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DIURON

Pesticide Registration Standard

(035505)

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Office of Pesticides and Toxic Substances

Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

004214

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II. REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

This chapter describes the regulatory position of the Environmental Protection Agency ("the Agency") on diuron based on an evaluation of all registered manufacturing-use products (MUP's) containing diuron as the sole active ingredient. Future requests for registrations 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 and tolerances.

"Diuron" is the accepted common name for the compound, 3-(3,4-Dichlorophenyl) 1,1-dimethylurea recognized by the American National Standards Institute. Trade and other names used for diuron include: Cekiuron®, Dailon®, Diater®, Di-on®, Diurox®, Diurol®, Drexel Diuron 4L®, Dynex®, Karmex®, Unidron®, Urox® and Vonduron®. The Chemical Abstracts Service (CAS) Registry number is 150-68-5. The Office of Pesticides Program's Internal Control Number (EPA Shaughnessy number) is 035505.

B. USE PROFILE

Diuron is a substituted urea herbicide for the control of a wide variety of annual and perennial broadleaved and grassy weeds on both crop and noncrop sites. Usually, diuron is applied to the soil prior to germination of weed seeds or when weeds are in an active growth stage. Adequate moisture must be present to allow movement of the herbicide into the root zone. Diuron also has a limited contact action and is normally applied with a surfactant when used in this manner. The mechanism of action is the inhibition of photosynthesis. Diuron is registered for use on numerous crop sites such as forage crops, field crops, fruits, vegetables, nuts, and ornamental crops. In non-crop applications, diuron is used on industrial sites, on rights-of-way, around farm buildings, and on irrigation and drainage ditches.

Diuron was patented by (ICI) and (Merck) in 1956, (US Patent No. 2,655,445 and 2,768,971) and was first registered for use in 1966. Technical diuron is currently being produced in the United States by E. I. duPont de Nemours and Company.

Diuron is available as a technical material, at 95-98% active ingredient and as a manufacturing use product containing 80% diuron for formulation of diuron end-use formulations or as manufacturing use products. As a sole active ingredient diuron is available in wettable powder, granular, flowables, pelleted/tableted, liquid suspensions, and soluble concentrate formulations.

C. REGULATORY POSITION

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

1. Manufacturing-use pesticide products containing diuron as a sole active ingredient may be registered for sale, distribution, formulation and use in the United States, subject to the terms and conditions specified in this standard. Applicants having products not conforming to this standard must apply to amend the document so those products containing diuron may be registered and reregistered under this standard. Mixtures and end-use products containing diuron are not covered under this standard.

2. Available data do not show that any of the risk criteria listed in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for the uses of diuron specified in this standard.

3. Since studies of linuron (a similar substituted urea compound to diuron) have exhibited testicular adenomas in rats and liver cell adenomas in female mice, the protocols for related studies of diuron should reflect the concerns raised by the linuron data. Currently, the Agency is reviewing the positive oncogenic response of linuron in the rat testes and mouse liver.

4. The Agency believes that the use of diuron on irrigation and drainage ditches in certain states is a food use because of the potential for residues to be found in the irrigated crop. If this use is to be approved, diuron residue data and/or other data demonstrating that such use will or will not result in residues in water or in crops receiving irrigation water will be required. If residues occur in crops, tolerances will be required.

5. Data to support the establishment of reentry protection standards are not required because the Agency has determined that the criteria for 40 CFR § 158.140 have not been met, based on the use patterns and available toxicology data for diuron.

6. During the next year, the Agency will propose changes in the tolerance levels of diuron in or on the commodities listed in 40 CFR, Part § 180.106.

7. Registrants must provide or agree to develop additional data, as specified in the tables attached to this standard, in order to maintain existing registrations or to permit new diuron registrations.

D. REGULATORY RATIONALE

The Agency has determined the following:

1. The available data indicate that technical diuron has low oral and dermal toxicities, and primary dermal and eye irritation. The toxicity categories assigned to diuron are III for oral and dermal toxicities and IV for dermal and eye irritation respectively.

Subchronic dermal testing is waived because of low toxicity shown by the acute oral amd dermal studies. The requirement for a subchronic inhalation study is being deferred until an acute inhalation study has been completed.

In a two-year chronic feeding study(00017764), male and female rats were given diets containing 0, 25, 125, 250, and 2,500 ppm diuron. The authors noted slight anemia, enlarged spleens, increased erythrogenic activity in bone marrow, and abnormal pigments in the blood of groups fed 125 ppm or more. The no-observed-effect-level was 25ppm in rats. No evidence of tumorigenicity was found.

A two-year feeding study(00017763) in male and female dogs was done at levels of 0, 25, 125, 250, and 1,250 ppm diuron in the diet . The 1,250 ppm dose caused weight loss, depressed red cell counts, erythrogenic activity in bone marrow, elevated liver weight, increased pigment deposition in liver cells. Also, abnormal pigments were found in the blood of males at levels higher than 25 ppm and females at levels above 125 ppm. The no-observed-effect-level in dogs was 25 ppm. No evidence of tumorigenicity was found.

However, because of diuron's similarity to linuron, whose studies have shown testicular adenomas in rats and liver cell adenomas in female mice, specially designed studies are needed to fulfill the existing oncogenic data gap for diuron. The protocols for these studies need to consider the ability to detect increases in testicular intersitial cell adenomas in the strain of rats utilized and the dose response at high levels for the mouse.

2. Since diuron is slightly toxic to birds (avian acute oral study ((>2,000 mg/kg) GS0046-010), its uses are not expected to affect avian wildlife.

There are sufficient data to characterize the acute toxicity as moderate to freshwater fish and highly toxic to some invertebrates. Chronic toxicity to freshwater invertebrates is also supported by adequate data.

There are insufficient data to characterize the acute and chronic toxic effects of diuron on estuarine fish, shrimp, and oysters. When additional ecological effects data are submitted, a complete hazard assessment can be made. An aquatic field study may be needed for the aquatic uses pending the outcome of the environmental fate studies.

3. The available environmental fate data are insufficient to fully assess the potential for exposure of humans and non-target organisms to diuron. When additional studies are submitted, a complete environmental exposure assessment can be made.

4. The available diuron product chemistry data are insufficient to fully assess the chemical at this time. The data gaps outlined in the product chemistry data tables are tests needed to adequately support the registration of a diuron product.

5. It is not the Agency's policy to cancel or to withhold registration merely because data are missing or inadequate (See Sections 3(c)(2)(B) and 3(C)(7) of the FIFRA). Rather, publication of this standard provides a mechanism for identifying data needs for registration under the standard and allows for the upgrading of labels during the period in which the required data are being developed. These data will be reviewed and evaluated when they are received and the Agency will determine at that time whether they will affect the registration(s) of diuron.

E. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

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

1. Contain diuron 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.

The applicant for registration or reregistration of products subject to this standard must comply with all terms and conditions described in it, including commmiting to fill data gaps on a schedule agreed to by both this agency and the applicant. All applicants 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 RANGES AND LIMITS

1. Product Composition Standard

Technical grade products must contain at least 95 percent diuron 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 diuron products must be substantially similar to that in currently registered technical products. Any manufacturing-use product not meeting these requirements will be considered a new product and will not be registerable under this standard.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing diuron with toxicity category III for acute oral and dermal toxicities and toxicity category IV for dermal and eye irritation, provided that the labeling of those products bear appropriate precautionary statements.

3. Use Patterns

To be registered under this standard, manufacturing-use products containing diuron may be labeled for formulation only into end-use products for herbicides used for the control of a wide variety of annual and perennial broadleaved and grassy weeds on both crop and noncrop sites. Diuron is registered for use on numerous crop sites such as forage crops, field crops, fruits, vegetables, nuts, and ornamental crops. In noncrop applications, diuron is used on industrial sites, on rights-of-way, around farm buildings, and on irrigation and drainage ditches.

G. REQUIRED LABELING

All technical grade, manufacturing-use, and end-use products containing diuron must bear appropriate labeling stating the sites of use. Other portions of the guidance package contain specific information regarding label requirements as specified in 40 CFR, § 162.10.

In Addition, the following environmental hazard statement must appear on all manufacturing-use product labels:

"This pesticide is toxic to aquatic invertebrates. Do not discharge into lakes, streams, ponds, or public water unless in accordance with an NPDES permit. For guidance, contact your Regional Office of the Environmental Protection Agency".

H. TOLERANCE REASSESSMENT

For diuron, the present Theoretical Maximum Residue Contribution(TMRC) is 0.68325 mg/day/1.5 kg diet and it presently amounts to 182% of an Acceptable Daily Intake (ADI) of mg/kg/day which for a 60 kg person is 0.3750 mg/day.

A reassessment of the diuron tolerances indicates that those originally set for certain commodities in 40 CFR, § 180.106 were too high. The Agency will propose the following reduction of tolerances for apples, citrus fruits, corn in grain or ear form (including sweet corn, field corn and popcorn), potatoes and wheat to a uniform level of 0.6 ppm, and those for meat, fat and meat by products (except liver and kidney) of cattle, goats, hogs, horses, and sheep to 0.2 ppm, with liver and kidney unchanged at 1.0 ppm. These new levels are roughly equivalent to double the maximal observed residue values from the established uses of diuron. Barley, oats, rye and sorghum grains should in the interest of consistency, be reduced to 0.6 ppm at the same time. In this case the TMRC would be reduced to 103% of the ADI. This option is better suited to enforcement and amenable to crop grouping.

A new tolerance application on nectarines is being reviewed by the Agency.

Presently, in the United States tolerances are established for diuron in or on the commodities listed below:

0.1 ppm (Negligible residues) in Bananas, Nuts, and Peaches;

0.5 ppm in Papayas;

1.0 ppm in Apples; Artichokes; Barley grain, Blackberries, Blueberries, Boysenberries, Fat of cattle, goats, hogs, horses, and sheep; Meat of cattle, goats, hogs, horses, and sheep; Meat Byproducts of cattle, goats, hogs, horses, and sheep: Citrus fruits; Corn, field ear; Corn grain; Popcorn, ear; Sweetcorn, ear; Cotton, seed: Currants; Dewberries; Gooseberries; Grapes; Huckleberries, Loganberries; Oats grain; Olives; Pears; Peas; Pineapple; Potatoes; Raspberries; Rye grain; Sorghum grain; Sugarcane; Vetch, seed; and Wheat grain;

2.0 ppm in Alfalfa; Barley forage, hay, and straw; Clover forage and hay; Corn fodder and forage; Popcorn fodder and forage; Sweetcorn fodder and forage; Grass crops and grass hay, (except Bermuda grass and Bermudagrass hay); Rye forage, hay, and straw; Pea forage and hay; Peppermint hay; Sorghum forage and fodder; Oats forage, hay, and straw; Trefoil, birdsfoot forage and hay; Vetch forage and hay; Wheat forage, hay, and straw.

4.0 ppm (food additive) in Dried citrus pulp;

7.0 ppm in Asparagus; and Bermudagrass and Bermudagrass hay.

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has 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 numerically by "Master Record Identifier", or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   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 has 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. 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 (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', 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.

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00017921 E.I. du Pont de Nemours & Co. (19??) Recovery Studies: Diuron—Oats, Vetch, Peas—(Seed): Table 23. (Unpublished study received Dec 10, 1964 under unknown admin. no.; CDL: 120137-Y)

00017922 E.I. du Pont de Nemours & Co. (19??) Recovery Data: Diuron—Oats, Vetch, Hay: Table 24. (Unpublished study received Dec 10, 1964 under unknown admin. no.; CDL: 120137-Z)

00017923 E.I. du Pont de Nemours & Co. (19??) Recovery Data: Diuron—Added to Olives: Table 25. (Unpublished study received Dec 10, 1964 under unknown admin. no.; CDL: 120137-AA)

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

ata 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)?
158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	TGAI	Partially	00020082 00020122 00028099	Yes 2/ 3 mos.
61-2 - Statement of Composition	TGAI	Partially	00017776 00020082 00028099	Yes 6 mos.
61-3 - Discussion of Formation of Ingredients	TGAI	Partially	00020122 05018952	Yes 4/ 12 mos.
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	Partially	00017793 00020082	Yes 3/ 3 mos.
62-2 - Certification of Limits	TGAI	Partially	00020122 00020082	Yes 3/ 3 mos.
62-3 - Analytical Methods for Enforcement of Limits	TGAI	Yes	GS0046-013	No
Physical and Chemical Characteristics				
63-2 - Color	TGAI	No	-	Yes 5/
63-3 - Physical State	TGAI	Yes	00017744 00020122	No
63-4 - Odor	TGAI	Partially	00017744	Yes 5/

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

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)?
Physical and Chemical Characteristics				
63-5 - Melting Point	TGAI	Partially	00017744 00028099	Yes 5/
63-6 - Boiling Point	TGAI	n/a 6/		
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	partially	00020122	Yes 5/
63-8 - Solubility	TGAI OR PAI	No	-	Yes 5/
63-9 - Vapor Pressure	PAI	Yes	00017744 00028099	No
63-10 - Dissociation constant	PAI	n/a		
63-11 - Octanol/water partition coefficient	PAI	No	-	Yes 5/
63-12 - pH	TGAI	n/a		
63-13 - Stability	TGAI	No	-	Yes 5/
Other Requirements:				
64-1 - Submittal of samples	Choice			

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

§158.120 Product Chemistry

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/ Updated information must be supplied on identity and quantity of impurities and inerts.
3/ A certification of ingredient limits must be supplied.
4/ Information on the presence of nitrosoamines is needed.
5/ Data must be submitted no later than twelve months from the issue date of the guidance package.
6/ N/a= Not applicable: Data requirement is not necessary for purposes of this standard.

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

ata 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					
171-4 - Nature of Residue (Metabolism)					
- Plants	PAIRA	Yes	05012084 05016644 05016668 05017270 05017278 05017282 05017776 05018237 05018348 05018749 05018775	05018778 05019000 05019267 05019372 05019491 05019802 05020009 05020294 05020492 05021633	No
- Livestock	PAIRA and plant metabolites	Yes	00015819 00015877 00015886	05016946 05018056	No
171-4 - Residue Analytical Method					
- Plant residues			00016639 05016655 05016663 05016666 05016802 05016941 05017240	05017251 05019371 05020201 05020290 05020316 05020351	No
- Animal residues	TGAI and metabolites	Yes	00015819 00015877	00015886	No
171-4 - Storage Stability Data	PAI	No			Yes

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

ta 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/
58.125 Residue Chemistry					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
- Crop Group					
Alfalfa	TEP	Yes	00017927		No
Apples	TEP	Yes	00017879 00017919	00028025	No
Artichokes	TEP	Yes	00017873 00017887	05018613	No
Asparagus	TEP	Yes	00015898 00017872	00017886	No
Bananas	TEP	Yes	00028062	05017240	No
Barley 3/	TEP	Yes		00017874 00017888	No
Berries 4/	TEP	Yes	00015875 00017738 00017740 00017878 00020134 00027601 00028158 00028160 00017876	00017737 00017739 00017877 00020133 00027600 00028154 00028159 00028161	No

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

ata 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]
Residue Studies				
Citrus fruits	TEP	Yes	00017746 00017751 00028047	No
Cherries	TEP	No	-	Yes [5]
Clover, Forage & hay	TEP	Yes	00017875 00017889	No
Corn [6]	TEP	Yes	00017752 00017754 00017755 00017760 00017894 00017930 00020076 00020077 00024165 00028051 00032183 00052112	No
Cotton, Seed	TEP	Yes	00017811 00028139 00022911 05016614 00028055	No
Grapes (Currants)	TEP	Yes	00015799 00032186	No
Grass, Bermuda [7]	TEP	Yes	00020114	No
Grasses (except Bermuda grass)	TEP	Yes	GS0046-006	No [8]
Nuts	TEP	Yes	00017868 00017892 00028068 00030633	No
Oats [9]	TEP	Yes	00017881 00017882 00017883 00017921 00017922	No
Olives	TEP	Yes	00017884 00017923	No

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

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/
171-4 - Magnitude of the Residue Residue Studies				
Papayas	TEP	Yes	00017741 00017745 GS0046-001	No 10/
Peaches	TEP	Yes	GS0046-002	No 11/
Pears	TEP	Yes	00017880 00017920	No
Peas	TEP	Yes	00017881 00017921	No 12/
Peppermint, hay	TEP	Yes	00017868	No
Pineapples	TEP	Partially	00028055	Yes 13/
Potatoes	TEP	Yes	00028064	No
Rye 14/	TEP	Yes	00017874 00017888	No
Sorghum 15/	TEP	Yes	00017885 00017924	No
Sugarcane	TEP	Yes	00028055 00029724 GS0046-003	No 16/
Trefoil, Birdsfoot forage and hay	TEP	Yes	00028029	No
Vetch 17/	TEP	Yes	00017881 00017921	No
Wheat	TEP	Partially	00017925 00028111 00017926 GS0046-004	Yes 18/

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

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/
171-4 - Magnitude of the Residue Residue Studies				
Processed Crops				
Citrus pulp	TEP	Yes	00017746	No
Pineapple bran	TEP	No	-	Yes 13/
Meat and Milk	TGAI	Yes	00015819 00015877 00015886	No
Poultry and Eggs	TGAI	Yes	GS0046-005	No 19/

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

§158.125 Residue Chemistry

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; PAI = Pure active ingredient; TEP = Typical end-use product.
2/ Data must be submitted no later than 48 months from receipt of this guidance package.
3/ Barley includes barley grain, barley forage, barley hay, and barley straw.
4/ Berries include blackberries, blueberries, boysenberries, currants, dewberries, gooseberries, huckleberries, loganberries, and raspberries.
5/ Data on residues in cherries is needed to support a tolerance (in Utah).
6/ Corn includes corn grain; ears, fodder, and forage of field corn; ears, fodder, and forage of pop corn; and ears, fodder, and forage of sweet corn.
7/ Bermudagrass and Bermudagrass hay.
8/ Grasses and grass hay, except Bermuda grass and Bermudagrass hay: PP42.
9/ Oats includes oat grain, oat forage, oat hay, and oat straw.
10/ Papayas: PP 1E1164, p 19-31.
11/ Peaches: PP 2E1263, Section D, p.13-31.
12/ Peas include peas, pea forage, and pea hay.
13/ Data on residues in dried pineapple bran is required.
14/ Rye includes rye grain, rye forage, rye hay, and rye straw.
15/ Sorghum includes grain, fodder, and forage.
16/ Sugarcane: PP17, Section D, p.1-14,
17/ Vetch includes seed, forage,and hay.
18/ Wheat includes wheat grain, wheat forage, wheat hay and wheat straw. Data on residues in milling fractions of wheat is required: PP220, Section D.
19/ Poultry and eggs: PP356, Supplemental data with letter of March 15,1963, T.W. Hanavan to W.Stokes, submitted by E.I.du Pont de Nemours & Company.

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

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)?
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C,D,E	No	-	Yes 3/
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B,C	No	-	Yes 3/
161-3 - In soil	TGAI or PAIRA	A	No	-	Yes 3/
161-4 - In Air	TGAI or PAIRA	A	n/a 4/	-	
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,D,E	Yes	05020274 05017253	No
162-2 - Anaerobic Soil	TGAI or PAIRA	A 11/	No	-	Yes 3/
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C	No	-	Yes 3/ 5/
162-4 - Aerobic Aquatic	TGAI or PAIRA	C	No	-	Yes 3/
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,C,D,E	Partial	00001450 00040776 00044017 05016640 05017166 05018028 05019132 05019486	Yes 3/ 6/

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GENERIC DATA REQUIREMENTS FOR DIURON

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)?
MOBILITY STUDIES:					
163-1 - Leaching				05019491 05019946 05020274 05020826 05022048	
163-2 - Volatility (Lab)	TEP	A,D	No	-	Yes 3/
163-3 - Volatility (Field)	TEP	A,D	No	-	Yes 3/
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B,E	No	-	Yes 3/
164-2 - Aquatic	TEP	C	No	-	Yes 3/
164-3 - Forestry	TEP	B,C	n/a 4/		
164-4 - Combination and Tank Mixes			n/a 4/		
164-5 - Soil, Long-term	TEP	A 11/	No	-	Yes 3/ 7/

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ata 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)?
ACCUMULATION STUDIES:					
165-1 - Rotational Crops 9/ (Confined)	PAIRA	A	Partially	05020274	Yes 3/ 8/
165-2 - Rotational Crops 9/ (Field)	TEP	A	No	-	Yes 3/
165-3 - Irrigated Crops 10/	TEP	C	No	-	Yes 3/
165-4 - In Fish	TGAI or PAIRA	A,B,C	No	-	Yes 3/
165-5 - In Aquatic Non-Target Organisms	TEP	C	No	-	Yes 3/

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§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, Non-Food; D= Greenhouse, Non-Food; E=Domestic Outdoor.
3/ Data must be submitted no later than four years from the issue date of the guidance package.
4/ N/a= Not applicable: data requirement is not necessary for the purposes of this standard.
5/ This study may substitute for the anaerobic soil metabolism study, but the reverse is not true.
6/ Additional data are needed to assess the mobility of diuron degradation products. Data on the adsorption of DCPMU are acceptable.
7/ Long-term field dissipation studies will be required if the dissipation rate shown by tests per Section 162-1 or 164-1 is less than 50% prior to subsequent application.
8/ All specified data are needed except those for small grains planted 30-120 days after soil treatment.
9/ 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.
10/ In instances where water from treated irrigation or drainage ditches becomes contaminated with pesticide residues, any one of the following will apply:
   a. A tolerance must be obtained for any crop exposed to contaminated water,
   b. The product label must include a restriction against the use of water containing pesticide residues on crops grown for food or feed,
   c. Data must be provided to demonstrate conditions under which water exposed to treated irrigation or drainage ditches can be used on crops without resulting in illegal plant residues.
11/ Required for field and vegetable crop uses only.

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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 LD_{50} - Rat	TGAI	A,B,C,D,E	Yes	00028006	No
81-2 - Dermal LD_{50}	TGAI	A,B,C,D,E	Yes	00017795	No
81-3 - Inhalation LC_{50} - Rat	TGAI	A,B,C,D,E	No	DAC 001473	Yes, 14 months
81-6 - Dermal Sensitization	TGAI	A,B,C,D,E	No	-	Yes
81-7 - Acute Delayed Neurotoxicity-Hen	TGAI	A,B,C,D,E	n/a 3/		
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A,B,C,D,E	n/a		
82-2 - 21-Day Dermal	TGAI	A,B,C,D,E	n/a		
82-3 - 90-Day Dermal	TGAI	A,B,C,D,E	n/a		
82-4 - 90-Day Inhalation - Rat	TGAI	A,B,C,D,E	No	-	Deferred 4/
82-5 - 90-Day Neurotoxicity-Hen/Mammal	TGAI	A,B,C,D,E	n/a		

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

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	00017763 00017764	No
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	A & B	No	-	Yes 5/
83-3 - Teratogenicity - 2 species	TGAI	A & B	Partially	00017763 00027598 05018751	Yes, 6 months 6/
83-4 - Reproduction, 2-generation	TGAI	A & B	Yes	GS0046-012	No
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A & B	No	-	Yes, 26 months 7/
84-2 - Chromosomal Aberration	TGAI	A & B	No	-	Yes, 26 months 7/
84-2 - Other Mechanisms of Mutagenicity	TGAI	A & B	No	-	Yes, 26 months 7/

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

ata 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)?
58.135 Toxicology (continued)					
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A & B	Partially	00037664 05017260	Yes, 24 months 8/
85-2 - Domestic Animal Safety	Choice				

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

§158.135 Toxicology

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; PAI = Pure active ingredient; TEP = Typical end use product; CHOICE = 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, Non-Food; D=Greenhouse, Non-Food; E=Domestic Outdoor.
3/ N/a = Not applicable: Data requirement is not necessary for the purposes of this standard.
4/ The decision whether testing is required cannot be made until the results of the acute inhalation toxicity testing are submitted and reviewed.
5/ Two oncogenicity tests are required, one in rat and one in another species.
6/ Two teratogenicity studies are required, one in rat and one in another species (rabbit).
7/ The following mutagenicity data are required:
   a. A test for gene mutations in bacterial (Salmonella typhimurium) plate test to include strains TA98 and TA100 with and without activation.
   b. A test for gene mutation in mammalian cells in culture(e.g. mouse lymphoma L5178Y cells using TK locus).
   c. A test for DNA repair induction: in vivo mammalian sister chromatid exchange test.
   d. A test for chromosome effects (either in vivo or in vitro mammalian chromosome aberration analysis).
8/ A radioactive tracer metabolism study in a nonruminant species may be required when the other toxicology data gaps are fulfilled.

TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

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)?
158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI	A,B,C,E	Yes	GS0046-010 3/	No
71-2 - Avian Dietary LC_{50}	TGAI	A,B,C,E	Yes	00028/57 3/	No
71-3 - Wild Mammal Toxicity	TGAI	A,B,C,E	n/a 4/		
71-4 - Avian Reproduction	TGAI	A,B,C,E	n/a 4/		
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A,B,C	n/a 4/		
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50}	TGAI	A,B,C,E	Yes	00003503 3/ GS0046-007 3/ GS0046-008 3/ GS0046-011 3/	No No
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A,B,C,E	Yes	00003503 3/	No
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A,B,C,E	No		Yes 5/
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A,B,C,E	Partial	GS0046-011 GS0046-009	Yes 6/

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

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)?
158.145 Wildlife and Aquatic Organisms (continued)					
72-5 - Fish - Life-Cycle	TGAI		n/a		
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product	A,B,C	Partially	GS0046-011	Yes
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP		Partially	05020229	Reserved 7/

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

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)?
158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact LD_{50}	TGAI	A,B	Yes	00001999	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B	n/a		
141-3 - Wild bees toxicity of residues on foliage	TEP	A,B	n/a		
141-4 - Honey bee subacute feeding study	(Reserved) 8/				
141-5 - Field testing for pollinators	TEP	A,B	n/a		

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

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)?
158.155 Nontarget Insect (continued)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	(Reserved) 9/				
142-2 - Aquatic insect life-cycle study	(Reserved) 9/				
142-3 - Simulated or actual field testing for aquatic insects	(Reserved) 9/				
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved) 9/				

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIURON

§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, Non-Food; D=Greenhouse, Non-Food; E=Domestic Outdoor.
3/ Studies that totally fulfill the data requirements.
4/ N/a: Not applicable= Data requirement is not necessary for the purposes of this standard.
5/ Acute toxicity studies on estuarine fish, shrimp and oysters are required for the citrus, sugarcane and aquatic uses. They may be required for the cotton, corn and soybean uses pending environmental fate data.
6/ Freshwater chronic toxicity studies are required for rights-of way, aquatic, corn, soybean, cotton and citrus uses. The invertebrate life-cycle study requirement has been fulfilled. The freshwater fish chronic study is deficient but can fulfill data requirements. An estuarine life-cycle study on mysid shrimp and an early-life stage study on sheepshead minnow may be required for citrus, sugarcane, corn, soybean, cotton and aquatic uses pending results of the acute toxicity estuarine studies and the environmental fate data.
7/ An actual aquatic field study may be needed for the aquatic uses pending environmental fate data.
8/ Reserved pending development of test methodology.
9/ Reserved pending decision as to whether data requirement should be established.

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TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DIURON

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)?
158.120 Product Chemistry				
Product Identity				
61-1 - Identity of Ingredients	MP	Partially	00020082 00020122 00028099	Yes 2/ 3 mos
61-2 - Statement of Composition	MP	No	00017776 00020082 00028099	Yes 6mos
61-3 - Discussion of Formation of Ingredients	MP	No	00020122 05018952	Yes 2/ 12 mos
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis	MP	Partially	00017793 00020082	Yes 3/ 3 mos
62-2 - Certification of Limits	MP	Partially	00020122 00020082	Yes 3/ 3 mos
62-3 - Analytical Methods for Enforcement of Limits	MP	Yes	GS0046-013	No
Physical and Chemical Characteristics				
63-2 - Color	MP	No	-	Yes 4/
63-3 - Physical State	MP	Yes	00017744 00020122	No
63-4 - Odor	MP	No		Yes 4/

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

ata 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)?
158.120 Product Chemistry (continued)				
63-7 - Density, bulk density, or specific gravity	MP	Partial	00020122	Yes 4/
63-12 - pH	MP	n/a 5/		
63-14 - Oxidizing or reducing action	MP	No	-	Yes 4/
63-15 - Flammability	MP	n/a		
63-16 - Explodability	MP	No	-	Yes 4/
63-17 - Storage Stability	MP	Partial	00017744	Yes 4/
63-18 - Viscosity	MP	n/a		
63-19 - Miscibility	MP	n/a		
Other Requirements				
64- 1 - Submittal of Samples	Choice			

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§158.120 Product Chemistry

1/ Composition: MP = Manufacturing-use product; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Updated information must be supplied on identity and quantity of impurities and inerts.
3/ A certification of ingredient limits must be supplied.
4/ Data must be submitted no later than twelve months from the issue date of the guidance package.
5/ N/a= Not applicable: Data requirement is not necessary for purposes of this standard.

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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 LD_{50} - Rat	MP	Yes	00028006	No
81-2 - Dermal LD_{50}	MP	Yes	00017795	No
81-3 - Inhalation LC_{50}- Rat	MP	No	-	Yes, 14 months
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	00028009	No
81-5 - Primary Dermal Irritation	MP	Yes	00017796	No
81-6 - Dermal Sensitization	MP	No	-	Yes, 14 months 3/

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§158.135 Toxicology
(continued)

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted no later than fourteen months from the issued date of this standard.
3/ A test for dermal sensitization will be required unless the Agency receives a study showing lack of sensitization among workers in the manufacturing plant.

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