GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

LINURON

AS THE ACTIVE INGREDIENT

EPA CASE NUMBER: 47

(035506)

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

JUNE 29, 1984

TABLE OF CONTENTS

APPENDICES

Note: Appendices V-1, V-5 and V-6 are not germane to this document and are not included.

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To fulfill this Congressional mandate, we have established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end-use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that certain registrants submit generic data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(B) provides that these data are to be submitted by those registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use product producers (basic

suppliers of the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to discontinue the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time-frames outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

This Guidance Document will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in this Guidance Document which do not relate to compliance with the §3(c)(1)(D) provisions and to supplement the Document with additional guidance when circumstances permit. Failure to comply with the provisions of the subsequent guidance will also result in issuance by EPA of an intent to cancel the affected product registration(s).

Registrants are reminded that §6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End-use products of registrants who also produce a manufacturing-use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

II. REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

This chapter describes the regulatory position of the Environmental Protection Agency ("the Agency") on linuron based on an evaluation of all registered manufacturing-use products (MUP's) containing linuron as the sole active ingredient. Future requests for registration of substantially similar products will be covered by this standard. Dissimilar products will require amendments to the standard. This document provides the rationale for the Agency's position and the criteria for registration. It also discusses labeling requirements for bboth MUP's and end-use products (EUP's) and tolerances.

In developing its regulatory position, the Agency determines whether available data indicate that a pesticide has met the criteria for adverse effects found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations (CFR). Pesticides meeting these criteria are candidates for a Special Review, an intensive risk/benefit analysis which is a modification of the Rebuttable Presumption Against Registration (RPAR) process. The Agency's determination as to whether any criteria has been met and its rationale for any regulatory action are summarized in the regulatory position of this standard.

"Linuron" is the accepted common name for the compound, 3-(3,4-dichlorophenyl) 1-methoxy-1-methylurea recognized by the American National Standards Institute. Trade and other names used for linuron include: Lorox® Weed Killer, and Lorox® 4L Weed Killer. The Chemical Abstracts Service (CAS) Registry number is 330-55-2, and the Office of Pesticide Programs' Internal Control Number (EPA Shaughnessy Number) is 035506.

B. USE PROFILE

Linuron is a substituted urea herbicide used for preemergent and postemergent control of many annual grasses and broadleved weeds on the following terrrestrial food crop and nonfood site: Food - soybeans, field and sweet corn, cotton, sorghum, wheat, asparagus, carrots, celery, parsnips, and potatoes: Nonfood-alleys, fencerows, fairways, golf tees, highway righ-of-way, sodfields, streets and vacant lots. Linuron has been shown to inhibit photosynthesis in plants. Linuron has a limited contact action and is normally applied with a surfactant when used in this matter.

Linuron was patented by Farbwek Hoechst A. G. in 1960, (US Patent No. 2,960,234). It was first registered for use in 1966. Technical linuron is currently being producted in the United States by E. I. duPont de Nemours and Company, Inc., Drexel Chemical Company, and Griffin Corporation.

Linuron is available as a technical material, at 95% active ingredient and as a manufacturing ue product containing 50% linuron for formulation of linuron end-use formulations or as manufactuing use products. As a sole active ingredient linuron is available in wettable powders, flowables, and liquid suspensions.

C. REGULATORY POSITION

Based on a review and evaluation of the available data and other relevant information on linuron, the Agency has made the following determinations:

1. Linuron has oncogenic potential. Registrants of linuron products are hereby notified that linuron has met the risk criterion for oncogenicity in Section 162.11(a) of Title 40 (CFR). A Notice announcing the Agency's decision to initiate a Special Review will be published in the Federal Register.

2. The Agency is concerned about the oncogenic potential of linuron and is requiring that certain data needed for the Special Review be submitted on an expedited basis. These data include the following:
   a. Residue Chemistry as specified in the data tables under § 158.125,
   b. Environmental Fate as specified in the data tables under § 158.130,
   c. Toxicology as specified in the data tables under § 158.120.
   d. Applicator exposure data as specified in the data tables under § 158.130.

3. To reduce risk, and to maintain existing registrations, registrants must take certain interim measures by revising the product label as specified below. The labeling must include a statement concerning tumors, a requirement to use protective clothing, and a restricted use statement. (Refer to Section G. "Required Labeling")

4. The Agency is concerned about surface water and possible groundwater contamination by linuron. In order to characterize the potential for linuron to enter groundwater, the Agency will require the following studies:
   a. Environmental Fate data as specified in the data tables under § 158.130,
   b. Product Chemistry data as specified in the data tables under § 158.120.

5. In the absence of data to estimate reentry exposure to workers entering areas treated with linuron, the Agency is imposing an interim 24 hour reentry interval.

6. Within 90 days after receipt of this document, registrants must commit to perform all of the required studies.

7. The Agency will not consider for reregistration any current products containing linuron as a sole active ingredient until the Agency concludes the Special Review. However, all currently registered products will remain registered while the Special Review is in process.

8. Registrants not qualifying for a formulator exemption must provide or agree to develop all data specified in the tables of this standard to maintain existing registrations. The Agency may amend this standard or initiate further regulatory actions after it has reviewed the submitted data. All data must be generated according to the Good Laboratory Practices specified in 48 FR 53946.

9. Applicants having products not conforming to this standard may apply to amend the document so those products containing linuron may be registered and reregistered under this standard. Mixtures and end-use products containing linuron are covered under this standard for the purposes of labeling.

D. REGULATORY RATIONALE

The Agency has determined the following:

1. Linuron has demonstrated oncogenic potential in rats and mice. Dietary exposure to linuron has induced dose related tumors in mice and rats, indicating clear evidence of oncogenicity using the National Toxicology Program (NTP) criteria.

2. Based on surrogate data, risk estimates indicate that an unreasonable risk may exist for farmers exposed to linuron while mixing/loading and applying linuron. Dietary risk estimates indicate that an unreasonable risk may exist for the general population via consumption of agricultural commodities treated with linuron.

   To fully evaluate these risks during Special Review, the Agency is requiring exposure, toxicology, and residue chemistry data. To reduce the risk while it conducts the Special Review, the Agency is imposing certain interim measures by restricting linuron's use and requiring label amendments.

3. There are no data to estimate reentry exposure to workers entering areas treated with linuron. Coupled with the fact that linuron is an oncogen, the Agency has set an interim time interval of 24 hours to caution any worker from reentering the treated areas and being exposed to residual quantities of linuron. This data gap requires the submission of linuron reentry data in accordance with 40 CFR Part 158.140 (Reentry Protection Data Requirements). When the data are submitted, the Agency will evaluate the data and impose an appropriate time interval.

4. The Agency has designated for further study, certain chemicals including linuron which may have a potential to enter groundwater supplies in the United States based on such factors as chemical structure, solubility and use patterns. Exposure of humans to linuron through contamination of groundwater is possible, depending on how the well water is used.

   Exposure of humans to linuron through runoff contamination of surface water after heavy Spring precipitation is likely. Between April and August 1982, monitoring samplers detected linuron in six Northwestern Ohio rivers at levels of 2.32 to 13.1 micrograms/ liter (parts per billion). Between April and August 1983, monitoring samplers detected linuron in tap water from the Tiffin and Bowling Green, Ohio municipal water treatment plants (using the rivers as water sources) at levels of 0.39 to 0.61 micrograms/ liter. The Agency will evaluate the risks posed by runoff and the resulting contamination of surface water as part of the Special Review process for the oncogenic potential of linuron.

5. The available environmental fate data are insufficient to fully assess the potential for exposure of humans and non-target organisms to linuron. When the required studies under §158.130 are submitted, a complete environmental exposure assessment can be made.

6. There are insufficient data to characterize the acute and chronic toxic effects of linuron on birds, fish, and aquatic invertebrates. When additional ecological effects data are submitted, a complete hazard assessment can be made.

7. The available product chemistry data are insufficient to fully assess the chemical at this time. When the required chemistry tests under § 158.120 are submitted, a complete product chemistry evaluation can be performed .

8. Available monitoring data do not indicate human or wildlife fatalities from poisoning incidents.

E. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

To be subject to this standard, manufacturing-use products must meet the following conditions:

1. Contain linuron as the sole active ingredient and,

2. Conform to the acute toxicity limits, product composition, and use pattern requirements listed in Section F of this document.

Registration of products subject to this standard must comply with all terms and conditions described in it, including commiting to fill data gaps on a schedule agreed to by both this Agency and the registrant. All registrants for registration under this standard must follow the instructions contained in this standard and complete and submit the appropriate forms within the time specified.

F. ACCEPTABLE RANGE AND LIMITS

1. Product Composition Standard

Technical grade products must contain at least 90 percent linuron as the sole active ingredient. Each manufacturing-use product formulation proposed for registration must be fully described with an appropriate certification of limits. In addition, the active ingredient found in the manufacturing-use linuron products must be substantially similar to that in currently registered technical products. Any manufaturing-use product not meeting these requirements will be considered a new product and will not be registered under this standard.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and mnaufacturing-use products containing linuron with Toxicity Category III for acute oral and dermal toxicities, Toxicity Category III for dermal and eye irritation, and Toxicity Category IV for acute inhalation, provided that the labeling of those products bears appropriate precautionary statements.

3. Use Patterns

To be registered under this standard, manufacturing-use products containing linuron must be labeled for formulation only into end-use products for herbicides used for the control of a wide variety of annual grasses and broadleaved weeds on the following terrestrial food crop and nonfood sites: food- soybeans, field and sweet corn, cotton, sorghum, wheat, asparagus, carrots, celery, parsnips, and potatoes; nonfood-alleys, fencerows, fairways, golf tees, highway right-of-way, sodfields, streets, and vacant lots.

G. REQUIRED LABELING

All technical grade, manufacturing-use (MUP), and end-use products(EUP) containing linuron must bear appropriate labeling as specified in 40 CFR § 162.10. Other portions of this guidance package contain specific information regarding label requirements.

Existing stocks of product covered by this document, related brochures, technical pamphlets and similar materials must be labeled to comply with all label requirements within six months after the receipt of this guidance document.

1. Manufacturing-Use Product Statements

Products intended for formulation into end-use products must bear the following statement:

"The use of this product may be hazardous to your health. This product contains linuron, which has been determined to cause tumors in laboratory animals".

"Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency".

2. End-Use Product Statements

All end-use products must bear the following statements:

"RESTRICTED USE PESTICIDE",

"For retail sale to and application only by certified applicators or personnel under their direct supervision"

"The use of this product may be hazardous to your health. This product contains linuron, which has been determined to cause tumors in laboratory animals."

"Required clothing and equipment for mixing/loading and applying linuron:

One-piece overalls which have long sleeves and long pants constructed of finely woven fabric as specified in the USDA/EPA Guide for Commercial Applicators.

Wide-brimed hat.

Heavy-duty fabric work gloves.

Any article worn while applying linuron must be cleaned before reusing. Clothing which has been drenched or has otherwise absorbed concentrated pesticide must be disposed in a sanitary landfill, or incinerated, or if allowed by state and local authorities, by burning.

Instead of clothing and equipment specified above, the applicator can use an enclosed tractor cab which provides a filtered air supply (as described by Taschenberg and Bourke, 1975)."

Non-aquatic

"Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes."

Rotational Crop Restrictions

"Do not rotate crops used for food or feed, which are not registered for use with linuron onto areas previously treated with this chemical."

Reentry Restriction

"Do not reenter treated areas for 24 hours following application unless protective clothing is worn."

H. TOLERANCE REASSESSMENT

For linuron, the present Theoretical Maximum Residue Contribution (TMRC) is 0.3248 mg/day/1.5 kg diet. This amounts to 86.6% of the present Acceptable Daily Intake (ADI) of 0.00063 mg/kg/day which for a 60 kg person is 0.3750mg/day.

This Acceptable Daily Intake (ADI) for linuron is based on blood dyscrasias. As indicated above, these values may change because the No-Observed-Effect-Level (NOEL) for linuron is not well established. The Agency will require a chronic study which could affect the ADI.

Presently, in the United States, tolerances are established for residues of linuron (§ 180.184) in or on the raw agricultural commodities listed below:

Commodities	Parts per million
Asparagus	3.0
Carrots	1.0
Cattle, fat	1.0
Cattle, meat by-products	1.0
Cattle, meat	1.0
Celery	1.0
Corn, field, fodder	1.0
Corn, field, forage	1.0
Corn, fresh, (sweet)	0.25
Corn, grain (incl. pop)	0.25
Corn, pop, fodder	1.0
Corn, pop, forage	1.0
Corn, sweet, fodder	1.0
Corn, sweet, forage	0.25
Goats, fat	1.0
Goats, meat by-products	1.0
Goats, meat	1.0
Hogs, fat	1.0
Hogs, meat by-products	1.0
Hogs, meat	1.0
Horses, fat	1.0
Horses, meat by-products	1.0
Horses, meat	1.0
Parsnips (with or without tops)	0.5
Parsnips, tops	0.5
Potatoes	1.0

Commodities	Parts per million
Sheep, fat	1.0
Sheep, meat by-products	1.0
Sheep, meat	1.0
Sorghum, fodder	1.0
Sorghum, forage	1.0
Sorghum, grain(milo)	0.25
Soybeans (dry or succulent)	1.0
Soybeans, forage	1.0
Soybeans, hay	1.0
Wheat, forage	0.5
Wheat, grain	0.25
Wheat, hay	0.5
Wheat, straw	0.5

The available residue chemistry data are insufficient to fully assess linuron at this time. When the required residue tests under § 158.125 are submitted, a complete residue evaluation can be made.

In addition, linuron and diuron have certain metabolites in common: 1-(3,4 dichlorophenyl)-3-methylurea (DCPMU), and 3,4-dichlorophenylurea (DCPU). Therefore, the Agency can consider diuron's residue contribution in the full tolerance reassessment of linuron for the following commodities: corn, sorghum grains, wheat, asparagus, meat(red), and cottonseed.

If the complete tolerance reassessments for the above commodities are favorable, tolerances for residues of linuron and metabolites which will hydrolyze to form 3,4-dichloroaniline of 0.05 ppm will have to be proposed for residues in milk and eggs.

I. PRELIMINARY ANALYSIS OF CURRENT BENEFITS AND RISKS

1. Current Benefits Review

a. Introduction

The Agency has completed a current benefits review for linuron. The following information is preliminary in nature and will be expanded upon during the Special Review.

b. Use Site Study

Linuron herbicide is federally registered for use on the agricultural sites soybeans, carrots, celery, asparagus, corn (field, sweet), cotton, parsnips, potatoes, sorghum, and winter wheat. Registered non-food sites include golf course fairways, golf tee areas, sodfields, fencerows, highway rights-of-way, streets, alleys, and vacant lots. Linuron is currently used in Michigan, under 24c registration, for weed control in hybrid poplar plantings. In 1982, a Section 18 emergency exemption from tolerance was granted to the state of Massachusetts for use of linuron on 300 acres of dry bulb onions to control galinsoga and other broadleaf weeds previously controlled by nitrofen (TOK®). Of the above mentioned linuron use sites, the majority is used on soybeans. For this reason, the Agency will limit this preliminary analysis to linuron's use on soybeans.

E.I. duPont de Nemours Company, Inc. is the major producer of the technical product. Griffin Corporation and Drexel Chemical Company currently hold the other technical registrations. The most common formulation is the liquid flowable formulation (4 pounds active ingredient per gallon), which mixes more readily in the spray tank than other linuron formulations.

c. Benefits on Soybeans

Most linuron application as a broadleaf herbicide is in tank mix combination with grass control herbicides. In the majority of applications, linuron is mixed with alachlor and applied at one fourth the application rate of alachlor. In a small percentage of applications, linuron is mixed with metolachlor. When mixed with either of these chemicals, the linuron application rate drops significantly. The rate ranges drop from 0.5 to 3.0 pounds active ingredient per acre when applied alone to 0.33 to 1.5 pounds active ingredient per acre when used with alachlor or metolachlor. The linuron rate selected within the range is dependent on soil texture. Linuron is primarily applied to soybeans once a year as a preemergence broadcast ground application in the spring, after planting and before crop emergence. Linuron is not currently applied aerially on soybeans.

Linuron is selected over other currently available soybean herbicides for several reasons. First, it controls persistent annual broadleaf weeds through its 4 to 8 week residual effect. Major weeds controlled by linuron include pigweed species common lambsquarters, broadleaf signalgrass, common ragweed, and smartweed species. Second, it consistently controls weeds on sandy, sandy loam, and loamy sand soils with less than 2 percent organic matter content. Third, it provides a consistent preemergence control of triazine resistant weeds such as pigweed and common lambsquarters. Fourth, it is used as a tank mix with alachlor (Lasso®) or metolachlor (Dual®) for control of black and Eastern black nightshade, two weeds increasing in severity in the Central and Plains states. Finally, linuron is one of the least costly herbicides available for farmers for soybean use.

Linuron exhibits both contact and residual activity on seedling weeds when applied as a preemergent (at planting) treatment to wheat stubble. For this no-till use, linuron is mixed with alachlor or metolachlor primarily for their for preemergence grass control, plus paraquat or glyphosate for postemergence activity on emerged weeds. The no-till use of linuron comprises approximately 20 percent of total linuron use on soybeans.

Linuron is also registered for use as a postemergence-directed spray for contact control of seedling weeds, after the soybeans are 8 inches tall. The postemergence directed use of linuron on soybeans comprises approximately 4 percent of total usage. Linuron controls a different spectrum of weeds when used postdirected as opposed to the preemergence use.

d. Other Registered Herbicides for Soybeans

Currently, a limited number of preemergence soybean herbicides with linuron's broad spectrum of weed control are registered. Linuron's major competitor is metribuzin (Sencor®, Lexone®) herbicide. Metribuzin is used on a larger number of total soybean acres than linuron. However, metribuzin is restricted from use on sandy and loamy soils with less than 2 percent organic matter. Due to plant injury, it is also restricted from use on Tracy, Semmes, Altona, Vansoy, and Coker 102 soybean varieties. In these situations, linuron is preferred over metribuzin or the other available preemergence broadleaf herbicide chloramben (Amiben®).

Chloramben herbicide is used to a much lesser extent by soybean growers than linuron or metribuzin because chloramben is registered for a much smaller spectrum of weeds. There are no soil or varietal restrictions on chloramben's use on soybeans.

In the Northeastern U.S., the alachlor/linuron tank mix is the standard treatment for soybeans. There are other broadleaf herbicides available for weed control in soybeans. These herbicides are applied either at-cracking or over-the-top (OT) of emerged soybeans and weeds. At-cracking (AC) refers

to the time when soybeans crack the ground surface or emerge from the soil. This ranges from 5 to 7 days after planting to before the soybean true leaves open. These alternative herbicides include (1) naptalam plus dinoseb (Dyanap®), AC; (2) bentazon (Basagran®), OT; (3) acifluorfen (Blazer®), OT; (4) naptalam plus 2,4-DB (Rescue®), OT; (5) fluazifop-butyl (Fusilade®), OT, for grass control only; and (6) BAS 9052 OH (Poast®), OT, for grass control only. Toxaphene (Attac®) is also available for sicklepod control. However, the Agency has cancelled the registration of toxaphene and existing stocks may only be used until January 1, 1986. As a result, the use of linuron as a post directed spray for sicklepod control is expected to increase. (A post directed spray means to spray under the soybean plant and over the weeds). The above listed AC and OT herbicides are efficaceous only if applied to weeds that are in the label specified stage of growth. Therefore, application timing is critical for successful weed control and for minimal injury to the soybeans. The above listed AC and OT herbicides do not provide four to eight week residual control equal to that of linuron. Thus, additional treatments are often necessary throughout the growing season. Also, these individual herbicides do not control the entire spectrum of weeds controlled by linuron.

When used as a postemergence directed spray when soybeans are at least 8 inches tall, linuron controls a different spectrum of weeds. Other available herbicides competitive with this contact activity include metribuzin and chloramben. The herbicide selected is dependent on the spectrum of weeds infesting the field. All three herbicides control emerged broadleaf weeds. However, claims for specific weed control vary considerably. Once again, metribuzin is restricted from post directed use on sandy and loamy soils with less than 2 percent organic matter and from use on certain soybean varieties. Postemergence directed use of linuron comprises only a minor amount of total linuron used on soybeans.

e. Other Linuron Use Sites

The other linuron use sites previously listed are considered "minor" usage sites in comparison to soybeans. The benefits of linuron on certain of these sites, however, are quite large. Linuron is primarily applied as a ground postemergence over-the-top or directed treatment for control of annual broadleaf weeds and certain grasses.

In comparison with other available broadleaf herbicides, linuron is reportedly the only herbicide currently available for postemergence ragweed and galinsoga control in carrots and parsnips. Linuron is the only broadleaf herbicide for use on asparagus that can be used on seedling or established

beds in the early stages of asparagus growth without injurying the plants. On the other registered use sites, a number of other herbicides appear to be available for postemergence broadleaf weed control. In comparison to these, however, linuron is selected in certain growing areas for specific properties. In the Northeast U.S., linuron is selected by celery growers for its residual properties, which allows for double cropping. In corn, linuron is used as a post-directed spray in combination with liquid nitrogen. The addition of liquid nitrogen enhances the "burn-down" activity of linuron on emerged weeds and provides residual control of emerging weeds. Linuron is used on potatoes in courser (lighter) soil textures in Maine, Wisconsin, and New York. The four month soil residual allows for recropping, if necessary. In sorghum, linuron is used in the Southwest U.S. as a postemergence-directed application for control of pigweeds that have escaped other treatments. Pigweeds must be removed before harvest to prevent interference with combining. In wheat, linuron is applied both aerially and with ground equipment primarily in Oregon, Idaho, and Washington to control groundsel, knawel, wild buckwheat, and rattail fescue species. In cotton, linuron is primarily applied as a post-directed spray at layby for annual morningglory and grassy weeds. Linuron's residual properties permit planting fall and winter crops as listed on labels as rotational crops.

In 1982, a Section 18 submission documented linuron as the only available herbicide for control of galinsoga and the common weeds lambsquarters, purslane, common ragweed, redroot pigweed, and barnyardgrass in dry bulb onions in Massachusetts. Excessive cultivation late into the growing season would have damaged the onion bulbs. In the same year, the Agency received another Section 18 submission for the use of linuron in California sugarbeets for postemergence over-the-top control of sowthistle, common mallow, sourclover, and goosefoot species. The action was withdrawn because of a pending review of the mouse oncogenicity study.

Linuron usage on non-food sites is considered insignificant, when compared to the minor food sites. Linuron may be selected for its short-term soil residual on the non-crop sites where this characteristic is desired. It is used on ornamental turf sites for control of the hard to kill weed Poa annua (annual bluegrass). Linuron is currently the only broadleaf herbicide registered for control of weeds in hybrid poplar plantings in Michigan (24c).

2. Preliminary Risk Analysis

a. Introduction

Data indicate that linuron induces dose-related tumors in rats. In a two year study conducted at Haskell Laboratory (Kaplan, A.M. et al., MRID 00029680), researchers fed linuron to three dose groups. A control group was also used. Male rats developed interstitial cell testicular adenomas. Most were discovered at the end of the study. The frequency of these adenomas increased with the dose, and the increase in number was statistically significant for the two high dose groups. At the high dose group, researchers observed losses in female body weights and increased testicular weights.

In a two-year study (Wood, C. et al., MRID 00124195), researchers fed linuron to mice. Researchers at Haskell Laboratory used a control and three dose groups. Female mice developed a statistically significant increase in hepatocellular adenomas in the highest dose group, and male mice developed border-line statistically significant hepatocellular adenomas only in the lowest dose group. Microscopic examination of mouse tissues and organs showed abnormalities in the liver and spleen of male and female mice. Compound related effects in the liver included hepatocytomegaly, hepatocellular cytoplasmic alteration, hepatocellular vacuolization, hemorrhage, and necrosis.

The Agency evaluated these studies using both the International Agency for Research on Cancer (IARC) and National Toxicology Program (NTP) criteria. Using IARC criteria, the weight of evidence for carcinogenicity of linuron is "very limited." Using the NTP criteria to evaluate the rat study, the data indicate a "clear evidence" of carcinogenicity. The Agency feels that the rat study provides the best model for assessing risk. This study provides the best evidence and the most definitive increase in tumors.

The Pesticide Registration Standard for Diuron is requiring specially designed studies to fulfill the oncogenic data gap for diuron. Due to diuron's structural similarity to linuron, the Agency will reviewed the results of the diuron studies. Then the Agency will determine whether it is appropriate to combine regulatory actions for these two herbicides.

b. Exposure Analysis

1) Non-dietary Exposure

The Agency has limited the non-dietary exposure analysis for linuron to the major use site, soybeans. The Agency employed

a surrogate study based on alachlor application to soybeans to estimate exposure (Monsanto Company, GS0063-0028). The type of formulation and method of application of alachlor are the same as for linuron. The application rate for linuron is one fourth the rate of alachlor in all formulations for soybean application. Therefore, the Agency assumes a farmer's exposure to linuron to be one fourth the exposure to alachlor.

A registrant submitted an exposure study on linuron, but it did not contain adequate information for this preliminary risk assessment. The study was based on one application to one 10-acre plot and involved three workers. The Agency considers these data inadequate to determine exposure. In addition, no information was provided on the analytical method. Control samples were not included in the study report, and some conclusions were based on samples lost during analysis.

The exposure risk may actually be higher than Agency calculations predict. First, commercial applicator exposure was not included in this preliminary risk analysis. The Agency will include this exposure in the risk assessment developed during the special review process.

The Agency used the following assumptions to estimate linuron exposure to a soybean farmer during ground application of linuron.

i) The farmer is a 70 kg man.

ii) As an applicator, the farmer may treat a 100 acre plot per day and may treat up to 600 acres per year. Consequently, he may be exposed to linuron from 1 to 6 days per year.

iii) As a mixer/loader, the farmer may be exposed for approximately 15 minutes for every 100 acres treated at 1 pound active ingredient per acre.

iv) Because of the application method, the Agency assumes respiratory exposure is negligible.

v) In the absence of data, the Agency assumes 100 percent dermal penetration.

vi) The Agency assumes a lifetime exposure of 30 working years.

The Agency estimated the potential exposure for a farmer as an applicator, mixer/loader, or both.

The Agency used three scenarios to estimate exposure to farmers using linuron. Scenario one assumes maximum exposure because the farmer is not wearing protective clothing. This is the most realistic scenario for linuron since current labeling does not require any protective clothing.

Scenario two assumes the farmer is wearing protective clothing, such as coveralls, which the Agency assumes reduces exposure 80 percent. Normal work clothes are not considered protective clothing. The Agency assumes the farmer is wearing rubber gloves during mixing/loading, which reduces exposure to the hands. The farmer is not wearing gloves during application.

Scenario three assumes the farmer is wearing the same clothing as in scenario two, but that the clothing reduces exposure by 100 percent. Therefore, the only route of exposure are those areas of the body not protected by clothing.

The Agency has not presented a detailed explanation of the non-dietary exposure analysis because it was based on surrogate data submitted by Monsanto Company. Presently, there is an existing injunction in Monsanto vs. Ruckelshaus, which prohibits "any ... disclosure to any other person ... of any [Monsanto] information, research, and test data" without Monsanto's written permission. To avoid any possible violation of this injunction, the Agency omitted all calculations, figures, and other information in the exposure assessment, which might reveal any data submitted by Monsanto.

2) Dietary

The estimates of dietary exposure to pesticide residues in the diet are a function of several factors. These factors include (1) the residues remaining in or on a commodity; (2) the amount of a commodity in a daily diet of 1.5 kg (food factor); and (3) 60 kg average body weight. The residues are measured in ppm, and human exposure to pesticide residues in a commodity is measured in terms of mg of pesticide per kg of body weight per day.

The Agency's dietary estimates assume a uniform distribution of treated crops among the U.S. population and an average daily consumption of those crops by individuals. Although an individual's exposure could vary considerably depending upon eating habits and geographic location, the values are considered representative for the total U.S. population over a lifetime.

The Agency used three methods to calculate the potential dietary exposure of linuron. The first method assumed the residues are at 100 percent of the tolerance levels. The second method used the maximum residue expected (MRE) and is based on actual residue levels found in the field. The third method used the MRE multiplied by a rough estimate of percent crop treated to give an estimate of residues which may realistically reach humans through the diet. Pending tolerances for lettuce and sugar are not included in any of the methods.

It should be noted that exposure to linuron through groundwater contamination is possible. The Agency is requesting additional data in this standard to make a determination of possible groundwater contamination.

c. Risk Estimates

The Agency's Interim Cancer Assessment Guidelines (41 FR 21402) state that when the Agency judges a chemical to be a potential human carcinogen, the Agency must estimate its possible impact on public health at current and anticipated levels of exposure. The Agency recognizes that the available techniques for assessing the magnitude of cancer risk to human populations based on animal data are crude. Uncertainties in the extrapolation of dose response data to very low dose levels occur. Also, animals and humans have varying levels of susceptibility. Thus, these estimates should be viewed as a health hazard index that reflects the degree of oncogenic activity and human exposure to linuron.

The Agency used several mathematical models, but none provided adequate fit to the rat data when the complete data set was used. The Agency deleted the high dose results and use the models again. The Multi-Stage Model provided an almost perfect fit.

1) Non-dietary

The Agency's estimates of a farmer's oncogenic risk to ground application to soybeans are presented in the following table.

Oncogenic Risk to Ground Applicators of Linuron

CONDITION	RISK (100 A/yr x 30yr)	RISK (600 A/yr x 30yr)
No Protection		
Mixer/loader	3.5×10^{-4}	2.1×10^{-3}
Applicator	1.2×10^{-5}	7.4×10^{-5}
Combined	3.6×10^{-4}	2.2×10^{-3}
80% Protection		
Mixer/loader	4.2×10^{-5}	2.5×10^{-4}
Applicator	3.8×10^{-6}	2.3×10^{-5}
Combined	4.6×10^{-5}	2.7×10^{-4}
100% Protection		
Mixer/loader	9.5×10^{-6}	5.7×10^{-5}
Applicator	2.0×10^{-6}	1.2×10^{-5}
Combined	1.1×10^{-5}	6.9×10^{-5}

2) Dietary

The Agency's estimates of dietary risk to linuron are presented in the table below.

Oncogenic Risk from Dietary Exposure to Linuron

Assumption	"TMRC" (mg/day)	RISK
100% tolerance	0.3248	1.2×10^{-3}
MRE	0.0790	4.3×10^{-4}
MRE x % of crop treated	0.0027	1.5×10^{-5}

d. Conclusions

The Agency has determined that linuron has exceeded the oncogenicity risk criterion for special review. This determination is based on several factors. The oral administration of linuron to the rat indicated clear evidence of oncogenicity for male rats using NTP criteria. Using these data the Agency calculated nondietary risk. The most realistic scenario is a farmer with no protection, who mixes/loads and applies this herbicide. This calculation resulted in a risk of 3.6×10^{-4} to 2.2×10^{-3}. It is possible that the actual risk may even be higher, because commercial applicator exposure was not included. The Agency also calculated dietary risk. The most realistic scenario for dietary risk is the combination of MRE and percent crop treated, which resulted in a 1.5×10^{-5}.

Pending further review, the Agency cannot permit the registration of new products and reregistration of current products containing linuron until the Agency has reviewed the data required by this Standard.

The Agency will not consider for reregistration any current products containing linuron as a sole active ingredient until the Agency concludes the Special Review. However, all currently registered products will remain registered while the Special Review is in process.

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data 1/ Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines 2/, or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that

---

1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

---

*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.
(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

h035506

LINURON*

TYPE PESTICIDE: Herbicide

FORMULATIONS: Tech (95%); FI (50%); G (0.154%, 0.231%, 0.25%, 0.308%, 3%, 3.5%, 5%); WP (7.5%, 12.5%, 15%, 20%, 20.5%, 25%, 30.8%, 50%); EC (1 lb/gal); FlC (0.9 lb/gal, 1.5 lb/gal, 4.34%)

GENERAL WARNINGS AND LIMITATIONS: A selective, systemic herbicide used to control annual grasses and broadleaf weeds in certain crops. May be applied either preemergence or postemergence. It provides nonselective weed control on noncrop areas. Soils with a high clay or organic matter content will require the higher dosages. Moisture is necessary to activate the chemical and move it into the soil. For best results, apply to young, succulent weeds under conditions of high humidity and temperatures of 70 F (21.1 C) or higher. Do not allow the chemical to come in contact with roots of desirable plants. Reduce dosage in proportion to band area actually treated.

Livestock Tolerances:
1 ppm in meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep.

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Chlorosis and necrosis of the leaves.

PHYTOTOXICITY TO CROPS: Not located.

MODE OF ACTION: Inhibits the Hill reaction in photosynthesis.

BROADLEAF WEEDS CONTROLLED:

@PAAAAAC	broadleaf weeds	
@PADABBA	carpetweed	
@PAZAAAC	chickweed	
@PBFDQAA	cocklebur	(a)
@PAZAOBB	common chickweed	
@PBFAEBA	common ragweed	
@PBFBIBB	dogfennel	
@PARABAA	fiddleneck	
@PEMAEBB	florida pusley	
@PBFBOAA	galinsoga	
@PBFCXAA	groundsel	
@PAZAKBA	knawel	
@PBDAEAB	lambsquarters	
@PBKAAAC	mustard	
@PBDAEBI	nettleleaf goosefoot	
@PAAAABI	pigweed	
@PDAAJBF	prickly sida	(a)
@PAAAABP	purslane	

List continued on the next page.

*3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea

Issued: 6-01-79

BROADLEAF WEEDS CONTROLLED (continued)

@PBFAEAA	ragweed	
@PAFACHI	redroot pigweed	
@PCQBSAA	sesbania	
@PCQAMBF	sicklepod	(a)
@PEAAGAD	smartweed	
@PBGAFBL	tall morningglory	(a)
@PDAABBB	velvetleaf	(a)
@PEAAGBH	wild buckwheat	
@PBKBABA	wild radish	

(a) Preemergence application provides partial control.

GRASSES AND OTHER MONOCOTS CONTROLLED:

@PCACKBA	annual bluegrass
@PCAAAAB	annual grasses
@PCABHBB	barnyardgrass
@PCACHBB	canarygrass
@PCABFAA	crabgrass
@PCACEBD	fall panicum
@PCACUAA	foxtail
@PCACUBA	giant foxtail
@PCABIBA	goosegrass
@PCACUBF	green foxtail
@PCABFBF	large crabgrass
@PCABZBA	italian ryegrass
@PCABMBB	rattail fescue
@PCABFBD	smooth crabgrass
@PCACEBL	texas panicum
@PCACUBD	yellow foxtail

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	AGRICULTURAL CROPS	
/1400300	Carrot	1 ppm General Information: Linuron may be applied 1 day after or 2 weeks before a stoddard solvent application. Do not apply as a tank mix with stoddard solvent, surfactants, nitrogen solution, other pesticides, or when temperatures exceed 85 F (29.4 C). Multiple applications may be made, but the total dosage should not exceed 2 pounds of active ingredient per acre. Do not treat susceptible varieties.
	--	LA state label Registration Number 037820-08428
$1400302 &050.0006	0.50-1.50 (50% WP)	Preemergence. Broadcast. Make a single application in 25 to 40 gallons of water per acre. Use the lower dosage for soils low in organic matter. Apply after planting, but before crop emerges.
$1400301 &050.0006	0.75-1.50 (50% WP)	Postemergence. Broadcast or band. Apply in a minimum of 25 gallons of water per acre after carrots are at least 3 inches in height. Use the lower dosage for smaller weeds, and the higher dosage for larger, established weeds. Apply before annual grasses exceed 2 inches in height, and before broadleaf weeds exceed 6 inches.
/2800300	Celery	0.5 ppm
	--	LA state label Registration Number 037820-08428
/2800600	Corn, Field	0.25 ppm (grain and fresh corn including sweet corn (kernels plus cob with husks removed)) 1 ppm (forage and fodder)
	--	LA state label Registration Number 037820-08428 TX state label Registration Number 006735-04820
F		Formulated with atrazine and related compounds.

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Corn, Field (continued)	
$2800602 &050.0006 I9900300	0.33-1.50 (50% WP)	Use limited to east of the Rocky Mountains. Preemergence. Broadcast or band. Tank mix with alachlor, atrazine or 2-chloro-N-isopropylacetanilide. Apply in 25 to 40 gallons of water per acre after planting, but before crop emerges. Seeds should be planted in flat or raised seedbeds to avoid injury.
F &005.0004 &101.0012 &015.0006 &020.0006	0.33-1.50 (5% G) 0.34-1.50 (1 lb/gal EC) 0.75-1.50 (15% WP) (20% WP)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Plant seed at least 1.75 inches deep or injury may result. Do not use on sand or loamy sand soils, or on soils with less than 1 percent organic matter. Apply the wettable powders and emulsifiable concentrate in 25 to 40 gallons of water per acre. Formulated with 2-chloro-N-isopropylacetanilide.
F &030.8006	0.49-1.54 (30.8% WP)	Preemergence. Broadcast or band. Apply in 25 to 40 gallons of water per acre after planting and prior to crop emergence. Do not use on sand or loamy sand soils. Plant seed at least 1.75 inches deep or crop injury may result. Formulated with atrazine and related compounds.
F &020.5006	0.33-1.03 (20.5% WP)	Use limited to MO. Preemergence. Broadcast or band. Apply in 25 to 40 gallons of water per acre after planting and prior to crop emergence. Do not use on sand or loamy sand soils. Plant seed at least 1.75 inches deep or crop injury may result. Formulated with atrazine and related compounds.
&050.0006	0.62-1.50 (50% WP)	Postemergence. Directed spray. Apply in a minimum of 25 gallons of water per acre after corn is at least 15 inches in height. The chemical should not contact upper leaves or whorls of corn. Use the lower dosage on weeds that are less than 2 inches in height, and the higher dosage on weeds that are less than 5 inches in height. Use with a surfactant.

LINURON

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/1500500	Corn, Sweet	1 ppm (forage and fodder)
	--	LA state label Registration Number 037820-08428
$1500502 &050.0006	0.62-1.50 (50% WP)	Postemergence. Directed spray. Apply in a minimum of 25 gallons of water per acre after corn is at least 15 inches in height. The chemical should not contact upper leaves or whorls of corn. Use the lower dosage on weeds that are less than 2 inches in height, and the higher dosage on weeds that are less than 5 inches in height.
/2800700	Cotton	0.25 ppm (cottonseed) Do not graze or feed forage from treated areas to livestock. Do not feed gin trash to livestock. General Information: Do not use on pima cotton varieties. Do not spray over top of cotton.
		LA state label Registration Number 037820-08428
$2800702 &050.0006	0.50-1.50 (50% WP)	Use limited to east of the Rocky Mountains. Postemergence. Directed spray. Apply in a minimum of 25 gallons of water per acre. Use the lower dosage when cotton is at least 15 inches in height and the weeds are less than 2 inches in height. A second application may be made 1 week after initial treatment. If cotton is 20 inches in height, make 1 application at the higher dosage following the last cultivation. Use with a surfactant.
/1401200	Parsnip	0.5 ppm (tops) 0.5 ppm (with or without tops)
	--	LA state label Registration Number 037820-08428
$1401202 &050.0006	0.75-1.50 (50% WP)	Preemergence. Broadcast or band. Apply in 25 to 40 gallons of water per acre. Use the lower dosage on soils low in organic matter. Apply after planting, but before crop emerges.

LINURON

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/1401300 I9001500	Potato	1 ppm General Information: Apply in 25 to 40 gallons of water per acre by ground, or 5 to 10 gallons by air.
	--	LA state label Registration Number 037820-08428
$1401302 &050.0006	0.75-2.00 (50% WP)	Use limited to east of the Rocky Mountains and Pacific Northwest. Preemergence. Broadcast. Do not spray over the top of emerged potatoes. Apply before grasses are 2 inches in height and broadleaf weeds are 6 inches in height. When emerged weeds are present, use with a surfactant. Use the lower dosage on light soils (sandy loams, silt loams) and the higher dosage on heavy soils (clay loams, silts).
&050.0006	0.50-1.00 (50% WP)	Use limited to WI, central sands area. Preemergence. Broadcast. Do not spray over the top of emerged potatoes. Apply before grasses are 2 inches in height and broadleaf weeds are 6 inches in height. When emerged weeds are present, use with a surfactant. Use the lower dosage on sands, and the higher dosage on loamy sands.
/2801900	Sorghum	0.25 ppm (grain) 1 ppm (forage and fodder) Do not graze or feed sorghum forage or silage from treated fields to dairy animals.
	--	LA state label Registration Number 037820-08428
$2801902 &050.0006 I9900300	0.30-1.00 (50% WP)	Use limited to the Southwest. Preemergence. Broadcast or band. Tank mix with propazine. Apply in 25 to 40 gallons of water per acre after planting, but before crop emerges.
I9900300 &050.0006	0.33-1.50 (50% WP)	Use limited to the Great Plains. Preemergence. Broadcast. Tank mix with 2-chloro-N-isopropylacetanilide. Apply in 25 to 40 gallons of water per acre after planting, but before crop emerges.

LINURON

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/2400600	Sorghum (grain crop)	0.25 ppm (grain) 1 ppm (forage and fodder) Do not graze or feed forage or silage from treated areas to livestock.
	--	TX state labels Registration Number 006735-04809
F		Formulated with propazine. Registration Number 006735-04810
F		Formulated with propazine. Registration Number 006735-04821
F		Formulated with propazine. Registration Number 006735-04822
F		Formulated with propazine. Registration Number 006735-04823
F		Formulated with propazine.
$2400602 &101.0012 F	0.34-1.50 (1 lb/gal EC)	Use limited to the Great Plains. Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Plant seed at least 1 inch deep. Do not use on sand or loamy sand soils, or on soils with less than 1 percent organic matter. Apply in 25 to 40 gallons of water per acre. Formulated with 2-chloro-N-isopropylacetanilide.
/2802300	Soybeans	1 ppm (dry or succulent soybeans) 1 ppm (forage, hay) Do not apply within 60 days of harvest. Do not feed forage or hay from treated fields to livestock.
	--	LA state labels Registration Number 001339-06934
F		Formulated with alachlor. Registration Number 037820-08428 MO state label Registration Number 010371-07538
F		Formulated with 4-(2,4-dichlorophenoxy)butyric acid, dimethylamine salt.
$2802302 &050.0006	0.50-3.00 (50% WP)	Preemergence. Broadcast or band. Apply in 25 to 40 gallons of water per acre. Use the lower dosage on sandy loam soils with low organic matter content (0.5 to 2 percent), and the higher dosage on clay loam soils with moderate organic matter content (2 to 5 percent). When weeds have emerged, use with a surfactant.

Issued: 6-01-79

LINURON

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Soybeans (continued)	
I9900300 &050.0006	0.50-1.50 (50% WP)	Use limited to east of the Rocky Mountains. Preemergence. Broadcast or band. Tank mix with alachlor. Apply in 25 to 40 gallons of water per acre. Use the lower dosage on silt loam soils with low organic matter content (0.5 to 3 percent), and the higher dosage on clay loam soils with moderate organic matter content (3 to 6 percent).
&050.0006	0.25-1.25 (50% WP)	Preemergence. Broadcast or band. Sequential application following preplant incorporation of trifluralin. Apply in 25 to 40 gallons of water per acre. Use the lower dosage on sandy loam soils with low organic matter content (0.5 to 2 percent), and the higher dosage on clay loam soils with over 5 percent organic matter content.
F &012.5006	0.50 (12.5% WP)	Preemergence. Broadcast or band. Apply at planting in 25 to 40 gallons of water per acre. Use on loam soils only. Plant seed at least 1.5 inches deep on flat or raised beds. Formulated with chloramben, sodium salt.
F &003.0004	0.45-1.00 (3% G)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Apply the wettable powder in a minimum of 20 gallons of water per acre. Do not apply over the top of emerged soybeans. Plant seed at least 1.5 to 1.75 inches deep. Avoid use on loamy sand, sand or gravely soils, or on soils with less than 1 percent organic matter, as injury may result. Formulated with dimethyl tetrachloroterephthalate.
&007.5006	0.45-1.01 (7.5% WP)	
&050.0006	0.50-1.00 (50% WP)	Use limited to the Midsouth and Southeast. Postemergence. Directed spray. Apply in a minimum of 25 gallons of water per acre when soybeans are at least 12 inches in height and weeds do not exceed 4 inches in height. Do not spray higher than 3 inches on soybean stem. When applying as a single application, use with a surfactant. A split application of the lower dosage can be made 1 week apart. Do not use on soils with less than 0.5 percent organic matter. Do not apply more than 1 pound active ingredient per acre per growing season.

Issued: 6-01-79

LINURON

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/2802300	Soybeans (seed crop)	N.F. Do not feed forage or hay from treated fields to livestock.
$2802305 &050.0006 I9900300	0.33-1.50 (50% WP)	Preemergence. Broadcast or band. Tank mix with propachlor. Apply in 25 to 40 gallons of water per acre. Use the lower dosage on sandy loam soils with low organic matter content (1 to 3 percent), and the higher dosage on clay loam soils with moderate organic matter content (3 to 6 percent).
F &005.0004	0.33-1.50 (5% G)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Plant seed at least 1.75 inches deep. Do not use on sand or loamy sand soils, or on soils with less than 1 percent organic matter. Apply the emulsifiable concentrate in 25 to 40 gallons of water per acre. Formulated with 2-chloro-N-isopropylacetanilide.
&101.0012	0.34-1.50 (1 lb/gal EC)	
/2400700	Wheat (winter) (drill planted)	0.25 ppm (grain) 0.5 ppm (forage) Do not graze or feed immature plants to livestock. General Information: Do not apply on sand or loamy sand soils, on gravelly or sandy loams with less than 1 percent organic matter, or on thinly covered or exposed subsoil areas. Do not treat wheat planted less than 1 inch deep. Do no apply when daily temperatures exceed 60 F (15.6 C), or when winter climatic conditions have produced heaving of plants. Do not treat when crop lacks vigor. Do not use in conjunction with other pesticides, surfactants or nitrogen solutions after wheat has emerged. Do not treat after the boot stage. Do not replant treated areas with any rotation crop within 6 months after last application. LA state label Registration Number 037820-08428

Issued: 6-01-79

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Wheat (winter) (drill planted) (continued)	
\$2400702 &050.0006 I9001500	0.50-0.75 (50% WP)	Use limited to ID, OR and WA, east of the Cascade Range where the average annual rainfall is 10 to 16 inches. Preemergence. Broadcast. Fall or winter treatment. Apply after wheat is planted in the fall, when there is sufficient moisture available to germinate wheat seed, and when weeds are less than 2 inches in height. Do not apply if the soil temperature is below freezing. Apply in 25 to 40 gallons of water per acre by ground, or 5 to 10 gallons by air.
I9001500 &050.0006	0.50-0.75 (50% WP)	Use limited to ID, OR and WA, east of the Cascade Range where the average annual rainfall exceeds 16 inches. Preemergence. Broadcast. Fall treatment. Apply to early planted wheat (seeded before September 10) before weeds are 2 inches in height. Do not apply after soil freezes. Apply in 25 to 40 gallons of water per acre by ground, or 5 to 10 gallons by air. If fall planted wheat fails to grow due to adverse growing conditions after treatment, wait 4 months before planting spring wheat. Do not retreat the same field within 1 year.
I9001500 &050.0006	1.00-1.75 (50% WP)	Use limited to OR and WA, west of the Cascade Range. Preemergence. Broadcast. Apply in 25 to 40 gallons of water per acre by ground, or 5 to 10 gallons by air. Chlorosis may occur if applied to actively growing plants. Apply as soon as possible after planting, using the lower dosage on soils low in organic matter. If weeds and wheat have emerged, apply before weeds are 3 to 4 inches in height.
\$2400701 &050.0006	0.50-0.75 (50% WP)	Use limited to ID, OR and WA, east of the Cascade Range where the average annual rainfall exceeds 16 inches. Postemergence. Broadcast. Fall treatment. Apply to early planted wheat (seeded before September 10) before weeds are 2 inches in height. Do not apply after soil freezes. If fall planted wheat fails to grow due to adverse growing conditions after treatment, wait 4 months before planting spring wheat. Do not retreat the same field within 1 year.

Issued: 6-01-79

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Wheat (winter) (drill planted) (continued)	
&050.0006	0.50-0.62 (50% WP)	Use limited to ID, OR and WA, east of the Cascade Range where the average annual rainfall exceeds 16 inches. Postemergence. Broadcast. Spring treatment. Apply as soon as wheat emerges, and before weeds are 2 inches in height.
$2400715 &050.0006 I9001500	1.00-1.75 (50% WP)	Use limited to OR and WA, west of the Cascade Range. Semi-dormant application. Broadcast. Apply in 25 to 40 gallons of water per acre by ground, or 5 to 10 gallons by air. Chlorosis may occur if applied to actively growing plants. Use the lower dosage on soils low in organic matter.
=	AGRICULTURAL PREMISES	
/6600100	Fencerows (agricultural)	N.F.
	--	LA state label Registration Number 037820-08428
$6600101 &050.0006	1.00-3.00 (50% WP)	Broadcast. Apply in 40 to 100 gallons of water per acre. To control established annual weeds use with a surfactant. Apply when daily temperatures exceed 70 F (21.1 C), and before weeds exceed 8 inches in height.
F &025.0006	1.00-2.00 (25% WP)	Use limited to CA. Broadcast. Apply in 20 to 100 gallons of water per acre in early spring or at the start of the rainy season, before weeds are 8 inches in height. Use the higher dosage when weeds are 6 to 8 inches in height. A surfactant may be used. Formulated with amitrole.

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	ORNAMENTALS	
	General Warnings and Limitations: Do not use on bentgrass, fescue, fescue mixtures, ryegrass or ryegrass mixtures. Delay application until after the third mowing on newly seeded bluegrass. No more than 8.92 pounds active ingredient should be applied per acre per year. Soil moisture that is adequate for active growth, and temperatures of 70 F (21.1 C) or higher, will enhance control.	
/3303400	Kentucky Bluegrass (golf course fairways, tees)	N.F.
$3303401 &003.5004	2.21-2.94 (3.5% G)	Broadcast. Apply by spreader when annual bluegrass is growing actively. Water immediately following application. Two applications per year, for 2 to 3 years, are required. Wait at least 4 weeks before retreating. Seeding should be delayed for 2 months following these applications.
/3303400	Kentucky Bluegrass (sod production fields)	N.F.
$3303401 &003.5004	2.94-4.42 (3.5% G)	Broadcast. Apply by spreader when annual bluegrass is growing actively. Water immediately following application. Repeat applications may be necessary in cooler weather. Use the higher dosage on organic soils such as muck or peat, and the lower dosage on mineral soils. Seeding should be delayed for 3 months after application on organic soils, and 2 months after application on mineral soils. Do not cut treated sod within 10 weeks after application.
=	RIGHTS-OF-WAY	
/6700400	Highway Rights-of-Way	N.F. General Information: Highway rights-of-way include alleys, streets and roadsides.
	--	LA state label Registration Number 037820-08428
$6700401 S6600101		Broadcast. Refer to AGRICULTURAL PREMISES, Fencerows (agricultural) for use and limitation information.

Issued: 6-01-79

LINURON

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	COMMERCIAL AND INDUSTRIAL PREMISES	
/6701500	Fencerows	N.F.
	--	LA state label Registration Number 037820-08428
$6701501 S6600101		Broadcast. Refer to AGRICULTURAL PREMISES, Fencerows (agricultural) for use and limitation information.
/6700000	Vacant Lots	N.F.
$6700001 &025.0006 F	1.00-2.00 (25% WP)	Use limited to CA. Broadcast. Apply in 20 to 100 gallons of water per acre in early spring or at the start of the rainy season, before weeds are 8 inches in height. Use the higher dosage when weeds are 6 to 8 inches in height. A surfactant may be used. Formulated with amitrole.
	AERIAL AND TANK MIX APPLICATIONS	
	Aerial Application	
	--	Refer to AGRICULTURAL CROPS Potato, Wheat (winter)(drill planted)
	Tank Mix	
	--	Refer to AGRICULTURAL CROPS Corn (Field), Sorghum, Soybeans, Soybeans (seed crop)

Issued: 6-01-79

LINURON

Listing of Registered Pesticide Products by Formulation

&095.0001 95% technical chemical
linuron (035506)
000352-00326

&050.0002 50% formulation intermediate
linuron (035506)
000352-00339

&000.1504 0.154% granular
linuron (035506) plus propazine (080808)
006735-04822

&000.2304 0.231% granular
linuron (035506) plus propazine (080808)
006735-04821

&000.2504 0.25% granular
linuron (035506) plus atrazine and related compounds (080803)
006735-04820

&000.3104 0.308% granular
linuron (035506) plus propazine (080808)
006735-04823

&003.0004 3% granular
linuron (035506) plus dimethyl tetrachloroterephthalate (078701)
000677-00307

&003.5004 3.5% granular
linuron (035506)
000538-00110

&005.0004 5% granular
linuron (035506) plus 2-chloro-N-isopropylacetanilide (019101)
000352-00334 000524-00289

&007.5006 7.5% wettable powder
linuron (035506) plus dimethyl tetrachloroterephthalate (078701)
000677-00285

&012.5006 12.5% wettable powder
linuron (035506) plus chloramben, sodium salt (029906)
000264-00254

&015.0006 15% wettable powder
linuron (035506) plus 2-chloro-N-isopropylacetanilide (019101)
000524-00288

&020.0006 20% wettable powder
linuron (035506) plus 2-chloro-N-isopropylacetanilide (019101)
008461-00003

Issued: 6-01-79

Listing of Registered Pesticide Products by Formulation (continued)

&020.5006 20.5% wettable powder
linuron (035506) plus atrazine and related compounds (080803)
008461-00029

&025.0006 25% wettable powder
linuron (035506) plus amitrole (004401)
000264-00246

&030.8006 30.8% wettable powder
linuron (035506) plus atrazine and related compounds (080803)
000595-00268 001386-00493 003770-00158 006735-04810
008461-00001 008590-00271

&050.0006 50% wettable powder
linuron (035506)
000352-00270 002749-00158 037820-08428

&101.0012 1 lb/gal emulsifiable concentrate
linuron (035506) plus 2-chloro-N-isopropylacetanilide (019101)
000352-00345

&100.9014 0.9 lb/gal flowable concentrate
linuron (035506) plus propazine (080808)
006735-04809

&101.5014 1.5 lb/gal flowable concentrate
linuron (035506) plus alachlor (090501)
001339-06934

&204.3414 4.34% flowable concentrate
linuron (035506) plus 4-(2,4-dichlorophenoxy)butyric acid, dimethylamine
salt (030819)
010371-07538

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This chapter applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	TGAI	Partially	00018443, 00018446 00018444, 00018447	Yes 3/
61-2 - Statement of Composition	TGAI	Partially	00018443, 00018446 00018444, 00018447	Yes 3/
61-3 - Discussion of Formation of Ingredients	TGAI	No	-	Yes 3/
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	No	-	Yes 3/
62-2 - Certification of Limits	TGAI	No	-	Yes 3/
62-3 - Analytical Methods for Enforcement of Limits	TGAI	No	-	Yes 3/
Physical and Chemical Characteristics				
63-2 - Color	TGAI	No	-	Yes 3/
63-3 - Physical State	TGAI	No	-	Yes 3/
63-4 - Odor	TGAI	No	-	Yes 3/
63-5 - Melting Point	TGAI	No	-	Yes 3/
63-6 - Boiling Point	TGAI	N/A 5/		
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No	-	Yes 3/

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry (continued)				
63- 8 - Solubility	TGAI	No	-	Yes 3/4/
63- 9 - Vapor Pressure	PAI	No	-	Yes 3/4/
63-10 - Dissociation constant	PAI	No	-	Yes 3/
63-11 - Octanol/water partition coefficient	PAI	No	-	Yes 3/4/
63-12 - pH	TGAI	No	-	Yes 3/
63-13 - Stability	TGAI	No	-	Yes 3/
Other Requirements:				
64- 1 - Submittal of samples	Choice	N/A 5/		

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

§158.120 Product Chemistry
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than six months from the receipt date of this guidance package.
3/ Physical/chemical properties for which data were not submitted constitute product chemistry data gaps.
4/ Chemistry data are required because of the Agency's concern for possible groundwater contamination.

5/ N/A= Not applicable for purposes of this standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partially	00018173,00027624 00018176	Yes 3/
- Livestock	PAIRA and plant metabolites	Yes	00029932	No
171-4 - Residue Analytical Method				
- Plant residues	TGAI and metabolites	Yes	00018087,00018176 00018089	No
- Animal residues	TGAI and metabolites	Yes	00018127	No
171-4 - Storage Stability Data	PAI	No	-	Yes
171-4 - Magnitude of the Residue- Residue Studies for Each Food Use				
° Asparagus	TEP	Partially	00018089,00018087	Yes 4/
° Carrots (With, without tops)	TEP	Partially	00018172,00027635	Yes 4/
° Celery	TEP	Partally	00018443	Yes 4/

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry				
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
° Corn (Field and Sweet)	TEP	Partially	00018171,00018206 00018375,00018382 00018450	Yes 4/
° Cotton (Cottonseed)	TEP	Partially	00018067	Yes 4/
° Parsnips (With, without tops)	TEP	Partially	00018171	Yes 4/
° Potatoes	TEP	Partially	00027635	Yes 4/
° Sorghum	TEP	Partially	00018171,00018148	Yes 4/
° Soybeans	TEP	Partially	00018076,00018206 00027635	Yes 4/
° Wheat	TEP	Partially	00018171,00018175	Yes 4/

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue Studies (continued)				
- Potable Water	EP	N/A 6/		
- Fish	EP	N/A		
- Irrigated Crops	EP	N/A		
-- Field trials	EP	N/A		
-- Processed Food/Feed	EP	No		Yes 5/
- Food Handling	EP	N/A		
- Meat/milk/poultry/eggs				
° Cattle	TGAI	Yes	00018209,00018210 00018375,00018450 00018775	No
° Goats	TGAI	Yes	00029932	No
° Poultry Eggs	TGAI	Yes	00018383	No

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

§158.125 Residue Chemistry
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.
2/ Data must be submitted no later than one year from the receipt date of this guidance package.
3/ The Agency will decide shortly whether data on 3,3,4',4'-tetrachloroazobenzene formation is required or not.
4/ Residue data for asparagus, carrots, celery, corn, cottonseed, parsnips, potatoes, sorghum, soybeans, and wheat are required to reflect uses of the 50%, dry flowable (DF) and 4 lb/gal, flowable concentrate (FIC) formulations. Data reflecting uses of the 50% DF are required for the following commodities: carrots (aerial applications), potatoes (aerial applications), soybeans (preemergence), sorghum (forage), wheat (forage and hay), asparagus (preemergence), and cottonseed (two applications per season).

5/ Data pertaining to residues in dehydrated potato products are required.

6/ N/A= Not applicable for the purposes of this standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B	No	-	Yes 4/
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B	No	-	Yes 4/
161-3 - On soil	TGAI or PAIRA	A,B	No	-	Yes 4/
161-4 - In Air	TGAI or PAIRA	A	No	-	Yes
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	No	-	Yes 5/
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes 5/
162-3 - Anaerobic Aquatic	TGAI or PAIRA		N/A 10/		
162-4 - Aerobic Aquatic	TGAI or PAIRA		N/A		
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B	Partial	05016640 05019500	Yes 4/ 6/
163-2 - Volatility (Lab)	TEP	A	No		Yes
163-3 - Volatility (Field)	TEP	A	No		Yes

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.130 Environmental Fate					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B	No	-	Yes 5/
164-2 - Aquatic (Sediment)	TEP		N/A 10/		
164-3 - Forestry	TEP		N/A		
164-4 - Combination and Tank Mixes			N/A		
164-5 - Soil, Long-term	TEP	A	No	-	Yes
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes 7/
165-2 - Rotational Crops (Field)	TEP	A	No	-	Yes 7/
165-3 - Irrigated Crops	TEP		N/A		
165-4 - In Fish	TGAI or PAIRA	A,B	No		Yes
165-5 - In Aquatic Non-Target Organisms	TEP		N/A		
SPECIAL TESTING:					
- Applicator Exposure	TEP	A	No		Yes 9/
§Subpart K- Reentry	TEP	8/			Yes

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

§158.130 Environmental Fate
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = pure active ingredient, radiolabelled, TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D= Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than two years from the receipt date of this guidance package, unless otherwise noted.
4/ Data must be submitted no later than six months from the receipt date of this guidance package (Agency groundwater data requirements)
5/ Data must be submitted no later than two years from the receipt date of this guidance package (Agency groundwater data requirements)
6/ Additional data are needed to assess the mobility of linuron degradation products. Data on the parent compound are acceptable.
7/ For crops rotated on treated areas, any one of the following will apply:
   a. A tolerance must be obtained for the rotated crop,
   b. The product label must include a restriction against the rotation of crops used for food or feed on treated areas,
   c. Data must be provided to determine time intervals at which rotated crops planted on treated areas will be free of pesticide residues.
8/ Until data are submitted and evaluated, reentry into treated fields (post emergence) is restricted for 24 hours following the application of linuron unless protective clothing is worn.

9/ Dermal and inhalation applicator exposure data are required by the Agency. Data must be submitted in one year from the receipt date of this guidance package. The Agency needs these data for the special review of linuron. The registration should contact the Agency when designing studies.

10/ N/A= Not applicable for the purposes of this standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral Toxicity-Rat	TGAI	A,B	Yes	00027625, 05016511	No
81-2 - Dermal Toxicity	TGAI	A,B	Yes	00027625	No
81-3 - Inhalation Toxicity-Rat	TGAI	A,B	Yes	00018181	No
81-4 - Primary Eye Irritation	TGAI	A,B	Yes	00018178, 00018183 00018179, 00018196	No
81-5 - Primary Skin Irritation	TGAI	A,B	Yes	00018180	No
81-6 - Dermal Sensitization	TGAI	A,B	Partially	GS0047-0001	Yes
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,B	N/A 9/		
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A,B	N/A		
82-2 - 21-Day Dermal	TGAI	A,B	N/A		
82-3 - 90-Day Dermal	TGAI	A,B	N/A		
82-4 - 90-Day Inhalation - Rat	TGAI	A,B	N/A		
82-5 - 90-Day Neurotoxicity-Hen/Mammal	TGAI	A,B	N/A		

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)
§158.135 Toxicology (continued)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A,B	Yes	00018374, 00029680 00029679	No
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	A,B	Yes	00029680, 00124195 00029679	No
83-3 - Teratogenicity - 2 species	TGAI	A,B	Partially	00018167, 00018170	Yes 4/
83-4 - Reproduction, 2-generation	TGAI	A,B	Partially	00018169	Yes 3/ 5/
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A,B	Partially	00029933	Yes 6/ 8/
84-2 - Chromosomal Aberration	TGAI	A,B	Partially	00029933	Yes 6/ 8/
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B	No	-	Yes 6/ 8/

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)
§158.135 Toxicology (continued)					
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A,B	Partially	05016511	Yes 10/
85-2 - Domestic Animal Safety	Choice		N/A 9/	-	
Special Dietary Exposure	PAIRA	A,B	No	-	Yes 3/ 7/

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

§158.135 Toxicology
(continued)

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than two years from the receipt date of this guidance package.
4/ Two teratogenicity studies are required, one in rat and one in another species (rabbit). Data must be submitted no later than one year from the receipt date of this guidance package. The Agency needs these data for the special review of linuron.
5/ A two-generation reproduction study in rats is required; this study must be designed to incorporate concerns regarding the significance of interstitial cell adenomas. Note that in the former studies (rat and dog), reticulocytes and erythroid precursors were not measured. This is a data gap, since at the high dose level (625ppm), hemosiderin was observed in rats and also at 125 and 625 ppm in the dog.
(This data may be filled by appropriate design inclusion into the required reproduction study above. The registrant must consult with the Agency on the appropriate protocol.)
6/ Mutagenicity and related data are required, which (1) satisfy the 3 mutagenicity testing category requrements, (2) adequately identify the risks , and where possible identify the mechanisms associated with positive findings in rodent chronic studies. Data must be submitted no later than six months from the receipt date of this guidance package. The Agency needs these data for the special review of linuron.
7/ The Agency is requiring data, relating levels of sulf- and methemoglobin following dietary exposure for certain substituted phenyl urea compounds such as linuron. This testing may be combined with other testing involving dietary exposure, such as the reproduction study. Dose levels must be such that a NOEL may be established.
8/ The following four mutagenicity studies have been received and are in Agency review:
   a. "Mutagenicity Evaluation In (Salmonella typhimurium)",HLR 106-83, 5/5/83,
   b. "Unscheduled DNA Synthesis/ Rat Hepatocytes In Vitro", HLR 190-83, 6/3/83,
   c. "CHO/HGPRT Assay for Gene Mutation", HLR 540-83, 12/16/83,
   d. "In Vivo Bone Marrow Chromosome Study in Rats", HLO 378-83, 9/1/83.
9/ N/A= Not applicable for the purposes of this standard.

10/ Data must be submitted no later than six months from the receipt date of this guidance package. The Agency needs these data for the special review of linuron.

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral Toxicity	TGAI	A,B	No	-	Yes
71-2 - Avian Dietary Toxicity	TGAI	A,B	Yes	00034769	No
71-3 - Wild Mammal Toxicity	TGAI		N/A 6/		
71-4 - Avian Reproduction	TGAI		N/A		
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP		5/		
AQUATIC ORGANISM TESTING					
72-1 - Acute Toxicity Freshwater Fish	TGAI	A,B	No	-	Yes
72-2 - Acute Toxicity Freshwater Invertebrates	TGAI	A,B	No	-	Yes
72-3 - Acute Toxicity Estuarine and Marine Organisms	TGAI		N/A		
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI		5/		

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.145 Wildlife and Aquatic Organisms (continued)					
72-5 - Fish - Life-Cycle	TGAI		5/		
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product		5/		
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP		5/		

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact toxicity	TGAI	A,B	Yes	00018842	No
141-2 - Honey bee - toxicity of residues on foliage	TEP		N/A 6/		
141-3 - Wild bees important in alfalfa pollination - toxicity of residues on foliage	TEP		N/A		
141-4 - Honey bee subacute feeding study	(Reserved) 4/				
141-5 - Field testing for pollinators	TEP		N/A		

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.155 Nontarget Insect (continued)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	(Reserved) 5/				
142-2 - Aquatic insect life-cycle study	(Reserved) 5/				
142-3 - Simulated or actual field testing for aquatic insects	(Reserved) 5/				
143-1 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES thru 143-3	(Reserved) 5/				

TABLE A
GENERIC DATA REQUIREMENTS FOR LINURON

§158.145 Wildlife and Aquatic Organisms
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than two years after the receipt of this guidance package.
4/ [Reserved] Requirements reserved pending development of test methodology.
5/ [Reserved] Pending decision as to whether data requirement should be established.

6/ N/A= Not applicable for the purposes of this standard.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING LINURON

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	MP	Partially	00018443, 00018446 00018444, 00018447	Yes
61-2 - Statement of Composition	MP	Partially	00018443, 00018446 00018444, 00018447	Yes
61-3 - Discussion of Formation of Ingredients	MP	No	-	Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	MP	No	-	Yes
62-2 - Certification of Limits	MP	No	-	Yes
62-3 - Analytical Methods for Enforcement of Limits	MP	No	-	Yes
Physical and Chemical Characteristics				
63-2 - Color	MP	No	-	Yes
63-3 - Physical State	MP	No	-	Yes
63-4 - Odor	MP	No	-	Yes
63-5 - Melting Point	MP	No	-	Yes
63-6 - Boiling Point	MP	N/A 4/		
63-7 - Density, Bulk Density, or Specific Gravity	MP	No	-	Yes

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING LINURON

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry (continued)				
63- 8 - Solubility	MP	No	-	Yes 3/
63- 9 - Vapor Pressure	MP	No	-	Yes 3/
63-10 - Dissociation constant	MP	No	-	Yes
63-11 - Octanol/water partition coefficient	MP	No	-	Yes 3/
63-12 - pH	MP	No	-	Yes
63-13 - Stability	MP	No	-	Yes
Other Requirements:				
64- 1 - Submittal of samples	Choice	N/A 4/		

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING LINURON

§158.120 Product Chemistry
(continued)

1/ Composition: MP = Manufacturing-use product; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than six months from the receipt date of this guidance package.
3/ Chemistry data are required because of the Agency's concern for possible groundwater contamination.

4/ N/A= Not applicable for purposes of this standard.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING LINURON

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral Toxicity-Rat	MP	Yes	00027625, 05016511	No
81-2 - Dermal Toxicity	MP	Yes	00027625,	No
81-3 - Inhalation Toxicity-Rat	MP	Yes	00018181	No
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	00018178, 00018183 00018179, 00018196	No
81-5 - Primary Dermal Irritation	MP	Yes	00018180	No
81-6 - Dermal Sensitization	MP	Partially	GS0047-0001	Yes

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING LINURON

§158.135 Toxicology
(continued)

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted no later than six months from the receipt date of this guidance package.

IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This chapter applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10, Appendix IV-1 an IV-2], as indicated by the following paragraphs of this chapter of the guidance document.

You will be informed later when you must submit the revised labeling set forth in this guidance package.

A. Label Contents

40 CFR §162.10 (Appendix IV-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix IV-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix IV-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix IV-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds

and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix IV-1. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." See Appendix IV-1. [40 CFR §162.10(1)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Robert J. Taylor
Phone No. (703) 557-1800
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the revised labeling set forth in this guidance package.

Guide to Use of This Bibliography

1. Content of Bibliography: This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. The bibliography is divided into two sections: (1) citations that contributed information useful to the review of the chemical and that are considered to be part of the data base supporting registrations under the Standard, and (2) citations examined and judged to be inappropriate for use in developing the Standard. This second part of the bibliography exists in the Agency's files and does not accompany this Standard. Interested parties may request a copy from the Agency. 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, and the published technical literature.

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 attempted also 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 by author, date of the document, and title. Each entry bears, to the left of the citation proper, an eight-digit numeric identifier. This number is unique to the citations, and should be used at any time specific reference is required. This number is called the "Master Record Identifier", or "MRID". It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by an eight-character temporary identifier. This is also to be used whenever specific reference is needed.

4. Form of the Entry: In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow;

   a. Author: Whenever the Agency could confidently identify one, 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 author. As a last resort, the Agency had shown the first known submitter as author.

   b. Document Date: When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

   c. Title: This is the third element in the citation. In some cases it has been necessary for 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: Immediately following the word 'received' appears the date of the earliest known submission.

(2) Administrative Number: The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter: The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification: 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', standing 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. For example, within accession number 123456, the first study would be 123456-A; the second 123456-B; the 26th, 123456-Z, and the 27th 123456-AA.

Office of Pesticide Programs
Registration Standard Bibliography
Citations Considered to be Part of the Data Base
Supporting Registration Under the Linuron Standard

00018067 E. I. du Pont de Nemours & Co., Inc. (1961) Residue Data-- Linuron-- Sweetcorn, (unpublished study received April 8, 1963 Under unknown admin. no.; CDL:124702-B)

00018087 California, Department of Food and Agriculture (19??) Determination of Linuron Residues on Asparagus. Undated method. (Unpublished study/received March 20. 1975 under 3E1373; CDL:093663-8)

00018089 California, Department of Agriculture (1974) Linuron Recoveries from Asparagus by Alkaline Hydrolysis (200 gram samples). Method dated July 31, 1974. (Unpublished study received on unknown date under 3E1373; CDL:093662-B)

00018127 E. I. du Pont de Nemours & Co., Inc. (1962) Determination of 3-(3,4-Dichlorophenyl)-1-methoxy-1-methylurea (Linuron) in Soils and Plant Tissue. (Unpublished study received Nov. 8, 1962 under 352-270; CDL:026676-D)

00018148 E. I. du Pont de Nemours & Co., Inc. (1970) Residue Data: Table A, (Unpublished study received Sept. 16, 1971 under 352-270; CDL: 125817-A)

00018167 E.I. du Pont de Nemours & Co., Inc. (1978) Teratogenicity Study of Linuron in Rats: Haskell Laboratory Report No. 33-79. (Unpublshed study received Sept. 13, 1979 under 352-270: CDL: 240982-B)

00018169 Hodge, H.C.; Downs, W.L.; Maynerd, E.A. (1963) Second Reproduction Study of Rats Fed Linuron. (Unpublished study received Oct. 5, 1966 under 7F0542; prepared by Univ. of Rochester, Dept. of Pharmacology, submitted by E. I. du Pont de Nemours & Company, Inc., Wilmington, DE.; CDL:090665-A)

00018170 Powers, M.B. (1965) Reproduction Study-Rabbits. (Unpublished study received Oct. 5, 1966 under 7F0542; prepared by Hazelton Laboratories, Inc., submitted by E. I. du Pont de Nemours & Company, Inc., Wilmington, DE.; CDL:090665-B)

00018171 E. I. du Pont de Nemours & Co., Inc. (1966) Results of Tests on the Amount of Residue in Crops Grown on Treated Soil. (Unpublished study received Oct. 5, 1966 under 7F0542; CDL: 090665-C)

00018172 E. I. du Pont de Nemours & Company, Inc., (1963) Residue Data: Linuron-Carrots: Preemergence Treatment. (Unpublished study study received Oct. 5, 1966 under 7F0542; CDL: 090665-D)

00018173 Belasco, I.J. (1967) Absence of Tetrachloroazobenezene in Soils Treated with Diuron and Linuron. (Unpublished study received on unknown date under 7F0542; submitted by E. I. du Pont de Nemours & Company, Inc., Wilmington, DE.; CDL:092830-A)

00018175 E. I. du Pont de Nemours & Company, Inc., (19??) Residue Data: Linuron-Diuron: Cereal Grains. (Unpublished study received Oct. 14, 1966 under 7F0542; CDL: 092830-D)

00018176 Reasons, K.M.; Furtick, W.R.; Atkeson, G.A.; et al.(1966) Additional Data in Support of Petition. (Unpublished study received Oct. 14, 1966 under 7F0542; submitted by E. I. du Pont de Nemours & Company, Inc., Wilmington, DE.; CDL:092830-G)

00018178 Kapp, R.W. (1975) Final Report: Acute Eye Irritation Potential Study in Rabbits: Project No. 915-104. (Unpublished study received Dec. 19, 1977 under 33660-11; prepared by Hazelton Laboratories America, Inc., submitted by Industria Prodotti Chimici s.p.a.; Novate Milanese, Italy; CDL:232505-B)

00018179 Reno, F.E. (1976) Final Report: Acute Eye Irritation Potential Study in Rabbits: Project No. 915-118. (Unpublished study received Dec. 19, 1977 under 33660-11; prepared by Hazelton Laboratories America, Inc., submitted by Industria Prodotti Chimici s.p.a.; Novate Milanese, Italy; CDL:232505-C)

00018180 Kapp, R.W. (1975) Final Report: Primary Skin Irritation Study in Rabbits: Project No. 915-105. (Unpublished study received Dec. 19, 1977 under 33660-11; prepared by Hazelton Laboratories America, Inc., submitted by Industria Prodotti Chimici s.p.a.; Novate Milanese, Italy; CDL:232505-D)

00018181 Kapp, R.W. (1975) Final Report: Acute Inhalation Toxicity Study in Rats: Project No. M915-103. (Unpublished study received Dec. 19, 1977 under 33660-11; prepared by Hazelton Laboratories America, Inc., submitted by Industria Prodotti Chimici s.p.a.; Novate Milanese, Italy; CDL:232505-E)

00018183 Seaman, L.; Doyle, P.E. (1979) Primary Eye Irritation: Laboratory No. 9E-4148. (Unpublished study received Mar 14, 1979 under 1812-245; prepared by Cannon Laboratories, Inc., submitted by Griffin Corp., Valdosta, GA.; CDL:237806-B)

00018196 Edwards, D.F. (1979) Eye Irritation in Rabbits-EPA Pesticide Registration: Haskell Laboratory Report No. 2-79. (Unpublished study received June 21, 1979 under 352-394; submitted by E. I. du Pont de Nemours & Company, Inc., Wilmington, DE.; CDL:238656-D)

00018206 E. I. du Pont de Nemours & Co., Inc. (1962) Results of Tests on the Amount of Residue in Crops Grown on Treated Soil: Linuron. (Unpublished study received April 13, 1963 under PP0356; CDL: 092640-E)

00018209 E. I. du Pont de Nemours & Co., Inc. (19??) Feeding Study at 1 PPM in Corn Fodder. (Unpublished study received April 13, 1963 under PP0356; CDL: 092640-I)

00018210 E. I. du Pont de Nemours & Co., Inc. (1954?) Feeding Study at 50 PPM in Total Daily Diet. (Unpublished study received April 13, 1963 under PP0356; CDL:092640-J)

00018374 Hodge, H.C.; Downs, W.L.; Maynerd, E.A. (1963) Chronic Feeding Studies of Linuron (Herbicide 326) in Dogs. (Unpublished study received Feb. 7, 1966 under PP0356; prepared by Univ. of Rochester, Dept. of Pharmacology, submitted by E. I. du Pont de Nemours & Company, Inc., Wilmington, DE.; CDL:090386-A)

00018375 E. I. du Pont de Nemours & Co., Inc. (1962) Linuron Livestock Feeding Studies: Milk and Meat. (Unpublished study received Feb. 7, 1963 under PP0356; CDL:090386-B)

00018382 E. I. du Pont de Nemours & Co., Inc. (1962) Residue Data; Linuron--Sweetcorn --- 1962. (Unpublished study received April 13, 1962 under 352-270; CDL: 090385-D)

00018383 E. I. du Pont de Nemours & Co., Inc. (1963) Linuron: Poultry Feeding Studies: Residue Data -- Tissues and Eggs. (Unpublished study received April 13, 1962 under 352-270; CDL: 090385-E)

00018443 E. I. du Pont de Nemours & Co., Inc. (1970) The Results of Tests on the Amount of Linuron Residue Remaining on or in Celery including a Description of the Analytical Method Used. (Unpublished study received April 18, 1971 under 1E1148; submitted by Interregional Research Project No. 4, New Brunswick, N. J.; CDL: 090935-A)

00018444 IR-4 Project at Rutgers, the State University (19??) Annual Weeds Controlled at rates of 0.5 to 2 Pounds Actual Linuron per Acre. (Unpublished study received April 18, 1971 under 1E1148; CDL: 090935-B)

00018446 Agamalian,H.; Ries, S.K.; Boyd, W.I.;et al. (1969) Weed Control Record Sheet: Celery. (Unpublished study received April 18, 1971 under 1E1148; prepareed by Univ. of Calif., Agricultural Extension Service in Cooperation with Michigan State Univ., Barker Chemical Co. nad Univ. of Florida, Everglades Experiment Station, submitted by IR-4, New Brunswick, NJ; CDL:090935-D)

00018447 Orsenigo, J.R. (1966) Postemergence Herbicide for Celery Seedbeds, Pages 159-165, Proceedings of the Florida State Horticultural Society; Oct 24-27, 1966, Miami, FL. N.P. (Also "In" unpublished submission received April 18, 1971 under 1E1148, submitted by IR-4, New Brunswick, NJ; CDL:090935-E)

00018450 E. I. du Pont de Nemours & Co.,Inc. (1961) Du Pont Herbicide 326 Corn. (Unpublished study received on unknown date under PP0356; CDL: 0098656-A)

00018775 E. I. du Pont de Nemours & Co.,Inc. (1961) Linuron-Livestock Feeding Studies. (Unpublished study received on unknown date under PP0356; CDL: 0098656-B)

00018842 Atkins, E. L., Jr.; Anderson, L. D.: Greywood, E. A. (1969) Effect of Pesticides on Apiculture: Project No. 1499; Research Report CF-7501. (Unpublished study received May 8, 1971 under 1F1174; prepared by Univ. of California--Riverside, Dept. of Entomology, submitted by Ciba Agrochemical Co., Summit, N. J.; CDL: 090973-8)

00027624 E. I. du Pont de Nemours & Co., Inc. (1966) Name, Chemical Identity, and Composition: Linuron. (Unpublished study received Oct. 14, 1966 under 7F0542; CDL:092830-E)

00027625 Consultox Laboratories, Limited. (1974) Linuron: Acute Oral and Dermal Toxcity Evaluation: CL74: 46: 996G. (Unpublished study received Dec.19,1977 under 33660-11; submitted by Industrial Prodotti Chimici s.p.a., Nocate Milanese, Italy; CDL:232505-A)

00027635 E. I. du Pont de Nemours & Co.,Inc. (1963) Results of Tests on the Amount of Residue in Crops Grown on Linuron Treated Soils. (Unpublished study received Feb 18. 1963 under PP0413; CDL:090447-B)

00029679 Everett, R.M.; Graepel, G.J.; Blanchfield, T.F.; et al. (1980) 3(3,4-Dichlorophenyl)-1-methoxy-1-methylurea: INZ-326; Lorox® Linuron: Two-year Feeding Study-C6R-CD Rats (Two year Sacrifice). (Unpublished study received Feb. 29, 1980 under 352-270; submitted by E. I. du Pont de Nemours & Co., Inc. Wilmington, Del.; CDL241898-A)

00029680 Kaplan, A.M.; Mclack, J.W.; Hall, C.L.; et al. (1980) Long-Term Feeding Study in Rats with 3(3,4-Dichlorophenyl)-1-methoxy-1-methylurea: INZ-326; Lorox® Linuron: Haskell Laboratory Report No.100-80, (Unpublished study received Feb. 29, 1980 under 352-270; submitted by E. I. du Pont de Nemours & Co., Inc. Wilmington, Del.; CDL241897-A)

00029932 Belasco, I. J. (1979) The Metabolism of 14C-Phenyl Labeled Linuron in the Lactating Nanny Goat. (Unpublished study received Jan. 21, 1980 under 352-270; submitted by E. I. du Pont de Nemours & Co., Inc. Wilmington, Del.; CDL241635-C)

00029933 Shirasu, Y.; Moriya, M.; Watanabe, Y. (1976) Mutagenicity Testing on Linuron in Microbial Sysytems. (Unpublished study received Jan. 21, 1980 under 352-270; prepared by Institute of Environmental Toxicology, Toxicology Div., submitted by E. I. du Pont de Nemours & Co., Inc. Wilmington, Del.; CDL:241635-D)

00034769 Hill, E. F.; Heath, R. G.; Spann, J. W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds. By U. S. Fish and Wildlife Service, Patuxent Wildlife Research Center, Washington, D.C.: U. S. FWS. (Special Scientific Report--Wildlife No. 191; report no. 33423a; also In unpublished submission received March 28, 1979 under 3125-236; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:237905-B)

00124195 Wood, C.; Rickard, R,; Hall, C.; et al. (1982) Long-Term Feeding Study with (Lorox®; Linuron; INZ-326) in Mice. Haskell Laboratory Report No. 758-82 (Unpublished study received on Jan. 13, 1983 under 352-326, submitted by E. I. du Pont de Nemours & Co.,Inc., Wilmington, DE; CDL: 249255-A)

05016511 Hodge, H.C.; Downs, W.L.; Maynerd, E.A.; et al. (1968) Oral Toxicity of Linuron in Rats and Dogs. Food and Cosmetics Toxicology 6(2): 171-183.

05016640 Grover,R. (1975) Adsorption and desorption of urea herbicides on soils. Can. Journal of Soil Science 55(2): 127-135.

05019500 Abernathy, J.R. (1972) Linuron, Chlorbromuron, Nitrofen, and Fluorodifen Adsorption and Movement in Twelve Selected Illinois Soils. Doctoral dissertation. Urbana, Il: Univ. of Illinois at Urbana-Campaign. Univesity Microfilms, Ann Arbor, MI; 73-9861.

GS0047-0001 E. I. du Pont de Nemours & Co., Inc. (1961) Skin Sensitization/ Irritation: Guinea Pig (Unpublished study received Oct. 1961 Under unknown admin. no.; submitted by Haskell Laboratory; CDL:114108)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) 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	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				

63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

cacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:

(1) The data the applicant has submitted to EPA under paragraph (b) of this section;

(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and

(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.

(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:

(1) A notification of the applicant's intent to apply for registration, including the proposed product name;

(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);

(3) An identification of the item(s) of data to which the offer applies;

(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and

(5) The applicant's name, address, and telephone number.

(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on) the Administrator's consideration of) the following data:

(1) All data submitted or specifically cited by the applicant in support of the registration; and

(2) Each other item of data in the Agency's files which:

(i) Concerns the properties or effects of any such active ingredient; and

(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)

[41 FR 27983, May 11, 1976]

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or s...

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling...

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(8) *Final printed labeling.* (i) Except as provided in paragraph (a)(8)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of content.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement.*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two

those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(i) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD$_{50}$	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC$_{50}$	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter.
Dermal LD$_{50}$	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(ii) *Human hazard signal word—(A) Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(iii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iv) *Statement of practical treatment—(A) Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment in some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(v) *Placement and prominence.* All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Required signal word, all capitals	"Keep out of reach of Children"
	Points	Points
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed (inhaled or absorbed through skin). Do not breathe vapor (dust or spray mist). Do not get in eyes, on skin, or on clothing. (Front panel statement of practical treatment required.)	Corrosive, causes eye and skin damage (or skin irritation). Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. (Appropriate first aid statement required.)
II	May be fatal if swallowed (inhaled or absorbed through the skin). Do not breathe vapors (dust or spray mist). Do not get in eyes, on skin, or on clothing. (Appropriate first aid statements required.)	Causes eye (and skin) irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. (Appropriate first aid statement required.)
III	Harmful if swallowed (inhaled or absorbed through the skin). Avoid breathing vapors (dust or spray mist). Avoid contact with skin (eyes or clothing). (Appropriate first aid statement required.)	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	(No precautionary statements required.)	(No precautionary statements required.)

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precau-

tions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

(A) Pressurized Containers

Flash point at or below 20° F; if there is a flashback at any valve opening	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.

(B) Nonpressurized Containers

Flash point	Required text
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(b) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular;" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be

set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definition of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 31139, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 3736, Feb. 9, 1978]

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

RESTRICTED USE PESTICIDE

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER (8A)

ENVIRONMENTAL HAZARDS (8B)

PHYSICAL OR CHEMICAL HAZARDS (8C)

DIRECTIONS FOR USE (10D)

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable) (10A)

CATEGORY OF APPLICATOR

STORAGE AND DISPOSAL (10C)

STORAGE

DISPOSAL

CROP:

RESTRICTED USE PESTICIDE (9A)

FOR RETAIL SALE TO AND APPLICATION ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION

PRODUCT (1) NAME

ACTIVE INGREDIENT: _____ % (6A)
INERT INGREDIENTS. _____ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS CF PER GALLON (6B)

KEEP OUT OF REACH OF CHILDREN (7A)

(7B) DANGER — POISON

 (7C)

(7)

STATEMENT OF PRACTICAL TREATMENT (7D)

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY (2)
TOWN, STATE
ESTABLISHMENT NO. (4)
EPA REGISTRATION NO. (5)
NET CONTENTS (3)

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one (kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene