; **postemergence**, 1 or 2 applications at **0.5-1 lb ai/A.**

Established, applied by ground boom: **Preemergence, 1-2 lb ai/A; postemergence**, 1 to 4 applications at **0.5-1 lb ai/A.** Do not exceed 4 lb ai/A per season. PHI = 1 day. **Directed postemergence** application of **2-4 lb ai/A** may be used to control dudain melon.

BULBS, Calla lily, Daffodil, Dutch iris, Tulip (CA)

After planting, during growing season, apply **preemergence 1 lb ai/A** by ground boom.

CARROTS

Preemergence (FL, MI, OH, WI): **0.5-1.5 lb ai/A** by ground boom. Postemergence applications may be made later, but do not exceed a total of 4 lb. ai/A per season.

Postemergence (U.S.): **0.75-1.5 lb ai/A** by ground boom; if repeat applications are made do not exceed a total of 4 lb.ai/A (west of Rocky Mountains, 3 lb ai/A). PHI = 14 days.

CELERY (East of Rocky Mountains only)

Post-transplant ground boom application, **0.75-1.5 lb ai/A**, after celery is established but before it is 6 inches tall. In the Northeast, use only on celery grown on muck soils.

CORN, FIELD (East of Rocky Mountains only)

Preemergence, after planting, before crop emerges, by ground boom, as tank mix with alachlor or atrazine: **0.33-1.5 lb ai/A**.

CORN, FIELD AND SWEET

Directed postemergence, by ground boom: **0.63-1.5 lb ai/A**, after corn is 15 inches high.

COTTON (East of Rocky Mountains only)

Directed postemergence, by ground boom: **0.5-0.75 lb ai/A** when cotton is 15 inches tall; a second application may be made 7 or more days later. After cotton is 20 inches tall, a single application of **1-1.5 lb ai/A** may be made after last cultivation.

Do not graze treated fields or feed forage or gin trash to livestock.

HYBRID POPLAR (Midwest)

Before bud break, by ground boom: **1-2 lb ai/A. After bud break**, by directed ground spray, **1-2 lb ai/A.** More than one application may be made but do not exceed **4 lb ai/A** per year.

PARSNIPS

Preemergence, by ground boom, after planting, before crop emerges, **0.75-1.5 lb ai/A**, single application.

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POTATOES (East of Rocky Mountains)

Preemergence, between planting and crop emergence, by ground boom or aerial spray: **0.75-2 lb ai/A** (Wisconsin: **0.5 lb ai/A** on sands, **1 lb ai/A** on loamy sands).

SORGHUM

Preemergence, between planting and crop emergence, in tank mix with another registered herbicide: **0.31-1 lb ai/A**, by ground boom.

Postemergence, directed, after sorghum is 16 inches tall, **0.5-1 lb ai/A**. Livestock grazing/feeding restriction = 3 months.

SOYBEANS

Preemergence, between planting and crop emergence, by ground boom or aerial spray: **0.5-3 lb ai/A**. Do not use on sand or loamy sand.

Postemergence, directed, by ground boom, after soybeans are 8 inches tall (Midsouth) **0.25-0.5 lb ai/A.**, or after soybeans are 12 inches tall (Midsouth, Southeast), split application of **0.5 lb ai/A** each, at interval of 7 or more days. Do not exceed a total of 1 lb ai/A per season postemergence. PHI = 60 days; do not graze forage or feed hay to livestock from postemergence-treated fields.

WHEAT, WINTER (Drill-planted; ID, OR, WA)

Preemergence/early postemergence treatment, as soon as possible after planting (though crop may have emerged), by ground spray, West of Cascades: **1-1.75 lb ai/A.** East of Cascades, fall or winter treatment, **0.5-0.75 lb ai/A**; spring treatment, **0.5-0.62 lb ai/A**, as soon as growth starts. Do not apply after ground has frozen in fall.

NON-CROP SITES (e.g. roadsides, fencerows)

Preemergence/early postemergence treatment, just before weeds emerge or at early seedling stage, **1-3 lb ai/A** by ground spray.

Current Limitations on Use Practices:

- Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark.
- Do not apply aerially (DuPont only; Griffin allows aerial application to potatoes and soybeans, before crop emerges).
- Do not apply through any type of irrigation system.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of linuron. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

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The table below summarizes the pesticides use by site.

Table 1. Distribution of linuron usage by site

Crop	States of greatest usage	Acres planted (000)	Acres treated (000)	Pounds Active Ingredients (000)	Percent of crop treated	Percent of linuron usage
Soybeans	MI, OH, DE, IN, IL, MN, MD	59,000	2,500	1,400	4	**79**
Cotton	AR, LA, MS	13,700	110	80	8	4
Potatoes		1,400	55	80	6	4
Corn, field	MI, IN, OH, NC, PA, WI	76,000	140	95	<1	5
Carrots	CA, FL	85	65	90	**77**	5
Asparagus	CA, MI	85	15	15	18	1
Celery	CA, FL, NY	33	10	10	**30**	1
Sorghum		11,500	10	10	<1	1
Total				1,780		

D. Data Requirements

Data requested in the June 1984 Registration Standard for linuron included submission of studies on product chemistry, ecological effects, environmental fate, residue chemistry, and toxicology. These data were required to support the uses listed in the Registration Standard. In May 1986, a Data Call-In was issued for linuron requiring product chemistry, chronic toxicity, processing and cooking studies. Subsequent DCIs were issued in September 1990 and November 1993 requiring additional data to address ecological effects, phytotoxicity, and residue chemistry data gaps. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Linuron was registered in the United States in 1966 as a substituted urea herbicide for use on asparagus, barley, carrots, celery, corn (field and sweet), cottonseed, forage, grain, hay, oats, parsley, parsnips, potatoes, rye, sorghum, soybeans, straw, and wheat (winter). A Registration Standard for Linuron was issued in June 1984 (NTIS #PB 85-149011) which required the submission of product chemistry, residue chemistry, toxicology, ecological effects and environmental fate

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studies. In 1984, the Agency initiated a Special Review because linuron exceeded the oncogenicity risk criteria. The Agency was concerned about applicator exposure and dermal penetration. The Special Review was concluded in 1988 and in the Federal Register (dated 6/26/90), the Agency revised the toxicological classification of linuron from a quantifiable Group C carcinogen to an unquantifiable Group C carcinogen.

In 1991, DuPont voluntarily cancelled uses on cotton. However, other registrants have not deleted this use from their end-use product registration labels. Uses on barley, oats, rye, forage, grain, hay, and straw were also voluntarily cancelled and do not appear on any labels.

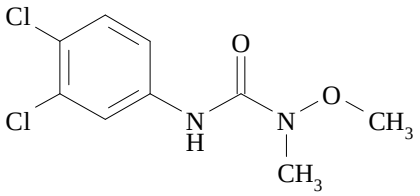
Three Data Call-Ins were subsequently issued (May 1986, September 1990, and November 1993) requiring additional data on product chemistry, chronic toxicity, processing and cooking studies, ecological effects, phytotoxicity and cropfield trials replacement data for studies generated by Craven Laboratories. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard and the subsequent DCIs.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

1. Description of Chemical

Linuron [3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea]:



Empirical Formula: $C_9H_{10}Cl_2N_2O_2$
Molecular Weight: 249.1
CAS Registry No.: 330-55-2
Shaughnessy No.: 035506

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2. Identification of Active Ingredient

Technical linuron is an odorless, white crystalline flake or powder with a melting range of 86-91°C. Linuron is soluble in water at 81 mg/L at 25°C, and is slightly soluble in aliphatic hydrocarbons and moderately soluble in ethanol and common aromatic solvents.

Assessments as to whether the various sources of technical linuron are substantially similar have been an integral part of the scientific review of the product chemistry database submitted in support of reregistration. The Linuron Guidance Document dated 6/29/84 required that additional data concerning all product chemistry topics be submitted in support of the reregistration of linuron. The Linuron Reregistration Standard Update, dated 6/20/90, required additional product chemistry data. Because sources for the registered technical products have changed repeatedly since the Linuron Update, the data requirements have also changed.

All pertinent TGAI data requirements are satisfied for the DuPont linuron technical. Only the nominal concentrations of the product components remain outstanding for the MP requirements. All of the registrants of linuron products must confirm the sources of linuron used for their products. The registrants are required to submit the product chemistry data for the linuron technical products, and either certify that the suppliers of the starting materials and the manufacturing process for the linuron TGAIs and MPs have not changed since the last comprehensive product chemistry review or submit a complete updated product chemistry data package.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base is adequate and will support reregistration of linuron as a food and non-food use pesticide.

a. Acute Toxicity

Acute toxicity values and categories for linuron are summarized in the following table.

TEST	RESULTS	CATEGORY
Oral LD_{50} - rat	2600 mg/kg	III
Dermal LD_{50} - rat	> 2000 mg/kg	III
Inhalation LC_{50} - rat	> 1.7 mg/L	III
Eye Irritation - rabbit*	Slight conjunctival redness at 24 hrs; clear at 72 hrs	III
Dermal Irritation - rabbit*	Not an irritant	IV
Dermal Sensitization - guinea pig*	Not a sensitizer	N/A

* Note: Data pertaining to acute eye irritation, dermal irritation, and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented for informational purposes.

In an acute oral toxicity study conducted in rats, the oral LD_{50} value for technical (96%) linuron was determined to be 2600 mg/kg (Toxicity Category III). In the same study, the dermal LD_{50} in rats was established at >2000 mg/kg (Toxicity Category III). Inhalation exposure of rats to 40.6% linuron resulted in a LC_{50} of >1.7 mg/L (Toxicity Category III). These acute oral, dermal, and inhalation studies satisfy Guidelines §81-1, §81-2, and §81-3, respectively. (MRIDs 00027625 and 00053769)

Application of 97.4% linuron to the rabbit eye resulted in slight conjunctival redness at 24 hours, which was clear by 72 hours (Toxicity Category III). No corneal opacity or irritation of the iris was noted. A primary dermal irritation study in rabbits demonstrated that application of 97.4% linuron produced no irritation (Toxicity Category IV). No dermal sensitization occurred with 95% linuron in guinea pigs. The primary eye and dermal studies and the guinea pig sensitization study satisfy Guidelines §81-4, §81-5, and §81-6, respectively. (MRIDs 00146868, 42849001, and 42849002)

b. Subchronic Toxicity

A 3-month subchronic study was conducted with linuron in rats at dietary levels of 80, 400, and 3000 ppm (4, 20, and 150 mg/kg/day). Observations of decreased red blood cell count and increased white blood cell count were noted at 400 ppm. At the high-dose (3000 ppm) growth was retarded. Based upon hematological findings, 400 ppm (20 mg/kg/day) was established as the LOEL; the NOEL was 80 ppm (4 mg/kg/day) (US Government, 1963).

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The requirement for a 90-day feeding study in dogs (§82-1) was satisfied by the completion of two acceptable chronic studies conducted with linuron in beagles.

c. Chronic Toxicity and Carcinogenicity

In a 1-year dog study 96.2% linuron was fed to groups of 4 beagles/sex/dose at dietary levels of 10, 25, 125, or 625 ppm (male: 0.29, 0.79, 4.17, or 18.6 mg/kg/day; females: 0.3, 0.77, 3.49, or 16.1 mg/kg/day, respectively); this study satisfies the §83-1(b) guideline requirement for a chronic canine toxicity study. In a previous 2-year dog study, linuron was administered in the diet to beagle dogs at 25, 125, or 625 ppm (0.625, 3.13, or 15.63 mg/kg/day); an abnormal pigment was observed in the blood of animals at all dose levels. Decreased red blood cell count, hematocrit, and hemoglobin levels were also noted in males at 625 ppm. Since the abnormal pigment was postulated to be met- and sulfhemoglobin, assays for these substances were conducted on the 1-year study. The presence of one or both substances in the blood was confirmed for both sexes in the 125 and 625 ppm dose groups at all intervals tested (3, 6, 9, and 12 months). At 625 ppm, evidence of red blood cell destruction was noted as increased hemosiderin deposition on the Kupffer cells of the liver (male and female), slight decreases in erythrocyte count, hemoglobin, and hematocrit levels at all time periods tested, and a small increase in erythropoietic activity in the bone marrow. Secondary hematological changes at 625 ppm included increased platelet count, leukocyte count, and serum cholesterol levels. In addition, absolute liver weight was increased in males at 625 ppm; relative liver weight was increased in males at 125 and 625 ppm. Based upon hematology changes, the LOEL for systemic toxicity was determined as 125 ppm (4.17 mg/kg/day for males; 3.49 mg/kg/day for females). The NOEL for systemic toxicity is 25 ppm (0.79 mg/kg/day for males; 0.77 mg/kg/day for females). (MRIDs 40952601, 00018374, and 00018376)

In a 2-year feeding/carcinogenicity study, linuron (97%) was administered to Crl:CD(SD)BR Sprague-Dawley rats at dietary levels of 50, 125, or 625 ppm (2.5, 6.25, or 31.25 mg/kg/day). Testicular interstitial cell adenomas were observed at a significantly increased incidence in mid- and high-dose males (125 and 625 ppm, respectively). In addition, various indications of blood cell destruction and turnover (increased mean corpuscular volume, decreased red blood cell count, and possible reticulocytosis) were observed in both sexes at 125 and 625 ppm. Analysis of percent hemoglobin to evaluate hematotoxicity

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indicated that males were not affected, but percent hemoglobin was decreased for females at 6 and 12 months for the high-dose group, and at 12 months for the mid-dose group. Therefore, based upon hematotoxicity, observed as a decrease in the percent hemoglobin, the LOEL for systemic toxicity for females was 125 ppm (6.25 mg/kg/day). The systemic NOEL for females was 50 ppm (2.5 mg/kg/day), and the systemic NOEL for males was 625 ppm (31.25 mg/kg/day). The requirements for chronic and oncogenicity testing in rodents [Guidelines §83-1(a) and §83-2(a)] were satisfied by this study. (MRID 00029680)

In another two-year rat feeding study, in which groups of albino rats were treated with dietary linuron at levels of 25, 125, or 625 ppm (1.25, 6.25, or 31.25 mg/kg/day), the systemic NOEL was determined to be 125 ppm. At the LOEL of 625 ppm (31.25 mg/kg/day), growth retardation was observed. In addition, at that dietary level, hemosiderin content of the spleen was increased for both sexes, marrow fat was reduced for females, the ratio of myeloid-to-erythroid precursors was reduced for males, and the incidence of endometrial hypoplasia was increased for females. These findings were considered to be indicative of hemolysis (MRID 00018379).

An 18-month feeding study was conducted in Crl:CD(SD)BR rats to study the effects of linuron (94.5%) on methemoglobin and sulfhemoglobin blood concentrations. The dietary levels tested were 25, 125, or 625 ppm (1.25, 6.25, or 31.25 mg/kg/day). Based upon significant changes noted in blood pigments in mid- and high-dose female rats and in high-dose male rats, the LOEL was determined to be 625 ppm (31.25 mg/kg/day) and 125 ppm (6.25 mg/kg/day) for male and female rats, respectively. The corresponding NOELs for male and female rats were 125 and 25 ppm (6.25 and 1.25 mg/kg/day). (MRID 00149883)

In a two-year feeding/oncogenicity study in CD-1 mice, linuron was administered in the diet at levels of 50, 150, or 1500 ppm (12, 35, or 455 mg/kg/day). This study satisfied the requirement for Guideline §83-2(b) carcinogenicity study in a second rodent species. A statistically significant increase in the incidence of hepatocellular adenomas was observed at 1500 ppm for female mice, and border-line statistical significance was attained for hepatocellular adenomas at 50 ppm for male mice. At 1500 ppm, body weight and body weight gain were decreased for both males and females throughout the study. Methemoglobin values were increased at all dietary levels for both sexes. Mean absolute and relative liver weights were increased for

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females at 1500 ppm. For both males and females at that level, histopathological evaluation identified increased incidences of hemosiderosis of the spleen and hepatocytomegaly, hepatocellular cytoplasmic alteration, hepatocellular vacuolization, hemorrhage, and necrosis of the liver. A NOEL was not established; the systemic toxicity LOEL, based on increased methemoglobin values, was ≤ 50 ppm (12 mg/kg/day). (MRID 00124195)

Linuron was placed in Special Review for carcinogenesis in 1982. It was later classified as a Group C carcinogen with a Q_1* of 2 x 10^{-5} on the basis of a dose-related increase in interstitial cell hyperplasia and adenomas in a two-year rat feeding study and hepatocellular tumors that appeared in low-dose male and high-dose female mice in a two-year feeding study. Subsequent review by the OPP/HED Peer Review Committee and the Science Advisory Panel resulted in the elimination of the Q_1*, since the weight of evidence suggested that the carcinogenic potential of linuron in humans is weak and **it should not be regulated using a linearized multi-stage risk assessment model**. (MRIDs 00029680, 00124195, and U.S. EPA, 1989)

d. Developmental Toxicity

In a developmental toxicity study conducted with 97% linuron in Sprague-Dawley rats, dietary doses of 50, 125, or 625 ppm (5.0, 12.1, or 49.8 mg/kg/day, respectively) were administered on days 6-15 of gestation; this study satisfied Guideline §83-3(a) requirement for a developmental toxicity study in rodents. The NOELs for maternal systemic toxicity and developmental toxicity were 125 ppm (12.1 mg/kg/day). The LOEL of 625 ppm (49.8 mg/kg/day) for maternal systemic toxic effects was based upon decreased body weight and food consumption values. The developmental toxicity LOEL of 625 ppm (49.8 mg/kg/day) was based on increases in postimplantation loss and increases in the litter and fetal incidences of resorptions. (MRID 00018167)

When 96.2% linuron was administered by gavage to New Zealand White rabbits at doses of 5, 25, or 100 mg/kg/day on days 7 through 19 of gestation, a maternal systemic toxicity LOEL was observed at the 25 mg/kg/day level, based upon reduced maternal body weight, thereby defining the NOEL as 5 mg/kg/day. At the high-dose level (100 mg/kg/day), maternal body weight, food consumption, absolute liver weight, and liver-to-body weight ratios were decreased. The developmental toxicity NOEL was determined to be 25 mg/kg/day,

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based upon an increased number of abortions, decreased mean number of fetuses per litter, decreased fetal body weight, and increased incidence of fetuses with skeletal variations of the skull at the 100 mg/kg/day level (the developmental toxicity LOEL). This study satisfied Guideline §83-3(b) data requirements for a developmental toxicity study in rabbits. (MRID 00153867)

e. Reproductive Toxicity

In a two-generation reproductive toxicity study in Sprague-Dawley rats, dietary levels of 12.5, 100, or 625 ppm linuron (96.2%) (males: 0.84, 6.8, or 44.75 mg/kg/day; females: 1.0, 8.3, or 54.1 mg/kg/day) were administered. This study satisfied the data requirements for Guideline §83-4 for a multigeneration reproductive toxicity study in rats. Since no evidence of adverse effects on fertility or reproductive performance was noted, the reproductive toxicity LOEL was undetermined, and the reproductive toxicity NOEL was estimated to be greater than 625 ppm (44.75 and 54.1 mg/kg/day for males and females, respectively). The parental systemic toxicity NOEL was 12.5 ppm, and the systemic LOEL was 100 ppm, based upon decrements in parental body weight gain. In addition, at the 625 ppm level, testicular and epididymal abnormalities (testicular atrophy and intratubular fibrosis; epididymal inflammatory response or oligospermia) and ocular abnormalities (mineralization of the cornea; lens degeneration) were observed at histopathological evaluation of the F1 adults. Further evaluation of reproductive organ weight and hormone data from the F1 adults of this 2-generation study combined with an in vitro analysis of the ability of linuron and its metabolites to compete for binding to the androgen receptor resulted in the conclusion that linuron is a weak androgen receptor antagonist. These results support the hypothesis that rats exposed to linuron could develop interstitial cell hyperplasia and subsequent adenomas (Leydig cell tumors) of the testicular tissue via a mechanism of sustained hypersecretion of luteinizing hormone induced by the antiandrogenic potential of linuron. (MRID 41463401, 41864701, 41630101)

A three-generation reproductive toxicity study in Sprague-Dawley rats, was conducted with 94.5% linuron at dietary levels of 25, 125, or 625 ppm (approximately 1.25, 6.25, and 31.25 mg/kg/day). Parental systemic effects observed included reduced premating body weight in females of all three generations at 125 and 625 ppm, reduced body weights at weaning for 125 ppm dams, and alopecia in both sexes for the F0 and F1b adults at 625 ppm. Based upon the findings at the

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mid-dose level, the systemic LOEL was determined to be 125 ppm (6.25 mg/kg/day), and the systemic NOEL was 25 ppm (1.25 mg/kg/day). The reproductive toxicity NOEL was 25 ppm (1.25 mg/kg/day) and the reproductive toxicity LOEL was determined to be 125 ppm (6.25 mg/kg/day), based on the following findings. Fertility was reduced in generations at 625 ppm F2a through F3a. Pup survival was consistently decreased for pups at 625 ppm, with most deaths occurring in the first 24 hours postpartum, and a trend for decreased viability from days 1-4. Weanling body weights were decreased for F1b and F2b male and female pups at 125 ppm and 625 ppm. Absolute liver and kidney weights of weanlings (both sexes) were decreased, and histopathology of the 625 ppm F2b weanlings identified a frequent incidence of liver atrophy (decreased cytoplasmic clear spaces of hepatocytes). This study was flawed by the lack of histopathological data on the adult animals; however, the systemic study results are considered to be supportive of those obtained from the two-generation study on linuron. (MRIDs 00146071 and 41463401)

f. Mutagenicity

Technical linuron did not produce gene mutation in an Ames assay, in which Salmonella typhimurium bacteria were tested without activation up to 5.0 µg/plate and with activation up to 100 µg/plate. In an in vitro assay using CHO cells, linuron did not produce gene mutations when tested up to 0.50 mM in a nonactivated system and up to 1.0 mM in an S9-activated system. Similarly, linuron did not induce bone marrow chromosome aberrations in vivo, and in other tests for genotoxicity, linuron did not induce unscheduled DNA synthesis in isolated rat hepatocytes. These studies met the mutagenicity testing requirements for Guidelines §84-2(a), §84-2(b), and §84-4 (gene mutation, structural chromosomal aberration, and other genotoxic effects). (MRIDs 00131738, 00137152, 00137153, and 00132583)

g. Metabolism

The metabolism and tissue distribution of [phenyl-^{14}C](U) linuron was studied in male and female Sprague-Dawley rats. The results of several metabolism studies and communications containing supplemental information were combined to satisfy the requirements for Guideline §85-1 metabolism study. In the first study, labeled linuron was administered as a single gavage dose to 2 rats/sex/dose at 24 mg/kg and 400 mg/kg and also as a single 400 mg/kg gavage dose following dietary pretreatment at 100 ppm (approximately 10 mg/kg) to 2

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rats/sex/dose. To further elucidate the metabolic pathway of linuron, a second study was conducted in which a single oral dose of 400 mg/kg of ^{14}C-linuron was administered by gavage to five Sprague-Dawley rats per sex. The results from these studies indicate that linuron was extensively metabolized by male and female rats at both the low- (24 mg/kg) and high-dose (400 mg/kg) levels when administered by gavage. The majority of the administered ^{14}C-linuron was eliminated in the urine and, to a lesser extent, in the feces, within 96-120 hours. In general, tissue and organ residues were very low (<1%) at both dose levels, and there was no indication of accumulation or retention of linuron or its metabolites. The major metabolites identified in the urine and feces were hydroxy-norlinuron and norlinuron. Approximately 4-5% and 6-8% of the urinary and fecal metabolites, respectively, remained unidentified. Exposure to linuron appears to induce mixed function oxidative enzymes. (MRIDs 00146489, 40142401, 41960001, 42006801, 42318701)

h. Reference Dose (RfD) for Chronic Oral Exposure

The RfD for linuron was determined to be 0.0077 (0.008) mg/kg bodyweight per day. This was based on results of a one-year chronic dog study in which hematological changes demonstrated LOELs of 4.17 and 3.49 mg/kg/day for males and females, and NOELs of 0.79 and 0.77 mg/kg/day. The RfD calculation was based upon the NOEL of 0.77 mg/kg/day and used an uncertainty factor of 100 to account for inter-species extrapolation and intra-species variability. (MRID 40952601)

There has been no WHO RfD determination yet.

i. Dermal Absorption

In a dermal absorption study rats were exposed to dose levels of 0.12, 0.87, and 7.4 mg of linuron, as a radiolabelled Lorax L formulation, with both sexes at the low-dose level, and males only at the mid- and high-dose levels. Although the study was found to be unacceptable by current Agency standards, a dermal absorption value could be determined. The potential dermal absorption of linuron to humans is estimated to be approximately 2% per hour or 16% per 8-hour workday. (Accession NO. 254943)

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2. Exposure Assessment

a. Dietary Exposure

Tolerances for residues of linuron in/on plant and animal commodities are expressed in terms of linuron *per se* [40 CFR §180.184(a) and (b)]. No food/feed additive tolerances have been established for linuron residues. The established tolerances listed in 40 CFR §180.184 range from 0.25 ppm to 3 ppm. The Health Effects Division's Metabolism Committee has concluded that the residues of concern are linuron and its metabolites convertible to 3,4-dichloroaniline, expressed as linuron; residues of 3,4-dichloroaniline *per se* need not be regulated separately. The committee expressed concern that 3,4-DCA may be a carcinogen in light of the fact that p-chloroaniline is a quantifiable carcinogen. Because of the low levels found; however, the committee decided that 3,4-DCA could pose no greater than a negligible risk in connection with the registered use of linuron. Adequate enforcement methods are available for the determination of linuron residues of concern in/on plant and animal tissues. The current enforcement methods determine linuron and all metabolites hydrolyzable to 3,4-dichloroaniline.

Plant Metabolism: The qualitative nature of the residue in plants is adequately understood. Metabolism studies with corn, soybeans, and potatoes indicate that linuron is absorbed from the soil and translocated (i.e., systemic). The metabolic pathway involves demethylation to 3-(3,4-dichlorophenyl)-1-methoxyurea which is further metabolized to 3,4-dichloroaniline; metabolism may also occur through demethoxylation of linuron. The terminal residues of concern are the parent and its metabolites which are convertible to 3,4-dichloroaniline. (MRIDs 00018173, 00018176, 00027624, 40084801, 42542101, and 42548401).

Animal Metabolism: The qualitative nature of the residue in ruminants and poultry is adequately understood. An acceptable metabolism study with goats indicates that linuron is rapidly metabolized by demethylation, demethoxylation, and hydroxylation and is primarily eliminated by excretion. The metabolism of linuron in poultry has been found to be consistent with the goat study. The terminal residues of concern are the parent and its metabolites which are convertible to 3,4-dichloroaniline. (MRIDs 00029932, 42635401, and 43245101).

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Residue Analytical Methods - Plants/Animals: Adequate enforcement methods are available for the determination of linuron in plant and animal commodities. The Pesticide Analytical Manual (PAM) Vol. II lists a colorimetric method (Method I, Bleidner et. al.) and a paper chromatographic method (Method II). Residues of diuron may interfere in Method I. A modified version of Method I (H. L. Pease, *Journal of Agric. and Food Chem.*, 1962, Vol. 10, p. 279), which includes a cellulose column step to separate linuron from diuron, is currently the preferred method for the enforcement of tolerances. Both these methods determine linuron and all metabolites hydrolyzable to 3,4-dichloroaniline and have limits of detection of 0.05 ppm. A GLC/ECD method for linuron residues in/on asparagus from the CA Department of Food and Agriculture has been validated by the Agency and sent to FDA to be published in PAM Vol. II as Method III. This method determines residues of linuron *per se* and the limit of detection is 0.05 ppm. However, this method is inadequate for tolerance enforcement since it does not determine all the residues of concern. In addition, this method uses benzene as the extraction solvent. (MRIDs 00018087, 00018089, 00018127, and 00018176).

The FDA Pestrak Database (PAM Vol. I) contains data concerning the applicability of multiresidue methods D and E (fatty and nonfatty foods) for recovery of linuron and its metabolites 3-(3,4-dichlorophenyl)-1-methoxyurea, 3-(3,4-dichlorophenyl)-1-methylurea, 3,4-dichlorophenyl urea and 3,4-dichloroaniline. Linuron is partially recovered using Multiresidue Method E (fatty and nonfatty foods); recovery using Method D is variable. Linuron metabolites 3-(3,4-dichlorophenyl)-1-methoxyurea, 3-(3,4-dichlorophenyl)-1-methylurea, and 3,4-dichlorophenyl urea are not recovered using Method E (fatty and nonfatty foods); 3-(3,4-dichlorophenyl)-1-methylurea is recovered using Method D but 3-(3,4-dichlorophenyl)-1-methoxyurea is not likely to be recovered using this method. Linuron metabolite 3,4-dichloroaniline is not recovered using Method E (nonfatty foods) and has variable recovery using Method D.

Storage Stability: Residues of linuron in frozen analytical samples of potatoes have been shown to be stable for a period of at least 12 months. Residues in/on soybeans, sugar beet tops, carrots, and asparagus have been shown to be stable for up to approximately two years of storage at -20EC. The Agency will translate this data in accordance wtih the Storage Stability Guidance Document (1/93) concerning translation of crop stability to crop groupings. The Agency concludes that linuron is stable in oilseeds/nuts, leafy vegetables, and

root vegetables for a period of at least two years. The conclusion regarding this latter crop group assumes that the 18 month storage interval data for the potato and processed potato commodity storage stability study, currently in review, are found to be acceptable.

Linuron has been shown to be stable in corn grain, corn oil, sorghum grain, and sorghum starch for a period of at least 3 months. The Agency concludes that linuron is stable on non-oily grain crops for a period of at least one year, providing the 12-month storage stability data, currently in review, are found to be acceptable.

The Agency concludes that additional storage stability data will not be necessary provided that storage intervals do not exceed one-year for non-oily grains and two years for oilseeds/nuts, leafy vegetables, and root crops: the registrant has provided sufficient data to indicate that significant linuron residue declines are not expected to occur in oilseeds/nuts, leafy vegetables, root vegetables, and non-oily grains over short to intermediate storage intervals. Since residues have been shown to be stable in several matrices, no additional storage stability data other than the studies currently in review (discussed above) will be required, provided that linuron is not registered for use on fruits, fruiting vegetables, or citrus. (MRIDs 00159802, 41716103, 42836701, 42836702, 43040001, 42913301, and 42974401).

Magnitude of the Residue in Plants: All data for magnitude of the residue in carrots, corn field, grain; corn field, forage and fodder; celery, parsley, parsnips, potatoes, sorghum grain, soybeans, and wheat grain and straw have been evaluated and deemed adequate to reassess tolerances for these commodities.

Field residue data remain outstanding for the following crops: asparagus; corn, sweet (K + CWHR); corn, sweet, forage; sorghum forage and fodder; soybeans forage and hay; and wheat forage. In addition, aspirated grain fraction data remains outstanding for field corn.

Sufficient data to reassess tolerances for these commodities are not available at this time. Although sufficient field trial data are not available to reassess tolerances for all crops, sufficient data are available to do a reliable exposure assessment. (MRIDs 00018067, 00018076, 00018087, 00018089, 00018148, 00018171, 00018172, 00018175, 00018206, 00018375, 00018382, 00018443, 00018450, 00027635, 00163267, 40210901, 40537601, 41189801, 41377601, 41452601,

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41452701, 41501501, 41503401, 41569901, 42605901, 42948501, 43039101, and 43044101).

Two additional field residue studies on corn and soybean raw agricultural commodities have been submitted. However, data from these submissions were not evaluated because they were generated by Craven Laboratories. Replacement data for field corn commodities and soybean grain were found to be adequate. Replacement data are still needed for sweet corn raw agricultural commodities and soybean forage and hay. The existing feeding restriction prohibiting the feeding of soybean forage and hay should be removed because the feeding restriction is no longer considered practical *(see Livestock Feeds Table, 6/94 Subdivision O, Residue Chemistry. Guidelines)* (MRIDs 41510501, 41591801, 43039101, and 43044101).

Processed Food/Feed: All data for magnitude of the residue in processed food/feed have been evaluated and deemed adequate except that a full processing study is required for cottonseed and additional data are required to upgrade an existing potato processing study. In 1991, DuPont voluntarily deleted the linuron use on cotton. However, other registrants have not deleted the cotton use from their end-use product labels. Registrants are required to either submit the required processing study for cottonseed or amend their labels deleting the cotton use. The tolerance for cottonseed will be revoked if no registrants support this use.

Outstanding potato processing data are required for chips, granules, dry and wet peel waste; sufficient data are available to reassess tolerances and estimate dietary exposure for potato processed products. Because linuron is assessed as a Group C nonquantifiable carcinogen, it is subject to the Delaney clause of the FFDCA. See Section IV.B.1 "Tolerance Reassessment." (MRIDs 00018206, 42462901, 42542102, and 42560001).

Magnitude of the Residue in Meat, Milk, Poultry and Eggs: All data for magnitude of the residues in meat, milk, poultry, and eggs have been evaluated and deemed adequate. No tolerances are required for poultry and eggs. (MRIDs 00018209, 00018210, 00018375, 00018383, 00018450, 00018775, and 00029932).

Recently the Agency received interim data from DuPont indicating that residue levels of linuron in or on corn fodder exceeded the 1 ppm tolerance. Preliminary data from field trials on corn indicate

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a tolerance of 6 ppm will be required to cover residues resulting from current registered uses. These data were submitted to the Agency under 6(A) (2) of FIFRA. Since corn fodder is a major feed item for ruminants throughout the U.S., a revision to the previously estimated dietary burden to ruminants is required. The Residue Chemistry Chapter (6/29/82) to the Linuron Registration Standard previously estimated a "maximum plausible dietary load of 1.4 ppm." This estimate utilized the established tolerance of 1.0 ppm in or on corn fodder. However, assuming residues are present at levels of approximately 6 ppm (the level at which tolerances may be required considering the currently available 6 (a)(2) data) a hypothetical diet based on feeding 50% corn grain and 50% corn fodder would result in a dietary burden of approximately 3.1 ppm.

Based on available ruminant feeding studies, the Agency concludes that established tolerances for meat and milk are adequate to cover the increased dietary burden of 3.1 ppm. It should be noted however that the estimated residue level in ruminant liver (0.81 ppm) and kidney (0.81 ppm) are approaching the established tolerances of 1.0 ppm. Should the currently estimated ruminant dietary burden of 3.1 ppm be increased, established linuron tolerances for ruminant liver and kidney will need to be reassessed.

Confined/Field Rotational Crops: All data for nature of the residue in confined rotational crops have been evaluated and deemed adequate. The requirement for field rotational crop studies has been waived. (MRIDs 40104101 and 40730101). The following are rotational crop restrictions:

> "If initial seeding fails to produce a stand, crops registered for the rate of "name of product" that has been applied may be planted into the treated area."
>
> Unless otherwise directed, any crop may be planted after 4 months except for cereals where only barley, oats, rye, and wheat may be planted.

Reduction of Residues: All data for reduction of residues have been evaluated and deemed adequate except that additional information to upgrade existing potato and carrot cooking studies remains outstanding. However, since there is not a dietary risk, the additional information to upgrade the cooking studies will not be required. (MRIDs 41241201, 42379901, 42397201, 42462901, and 42462902).

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The asparagus cooking study shows washing with water reduces residues by 40%. Boiling removes an additional 25% of the residues, while steaming had little or no effect on reducing residue levels in or on asparagus.

A carrot cooking study reviewed and found to be unacceptable due to residues below the limit of quantitation does indicate that cooking in boiling water does reduce overall residues.

The potato cooking study shows that linuron residues concentrate in or on oven baked potatoes (1.5X) and microwave baked potatoes (1.6X), but are reduced in or on boiled potatoes (0.48X).

b. Occupational and Residential

Linuron is a substituted urea herbicide used to control germinating and newly emerging grasses and broad-leaved weeds. It is applied to agricultural crops, ornamental bulbs, and to poplar trees, for use in shelterbelts, in the mid-west. Formulations include water dispersable granules, wettable powders, flowable concentrates, and emulsifiable concentrates. Linuron is usually applied after the crop has been planted, but before the weeds emerge. In some cases, over-top sprays are applied to newly emerging crops such as carrots and celery. In asparagus, sprays may be applied between cuttings of newly emerging spears for weed control during harvesting activities. Current label directions allow for both ground and aerial applications. Although some registered uses are for crops that may be grown in home gardens, the Agency is not aware of any products that are labelled primarily for home use.

Postapplication/reentry and mixer/loader/applicator exposure data are required when both toxicity and human exposure criteria are met. The application methods (broadcast and directed) result in direct exposure of mixer/loaders and applicators to the formulated product. When workers enter treated areas to perform hand labor tasks, such as thinning, cultivation, and harvesting, or to perform irrigation-related tasks, they may be exposed to residues on the soil surface and to residues on the foliage following post-emergence applications. Therefore, linuron meets the Agency's human exposure criteria. The OPP/HED Toxicology Endpoint Selection Committee identifies two endpoints for assessing short-term and intermediate occupational exposure to linuron. Therefore, linuron meets the toxicity criteria.

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Mixer/Loader/Applicator Exposure (Handlers):

In the Guidance for the Reregistration of Linuron (June 29, 1984), the following personal protective equipment were required for mixer/loader/applicators handling linuron:

> One-piece overalls which have long sleeves and long pants constructed of finely woven fabric as specified in the USDA/WPA Guide for Commercial Applicators.
>
> Wide-brimmed hat and heavy-duty fabric work gloves.
>
> Instead of clothing and equipment specified above, the applicator can use an enclosed tractor cab which provides a filtered air supply.

The PPE requirements were based on concerns for linuron as a carcinogen, and that lifetime exposures for mixer/loader/applicators resulted in an unacceptable risk, without those PPE. In a subsequent OPP/HED Peer Review Committee and Science Advisory Panel, it was determined that the carcinogenic potential of linuron in humans is weak, and it should not be regulated using a linear multi-stage risk assessment model.

Since the issuance of the Registration Standard in 1984, linuron product labels have been modified in response to PR Notice 93-7, which implemented the labelling requirements of the 1992 Worker Protection Standard for Agricultural Pesticides. These WPS-mandated label modifications established personal protective equipment (PPE) requirements on each end-use product depending on the acute toxicity of the end-use product. However, if the existing labelling contained PPE requirements more stringent than those that the WPS would establish, the more stringent requirements would be retained. Current linuron labels, therefore, may contain a variety of PPE requirements, depending on what other active ingredients and on what inert ingredients are included in a particular formulation.

Mixer/loader/applicator (handler) exposure to linuron was derived from data in the Pesticide Handlers Exposure Database (PHED). Exposure for ground-boom and aerial applicators was addressed as well as exposure for mixer/loaders using wettable powder and liquid formulations.

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The data in PHED are normalized by pounds of active ingredient handled, and, are referred to as unit exposures. Whenever possible, surrogate unit exposures are chosen from studies having the same PPE as required on the labelling of the chemical currently being evaluated. When data are not available for certain clothing scenarios, existing data points are adjusted using a protection factor based on the type of PPE (eg. a 50% reduction to hand exposure for the use of gloves). Although a 90% protection factor for gloves has been used in the past, a conservative 50% reduction was used in this assessment. The handler assessment presented in this memorandum assumes the use of long sleeved shirt, long pants, gloves, and coveralls. This double layer is an upgrade to existing PPE.

Postapplication/Reentry Exposure (Workers):

The potential for postapplication/reentry exposure is unlikely following most applications of linuron. This is because most applications are made early in the season before reentry tasks are likely or are made to crops that are mechanically harvested. The notable exception is asparagus where applications of linuron are made between asparagus cuttings. Current labelling indicates a 24-hour reentry interval, which was established in the 1984 Registration Standard Guidance Document. The 24-hour reentry interval established by the 1984 Registration Standard Guidance Document was converted into a 24-hour restricted-entry interval through modifications to the labelling specified in PR Notice 93-7, which implemented the labelling requirements of the 1992 Worker Protection Standard for Agricultural Pesticides.

To formally establish a REI, the registrant submitted a worker exposure study addressing asparagus worker exposure "Exposure of Asparagus Harvesters to Lorox® (Linuron) Herbicide in California, 1986." In the study, the registrant measured exposures for three worker tasks; harvesters, sledders, and off-loaders. Harvesters cut the spears and leave them in bundles at various locations in the field. Sledders drive a tractor and wagon along the field and pick up the bundles of asparagus left by the harvesters. Off-loaders unload the asparagus from the wagons at the packing house. Because asparagus harvesting occurs over a long period of time, the use of both the short-term and the intermediate-term end-points are appropriate for addressing postapplication/reentry exposure. (MRID 40341801)

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The following confirmatory occupational exposure data are required:

132-1a Foliar Dislodgeable Residues (carrots and celery)
132-1b Soil Dislodgeable Residues (carrots and celery)
133-3 Dermal Exposure (carrots and celery)
133-4 Inhalation Exposure (carrots and celery)

The Agency requires that foliar and soil dislodgeable residue studies, and dermal and inhalation exposure studies be conducted concurrently.

3. Risk Assessment

a. Dietary

The acute dietary endpoint for one day was based on a developmental toxicity study in the rabbit. When 96.2% linuron was administered by gavage to New Zealand White rabbits at doses of 5, 25 or 100 mg/kg/day on days 7 through 19 of gestation, a maternal systemic toxicity was observed at 25 mg/kg/day, based upon reduced maternal body weight. The developmental toxicity NOEL was determined to be 25 mg/kg/day based upon an increased number of abortions, decreased mean number of fetuses per litter, decreased fetal body weight, and increased incidence of fetuses with skeletal variations of the skull at 100 mg/kg/day. The endpoint and dose for use in risk assessment is a NOEL of 25 mg/kg/day (basis described above). (MRID 00260064)

The RfD for linuron was determined to be 0.0077 (0.008) mg/kg bodyweight per day. This was based on results of a one-year chronic dog study in which hematological changes demonstrated LOELs of 4.17 and 3.49 mg/kg/day for males and females, and NOELs of 0.79 and 0.77 mg/kg/day. The RfD calculation was based upon the NOEL of 0.77 mg/kg/day and used an uncertainty factor of 100 to account for inter-species extrapolation and intra-species variability. (MRID 40952601)

There has been no WHO RfD determination at this time.

The Health Effects Division Metabolism Committee discussed the possible significance of 3,4-dichloroaniline residues in plants and animal tissues resulting from treatment with linuron. The Committee

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expressed concern that 3,4-DCA may be a carcinogen in light of the fact that p-chloroaniline is a quantifiable carcinogen. 3,4-DCA does not pose dietary risks of concern. Nonetheless, the Agency still considers linuron to be a chemical that "induces cancer" within the meaning of section 409 of the FFDCA.

Residues

Anticipated residues from the 1987 Special Review of Linuron were used in the analysis of chronic exposure.

Information on percent of crop treated was supplied by the Biological and Economic Analysis Division, a table entitled "Typical Annual Usage (1992) and Percentage of various U.S. Crops Treated with Linuron". For most crops, the estimate of percent crop treated is the same as or lower than the 1989 estimates provided by BEAD. However, no estimates were supplied for "small grains" in the 1993 table, whereas the estimate was "< 1%" in 1989. In cases where no estimates are supplied, Dietary Risk Evaluation System (DRES) policy is to assume that 100% of the crop is treated. Thus, the percent of crop treated value used in the DRES run went from 1% to 100% for barley, oats, and rye. DRES believes that this is likely to be an overestimate, and that the acutal (domestic) use on these crops may even be 0% since there are no registered products for these uses. However, in the absence of confirmation from BEAD, the default value of 100% was assumed.

Although this DRES analysis uses anticipated residues and percent of crop treated where available, a separate part of the analysis uses tolerances to estimate theoretical maximum exposure. The tolerance reassessment suggested that some tolerances should be revoked (barley, oats, rye, and popcorn) or that there were insufficient data to support a tolerance (asparagus, sheep). In these cases, the DRES analysis used the existing tolerance rather than the reassessed tolerance. The resulting Theoretical Maximum Residue Contribution (TMRC) is thus likely to be higher than what would be expected if all of the tolerances suggested in the tolerance reassessment were implemented. (It is possible, however, that a reassessed tolerance for asparagus and sheep could raise exposure above what is estimated in the TMRC.)

For the acute dietary exposure analysis, tolerance values were used. Anticipated residues for acute analysis were not provided. Information on percent of crop treated was not used.

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Proposed tolerances for lettuce, ginger, and taro, and proposed tolerance revisions for potatoes and meat byproducts, are not included in this DRES analysis.

Results

Chronic exposure: Exposure to the general population based on anticipated residues is expected to be approximately 0.000185 mg/kg bodyweight/day, or 2% of the Reference Dose. Of the standard subgroups routinely analyzed by the Dietary Risk Evaluation System, the two subgroups with the highest exposures are non-nursing infants less than 1 year old, with expected exposures of 0.000485 mg/kg/day (6% of the RfD), and children 1 through 6 years old, with expected exposures of 0.000343 mg/kg/day (4% of the RfD).

Acute exposure: High-end exposure to females 13 years of age or older (DRES' approximation of women of childbearing age) on any given day is expected to be 0.015 mg/kg/day, or result in a MOE of 1667 for developmental toxicity. Mean exposure is expected to be 0.003365 mg/kg/day, or 7400 times less than the NOEL for developmental toxicity.

The estimate of acute exposure is likely to be an overestimate inasmuch as it assumes that consumers will eat tolerance levels of linuron residue on all items simultaneously. This is an unlikely occurrence, given that less than 100% of any one crop is treated with linuron, and that residues are rarely at tolerance level on all fields that are treated.

b. Occupational and Residential

Occupational and Residential risk

The short term occupational or residential exposure for 1 to 7 days was based on a developmental toxicity study in the rat. Sprague-Dawley rats were given dietary doses of 50, 125 or 625 ppm (equivalent to 5.0, 12.1 or 49.8 mg/kg/day) on days 6-15 of gestation. The maternal and developmental NOEL is 12.1 mg/kg/day. The LOEL is 49.8 mg/kg/day based upon decreased maternal body weight and food consumption, and increased postimplantation loss and increased in litter and fetal incidences of resorptions (maternal and developmental effects, respectively). The endpoint and dose for use in risk assessment is a NOEL of 12.1 mg/kg/day as described above. (MRID 00018167)

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The intermediate term occupational or residential exposure (1 week to several months) was based on a three-generation reproduction study in the rat. Sprague-Dawley rats were given dietary doses of 0, 25, 125 or 625 ppm linuron (equivalent to 0, 1.25, 6.25 or 31.25 mg/kg/day) through three successive generations. Parental systemic effects observed included reduced premating body weight in females of all three generations at 125 and 625 ppm, reduced body weights at weaning for 125 ppm dams, and alopecia in both sexes for the F0 and F1b adults at 625 ppm. Based upon the findings at the mid-dose level, the systemic LOEL was determined to be 125 ppm (6.25 mg/kg/day), and systemic NOEL was 25 ppm (1.25 mg/kg/day). The reproductive NOEL was also 25 ppm based upon reduced fertility in the F2a through F3a generations at doses of 125 ppm or greater. The endpoint and dose for use in risk assessment is a NOEL of 1.25 mg/kg/day based upon reduced fertility at the LOEL of 6.25 mg/kg/day. (MRID 00146071)

Table 3 gives the Margins of Exposure (MOE's) for applicator and mixer/loader exposure scenarios. Information regarding the studies from which the surrogate data were selected is provided in Table 4. For all of the applicator scenarios, MOE's are greater than 100. However, MOE's for certain mixer/loader scenarios are below 100 for both short-term and intermediate-term exposure. Particularly low, are those MOE's for mixer/loaders supporting the aerial applications. For those scenarios, MOE's are below 100 for intermediate-term exposure, even with the use of closed mixing/loading systems.

MOE's are also low for handlers using open mixing/loading for ground-boom applications. MOE's for closed mixing/loading systems appear to be adequate.

Margins of exposure may be calculated from:

$$MOE = \frac{NOEL}{exposure}$$

- The NOEL equals 12.1 mg/kg/day for short-term (1-7 days) exposure
- The NOEL equals 1.25 mg/kg/day for intermediate (> 7 days) exposure

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Postapplication/Reentry Exposure (Workers):

The study "Exposure of Asparagus Harvesters to Lorox® (Linuron) Herbicide in California, 1986" (MRID 40341801) is considered supplemental, and can be used to evaluate the current use of linuron on asparagus. The sampling schedule was limited to 0 day, 1 day, and 3 days postapplication because of inclement weather. Therefore, a dissipation curve could not be established. However, off-loader exposure was measured on the first day of the study for workers handling asparagus treated 14 days prior to the initiation of the study. High winds and other complicating factors rendered the inhalation data unacceptable. The Agency decided to use these supplemental data because the major route of exposure is via the dermal route. The task specific worker MOE's are presented in the following table:

MOE's for Asparagus Reentry Workers

TASK (DAT)	HOURLY EXPOSURE (mg/hour)	AVERAGE DAILY EXPOSURE (ADE) (mg/kg/day)	Short-Term (1 - 7 days) MOE	Intermediate (> 7 days) MOE
Harvest (1)	3.386	0.009	1344	138
Sledder (1)	2.161	0.006	2017	208
Off-Loader (1)	2.022	0.005	2420	250

DAT - Days After Treatment

ADE = hourly exposure x 2% x 8 hr (dermal absorption rate, MRID 00143622, Acc#254933)
60 kg (body wt.)

Restricted-Entry Interval (REI):

The Agency recommends a restricted-entry interval (REI) of 24 hours for all crops. The REI is based on the MOE's calculated above. For crops such as celery and carrots, where intermediate exposure is likely, the 24 hour REI is required until worker exposure data are submitted by the registrant and evaluated by the Agency.

The early-entry personal protective equipment requirements established for the products containing linuron are coveralls, chemical-resistant gloves, shoes, and socks.

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Personal Protective Equipment (PPE) Requirements:

The personal protective equipment requirements for pesticide handlers of products containing linuron should, in general, be established based on the acute toxicity of the end-use product by route of entry as described in PR Notice 93-7 or other EPA guidance. However, due to concerns for the short-term and intermediate-term risks, the Agency establishes minimum handler personal protective equipment requirements for any end-use product containing linuron. Products containing linuron may contain more stringent PPE, but in no case may they require less stringent PPE than the following: coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant apron.

Since the Agency is unaware of any linuron end-use products that are primarily intended for home-use, the Agency will not establish entry restrictions or personal protective equipment requirements for home-use products at this time.

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Table 3. Summary Exposure Values for Linuron[A]

Exposure Scenario	Application Type	Application Targets	Application Timing	Treatment Rate (lb ai/acre)[B]	Daily Maximum Treated (acres)[C]	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	ADE[D] Combined Systemic Dose (mg/kg/day)	Short-term exposure MOE 1 to 7 days	Intermediate exposure MOE 7 days to several months
Mixer Loader Exposure Levels										
Open Pour Liquids (I)	Aerial	Variable	Variable	1 - 2.5	350	0.113	0.00057	0.014 - 0.033	360 - 880	40 - 88
Open Mix Wettable Powder (II)	Aerial	Variable	Variable	1 - 2.5	350	0.2	0.0037	0.026 -0.065	184 - 464	16 - 48
Open Pour Liquids (I)	Ground-boom	Variable	Variable	1 - 2.5	100	0.113	0.00057	0.004 - 0.008	>1000	128 - 336
Open Mix Wettable Powder (II)	Ground-boom	Variable	Variable	1 - 2.5	100	0.2	0.0037	0.008 - 0.019	>500	64 - 168
Closed Mix (III)	Ground-boom	Variable	Variable	1 - 2.5	100	0.02	0.0003	0.008 - 0.0019	>1000	>500
Closed Mix (III)	Aerial	Variable	Variable	1 - 2.5	350	0.02	0.0003	0.003 - 0.0063	> 1000	>100
Applicator Exposure Levels										
Ground-boom Application (IV)	Broadcast	**Asparagus**, Direct Seeded or newly planted crowns	Preemergence	1 - 2 Two lb ai per season	50	0.014	0.0004	0.002 - 0.004	> 1000	> 300
Ground-boom	Broadcast	**Asparagus**, Direct Seeded or newly planted crowns	Postemergence	0.5 - 1 One to two applications per season	50	0.014	0.0004	0.001 - 0.002	> 1000	> 500
Ground-boom	Broadcast	**Asparagus**, Established Beds	Preemergence	1 - 2 One application	50	0.014	0.0004	0.002 - 0.004	> 1000	> 300
Ground-boom	Broadcast	**Asparagus**, Established Beds	Postemergence, before cutting season or immediately after cutting	0.5 - 1 One to four applications	50	0.014	0.0004	0.001 - 0.002	> 1000	> 500
Ground-boom	Broadcast	**Asparagus**, Established Beds (fern stage)	Directed Postemergence	2 - 4 One application	50	0.014	0.0004	0.004 - 0.004	> 1000	> 100
Ground-boom	Broadcast	**Bulbs**, (calla lily, daffodil, tulip, Dutch iris)	After Planting, before plants emerge	1 One application	25	0.014	0.0004	0.001	> 1000	> 1000

Table 3 (continued)

Exposure Scenario	Application Type	Application Targets	Application Timing	Treatment Rate (lb ai/acre)[B]	Daily Maximum Treated (acres)[C]	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	ADE[D] Combined Systemic Dose (mg/kg/day)	Short-term exposure MOE 1 to 7 days	Intermediate exposure MOE 7 days to several months
Ground-boom	Broadcast	**Carrots**, Florida	Preemergence	0.5 - 1 No more than 2 lb ai per season	100	0.014	0.0004	0.002 - 0.004	> 1000	> 250
Ground-boom	Broadcast	**Carrots**, Ohio Michigan, and Wisconsin	Preemergence	0.5 - 1.5 No more than 2 lb ai per season	60	0.014	0.0004	0.001 - 0.004	> 1000	> 250
Ground-boom	Broadcast	**Carrots**, East of the Rocky Mountains	Postemergence, Non-directed spray after carrots are 3" tall	0.75 - 1.5 A repeat application may be made. No more than 2 lb ai/crop	15	0.014	0.0004	0.001	> 1000	> 1000
Ground-boom	Broadcast	**Celery**, East of the Rocky Mountains	Non-Directed Spray After Transplanting	0.75 - 1.5 One application	100	0.014	0.0004	0.003 - 0.007	> 1000	> 150
Ground-boom	Broadcast	**Corn**, East of the Rocky Mountains	Preemergence, after planting	0.375 - 1.5 One application	100	0.014	0.0004	0.002 - 0.007	> 1000	> 150
Ground-boom	Broadcast	**Corn (Field and Sweet)**	Postemergence, directed spray after corn is at least 15" high	0.625 - 1.5 One application	100	0.014	0.0004	0.003 - 0.007	> 1000	> 150

Table 3 (continued)

Exposure Scenario	Application Type	Application Targets	Application Timing	Treatment Rate (lb ai/acre)[B]	Daily Maximum Treated (acres)[C]	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (mg/lb ai)	ADE[D] Combined Systemic Dose (mg/kg/day)	Short-term exposure MOE 1 to 7 days	Intermediate exposure MOE 7 days to several months
Ground-boom	Broadcast	**Parsley,** Texas	Preemergence, after planting	1.5 One application	25	0.014	0.0004	0.002	> 1000	> 700
Ground-boom	Broadcast	**Parsnips**	Preemergence, after planting	0.75 - 1.5 One application	15	0.014	0.0004	0.0001	> 1000	> 1000
Ground-boom	Broadcast	**Poplar (Shelterbelt)**, Midwest	Directed spray after bud break in the spring	1 - 2 No more than 4 lb ai/year	25	0.014	0.0004	0.001 - 0.002	> 1000	> 600
Ground-boom	Broadcast	**Potatoes**, East of the Rocky Mountains	Preemergence, after planting	0.75 - 2 One application	100	0.014	0.0004	0.003 - 0.007	> 1000	> 150
Ground-boom	Broadcast	**Potatoes**, Wisconsin (Central Sands Area)	Preemergence, after planting	0.5 - 1 One application	100	0.014	0.0004	0.002 - 0.004	> 1000	> 250
Ground-boom	Broadcast	**Sorghum**	Preemergence	0.313 - 1 One application	100	0.014	0.0004	0.001 - 0.004	> 1000	> 300
Ground-boom	Broadcast	**Sorghum**	Postemergence, Directed spray	0.5 - 1 One application	100	0.014	0.0004	0.002 - 0.004	> 1000	> 250
Ground-boom	Broadcast	**Soybeans**, Conventional Tillage	Preemergence	0.16 - 2.5 One application	100	0.014	0.0004	0.001 - 0.01	> 1000	> 100
Ground-boom	Broadcast	**Soybeans**, Minimum or No-Tillage	Preemergence	0.375 - 2.5 One application	100	0.014	0.0004	0.001 - 0.01	> 1000	> 100
Ground-boom	Broadcast	**Soybeans**	Postemergence, Directed spray	0.5 -1 Up to two applications not to exceed 1 lb ai	100	0.014	0.0004	0.002 - 0.004	> 1000	> 250
Aerial (total deposition) (V)	Broadcast	Variable	Variable (not including directed sprays)	1 - 2.5	350	0.004	0.0002	0.005 - 0.01	> 1000	> 100

[A] Liquid and wettable powder linuron formulations were chosen to represent best and worst case scenarios respectively.

[B] A range of application rates are provided whenever the amount used is based on soil types, cropping systems, tank mixes, or weed species.

[C] Daily maximum treated acres are based either on the amount acreage that can be treated in one day or based on average farm size. The average farm size is based on data presented in the 1987 Census of Agriculture.

[D] The Average Daily Exposure (ADE) (mg/kg/day) = [(Exposure (mg/lb ai) * Appl. Rate (lb ai/acre) * Acres Treated)/60 kg]. A 16% dermal absorption rate was assumed for dermal exposure and 100% absorption was assumed for inhalation exposure. Values presented in this column were rounded to the second decimal place for mixer/loaders and to the third decimal place for applicators. The Margins of Exposure (MOE) were calculated using the unrounded values.

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Table 4. Exposure Scenario Descriptions for Linuron[a]

Exposure Scenario (Scene #)	Data Source	Clothing Scenario	Equipment	Formulations	Standard Assumptions (8-hour work day)	Comments
Mixer/Loader Exposure Levels						
Open Pour Liquids (I)	PHED	Long Pants, Long-Sleeves, No Gloves	Open System	All Liquids	For all liquid formulations plus dry flowables such as water dispersable granulars	Acceptable PHED grades, 14+ replicates, 50% protection factor applied to hand exposure to account for the use of chemical resistant gloves.
Open Mix Wettable Powders (II)	PHED	Total Deposition	Open System	PHED Wettable Powder Category	Wettable powder only	All PHED grades, 3 to 14 replicates, 50% protection factor applied to dermal and to hand exposure levels to account for the use of normal work clothing and chemical resistant gloves.
Closed Mix Liquids (III)	PHED	Total Deposition	Closed System	PHED Closed System Category	All closed systems considered similar for this assessment	PHED grades A/B/C, 13 replicates, 50% protection factor applied to dermal and to hand exposure levels to account for the use of normal work clothing and chemical resistant gloves.
Applicator Exposure Levels						
Ground-boom Application (IV)	PHED	Long Pants, Long-Sleeves, No Gloves	PHED Ground-boom Category/Open Cab	All Formulations	Tractor based ground-boom	PHED grades A/B/C, 6+ replicates, 50% protection factor applied to hand exposure to account for the use of chemical resistant gloves, and for the use of coveralls.
Aerial (V)	PHED	Long Pants, Long-Sleeves, No Gloves	PHED Aerial Fixed Wing Category	All Formulations	All fixed-wing aerial data	No helicopter data available, all PHED grades, 4 to 41 replicates, 50% protection factor applied to hand exposure to account for the use of chemical resistant gloves when entering and exiting aircraft.

[a] All exposure levels presented in Appendix 1 reflect the current PPE requirements for linuron handlers. Any exposure values which did not reflect the required clothing scenario were adjusted using protection factors (see comments). Unit dermal exposure was assumed to be 50 percent hand exposure and 50 percent remaining dermal exposure. All dermal exposure values are the "best" fit mean. The "best" fit mean is the composite total dermal exposure based on using the geometric mean for lognormal distributed data, arithmetic mean for normal distributed data, and the median for all other distribution types.

C. Environmental Assessment

1. Environmental Fate

At this time, two data requirements in the environmental fate guidelines are not fulfilled for linuron: leaching/adsorption/desorption (163-1) and terrestrial field dissipation (164-1). The environmental data base for only the parent linuron is essentially complete. Information on the persistence, mobility, and dissipation pathways of several primary degradates of linuron is not currently available; therefore, the environmental fate assessment must be considered incomplete and tentative.

a. Environmental Chemistry, Fate and Transport

Hydrolysis

Phenyl-labeled [^{14}C] linuron did not degrade via hydrolysis in sterile buffer solutions at pH 5, 7, or 9 and incubated in the dark at 25 ± 1 °C for 30 days. The registrant calculated half-lives for linuron in the buffer solutions averaged 945 days. (MRID 40916201)

Photodegradation in Water

Phenyl-labeled [^{14}C] linuron degraded slowly with a half-life greater than 30 days (registrant-calculated half-life of 49 days) in sterile aqueous pH 5 buffer solution irradiated with natural sunlight at 25° C. At 30 days posttreatment (total light intensity = 196,006 Watt-hours/m^2), linuron comprised 61.6% of the applied radioactivity; volatiles totaled 10.2% of the applied and unidentified degradates (at least 8 separate peaks) each accounted for up to 5.1% of the applied. In the dark control after 30 days, 92.1% of the recovered was undegraded parent linuron, suggesting the observed degradation was primarily photolytic rather than hydrolytic. The ultraviolet-visible light absorption spectrum for linuron at 18 ppm displayed absorption maxima at 210, 245, and 280 nm with some overlap at greater than 290 nm, further supporting direct photolysis of the parent linuron. (MRID 40103601)

Photodegradation in Soil

Phenyl-labeled [^{14}C] linuron degraded with a half-life greater than 15 days on silt loam soil irradiated continuously with a Pyrex glass-filtered xenon arc light at 25° C. After 15 days of irradiation, the soil contained 78.8% of the recovered radioactivity as parent linuron. Minor degradates identified were norlinuron, desmethyl linuron, and 3,4-dichloroaniline (each less than 8.4% of the recovered). Unidentified polar compounds comprised less than 4% of the recovered, unextractable compounds were less than 2.5% of the recovered, and volatiles were less than 0.1% of the recovered at all sampling intervals. In the dark controls, parent linuron accounted for 96.5% of the recovered radioactivity after 15 days, suggesting that degradation was primarily photolytic and not biologically-mediated. (MRID 40171711)

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Photodegradation in Air

No studies were reviewed. The data requirement was waived because the reported vapor pressure for linuron was 1.5×10^{-5} mm Hg at 24E C; therefore, volatilization and subsequent photodegradation in air are not considered probable routes of dissipation.

Aerobic Soil Metabolism

Linuron degraded with a half-life of 49 days in sandy loam soil that was incubated in the dark at 25° C and 75% of 0.33 bar moisture content. The primary nonvolatile degradate was 3-(3,4-dichlorophenyl)-1-methylurea (desmethoxy linuron; maximum average concentration of 3.0% of the applied at 120 days posttreatment, decreasing to 1.9% of the applied by 365 days); other nonvolatile degradates were 3-(3,4-dichlorophenyl)-1-methoxyurea (desmethyl linuron; maximum average concentration of 2.1% of the applied at 365 days posttreatment) and 1-(3,4-dichlorophenyl)urea (norlinuron; maximum average concentration of 1.9% of the applied at 28 days). By 12 months posttreatment, unidentified polar [^{14}C]residues increased to 4.7% (0.20 ppm) of the applied and "other" unidentified [^{14}C]residues comprised 1.8% (0.07 ppm). At 12 months posttreatment, $^{14}CO_2$ was the major degradate (totaled 69% of the applied). (MRID 41625401)

Anaerobic Soil Metabolism

No studies were reviewed. The anaerobic aquatic metabolism study was used to fulfill this data requirement. (MRID 40142501)

Anaerobic Aquatic Metabolism

Phenyl-labeled [^{14}C] linuron degraded with a half-life of less than 3 weeks in nonsterile anaerobic silt loam and sand soil: water (1:1) systems incubated in the dark at 24° C. Primary degradates were desmethoxy linuron, desmethoxy monolinuron, and norlinuron. Minor degradates were desmethyl linuron and dichloroaniline. (MRID 40142501)

Aerobic Aquatic Metabolism

No studies were required because there are no aquatic uses of linuron.

Leaching and Adsorption/Desorption

Based on the results of two studies reviewed by the Agency and supplemental information from three peer-reviewed journal publications on linuron mobility, linuron appears to be slightly mobile in coarse-textured soils (K_{ads} = 2.7-5.0 for sandy loams) and relatively immobile in fine-textured soils (K_{ads} = 7.2-7.7 for silt loams). Adsorption of linuron is probably related to the

organic matter content with increased adsorption reported for soils with higher organic matter content ($K_{ads,om}$ less than 200 for two soils with greater than4 % OM). The leaching/adsorption/ desorption (163-1) studies are partially acceptable because information on the K_ds for the primary linuron degradates formed under anaerobic conditions (desmethoxy linuron, desmethoxy monolinuron, norlinuron) is not currently available. Adsorption coefficients (K_ds) may be determined using batch equilibrium test methodology. **A new leaching/adsorption/ desorption study is required**. The additional data required will be used to assess the mobility of the primary degradates of linuron and may be applied to complete computer simulation modeling for the fate and transport of the primary degradates.(MRIDs 00148443 and 00146073)

Volatility

No studies were reviewed. The data requirement was waived because the reported vapor pressure of linuron is 1.5×10^{-5} mm Hg at 24EC; therefore, volatilization is not considered a probable route of dissipation.

Terrestrial Field Dissipation

Additional data are required for the terrestrial field dissipation studies to assess the rates and pathways of dissipation of parent linuron and its primary degradates. Three field studies were reviewed; (MRID# 41734201, 41734202) which provided partially acceptable or supplemental information on the field dissipation of linuron in California (1988 and 1989) and Delaware (1988). The data requirement is not fulfilled because the patterns of formation and decline of total linuron residues could not be assessed, and field test procedures and analytical methodology were not completely described. The California (1988) study may be upgradable if additional information on study methods and early soil sample results can be provided; however, the Delaware and the 1989 California studies can not be upgraded because the consistent presence of linuron in the control plot confounds accurate assessment of the pattern of formation and decline of total linuron residues. A new study is needed to satisfy the data requirement. The 1988 California study may be upgraded. (MRIDs 41734201, 41734202)

Bioaccumulation in Fish

Linuron residues accumulated in bluegill sunfish during 28 days of exposure to water treated at 0.1 and 1.0 ppm [^{14}C] linuron. Maximum bioconcentration factors were 49x for whole fish, 240x for viscera, 34x for muscle and 39x for carcass tissues. After 28 days of exposure, linuron residues in the viscera were identified as desmethyl linuron, norlinuron, and glucuronide conjugates. The edible tissues were not analyzed for linuron residues. Residues rapidly declined to approximately 10 % of maximum levels after the 14-day depuration period. (Accession # 258300)

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Droplet Size Spectrum and Drift Field Evaluation

No studies were reviewed. The registrant is a participating member of the Spray Drift Task Force. Information regarding spray drift of linuron must be provided upon completion of the Spray Drift Task Force data base. These studies may be required by the Agency when toxicological considerations are indicated by either the Ecological Effects Branch and/or the Health Effects Division. Information on spray drift of linuron for ground boom application may be estimated from the forthcoming results of the Spray Drift Task Force.

b. Environmental Fate Assessment

The review of acceptable, partially acceptable and supplemental information in the environmental fate data base, indicates that parent linuron appears to be moderately persistent and relatively immobile. Increased mobility of linuron may occur under specific environmental conditions such as coarse textured soils and soils with low organic matter levels.

Linuron dissipates principally by biotic processes such as microbial degradation. Degradation of linuron by abiotic processes (hydrolysis, photolysis, volatilization) does not appear to be a significant route of dissipation.

Partially acceptable and supplemental information on leaching and adsorption/desorption suggests that linuron is primarily adsorbed to soil organic matter with limited adsorption to the inorganic, mineral phase of soil. Linuron would tend to be more mobile in surface soils with low organic matter levels or in subsoils exposed on the land surface because of erosion. Decreased adsorption in low organic matter soil horizons may result in enhanced mobility and increased leaching potential of parent linuron. For surface soils with adequate organic matter levels, the combined processes of adsorption and microbial degradation would limit the potential for linuron to migrate to ground water.

Transport of linuron dissolved in surface runoff and/or in suspended sediment through runoff to surface water bodies (lakes, streams, etc.) could result; however, based on degradation rates and by-products from anaerobic aquatic metabolism studies, fairly rapid degradation of parent linuron to three primary metabolites (desmethoxy linuron, desmethoxy monolinuron, norlinuron) would occur. Information on the mobility and persistence of these primary degradates is not currently available from the studies submitted for the environmental fate data base.

Ground Water. Linuron has been detected in ground water in four states including Georgia, Missouri, Virginia, and Wisconsin at levels ranging up to 5.00 Fg/L (Hoheisel et al., 1992). A review of the studies in which the ground water detections were reported gave the following results:

1. Georgia

Detections in ground water were solely from STORET which did not allow a detailed review. Concentrations of linuron ranged from 1 to 5 Fg/L (ppb). Recent information submitted by the State of Georgia indicates that this data is suspect.

2. Missouri

Rural private wells in agricultural areas of Missouri were monitored for pesticide residues. Linuron was detected at concentrations ranging from 0.5 to 1.9 Fg/L (Sievers and Fulhage, 1989a and 1991). In another study conducted in Missouri (Sievers and Fulhage, 1989b), linuron was also detected in ground water in rural agricultural wells at levels ranging from 0.48 to 0.9 Fg/L. The study examined ground-water quality in eight major agricultural areas in the state, without regard to the vulnerability of the soils to leaching, nor to areas of high linuron use.

Although there is indication that there were some interference problems with the mass spectrometer detector due to sulfur and organic matter for linuron detections below 1 Fg/L, results for detections reported above 1 Fg/L appear valid. No information was provided about the wells, depth to ground water, or detection limits.

3. Virginia

Eight monitoring wells and four household wells were sampled for a suite of pesticides including linuron (Mostaghimi, 1992). There were no indications of point-source contamination or problems with the wells during the study. Linuron was detected in 50 % of the monitoring wells (4 of 8 wells) at levels ranging from 0.35 to 1.31 Fg/L. The extensive QA/QC plan for the sampling program and GC analysis provided a high degree of confidence for these detections.

4. Wisconsin

In a Wisconsin study (Postle and Brey, 1991), monitoring wells were located in areas that were highly vulnerable to ground-water contamination. All detections were from areas with normal field use conditions. Linuron was detected at one site at concentrations that ranged from 1.3 to 2.7 Fg/L.

Linuron exhibits some of the properties and characteristics associated with chemicals that have been detected in ground water. Linuron is a moderately persistent chemical with an aerobic soil metabolism half-life that ranges from 49 to 91 days. In addition, its field dissipation half-life has been reported to range from a minimum of 57 days to a maximum of 100 days (.8 to .14 weeks, respectively). Because linuron is sufficiently persistent and may be

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mobile under certain environmental conditions, it has the potential to impact ground-water quality.

Surface Water. Linuron can be applied by ground spray and therefore could contaminate surface waters by spray drift. Substantial quantities of linuron could be available for runoff to surface waters for several weeks post-application (photodegradation on soil half-life = approximately one month; aerobic soil half-life =49 days; terrestrial field dissipation half-lives = 57 and 100 days). The moderately low to intermediate soil/water partitioning of linuron (K_d = 2.7, 5.0, 7.7, and 7.2; K_{oc} from SCS database = 370) indicates that substantial fractions of linuron runoff could occur as both dissolution in runoff water and adsorption to eroding soil.

Resistance to abiotic hydrolysis coupled with only moderate susceptibility to direct photolysis in water (half-life = 1-2 months) and aerobic biodegradation indicates that linuron has the potential to be somewhat persistent in surface waters, particularly those with low microbiological activities and long hydrological residence times. Its reported half-life in an anaerobic aquatic metabolism study (less than 21 days) indicates that it may be less persistent in water and sediment under anaerobic conditions than under aerobic conditions. Based upon its relatively low to intermediate soil and sediment to water partitioning, significant fractions of any linuron in water could exist both dissolved in the water column and adsorbed to suspended and bottom sediment. The reported BCFs for linuron (ranging from 40x to 240x) indicate that the bioconcentration potential for linuron is relatively low.

The available data on the major degradates of linuron are insufficient to assess their runoff potential or persistence in surface water.

Baker (1988) sampled 8 tributaries of Lake Erie from April 15 to August 15 of 1983 through 1985. He reported April 15-August 15 time weighted mean concentrations of linuron ranging from below the detection limit of 0.001 µg/L to 0.860 µg/L and an average April 15-August time weighted mean of 0.21 µg/L. He reported maximum concentrations ranging from below the detection limit to 10.9, 14.2 and 160 µg/L and an average maximum of 8.8 µg/L. The USGS sampled 8 widely spread locations within the Mississippi Basin at frequent intervals from April 1991 to April 1992. Linuron was detected at a concentration of approximately 0.1 µg/L in one of the 46 samples collected from the White River. Linuron was not detected above a detection limit of 0.01 µg/L in any of the samples collected from the other 7 locations.

The Agency has used the computer model PRZM to compare the relative leaching potential of linuron and 12 other corn herbicides to that of atrazine. Based upon that analysis, the Agency predicted that under the conditions modeled, the percent of applied linuron removed by runoff could be comparable to somewhat greater than atrazine.

Linuron is not currently regulated under the Safe Drinking Water Act (SDWA). Therefore, no MCL has been established for it and water supply systems are not required to sample and analyze for it. In addition, no drinking water health advisories have been established for linuron. However, based upon the Reference Dose, the

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Agency has (for screening purposes only) a low lifetime health advisory for linuron of 6.0 µg/L. Although the available data suggests that the average annual linuron concentration will generally be well below 6 µg/L, the available data do not necessarily include those from watersheds that drain high linuron use areas. In addition, the relatively low to intermediate soil to water partitioning of linuron indicates that the primary treatment processes employed by most water supply systems to remove suspended sediment may not always be completely effective in removing linuron. Consequently, the Agency does have some moderate concerns for potential risks of linuron to surface water source supply systems.

2. Ecological Effects

a. Ecological Effects Data

(1) Terrestrial Animal Data

Avian Acute Toxicity

Avian Acute Oral Toxicity Findings			
Species	**% Test Material (TGAI)**	**LD_{50}**	**Conclusion**
Bobwhite Quail	92.8	940 mg/kg	slightly toxic

These results show that linuron is slightly toxic to birds on an acute basis. The guideline requirement for the avian acute oral LD_{50} study is fulfilled. (MRID 00150170)

Avian Subacute Dietary Toxicity

No acceptable avian dietary toxicity studies on technical linuron have been submitted for review. However, the following data from the USFWS (United States Fish and Wildlife Service) using a 50% formulation were considered. Some toxicity in formulation testing may be due to ingredients other than the active ingredient. Other formulations may be more or less toxic, depending on their ingredients. Technical testing allows prediction of the toxicity due to the active ingredient across all formulations. Therefore, tests with the technical material are still required.

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Avian Subacute Dietary Toxicity Findings			
Species	**% Test Material**	**LC_{50}**	**Conclusions**
Mallard Duck	50	3083 ppm	slightly toxic
Japanese Quail	50	>5,000 ppm	practically nontoxic
Ring-necked Pheasant	50	3438 ppm	slightly toxic

The USFWS extrapolation suggests that 100 precent active ingredient material would be considered "slightly toxic" to the mallard and ring-necked pheasant and "practically nontoxic" to the Japanese quail. (MRID 00034769).

Avian Reproductive Toxicity

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 linuron is persistent and can be applied more than one time during a season these studies were required.

Avian Reproductive Toxicity		
Species	**% Test Material**	**Results**
Mallard Duck	98.4	NOEL = 100 ppm LOEL = 300ppm(1)
Bobwhite Quail	98.4	NOEL = 100 ppm LOEL = 300 ppm(2)

(1) Treatment-related effects in adult body weight, feed consumption, egg production, and eggshell thickness.
(2) Treatment-related effects in egg production, hatchability, and offspring survival.

There are sufficient data to characterize the effects of linuron on avian reproduction. The No Observable Effects Level for the mallard duck is 100 ppm and the Lowest Observable Effects Level is 300 ppm. (MRID 42541802)

The No Observable Effects Level for the bobwhite quail is 100 ppm and the Lowest Observable Effects Level is 300 ppm. (MRID 42541801)

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Toxicity to Mammals

Mammalian Acute Oral Toxicity Findings		
Species	**LD_{50}(mg/kg)**	**Conclusion**
Rat	2100	practically nontoxic

The available data indicate that at a lowest acute oral LD50 of 2100 mg/kg, linuron is practically nontoxic to the rat.

Toxicity to Insects

The minimum data required to establish the acute toxicity to honey bees is an acute contact LD_{50} study with the technical material.

Acute Toxicity to Insects			
Species	**% Test Material**	**LD_{50}**	**Conclusion**
Apis mellifera	not reported	120.86 ug/bee	practically nontoxic

There is sufficient information to characterize linuron as practically non-toxic to bees. (MRID 00018842).

(2) Aquatic Animal Data

Freshwater Fish Toxicity

Acute testing with the TGAI

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 freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish).

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Freshwater Fish Acute Oral Toxicity			
Species	**% Test Material (TGAI)**	**LC_{50}**	**Conclusions**
Rainbow trout	96.2	3 ppm	moderately toxic
Bluegill sunfish	96.2	9.6 ppm	moderately toxic

The results of the 96-hour acute toxicity studies indicate that linuron can be characterized as being moderately toxic to both cold and warm water fish. (MRIDs 40445501 and 40354201).

Acute testing with the formulated product

Formulated product testing is specified if there is direct application to an aquatic environment or if EECs are greater than or equal to the LC50. Linuron is registered for use on rights-of-way (ROWs) which can result in a direct application to aquatic environments.

Freshwater Fish Acute Testing with the Formulated Product			
Species	**% A.I.**	**Result LC50**	**Conclusions**
Rainbow trout	Lorox 50 (WP)	16.4 ppm	slightly toxic
Bluegill sunfish	Lorox 50 (WP)	16.2 ppm	slightly toxic
Bluegill sunfish	Lorox 50 (DF)	9.2 ppm	moderately toxic

The results of the 96-hour EC50 studies indicate that Lorox 50 WP (wettable powder) is slightly toxic to rainbow trout and bluegill sunfish. Lorox 50 DF (dry flowable) is considered moderately toxic to bluegill sunfish. (MRIDs 00018165, 00018165, and 00018198).

Chronic Test-Early Life Stage

The fish early life stage is required to support reregistration of a chemical if exposure is expected to be continuous, recurrent or persistent, and multiple applications of the chemical may occur. The minimum data required to establish chronic toxicity of linuron to fish is the early life stage toxicity test based on survival of fish embryos and post-hatch larvae.

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Chronic Test-Early Life Cycle		
Species	**% A.I.**	**NOEC**
Rainbow trout	98.4	< 0.042 ppm

The Maximum Allowable Toxicant Concentration (MATC) could not be determined for linuron since effects on fish length were seen at the lowest test level. At present, the Agency does not know at what level linuron will not have adverse effects on fish, since a NOEL (No Observable Effects Level) was not determined in fish testing. Submission of a core study will enable the Agency to determine this level, and thus determine what maximum application rate of linuron could be used without producing residues capable of causing the kinds of chronic effects evaluated under current test protocols. Therefore, additional testing is required. (MRID 42061804).

Freshwater Invertebrate Toxicity

Acute testing with the TGAI

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

Freshwater Invertebrate Toxicity Findings			
Species	**% Test Material (TGAI)**	**EC_{50}**	**Conclusion**
Daphnia magna	94.4	0.12 ppm	highly toxic

There is sufficient information to characterize linuron as highly toxic to aquatic invertebrates. (MRID 00142932).

Acute testing with the formulated product

The minimum data requirement to establish acute toxicity of the formulated product to freshwater invertebrates is a 48-hour acute study.

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Acute Toxicity Findings on the End-Use Formulation			
Species	**% A.I. formulated**	**LC50**	**Conclusion**
Daphnia magna	54	1.1 ppm	moderately toxic

There is sufficient information to characterize the formulated product of linuron as moderately toxic to freshwater aquatic invertebrates. (MRID 00018199).

Chronic Test-life cycle

The *Daphnia* Life Cycle is required to support reregistration if the chemical's presence in water is likely to be continuous, recurrent or persistent, and multiple applications of the chemical may occur. The minimum data required to establish chronic toxicity of linuron to invertebrates is the Daphnia life cycle test based on reproduction, growth and survival.

Chronic Test-Life Cycle		
Species	**% A.I.**	**Results**
Daphnia magna	98.4	MATC > 0.13 < 0.24 ppm

Based on the data submitted, the MATC is greater than 0.13 and less than 0.24 ppm. The Agency has chronic invertebrate data that appear inconsistent with acute data: chronic effects were not seen until levels higher than those causing acute effects. Also, invertebrates were more sensitive than fish in acute tests, but appear considerably less sensitive in the chronic test. Therefore, additional testing is required based on inconsistent results with the acute toxicity data. (MRID 42153401)

Estuarine/Marine Toxicity

Acute testing with the TGAI

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.

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The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters.

Estuarine/Marine Acute Toxicity Findings			
Species	**% Test Material (TGAI)**	**LC_{50}**	**Conclusions**
Sheepshead minnow	98.4	0.89 ppm	highly toxic
Eastern oyster	98.4	5.4 ppm	moderately toxic
Mysid shrimp	98.4	3.3 ppm	moderately toxic

There is sufficient information to characterize the TGAI of linuron as highly toxic to the sheepshead minnow and moderately toxic to the eastern oyster and mysid shrimp. (MRIDs 42061801, 42061802, and 42061803).

Acute testing with the formulated product

Marine and estuarine testing using the formulated products is required due to the ROW (Rights-of-way) use. ROWs could cross virtually any habitat, including marine aquatic habitat such as salt marshes. Data are not currently available. Testing is required with at least the most sensitive species in acute testing (sheepshead minnow) using the DF (dry flowable) formulation. A DF formulation was found to be more toxic than expected based on active ingredient testing. Because of the ROW (right-of-way) use, there could be direct exposure to the aquatic environment by the formulated product. TEP testing will enable the Agency to assess the risk of specific formulation(s) actually used on ROWs. Additional species and/or formulations may also be required.

Chronic effects

Chronic marine and estuarine testing are indicated based on the same criteria as freshwater species. In the case of linuron, these indications include (1) LC50 value less than 1 mg/l, (2) EEC $ 0.01 LC50 and (3) aquatic half-life of less than 4 days. Sheepshead minnow and mysid shrimp should be tested.

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(3) Non-Target Plants Data

Toxicity to Terrestrial Plants

Data requirements for determining toxicity to terrestrial plants (Tier 2) remain outstanding. These data are required for linuron because it is an herbicide registered for use on terrestrial food and nonfood sites and the vapor pressure is $ 1.0 X 10^{-5}. Labeling indicate that aerial application can be used for soybeans, as well as ground boom spray for other crops. However, a plant risk assessment for linuron cannot be performed without the phytotoxicity data.

Toxicity to Aquatic Plants

Only one of the five required species for testing for toxicity to aquatic plants has been submitted. Testing for *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom remain outstanding. These data are required for linuron as it is an herbicide registered for use on terrestrial food/nonfood sites, has a vapor pressure $ 1.0 X 10^{-5} mm Hg, and a water solubility greater than 10 ppm. These data are required to conduct the plant risk assessment for linuron.

Aquatic Plant Toxicity		
Species	**% A.I.**	**EC_{50}**
Selenastrum capricornutum	**100**	**5-day = 0.067 mg ai/l**

With a 5-day exposure of 0.067 mg active ingredient per liter of linuron, *S. capricornutum* can be expected to sustain a 50% reduction in density or number of cells. (MRID 42086801).

b. Ecological Effects Risk Assessment

(1) Risk to Terrestrial Animals

Nontarget insects

Although honeybees could be exposed to linuron, when used on corn and cotton specifically, minimal risk is expected as linuron is considered "practically nontoxic" (LD_{50} = 120.86 ug/bee) to honey bees.

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Avian and mammalian species

Avian and mammalian species may be exposed to linuron through multiple routes, including dietary and dermal. The criterion for the presumption of high risk from exposure for acute avian and mammalian species is a value greater than or equal to 0.5 for the quotient of the estimated environmental concentration (EEC) divided by the lowest LC_{50} value for birds and mammals--this is known as the risk quotient (RQ).

Acute RQ = EEC/LC50 $ 0.5 for birds and mammals

Calculation of estimated environmental residues are based on the work by Hoerger and Kenaga (1972).

Avian Acute/Subacute Risk

High Risk LOCs are not exceeded at any application rate for a single application. Restricted Use Levels of Concern (LOC) are exceeded on short grass at the 3 and 4 lbs a.i./A rates. Endangered species LOC are exceeded for all the rates evaluated. Residues on insects would not exceed LOCs (see Table 1).

Table 1. Avian Acute Risk Quotient and LOC exceedance for the maximum application rates of linuron by use site. EEC for short grass = application rate (al ai/A) x 240 ppm/lb ai. EEC for insects = application rate x 58 ppm/lb ai. Lowest avian LC50 = 3083 ppm (mallard duck) Risk Quotient = EEC/LC50.

Use Site	Application Rate	Substrate (EEC)	Risk Quotient (EEC/LC50)	LOC
Carrots, celery, sweet corn, cottonseed, parsley, parsnips, sorghum; ornamental herbaceous plants	1.5 lbs ai	Short Grass (360)	0.12	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
		Insects (87)	0.03	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
Field corn	1.54 lbs ai	short grass (370)	0.12	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
		Insects (89)	0.03	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
Winter wheat (drill planted)	1.75 lbs ai	short grass (420)	0.14	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
		Insects (101.5)	0.03	High Risk $ 0.5 RU $ 0.2 ES $ 0.1

Use Site	Application Rate	Substrate (EEC)	Risk Quotient (EEC/LC50)	LOC
Potatoes; poplar (forest/ shelterbelt)	2.0 lbs ai	short grass (480)	0.16	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
		Insects (116)	0.04	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
Soybeans; non-ag. ROW/fencerows/ hedgerows/ uncultiv. areas/ soils	3.0 lbs ai	short grass (720)	0.23	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
		Insects (174)	0.06	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
Asparagus	4.0 lbs ai	short grass (960)	0.31	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
		Insects (232)	0.08	High Risk $ 0.5 RU $ 0.2 ES $ 0.1

RU = Restricted Use ES = Endangered Species

Avian Chronic and Reproductive Risk

The avian reproduction NOEL is considered 100 ppm, with effects seen at 300 ppm. Both of these levels are below those residue levels that could occur on short grass within the treated area at even the lowest of the maximum application rates by crop, from a single application. Given this, as well as the persistence of linuron described by the Agency, it appears that chronic avian risk is present for all use sites.

Table 2. Avian Chronic Risk Quotient and LOC exceedance for the maximum application rates of linuron by use site. (NOEL = 100 ppm). Table uses same EECs as Table 1. Risk Quotient = EEC/NOEL.

Use Site	Application Rate	Substrate (EEC)	Risk Quotient (EEC/NOEL)	LOC
Carrots, celery, sweet corn, cottonseed, parsley, parsnips, sorghum; ornamental herbaceous plants	1.5 lbs ai	Short Grass (360)	3.60	Chronic Risk* $\geq$ 1
		Insects (87)	0.87	Chronic Risk* $\geq$ 1
Field corn	1.54 lbs ai	short grass (370)	3.70	Chronic Risk* $\geq$ 1
		Insects (89)	0.89	Chronic Risk* $\geq$ 1

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Use Site	Application Rate	Substrate (EEC)	Risk Quotient (EEC/NOEL)	LOC
Winter wheat (drill planted)	1.75 lbs ai	short grass (420)	4.20	Chronic Risk* ≥ 1
		Insects (101.5)	1.02	Chronic Risk* ≥ 1
Potatoes; poplar (forest/ shelterbelt)	2.0 lbs ai	short grass (480)	4.80	Chronic Risk* ≥ 1
		Insects (116)	1.16	Chronic Risk* ≥ 1
Soybeans; non-ag. ROW/fencerows/ hedgerows/ uncultiv. areas/ soils	3.0 lbs ai	short grass (720)	7.20	Chronic Risk* ≥ 1
		Insects (174)	1.74	Chronic Risk* ≥ 1
Asparagus	4.0 lbs ai	short grass (960)	9.60	Chronic Risk* ≥ 1
		Insects (232)	2.32	Chronic Risk* ≥ 1

* "Chronic risk, endangered birds may be affected, restricted use recommended"

In addition to risk from direct application, there can be risk to birds feeding in areas adjacent to treated fields, due to drift, particularly with aerial application. The current Agecncy estimate is 5%. This added risk, based on this assumption, does not by itself exceed the LOC (see Table 3).

Table 3. Avian Chronic Risk Quotient and LOC exceedance -- off-site exposure with soybeans. Off-site drift estimate = 5% of EEC (from Table 1).

Use Site	Application Rate	Substrate	Risk Quotient (EEC/NOEL)	LOC
Soybeans	3.0 lbs ai	short grass (36)	0.36	Chronic Risk* ≥ 1
		Insects (8.7)	0.087	Chronic Risk* ≥ 1

* "Chronic risk, endangered birds may be affected, restricted use recommended"

Risk to Mammals

Tables 4 and 5 show LD50s/sq. ft. for the use sites, for two small mammals. LD50s/sq. ft. will vary with the weight of the animal, since LD50s are expressed in mg/kg body weight (i.e., for a given LD50, a smaller animal will require less toxicant to receive a lethal dose). For linuron, all LOCs are exceeded for the small, carnivorous least shrew whereas none are for the much heavier, omnivorous rat.

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Table 4. Mammalian Risk Quotient and LOC exceedance for the maximum application rates of linuron by use site. (lowest LD50 = 2100 mg/kg; mammal body weight= 0.005 kg, least shrew). Mg ai/sq. ft = lb ai/A x 10.4 (conversion factor). Risk Quotient = LD 50/sq.ft. = mg ai/sq.ft./LD50 x animal weight).

Use Site	Application Rate	mg ai/sq. ft.	Risk Quotient LD50/sq. ft.	LOC
Carrots, celery, sweet corn, cottonseed, parsley, parsnips, sorghum; ornamental herbaceous plants	1.5 lbs ai	15.6	1.49	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
Field corn	1.54 lbs ai	16.0	1.52	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
Winter wheat (drill planted)	1.75 lbs ai	18.2	1.7	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
Potatoes; poplar (forest/ shelterbelt)	2.0 lbs ai	20.8	2.0	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
Soybeans; non-ag. ROW/fencerows/ hedgerows/ uncultiv. areas/ soils	3.0 lbs ai	31.2	3.0	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
Asparagus	4.0 lbs ai	41.6	4.0	High Risk $ 0.5 RU $ 0.2 ES $ 0.1

RU = Restricted Use ES = Endangered Species

Table 5. Mammalian Risk Quotient and LOC exceedance for the maximum application rates of linuron by use site. (lowest LD50 = 2100 mg/kg; mammal body weight= 0.3 kg, rat).

Use Site	Application Rate	mg ai/sq. ft.	Risk Quotient LD50/sq. ft.	LOC
Carrots, celery, sweet corn, cottonseed, parsley, parsnips, sorghum; ornamental herbaceous plants	1.5 lbs ai	15.6	0.02	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
Field corn	1.54 lbs ai	16.0	0.03	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
Winter wheat (drill planted)	1.75 lbs ai	18.2	0.03	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
Potatoes; poplar (forest/ shelterbelt)	2.0 lbs ai	20.8	0.03	High Risk $ 0.5 RU $ 0.2 ES $ 0.1

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Use Site	Application Rate	mg ai/sq. ft.	Risk Quotient LD50/sq. ft.	LOC
Soybeans; non-ag. ROW/fencerows/ hedgerows/ uncultiv. areas/ soils	3.0 lbs ai	31.2	0.05	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
Asparagus	4.0 lbs ai	41.6	0.07	High Risk $ 0.5 RU $ 0.2 ES $ 0.1

RU = Restricted Use ES = Endangered Species

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Mammalian Chronic Risk

The lowest NOEL dietary concentration reported in submitted data is 25 ppm, seen in a 1-year dog feeding study and in a 3-generation reproduction study in rats. Oncogenic effects were reported in both mice and rat studies. For mice, "hepatocellular adenomas were significantly increased in the high dose group [1500 ppm] and reached borderline significance in the low dose group [50 ppm]". For rats, "testicular interstitial cell adenomas increased in 125 and 625 ppm males" (submitted data). Given the persistence of linuron in the field and the effects seen in the lab at concentrations well below those expected after initial application, it appears that chronic effects in wild mammals are likely.

(2) Aquatic Risk

Aquatic - Acute Risk

Acute risk to aquatic organisms has been estimated by comparing EECs to the lowest available linuron technical LC_{50} or EC_{50} for fish and aquatic invertebrates. EECs used were derived from two models, one involving runoff to a 6' water body (A) and the second involving runoff to a 6" water body or wetland (B). The latter is to be used for linuron only for the ROW use. Table 6 shows that fish restricted use LOCs are exceeded under model B (ROWs). Fish endangered species LOCs are exceeded under model B (ROWs) and also under model A for the 4 lb ai/A rate.

Table 7 shows that the aquatic invertebrate high risk LOC is exceeded with model B (ROWs). Aquatic invertebrate restricted use and endangered species LOCs are exceeded for all sites with both models.

Direct application to aquatic habitat could also potentially occur with a ROW use. Direct application to 6" of water would result in 2202 ppb at a 3 lb ai/A rate. This would produce a risk quotient of 2,474 for fish and 18,350 for aquatic invertebrates, vastly exceeding all LOCs.

Table 6. Fish Risk Quotient and LOC exceedance for the maximum application rates of linuron by use site. (lowest LC50 = 0.89 ppm). EEC for model A (runoff to 6' pond) = [application rate (lb ai/A) x % runoff x 10 acre drainage basin] x 61 ppb/lb ai. where % runoff = 2% (based on linuron water solubility of 81 ppm). EEC for model B (runoff to 6" wetland) = [application rate (lb ai/A x % runoff x 10 acre drainage basin] x 734 ppb/lb ai. with 2% runoff. Risk Quotient = EEC/EC50 where fish LC 50 = 0.89 ppm (sheepshead minnow).

Use Site	Application Rate	RQ (EEC/EC50) (model[1])	LOC
Carrots, celery, sweet corn, cottonseed, parsley, parsnips, sorghum; ornamental herbaceous plants	1.5 lbs ai	0.021 (A)	High Risk $ 0.5 RU $ 0.1 ES $ 0.05
Field corn	1.54 lbs ai	0.021 (A)	High Risk $ 0.5 RU $ 0.1 ES $ 0.05
Winter wheat (drill planted)	1.75 lbs ai	0.024 (A)	High Risk $ 0.5 RU $ 0.1 ES $ 0.05
Potatoes; poplar (forest/ shelterbelt)	2.0 lbs ai	0.027 (A)	High Risk $ 0.5 RU $ 0.1 ES $ 0.05
Soybeans; non-ag. ROW/fencerows/ hedgerows/ uncultiv. areas/ soils	3.0 lbs ai	0.041 (A) 0.49 (B) (ROW)	High Risk $ 0.5 RU $ 0.1 (B) ES $ 0.05 (B)
Asparagus	4.0 lbs ai	0.055(A)	High Risk $ 0.5 RU $ 0.1 ES $ 0.05 (A)

RU = Restricted Use ES = Endangered Species

1. model: A =runoff to 6' pond; B = runoff to 6" wetland

Table 7. Aquatic Invertebrate Risk Quotient and LOC exceedance for the maximum application rates of linuron by use site. (lowest EC50 = 0.12 ppm). EEC for model A (runoff to 6' pond) = [application rate (lb ai/A) x % runoff x 10 acre drainage basin] x 61 ppb/lb ai. where % runoff = 2% (based on linuron water solubility of 81 ppm).EEC for model B (runoff to 6" wetland) = [application rate (lb ai/A x % runoff x 10 acre drainage basin] x 734 ppb/lb ai. with 2% runoff. Risk Quotient = EEC/LC50 where lowest aquatic invertebrate = 0.12 ppm (*D. Magna*)

Use Site	Application Rate	RQ (EEC/EC50) (model[1])	LOC
Carrots, celery, sweet corn, cottonseed, parsley, parsnips, sorghum; ornamental herbaceous plants	1.5 lbs ai	0.15 (A)	High Risk $ 0.5 RU $ 0.1 (A) ES $ 0.05 (A)
Field corn	1.54 lbs ai	0.157 (A)	High Risk $ 0.5 RU $ 0.1 (A) ES $ 0.05 (A)

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Use Site	Application Rate	RQ (EEC/EC50) (model[1])	LOC
Winter wheat (drill planted)	1.75 lbs ai	0.178 (A)	High Risk $ 0.5 RU $ 0.1 (A) ES $ 0.05 (A)
Potatoes; poplar (forest/ shelterbelt)	2.0 lbs ai	0.203 (A)	High Risk $ 0.5 RU $ 0.1 (A) ES $ 0.05 (A)
Soybeans; non-ag. ROW/fencerows/ hedgerows/ uncultiv. areas/ soils	3.0 lbs ai	0.305 (A) 3.67 (B) (ROW)	High Risk $ 0.5 (B) RU $ 0.1 (A,B) ES $ 0.05 (A,B)
Asparagus	4.0 lbs ai	0.4 (A)	High Risk $ 0.5 RU $ 0.1 (A,B) ES $ 0.05 (A,B)

RU = Restricted Use ES = Endangered Species

1. model: A = runoff to 6' pond; B = runoff to 6" wetland

Aquatic - Chronic Risk

Chronic aquatic effects cannot be fully assessed at this time. Effects on fish length were seen at the lowest concentration (0.042 ppm) with rainbow trout in an early life stage test. The "rough-cut" EECs used for the above tables under model A exceed this effect level at the 4 lb ai/A rate and under model B at the 3 lb ai rate (ROWs). Since the NOEL for this study was some untested level below 0.042 ppm, there would likely be further exceedances of the NOEL and thus the chronic LOC (EEC/NOEL $\geq$ 1).

Although the above comparisons were derived from "preliminary qaulitative" EECs, available environmental fate information from EFED (see above) indicates potential persistence in water. There is little or no effect of hydrolysis or photolysis (both half-lives greater than 30 days). Microbial degradation is described by EFED; the anaerobic aquatic half-life is reported as less than 21 days. Three degradates of unknown toxicity have been identified by EFED. Thus, the toxicity of the combined degradates plus remaining parent linuron is also not known.

The chronic effect level for *D. magna* is reportedly 2x the LC_{50} seen in a previous acute study, a major inconsistency. Also, invertebrates were more sensitive than fish in acute tests, but appear considerably less sensitive in the chronic test. Further testing with the acute would be necessary to resolve this problem.

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(3) Plants

Valid data on the toxicity of linuron to nontarget plants is available for only one of five aquatic plants, and not available at all for the ten required terrestrial species. Exposure of nontarget terrestrial and aquatic plants to linuron is expected primarily due to runoff from ground applications (all use sites) and from runoff and drift for aerial applications (certain soybean product labels).

No terrestrial plant risk assessment can be done due to the lack of adequate data.

Only a preliminary aquatic plant risk assessment can be done since adequate data are available for just one of five species. High risk and endangered plant LOCs are exceeded for aquatic plants if the $EEC/EC_{50} \geq 1$. Based on the EECs previously calculated to evaluate risk to aquatic animals, and the one available EC_{50} (0.067 ppm), these LOCs are exceeded under the runoff to wetland model (6") for ROWs, but not the runoff to 6' pond model for all other uses.

(4) Endangered Species

As described in the above risk assessment sections, endangered species LOCs are exceeded in some instances for acute effects to birds, wild mammals, aquatic organisms and nontarget plants. Endangered species LOCs are exceeded for chronic effects to birds, wild mammals, and aquatic organisms.

The Endangered Species Protection Program is expected to become final in 1995. Limitations on the use of linuron will be required to protect endangered and threatened species, but these limitations have not yet been defined (and may be formulation specific). OPP anticipates that consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county bulletins.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient 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 linuron active ingredient. The Agency has completed its review of these generic data, and has determined that based on the information currently available, there is data to support the reregistration of all products containing linuron, with the exception of use on cotton, potato, non-cropland (rights-of-way), and sweet corn. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of linuron, 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 linuron and to determine that except for the cotton, potato, non-cropland, and sweet corn uses, linuron can be used without resulting in unreasonable adverse effects to humans and the environment. To ensure that the potential risks of linuron are not unreasonable, the Agency is requiring the registrant to implement certain risk mitigation measures. Provided that these measures are implemented, as discussed below, the Agency therefore finds that all products containing linuron as the sole active ingredient with the exception of cotton, potato, non-cropland (rights-of-way), and sweet corn, 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 and the data identified in Appendix B. The Agency has found that all uses of linuron, except for the cotton, potato, non-cropland (rights-of-way), and sweet corn uses, are eligible for reregistration. **At this time, the Agency is unable to make a reregistration eligibility decision on the use of linuron on potatoes because under current policies tolerances under Section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) are needed for this use, but such a tolerance may be barred by the Delaney clause in Section 409. Refer to the discussion under "Tolerance Reassessment."**

As a risk reduction measure for linuron, DuPont has agreed to voluntarily cancel the Hybrid poplar and non-cropland (rights-of-way) uses. In addition, DuPont has already voluntarily cancelled the cotton use of linuron. However, data remain outstanding for the cotton, rights-of-way, and sweet corn uses. Registrants must either amend their labels deleting these uses or submit the required data. Therefore, the Agency is unable to make a reregistration eligibility decision for the use of linuron on cotton, rights-of-way, and sweet corn.

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 linuron, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient linuron, the Agency has sufficient information on the health effects of linuron and on its potential for causing adverse effects in fish and wildlife and the environment. Although levels of concern are exceeded for ecological effects and groundwater quality, the Agency concludes that most of the uses of products containing linuron, with the exception of cotton, potato, non-cropland (rights-of-way), and sweet corn, amended to reflect the risk mitigation measures imposed in this RED are eligible for reregistration.

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The Agency is unable to make a reregistration eligibilty decision for the use of linuron on cotton, potato, non-cropland (rights-of-way), and sweet corn until additional generic data are submitted. The Agency is unable to make a reregistration eligibility decision on the use of linuron on potatoes because under current policies tolerances under Section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) are needed for this use, but such a tolerance may be barred by the Delaney clause in Section 409.

The Agency has determined that eligible linuron products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of linuron, with the exception of cotton, potato, non-cropland (rights-of-way), and sweet corn, are eligible for reregistration.

B. Regulatory Position

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

1. Tolerance Reassessment

Tolerances Listed Under 40 CFR §180.184(a)

The tolerances listed under 40 CFR §180.184(a) for residues of linuron in/on plant and animal commodities are expressed in terms of residues of linuron *per se*. The tolerance expression under 40 CFR §180.184(a) should be revised as follows: "Tolerances are established for the combined residues of the herbicide linuron (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea) and its metabolites convertible to 3,4-dichloroaniline, calculated as linuron, in or on the following raw agricultural commodities:". A summary of the reassessment of tolerances listed in 40 CFR §180.184(a) is presented in Table D.

Sufficient data are available to support the established tolerances for the following crops: carrots; corn, field, grain; corn, field, forage and fodder; celery; cottonseed; parsnips; potatoes; sorghum, grain; soybeans; and wheat, grain and straw.

Additional residue data are required if all registered uses of linuron are to be covered under established tolerances for: asparagus; corn, sweet (K + CWHR); corn, sweet, forage; sorghum forage and fodder; soybeans, forage and hay; and wheat forage. In addition, aspirated grain fraction data remain outstanding for field corn.

A processing study remains outstanding for cottonseed, if registrants other than DuPont decide to support use on cotton. The tolerance for cottonseed must be revoked, if no registrant is supporting the cotton use.

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Food additive tolerance proposals are required for "potatoes, granules" at 0.8 ppm and "potatoes, chips" at 0.6 ppm, and a feed additive tolerance proposal is required for "potatoes, waste from processing" at 10 ppm.

However, under the Delaney clause of the FFDCA, a food/feed additive regulation for a processed food may not be established for a pesticide which induces cancer in man or animals. Linuron may meet this criterion (see discussion in Section III.B.1.c. of this document). The Ninth Circuit Court of Appeals has ruled that EPA must interpret this provision strictly. EPA is in the process of revoking food additive tolerances that violate the Delaney clause.

Under current EPA policy, if a food/feed additive tolerance cannot be established due to the Delaney clause, EPA will neither establish nor continue in effect a tolerance for the associated raw agricultural commodity.

At this time, the Agency is unable to make a reregistration eligibility decision on potatoes because EPA is currently evaluating legal challenges to its policies related to the coordination of actions under Section 409's Delaney clause and FFDCA Section 408 and FIFRA. But in the event that the Agency will allow the use of linuron on potatoes, additional data to upgrade the existing potato processing study will be required.

The established tolerances for corn, grain (inc. pop); corn, pop, forage; corn, pop, fodder; barley, oats, and rye forage, grain, hay, and straw will be revoked since there are no registered uses of linuron on these commodities. In addition, the established tolerances for corn, sweet, fodder; parsnips, tops; and wheat, hay will be revoked since these commodities are not listed as raw agricultural commodities of sweet corn, parsnips, and wheat, respectively.

Tolerances have been proposed for lettuce at 0.1 ppm (PP#1E02486), and ginger and taro at 1 ppm (PP#3E2920). Tolerance revisions have been proposed for potatoes at 0.2 ppm; the meat, fat, and meat-by-product (except kidney and liver) of cattle, goats, hogs, horses, and sheep at 0.1 ppm; and the liver and kidney of cattle, goats, hogs, horses, and sheep at 1.0 ppm (PP#0F3832).

A 6(a)(2) data submission indicates linuron residues in or on corn fodder will need to be raised to cover residues up to 5.5 ppm in corn fodder. The current tolerance is 1 ppm.

Tolerances Listed Under 40 CFR §180.184(b)

The tolerance listed under 40 CFR §180.184(b) is with regional restriction and is expressed in terms of residues of linuron *per se*. The tolerance expression under 40 CFR §180.184(b) should be revised as follows: "Tolerances are established for the combined residues of the herbicide linuron (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea) and its metabolites convertible to 3,4-dichloroaniline, calculated as linuron, in or on the following raw agricultural commodities:". A summary of the reassessment of tolerances listed in 40 CFR §180.184(b) is presented in Table D.

Sufficient data are available to support the established tolerance for parsley.

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Table D. Tolerance Reassessment Summary.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR 180.184(a):			
Asparagus	3	Reserved	Data are still needed for the FlC. The current tolerance is inadequate. Based on available data, the tolerance will need to be raised to 7 ppm.
Barley, forage	0.5	Revoke	No registered uses.
Barley, grain	0.25	Revoke	No registered uses.
Barley, hay	0.5	Revoke	No registered uses; not regulated as a RAC.
Barley, straw	0.5	Revoke	No registered uses.
Carrots	1	1	A 14-day PHI is required.
Cattle, fat	1	0.1	Proposed tolerance revision 0.1 ppm. PP#0F3832
Cattle, mbyp	1	1 0.1	*Cattle, kidney* *Cattle, liver* *Cattle, mbyp (exc. liver and kidney)*/Proposed tolerance revision 0.1 ppm. PP#0F3832
Cattle, meat	1	0.1	Proposed tolerance revision 0.1 ppm. PP#0F3832
Celery	0.5	0.5	The available data support use west of the Rocky Mountains, all labels must reflect this restriction.
Corn, field, fodder	1	Increase to 6	6(a)(2) data have been submitted by DuPont indicating a higher tolerance 6 ppm in/on fodder is required.
Corn, field, forage	1	1	
Corn, fresh (inc. sweet K + CWHR)	0.25	Reserved	*Corn, sweet (K + CWHR)* Additional data are required.
Corn, grain (inc. pop)	0.25	0.1	*Corn, field, grain* Pop corn grain tolerance should be deleted since there are no registered uses.
Corn, pop, fodder	1	Revoke	No registered uses.
Corn, pop, forage	1	Revoke	
Corn, sweet, fodder	1	Revoke	Not regulated as a RAC.
Corn, sweet, forage	1	Reserved	Additional data required.

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Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Cottonseed	0.25	Revoke	*Cotton, seed* Use is not supported by DuPont; If other registrants support use, a processing study is required. Otherwise, use should be cancelled and tolerance revoked.
Goats, fat	1	0.1	Proposed tolerance revision to 0.1 ppm.
Goats, mbyp	1	1 0.1	*Goats, kidney* *Goats, liver* *Goats, mbyp (exc. liver and kidney)*/Proposed tolerance revision to 0.1 ppm. PP#0F3832
Goats, meat	1	0.1	Proposed tolerance revision to 0.1 ppm. PP#0F3832
Hogs, fat	1	0.1	Proposed tolerance revision to 0.1 ppm. PP#0F3832
Hogs, mbyp	1	1 0.1	*Hogs, kidney* *Hogs, liver* *Hogs, mbyp (exc. liver and kidney*/Proposed tolerance revision to 0.1 ppm. PP#0F3832
Hogs, meat	1	0.1	Proposed tolerance revision to 0.1 ppm. PP#0F3832
Horses, fat	1	0.1	Proposed tolerance revision to 0.1 ppm. PP#0F3832
Horses, mbyp	1	1 0.1	*Horses, kidney* *Horses, liver* *Horses, mbyp (exc. liver and kidney*/Proposed tolerance revision to 0.1 ppm. PP#0F3832
Horses, meat	1	0.1	Proposed tolerance revision to 0.1 ppm. PP#0F3832
Oats, forage	0.5	Revoke	No registered uses.
Oats, grain	0.25	Revoke	No registered uses.
Oats, hay	0.5	Revoke	No registered uses; not regulated as a RAC.
Oats, straw	0.5	Revoke	No registered uses.
Parsnips (with or without tops)	0.5	0.5	*Parsnips, roots*
Parsnips, tops	0.5	Revoke	Not regulated as a RAC.

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Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Potatoes	1	0.2[*1]	Proposed revision to the established tolerance. [*] - All registrants must submit revised labels prohibiting use west of the Rocky Mountains.
Rye, forage	0.5	Revoke	No registered uses.
Rye, grain	0.25	Revoke	No registered uses.
Rye, hay	0.5	Revoke	No registered uses; not regulated as a RAC.
Rye, straw	0.5	Revoke	No registered uses.
Sheep, fat	1	0.1	Proposed tolerance revision to 0.1 ppm. PP#0F3832
Sheep, mbyp	1	1 0.1	*Sheep, kidney* *Sheep, liver* *Sheep, mbyp (exc. liver and kidney)*/Proposed tolerance revision to 0.1 ppm. PP#0F3832
Sheep, meat	1	0.1	Proposed tolerance revision to 0.1 ppm. PP#0F3832
Sorghum, fodder	1	Reserved	
Sorghum, forage	1	Reserved	
Sorghum, grain (milo)	0.25	0.2	*Sorghum, grain*
Soybeans, (dry or succulent)	1	1	*Soybeans*
Soybeans, forage	1	Reserved	Feeding restrictions prohibited per June 1994 document. Additional data required.
Soybeans, hay	1	Reserved	Feeding restrictions prohibited per June 94 document. Additional data required.
Wheat, forage	0.5	Reserved	Additional data required.
Wheat, grain	0.25	0.1	
Wheat, hay	0.5	Revoke	Not regulated as a RAC.
Wheat, straw	0.5	2.0	PP#4F4293
Tolerances listed under 40 CFR 180.184(b):			
Lettuce	--	0.1	Proposed tolerance. PP#1E02486
Ginger	--	1	Proposed tolerance. PP#3E2920
Parsley	0.25	0.25	
Taro	--	1	Proposed tolerance. PP#3E2920
Tolerances to be proposed under 40 CFR 185 and 186 [1]			
Potatoes, chips	--	0.6	Proposed tolerance.
Potatoes, granules	--	0.8	Proposed tolerance.
Potatoes, waste from processing	--	10	Proposed tolerance.

[1] Delaney issues may prevent the establishment of these tolerances.

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CODEX HARMONIZATION

No Codex MRLs have been established for linuron; therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist.

2. Restricted Use Classification

Linuron meets the proposed triggers for candidacy as a restricted use chemical for groundwater concerns. The Agency will consider linuron as a candidate for classification as a restricted use chemical after the groundwater restricted use rule is finalized.

3. Risk Mitigation

The Agency has determined that the current uses of linuron exceed levels of concern for many uses. Several risk mitigation measures proposed by the technical registrant, DuPont, and accepted by the Agency are being required. These risk mitigation measures include reducing application rates, cancellation of high application rate uses, prohibiting use in certain vulnerable soil types, prohibiting aerial uses, adding groundwater and surface water label advisories. These risk mitigation measures are required for all linuron registrants.

The technical registrant, DuPont, is reducing the application rates of linuron on soybeans to 1.0 lb ai/A, corn field to 0.75 lb ai/A, potatoes to 1.5 lbs ai/A, and asparagus to 2.0 lbs ai/A. DuPont is also limiting the use of linuron on soybeans, field corn, potatoes to 1 application per year (pre-emergent use only) and limiting the use of linuron on asparagus to 3 applications per year. Reduction of the application rates for soybeans and asparagus will also improve the MOEs for handlers.

DuPont has also agreed to prohibit the aerial uses of linuron, prohibit the use of linuron on sand or loamy sand, and on soils of <1% organic matter. Furthermore, DuPont has agreed to voluntarily cancel the high application rate uses including Hybrid poplar and Non-cropland uses (Rights-of-way).

Groundwater Concerns: Due to groundwater quality concerns, the following mitigation steps are required:

- Linuron has been detected in groundwater. Therefore **all product labels must carry a groundwater advisory.** The label language for this advisory can be found in Section V. of this document.

Surface Water Concerns:

Linuron can be applied by ground spray and therefore could contaminate surface waters by spray drift. The available data on the major degradates of linuron are insufficient to assess their runoff potential or persistence in surface water. Linuron is not currently regulated under the Safe Drinking Water Act (SDWA). Therefore, no MCL has been established for it and water supply systems are not required to sample and analyze for it. In addition, no drinking water health advisories have been established for linuron. However,

based upon the Reference Dose, the Agency has (for screening purposes only) a low lifetime health advisory for linuron of 6.0 ug/L. Although the available data suggests that the average annual linuron concentration will generally be well below 6 ug/L, the available data do not necessarily include those from watersheds that drain high linuron use areas. In addition, the relatively low to intermediate soil to water partitioning of linuron indicates that the primary treatment processes employed by most water supply systems to remove suspended sediment may not always be completely effective in removing linuron. Consequently, the Agency does have some moderate concerns for potential risks of linuron to surface water source supply systems.

Spray Drift Advisory: The potential for spray drift exists because linuron can also be applied by ground spray. However, a spray drift labeling statement will not be imposed until spray drift data is submitted and reviewed by the Agency.

4. Endangered Species Statement

The Agency has concerns about the exposure of threatened and endangered plant and animal species to linuron. Based on the conclusions discussed in the preceding sections of this risk assessment, endangered species LOCs are exceeded in some instances for acute effects to birds, wild mammals, aquatic organisms, and nontarget plants. Endangered species LOCs are also exceeded for chronic effects to birds, wild mammals, and aquatic organisms.

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish in the Federal Register a description of the program and have available enforceable county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

5. Labeling Rationale

Worker Protection Standard

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

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directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

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

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

Uses within the scope of the Worker Protection Standard

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in.

Some of the registered uses of linuron are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) and some uses are outside the scope of the WPS. Those that are outside the scope of the WPS include use:

- on plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for decorative or environmental benefit.
- in a manner not directly related to the production of agricultural plants, including, for example, control of vegetation along rights-of-way and shelterbelts.

Entry Restrictions

Entry Restrictions for Occupational-Use Products (WPS Uses)

Some registered uses of linuron are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) and some are outside the scope of the WPS.

Restricted Entry Interval -- Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the

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active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

For occupational end-use products containing linuron as an active ingredient, the Agency is establishing a **24-hour restricted-entry interval** for each use of the product that is within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The basis of the 24-hour REI is a post-application risk assessment using asparagus reentry data and the toxicological endpoint for developmental toxicity.

The WPS places very specific restrictions on entry during restricted-entry intervals when that entry involves contact with treated surfaces. The Agency believes that these existing WPS protections are sufficient to mitigate post-application exposures of workers who contact surfaces treated with linuron.

Entry Restrictions for Occupational-Use Products (NonWPS Uses)

Some registered uses of linuron are outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The Agency is establishing the following entry restrictions for all nonWPS occupational uses of linuron end-use products:

For liquid applications:
"Do not enter or allow others to enter the treated area until sprays have dried."

Personal Protective Equipment (PPE) Requirements

PPE for Handlers (Mixer/ Loader/Applicators)

For each end-use product, PPE requirements for pesticide handlers will be set during reregistration in one of two ways:

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

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2. If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc):

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most occupational end-use products containing that active ingredient.

- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.

- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

There are special toxicological concerns about linuron that warrant the establishment of active-ingredient-based PPE requirements for handlers. The MOE's were calculated as being acceptable only when (1) a closed system is used for mixing and loading to support aerial application and (2) specified personal protective equipment is worn by other mixers and loaders.

Handler PPE for Occupational-Use Products

Some of the registered uses of linuron are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) and some are outside the scope of the WPS. However, the minimum (baseline) PPE requirements for both the WPS and nonWPS uses are the same, since the potential exposure to handlers is similar for WPS and nonWPS uses.

The minimum (baseline) PPE for mixers and loaders supporting ground equipment applications for all WPS and nonWPS uses of linuron end-use products is: coveralls over long-sleeve shirt and long pants, chemical-resistant footwear, chemical-resistant gloves, and chemical-resistant apron.

No minimum (baseline) PPE for applicators and other handlers (other than mixers and loaders) is being established by the Agency through this RED.

Early-Entry PPE

The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and requirement that personal protective equipment be worn. Personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the toxicity concerns about the active ingredient. The requirements are set in one of two ways.

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1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements based on the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient.

2. If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects, cancer, developmental toxicity, or reproductive effects, it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Since linuron is classified as category III for eye irritation potential, skin irritation potential, and acute dermal toxicity, the PPE required for early entry is: coveralls, chemical-resistant gloves, shoes, and socks. EPA believes that the potential adverse effects of linuron will be mitigated with this attire, provided the entry limitations established by the WPS are complied with.

V. ACTIONS REQUIRED BY 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

In summary, all uses of linuron are eligible for reregistration, with the exception of cotton, potato, non-cropland (rights-of-way), and sweet corn. The Agency is unable to make a reregistration eligibility decision for the use of linuron on cotton, non-cropland (rights-of-way), and sweet corn until additional data are submitted and evaluated. **Also, a reregistration eligibility decision will not be made on the potato use of linuron until a decision on EPA's Coordination Policy has been made.** Furthermore, the Agency is requiring that additional confirmatory data be submitted to fulfill the generic data requirements for reregistration of linuron.

Starting Materials and Manufacturing Process

Foliar Dislodgeable Residues (Carrots/Celery)
Soil Dislodgeable Residues (Carrots/Celery)
Dermal Exposure (Carrots/Celery)
Inhalation Exposure (Carrots/Celery)

Cropfield Trials - Asparagus; Corn Aspirated Fractions, Sorghum, Forage and Hay; and Wheat, Forage
Cropfield Trials - Soybeans Forage and Hay - required due to change in Agency policy on grazing restrictions

Acute Avian Dietary Toxicity w/TGAI - Quail and Duck
Acute Aquatic Invertebrate Toxicity
Fish Early Life Stage - both Rainbow Trout and Sheepshead Minnow

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Aquatic Invertebrate Life Cycle - Mysid shrimp
Leaching/Adsorption/Desorption
Terrestrial Field Dissipation

In order to support the use of linuron on cotton and sweet corn, the following residue data are required:

Cottonseed processing study
Cropfield trials - sweet corn

In order to support the use of linuron on and non-cropland (rights-of-way) uses, the following data are required:

Acute Marine/Estuarine (TEP) - Sheepshead Minnow using DF Formulation for Rights-of-Ways

Certain data are not part of the target database for linuron, but are also required:

Seed germination/seedling emergence - 10 species
Vegetative vigor - 10 species
Aquatic plant growth - 4 additional species

2. Labeling Requirements for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

"Only for formulation into a herbicide for the following uses(s): _____ (fill blank only with those uses that are being supported by MP registrant)."

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

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

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

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B. End-Use Products

1. Additional Product-Specific Data Requirements

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

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

2. Labeling Requirements for End-Use Products

a. Worker Protection

(1) Entry Restrictions; Labeling

Entry Restrictions for Occupational-Use Products (WPS Uses)

In order to be in compliance with FIFRA, a 24 hour restricted entry interval (REI) is required for all uses within the scope of the Worker Protection Standard. This REI must be inserted into the standardized REI statement specified in the WPS as explained by the EPA guidance in PR Notice 93-7. The personal protective equipment for early entry must be the PPE required for handlers of linuron (see Section 2 below). This PPE must be inserted into the standardized REI statement specified by the WPS as explained in the EPA guidance in PR Notice 93-7.

In order to be in compliance with FIFRA, labels of sole active ingredient end-use products that contain linuron must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on their current labeling must be removed.

In order to be in compliance with FIFRA, labels of multiple-active-ingredient end-use products that contain linuron must bear the more protective of either the entry restrictions set forth in this section or the entry restrictions on the current labeling.

Entry Restrictions for Occupational-Use Products (NonWPS Uses)

Some registered uses of linuron are outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The Agency is establishing the following entry restrictions for all nonWPS occupational uses of linuron end-use products:

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For liquid applications:
"Do not enter or allow others to enter the treated area until sprays have dried."

(2) Personal Protective Equipment Requirements; Labeling

Handler PPE for Occupational Use Products: For all uses of linuron, (includes uses both within the scope of WPS and non-WPS uses) the minimum (baseline) PPE requirements for pesticide handlers on all linuron end-use products are:

- coveralls over long-sleeve shirt and long pants
- chemical-resistant footwear
- chemical-resistant gloves
- chemical-resistant apron

No minimum (baseline) PPE for applicators and other handlers (other than mixers and loaders) is being established by the Agency through this RED.

Early Entry PPE: Since linuron is classified as category III for eye irritation potential, skin irritation potential, and acute dermal toxicity, the PPE required for early entry is: **coveralls, chemical-resistant gloves, shoes, and socks.** EPA believes that the potential adverse effects of linuron will be mitigated with this attire, provided the entry limitations established by the WPS are complied with.

Products containing linuron may contain more stringent PPE, but in no case may they require less stringent PPE than the above requirements.

Producers of end-use products that contain linuron must compare the PPE requirements set forth in this section to the PPE requirements, if any, on current labeling and retain the more protective. For guidance in choosing which requirement is more protective, see supplement 3 of PR Notice 93-7.

b. Other Labeling Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing linuron that are intended primarily for occupational use:

(1) The labels of all linuron end-use products must be revised to bear the following under the **Environmental Hazard Section**:

Ground Water Advisory

"This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."

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Surface Water Advisory

"Linuron may contaminate surface water through spray drift or, under certain conditions, from surface runoff into adjacent surface water bodies (pond, lakes, streams, etc.) For several weeks post-application, linuron has a high potential to runoff when applied to fields with any of the following conditions: sloping land draining into nearby surface waters; very poorly to somewhat poorly drained soils; areas with extremely shallow ground water; frequently flooded areas; fields with surface water canals or ditches; and highly erodible land cultivated with poor managment practices."

For terrestrial uses except rights-of-way

"This pesticide is toxic to fish and aquatic invertebrates. Do not apply to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from treated areas. Do not contaminate water when disposing of equipment wash water or rinsate."

For rights-of-way

If a registrant chooses to support the rights-of-way use, he must submit the data required in this RED document associated with the rights-of-way use of linuron and his labels must also bear the following labeling statement:

"This pesticide is toxic to fish and aquatic invertebrates. Do not contaminate water when disposing of equipment washwaters or rinsate."

However, if a registrant does not support the rights-of-way use, the registrant must amend his product label by deleting the rights-of-way use in accordance with the procedures in PR Notice 91-1.

(2) The labels of all linuron end-use products must be revised to bear the following application restrictions under the **Directions for Use Section**:

Application Restrictions:

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

"Aerial application is prohibited."

"Use on sand or loamy sand is prohibited."

"Use on soils of <1% organic matter is prohibited."

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(3) The labels of all linuron end-use products must be revised to bear the following application rates under the **Crop Uses Section** for the respective crops:

Application Rates

For linuron use on soybeans:
A maximum application rate of 1.0 lb ai/A, with use limited to single application (pre-emergent use only) per year.

For linuron use on corn, field:
A maximum application rate of 0.75 lb ai/A, with use limited to single application (pre-emergent use only) per year.

For linuron use on potatoes:
A maximum application rate of 1.5 lbs ai/A, with use limited to single application (pre-emergent use only) per year.

For linuron use on asparagus:
A maximum application rate of 2.0 lbs ai/A per year, with use limited to 3 applications per year.

Do not exceed 2.0 lbs total per acre per year.

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

C. Existing Stocks

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

The Agency has determined that registrants may distribute and sell products bearing old labels/labeling, i.e., labels absent the modifications specified in this RED document, except as noted below, 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.

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VI. APPENDICES

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APPENDIX A. Table of Use Patterns Subject to Reregistration

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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	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED													
Broadcast., Postemergence., Boom sprayer.	DF	NA	1 lb A	*	4	NS	4 lb	NS	NS	1			C40, C46, C92, CCA, H01(1)
	DF	NA	1 lb A	*	4	NS	4 lb	NS	NS	1	CA		C40, C46, C87, CCA
	DF	NA	1 lb A	*	4	NS	4 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C40, C46, C92, CCA, H01(1)
	DF	NA	1 lb A	*	4	NS	4 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C46, C87, CCA
	DF	NA	1 lb A	*	4	NS	4 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C46, C92, CCA
	FlC	NA	1 lb A	*	4	NS	4 lb	NS	NS	1	CA		C40, C46, C92, CCA, H01(1)
	FlC	NA	1 lb A	*	4	NS	4 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C46, C93, CAG, CCA
	FlC	NA	1 lb A	*	4	NS	4 lb	NS	NS	NS	CA, MI, MN, NC, OR, WA		C40, C46, CAD, CCA, H01(1)
	FlC	NA	1 lb A	*	NS	NS	NS	NS	NS	1	CA, MI, MN, NC, OR, WA		C40, C46, C92, CCA, H01(1)
	WP	NA	1 lb A	*	4	NS	4 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C46, CCA
Broadcast., Preemergence., Boom sprayer.	DF	NA	2 lb A	*	1	NS	2 lb	NS	NS	1			C40, C46, C92, CCA, H01(1)
	DF	NA	2 lb A	*	1	NS	2 lb	NS	NS	1	CA		C40, C46, C87, CCA

Note: All DuPont labels, except for package mixes with chlorimuron for soybeans only, and certain other manufacturers' labels, carry the following limitations not captured in the codes; other labels lack one or both limitations:

- Do not use on any crop in Kern County, California, except asparagus and carrots when a permit has been obtained form the Agriculture Commission.
- In the Columbia River Basin, use Linuron only if the crop is sprinkler irrigated.

ASPARAGUS — Use Group: TERRESTRIAL FOOD CROP

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 Max. /crop	/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													
FOOD/FEED													
ASPARAGUS (con't)			Use Group: TERRESTRIAL FOOD CROP (con't)										
	DF	NA	2 lb A	*	1	NS	2 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C40, C46, C92, CCA, H01(1)
	DF	NA	2 lb A	*	1	NS	2 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C46, C92, CCA
	DF	NA	2 lb A	*	1	NS	4 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C46, C87, CCA
	FlC	NA	2 lb A	*	1	NS	2 lb	NS	NS	1	CA		C40, C46, C92, CCA, H01(1)
	FlC	NA	2 lb A	*	1	NS	2 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C40, C46, C92, CCA, H01(1)
	FlC	NA	2 lb A	*	1	NS	2 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C46, C93, CAG, CCA
	FlC	NA	2 lb A	*	1	NS	2 lb	NS	NS	NS	CA, MI, MN, NC, OR, WA		C40, C46, CAD, CCA, H01(1)
	WP	NA	2 lb A	*	1	NS	2 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C46, CCA
Directed spray., Postemergence., Boom sprayer.	DF	NA	4 lb A	*	1	NS	4 lb	NS	NS	1			C40, C46, C92, CCA, H01(1)
	DF	NA	4 lb A	*	1	NS	4 lb	NS	NS	1	CA		C40, C46, C87, CCA
	DF	NA	4 lb A	*	1	NS	4 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C40, C46, C92, CCA, H01(1)
	DF	NA	4 lb A	*	1	NS	4 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C46, C87, CCA
	DF	NA	4 lb A	*	1	NS	4 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C46, C92, CCA
	FlC	NA	4 lb A	*	1	NS	4 lb	NS	NS	1	CA		C40, C46, C92, CCA, H01(1)

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 Max. /crop	/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													
FOOD/FEED													
ASPARAGUS (con't)			Use Group: TERRESTRIAL FOOD CROP (con't)										
	FlC	NA	4 lb A	*	1	NS	4 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C46, C93, CAG, CCA
	FlC	NA	4 lb A	*	1	NS	4 lb	NS	NS	NS	CA, MI, MN, NC, OR, WA		C40, C46, CAD, CCA, H01(1)
	FlC	NA	4 lb A	*	NS	NS	NS	NS	NS	1	CA, MI, MN, NC, OR, WA		C40, C46, C92, CCA, H01(1)
	WP	NA	4 lb A	*	1	NS	4 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C46, CCA
Spray., Postemergence., Boom sprayer.	FlC	NA	1 lb A	*	NS	NS	NS	NS	NS	1	CA, MI, MN, NC, OR, WA		C40, C46, C92, CCA, H01(1)
Spray., Preemergence., Boom sprayer.	DF	NA	2 lb A	*	1	NS	2 lb	NS	NS	1	CA		C40, C46, C87, CCA
	FlC	NA	2 lb A	*	NS	NS	NS	NS	NS	1	CA		C40, C46, C92, CCA, H01(1)
	WP	NA	2 lb A	*	1	NS	2 lb	NS	NS	1	CA, MI, MN, NC, OR, WA		C46, CCA
CARROT (INCLUDING TOPS)			Use Group: TERRESTRIAL FOOD CROP										
Spray., Postemergence., Boom sprayer.	DF	NA	1.5 lb A	*	NS	NS	2 lb	NS	NS	1			C40, C46, C87, H01(14)
	DF	NA	1.5 lb A	*	NS	NS	2 lb	NS	NS	1			C40, C46, C92, H01(14)
	DF	NA	1.5 lb A	*	NS	NS	2 lb	NS	NS	1			C46, C92, H01(14)
	DF	NA	1.5 lb A	*	NS	NS	2 lb	NS	NS	1	FL, MI, OH, WI		C46, C87, H01(14)
	FlC	NA	1.5 lb A	*	2	NS	2 lb	NS	NS	1			C40, C46, C92, H01(14)
	FlC	NA	1.5 lb A	*	NS	NS	2 lb	NS	NS	0.5			C40, C87

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Dose	Max. # Apps @ Max. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED											
CARROT (INCLUDING TOPS) (con't)			Use Group: TERRESTRIAL FOOD CROP (con't)								
	FlC	NA	1.5 lb A	*	NS NS	2 lb	NS	NS 1			C40, C46, C92, H01(14)
	FlC	NA	1.5 lb A	*	NS NS	2 lb	NS	NS 1			C46, C93, CAG, H01(14)
	FlC	NA	1.5 lb A	*	NS NS	2 lb	NS	NS NS			C40, C46, CAD, H01(14)Report Run
	WP	NA	1.5 lb A	*	NS NS	2 lb	NS	NS 1			C46
Spray., Postplant., Boom sprayer.	FlC	NA	1.5 lb A	*	NS NS	2 lb	NS	NS 0.5			C40, C87
Spray., Preemergence., Boom sprayer.	DF	NA	1.5 lb A	*	NS NS	2 lb	NS	NS 1	FL, MI, OH, WI		C40, C46, C92, H01(14)
	DF	NA	1.5 lb A	*	NS NS	2 lb	NS	NS 1	FL, MI, OH, WI		C46, C87, H01(14)
	DF	NA	1.5 lb A	*	NS NS	2 lb	NS	NS 1	FL, MI, OH, WI		C46, C92, H01(14)
	DF	NA	1.5 lb A	*	NS NS	2 lb	NS	NS 1	FL, MI, WI		C40, C46, C87, H01(14)
	FlC	NA	1.5 lb A	*	2 NS	2 lb	NS	NS 1	FL, MI, OH, WI 013		C40, C46, C92
			Geo.013: In Florida apply 2 pints of product per acre; in Michigan, Ohio, and Wisconsin, apply 3 pints of product per acre.								
	FlC	NA	1.5 lb A	*	NS NS	2 lb	NS	NS 0.5			C40, C87
	FlC	NA	1.5 lb A	*	NS NS	2 lb	NS	NS 1	FL, MI, OH, WI		C40, C46, C92, H01(14)
	FlC	NA	1.5 lb A	*	NS NS	2 lb	NS	NS 1	FL, MI, OH, WI		C46, C93, CAG
	FlC	NA	1.5 lb A	*	NS NS	2 lb	NS	NS NS	FL, MI, OH, WI		C40, C46, CAD, H01(14)

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

USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED

CARROT (INCLUDING TOPS) (con't) — Use Group: TERRESTRIAL FOOD CROP (con't)

	WP	NA	1.5 lb A	*	NS	NS	2 lb	NS	NS	1	FL, MI, OH, WI		C46
Spray., Preemergence., Ground.	DF	NA	1 lb A	*	NS	1/1 yr	NS	1 lb	NS	1	CA		C46, H01(14)

CELERY — Use Group: TERRESTRIAL FOOD CROP

Spray., Posttransplant., Boom sprayer.	DF	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	1	013		C40, C46, C92
					Geo.013: Apply East of the Rocky Mountains only. In the Northeast, use only on celery grown on muck soils.								
	DF	NA	1.5 lb A	*	1	NS	NS	NS	NS	1	013		C46, C92
					Geo.013: In the Northeast, use the product on celery grown only on muck soils. Apply only East of the Rocky Mountains.								
	DF	NA	1.5 lb A	*	NS	NS	NS	NS	NS	1	013		C40, C46, C87
					Geo.013: Apply East of the Rocky Mountains only. In the Northeast, use only on celery grown on muck soils.								
	DF	NA	1.5 lb A	*	NS	NS	NS	NS	NS	1	013		C46, C87
					Geo.013: See above								
	FlC	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	0.5	013		C40, C87
					In the Northeast, use only on celery grown on muck soils.								
	FlC	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	1	013		C40, C46, C92
					Geo.013: Apply East of the Rocky Mountains only. In the Northeast, use only on celery grown on muck soils.								
	FlC	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	1	013	013	C40, C46, C92
					Geo.013: Apply East of the Rocky Mountains only. In the Northeast, use only on celery grown on muck soils.								
	FlC	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	NS	013		C40, C46, CAD
					Geo.013: Apply East of the Rocky Mountains only. In the Northeast, use only on celery grown on muck soils.								

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Dose	Max. # Apps @ Max. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED											
CELERY (con't)				Use Group: TERRESTRIAL FOOD CROP (con't)							
	FlC	NA	1.5 lb A	*	NS NS	NS	NS NS	1	013		C46, C93, CAG
Geo.013: Apply East of the Rocky Mountains only. In Northeast, use only on celery grown on muck soils.											
	WP	NA	1.5 lb A	*	NS NS	NS	NS NS	1	013		C46
Geo.013: Apply East of the Rocky Mountains. In the Northeast, use only on celery grown on muck soils.											
CORN, FIELD				Use Group: TERRESTRIAL FOOD+FEED CROP							
Band treatment., Postemergence., Boom sprayer.	WP	NA	.524 lb A .524 lb A .400 lb A .154 lb A	* F M C	NS 1/1 yr	NS .77 lb	NS	1			C40, C46, CAD
Band treatment., Postemergence., Tractor-mounted sprayer.	WP	NA	.524 lb A .524 lb A .400 lb A .154 lb A	* F M C	NS 1/1 yr	NS .77 lb	NS	1			C40, C46, CAD
Band treatment., Preemergence., Boom sprayer.	WP	NA	.524 lb A .524 lb A .400 lb A .154 lb A	* F M C	NS 1/1 yr	NS .77 lb	NS	1			C40, C46, CAD
Band treatment., Preemergence., Tractor-mounted sprayer.	WP	NA	.524 lb A .524 lb A .400 lb A .154 lb A	* F M C	NS 1/1 yr	NS .77 lb	NS	1			C40, C46, CAD
Directed spray., Postemergence., Boom sprayer.	DF	NA	1.5 lb A	*	1 NS	1.5 lb	NS	1			C40, C46, C92
	DF	NA	1.5 lb A	*	1 NS	NS	NS NS	1	013		C46, C92
Geo.013: For use 'East of the Rocky Mountains only.'											

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Dose	Max. # Apps @ Max. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED											
CORN, FIELD (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
	DF	NA	1.5 lb A	*	NS NS	NS	NS	NS	1		C40, C46, C87
	DF	NA	1.5 lb A	*	NS NS	NS	NS	NS	1		C46, C87
	FlC	NA	1.5 lb A	*	1 NS	1.5 lb	NS	NS	0.5		C40, C87
	FlC	NA	1.5 lb A	*	1 NS	1.5 lb	NS	NS	1		C40, C46, C92
	FlC	NA	1.5 lb A	*	1 NS	1.5 lb	NS	NS	NS		C40, C46, CAD
	FlC	NA	1.5 lb A	*	NS NS	NS	NS	NS	1		C46, C93, CAG
	FlC	NA	1.5 lb A	*	NS NS	NS	NS	NS	1		C40, C46, C92
	WP	NA	1.5 lb A	*	NS NS	NS	NS	NS	1		C46
Spray., Postemergence., Boom sprayer.	WP	NA	1.54 lb A 1.54 lb A 1.232 lb A .493 lb A	* F M C	NS 1/1 yr	NS	.77 lb	NS	1		C40, C46, CAD
Spray., Postemergence., Tractor-mounted sprayer.	WP	NA		*	NS 1/1 yr	NS	.77 lb	NS	1		C40, C46, CAD
Spray., Preemergence., Boom sprayer.	DF	NA	1.5 lb A 1.5 lb A 1.25 lb A 1 lb A	* F M C	1 NS Geo.013: Apply East of the Rocky Mountains only.	1.5 lb	NS	NS	1 013		C40, C46, C92
	DF	NA	1.5 lb A 1.5 lb A 1.25 lb A 1 lb A	* F M C	1 NS Geo.013: For use 'East of the Rocky Mountains only.'	NS	NS	NS	1 013		C46, C92

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 Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED													
CORN, FIELD (con't)						Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
	DF	NA			*	NS	NS	NS	NS	NS	1	013	C40, C46, C87
						Geo.013: Apply East of the Rocky Mountains only.							
	DF	NA	1.5	lb A	*	NS	NS	NS	NS	NS	1	013	C46, C87
			1.5	lb A	F	Geo.013: See above							
			1.25	lb A	M								
			1	lb A	C								
	FlC	NA	1.5	lb A	*	1	NS	1.5 lb	NS	NS	0.5	013	C40, C87
			1.5	lb A	F	Geo.013: Apply East of the Rocky Mountains only.							
			1.25	lb A	M								
			1	lb A	C								
	FlC	NA	1.5	lb A	*	1	NS	1.5 lb	NS	NS	1	013	C40, C46, C92
			1.5	lb A	F	Geo.013: Apply East of the Rocky Mountains only.							
			1.25	lb A	M								
			1	lb A	C								
	FlC	NA	1.5	lb A	*	1	NS	1.5 lb	NS	NS	NS	013	C40, C46, CAD
			1.5	lb A	F	Geo.013: See above							
			1.25	lb A	M								
			1	lb A	C								
	FlC	NA			*	NS	NS	NS	NS	NS	1	013	C46, C93, CAG
						Geo.013: Apply East of the Rocky mountains only.							
	FlC	NA	1.5	lb A	*	NS	NS	NS	NS	NS	1	013 013	C40, C46, C92
			1.5	lb A	F	Geo.013: Apply East of the Rocky Mountains.							
			1.25	lb A	M								
			1	lb A	C								
	WP	NA	1.54	lb A	*	NS	1/1 yr	NS	.77 lb	NS	1		C40, C46, CAD
			1.54	lb A	F								
			1.232	lb A	M								
			.493	lb A	C								

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Dose	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED											
CORN, FIELD (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
	WP	NA	1.5 lb A 1.5 lb A 1.25 lb A 1 lb A	* F M C	NS	NS	NS	NS	NS	1 013 Geo.013: Apply East of the Rocky Mountains only.	C46
Spray., Preemergence., Tractor-mounted sprayer.	WP	NA	1.54 lb A 1.54 lb A 1.232 lb A .493 lb A	* F M C	NS	1/1 yr	NS	.77 lb	NS	1	C40, C46, CAD
PARSLEY				Use Group: TERRESTRIAL FOOD CROP							
Broadcast., Preemergence., Boom sprayer.	DF	NA	UC	*	NS	1/1 yr	NS	UC	NS	1 TX	C46
PARSNIP				Use Group: TERRESTRIAL FOOD CROP							
Spray., Preemergence., Boom sprayer.	DF	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	1	C40, C46, C92
	DF	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	1	C46, C92
Spray., Postplant., Boom sprayer.	FlC	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	0.5	C40, C87
Spray., Preemergence., Boom sprayer.	DF	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	1	C40, C46, C92
	DF	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	1	C46, C92

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Dose	Max. # Apps @ Max. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED											
PARSNIP (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
	DF	NA	1.5 lb A	*	NS	NS	NS	NS	NS	1	C40, C46, C87
	DF	NA	1.5 lb A	*	NS	NS	NS	NS	NS	1	C46, C87
	FlC	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	0.5	C40, C87
	FlC	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	1	C40, C46, C92
	FlC	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	1	C40, C46, C92
	FlC	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	NS	C40, C46, CAD
	FlC	NA	1.5 lb A	*	NS	NS	NS	NS	NS	1	C46, C93, CAG
	WP	NA	1.5 lb A	*	NS	NS	NS	NS	NS	1	C46
SORGHUM			Use Group: TERRESTRIAL FOOD+FEED CROP								
Directed spray., Postemergence., Boom sprayer.	DF	NA	1 lb A	*	1	NS	NS	NS	NS	1	C46, C92, G74
	DF	NA	1 lb A	*	NS	NS	NS	NS	NS	1	C40, C46, C87
	DF	NA	1 lb A	*	NS	NS	NS	NS	NS	1	C40, C46, C92, G01(90)
	DF	NA	1 lb A	*	NS	NS	NS	NS	NS	1	C46, C87, G03, GC9
	FlC	NA	1 lb A	*	1	NS	1 lb	NS	NS	0.5	C40, C87, G74
	FlC	NA	UC	*	NS	NS	NS	NS	NS	1	C40, C46, C92, G01(90)
	FlC	NA	1 lb A	*	NS	NS	NS	NS	NS	1	C46, C93, CAG
	FlC	NA	1 lb A	*	NS	NS	NS	NS	NS	1	C40, C46, C92, G01(90)
	FlC	NA	1 lb A	*	NS	NS	NS	NS	NS	NS	C40, C46, CAD, G01(90)

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													
SORGHUM (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
	WP	NA	1 lb A	*	NS	NS	NS	NS	NS	1			C46
Spray., Postplant., Boom sprayer.	FlC	NA		*	NS	NS	NS	NS	NS	0.5			C40, C87, G74, GI8
Spray., Preemergence., Boom sprayer.	DF	NA	1 lb A 1 lb A .75 lb A	* M C	1	NS	1 lb	NS	NS	1			C40, C46, C92, G01(90)
	DF	NA	1 lb A 1 lb A .75 lb A	* M C	1	NS	NS	NS	NS	1			C46, C92, G74
	DF	NA	1.5 lb A	*	NS	NS	NS	NS	NS	1			C40, C46, C87
	DF	NA	1 lb A 1 lb A .75 lb A	* M C	NS	NS	NS	NS	NS	1			C46, C87, G03, GC9, GI8
	FlC	NA	1 lb A 1 lb A .75 lb A	* M C	1	NS	1 lb	NS	NS	1			C40, C46, C92, G01(90)
	FlC	NA	1 lb A 1 lb A .75 lb A	* M C	1	NS	1 lb	NS	NS	NS			C40, C46, CAD, G01(90)
	FlC	NA	1.5 lb A 1 lb A .75 lb A	* M C	1	NS	1.5 lb	NS	NS	0.5			C40, C87, G74, GI8
	FlC	NA		*	NS	NS	NS	NS	NS	1			C46, C93, CAG, G03, GI8
	FlC	NA	1.5 lb A 1.5 lb A 1 lb A .75 lb A	* F M C	NS	NS	NS	NS	NS	1			C40, C46, C92, G01(90)

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 Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED											
SORGHUM (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
	WP	NA	1 lb A 1 lb A .75 lb A	* M C	NS	NS	NS	NS	NS	1	C46
SOYBEANS (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP								
Broadcast., Postemergence., Boom sprayer.	FlC	NA	1 lb A	*	NS	NS	NS	NS	NS	1	C40, C46, C92, H01(60)
Directed spray., Postemergence., Boom sprayer.	DF	NA	1 lb A	*	1	NS	1 lb	NS	NS	1	C46, C92, GH9, H01(60)
	DF	NA	1 lb A	*	NS	NS	1 lb	NS	NS	1	C40, C46, C87, H01(60)
	DF	NA	1 lb A	*	NS	NS	1 lb	NS	NS	1	C46, C87, H01(60)
	DF	NA	.6401 lb A	*	NS	NS	NS	NS	NS	0.5	C40, C46, C92, GE8
	DF	NA	1 lb A	*	NS	NS	NS	NS	NS	1	C40, C46, C92, G74
	DF	NA	1 lb A	*	NS	NS	NS	NS	NS	1	C40, C46, C92, G74, G94, H01(60)
	FlC	NA	1 lb A	*	NS	NS	1 lb	NS	NS	1	C40, C46, C92, G74, G94, H01(60)
	FlC	NA	.75 lb A .75 lb A .375 lb A .25 lb A	* F M C	NS	NS	1 lb	NS	NS	1	C46, C93, CAG, H01(60)
	FlC	NA	1 lb A	*	NS	NS	1 lb	NS	NS	1	C40, C46, C92

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 Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED											
SOYBEANS (UNSPECIFIED) (con't) Use Group: TERRESTRIAL FOOD+FEED CROP (con't)											
	FlC	NA	1 lb A	*	NS NS NS NS NS 0.5	013					C40, C87, H01(60)
					Geo.013: In Midsouth and Southeast apply when soybeans are at least 12 inches tall and when weeds do not exceed 4 inches in height. In Midsouth, application may be made when soybeans are at least 8 inches tall and weeds do not exceed 2 inches in height. Make a single application of 1 to 2 pints per acre (0.5 to 1 pint per acre on 8 inch soybeans). Alternatively, if application is made to 12 inch soybeans, make a split application of 1 pint per acre followed by a second application at same rate after a week or later. Overall dosage not to exceed 2 pints per acre per season, for postemergence treatment.						
	FlC	NA	1 lb A	*	NS NS NS NS NS NS						C40, C46, CAD, G74, H01(60)
	WP	NA	1 lb A	*	NS NS 1 lb NS NS 1						C46, G94
Soil incorporated treatment., Early preplant., Boom sprayer.	DF	NA	.6401 lb A .6401 lb A .569 lb A .4979 lb A	* F M C	NS NS NS NS NS 0.5						C40, C46, C92, GE8
Soil incorporated treatment., Preplant., Boom sprayer.	DF	NA	.6401 lb A	*	NS NS NS NS NS 0.5						C40, C46, C92, GE8
	DF	NA	.6401 lb A .6401 lb A .569 lb A .4979 lb A	* F M C	NS NS NS NS NS 0.5						CAA, GE8
	DF	NA	.831 lb A .831 lb A .693 lb A .554 lb A	* F M C	NS NS NS NS NS 0.5	VA, WV, DE, MD, NC, PA					C46, GE8
Spray., Early preplant., Boom sprayer.	DF	NA	.6401 lb A .6401 lb A .569 lb A .4979 lb A	* F M C	NS NS NS NS NS 0.5						CAA, GE8

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 Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED											
SOYBEANS (UNSPECIFIED) (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
Spray., Preemergence., Aircraft.	DF	NA	UC	*	1	NS	NS	NS	NS	1	C46, C92, GH9
	DF	NA	UC	*	NS	NS	NS	NS	NS	1	C46, C87
	FlC	NA	2.5 lb A 2.5 lb A 2 lb A 1.5 lb A	* F M C	NS	NS	NS	NS	NS	0.5	C40, C87
	FlC	NA	3 lb A 2.5 lb A 2 lb A 1.5 lb A	* F M C	NS	NS	NS	NS	NS	1	C46, C93, CAG
Spray., Preemergence., Boom sprayer.	DF	NA	3 lb A 2.5 lb A 2 lb A 1.5 lb A	* F M C	1	NS	NS	NS	NS	1	C46, C92, GH9
	DF	NA	.6401 lb A .6401 lb A .569 lb A .4979 lb A	* F M C	NS	NS	NS	NS	NS	0.5	C40, C46, C92, GE8
	DF	NA	.6401 lb A .6401 lb A .569 lb A .4979 lb A	* F M C	NS	NS	NS	NS	NS	0.5	CAA, GE8
	DF	NA	.831 lb A .831 lb A .693 lb A .554 lb A	* F M C	NS	NS	NS	NS	NS	0.5	VA, WV, DE, MD, NC, PA C46, GE8
	DF	NA	1.5 lb A	*	NS	NS	NS	NS	NS	1	C40, C46, C87
	DF	NA	2.5 lb A 3 lb A 2 lb A 1.5 lb A	* F M C	NS	NS	NS	NS	NS	1	C40, C46, C92, G74

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USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED												
SOYBEANS (UNSPECIFIED) (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
	DF	NA	1.75 lb A	*	NS	NS	NS	NS	NS	1		C46, C87, G63
			2.5 lb A	F								
			2 lb A	M								
			1.5 lb A	C								
	FlC	NA	3 lb A	*	1	NS	3 lb	NS	NS	1		C40, C46, C92, G99
			3 lb A	F								
			2 lb A	M								
			1.5 lb A	C								
	FlC	NA	2.5 lb A	*	NS	NS	NS	NS	NS	0.5		C40, C87, GI7, GK3
			2.5 lb A	F								
			2 lb A	M								
			1.5 lb A	C								
	FlC	NA	2.5 lb A	*	NS	NS	NS	NS	NS	1		C40, C46, C92, G74
			3 lb A	F								
			2 lb A	M								
			1.5 lb A	C								
	FlC	NA	3 lb A	*	NS	NS	NS	NS	NS	1		C46, C93, CAG
			3 lb A	F								
			2 lb A	M								
			1.5 lb A	C								
	FlC	NA	1.5 lb A	*	NS	NS	NS	NS	NS	NS		C40, C46, CAD, G74
			3 lb A	F								
			2 lb A	M								
			1.5 lb A	C								
	WP	NA	1 lb A	*	NS	NS	NS	NS	NS	1		C46, GA3
			3 lb A	F								
			2 lb A	M								
			1.5 lb A	C								

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Dose	Max. # Apps @ Max. Rate /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													
WHEAT				Use Group: TERRESTRIAL FOOD+FEED CROP									
Spray., Fall., Boom sprayer.	FlC	NA	.75 lb A	*	NS	NS	NS	NS	NS	0.5	013		C40, C87
					Geo.013: Extracted information applies to areas East of Cascade Range.								
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	NS	1	ID, OR, WA		C46, C93, CAG
	FlC	NA	.75 lb A	*	NS	NS	NS	NS	NS	1	ID, OR, WA	013	C40, C46, C92
					Geo.013: Extracted information applies to areas East of Cascade Range.								
Spray., Postemergence., Boom sprayer.	FlC	NA	1.75 lb A	*	NS	NS	NS	NS	NS	0.5			C40, C87
	FlC	NA	1.75 lb A	*	NS	NS	NS	NS	NS	1	ID, OR, WA		C40, C46, C92
Spray., Preemergence., Boom sprayer.	FlC	NA	1.75 lb A	*	NS	NS	NS	NS	NS	0.5	013		C40, C87
					Geo.013: The extracted data (max.dose per application) applies to areas west of Cascade Range.								
	FlC	NA	1.75 lb A	*	NS	NS	NS	NS	NS	1	ID, OR, WA		C46, C93, CAG
	FlC	NA	1.75 lb A	*	NS	NS	NS	NS	NS	1	ID, OR, WA	013	C40, C46, C92
					Geo.013: The extracted data (max.dose per application) applies to areas west of Cascade Range.								
Spray., Spring., Boom sprayer.	FlC	NA	.625 lb A	*	NS	NS	NS	NS	NS	0.5	013		C40, C87
					Geo.013: Extracted data refers to area east of Cascade Range and where Average Annual rainfall exceeds 16 inches; however in areas east of Cascade Range, with an average rainfall of 10 to 20 inches the dosage is reduced to 0.5 pint and as a tank mixture with another herbicide.								
	FlC	NA	.625 lb A	*	NS	NS	NS	NS	NS	1	ID, OR, WA		C46, C93, CAG
	FlC	NA	.625 lb A	*	NS	NS	NS	NS	NS	1	ID, OR, WA	013	C40, C46, C92
					Geo.013: Extracted data refers to area east of Cascade Range and where Average Annual rainfall exceeds 16 inches; however in areas east of Cascade Range, with an average rainfall of 10 to 20 inches the dosage is reduced to 0.5 pint and as a tank mixture with another herbicide.								

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Dose	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED											
WHEAT (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
Spray., Winter., Boom sprayer.	FlC	NA	.75 lb A	*	NS NS	NS	NS NS	0.5	013		C40, C87
					Geo.013: Extracted data refers to East of Cascade Range and where average annual rainfall is 10 to 16 inches.						
	FlC	NA	.75 lb A	*	NS NS	NS	NS NS	1	ID, OR, WA		C46, C93, CAG
	FlC	NA	.75 lb A	*	NS NS	NS	NS NS	1	ID, OR, WA	013	C40, C46, C92
					Geo.013: Extracted data refers to East of Cascade Range and where average annual rainfall is 10 to 16 inches.						

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Dose	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED													
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS			Use Group: TERRESTRIAL NON-FOOD CROP										
Spray., When needed., Boom sprayer.	DF	NA	3 lb A	*	NS	NS	NS	NS	NS	1			C40, C46, C87
	DF	NA	3 lb A	*	NS	NS	NS	NS	NS	1			C40, C46, C92
	DF	NA	3 lb A	*	NS	NS	NS	NS	NS	1			C46, C87
	DF	NA	3 lb A	*	NS	NS	NS	NS	NS	1			C46, C92
	FlC	NA	UC	*	NS	NS	NS	NS	NS	0.5			C40, C87
	FlC	NA	3 lb A	*	NS	NS	NS	NS	NS	1			C40, C46, C92
	FlC	NA	3 lb A	*	NS	NS	NS	NS	NS	1			C46, C93, CAG
	FlC	NA	3 lb A	*	NS	NS	NS	NS	NS	1			C40, C46, C92
	FlC	NA	3 lb A	*	NS	NS	NS	NS	NS	NS			C40, C46, CAD
	WP	NA	3 lb A	*	NS	NS	NS	NS	NS	1			C46
ORNAMENTAL HERBACEOUS PLANTS			Use Group: TERRESTRIAL NON-FOOD CROP										
Spray., Preemergence., Boom sprayer.	DF	NA	1 lb A	*	1	NS	1 lb	NS	NS	1	CA		C46, C92
	DF	NA	1 lb A	*	1	NS	NS	NS	NS	1	CA		C46, C87
	FlC	NA	1 lb A	*	1	NS	1 lb	NS	NS	1	CA		C40, C46, C47, CAD
	FlC	NA	1 lb A	*	1	NS	1 lb	NS	NS	1	CA		C46, C93, CAG
	WP	NA	1 lb A	*	1	NS	NS	NS	NS	1	CA		C46

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USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED											
POPLAR (FOREST/SHELTERBELT)				Use Group: FORESTRY							
Spray., Spring., Boom sprayer. Before bud break (Use Directed Spray after bud break.)	DF	NA	2 lb A	*	NS	NS	NS	4 lb	NS	1	013	C40, C46, C92
					Geo.013: Apply in the Midwest only.							
	DF	NA	2 lb A	*	NS	NS	NS	4 lb	NS	1	013	C46, C87
	DF	NA	2 lb A	*	NS	NS	NS	4 lb	NS	1	013	C46, C92
					Geo.013: Apply in the Midwest only.							
	FlC	NA	2 lb A	*	NS	NS	NS	4 lb	NS	1	013	C40, C46, C92
					Geo.013: Apply in the Midwest only.							
	FlC	NA	2 lb A	*	NS	NS	NS	4 lb	NS	1	013	C46, C93, CAG
					Geo.013: See above							
	FlC	NA	2 lb A	*	NS	NS	NS	4 lb	NS	NS	013	C40, C46, CAD
					Geo.013: See above							
	WP	NA	2 lb A	*	NS	NS	NS	4 lb	NS	1	013	C46
					Geo.013: See above							

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Dose	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED													
CORN, SWEET			Use Group: TERRESTRIAL FOOD+FEED CROP										
Directed spray., Postemergence., Boom sprayer.	DF	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	1			C40, C46, C92
	DF	NA	1.5 lb A	*	1	NS		NS	NS	1			C46, C92
	DF	NA	.625 lb A	*	NS	NS		NS	NS	1			C40, C46, C87
	DF	NA	1.5 lb A	*	NS	NS		NS	NS	1			C46, C87
	FlC	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	0.5			C40, C87
	FlC	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	1			C40, C46, C92
	FlC	NA	1.5 lb A	*	1	NS	1.5 lb	NS	NS	NS			C40, C46, CAD
	FlC	NA	1.5 lb A	*	NS	NS		NS	NS	1			C46, C93, CAG
	FlC	NA	1.5 lb A	*	NS	NS		NS	NS	1			C40, C46, C92
	WP	NA	1.5 lb A	*	NS	NS		NS	NS	1			C46
COTTON			Use Group: TERRESTRIAL FOOD+FEED CROP										
Directed spray., Postemergence., Boom sprayer.	DF	NA	1.5 lb A	*	NS	NS		NS	NS	1	013		C40, C46, C87, G03, G14, GA4
					Geo.013: Apply East of the Rocky Mountains only.								
	DF	NA	1.5 lb A	*	NS	NS		NS	NS	1	013		C46, C87, G03, G14, GA4
					Geo.013: See above								
	DF	NA	1.5 lb A	*	NS	NS		NS	NS	1	013		C46, C92, G03, G14
					Geo.013: Apply east of the Rocky Mountains only.								
	FlC	NA	1.5 lb A	*	NS	NS		NS	NS	0.5	013		C40, C87, G03, G14, GA4
					Geo.013: Apply East of the Rocky Mountains only.								
	FlC	NA	1.5 lb A	*	NS	NS		NS	NS	1	013		C40, C46, C47, CAD, G14, G74
					Geo.013: Use east of Rocky Mountains.								

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USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED											
COTTON (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
	FlC	NA	1.5 lb A	*	NS NS	NS	NS	NS	013		C46, C93, CAG, G03, G14, GA4
					Geo.013: Apply East of the Rocky Mountains only.						
	FlC	NA	1.5 lb A	*	NS NS	NS	NS	NS	013	013	C40, C46, C92, G03, G14, GA4
					Geo.013: Apply East of the Rocky Mountains only.						
Spray., Postemergence., Boom sprayer.	FlC	NA	.75 lb A	*	NS NS	NS	NS	NS 0.5	013		C40, C87, G03, G28
					Geo.013: Apply East of Rocky Mountains.						
POTATO, WHITE/IRISH				Use Group: TERRESTRIAL FOOD+FEED CROP							
Spray., Postplant., Boom sprayer.	FlC	NA		*	NS NS	NS	NS	NS 0.5	013		C40, C87
					Geo.013: Apply extracted dosages East of Rocky mountains.						
Spray., Preemergence., Aircraft.	DF	NA	UC	*	NS NS	NS	NS	NS 1			C46, C87
	DF	NA	2 lb A	*	NS NS	NS	NS	NS 1	013	013	C46, C92
					Geo.013: Use East of Rocky Mountains, Northeast and in Central Sands Area of Wisconsin.						
	FlC	NA		*	NS NS	NS	NS	NS 1			C46, C93, CAG
Spray., Preemergence., Boom sprayer.	DF	NA	2 lb A	*	1 NS	2 lb	NS	NS 1	013		C40, C46, C92
			2 lb A	F	Geo.013: Apply extracted dosages East of the Rocky Mountains. In Wisconsin - Central Sands						
			2 lb A	M	Area, apply 1 pound product per acre on sands and 2 pounds per acre on loamy sands. In						
			1.25 lb A	C	Northeast, apply 2 pounds per acre on coarse soils with 3 to 5 percent organic matter. Apply 2.5 pounds of product on medium soils with 3 to 5 percent organic matter.						
	DF	NA	2 lb A	*	1 NS	NS	NS	NS 1	013	013	C46, C92
			2 lb A	F	Geo.013: Use East of Rocky Mountains,Northeast						
			2 lb A	M	Apply extracted dosages East of the Rocky Mountains and in Central Sands Area of Wisconsin.						
			1.25 lb A	C							

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USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED												
POTATO, WHITE/IRISH (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
	DF	NA	2 lb A	*	NS	NS	NS	NS	NS	1	013	C40, C46, C87
			2 lb A	F	Geo.013: Apply extracted dosages East of the Rocky mountains. In Wisconsin - Central Sands							
			2 lb A	M	Area, apply 1 pound product per acre on sands and 2 pounds per acre on loamy sands. In the							
			1.25 lb A	C	Northeast, apply 2 pounds per acre on coarse soils with 3 percent to 5 percent organic matter. Apply 2.5 pounds of product per acre on medium soils with 3 percent to 5 percent organic matter.							
	DF	NA		*	NS	NS	NS	NS	NS	1	013	C46, C87
					Geo.013: Apply extracted dosages East of the Rocky mountains. In Wisconsin - Central Sands Area, apply 1 pound product per acre on sands and 2 pounds per acre on loamy sands.							
	FlC	NA	2 lb A	*	1	NS	2 lb	NS	NS	1	013	C40, C46, C92
			2 lb A	F	Geo.013: Apply extracted dosages East of the Rocky Mountains. In Wisconsin - Central Sands							
			2 lb A	M	Area, apply 1 pint of product per acre on sands and 2 pints per acre on loamy sands. In							
			1.25 lb A	C	Northeast, apply 2 pints per acre on coarse soils with 3 to 5 percent organic matter. Apply 2.5 pints of product on medium soils with 3 to 5 percent organic matter.							
	FlC	NA	2 lb A	*	1	NS	2 lb	NS	NS	NS	013	C40, C46, CAD
			2 lb A	F	Geo.013: See above							
			2 lb A	M								
			1.25 lb A	C								
	FlC	NA	2 lb A	*	NS	NS	NS	NS	NS	0.5	013	C40, C87
			2 lb A	F	Geo.013: Apply extracted dosages East of Rocky mountain, whereas, in Wisconsin apply dosages							
			2 lb A	M	according to soil type specified.							
			1.25 lb A	C								
	FlC	NA		*	NS	NS	NS	NS	NS	1	013	C46, C93, CAG
					Geo.013: Apply extracted dosages East of the Rocky Mountains. In Wisconsin - Central Sands Area, apply 1 pint product per acre on sands and 2 pints per acre on loamy sands. In the Northeast, apply 2 pints per acre on coarse soils with 3 percentr to 5 percent organic matter. Apply 2.5 pints of product per acre on medium soils with 3 percent to 5 percent organic matter.							
	FlC	NA	2 lb A	*	NS	NS	NS	NS	NS	1	013 013	C40, C46, C92
			2 lb A	F	Geo.013: " Do not use on any crop in Kern County, California. Apply extracted dosages East							
			2 lb A	M	of the Rocky mountains. Do not apply in Kern County, CA.							
			1.25 lb A	C								

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Dose	Max. # Apps @ Max. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED											
POTATO, WHITE/IRISH (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
	WP	NA	1.25 lb A 2 lb A 2 lb A 1.25 lb A	* F M C	NS NS NS NS NS 1	013					C46 Geo.013: Apply East of the Rocky Mountains. In Wisconsin - Central Sands Area, apply 1 pound product per acre on sands and 2 pounds per acre on loamy sands. In the Northeast, apply 2 pounds per acre on coarse soils with 3 percent to 5 percent organic matter. Apply 2.5 pounds of product on medium soils with 3 percent to 5 percent organic matter.
NON-FOOD/NON-FEED USES											
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS			Use Group: TERRESTRIAL NON-FOOD CROP								
Spray., When needed., Boom sprayer.	DF	NA	3 lb A	*	NS NS NS NS NS 1						C40, C46, C87
	DF	NA	3 lb A	*	NS NS NS NS NS 1						C40, C46, C92
	DF	NA	3 lb A	*	NS NS NS NS NS 1						C46, C87
	DF	NA	3 lb A	*	NS NS NS NS NS 1						C46, C92
	FlC	NA	UC	*	NS NS NS NS NS 0.5						C40, C87
	FlC	NA	3 lb A	*	NS NS NS NS NS 1						C40, C46, C92
	FlC	NA	3 lb A	*	NS NS NS NS NS 1						C46, C93, CAG
	FlC	NA	3 lb A	*	NS NS NS NS NS 1						C40, C46, C92
	FlC	NA	3 lb A	*	NS NS NS NS NS NS						C40, C46, CAD
	WP	NA	3 lb A	*	NS NS NS NS NS 1						C46

LEGEND
444444

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
DF : WATER DISPERSIBLE GRANULES (DRY FLOWABLE)
FlC : FLOWABLE CONCENTRATE
WP : WETTABLE POWDER

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"

USEuSE LIMITATIONS CODES
C14 : Grown for seed only.
C40 : Do not apply by aircraft.
C46 : Do not apply through any type of irrigation system.
C47 : Do not enter treated areas without protective clothing until 24 hours after application.
C87 : Do not apply directly to water or wetlands, or where runoff is likely to occur.
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.
C93 : Do not apply directly to water.
CAA : Do not apply to any body of water.
CAD : Do not apply directly to water or wetlands.
CAG : Do not apply where runoff is likely to occur.
CCA : Application rates are for crops established 1 year or more. For newly seeded or transplanted crop, maximum dose per application is 2 lb ai/A preemergence and 1 lb ai/A posetemregence; and per crop cycle is 2 lb ai/A.
G01 : __ day(s) pregrazing interval.
G03 : Do not graze livestock in treated areas.
G14 : Do not feed gin trash or treated foliage to livestock.
G28 : Do not feed gin trash or treated foliage to dairy animals.
G63 : No parts of treated plants may be used as food or feed.
G74 : Do not feed treated foliage to livestock or graze treated areas.

G94 : Do not feed treated forage or hay to livestock.
G99 : Do not feed or graze animals on treated areas.
GA3 : Do not graze livestock in treated areas or harvest for forage.
GA4 : Do not feed treated forage to livestock.
GC9 : Do not graze or forage crop grown in treated soil or cut for hay or silage.
GE8 : Do not graze or harvest for forage or hay.
GH9 : Do not feed livestock on treated plant parts.
GI7 : Do not use seed for food, feed or oil purposes.
GI8 : Do not graze or feed forage, silage or fodder (stubble) from treated fields to dairy animals.
GK3 : Do not feed forage to livestock or allow livestock to graze in treated areas.
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
CA : California
DE : Delaware
FL : Florida
ID : Idaho
MD : Maryland
MI : Michigan
MN : Minnesota
NC : North Carolina
OH : Ohio
OR : Oregon
PA : Pennsylvania
TX : Texas
VA : Virginia
WA : Washington
WI : Wisconsin
WV : West Virginia

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APPENDIX B. Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision

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GUIDE TO APPENDIX B

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

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APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Linuron

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**		00162140, 42927301, 42927302, 42927303, 42959301
61-2A	**Start. Mat. & Mnfg. Process**		00162140, 42927301, 42927302, 42927303, 42959301 - **DATA GAP**
61-2B	**Formation of Impurities**		00162140, 42927301, 42927302, 42927303, 42959301
62-1	**Preliminary Analysis**		00162140, 42927301, 42927302, 42927303, 42959301
62-2	**Certification of limits**		42493101, 42927301, 42927302, 42927303, 42959301
62-3	**Analytical Method**		00162140, 42213301
63-2	**Color**		00162140, 42213301
63-3	**Physical State**		00162140, 42213301
63-4	**Odor**		00162140, 42213301
63-5	**Melting Point**		00162140, 42213301
63-6	**Boiling Point**		N/A - Not applicable
63-7	**Density**		00162140, 42213301
63-8	**Solubility**		00162140, 42213301
63-9	**Vapor Pressure**		00162140, 42213303
63-10	**Dissociation Constant**		00162140, 42213302

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REQUIREMENT		USE PATTERN	CITATION(S)
63-11	**Octanol/Water Partition**		00162140, 42213302
63-12	**pH**		00162140, 42213301
63-13	**Stability**		00162140, 42213301
63-14	**Oxidizing/Reducing Action**		00162140, 42213301
63-15	**Flammability**		N/A - Not applicable
63-16	**Explodability**		00162140
63-17	**Storage stability**		00162140
63-18	**Viscosity**		N/A
63-19	**Miscibility**		N/A
63-20	**Corrosion characteristics**		00162140
63-21	**Dielectric breakdown volt**		N/A
64-1	**Submittal of Samples**		N/A
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	A,C,E,J,K	00150170
71-1B	**Acute Avian Oral - Quail/Duck TEP**	A,C,E,J,K	00150170
71-2A	**Avian Dietary - Quail**	A,C,E,J,K	00034769 - **DATA GAP**
71-2B	**Avian Dietary - Duck**	A,C,E,J,K	00034769 - **DATA GAP**
71-3	**Wild Mammal Toxicity**		N/A - Not applicable
71-4A	**Avian Reproduction - Quail**		N/A
71-4B	**Avian Reproduction - Duck**		N/A

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Data Supporting Guideline Requirements for the Reregistration of Linuron

REQUIREMENT		USE PATTERN	CITATION(S)
71-5A	**Simulated Field Study**	A,C,E,J,K	Reserved
71-5B	**Actual Field Study**	A,C,E,J,K	Reserved
72-1A	**Fish Toxicity Bluegill**	A,C,E,J,K	40354201
72-1B	**Fish Toxicity Bluegill - TEP**	A,C,E,J,K	00018165, 00018198
72-1C	**Fish Toxicity Rainbow Trout**	A,C,E,J,K	40445501
72-1D	**Fish Toxicity Rainbow Trout- TEP**	A,C,E,J,K	00018165
72-2A	**Invertebrate Toxicity**	A,C,E,J,K	00142932 - **DATA GAP**
72-2B	**Invertebrate Toxicity - TEP**	A,C,E,J,K	00018199
72-3A	**Estuarine/Marine Toxicity - Fish**	A,C,E,J,K	42061801
72-3B	**Estuarine/Marine Toxicity - Mollusk**	A,C,E,J,K	42061802
72-3C	**Estuarine/Marine Toxicity - Shrimp**	A,C,E,J,K	42061803
72-3D	**Estuarine/Marine Toxicity Fish- TEP**	A,C,E,J,K	**DATA GAP**
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**	A,C,E,J,K	**DATA GAP**
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**	A,C,E,J,K	**DATA GAP**
72-4A	**Early Life Stage Fish**	A,C,E,J,K	42061804 - **DATA GAP**
72-4B	**Life Cycle Invertebrate**	A,C,E,J,K	42153401 - **DATA GAP**
72-5	**Life Cycle Fish**	A,C,E,J,K	Reserved
72-6	**Aquatic Organism Accumulation**	A,C,E,J,K	Reserved

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REQUIREMENT		USE PATTERN	CITATION(S)
72-7A	**Simulated Field - Aquatic Organisms**	A,C,E,J,K	Reserved
72-7B	**Actual Field - Aquatic Organisms**	A,C,E,J,K	Reserved
122-1A	**Seed Germination/Seedling Emergence**	A,C,E,J,K	Reserved
122-1B	**Vegetative Vigor**	A,C,E,J,K	Reserved
122-2	**Aquatic Plant Growth**	A,C,E,J,K	Reserved
123-1A	**Seed Germination/Seedling Emergence**	A,C,E,J,K	**DATA GAP**
123-1B	**Vegetative Vigor**	A,C,E,J,K	**DATA GAP**
123-2	**Aquatic Plant Growth**	A,C,E,J,K	42086801 - **DATA GAP**
124-1	**Terrestrial Field**		N/A
124-2	**Aquatic Field**		N/A
141-1	**Honey Bee Acute Contact**	A,C,E,J,K	00018842
141-2	**Honey Bee Residue on Foliage**		N/A
141-5	**Field Test for Pollinators**		N/A
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	A,B	00027625, 05016511
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	A,B	00027625
81-3	**Acute Inhalation Toxicity - Rat**	A,B	00018181
81-4	**Primary Eye Irritation - Rabbit**	A,B	00018178, 00018183, 00018179, 00018196

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REQUIREMENT		USE PATTERN	CITATION(S)
81-5	**Primary Dermal Irritation - Rabbit**	A,B	00018180
81-6	**Dermal Sensitization - Guinea Pig**	A,B	GS00047-0001, 40187601
81-7	**Acute Delayed Neurotoxicity - Hen**	A,B	N/A
82-1A	**90-Day Feeding - Rodent**	A,B	N/A
82-1B	**90-Day Feeding - Non-rodent**	A,B	N/A
82-2	**21-Day Dermal - Rabbit/Rat**	A,B	N/A
82-3	**90-Day Dermal - Rodent**	A,B	N/A
82-4	**90-Day Inhalation - Rat**	A,B	N/A
82-5A	**90-Day Neurotoxicity - Hen**	A,B	N/A
82-5B	**90-Day Neurotoxicity - Mammal**	A,B	N/A
83-1A	**Chronic Feeding Toxicity - Rodent**	A,B	00018374, 00029680, 00029679, 00164093, 00164117
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	A,B	00018374, 00029680, 00029679, 40952601
83-2A	**Oncogenicity - Rat**	A,B	00029679, 00029680, 00124195,
83-2B	**Oncogenicity - Mouse**	A,B	00029679, 00029680, 00124195,
83-3A	**Developmental Toxicity - Rat**	A,B	00018167, 00018170
83-3B	**Developmental Toxicity - Rabbit**	A,B	00018167, 00018170, 40437201
83-4	**2-Generation Reproduction - Rat**	A,B	00018169, 00146071, 00159846, 41463401, 41630101, 41864701
84-2A	**Gene Mutation (Ames Test)**	A,B	00029933, 00131738

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REQUIREMENT		USE PATTERN	CITATION(S)
84-2B	**Structural Chromosomal Aberration**	A,B	00029933, 00132583, 00137153
84-4	**Other Genotoxic Effects**	A,B	00137152
85-1	**General Metabolism**	A,B	00146489, 05016511, 40142401, 41960001, 42086801, 42318701
85-2	**Dermal Penetration**	A,B	00163837
86-1	**Domestic Animal Safety**		N/A
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**		40341801, 00163268 - **DATA GAP**
132-1B	**Soil Residue Dissipation**		40341801 - **DATA GAP**
133-3	**Dermal Passive Dosimetry Exposure**		40341801, 00163268 - **DATA GAP**
133-4	**Inhalation Passive Dosimetry Exposure**		40341801, 00163268 - **DATA GAP**
231	**Estimation of Dermal Exposure at Outdoor Sites**		N/A
232	**Estimation of Inhalation Exposure at Outdoor Sites**		N/A
233	**Estimation of Dermal Exposure at Indoor Sites**		N/A
234	**Estimation of Inhalation Exposure at Indoor Sites**		N/A
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**		

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REQUIREMENT		USE PATTERN	CITATION(S)
161-1	**Hydrolysis**	A,B,G	40916201
161-2	**Photodegradation - Water**	A,B,G	40103601
161-3	**Photodegradation - Soil**	A,G	00144569, 40171701
161-4	**Photodegradation - Air**	A	**WAIVED**
162-1	**Aerobic Soil Metabolism**	A,B,G	00125244, 41625401
162-2	**Anaerobic Soil Metabolism**	A	40142501
162-3	**Anaerobic Aquatic Metabolism**	G	40142501
162-4	**Aerobic Aquatic Metabolism**		N/A
163-1	**Leaching/Adsorption/Desorption**	A,B,G	00148443, 000146073, 05016640, 05019500 - **DATA GAP**
163-2	**Volatility - Lab**	A	**WAIVED**
163-3	**Volatility - Field**	A	**WAIVED**
164-1	**Terrestrial Field Dissipation**	A,B	41734201, 41734202, 42422801 - **DATA GAP**
164-2	**Aquatic Field Dissipation**		N/A
164-3	**Forest Field Dissipation**		N/A
164-4	**Combination and Tank Mixes**		N/A
164-5	**Long Term Soil Dissipation**		Reserved
165-1	**Confined Rotational Crop**	A	40104101, 40730101
165-2	**Field Rotational Crop**	A	**WAIVED**
165-3	**Accumulation - Irrigated Crop**		N/A
165-4	**Bioaccumulation in Fish**	A,B,G	00142933

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REQUIREMENT		USE PATTERN	CITATION(S)
165-5	**Bioaccumulation - Aquatic NonTarget**		N/A
166-1	**Ground Water - Small Prospective**		N/A
166-2	**Ground Water - Small Retrospective**		N/A
166-3	**Ground Water - Irrigated Retrospective**		N/A
201-1	**Droplet Size Spectrum**		Reserved
202-1	**Drift Field Evaluation**		Reserved
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**		00018173, 00018176, 00027624, 40084801, 42542101, 42548401
171-4B	**Nature of Residue - Livestock**		00029932, 42635401, 43245101
171-4C	**Residue Analytical Method - Plants**		00018087, 00018089, 00018176
171-4D	**Residue Analytical Method - Animal**		00018127
171-4E	**Storage Stability**		00159802, 41716103, 42836701, 42836702, 42913301, 42974401, 43040001, 43104401, 43288301, 43288302
171-4F	**Magnitude of Residues - Potable H2O**		N/A
171-4G	**Magnitude of Residues in Fish**		N/A

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Data Supporting Guideline Requirements for the Reregistration of Linuron

REQUIREMENT		USE PATTERN	CITATION(S)
171-4H	**Magnitude of Residues - Irrigated Crop**		N/A
171-4I	**Magnitude of Residues - Food Handling**		N/A
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**		00018209, 00018210, 00018375, 00018383, 00018450, 00018775, 00029932
171-4K	**Magnitude of Residues in Plants**		
	Root and Tuber Vegetable Group		
	- Carrots		00018172, 00027635, 00163267, 40210901, 40537601, 41503401
	- Parsnips, and Parsnips, tops		00018171
	- Potatoes		00027635, 00163267, 40210901, 41452701
	Leafy Vegetables Group		
	- Celery		00018443, 40537601, 41501501
	- Parsley		41189801
	Legume Vegetables Group		
	- Soybeans		00018076, 00018206, 00027635, 00163267, 40210901, 43039101
	Foliage of Legume Vegetables Group		
	- Soybean forage and hay		00018076, 00018206, 00027635 - **DATA GAP**

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REQUIREMENT	USE PATTERN	CITATION(S)
Cereal Grains Group		
- Barley, grain		**USE DELETED**
- Corn, field, grain		00018171, 00018206, 00018375, 00018382, 00018450, 00163267, 40210901, 40537601, 42948501
- Corn, pop, grain		**USE DELETED**
- Corn, sweet (K + CWHR)		00018171, 00018206, 00018375, 00018382, 00018450 - **DATA GAP**
- Sorghum, grain		00018171, 00018148, 40537601, 41377601
- Wheat, grain		00018171, 00018175, 42605901, 40537601
- Oats, grain		**USE DELETED**
- Rye, grain		**USE DELETED**
Forage, Fodder, and Straw of Cereal Grains Group		
- Barley, forage, hay and straw		**USE DELETED**
- Corn, field, forage and fodder		00018171, 00018206, 00018375, 00018382, 00018450, 00163267, 40210901, 40537601 - **DATA GAP**
- Corn, pop, forage and fodder		N/A
- Corn, sweet, fodder		N/A
- Corn, sweet, forage		00018171, 00018206, 00018375, 00018382, 00018450, 00163267, 40210901, 40537601 - **DATA GAP**

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Data Supporting Guideline Requirements for the Reregistration of Linuron

REQUIREMENT		USE PATTERN	CITATION(S)
	- Oats, forage, hay and straw		**USE DELETED**
	- Rye, forage, hay and straw		**USE DELETED**
	- Sorghum forage and fodder		00018171, 00018148, 40537601
	- Wheat forage and straw		00018171, 40537601, 42605901 - **DATA GAP**
	- Wheat, hay		N/A - No longer a raw agricultural commodity for linuron
	Miscellaneous Commodities		
	- Asparagus		00018087, 00018089, 00163267, 40210901, 41452601 - **DATA GAP**
	- Cotton, seed		00018067, 41569901 - **DATA GAP**
171-4L	**Processed Food**		
	- Corn, field		42560001
	- Cotton, seed		**DATA GAP**
	- Potatoes		See Footnote[1]
	- Sorghum, grain		42542102
	- Soybeans		00018206, 41241202, 42462901
	- Wheat, grain		**WAIVED**
171-5	**Reduction of Residues**		42462901, 42462902

[1] At this time, the Agency is unable to make a reregistration eligibility decision on the use of linuron on potatoes because EPA is currently evaluating legal challenges to its policies related to coordination of actions under Section 409's Delaney clause and the Federal Food, Drug and Cosmetic Act (FFDCA) section 408 and FIFRA. But in the event that the Agency allows the use of linuron on potatoes, additional data to upgrade an existing potato processing study will be required.

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Data Supporting Guideline Requirements for the Reregistration of Linuron

REQUIREMENT		USE PATTERN	CITATION(S)
171-6	**Proposed Tolerance**		N/A
171-7	**Support for Tolerance**		N/A
171-13	**Analtyical Reference Standard**		N/A

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APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Linuron

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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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41452701	Elbe, J. (1990) Magnitude of Lorox L Herbicide Residues in Potatoes : Lab Project Number: AMR-1132-88. Unpublished study prepared by Morse Laboratories. 47 p.
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42213301	Hogg, A. (1992) Linuron: Determination of Physico-Chemical Properties: Lab Project Number: 8/100/A. Unpublished study prepared by Safepharm Laboratories Ltd. 47 p.
42213302	Hogg, A. (1992) Linuron: Determination of Dissociation Constant and Partition Coefficient: Lab Project Number: 8/100/B. Unpublished study prepared by Safephram Labs., Ltd. 17 p.
42213303	Taylor, N. (1992) Linuron: Determination of Vapor Pressure by Balance Method: Lab Project Number: 114308. Unpublished study prepared by Univ. of Leeds. 34 p.
42318701	Brown, A. (1992) Supplement No. 2 to: Metabolism of carbon 14 (U)-Phenyl Linuron by the Laboratory Rat: Lab Project Number: HLR 351-91. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 21 p.
42422801	Tomic, D. (1992) Freezer Storage Stability of Linuron in Soil: Lab Project Number: AMR 1677-90: 02-8906. Unpublished study prepared by E.I. du Pont de Nemours and Co. 58 p.
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42493101	I.pi.ci. Industria Prodotti Chimici SpA. (1992) Linuron Technical Product Chemistry--Certified Limits: Lab Project Number: 944. Unpublished study prepared by I.pi.ci. Ananlytical Laboratory. 9 p.
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42927303	Castles, M.; Lomax, N. (1993) Supplement #1 to: Determination of TCAB, TCAOB, and TCB in Technical Grade Linuron for Product Chemistry Portion of EPA Registration MRI Project No. 9676-A: Lab Project Number: LINU/PCH-25. Unpublished study prepared by Midwest Research Institute and E.I. du Pont de Nemours and Co., Inc. 15 p.
42959301	Muller, S. (1993) Determination of Nitrosamines in Linurex Technical: Lab Project Number: NA 93 9395. Unpublished study prepared by NATEC Institut. 109 p.
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APPENDIX D. List of Available Related Documents

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

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Linuron RED Fact Sheet

4. PR Notice 86-5 (included in this appendix)

5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement

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APPENDIX E. PR Notices 86-5 and 91-2

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PR Notice 86-5

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 86-5

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the

entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

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A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.

- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an

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application for an EUP should be subdivided into sections A, B, C,... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, ...250 of 250).

- Include a company name or mark and study number on each page of the study, e g , Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product

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produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

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D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE**. An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI

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claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d)(1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit

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disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided ln three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

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V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.

/S/

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

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ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

[+]Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

[+]Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

Vol n Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____ _____
Name Signature

Company Name _____

Company Contact: _____ _____
Name Phone

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ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

Page 1 of X
(X is the total number of pages in the study)

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ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ Signature _____

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

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ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information in voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

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ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE REFERENCE	LINES	REASON FOR THE DELETION	FIFRA
6	14	Identity of Inert Ingredient	§10(d)(C)
28	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PAGES(S): are attached immediately behind this page

PAGES	REASON FOR THE DELETION	FIFRA REFERENCE
35-41.	Description of product manufacturing process	§10(d)(1)(A)

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ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

Submitter_____

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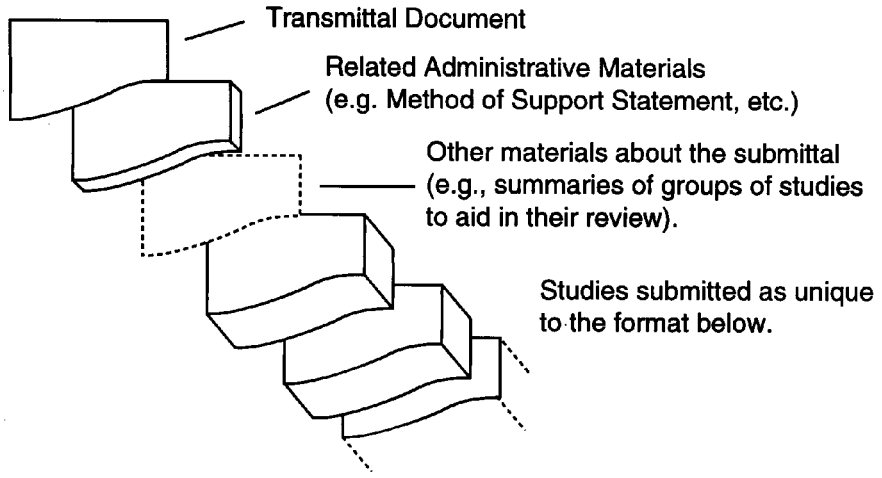
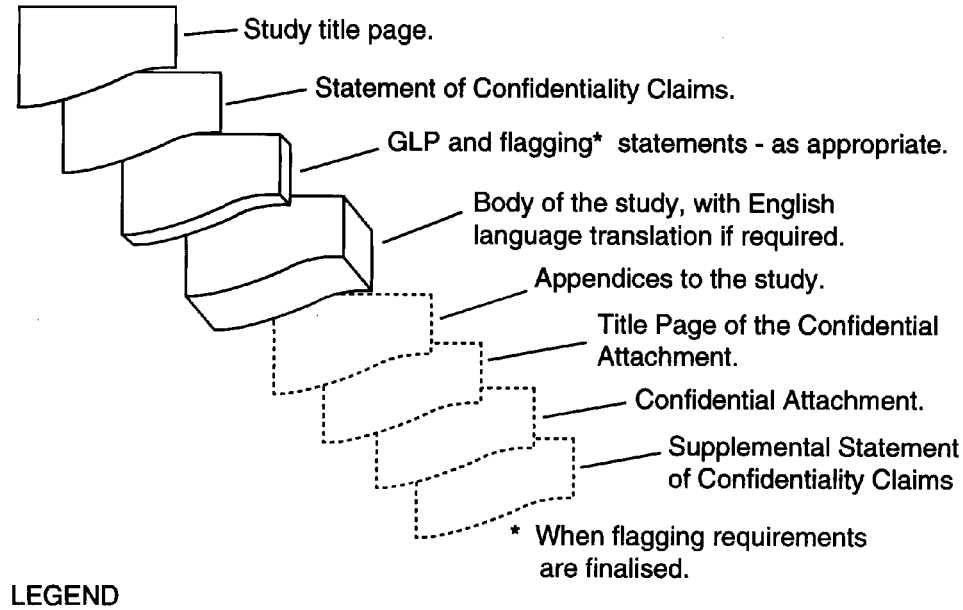
ATTACHMENT 7.

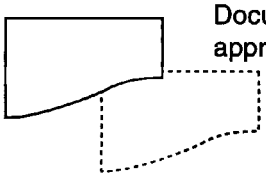
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



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PR Notice 91-2

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual

product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section l0(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE,"** all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be **set based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient StatementS must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

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(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 308-7031.

/s/
Anne E. Lindsay, Director
Registration Division (H-7505C)

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APPENDIX F. Combined Generic and Product Specific Data Call-In

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GENERIC AND PRODUCT SPECIFIC
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 A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. 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 7; or

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-96).

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:

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1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredients.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/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 the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes 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 (Telephone number: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

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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

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and 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

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic 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.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (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.

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a. 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 completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms 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.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Registrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

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

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

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

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If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for 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.

2. Product Specific Data Requirements

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 choose 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.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). 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 also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. 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.

a. 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

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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 both the Generic and Product Specific Data Call-In Response Forms. If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

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

b. 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.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Registrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic 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 you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (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)

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(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the 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

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If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the 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 to 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 burden 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 normally will 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.

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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 '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, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must 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 usually are not available for such studies.

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

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such 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.

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

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

Option 6. Citing Existing Studies

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

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

2. Product Specific Data

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

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(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 -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, 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.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

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, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to

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grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

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

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

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

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

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(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

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 product specific 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.

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SECTION 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:

   i. 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.

   ii. Fulfill the commitment to develop and submit the data as required by this Notice; or

   iii. 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.

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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 generally would 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 also must 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 a 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

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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 must include completed Data Call-In Response Forms (Attachment 2)and completed Requirements Status and Registrant's Response Forms (Attachment 3), for both (generic and 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 Generic and Product Specific Data Call-In Response Forms need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Peter Caulkins, Acting Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

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

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Attachment 1. Chemical Status Sheets

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LINURON DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for linuron are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on linuron are needed. These data are needed to fully complete the reregistration of all eligible linuron products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Karen Jones at (703) 308-8047.

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

Karen Jones, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Linuron

US EPA ARCHIVE DOCUMENT

LINURON DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 linuron. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this linuron Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for linuron are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on linuron 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 linuron products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of linuron, please contact Karen Jones at (703) 308-8047.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact C.P. Moran at (703) 308-8590.

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

C.P. Moran, 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: **Linuron**

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Attachment 2. Combined Generic and Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions

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Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of data call-in (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form**. **BOTH** "Data Call-In Response" forms must be completed.

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The 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, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

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INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 1.**ON BOTH FORMS**: This item identifies your company name, number and address.

Item 2.**ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3.**ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4.**ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5.**ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a.**ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b.**ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a.**ON THE PRODUCT SPECIFIC DATA FORM:** 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."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do 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.

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.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 8.**ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9.**ON BOTH FORMS:** Enter the date of signature.

Item 10.**ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11.**ON BOTH FORMS:** Enter the phone number of your company contact.

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

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Attachment 3. Generic and Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions

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Instructions For Completing
The
"Requirements Status and Registrant's Response Forms"
For The Generic and Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.** Both "Requirements Status and Registrant's Response" forms must be completed.

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

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INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In 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. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

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

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

A Terrestrial food
B Terrestrial feed

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C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

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

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Indredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

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ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

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

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

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

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency 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.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. 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 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 apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for

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submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

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

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

However, for Product Specific Data, 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 the Agency 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). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" for generic data.

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

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

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than lowvolume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

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<u>FOR PRODUCT SPECIFIC DATA</u>: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" for product specific data.

Option 7. (<u>Waiver Request</u>) I request a waiver for this study because it is inappropriate for my product. 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" form specifying 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.

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

Item 11. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

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

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Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

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EPA'S BATCHING OF LINURON 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 the active ingredient Linuron, 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.

Batching has been accomplished using the readily available information described above, and frequently acute toxicity data on individual products has been found to be incomplete. Notwithstanding 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.

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.

Tables 1 and 2 below show the products which were batched together in batches numbered one through four.

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Table 1

BATCH NO.	EPA REG. NO.	% of Linuron	Formulation Type
1	352-391	40.7% - Linuron	Flowable Concentrate
	1812-245	40.6% - Linuon	Flowable Concentrate
	19713-97	41.0% - Linuron	Flowable Concentrate
	34704-703	40.7% - Linuron	Flowable Concentrate
	51036-78	40.6% - Linuron	Flowable Concentrate
2	352-270	50.0% - Linuron	Wettable Powder
	352-394	50.0% - Linuron	Water Dispersible Granules
	352-562	50.0% - Linuron	Water Dispersible Granules
	1812-320	50.0% - Linuron	Water Dispersible Granules
	1812-356	50.0% - Linuron	Water Dispersible Granules
	19713-251	50.0% - Linuron	Water Dispersible Granules
	CA 820042	50.0% - Linuron	Water Dispersible Granules
	OR 940018	50.0% - Linuron	Water Dispersible Granules
	TX 920021	50.0% - Linuron	Water Dispersible Granules
	WA 900017	50.0% - Linuron	Water Dispersible Granules
	WA 940040	50.0% - Linuron	Water Dispersible Granules
	WI 940004	50.0% - Linuron	Water Dispersible Granules
	WI 940005	50.0% - Linuron	Water Dispersible Granules

Table 2

BATCH NO.	EPA REG. NO.	% of Linuron & Other Active Ingredients	Formulation Type
3	352-543	56.5% - Linuron 3.5% - Chlorimuron Ethyl	Water Dispersible Granules
	352-544	55.4% - Linuron 4.6% - Chlorimuron Ethyl	Water Dispersible Granules
4	352-326	92.0% - Linuron	Technical
	1812-270	95.0% - Linuron	Technical
	19713-158	95.0% - Linuron	Technical
	19713-367	92.0% - Linuron	Technical
	19713-368	95.0% - Linuron	Technical

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Table 3 below shows the two remaining products which were not batched. These products were considered either not similar for purposes of acute toxicity or insufficient information existed to make a determination concerning similarity. The registrant of these products is responsible for meeting the acute toxicity data requirements specified in the data matrix.

Table 3

EPA REG. NO.	% of Fenamiphos & Other Active Ingredients	Formulation Type
352-451	56.9% - Linuron 3.1% - Chlorimuron Ethyl	Water Dispersible Granules
19713-79	30.8% - Linuron 29.3% - Atrazine	Wettable Powder

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Attachment 5. EPA Acceptance Criteria

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SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

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61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Name of technical material tested (include product name and trade name, if appropriate).

2.____ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.

3.____ Name and upper certified limit for each impurity or each group of impurities present at $\geq$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at <0.1%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.
- ____ EPA Registration Number if registered;
  for other beginning materials, the following:
- ____ Name and address of manufacturer or supplier.
- ____ Brand name, trade name or commercial designation.
- ____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____Description of manufacturing process.
- ____ Statement of whether batch or continuous process.
- ____ Relative amounts of beginning materials and order in which they are added.
- ____ Description of equipment.
- ____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
- ____ Statement of whether process involves intended chemical reactions.
- ____ Flow chart with chemical equations for each intended chemical reaction.
- ____ Duration of each step of process.
- ____ Description of purification procedures.
- ____ Description of measures taken to assure quality of final product.

9.____ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1.____ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at ≥ 0.1%.
2.____ Degree of accountability or closure ≥ ca 98%.
3.____ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.].
4.____ Complete and detailed description of each step in analytical method used to analyze above samples.
5.____ Statement of precision and accuracy of analytical method used to analyze above samples.
6.____ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at ≥ 0.1% and for certain toxicologically significant impurities at <0.1% along with explanation of how limit determined.
9.____ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10.____ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

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63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color
____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State
____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25° C

63-4 Odor
____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point
____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point
____ Reported in °C
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity
____ Measured at about 20-25° C
____ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility
____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25° C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure
____ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant
____ Experimental method described
____ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient
____ Measured at about 20-25° C
____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
____ Data supporting reported value provided

63-12 pH
____ Measured at about 20-25° C
____ Measured following dilution or dispersion in distilled water

63-13 Stability
____ Sensitivity to metal ions and metal determined
____ Stability at normal and elevated temperatures
____ Sensitivity to sunlight determined

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SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

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81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ At least 5 young adult rats/sex/group.
3.____ Dosing, single oral may be administered over 24 hrs.
4.*___ Vehicle control if other than water.
5.____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6.____ Individual observations at least once a day.
7.____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8.____ Individual daily observations.
9.____ Individual body weights.
10.____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

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81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc).
2._____ At least 5 animals/sex/group.
3.*_____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4._____ Dosing, single dermal.
5._____ Dosing duration at least 24 hours.
6.*_____ Vehicle control, only if toxicity of vehicle is unknown.
7._____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8._____ Application site clipped or shaved at least 24 hours before dosing.
9._____ Application site at least 10% of body surface area.
10._____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11._____ Individual observations at least once a day.
12._____ Observation period to last at least 14 days.
13._____ Individual body weights.
14._____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

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81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 µm or less).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22° C ($\pm 2^{\circ}$), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11.___ Individual observations at least once a day.
12.___ Observation period to last at least 14 days.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

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81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of $\leq$2 or $\geq$11.5.
3.____ 6 adult rabbits.
4.____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.____ Solid or granular test material ground to a fine dust.
7.____ Eyes not washed for at least 24 hours.
8.____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.*___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

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81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive or has a pH of $\leq$2 or $\geq$11.5.
3.____ 6 adult animals.
4.____ Dosing, single dermal.
5.____ Dosing duration 4 hours.
6.____ Application site shaved or clipped at least 24 hours prior to dosing.
7.____ Application site approximately 6 cm^2.
8.____ Application site covered with a gauze patch held in place with nonirritating tape.
9.____ Material removed, washed with water, without trauma to application site.
10.___ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.*__ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

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81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of $\leq$2 or $\geq$11.5.
3.___ One of the following methods is utilized:
_____ Freund's complete adjuvant test
_____ Guinea pig maximization test
_____ Split adjuvant technique
_____ Buehler test
_____ Open epicutaneous test
_____ Mauer optimization test
_____ Footpad technique in guinea pig.
4.___ Complete description of test.
5.*___ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an * are supplemental and may not be required for every study.

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Attachment 6. List of All Registrants Sent This Data Call-In (insert) Notice

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Attachment 7. Cost Share, Data Compensation Forms, Confidential Statement of Formula Form and Instructions

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

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

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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.

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United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
2070-0057
Approval Expires 3-31-96

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

Please fill in blanks below.

Company Name	Company Number
Product Name	**EPA Reg. No.**

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

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

US EPA ARCHIVE DOCUMENT

United States Environmental Protection Agency
Washington, DC 20460

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date
Name and Title (Please Type or Print)	

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

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-96)

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APPENDIX G. FACT SHEET

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United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-003 March 1995

R.E.D. FACTS

Linuron

Pesticide Reregistration

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

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

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0047, 3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea, commonly known as linuron.

Use Profile

Linuron is a herbicide used to control germinating and newly emerging grasses and broad-leafed weeds. It is applied to agricultural crops, ornamental bulbs, and poplar trees for use in shelterbelts in the mid-west. Most of the linuron applied in the U.S. is to soybean crops. Formulations include water dispersable granules, wettable powders, flowable concentrates, and emulsifiable concentrates/liquid suspensions.

Linuron usually is applied after a crop has been planted but before weeds emerge, using ground or aerial equipment. In some crops, such as carrots and celery, linuron is applied to newly emerging plants as an over-top spray. In asparagus, linuron is applied between cuttings of newly emerging spears for weed control during harvest.

Use practice limitations include prohibitions against applying linuron directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark; applying linuron aerially (DuPont only; Griffin allows aerial application to potatoes and soybeans before crop emerges); and applying linuron through any type of irrigation system.

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Regulatory History

Linuron was first registered as a pesticide in the U.S. in 1966. EPA issued a Registration Standard for Linuron in June 1984 (NTIS #PB85-149011). From 1984 through 1988, linuron was the subject of a Special Review because it exceeded oncogenicity risk criteria. However, the weight of evidence suggested that its cancer-causing potential in humans is weak. EPA concluded that no regulatory action was warranted, and reduced linuron's cancer classification from a quantifiable to an unquantifiable Group C carcinogen (that is, a possible human carcinogen for which there is limited animal evidence).

EPA issued Data Call-In notices (DCIs) in May 1986, September 1990 and November 1993, requiring additional studies on product chemistry, chronic toxicity, processing and cooking, ecological effects, phytotoxicity, and residue chemistry, as well as cropfield trials replacement data for studies generated by Craven Laboratories. Currently, 23 linuron end-use products and 5 technical products are registered.

Human Health Assessment

Toxicity

Linuron is of relatively low acute toxicity. It is slightly toxic by the oral, dermal and inhalation routes, and has been placed in Toxicity Category III (the second-to-lowest of four categories) for these effects. It causes slight eye irritation in rabbits (Toxicity Category III), and is not a skin irritant (Toxicity Category IV) or sensitizer.

A subchronic toxicity study using rats resulted in changes in blood cell counts, and retarded growth at the high dose level.

In a chronic toxicity and carcinogenicity study using beagle dogs, linuron caused changes in blood, including red blood cell destruction, and in liver weight. A study using rats resulted in testicular tumors and blood cell destruction. Another rat study showed growth retardation and destruction of red blood cells. A third rat study showed significant changes in blood pigments. An oncogenicity study using mice caused a statistically significant increase in liver tumors, as well as decreased body weight and body weight gain, increased liver weights, and other liver effects. As a result of the Agency's Special Review, linuron remains classified as an unquantifiable Group C carcinogen (that is, a possible human carcinogen for which there is limited animal evidence).

In a developmental toxicity study using rats, the highest dose level caused maternal toxic effects including decreased body weight gain and food consumption, as well as increases in postimplantation loss and fetal resorptions. In a study using rabbits, linuron caused decreases in maternal body weight, food consumption and liver weight, as well as more abortions, fewer fetuses per litter, decreased fetal body weight, and an increased incidence of fetuses with skeletal skull variations.

In a 2-generation reproductive toxicity study using rats, linuron caused effects on the parents including decreased body weight gain and abnormalities in the eyes and testes. Linuron was shown to interfere with the transmission of male hormones. Rats exposed to linuron could develop cell tumors in testicular tissue. A 3-generation study using rats showed reduced body weights and fertility, decreased pup survival, and decreased weanling body, liver and kidney weights, as well as liver atrophy. Linuron does not appear to be mutagenic.

Dietary Exposure

People may be exposed to residues of linuron through the diet. Tolerances or maximum residue limits have been established for linuron in many vegetables, grain crops, meat, milk, and other agricultural commodities (please see 40 CFR 180.184(a) and (b)). EPA has reassessed these tolerances and found that sufficient data are available to support the established tolerances for carrots; field corn grain; field corn forage and fodder; celery; cottonseed; parsnips; potatoes; sorghum grain; wheat grain and straw; meat and milk. Additional residue data are required for asparagus; sweet corn; sweet corn forage; sorghum forage and fodder; soybean forage and hay; wheat forage; and field corn grain dust. Several existing tolerances for barley, oats, and rye, forage, grain, hay, and straw; and corn, popcorn, forage and fodder will be revoked since there are no registered uses of linuron on these commodities. New tolerances have been proposed for lettuce, ginger and taro; several tolerance revisions have been proposed; and a tolerance for corn fodder needs to be raised.

Food and feed additive tolerance proposals are required for potato granules, chips, and processing waste. Under the Delaney clause of the Federal Food, Drug, and Cosmetic Act (FFDCA), however, food and feed additive tolerances may not be established for pesticides that induce cancer in man or animals. Although its cancer-causing potential in humans is weak, EPA still considers linuron to be a chemical that "induces cancer" within the meaning of the Delaney clause. Therefore, under current policy, EPA would not issue these food and feed additive tolerances, and would not continue in effect the tolerance for the associated raw agricultural commodity, potatoes.

EPA currently is evaluating legal challenges to its policies regarding pesticide tolerances, registrations and the Delaney clause. Because of these issues, the Agency is unable to make a reregistration eligibility decision at this time regarding the use of linuron on potatoes.

Although the basic manufacturer of linuron deleted the cotton use in 1991, cotton still exists on linuron end-use product labels. Registrants of these end-use products must now either submit a required cottonseed processing study or delete the cotton use from their labels.

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EPA has assessed the dietary risk posed by linuron. For the overall U.S. population, chronic exposure from all existing linuron tolerances represents 2% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The two most highly exposed subgroups are non-nursing infants (less than 1 year old), whose exposure represents 6% of the RfD, and children age 1 to 6 years old, with exposures representing 4% of the RfD. Therefore, chronic dietary risk appears to be minimal.

Acute exposure to the subgroup of greatest concern, women of childbearing age, results in a Margin of Exposure (MOE) of 1,667 for developmental toxicity. This is likely to be an overestimate due to the conservative assumptions used. Thus, acute dietary risk also appears to be minimal.

Occupational and Residential Exposure

Based on current use patterns, workers may be exposed to linuron during and after applications to agricultural crops, ornamental bulbs and poplar trees. The Agency is not aware of any linuron products intended for home use.

Margins of Exposure (MOEs) were estimated for applicators and mixer/loaders of linuron. While most MOEs are greater than 100 (the margin generally considered acceptable), exposure of mixer/loaders during aerial applications is of concern, as is exposure of handlers using open mixing/loading methods.

Post-application/reentry worker exposure to linuron is unlikely, except during asparagus harvesting where linuron is applied between cuttings. However, a supplemental worker exposure study indicates that all the MOEs for asparagus harvesters are over 100. A 24-hour reentry interval required for this use was converted to a 24-hour restricted entry interval (REI) by the Worker Protection Standard (WPS). EPA is requiring a 24-hour REI for all linuron uses within the scope of the WPS, based on the asparagus reentry data.

Personal protective equipment (PPE) requirements for workers should be based on the acute toxicity of end-use products. However, due to concerns about worker risks, EPA is establishing minimum handler PPE requirements for any end-use product containing linuron. Such products may have more stringent PPE, but in no case may have less stringent PPE than: coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant apron.

Human Risk Assessment

Linuron is of relatively low acute toxicity, but is classified as an unquantifiable Group C carcinogen (that is, a possible human carcinogen for which there is limited animal evidence), and shows some evidence of developmental and reproductive toxicity.

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Although people may be exposed to residues of linuron in a number of food commodities, acute and chronic dietary risks appear to be minimal. Handler and post-application worker risks are of concern, but are being mitigated by requiring a 24-hour REI and minimum PPE for all agricultural uses of linuron.

Environmental Assessment

Environmental Fate

Although the environmental fate data base for parent linuron is essentially complete, two environmental fate data requirements (leaching/adsorption/desorption and terrestrial field dissipation studies) are not fulfilled. The environmental fate assessment for linuron is incomplete and tentative because information on the persistence, mobility and dissipation pathways of several degradates of linuron is not available.

Parent linuron appears to be moderately persistent and relatively immobile. Increased mobility may occur under specific environmental conditions such as in coarse textured soils and soils with low levels of organic matter. Linuron dissipates principally by biotic processes such as microbial degradation. In surface soils with adequate organic matter, the combined processes of adsorption and microbial degradation would limit linuron's potential to migrate to ground water. Linuron could runoff to surface water bodies. In that case, it would degrade fairly rapidly to three primary metabolites. However, information on the persistence and mobility of these degradates is not currently available.

Linuron exhibits some of the properties and characteristics of chemicals that have been detected in ground water, and linuron itself has been detected in ground water in four states (Georgia, Missouri, Virginia and Wisconsin). Linuron is moderately persistent with an aerobic soil metabolism half-life ranging from 57 to 100 days. Because linuron is sufficiently persistent and may be mobile under certain environmental conditions, it has the potential to impact ground water quality.

Linuron can be applied by ground spray and therefore could contaminate surface waters through spray drift. It has the potential to be somewhat persistent in surface waters, particularly those with low microbiological activity and long hydrological residence times. It may be less persistent in water and sediment under anaerobic conditions than under aerobic conditions. Its bioconcentration potential is relatively low.

Linuron is not currently regulated under the Safe Drinking Water Act, and water supply systems are not required to sample and analyze for it. No Maximum Contaminant Level (MCL) or drinking water health advisories have been established for linuron. The primary treatment processes employed by most water systems may not always be completely effective in removing linuron. As a result, the Agency does have some moderate

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concerns regarding potential risks of linuron to surface water source supply systems.

Ecological Effects

Linuron is practically nontoxic to mammals on an acute basis, and practically nontoxic to honey bees. Linuron is slightly toxic to birds on an acute basis. Though studies are not available, US Fish and Wildlife Service extrapolation suggests that linuron would be slightly toxic to practically nontoxic to birds on a subacute dietary basis. However, linuron causes reproductive effects in birds.

In acute oral toxicity studies, linuron is moderately toxic to both cold and warm water fish. Acute testing using a formulated product indicates that linuron is slightly toxic to moderately toxic to fish. In a fish early life stage chronic study, linuron caused effects on fish length even at the lowest dose level, so additional testing is required.

Linuron is highly toxic to aquatic invertebrates, while the formulated product is moderately toxic to freshwater aquatic invertebrates. A life cycle chronic test produced inconsistent results so additional testing is required. In estuarine/marine acute toxicity studies, linuron is highly toxic to the sheepshead minnow and moderately toxic to the eastern oyster and mysid shrimp.

A number of additional studies are required.

Ecological Effects Risk Assessment

Linuron poses minimal risk to honeybees. However, chronic risk to birds is posed at all use sites. Restricted use levels of concern are exceeded for birds on short grass, and endangered species levels of concern are exceeded for all uses evaluated.

Regarding mammals, the smaller the animal, the greater the level of concern for acute effects from exposure to linuron. For example, levels of concern are exceeded for the least shrew but not for the rat. Chronic effects in wild mammals are likely.

Regarding aquatic risks, restricted use and endangered species levels of concern are exceeded for fish from exposure to linuron in rights of way (ROW), and for aquatic invertebrates at all use sites evaluated. Chronic effects cannot be fully assessed without further testing.

Although further data on the toxicity of linuron to nontarget plants is needed, a preliminary aquatic plant risk assessment indicates that high risk and endangered plant levels of concern are exceeded for aquatic plants. The risk to terrestrial plants cannot be assessed without further data.

Endangered species levels of concern are exceeded in some circumstances for acute and chronic effects to birds, wild mammals and aquatic organisms, and for acute effects to nontarget plants. When the Endangered Species Protection Program goes into effect, limitations on the

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use of linuron will be required to protect endangered and threatened species.

Risk Mitigation

Since the current uses of linuron exceed ecological effects levels of concern in many circumstances, EPA is requiring the following risk mitigation measures proposed by the technical registrant, DuPont:

- Reduce application rates for use of linuron on soybeans, field corn, potatoes and asparagus.
- Limit the maximum number of applications to 1 per year (pre-emergent use only) for soybeans, field corn, and potatoes, and to 3 per year for asparagus.
- Prohibit aerial applications.
- Prohibit use on sand or loamy sand, and on soils of less than 1% organic matter.
- Voluntarily cancel the high application rate uses including hybrid poplar and non-cropland (rights-of-way) uses.
- Add a ground water advisory to all product labels.
- Add a surface water advisory to all product labels.

Since it meets the proposed triggers, EPA will consider linuron as a candidate for classification as a restricted use pesticide due to ground water concerns, once the ground water restricted use rule is finalized. Also, the potential for spray drift exists when linuron is applied by ground spray. Once pertinent data are submitted and reviewed, EPA will decide whether spray drift labeling statements are required for linuron.

Additional Data Required

EPA is requiring the following generic studies for linuron to confirm its regulatory assessments and conclusions:

Starting Materials and Manufacturing Process;

Foliar Dislodgeable Residues (Carrots/Celery);

Soil Dislodgeable Residues (Carrots/Celery);

Dermal Exposure (Carrots/Celery);

Inhalation Exposure (Carrots/Celery);

Cropfield Trials - Asparagus, Corn Aspirated Fractions (Grain Dust), Sorghum Forage and Fodder and Wheat;

Cropfield Trials - Soybean Forage and Hay;

Acute Avian Dietary Toxicity with TGAI - Quail and Duck;

Acute Aquatic Invertebrate Toxicity;

Fish Early Life Stage - Both Rainbow Trout and Sheepshead Minnow;

Aquatic Invertebrate Life Cycle - Mysid Shrimp;

Leaching/Adsorption/Desorption;

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Terrestrial Field Dissipation;

Cottonseed Processing Study - To support use on cotton;

Cropfield Trials - Sweet corn - To support use on sweet corn;

Acute Marine/Estuarine (TEP) - Sheepshead Minnow using DF formulation for rights-of-way.

The following studies also are required, though they are not part of the target data base:

Seed Germination/Seedling Emergence - 10 Species;

Vegetative Vigor - 10 Species;

Aquatic Plant Growth - 4 Additional Species.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs) and revised labeling for reregistration.

Product Labeling Changes Required

All linuron end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

Worker Protection Standard

Entry Restrictions

WPS Uses - A 24-hour restricted entry interval (REI) is required for all uses within the scope of the Worker Protection Standard (WPS). The personal protective equipment (PPE) required for early entry must be the PPE required for handlers of linuron (see below). Labels of multiple active ingredient products that contain linuron must bear the more protective of either these entry restrictions or those on current labeling.

Non-WPS Uses - Labels of products with uses outside the scope of the WPS must bear the following statement:

For liquid applications: "Do not enter or allow others to enter the treated area until sprays have dried."

Personal Protective Equipment Requirements

Products containing linuron may contain more stringent PPE, but in no case may require less stringent PPE than the following requirements. Producers must compare the PPE requirements in this section with those on current labeling and retain the more protective.

Handler PPE for Occupational Use Products - For all uses of linuron, both within and outside the scope of the WPS, the minimum or baseline PPE requirements for pesticide handlers (mixers and loaders) are:

- coveralls over long-sleeved shirt and long pants,
- chemical-resistant footwear,
- chemical-resistant gloves, and
- chemical-resistant apron.

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Early Entry PPE - Since linuron is in Toxicity Category III for eye and skin irritation potential and acute dermal toxicity, the PPE required for early entry is coveralls, chemical-resistant gloves, shoes and socks.

Other Labeling Requirements

Environmental Hazard Section - The labels of all linuron end-use products must be revised to bear the following statements under this section:

Ground Water Advisory

"This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."

Surface Water Advisory

"Linuron may contaminate surface water through spray drift or, under certain conditions, from surface runoff into adjacent surface water bodies (ponds, lakes, streams, etc.). For several weeks post-application, linuron has a high potential to runoff when applied to fields with any of the following conditions: sloping land draining into nearby surface waters; very poorly to somewhat poorly drained soils; areas with extremely shallow ground water; frequently flooded areas; fields with surface water canals or ditches; and highly erodible land cultivated with poor management practices."

For Terrestrial Uses Except Rights-of-Way

"This pesticide is toxic to fish and aquatic invertebrates. Do not apply to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from treated areas. Do not contaminate water when disposing of equipment wash water or rinsate."

For Rights-of-Way - If a registrant chooses to support the rights-of-way use, he must submit the data required in this RED document and his labels must bear the following statement:

"This pesticide is toxic to fish and aquatic invertebrates. Do not contaminate water when disposing of equipment washwaters or rinsate."

If a registrant does not support the rights-of-way use, he must amend his labels to delete this use.

Directions for Use Section - The labels of all linuron end-use products must be revised to bear the following statements under this section:

Application Restrictions:

"Do not apply this product in a way that will contact workers or other persons, either directly or through spray drift. Only protected handlers may be in the area during application."

"Aerial application is prohibited."

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"Use on sand or loamy sand is prohibited."

"Use on soils of <1% organic matter is prohibited."

Crop Uses Section - The labels of all linuron end-use products must be revised to bear the following application rates for the respective crops, under this section:

Application Rates:

For use on soybeans: A maximum application rate of 1.0 lb ai/A, with use limited to single application (pre-emergent use only) per year.

For use on corn, field: A maximum application rate of 0.75 lb ai/A, with use limited to single application (pre-emergent use only) per year.

For use on potatoes: A maximum application rate of 1.5 lbs ai/A, with use limited to single application (pre-emergent use only) per year.

For use on asparagus: A maximum application rate of 2.0 lbs ai/A per year, with use limited to 3 applications per year.

Do not exceed 2.0 lbs total per acre per year.

Regulatory Conclusion

Although levels of concern are exceeded for ecological effects and ground water quality, most uses of currently registered products containing linuron, amended to reflect the risk mitigation measures imposed in this RED, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, products containing linuron for all registered uses **except** use on cotton, non-cropland (rights-of-way), sweet corn, and potatoes are eligible for reregistration.

EPA is unable to make a reregistration eligibility decision for use of linuron on cotton, non-cropland (rights-of-way) and sweet corn because the Agency does not have key generic data to support these uses. The basic manufacturer, DuPont, has voluntarily cancelled or plans to cancel these uses, so end-use product registrants must either delete the uses from their labels or submit the required data.

EPA also is unable to make a reregistration eligibility decision regarding the use of linuron on potatoes because, under current policy, the food additive tolerances needed to support this use appear to be barred by the Delaney clause in the FFDCA.

Linuron products with eligible uses will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for linuron during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources

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Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

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

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

For more information about EPA's pesticide reregistration program, the linuron RED, or reregistration of individual products containing linuron, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 6:00 pm Central Time, Monday through Friday.

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