UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case norflurazon which includes the active ingredient, 4-chloro-5-(methylamino)-2-(α,α,α-trifluoro-*m*-tolyl)-3-(2*H*)-pyridazinone. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative, Veronica Dutch at (703) 308-8585. Address any questions on required generic data to the Special Review and Reregistration Division representative, Karen Jones at (703) 308-8047.

Sincerely yours,

Lois Rossi, Division Director
Special Review
and Reregistration Division

Enclosures

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

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

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

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

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

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

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

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

NORFLURAZON

LIST A

CASE 0229

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

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NORFLURAZON REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Harry Gaede	Economic Analysis Branch
James Saulmon	Biological Analysis Branch
Margaret Cogdell	LUIS

Environmental Fate and Effects Division

Mary Frankenberry	Science Analysis and Coordination Staff
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Renee Costello	Environmental Risk Characterization Branch
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Dana Spatz	Environmental Fate and Groundwater Branch

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Kathy Martin	Risk Characterization and Analysis Branch
Timothy McMahon	Toxicology Branch II
Carol Lang	Occupational and Residential Exposure Branch
David Miller	Reregistration Support Chemistry Branch

Registration Division

Eugene Wilson	Fungicide-Herbicide Branch
Jonanne Miller	Fungicide-Herbicide Branch
Tina Levine	Registration Support Branch

Special Review and Reregistration Division

Karen Jones	Reregistration Branch
Linda Propst	Reregistration Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

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

GLOSSARY OF TERMS AND ABBREVIATIONS

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

EXECUTIVE SUMMARY

EPA has completed its reregistration eligibility decision regarding the pesticide norflurazon, 4-chloro-5-(methylamino)-2-(α,α,α-trifluoro-*m*-tolyl)-3-(2*H*)-pyridazinone. This decision includes a comprehensive reassessment of the required target data base supporting the use patterns of currently registered products. Norflurazon is a selective preemergent herbicide used to control germinating annual grasses and broadleaf weeds in fruits, vegetables, nuts, cotton, peanuts, soybeans, and various nonagricultural and industrial areas. The Agency has concluded that all products registered for all uses, once amended to reflect the risk mitigation measures imposed in this RED, are eligible for reregistration.

To mitigate potential risks of dermal exposure to pesticide handlers, the Agency is requiring use of Personal Protective Equipment and a Restricted Entry Interval of 12 hours for norflurazon. The Agency has determined that norflurazon exceeds levels of concern for chronic effects to birds and mammals, and for nontarget plant species. Risk mitigation measures including reduced application rates and use precaution statements have been added to the product labels. The registrant has agreed to implement the following risk mitigation measures to further reduce the chronic risk to birds and mammals: 1) clarify the current soil incorporation statements on product labels; and 2) clarify use directions for banded treatments. The Agency is also requiring a surface water label advisory, a ground water label advisory, and a spray drift advisory in order to further reduce the risks of norflurazon to humans and the environment. Additional data on product chemistry, acute toxicity, gene mutation, residue chemistry, plant protection, batch equilibrium, spray drift, and ground water monitoring are required to confirm EPA's risk assessment and conclusions.

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

I. INTRODUCTION

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

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

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of norflurazon. The document consists of six sections. Section I is the introduction. Section II describes norflurazon, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for norflurazon. Section V discusses the reregistration requirements for norflurazon. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Norflurazon
- **Chemical Name:** 4-chloro-5-(methylamino)-2-(α,α,α-trifluoro-*m*-tolyl)-3-(2*H*)-pyridazinone
- **Chemical Family:** Fluorinated pyridazinone
- **CAS Registry Number:** 27314-13-2
- **OPP Chemical Code:** 105801
- **Empirical Formula:** $C_{12}H_9ClF_3N_3O$
- **Trade and Other Names:** Zorial®, Solicam®, and Evital®
- **Basic Manufacturer:** Sandoz Agro, Inc.

B. Use Profile

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

For **Norflurazon**:

Type of Pesticide: Herbicide

Mode of Action: Selective herbicide; suppresses the production of carotenoids through uptake of pesticide in the root system.

Use Sites:

TERRESTRIAL FOOD CROP:
Small Fruit (blackberry, blueberry, caneberries, cranberry, raspberry (black, red); Pome Fruit (pear); Stone Fruit (apricot, cherry, nectarine, peach, plum, prune); Miscellaneous Vegetable (asparagus); Subtropical Fruit (avocado); Tree Nut (filbert (hazelnut), pecan, walnut (English/black)).

TERRESTRIAL FOOD+FEED CROP:
Small Fruit (grapes); Citrus Fruit; Pome Fruit (apple); Tree Nut (almond); Flavoring/Spice Crop (hops); Fiber/Oil Crop (cotton); Legume/Oil Crop (peanuts, soybeans).

TERRESTRIAL NON-FOOD CROP:
Agricultural uncultivated areas; Industrial areas (outdoor); Nonagricultural rights-of-way/fencerows/hedgerows; Nonagricultural uncultivated areas/soils.

Target Pests: Broadleaf weeds, grasses and sedges.

Formulation Types Registered:

Type:	Technical grade, End use
Form:	Crystalline (97.8%), Dry flowable (78.6%), Flowable concentrate (52.7 to 80.0%), and Granular (5.0%)

Methods of Application:

Types of Treatment:
Aerial application, chemigation (drip and/or sprinkler), soil treatment (broadcast and incorporation), spray.

Equipment:
Aircraft, conventional hydraulic sprayers, drip and sprinkler irrigation equipment.

Timing:
Applied in early spring as a preplant or preemergence treatment, or applied in the fall after the plant/tree has gone dormant.

Maximum Rates of Application:

Terrestrial Food Crop
Apricot, Asparagus, Avocado, Blackberry, Blueberry, Cherry, Filbert (hazelnut), Nectarine, Peach, Pear, Pecan, Plum, Prune, Raspberry (black, red), and Walnut (English/black)--Coarse soil-2 lb/A, Medium soil-3 lb/A, Fine soil-4 lb/A;

Cranberry--8 lb/A.

Terrestrial Food+Feed Crop
Almond--Coarse soil-1 lb/A, Medium soil-3 lb/A, Fine soil-4 lb/A; Apple, Grape--Coarse soil-2 lb/A, Medium soil-3 lb/A, Fine soil-4 lb/A;

Citrus fruits--8 lb/A;

Hops--Coarse soil-2.5 lb/A, Medium soil-3.75 lb/A, Fine soil-5 lb/A;

Cotton-Coarse soil-1 lb/A, Medium soil-1.5 lb/A, Fine Soil-2 lb/A; Peanuts, Soybeans--2 lb/A.

Terrestrial Non-food Crop
Industrial areas (outdoor), Nonagricultural rights-of-way/fencerows/hedgerows, Nonagricultural uncultivated areas/soils--4 lb/A.

Use Practices Limitations for Zorial® 80 for Use on Cotton, Peanuts, and Soybeans:

Do not graze livestock in treated areas or cut treated crops for feed. Do not graze or harvest for forage or hay. Do not graze or feed for forage.

Do not apply through any type of irrigation system.

C. Estimated Usage of Pesticide

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

The table below summarizes the pesticides use by site.

AVERAGE ANNUAL USAGE OF NORFLURAZON ON CROPS
RECENT YEARS (1991-1994)

SITE[1]	ACRES GROWN	TYPICAL RATE (lbs. ai/acre)	ACRE TREATMENTS	% OF SITE TREATED	LBS. AI (1,000)	STATE USAGE[2]
Almonds	390,000	1.02	40,000	<10	40 - 60	
Apples	332,300	1.34	9,969	5	10 - 30	CA, OR, PA, WA
Cotton	10,115,000	0.58	2,114,035	20	1,000 - 1,500	AR, LA, MS
Cranberries	28,700	4 - 8	405	<10	10 - 20	WA, OR, WI
Grapefruit	129,600	3.04	20,995	10	50 - 150	FL
Grapes	743,300	1.87	40,882	10	60 - 80	CA, PA
Nectarines	27,000	1.67	5,400	20	10 - 15	CA
Oranges	670,900	3.53	205,295	20	300 - 600	CA, FL
Peaches	104,300	1.26	9,178	10	10 - 30	CA
Pecans	12,000	2	12,000	25	5 - 20	
Plums	41,900	2.23	7,123	20	15 - 25	CA
Soybeans	53,050,000	0.36	76,000	<1	10 - 40	
Other Crops[3]					20 - 40	
TOTAL			**2,541,282**		**1,540 - 2,610**	

[1]Site identification based on REFs.
[2]States listed are those for which norflurazon usage was detected in USDA/NASS surveys.
[3]Other crops include: tangelos, temples, apricots, blueberries, raspberries, sweet and tart cherries, pears, avocados, asparagus, hops, filberts, and walnuts.
Data based on proprietary sources, USDA/NASS, and USDA/NAPIAP surveys.

D. Data Requirements

Data requested in the 1984 Registration Standard for Norflurazon include studies on product chemistry, ecological effects, environmental fate, toxicology and residue chemistry. These data were required to support the uses listed in the Registration Standard. In June 1989, a Second Round Review draft document was completed for norflurazon and the studies required in the Second Round Review document were eventually levied in the August 1990 Data Call-In (DCI). A second DCI was issued in January 1993 requiring groundwater monitoring studies to address concerns about norflurazon's potential to contaminate groundwater. Most recently, in June 1993, a DCI was issued requiring an estuarine study because norflurazon is persistent in water. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Norflurazon was registered in the United States in 1974 as a selective preemergent herbicide used to control germinating annual grasses and broadleaf weeds in certain crop and noncrop areas. A Registration Standard was issued in December 1984. Additional data were required in Data Call-Ins issued in August 1990, January 1993 and June 1993. This Reregistration Eligibility Decision document reflects a reassessment of all data which were submitted in response to the Registration Standard and the subsequent DCIs.

III. SCIENCE ASSESSMENT

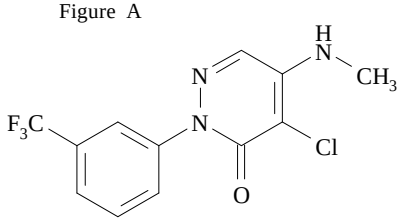
A. Physical Chemistry Assessment

The product chemistry data base is adequate to support reregistration of all pesticide products containing norflurazon as an active ingredient.

1. Identification of Active Ingredient

Norflurazon [4-chloro-5-(methylamino)-2-(α,α,α-trifluoro-*m*-tolyl)-3-(2*H*)-pyridazinone] is a selective herbicide used to control grasses and broadleaf weeds.

Figure A



Empirical Formula:	**$C_{12}H_9ClF_3N_3O$**
Molecular Weight:	**303.7**
CAS Registry No.:	**27314-13-2**
OPP Chemical Code:	**105801**

Norflurazon is a an odorless white crystalline solid with a melting point of 177°C. Norflurazon is noncorrosive and is stable under alkaline and acid conditions, but is sensitive to light. Norflurazon is only slightly soluble in water (<40 ppm) and is moderately soluble in acetone (5 g/100 mL) and ethanol (14.2 g/100 mL).

A search of the Reference Files System (REFS) conducted 3/16/95 identified a single norflurazon manufacturing-use product (MP) registered to

Sandoz Agro, Inc. under Shaughnessy No. 105801, the 97.8% technical (T; EPA Reg. No. 55947-55). Only the Sandoz 97.8% T is subject to a reregistration eligibility decision.

The Norflurazon Guidance Document dated 12/13/84 and the 1989 Second Round Review (SRR) required additional product chemistry data for the only registered manufacturing-use product, the Sandoz 97.8% T. Data submitted in response to the Guidance Document were reviewed in the SRR, and additional data are required for the Sandoz technical concerning GLNs 62-1, 63-17, and 63-20. Nitrosamine analyses were also required under 62-1. Although the Agency has received data from the registrant indicating that nitrosamine levels in the 97% T product are at less than detectable levels (i.e., <0.1 ppm), the Agency has some concerns with the quality of this data as a result of an EPA audit of the performing laboratory. The Agency earlier requested that additional freshly-produced batches of the 97% T be analyzed for nitrosamines, but these data have not yet been submitted by the registrant. Therefore, the Agency cannot at this time make a final judgement as to whether nitrosamine levels would cause dietary exposure concerns. Additional data on nitrosamine analyses for the 97% T are required.

B. Human Health Assessment

1. Hazard and Dose Response Assessment

The toxicological data base on norflurazon is adequate to support reregistration eligibility.

a. Acute Toxicity

Table I. Acute Toxicity Testing Using the Norflurazon Technical

TEST	RESULTS	CATEGORY
Oral LD_{50}--rat 81-1 MRID 00111612	9.3 g/kg (M)	IV
Dermal LD_{50}--rabbit* 81-2 MRID 00090786	>20,000 mg/kg	IV
81-3 Inhalation LC_{50}--rat	acceptable study unavailable	-
Eye Irritation--rabbit 81-4 MRID 00111612	non-irritating up to 7 days post-instillation of test material	IV
Dermal Irritation--rabbit 81-5 MRID 00111612	non-irritating up to 7 days post- application of test material	IV
Dermal Sensitization--guinea pig** 81-6 MRID 00111615	acceptable study unavailable	-

* The purity of the test material was not reported in this study.

** Norflurazon technical at a concentration of 0.1% produced no evidence of sensitization in male guinea pigs. However, the purity of the test material used in this study was not reported, and the positive control assay failed to demonstrate the sensitivity of the sensitization procedure used in this study.

b. Subchronic Toxicity

In a subchronic oral toxicity study, rats of the C.F.E. strain (20/sex) received SAN-9789 (Norflurazon) in the diet for 90 days at doses of 0, 250, 500, or 2500 parts per million (ppm) (0, 12.5, 25, or 125 mg/kg/day). There were no significant effects of norflurazon on survival, body weight, body weight gain or food consumption in male and female rats at any dose level. At the 2500 ppm dose level, the following effects were observed at 13 weeks: an increase in red cell count of 19% in male rats; a decrease in alkaline phosphatase activity of 38% and 42% in male and female rats, respectively; a decrease in aspartate aminotransferase activity of 36% in female rats; an increase in liver weight of 14% and 12% in male and female rats, respectively; an increase in thyroid weight of 96% in male rats; and an increase in the incidence of hypertrophic acinar epithelium and colloid depletion of the thyroid in male rats. At the 500 ppm dose level after 13 weeks of treatment, thyroid weight was increased by 20% in male rats with an increased incidence of hypertrophic acinar epithelium and colloid depletion. In addition, red cell count was increased by 14% in male rats, aspartate aminotranferase was decreased by 10% in female rats, and liver weight was increased by 14% in male rats. The systemic No Observed Effect Level (NOEL) was considered to be 12.5 mg/kg/day in male rats, and 25 mg/kg/day in female rats. The systemic lowest effect level (LEL) was considered to be 25 mg/kg/day in male rats based on an increased red cell count, increased thyroid and liver weight, and increased incidence of hypertrophic acinar epithelium and colloid deposition in the thyroid. The systemic LEL was considered to be 125 mg/kg/day in female rats, based on an increased liver weight and liver to body weight ratio. The decreased alkaline phosphatase and aspartate aminotranferase activity observed in females at this dose were of unknown biological significance. This study was classified as core supplementary data, based on the lack of dose level verification as well as verification of doses received in the diet (guideline §82-1; MRID 00091055). Although this guideline is not satisfied, acceptable chronic toxicity data are available; therefore, the information to upgrade this study to acceptable is requested, but is not required.

A twenty-one day dermal toxicity study was conducted with norflurazon 80% wettable powder (WP). In this study, male and female New Zealand white rabbits (3 males and 3 females) received repeated dermal application of norflurazon 80% WP at doses of 150 mg 80% WP/mL (approximately 375 mg/kg/day) and 400 mg 80% WP/mL (approximately 1000 mg/kg/day), 5 days per week, 6-8 hours per day,

for 21 days. The systemic NOEL is 375 mg/kg/day for males and females, and the systemic LEL is 1000 mg/kg/day for males and females, based on increases in alkaline phosphatase activity, liver weight, and liver to body weight ratio in both sexes. The dermal NOEL is 375 mg/kg/day for both sexes, and the dermal LEL is 1000 mg/kg/day for both sexes, based on slight erythema observed immediately after bandage removal (guideline §82-2; MRID 00063617).

c. Chronic Toxicity and Carcinogenicity

In a 6-month toxicity study, norflurazon technical was administered in the diet to male and female beagle dogs (4/sex/group) at dose levels of 0, 50, 150, or 450 ppm (0, 1.53, 5.02, and 14.27 mg/kg for males; 0, 1.58, 4.77, and 17.75 mg/kg for females). At the 150 ppm dose level, liver weight was increased by 38% in male dogs and by 23% in female dogs. Thyroid weight was increased by 33% in male dogs and 37% in female dogs at this dose level. Also noted at the 150 ppm dose level were increases in cholesterol in both sexes (23-40% in males, 6-34% in females), a decrease in SGPT (36-38% in males, 13-20% in females) and SGOT (4-23% in males, 13-23% in females). At the 450 ppm dose level, similar changes were observed in male and female dogs, with the additional observation of a decrease in red cell count in female dogs (79-92% of control). The systemic NOEL was determined to be 50 ppm (1.53 mg/kg/day [males]; 1.58 mg/kg/day [females]). The systemic LEL was determined to be 150 ppm (5.02 mg/kg/day [males]; 4.77 mg/kg/day [females]), based on increased absolute and relative liver weight and increased cholesterol in both sexes (guideline §83-1; MRID 00111618).

A nine-month oral toxicity study (MRID 00091056) was conducted using the F_0 generation of rats from a two-year carcinogenicity study (MRID 00082019). In this study, rats were given technical norflurazon in the diet at dose levels of 0, 125, 250, or 500 ppm (0, 6.25, 12.5, and 25 mg/kg/day) for 39 weeks. There were no significant effects of norflurazon on survival, body weight, body weight gain, food consumption, food efficiency, hematology, or clinical chemistry in male or female rats at any dose level tested. At 500 ppm, liver weight was increased by 14% and 23% in male and female rats respectively, at 39 weeks. Kidney weight was not significantly affected, but the incidence of hyaline pigment deposition (many tubules) in male rats and hyaline pigment deposition (few tubules) in female rats was increased, as was the incidence of medullary congestion in high dose female rats. The incidence of tubular degeneration was increased in both

sexes at the 500 ppm dose level. Thyroid weight was decreased in males by approximately 30% vs control, while thyroid weight was increased in females between 11-47% vs control. Gonadal weight (left gonad) was increased in female rats by 30%. At 250 ppm, thyroid weight was decreased by 30% in male rats, but was increased by 11-29% in female rats. However, there were no reported microscopic alterations in this organ at any dose level tested. Gonadal weight in female rats was increased by 17% vs. control. The systemic NOEL was determined to be 250 ppm (12.5 mg/kg/day) in both sexes. The systemic LEL was determined to be 500 ppm (25 mg/kg/day) in both sexes, based on the dose-related increase in liver weight in male and female rats at 39 weeks, the increase in gonad weight of females, and the microscopic changes observed in kidneys of both sexes. Although dramatic effects on thyroid weight were observed at 250 ppm in both sexes, there were no data indicating any alteration in histology of this organ. Thus, the weight change, while indicative of an effect of norflurazon, is not supported as a toxic effect based on available data (guideline: non-guideline study; classified as core supplementary; MRID 00091056).

A two-year carcinogenicity study was conducted in male and female CD-1 HaM/ICR Swiss mice in which 125 mice/sex/dose were administered technical norflurazon in the diet at dose levels of 0, 85, 340, or 1360 ppm (0, 12.8, 58.7, or 218.8 mg/kg/day) for 100-104 weeks. No significant effects were observed on body weight, body weight gain, clinical toxicity, or food consumption at any dose level tested. Liver weight was increased by 9% and 15% in male and female mice at the 340 ppm dose level, and by 27% and 21% at the 1360 ppm dose level, respectively. The liver to body weight ratio was increased by 19% and 4% in male and female mice at the 340 ppm dose level, and by 43% and 19% at the 1360 ppm dose level, respectively. Increased incidences of enlarged spleen, nephritis, swollen/enlarged liver, and nodular enlargement of the liver were observed in high dose male mice, while increased incidences of pyelonephritis, enlarged liver, and cystic ovaries were observed in high dose female mice. Carcinogenic potential was evidenced by an increased incidence of hepatic adenoma and combined adenoma/carcinoma in high dose male mice. The systemic NOEL was determined to be 12.8 mg/kg/day (85 ppm) for male mice, and 58.7 mg/kg/day (340 ppm) for female mice. The systemic LEL was determined to be 58.7 mg/kg/day (340 ppm) for male mice, based on the increased incidence of enlarged spleen, increased absolute and relative liver weight, and increased incidence of nephritis. The systemic LEL was determined to be 218.8 mg/kg/day (1360 ppm) for female mice,

based on the increased incidence of enlarged liver and cystic ovaries, the increased absolute and relative liver weight, and the increased incidence of pyelonephritis (guideline §83-2; MRID 00111649).

A chronic toxicity and carcinogenicity study was conducted in Sprague-Dawley rats. In this study, technical norflurazon was administered in the diet at dose levels of 0, 125, 375, or 1025 ppm (0, 6.25, 18.75, or 51.25 mg/kg/day) for 104 weeks. No significant effects of norflurazon were evident for survival, body weight, body weight gain, or food consumption in male or female rats at any dose level tested. At 375 ppm**,** liver weight was increased by 17% and 13% in male and female rats at 52 weeks and by 24% and 27% at 1025 ppm at 52 weeks for both sexes. At 104 weeks, liver weight was increased by 12-14% in male and female rats, and kidney weight by 16-39% vs controls. The weight of the thyroid was also increased at the 1025 ppm dose in male rats at 104 weeks. An increased incidence of hydronephrosis was observed in high dose male rats at 52 weeks vs control, while the incidence of nephritis was increased in male rats (terminal sacrifice + dying on test) at the 1025 ppm dose. The incidence of tubular casts was increased in female rats at the high dose in those rats surviving to study termination. Other microscopic alterations observed at the high dose included an increased incidence of parathyroid hyperplasia (both sexes), hemosiderin pigment deposition in the spleen (males only) and liver (both sexes), and endometritis and squamous metaplasia of the uterus (females).

The systemic NOEL was determined to be 375 ppm (18.75 mg/kg/day) for both sexes. The systemic LEL was determined to be 1025 ppm (51.25 mg/kg/day) in both sexes, based on the increased kidney weight and accompanying microscopic pathologic changes, as well as the increase in liver weight in male and female rats and the increase in thyroid weight in males. There was no evidence of carcinogenicity for norflurazon (guideline 83-5; MRIDs 00111617 and 00082019).

As a result of the July 18, 1990 meeting of the OPP/Health Effects Division Carcinogenicity Peer Review Committee, norflurazon was classified as a non quantifiable Group C - possible human carcinogen - based upon statistically significant pair-wise comparisons of the incidence of liver adenomas and combined liver adenomas/ carcinomas as well as statistically positive trends for these lesions in male CD-1 mice receiving 218.8 mg/kg/day norflurazon technical in the diet for up to 104 weeks (MRID 00111649).

d. Developmental and Reproductive Toxicity

In a developmental toxicity (teratology) study, rats of the Sprague-Dawley strain received either 0, 100, 200, or 400 mg/kg/day norflurazon technical by oral gavage on gestation days 6 through 15 inclusive. The maternal toxicity NOEL was determined to be < 100 mg/kg/day, and the maternal toxicity LEL was determined to be $\leq$ 100 mg/kg/day, based on reductions in body weight gain for the period of dosing and for the dosing plus post-dosing period. The developmental toxicity NOEL was determined to be $\geq$ 400 mg/kg/day, and the developmental toxicity LEL was determined to be > 400 mg/kg/day. Developmental toxicity was suggested at the 400 mg/kg/day dose level in the form of an increase in bipartite thoracic vertebrae (10th-13th) and an increase in rudimentary 14th ribs. However, these increases were not statistically significant and are believed to be secondary to maternal effects at the high dose (guideline 83-3; MRID 00063621).

A developmental toxicity study was conducted in New Zealand White rabbits, which received either 0, 10, 30, or 60 mg/kg/day norflurazon technical by oral gavage on gestation days 7 through 19 inclusive. The maternal toxicity NOEL was determined to be 30 mg/kg/day, and the maternal toxicity LEL was determined to be 60 mg/kg/day, based on decreased body weight gain and clinical toxicity (abortion) at this dose level. The developmental toxicity NOEL was determined to be 30 mg/kg/day, and the developmental toxicity LEL was determined to be 60 mg/kg/day, based on statistically significant increases in the fetal incidence of incompletely ossified frontal bones, 16 caudal vertebrae, unossified first metacarpal, unossified middle phalanx of the fifth digit of the forelimb, and unossified proximal epiphysis of the tibia at the 60 mg/kg/day dose level. A 12% decrease in mean fetal weight was also observed at the 60 mg/kg/day dose level (guideline 83-3; MRID 00131151 and 00131152).

A one-generation reproduction study was conducted in male and female CD-1 (HaM/ICR Swiss) mice. In this study, norflurazon technical was administered in the diet at nominal doses of 0, 85, 170, or 340 ppm (0, 12.1, 24.3, or 48.5 mg/kg/day). There were no treatment-related effects reported in parental mice or in offspring at any of the dose levels tested. The systemic and reproductive NOEL were determined to be $\geq$ 48.5 mg/kg/day, and the systemic and reproductive LEL were determined to be > 48.5 mg/kg/day. This study was classified as core supplementary data (guideline 83-3; MRID 00080751).

A three-generation reproductive toxicity study was conducted in male and female Sprague-Dawley rats. In this study, norflurazon technical (98.8% a.i.) was administered in the diet at nominal doses of 0, 125, 375, or 1025 ppm (0, 6.25, 18.75, or 51.25 mg/kg/day). The F_o generation of rats received norflurazon technical at nominal dose levels of 0, 125, 250, or 500 ppm (0, 6.25, 12.5, or 25.0 mg/kg/day) for 18 weeks prior to mating to produce the F_{1a} and F_{1b} generation. Subsequent to this, the F_{1a} generation was used for a two year feeding study, while the F_{1b} generation received norflurazon technical at 0, 125, 375, or 1025 ppm for 13 weeks and were then mated to produce the F_{2a} and F_{2b} generations. The F_{2a} litter continued to receive test article and were sacrificed just prior to delivery of a second litter (F_{3b}), which was examined for developmental effects. There were no data presented for parental rats in this study. Reproductive data presented indicated no apparent effects of norflurazon treatment on reproductive performance at any dose level tested. The systemic toxicity NOEL was determined to be 18.75 mg/kg/day, and the systemic toxicity LEL was determined to be 51.25 mg/kg/day. The reproductive toxicity NOEL was determined to be $\geq$ 51.25 mg/kg/day and the reproductive toxicity LEL was determined to be > 51.25 mg/kg/day. Due to the lack of parental toxicity data in this study, the systemic toxicity NOEL and LEL were based on the results of subchronic and chronic testing with norflurazon, in which an effect level of 25 mg/kg/day was indicated. However, the Health Effects Division RfD/Quality Assurance Committee determined that it was not appropriate to extrapolate a systemic NOEL/LEL to this study based on effects observed from subchronic and chronic toxicity studies. Nonetheless, the Committee felt that the conclusions drawn from the subchronic and chronic toxicity studies could be used to justify that the dose levels were probably adequate. Therefore, the systemic toxicity NOEL and LEL were considered appropriate (guideline 83-4; MRID 00080750).

A 2-generation reproductive toxicity study was conducted in male and female Wistar rats. In this study, norflurazon technical was administered in the diet at dose levels of 0, 150, 750, or 1500 ppm over 2 generations (0, 10.2, 50.8, or 102.5 mg/kg/day for F_0 males; 0, 12.1, 62.0, or 129.7 mg/kg/day for F_0 females; 0, 13.2, 67.8, or 138.6 mg/kg/day for F_1 males; 17.1, 81.7, and 173.0 mg/kg/day for F1 females). The NOEL for systemic toxicity was determined to be 150 ppm (10.2 mg/kg/day for males and 12.1 mg/kg/day for females), and the systemic toxicity LEL was determined to be 750 ppm (50.8 mg/kg/day for males and 62.0 mg/kg/day for females), based on significant increases in liver and kidney weights observed in both

generations of parental rats and the increased incidence of hepatocellular hypertrophy in both generations of parental rats. The reproductive toxicity NOEL was determined to be 750 ppm (50.8 mg/kg/day for males and 62.0 mg/kg/day for females), and the reproductive toxicity LEL was determined to be 1500 ppm (102.5 mg/kg/day for males and 129.7 mg/kg/day for females), based on an increase in pup deaths, an increase in stillborn pups in the F_{1b} and F_{2a} litters, and a decreased lactation index in the F_{2b} litter (guideline 83-4; MRID 435223-01).

The studies examining developmental and reproductive toxicity of norflurazon were considered by the Health Effects Division RfD/Peer Review Committee in a meeting held March 16, 1995. Overall, the committee concluded that treatment with norflurazon was associated with reproductive toxicity in the form of increased pup death, increased stillborn pups, and increased pup deaths between days 5-14 of lactation at a dose of 1500 ppm. Developmental toxicity was not evident in treated rats, but developmental toxicity in rabbits was evident at a dose of 60 mg/kg/day in the form of decreased mean fetal weight, slight delays in ossification of the skull and limbs, and an increase in the incidence of 13th ribs. These developmental effects occurred at a dose that was maternally toxic.

e. Mutagenicity

In a mutagenicity study, norflurazon technical was tested for the ability to cause mutations in *Salmonella typhimurium* strains TA-1535, 1537, 1538, 98, and 100 and in *Saccharomyces cerevisiae* strain D4 in the absence and presence of metabolic activation (Aroclor 1254 induced rat liver S-9). Norflurazon technical at concentrations of 0, 0.1, 1.0, 10, 100, or 500 μg/plate (non-activation) and concentrations of 0, 0.1, 1.0, 10.0, 100 or 500 μg/plate (activation) [1000 μg/plate for TA1537 in a second assay] showed no evidence of mutagenicity in this study. There was no evidence of cytotoxicity in any of the strains at any of the dose concentrations used. Positive controls appeared adequate for all strains except TA100, where positive controls in the absence and presence of S-9 gave less than 2 times the number of revertants observed in negative controls. In the absence of data demonstrating toxic effects, the highest concentration used in this study is inadequate and higher concentrations should have been assayed (guideline 84-2; MRID 00072974). In an <u>in vitro</u> chromosomal aberration assay, norflurazon did not cause a clastogenic response at doses of 63-500 μg/ml in the absence of liver S-9 and at doses of 125-1000 μg/ml in the presence of S-9 (guideline

84-2; MRID 00155734). In an in vitro unscheduled DNA synthesis assay (UDS), norflurazon at doses ranging from 1-333 μg/ml failed to induce unscheduled DNA synthesis in primary rat hepatocytes (guideline 84-2; MRID 00155375).

f. Metabolism

Norflurazon was administered as single oral doses of 2 or 110 mg/kg, a single i.v. dose of 2 mg/kg, or a single oral dose of 2 mg/kg following administration of 2 ppm in animal diet for 14 days to separate groups of rats. In urine, between 18.5-28.4% of the administered dose was eliminated by 96 hours post-dose, and between 65.3-79.5% of the administered dose was eliminated in feces. Thirteen metabolites of norflurazon were isolated. There appear to be 4 pathways for norflurazon metabolism: N-demethylation; displacement of the chlorine atom by glutathione; glutathione attack on the aromatic ring; and replacement of the chlorine atom by hydrogen (guideline 85-1; MRID 00260490). An additional metabolism study was conducted to determine the presence of the sulfone metabolite in rat excreta after a single low oral dose of 1 mg/kg, or a single high oral dose of 100 mg/kg. The sulfone metabolite was detected in both urine and feces of dosed rats. In urine, the sulfone metabolite accounted for 0.03% of urinary radioactivity at the low dose, and 0.2% of urinary radioactivity at the high dose. The sulfone metabolite accounted for 0.3% of fecal radioactivity at the low dose, and for 0.1% of fecal radioactivity at the high dose (guideline 85-1; MRID 430815-01).

g. Toxic Endpoints of Concern Identified for Use in Risk Assessment

The Health Effects Division's (HED) Less than Lifetime Committee selected the following toxicology endpoints for use in risk assessment for norflurazon (Toxicology Endpoint Selection Document, 4/21/95):

> The endpoint selected for the acute dietary risk assessment is a NOEL of 30 mg/kg/day. This is the developmental NOEL based on increased skeletal variations observed at the dose of 60 mg/kg/day in a rabbit developmental toxicity study.

The Reference Dose (RfD) for norflurazon was established at 0.015 mg/kg/day based upon a chronic toxicity (6 month) study in dogs with a NOEL of 1.58 mg/kg/day (RfD/Peer Review Report of Norflurazon, March 16, 1995). An uncertainty factor of 100 was applied to account for the interspecies extrapolation and intraspecies variability. Norflurazon has not been reviewed by the FAO/WHO Joint Committee on Pesticides Residues (JMPR), and therefore an Acceptable Daily Intake (ADI) has not been established.

A Q_1* has not been established for norflurazon. The Reference Dose (RfD) approach was selected for the quantification of potential human cancer risk.

Dermal absorption of norflurazon is estimated to be 0.1%, based on a rat dermal absorption study (MRID 00086808). It should be noted that dermal absorption estimates were not used/required since a systemic NOEL from a dermal exposure toxicity study was selected as the appropriate endpoint for occupational/residential risk assessment.

The endpoint selected for both the short and intermediate-term occupational/residential exposure assessment is a NOEL of 375 mg/kg/day. This is the systemic NOEL from a 21-day dermal toxicity study in rabbits where increased alkaline phosphatase activity and increased absolute and relative liver weights were observed at the dose level of 1000 mg/kg/day.

2. Exposure Assessment

a. Dietary Exposure

Regulatory Background

The Residue Chemistry Chapter of the Registration Standard was dated 7/6/84. Norflurazon was also the subject of a Residue Chemistry Chapter of the Second Round Review (SRR) Registration Standard

dated 5/10/89. These documents summarized regulatory conclusions of available residue chemistry data and specified that additional data were required for reregistration purposes. Several submissions of data have been received since the 1989 SRR. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to the reregistration of norflurazon.

Tolerances for residues of norflurazon in/on various raw agricultural commodities and processed food/feed commodities are currently expressed as the combined residues of norflurazon (4-chloro-5-(methylamino)-2-(α,α,α-trifluoro-*m*-tolyl)-3-(2*H*)-pyridazinone) and its desmethyl metabolite, 4-chloro-5-(amino)-2-(α,α,α-trifluoro-*m*-tolyl)-3-(2*H*)-pyridazinone [Source: 40 CFR §180.356 (a), §185.4550, and §186.4450]. Rotational crop tolerances have been established for the indirect combined residues of norflurazon and its desmethyl metabolite in/on peanuts and peanut hay, hulls, and vines resulting from the primary application of norflurazon to cotton [Source:40 CFR §180.356 (b)].

Directions for Use

Use directions for norflurazon (EPA Reg No. 55497-78) allow multiple applications during the growing season to the soil around avocado trees, blueberries, citrus trees, grape vines, nut trees, pome fruit trees, and stone fruit trees but do not specify preharvest intervals (PHIs) for these crops. The label for the 78.6% DF (EPA Reg. No. 55497-78) must be amended to include PHIs for the above fruit crops.

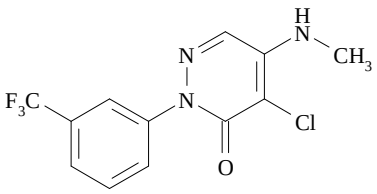
Plant Metabolism

For purposes of risk assessment, the qualitative nature of the residue in plants is adequately understood, and consists of norflurazon and its desmethyl norflurazon metabolite. However, for purposes of reregistration, additional confirmatory information are required in order to upgrade the existing [phenyl-^{14}C]norflurazon metabolism studies on peanuts, cotton, and citrus. Results from the adequate [pyridazinyl-^{14}C]norflurazon plant metabolism study support the registrant's proposed metabolic pathway involving formation of desmethyl norflurazon with subsequent conjugation via the primary amine.

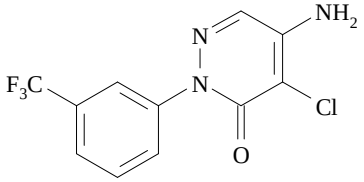
The residues of concern in plants are norflurazon and desmethyl norflurazon, pending submission of confirmatory [phenyl-^{14}C]

norflurazon metabolism studies; the chemical structures of these metabolites are presented in Figure B.

Figure B. Chemical names and structures of norflurazon and its metabolite in plants.



Norflurazon



Desmethyl Norflurazon

Plant metabolism studies reviewed in the norflurazon Residue Chemistry Chapter (7/84) indicated that norflurazon is translocated to the foliage, ears, and grain of corn, the roots of carrots, the foliage and nuts of peanuts, the foliage, heads, and grain of wheat, and the seeds and foliage of cotton. Plant metabolism studies reviewed in the 1989 SRR, although judged inadequate, also indicated that norflurazon is absorbed from the soil by citrus, soybean, and cotton. Conjugated and free forms of norflurazon and its desmethyl metabolite were identified in these plants at maturity. Since the 1989 SRR was issued, peanut, cotton, and citrus [pyridazinyl and phenyl-^{14}C]norflurazon metabolism studies have been submitted. Additional information on radiovalidation, liquid scintillation counts (LSC) and related data, and high performance liquid chromatograms (HPLC) are currently being reviewed by the Agency.

Animal Metabolism

For purposes of risk assessment, the qualitative nature of the residue in ruminants and poultry is adequately understood and consists of parent norflurazon and its desmethyl norflurazon metabolite.

Residue Analytical Methods - Plants and Animals

Methods are available for tolerance enforcement and data collection. Methods I and II listed in the Pesticide Analytical Method (PAM) Vol. II are available for tolerance enforcement for the determination of norflurazon and its desmethyl metabolite in/on cottonseed and cranberries. However, the Agency believes that these

methods may not adequately recover bound residues since they do not involve an initial alkaline hydrolysis step. Pending submission of data from the [^{14}C-phenyl]norflurazon metabolism study which confirms that norflurazon and desmethyl norflurazon residues are the only residues to be included in the tolerance expression, the Agency will recommend that the PAM Vol II methods be replaced with Sandoz Method AM-0820-1292-3 which has undergone EPA Beltsville radiovalidation (by means of Method AM-0820-0592-2), and deemed an adequate enforcement method for determination of these two residues in plants.

Method AM-0875-1092-1, a GC/ECD analytical method for the determination of norflurazon and desmethyl norflurazon in beef liver, kidney, muscle, and fat commodities, has also undergone a successful independent laboratory validation and an EPA Beltsville TMV: the method (subsequently revised and renamed AM-0875-1092-2) is suitable for enforcement purposes and will partially meet EPA's GDLN 171-4(d) requirements after incorporation of pertinent HED comments. The registrant is still required to submit a method and fortification recovery results for milk (but the Agency will not require either independent laboratory validation or a Beltsville TMV if the present method for beef liver, kidney, muscle, and fat is simply updated or modified slightly to incorporate analysis of a milk commodity).

The registrant is still required to submit radiovalidation data for the animal (AM-0875-1092-1) method.

The FDA PESTDATA database dated 1/94 (Pam Vol. I, Appendix II) indicates that norflurazon and desmethyl norflurazon are not recovered using PAM, Vol. I Multiresidue Protocol E Sections 303 or 304 and recoveries using Protocol D are variable.

Storage Stability

The requirements for storage stability data are satisfied for the purposes of reregistration and support the previously submitted RAC residue studies. Residues of norflurazon and desmethyl norflurazon are stable in frozen storage for at least 12 months in apples and milk and at least 39 months on the following commodities: alfalfa forage and hay, almonds, apples, asparagus, cottonseeds, cranberries, grapes, oranges, peaches, peanut forage, peanut hay, peanut hulls, peanut nutmeats, raisins, soybean forage, soybean grain, soybean hay, and walnuts. In addition, these data adequately support the recently submitted grape processing study. However, additional storage stability data were

required to support the storage intervals for processed fractions of citrus (12 months), cottonseed (5 months), and soybeans (6 months). These data were submitted in 12/95 and are currently being reviewed by the Agency.

Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

There are established tolerances for residues of norflurazon and desmethyl norflurazon in milk and meat, fat, and meat by-products of poultry, cattle, hog, horses, goat, and sheep. Tolerances for residues of norflurazon in eggs have not been established.

The norflurazon Guidance Document (12/84) concluded that acceptable data were available to support the established tolerances on meat, milk, and poultry. The HED Metabolism Committee determined that the residues of concern in ruminant commodities are norflurazon and its desmethyl metabolite.

Since total radioactive residues were 0.462 ppm, 0.021 ppm, and 0.101 ppm in poultry liver, fat, and eggs, respectively, following an ca. 100x dosage of [^{14}C-phenyl]-norflurazon to laying hens, the Agency concluded that there is no reasonable expectation of finite residues (40 CFR 180.6(a)(3)) and will not require the submission of a poultry feeding study; the tolerances on poultry commodities should therefore be revoked.

Magnitude of the Residue in Plants

The reregistration requirements for the magnitude of norflurazon residues in plants are fulfilled for almonds, apples, apricots, asparagus, avocados, blackberries, blueberries, cherries, citrus, cottonseed, cranberries, filberts, grapes, hops, nectarines, peaches, peanuts, pears, pecans, plums, raspberries, soybeans, soybean forage and hay, and walnuts. Adequate field trial data depicting residues of norflurazon and its desmethyl metabolite following applications made according to the maximum registered use patterns have been submitted for these commodities. Geographical representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted. Additional data are required on cotton gin by-products. No data are available for cotton-gin byproducts (formerly called cotton gin trash). Based on the revised Table II Residue Chemistry, September 1995, data are required on residues of norflurazon in/on cotton-gin byproducts harvested at normal maturity from plants treated at the

maximum seasonal application rate (2 lb ai/A/season). The cotton must be harvested by commercial equipment (or a simulation thereof) to provide an adequate representation of plant residue from the ginning process. The data should reflect three cropfield trials on stripped cotton and three picked cotton and represent the major U.S. cotton growing regions.

Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for the magnitude of the norflurazon residue in processed food/feed commodities are fulfilled for apples, grapes, hops, and plums. The registrant has submitted supplemental storage stability data for citrus, cottonseed, and soybean processed fractions which are currently being reviewed by the Agency. A summary of the available data and reregistration status for each commodity is presented below.

Apple: The norflurazon Guidance Document (12/84) required apple processing data. The Agency subsequently waived this data requirement because no detectable residues were found in/on apples treated at up to 3x the maximum registered use rate.

Citrus: Acceptable residue data are available for purposes of the risk assessment. However, for purposes of reregistration, acceptable data depicting the frozen storage stability of norflurazon and its desmethyl metabolite in citrus processed commodities for ca. 12 months are required.

The data indicated that the combined residues of norflurazon and desmethyl norflurazon concentrated 5.9x in citrus oil following two preemergence soil applications of the 80% DF formulation at an exaggerated rate of 5x. Provided that storage stability issues are adequately resolved, the data indicate that a 701 Maximum Residue Limit (MRL) for the combined residues of norflurazon and desmethyl norflurazon in/on citrus oil at 0.7 ppm is required. Citrus molasses is no longer considered a significant feed item (Table II, September 1995), and no tolerances are therefore necessary.

Cottonseed: Acceptable residue data are available for purposes of the risk assessment. However, for purposes of reregistration, acceptable data depicting the frozen storage stability of norflurazon and its desmethyl metabolite in cottonseed processed commodities for ca. 5 months are required. Residues of norflurazon and its desmethyl

metabolite were not detected in cottonseed samples that had been treated with a single preemergence soil application of the 80% DF formulation at an exaggerated rate of up to 5x nor were any residues detected in any fraction processed from treated cottonseed (i.e., seeds, hulls, meal, oil, and soapstock) (detection limit of 0.02 ppm). Provided that storage stability issues are adequately resolved, the data indicate that no food/feed additive tolerances are required for cottonseed processed commodities.

Grape: Acceptable residue data are available for grape processed commodities. The combined residues of norflurazon and its desmethyl metabolite in two samples each of raisins, wet pomace, dry pomace, or juice processed from grapes bearing detectable residues following treatment with a single preemergence soil application of the 80% DF formulation at an exaggerated rate of up to 5x were measured at <0.02 ppm. Combined residues in raisin waste were 0.265-0.320 ppm. However, raisin waste (wet pomace and dry pomace) are no longer considered significant feed items. These data indicate that food/feed additive tolerances are not needed for any processed grape commodity.

Plum: Data from a plum processing study (fresh prunes) indicated that no measurable weathered residues occur in plums (fresh prunes) treated at up to 3x the maximum registered use rate. Although the 3x application rate is less than OPP/HED's maximum theoretical concentration factor for plums/prunes, the processing study data available from grapes processed into raisins (considered similar to processing plums into fresh prunes) indicate that no concentration in fresh prunes is likely. No food/feed additive tolerances are required.

Soybean: Acceptable residue data are available for purposes of the risk assessment. However, for purposes of reregistration, acceptable data depicting the frozen storage stability of norflurazon and its desmethyl metabolite in soybean processed commodities are required.

The combined residues of norflurazon and its desmethyl metabolite in two samples each (one from each test) were as follows: soybean hulls, <0.045 and <0.06 ppm; meal, 0.065 and <0.104 ppm; crude and refined oil, <0.04 ppm; and soapstock, <0.04 and <0.052 ppm. The commodities were processed from soybeans treated with a single preemergence soil application of the 80% DF formulation at 2 or 6 lb ai/A (1x and 3x). The Agency concluded that because the 3x treatment rate reportedly affected the growth of the soybeans, the 3x data should not be used to determine if concentration occurs. Therefore,

provided that storage stability issues are adequately resolved, the available data indicate that combined residues of norflurazon and its desmethyl metabolite do not concentrate in soybean hulls, meal, crude oil, refined oil, or soapstock and that food/feed additive tolerances are not required. Also, the Agency has concluded that residue data on the aspirated grain fraction is not required due to the early season use of norflurazon.

Confined Rotational Crops

The nature of the residue in rotational crops is adequately understood. Norflurazon and its desmethyl metabolite are the residues of concern. Sandoz submitted a confined rotational crop study that was reviewed by the Agency. After the submission of additional information to the Agency, the study was deemed adequate. The Agency concluded that the data requirement for confined rotational crops was satisfied, and that a limited field trial in rotational crops study was required.

Field Rotational Crops

Limited field trial data were submitted depicting residues of norflurazon and desmethyl norflurazon in rotational crops planted following a single application of the 80% DF to cotton. The data from the limited field trial indicated that there are detectable residues in rotated crops after a 12-month rotational interval. The Agency required extended field trials for root and tuber vegetables, leafy vegetables, and cereal grains to support a 12-month rotational interval and recommended that a study protocol be submitted for review prior to commencing the studies. A study protocol was reviewed by the Agency and found acceptable providing the registrant follows the Agency's comments and recommendations. In April 1995, the registrant initiated the extended field trials. The final report is due in March 1998.

b. Occupational and Residential

All products containing norflurazon are intended primarily for occupational use. At this time no products containing norflurazon are intended for homeowner use. None of the registered occupational uses are likely to involve applications at residential sites.

The Agency has determined that there is a potential exposure to mixers, loaders, applicators, or other handlers during registered use-patterns associated with norflurazon. Specifically, the Agency is

concerned about potential exposures to handlers during the mixing, loading, flagging, and applying of norflurazon for groundboom, drop-type spreader, ring-drench, rights-of-way, backpack, low-pressure handwand, chemigation, and aerial applications.

Handler (Mixer/Loader and Applicator) Exposure

Generic data from the Pesticide Handler Exposure Database (PHED) version 1.1 were used to determine the potential exposure values for the specified uses of norflurazon.

Based on the use patterns and potential exposures described above, eight major exposure scenarios were identified for norflurazon: a) mixing/loading the granular formulation for drop-type spreader and aerial applications; b) mixing/loading the dry flowable formulation for groundboom and aerial applications; c) mixing/loading the dry flowable formulation for chemigation application; d) applying the granular formulation with a drop type spreader and with aerial equipment; e) applying the dry flowable formulation with groundboom and aerial equipment; f) applying the dry flowable formulation with the rights-of-way equipment; g) flagging for aerial application of the granular formulation; h) flagging for aerial application of the dry flowable formulation; i) mixing, loading, and applying the dry flowable formulation for low-pressure handwand application; j) mixing, loading, and applying the dry flowable formulation for backpack application; and k) mixing, loading, and applying the dry flowable formulation for ring-drench application.

The potential daily dermal dose is calculated using the following formula:

$$Potential\ Daily\ Dermal\ Dose\left(\frac{mg}{Kg\ Day}\right) = Daily\ Dermal\ Exposure\left(\frac{mg}{Day}\right) \cdot \left(\frac{1}{Body\ Weight\ (Kg)}\right)$$

These calculations of potential daily dermal dose of norflurazon received by handlers are used to assess the risk to those handlers. It should be noted that relative to dermal exposures, the estimated inhalation exposures for norflurazon are considered insignificant.

The potential exposure estimates for the above mentioned exposure scenarios are presented in Table III. Table IV summarizes the quality of this exposure data.

Table III. Short and Intermediate-Term Occupational Exposure to Norflurazon.

Exposure Scenario	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (µg/lb ai)	Maximum Label Application Rate[c] (lb ai / Acre)	Daily Maximum Area Treated[d] (Acres)	Daily Dermal Exposure[e,g] (mg/day)	Daily Inhalation Exposure[f,g] (mg/day)
Mixer/Loader						
Mixing/loading granulars for drop type spreader	0.006	1.7	8.0	80	3.8	1.09
Mixing/loading granulars for aerial application	0.006	1.7	8.0	800	38	10.9
Mixing/loading dry flowables for groundboom application	0.07	0.8	`7.86	80	44	0.5
Mixing/loading dry flowables for aerial application	0.07	0.8	1.97	800	110	1.26
Mixing/loading dry flowables for chemigation	0.07	0.8	3.93	800	220	1.26
Applicator						
Rights-of-way Sprayer	1.2	3.9	4.0	10	48	0.16
Granular drop-type spreader	0.01	1.2	8.0	80	6.4	0.77
Groundboom (dry flowable)	0.01	0.7	7.86	80	6.3	0.44
Aerial (granular)	0.002	1.3	8.0	800	12.8	8.3
Aerial (liquid spray)	0.05	0.3	1.97	800	79	0.47
Flagger						
Flagging (granular)	0.003	0.3	8.0	800	19	1.9
Flagging (liquid spray)	0.01	0.3	1.97	800	16	0.47
Mixer/Loader/Applicator						
Low Pressure Handwand (Field Grown Nursery)	4.1 (gloves)	31.2	2.4	2	19.7	0.15
Backpack Sprayer (Field Grown Nursery)	2.5 (gloves)	30.2	2.4	2	12.0	0.14
Ring Drench (dry flowable)	No data	No data	No data	No data	No data	No data

a Mixer/loader assessments are from using open mixing systems and using long pants, long-sleeve shirts, and chemical-resistant gloves. The application and flagger assessments are from using open tractor cabs and open cockpits and using long pants, long-sleeve shirts (no gloves). The mixer/loader/applicator assessments are from using hand-held equipment and long-sleeve shirt, long pants, and chemical-resistant gloves.

b No respirator.

c Label Reg No. 55947-57, 55947-78, 55947-154, 55947-77.

d Values represent the maximum area or the maximum volume of spray solution which can be used in a single day to complete treatments for each exposure scenario of concern.

e Daily dermal exposure (mg/day) = Dermal Unit Exposure (mg/lb ai) * Maximum Application Rate (lb ai/acre) * Maximum Area Treated (acres/day).

f Daily inhalation exposure (mg/day) = Inhalation Unit Exposure (ug/lb ai) * (1mg/1000ug) Unit Conversion * Maximum Application Rate (lb ai/acre) * Maximum Area Treated (acres/day).

g The exposure assessment was based on the minimum PPE that must appear on any label.

Table IV. Exposure Scenario Descriptors for Use of Norflurazon.

Exposure Scenario	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Mixer/Loader			
Mixing/loading granulars for drop type spreader	PHED V1.1	80 acres	**Baseline:** Dermal and inhalation grades acceptable. Dermal = 29 to 45 replicates; Inhalation = 58 replicates. High confidence in dermal and inhalation data.
Mixing/loading granulars for aerial application	PHED V1.1	800 acres	**Baseline:** Dermal and inhalation grades acceptable. Dermal = 29 to 45 replicates; Inhalation = 58 replicates. High confidence in dermal and inhalation data.
Mixing/loading dry flowables for groundboom application	PHED V1.1	80 acres	**Baseline:** Dermal and inhalation grades acceptable. Dermal = 19 to 26 replicates; Inhalation = 23 replicates. High confidence in dermal and inhalation data.
Mixing/loading dry flowables for aerial application	PHED V1.1	800 acres	**Baseline:** Dermal and inhalation grades acceptable. Dermal = 19 to 26 replicates; Inhalation = 23 replicates. High confidence in dermal and inhalation data.
Mixing/loading dry flowables for chemigation	PHED V1.1	800 acres	**Baseline:** Dermal and inhalation grades acceptable. Dermal = 19 to 26 replicates; Inhalation = 23 replicates. High confidence in dermal and inhalation data.
Applicator			
Rights-of-Way Sprayer	PHED V1.1	10 acres	**Baseline:** Dermal and inhalation grades acceptable. Dermal = 0 to 16 replicates; Inhalation = 16 replicates. Low confidence in dermal and high confidence for inhalation data.
Granular drop-type spreader	PHED V1.1	80 acres	**Baseline:** Dermal and inhalation grades acceptable. Dermal = 4 to 5 replicates; Inhalation = 5 replicates. Low confidence in dermal and inhalation data.
Groundboom (dry flowable)	PHED V1.1	80 acres	**Baseline:** Dermal and inhalation grades acceptable. Dermal = 23 to 42 replicates; Inhalation = 22 replicates. High confidence in dermal and inhalation data.
Aerial (granular)	PHED V1.1	800 acres	**Baseline:** Dermal and inhalation all grades. Dermal = 4 to 13 replicates; Inhalation = 13 replicates. Low confidence in dermal and inhalation data.
Aerial (liquid spray)	PHED V1.1	800 acres	**Baseline:** Dermal grades A, B, C and inhalation all grades. Dermal = 9 to 17 replicates; Inhalation = 17 replicates. Low confidence in dermal and inhalation data.
Flagger			
Flagging (granular)	PHED V1.1	800 acres	**Baseline:** Dermal and inhalation all grades. Dermal = 4 to 20 replicates; Inhalation = 4 replicates. Low confidence in dermal and inhalation data.
Flagging (liquid spray)	PHED V1.1	800 acres	**Baseline:** Dermal and inhalation grades acceptable. Dermal = 16 to 18 replicates; Inhalation = 18 replicates. High confidence in dermal and inhalation data.
Mixer/Loader/Applicator			
Low Pressure Handwand (Field Grown Nursery)	PHED V1.1	2 acres	**Baseline:** Dermal all grades and inhalation grades acceptable. Dermal = 15 to 96 replicates; Inhalation = 96 replicates. Low confidence in dermal and inhalation data.
Backpack Sprayer (Field Grown Nursery)	PHED V1.1	2 acres	**Baseline:** Dermal grades A,B,C and inhalation grades acceptable. Dermal = 9 to 11 replicates; Inhalation = 11 replicates. Low confidence in dermal and inhalation data.
Ring Drench (dry flowable)	No data	No data	**Baseline:** No data.

a Standard Assumptions based on a 8-hr work day as estimated by OREB. BEAD data were not available.
b "Acceptable grades," as defined by OREB SOP for meeting Subdivision U Guidelines, are grades A and B. All grades that do not meet OREB's SOP are listed individually.

Post-Application Exposure

There are no data available to address post application exposure for persons reentering areas treated with norflurazon. Based on the use patterns, post-application exposures are expected, particularly following applications in nurseries.

3. Risk Assessment

a. Dietary

Tolerances for norflurazon residues in/on agricultural and animal commodities are published in 40 CFR §180.356, in processed food in §185.4450, and in feed in §186.4450. The available data support the established tolerances on all commodities except hops, citrus oil, and poultry. Changes in the tolerance for citrus oil were not reflected in the DRES analysis since citrus oil is not a DRES commodity; the Agency concluded that poultry commodities are a 40 CFR 180.6(a)(3) situation and the tolerances on poultry commodities should therefore be revoked; Thus, for the purposes of this analysis, only the tolerance for hops was reassessed from 3 ppm to 2 ppm. As hops are now considered a RAC in both the fresh (green) and dried forms, the 1.0 ppm tolerance for hops, green and the 3 ppm tolerance for hops, dried (§185.4550) should be revoked, and a regional 2 ppm tolerance for hops (green and dried) should be established in §180.356(x).

Tolerance level residues and 100 percent crop treated assumptions were made for all commodities. No anticipated residue (AR) information was used in this analysis.

Acute Dietary Risk

The Agency does not have a concern for the acute dietary margin of exposure (MOE) for norflurazon. This is demonstrated by the MOE of 5,000 for females of child-bearing age when considering both the established and the proposed tolerances in the exposure assessment.

Chronic Dietary Risk

The chronic analysis for norflurazon is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with norflurazon. Based on the

exposure estimates in this analysis, chronic dietary risk from the uses of norflurazon being considered for reregistration is not of concern.

A DRES chronic exposure analysis was performed to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. This analysis results in a TMRC which is 10% of the RfD for the U.S. general population. For the highest subgroup, non-nursing infants (<1 year old), this subgroup's TMRC is 47% of the RfD.

b. Occupational and Residential

Risk from Occupational Exposures

Risk (MOE) is calculated as follows:

MOE = NOEL / Potential Daily Dermal Dose.

The NOEL for norflurazon is 375 mg/kg/day. It is a systemic NOEL from a 21-day dermal study.

MOEs, using occupational exposures as described in Table III, were estimated for handlers, and are presented in Table V.

The MOEs for short and intermediate-term occupational exposure subchronic systemic effects are greater than 100 for the exposure scenarios considered. There are no exposure data for the ring-drench application method. However, with the current information the Agency has about the ring drench method of application, ring-drench handlers would likely receive less exposure than from rights-of-way handlers using a hose or cannon on a truck. Since exposure to handlers for the rights-of-way use of norflurazon has been calculated to yield a margin of exposure greater than 100, the Agency expects the handler exposure for the ring drench method of application would also exceed 100. However, the Agency will impose a chemical-resistant glove requirement for ring-drench handlers, due to the lack of exposure data and the fact that chemical-resistant gloves are required for both the other mixer/loader/applicator scenarios.

Handler exposure studies are not required for norflurazon at this time.

Risk from Post-Application Exposure

There are no data available to address post application exposure for persons reentering areas treated with norflurazon. However, the Agency notes that: (1) the toxicological endpoint is based on relatively minor systemic effects, (2) the effects were observed at the dose-level of 1000 mg/kg/day, and (3) the MOEs for all handlers (using the NOEL of 375) were greater than 100 without the use of additional PPE, other than chemical-resistant gloves. These considerations have led the Agency to conclude that the risks from post-application exposures to norflurazon would be acceptable, provided entry does not occur immediately following application. Therefore, post-application exposure data are not required at this time.

Table V. Occupational Risks Associated with Uses of Norflurazon.

Exposure Scenario[a]	Daily Dermal Dose[b] (mg/kg/day)	Dermal MOE[c]
Mixer/Loader		
Mixing/loading granulars for drop type spreader	0.055	6800
Mixing/loading granulars for aerial application	0.55	680
Mixing/loading dry flowables for groundboom application	0.63	600
Mixing/loading dry flowables for aerial application	1.6	240
Mixing/loading dry flowables for chemigation	1.6	240
Applicator		
Rights-of-Way Sprayer	0.69	543
Granular drop type spreader	0.091	4100
Groundboom (dry flowable)	0.09	4200
Aerial (granular)	0.18	2050
Aerial (liquid spray)	1.1	330
Flagger		
Flagging (granular)	0.27	1400
Flagging (liquid spray)	0.23	1700
Mixer/Loader/Applicator		
Low Pressure Handwand (Field Grown Nursery)	0.28 (gloves)	1,339
Backpack Sprayer (Field Grown Nursery)	0.17 (gloves)	2,206
Ring Drench (dry flowable)	No data	No Data

a Mixer/loader assessments are from using open mixing systems and using long pants, long-sleeve shirts, and chemical-resistant gloves. The application and flagger assessments are from using open tractor cabs and open cockpits. and using long pants and long-sleeve shirts (no gloves). The mixer/loader/applicator assessments are from using hand-held equipment and long-sleeve shirt, long pants, and chemical-resistant gloves.

b Potential Daily Dermal Dose = Daily Dermal Exposure/Body Weight. Default body weight is 70 kg.

c MOE = NOEL / Potential Daily Dermal Dose. NOEL = 375 mg/kg/day (systemic NOEL from a 21-day dermal study). In comparison to the dermal route of exposure, inhalation exposure is considered insignificant.

C. Environmental Assessment

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of norflurazon to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail).

Avian Acute Oral Toxicity Findings

Species	% A.I.	LD_{50} mg/kg	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Mallard Duck	Technical	> 2510	00048362, Fink et al./1980	Practically nontoxic	Yes
Mallard Duck	80	> 1000	00092234 Shellenberger/1971	Slightly toxic	Yes for formulated product
Bobwhite Quail	80	> 1000	00092234 Shellenberger/1971	Slightly toxic	Yes for formulated product

Avian Subacute Dietary Toxicity Findings

Species	% A.I.	LC_{50} ppm	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	Technical	> 10,000	00037051 Fink/1972	Practically nontoxic	Yes
Mallard Duck	Technical	> 10,000	00077292 Fink/1972	Practically nontoxic	Yes

These results indicate that norflurazon is practically nontoxic to avian species on an acute oral and subacute dietary basis. The guideline requirements are fulfilled. (MRID 00048362, 00037051 & 00077292)

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed to a pesticide repeatedly or continuously through persistence, bioaccumulation, or multiple applications; or if mammalian reproduction tests indicate reproductive hazard. Norflurazon is persistent; therefore, avian reproduction studies were required.

Avian Reproduction Toxicity Findings

Species	% A.I.	NOEC ppm	LOEC ppm	Endpoints affected	MRID No. Author/Year	Fulfills Guideline Requirement
Northern Bobwhite	99.4	40	200	Reduced hatching success	42615301 Beavers et al./1992	Yes
Mallard Duck	99.4	40	200	Hatchling weight	42615302 Beavers et al./1992	Yes
Northern Bobwhite	98.8	40	> 40 ppm (two test levels - 4 & 40 ppm)	None	00039222 Fink/1972	No - this study will be considered supplemental.
Mallard Duck	98.8	40	> 40 ppm	None	00037051 Fink/1972	No - considered supplemental

These studies indicate that avian reproductive effects may occur at levels as low as 200 ppm. The guideline requirements are fulfilled. (MRID 42615301 & 42615302)

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. Acute toxicity studies show that norflurazon is not acutely toxic to the animals tested to date. Based on these conclusions and expected exposure, wild animal testing was not required for norflurazon.

In most cases, an acute oral LD_{50} from the Agency's Health Effects Division (HED) is used to determine toxicity to mammals. This LD_{50} is reported below.

Mammalian Acute Oral Toxicity Findings			
Species	**LD_{50} mg/kg**	**MRID #**	**Toxicity Category**
Rat (small mammal surrogate)	9300	00111612	Practically nontoxic

The available mammalian data indicate that norflurazon is practically nontoxic to small mammals on an acute oral basis. (MRID 00111612)

(4) Insects

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

Nontarget Insect Acute Contact Toxicity Findings					
Species	**% AI**	**LD_{50} μg a.i./bee**	**MRID No. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Honey Bee	97.6 & 80	> 235 & > 90 (respectively)	00146168 Atkins/1985	Practically nontoxic	Yes

There is sufficient information to characterize norflurazon as practically nontoxic to bees. The guideline requirement is fulfilled. (MRID 00146168)

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

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

Freshwater Fish Acute Toxicity Findings					
Species	**% A.I.**	**LC_{50} ppm a.i.**	**MRID No. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Rainbow trout	98.6	8.1	00087863 Stoll et al./ 1981	Moderately toxic	Yes
Bluegill Sunfish	98.6	16.3	00087862 Stoll et al./ 1981	Slightly toxic	Yes
Rainbow trout	Technical	N/A	00049204 Vilkas & Seminara/1980	N/A	No
Bluegill sunfish	Technical	N/A	00048361 Vilkas & Seminara/1980	N/A	No

The results of the 96-hour acute toxicity studies indicate that norflurazon is moderately to slightly toxic to fish. The guideline requirements are fulfilled. (MRID 00087863 & 00087862)

Data from fish early life-stage tests are required if any of the following criteria are met:

○ if the product is applied directly to water or expected to be transported to water from the intended use site;

○ if the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent, regardless of toxicity;

○ if any acute LC_{50} or EC_{50} is less than 1 mg/L;

○ if the EEC in water is equal to or greater than 0.01 of any acute EC_{50} or LC_{50} value;

○ if the actual or estimated environmental concentration in water is less than 0.01 of any acute EC_{50} or LC_{50} value and any of the following conditions exist: a) studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected; or b) physicochemical properties indicate cumulative effects; or c) the pesticide is persistent in water (e.g. half-life greater than 4 days).

Using these criteria, fish early-life stage testing was required for norflurazon.

Fish Early Life-Stage Toxicity Findings							
Species	**% A.I.**	**NOEC ppm**	**LOEC ppm**	**MATC ppm**	**MRID No. Author/Year**	**Endpoints Affected**	**Fulfills Guideline Requirement**
Rainbow trout	96.6	0.77	1.5	>0.77, <1.5	00248839 EG&G Bionomics/1982	Survival & growth of larvae	Yes
Fathead Minnow	96.6	1.1	2.1	>1.1, <2.1	00248828 EG&G Bionomics/1982	Weight & length development	Yes

The results indicate that adverse chronic effects to fish may occur at levels as low as 1.5 ppm. The guideline requirement is fulfilled. (MRID 00248839 & 00248828)

(2) Freshwater Invertebrates

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

Freshwater Invertebrate Toxicity Findings					
Species	**% A.I.**	**EC_{50} ppm**	**MRID NO. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Daphnia magna	99.4	> 15 (NOEC = 15)	00035709 Vilkas/1980	Slightly toxic	Yes

There is sufficient information to characterize norflurazon as slightly toxic to aquatic invertebrates. The guideline requirement is fulfilled. (MRID 00035709)

Aquatic invertebrate life-cycle tests are required if the criteria specified for the fish early life stage test are met. Therefore, aquatic invertebrate life-cycle testing was required.

Aquatic Invertebrate Life-Cycle Toxicity Findings							
Species	**% A.I.**	**NOEC ppm**	**LOEC ppm**	**MATC ppm**	**ACC. No. Author/Year**	**Endpoints Affected**	**Fulfills Guideline Requirement**
Daphnia magna	96.6	1.0	2.6	> 1.0, < 2.6	FAONOR03 EG&G Bionomics/1983	% survival & offspring production	Yes

The results indicate that chronic adverse effects to aquatic invertebrates may occur at levels as low as 2.6 ppm. The guideline requirement is fulfilled. (ACC.# FAONOR03)

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. Norflurazon is to be aerially applied to crops associated with estuarine and marine habitats (citrus, cotton, cranberries and soybeans) and it is persistent in water. Consequently, estuarine/marine toxicity studies were required.

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

Estuarine/Marine Acute Toxicity Findings

Species	% A.I.	LC_{50}/EC_{50} (mg/L)	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Atlantic oyster embryo larvae	98.8	NOEL > 10 mg/L	00045704 Bentley/1973	Slightly toxic	Yes
Mysid (*Mysidopsi bahia*)	99.4	5.53 (NOEC = 2.29)	42080402 Reed et al./1991	Moderately toxic	Yes
Sheepshead minnow	99.4	9.58 (NOEC = 4.58)	42080403 Reed et al./1991	Moderately toxic	Yes
Eastern oyster shell deposition	98.6	3.8 (NOEC = 1.2)	43041802 Graves & Swigert/1993	Moderately toxic	Yes
Grass shrimp & mud crab	98.8	N/A	00158302 Bentley/1973	N/A	No

There is sufficient information to characterize norflurazon as slightly to moderately toxic to estuarine/marine organisms. The guideline requirement is fulfilled. (MRID 00045704, 42080402, 42080403, & 43041802)

c. Toxicity to Plants

(1) Terrestrial

Terrestrial plant testing is required for herbicides which have terrestrial non-residential outdoor use patterns and meet any of the following criteria:

○ if the herbicide appears to move off site of application through volatilization (vapor pressure $\geq 1.0 \times 10^{-5}$mm Hg at 25ºC) or drift (aerial or irrigation);

○ if there are endangered or threatened plant species associated with the site of application.

Tier II seedling emergence, seed germination and vegetative vigor toxicity data on the technical material for the most sensitive species are listed below.

Nontarget Terrestrial Plant Toxicity Findings - Seedling Emergence

Species	% A.I.	Fresh Weight		MRID Author/Year	Fulfills Guideline Requirement
		EC_{25} lbs a.i./A	NOEC lbs a.i./A		
Dicot- radish	99.1	0.08	0.0032	42080404 - Backus, 1991	Yes
Monocot- onion	98.6	0.034	0.08	43312501 - Backus, 1994	Yes
Dicot- mustard	98.6	0.002	0.00064	43312501 - Backus, 1994	Yes

Nontarget Terrestrial Plant Toxicity Findings - Seed Germination

Species	% A.I.	Radicle Length		Seed germination		MRID Author/Year	Fulfills Guideline Requirement
		EC_{25} lbs a.i./A	NOEC lbs a.i./A	EC_{25} lbs a.i./A	NOEC lbs a.i./A		
Dicot- radish	99.1	0.1	4.0	> 100	2.0	42080404 - Backus, 1991	Yes

Nontarget Terrestrial Plant Toxicity Findings - Vegetative Vigor

Species	% A.I.	Fresh weight		MRID Author/Year	Fulfills Guideline Requirement
		EC_{25} lbs a.i./A	NOEC lbs a.i./A		
Dicot- cucumber	99.1	0.06	0.016	42080405 - Backus, 1991	Yes

The results indicate that exposure levels of norflurazon of 0.00065 lbs. a.i./A. or greater may cause detrimental effects to certain terrestrial plants. The guideline requirement for Tier II terrestrial plant testing is fulfilled. (MRID 42080405, 42080404, & 43312501)

(2) Aquatic

Aquatic plant testing is required for any herbicide which has outdoor non-residential terrestrial uses that may move off-site of application by runoff or by drift (aerial or irrigation). The following species should be tested: *Kirchneria subcapitata* (formerly known as *Selenastrum capricornutum*), *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

Tier II toxicity data on the technical material are listed below:

Nontarget Aquatic Plant Toxicity Findings

Species	% A.I.	EC_{50} ppb	NOEC ppb	MRID Author/Year	Fulfills Guideline Requirements
Lemna gibba	99.41	86	42.2	42080407 - Hughes & Alexander, 1991	Yes
Kirchneria subcapitata (formerly known as *Selenastrum capricornutum*)	99.41	13	6.23	42080406 - Hughes & Alexander, 1991	Yes

The results indicate that exposure levels of 6.23 ppb or greater may cause significant detrimental effects to the growth and reproduction of certain aquatic plants. The guideline requirement is partially fulfilled. (MRID 42080406 & 42080407)

Aquatic plant testing on the following species should be submitted: *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

2. Environmental Fate

a. Environmental Fate Assessment

The environmental fate of norflurazon is fairly well understood. In general, norflurazon may be described as a persistent and mobile compound. Ground water detections have been reported. Based on laboratory and field data, a Small-Scale Prospective Ground Water Monitoring study was required to better define the potential for norflurazon to contaminate ground water.

The primary route of dissipation appears to be photodegradation. In water, norflurazon degraded when exposed to natural sunlight with a half-life of less than three days. Norflurazon on soil photodegraded with a half-life of 12-15 days. The major degradates are desmethyl norflurazon, deschloroflurazon, and dimers of norflurazon. While photodegradation under laboratory conditions is fairly rapid, particularly in water, these degradative processes are mitigated somewhat under field conditions. Norflurazon reaching surface water or on the soil surface will photodegrade to some extent. However, it is likely that significant photolysis would occur only in the upper few centimeters because of low transmittance of UV light through soil as well as through natural waters with high dissolved and particulate organic loads. Once the compound moves below the surface of the water column or soil, photodegradation will cease.

Norflurazon does not undergo hydrolysis in sterile aqueous solutions of pH 5, 7, and 9. It is also persistent in aerobic soil and flooded aerobic sediment with half-lives of 130 days and 6-8 months, respectively. The degradates desmethyl norflurazon and CO_2 increased to 31-36% and 23-31% at 365 days, respectively in the aerobic soil study. Under anaerobic conditions, norflurazon is even more persistent with a half-life of 8 months in flooded loam sediment. Based on its pattern of formation and levels of accumulation, the degradate desmethyl norflurazon appears to be very persistent under both aerobic and anaerobic conditions.

Norflurazon can be generally characterized as mobile to very mobile in soil. Freundlich K_{ads} values ranged from 0.14-7.11 in two sands, a sandy loam, silt loam, clay loam and four loams. Binding appears to be positively correlated with organic matter, clay content, and cation exchange capacity. Desorption constants ranged from 1.4 to 10, indicating that any binding that does occur is reversible. Higher

Freundlich K_{ads} values were found with a clay and two peat soils, (peat soil is representative of the cranberry use area); 26, 72, and 63 respectively.

The mobility of the major degradate, desmethyl norflurazon, is not currently well defined, except in peat soils. Freundlich K_{ads} were 22 and 41 for a Wisconsin peat and a Washington peat, respectively. Based on these data, it can be concluded that desmethyl norflurazon is not mobile in high organic content peat soils.

The terrestrial field dissipation studies submitted to date have been of little value in helping to assess the persistence and mobility of norflurazon and desmethyl norflurazon in the field. Although the accuracy of the field data is questionable, the general indications are that norflurazon persists longer than one year in field soil and may potentially be mobile in some soils. The degradate, desmethyl norflurazon, is also persistent and may accumulate as a result of annual applications of norflurazon.

Fish accumulation data have shown that norflurazon has a low potential to bioaccumulate in bluegill sunfish. Bioconcentration factors ranged from 6 to 8x, 16 to 28x, and 30 to 59x for fillet, whole fish and viscera, respectively.

Norflurazon can contaminate surface water at application via spray drift. Substantial fractions of applied norflurazon could be available for runoff for several months post-application. The relatively low soil/water partitioning of norflurazon indicates that most of norflurazon runoff will generally be via dissolution in runoff water rather than via adsorption to eroding soil. The soil/water partitioning of norflurazon to high organic peat soils (representative of cranberry use areas) is substantially greater such that adsorption to eroding soil may also contribute substantially to the runoff from peat soils.

In most of the water column in surface waters with long hydrological residence times, norflurazon will probably be relatively persistent due to its resistance to abiotic hydrolysis, low volatilization potential (estimated Henry's Law constant of 2.49×10^{-10} atm*m^3/mol) and relatively low susceptibility to degradation under aerobic conditions. Norflurazon may be even more persistent in typically anaerobic sediments because it appears to be even less susceptible to degradation under anaerobic conditions than under aerobic conditions. However, the relatively low soil/water partitioning of norflurazon

indicates that most of the norflurazon mass in surface waters will be dissolved in the water column as opposed to adsorbed to suspended and bottom sediment.

The primary degradate of norflurazon under both aerobic and anaerobic conditions appears to be desmethyl norflurazon, which is persistent. Consequently, substantial amounts in terms of applied parent should be available for runoff for several to many months post-application.

Norflurazon is not currently regulated under the Safe Drinking Water Act (SDWA). Therefore no MCL has been established for it and water supply systems are not required to sample and analyze for it. In addition, the EPA's Office of Drinking Water has not developed any health advisory levels (HALs) for norflurazon. OPP has developed an estimated HAL of approximately 30 ppb that may be compared to levels found in ground water reported below.[1]

Data suggest that norflurazon leaches to ground water as a result of normal agricultural use. The Agency is therefore concerned about the impact of norflurazon on ground water quality. The registrant of norflurazon is currently performing ground water studies for the Agency and the State of Florida, to better evaluate the leaching potential of the herbicide. Appropriate mitigation measures, if any, will be determined on the basis of the results of these studies.

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[1] This estimated HAL was calculated using the NOEL (no effect level) of 3.75 mg/kg/day, assuming a 70 kg adult, 2 liters/day drinking water, and 20% exposure due to drinking water.

$$\text{RFD} = \frac{3.75 \text{ mg/kg/day}}{100 \text{ (safety factor)}} = 0.0375 \text{ mg/kg/day}$$

$$\text{DWEL} = \frac{0.04 \text{ mg/kg/day (70 kg adult)}}{2 \text{ liters/day}} = 1.4 \text{ mg/L}$$

$$\text{HAL} = \frac{1.4 \text{ mg/L}}{10^{*}} \times 20\% = \frac{0.280 \text{ mg/L}}{10} = 0.028 \text{ mg/L (30 ppb)}$$

*For class C carcinogens, the Office of Water applies an additional 10X safety factor to provide additional margin of safety to account for possible carcinogenic effects. The HAL is rounded off to 30 ppb.

b. Environmental Fate and Transport

(1) Degradation

Hydrolysis

Norflurazon does not undergo hydrolysis in sterile aqueous solutions of pH 5, 7, and 9. 4,5-Pyridazinyl-labeled [^{14}C]norflurazon at 0.1 ppm was stable in sterile aqueous buffered solutions adjusted to pH 5, 7, and 9 and incubated in the dark at 25°C for 30 days. During the study, norflurazon ranged from 97 to 99% of the applied and the material balances ranged from 95 to 102% of the applied. (MRID 00146165)

Photodegradation in Water

Norflurazon is very susceptible to photodegradation in water and degrades with a half-life of 2-3 days. Pyridazinyl-labeled [^{14}C]norflurazon at 1 ppm degraded with a half-life of 2-3 days in sterile buffered aqueous solutions (pH 7) maintained at 25°C ± 1°C and irradiated with natural sunlight. At 6 days posttreatment, 7% of the applied [^{14}C]norflurazon remained undegraded in the irradiated samples compared to 95% undegraded in the dark control. Non-volatile degradates identified in the irradiated solutions included desmethyl norflurazon, deschloroflurazon and dimers of norflurazon, one of which was found at 16% at day 6. (MRID 00148311)

Photodegradation on Soil

Exposure to natural sunlight enhances the degradation of norflurazon on soil. Pyridazinyl-labeled [^{14}C] norflurazon at 5 lbs ai/A degraded with an initial half-life of 12-15 days on loam soil irradiated outdoors in sealed flasks with natural sunlight. At 24 days posttreatment, 47% of the applied remained undegraded in the irradiated soil compared to 96% undegraded in the dark control. The major degradate in the irradiated soil, desmethyl norflurazon, was detected at a maximum 6% of the applied (days 15-43). (MRID 00148311)

(2) Metabolism

Aerobic Soil Metabolism

Norflurazon is moderately persistent in loam soil. The degradate desmethyl norflurazon appears to be more persistent than parent. 4,5-Pyridazinyl-labeled [^{14}C]norflurazon at 8.3 µg/g degraded with a half-life of 130 days in loam soil incubated at 22°C and 75% of 0.33 bar moisture. Norflurazon declined from 99% of the applied immediately posttreatment to 12-23% at 365 days posttreatment. The degradate desmethyl norflurazon increased from 1% of the applied immediately posttreatment to 31-36% at 365 days. At 365 days, $^{14}CO_2$ totaled 23-31% of the applied. (MRID 40079601)

Anaerobic Aquatic Metabolism

Norflurazon is persistent under anaerobic aquatic conditions with a half-life of approximately 8 months. 4,5-Pyridazinyl-labeled [^{14}C]norflurazon at 8.3 µg/g degraded with a half-life of approximately 8 months in flooded loam sediment incubated in dim light at 22°C under anaerobic conditions. Norflurazon declined from 94% of the applied radioactivity immediately posttreatment to 41-45% at 365 days. The degradate desmethyl norflurazon reached a maximum concentration of 19% of the applied at 365 days. (MRID 40079601)

Aerobic Aquatic Metabolism

Norflurazon is persistent under aerobic aquatic conditions with a half-life of approximately 6-8 months. 4,5-Pyridazinyl-labeled [^{14}C]norflurazon at 8.3 µg/g degraded with a half-life of approximately 6-8 months in a flooded loam sediment incubated in dim light at 22°C under aerobic aquatic conditions. Norflurazon declined from 98% of the applied immediately posttreatment to 67% at 90 days. The degradate desmethyl norflurazon reached a maximum concentration of 11% of the applied at 90 days posttreatment. (MRID 40079601)

(3) Mobility

Leaching and Adsorption/Desorption

Norflurazon is mobile in some soils, particularly those with low organic content, clay content and CEC's. Freundlich K_{ads} values for ^{14}C-norflurazon were 0.716, 2.37, 2.51, 2.77, and 7.11 for a Moss Landing sand, Salinas sandy loam, Mississippi silt loam, Mississippi sediment, and Gilroy clay loam, respectively. Desorption equilibrium K_{des} values were 1.37, 4.12, 3.56, 3.74, and 10.0 respectively. The results indicate that norflurazon is not strongly adsorbed to the five soils tested and may be mobile in soils, particularly those with low clay content and cation exchange capacities (CEC's).

In the aged study, a 30-day aerobic soil incubation of norflurazon produced only 6% desmethyl norflurazon, with parent comprising over 93% of the radioactivity in the extract. This extract containing primarily norflurazon was then applied to the batch equilibrium system. The calculated partition coefficients are, therefore, largely attributable to parent norflurazon and not its major degradate. There was an insufficient amount of desmethyl norflurazon in the system to generate a reliable partition coefficient. (MRID 41986904)

Based on a batch equilibrium experiment, Freundlich K_{ads} values were 0.14 for a sandy soil, 1.9 for a loam sediment, 1.9-2.3 for three loam soils, and 26 for a clay soil. Adsorption was positively correlated with organic matter, clay content, and CEC based on linear regression analysis. K_{des} values were 3.0-4.0 for the three loam soils, 3.5 for the sediment, and 10.1 for the clay soil.

Based on a column leaching study, unaged ^{14}C-norflurazon was mobile in a column of loam soil leached with deionized water over a 12-day period. 83% of the applied norflurazon was evenly distributed throughout the upper 24 cm of the 40 cm column after application of 51 cm of water. However, only 0.3% of the applied was found in the leachate. (MRID 00148312)

The adsorption/desorption properties of ^{14}C-desmethyl norflurazon were characterized in two peat soils typically found

in U.S. cranberry fields. Freundlich K_{ads} values were 22.1 for a Wisconsin peat and 41.4 for a Washington peat. Freundlich K_{des} values were 50.5 and 76.1 respectively. Based on these data, it can be concluded that ^{14}C-desmethyl norflurazon is not mobile in high organic content peat soils. (MRID 43681001)

Freundlich K_{ads} values for ^{14}C-norflurazon were 72.5 and 62.6 for Wisconsin and Washington peat soils, respectively. Desorption equilibrium K_{des} values were 17.7 and 13.9, respectively. These soils were collected in and are representative of cranberry fields in which norflurazon is used. The results indicate that norflurazon is not mobile in these two peat soils. (MRID 42710901)

(4) Field Dissipation

Soil Field Dissipation

The terrestrial field dissipation studies submitted to date have been of little value in helping to assess the persistence and mobility of norflurazon and desmethyl norflurazon in the field. The studies were found to be unacceptable for various reasons, including: a) inadequate sampling intervals; b) site contamination; c) high variability; d) inadequate sampling depth; e) inadequate number of soil cores per sampling interval; and f) unconfirmed application rates. Although the accuracy of the field data is questionable, the general indications are that norflurazon persists longer than one year in field soil and may potentially be mobile in some soils. The degradate, desmethyl norflurazon, is also persistent and may accumulate as a result of annual applications of norflurazon.

The terrestrial field dissipation data requirement was waived in 1991 in favor of a small-scale prospective ground water monitoring study. It was concluded at that time that sufficient data existed that raised concern about the potential for norflurazon to contaminate ground water. The laboratory and field data demonstrate that norflurazon is persistent and mobile in some soils; therefore, the results of a new field dissipation study would likely trigger a ground water monitoring study. A properly designed study could provide new information as well as address the field dissipation data gaps. The study should track the fate of norflurazon and desmethyl norflurazon from the point

of application and involve sampling soil, soil-water, and ground water. Sites chosen should represent all major terrestrial use sites for norflurazon.

(5) Accumulation

Accumulation in Fish

Norflurazon has a low potential to bioaccumulate in bluegill sunfish. In a flow-through system containing 0.13 mg norflurazon/L, bioconcentration factors (BCF) ranged from 6 to 8x, 16 to 28x, and 30 to 59x for fillet, whole fish and viscera, respectively. The tissue residues after 28 days of exposure were 0.95 mg/kg for fillet, 3.4 mg/kg for whole fish, and 7.7 mg/kg for viscera. The majority of the radioactivity in edible tissue was identified as norflurazon (50 to 57%) and desmethyl norflurazon (33%). Norflurazon accounted for 95 to 103% of the radioactivity in water samples. Tissue residues decreased rapidly during the depuration period with greater than 90%, 96%, and 97% of the radioactivity eliminated from fillet, whole fish, and viscera, respectively, after 14 days. (MRID 41986905)

c. Water Resources

(1) Surface Water

Norflurazon can contaminate surface water at application via spray drift. Substantial fractions of applied norflurazon could be available for runoff for several months post-application (aerobic soil metabolism half-life of 130 days; miscellaneous field data indicating extensive persistence greater than one year post-application). Norflurazon is moderately susceptible to photodegradation on soil (half-life of 12-15 days). However, only norflurazon on foliage or within approximately the top 1 mm of soil will be exposed to sunlight, whereas reversibly bound norflurazon within the top 1 cm or deeper will generally be available for runoff. The relatively low soil/water partitioning of norflurazon (ARS/SCS database K_{oc} of 700; Freundlich K_{ads} values of 0.72-7.1 and K_{des} values of 1.4-10) indicates that most of norflurazon runoff will generally be via dissolution in runoff water rather than via adsorption to eroding soil. The soil/water partitioning of norflurazon to high organic peat soils (representative of cranberry use areas) is substantially greater

such that adsorption to eroding soil may also contribute substantially to the runoff from peat soils.

Norflurazon is susceptible to direct aqueous photolysis (half-life of 2-3 days). However, even in relatively clear waters, sunlight rapidly becomes attenuated with increasing depth. Consequently, the effectiveness of direct photolysis in removing norflurazon from surface water is limited to the water column of clear shallow water bodies and to the upper portions of the water column in other surface waters. In most of the water column in surface waters with long hydrological residence times, norflurazon will probably be relatively persistent due to its resistance to abiotic hydrolysis, low volatilization potential (estimated Henry's Law constant of 2.49×10^{-10} atm*m^3/mol) and relatively low susceptibility to degradation under aerobic conditions (aerobic aquatic metabolism half-life of 6-8 months). Norflurazon may be even more persistent in typically anaerobic sediments because it appears to be even less susceptible to degradation under anaerobic conditions (anaerobic aquatic metabolism half-life of 8 months) than under aerobic conditions. However, the relatively low soil/water partitioning of norflurazon indicates that most of the norflurazon mass in surface waters will be dissolved in the water column as opposed to adsorbed to suspended and bottom sediment.

The primary degradate of norflurazon under both aerobic and anaerobic conditions appears to be desmethyl norflurazon, which is persistent. Consequently, substantial amounts in terms of applied parent should be available for runoff for several to many months post-application. Although the soil/water partitioning of desmethyl norflurazon has not been well characterized, the loss of a methyl group generally decreases the soil/water partitioning of compounds. Consequently, desmethyl norflurazon may exhibit comparable to somewhat lower soil/water partitioning than norflurazon, as appears to be the case for peat soils. Therefore, runoff of desmethyl norflurazon is probably primarily via dissolution in runoff water except from peat soils where adsorption to eroding soil may also contribute significantly to runoff. As with norflurazon, most of the desmethyl norflurazon mass in surface waters is probably dissolved in the water column as opposed to adsorbed to suspended and bottom sediment.

The South Florida Water Management District (Miles and Pfeuffer 1994) summarized norflurazon detections in samples collected every two to three months from 27 surface water sites within the SFWMD from November 1988 through November 1993. Approximately 810 samples (30 sampling intervals X 27 sites sampled/interval) were collected from the 27 sites from November 1988 through November 1993. Norflurazon was detected (detection limits not provided) in 7 samples at concentrations of 0.49, 0.85, 0.82, 1.6, 1.6, 1.6, and 1.7 ug/L. The Louisiana Department of Agriculture and Forestry sampled 32 sites once a month from May through October 1993. Norflurazon was detected (detection limit not provided) in 20 samples at a number of locations at concentrations ranging from 0.39 to 8.39 ug/L. Of the 21 detects, 13 were $\geq$ 1 ug/L of which two (5.81 and 8.39 ug/L) were $\geq$ 5 ug/L.

The monitoring data were derived from multiple pesticide studies. Consequently, they do not necessarily represent watersheds where norflurazon is known to be heavily used. Also, sampling intervals were not designed to collect samples in response to spray drift during norflurazon application and to runoff events following norflurazon applications. Therefore, the reported concentrations in Florida and Louisiana may reflect much less exposure to norflurazon than in watersheds where it is heavily used and less exposure than immediately following application or during post-application runoff events.

(2) Ground Water

Pesticides in Ground Water Database: Few data were included for norflurazon in the 1992 Pesticides in Ground Water Database (PGWDB). The PGWDB indicates that 194 wells had been tested for norflurazon, but none of the results were positive. Of the 194 wells reported, 188 were in Texas, and 6 were in California. The Texas monitoring program was a statewide survey in which analysis was performed for a large suite of chemicals, and was in no way targeted to areas in which norflurazon was used. In fact, norflurazon was not listed among the chemicals reported by well owners as having been used in the vicinity of the sampled wells.

Florida: In November, 1992, the registrant submitted a 6(a)2 report detailing detections of norflurazon in four Polk

County, Florida wells. The maximum concentration was 64 ppb. Further detections in Polk County that occurred in August 1993 were reported in a later 6(a)2 report. Four wells were reported to be contaminated with norflurazon, with a maximum detection of 29 ppb. Norflurazon was subsequently detected in drinking water wells at DeSoto City, in Highlands County. The detections in these wells ranged to 22 ppb.

In response to these detections, the registrant voluntarily began a prospective ground-water monitoring study for the State of Florida in March, 1994. Preliminary results indicate that norflurazon has leached to ground water in wells beneath and just off the edge of the applied field at levels comparable to the previous detections. The concentrations detected range from 0.5 to 21 ppb. Concentrations of norflurazon above the detection limit have been found to persist in some wells for more than a year.

North Carolina: The registrant reported to the EPA in an April 25, 1995 6(a)2 submission that the North Carolina Department of Agriculture detected norflurazon in two samples taken from a newly installed, 18-foot deep monitoring well. The detections were at concentrations of 1.7 and 5.3 ppb.

Small-Scale Prospective Monitoring Study: In light of norflurazon's potential to leach to ground water, the Agency requested in 1992 that the registrant perform a small-scale prospective ground-water monitoring study. They have submitted a protocol that reflects many revisions to the guidance document for prospective ground-water studies, and commenced work in 1995 on such a study, which is located in Macon County, Georgia. No results of ground water analyses from this study are currently available.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC): The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of

LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine if an LOC has been exceeded, a risk quotient must be derived and compared to the LOCs. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g., the estimated environmental concentration (EEC), by an appropriate toxicity test effect level, e.g., the LC_{50}. The acute effect levels typically are:

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

The chronic test results are the:

-NOEL (or NOEC) for avian and mammal reproduction studies, and either the NOEL for chronic aquatic studies, or the Maximum Allowable Toxicant Concentration (MATC), which is the geometric mean of the NOEL and the LOEL (or LOEC) for chronic aquatic studies.

When the risk quotient exceeds the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented along with the corresponding LOCs.

Levels of Concern (LOC) and associated Risk Presumption

Mammals, Birds

IF THE	LOC	PRESUMPTION
acute RQ≥	0.5	High acute risk
acute RQ≥	0.2	Risk that may be mitigated through restricted use
acute RQ≥	0.1	Endangered species may be affected acutely
chronic RQ≥	1	Chronic risk, endangered species may be affected chronically,

Fish, Aquatic invertebrates

IF THE	LOC	PRESUMPTION
acute RQ≥	0.5	High acute risk
acute RQ≥	0.1	Risk that may be mitigated through restricted use
acute RQ≥	0.05	Endangered species may be affected acutely

chronic RQ≥	1	Chronic risk, endangered species may be affected chronically

Plants

IF THE	LOC	PRESUMPTION
RQ≥	1	High risk
RQ≥	1	Endangered plants may be affected

Currently, no separate criteria for restricted use or chronic effects for plants exist.

(1) Exposure and Risk to Nontarget Terrestrial Animals

(a) Birds

Norflurazon residues found on dietary food items following application are compared to LC_{50} values to predict hazard. Chronic hazard is predicted by comparing the residues to the NOEC from a valid avian reproduction study.

The maximum concentrations of norflurazon residues which may occur on selected avian dietary food items following a single application of 7.86 lbs a.i./A (maximum application rate for citrus applied by ring-drench method), and 3.93 lbs a.i./A (typical maximum application rate for citrus and most other use sites) are provided in the table below:

Estimated Environmental Concentrations on Avian Dietary Food Items in PPM

Food items	EEC - 7.86 lbs a.i./A	RQ		EEC - 3.93 lbs a.i./A	RQ	
		Acute	Chronic		Acute	Chronic
Short Grasses	1886	< 0.19	47	943	<0.09	24
Long Grasses	865	<0.09	22	432	<0.04	11
Broadleaf Plants and Insects	1061	<0.11	27	531	<0.05	13
Fruits and Pods	118	<0.01	3	59	<0.006	1

The preceding **acute** risk quotients are not based on a definitive LC_{50} value for birds. Both the bobwhite and the mallard studies failed to determine an LC_{50} since there was not 50% mortality at any of the test levels, including the highest. The information gained from both

studies is that the LC_{50} is above 10,000 ppm. The acute risk quotients in the above table, being calculated based on an LC_{50} being equal to 10,000 ppm, are considered to be greater than the actual acute risk quotients (which are unknown) and thus are overly conservative. These risk quotients should be viewed as the upper limit of what the actual risk quotients could be; the actual risk quotients are unknown and could be much less. Thus, risk quotients greater than the LOC for restricted use and endangered species do not necessarily mean that risk is presumed, but rather that acute risk to endangered species cannot be ruled out based on the limited information available.

The use of norflurazon at rates of 7.86 lb a.i./A may cause adverse effects to endangered species of birds due to acute toxicity. At the use rate of 3.93, the RQs were determined to be less than 0.1, the LOC for presuming adverse effects to these endangered species. Therefore, the Agency concludes there will be no adverse effects to endangered birds by uses of norflurazon which have a maximum label rate of 3.93 lb a.i./A or less. This includes the crops cotton, soybeans, and peanuts. Although not calculated, the RQs for all terrestrial food crop uses which have use rates up to 4 lb a.i./A will also be less than 0.1, thereby yielding the conclusion of no adverse effects to endangered species.

Several reasons why risk to terrestrial birds and mammals would not be as great as predicted by the RQ method could be: First, with the ring drench and banded applications used on citrus, only 30% to 80% of the field receives herbicide application. This does not affect the risk quotient calculations, but it does indicate a somewhat reduced overall risk. Second, growth of weeds is normally prevented around the base of trees where this herbicide would be applied. The label for Solicam DF states the following:

> Solicam has no post-emergence activity and will not control established weeds. Existing weeds must be mechanically removed or controlled by using the suitable postemergence herbicide.

It thus appears likely that around the base of trees, there will be little vegetation that will be directly applied with norflurazon. Herbivorous birds and mammals would be more likely to feed in areas between the tree rows and on field margins where growth of weeds would be less controlled. Species which are not herbivorous may be more likely to feed under the trees, but norflurazon concentrations on these food items are expected to be considerably less than on grass and broadleaf vegetation. Finally, residues on all wildlife food items are predicted to be well below the avian dietary LC_{50} and the mammalian dietary LC_{50}'s estimated from the rat LD_{50}. Considering these factors, it is safe to conclude that the use of norflurazon on citrus will not harm any endangered species of birds and mammals through acute toxicity.

The **chronic** risk quotients are based on a definitive NOEC of 40 ppm. These risk quotients are far above the LOC for high risk. Furthermore, norflurazon is generally persistent in the terrestrial environment, which increases concern for possible chronic effects. The Agency thus concludes that application of liquid norflurazon on all sites poses a high chronic risk to birds and may affect avian endangered species. This conclusion does not apply to application of granular formulations on cranberries, which is discussed below.

(b) Mammals

Small mammal exposure is addressed using acute oral LD_{50} values converted to an estimated LC_{50} value for dietary exposure. The estimated LC_{50} is derived using the following formula:

$$LC_{50} = \frac{LD_{50} \times \text{body weight (g)}}{\text{food cons. per day (g)}}$$

Small Mammal Food Consumption in PPMs (Based on an LD_{50} = 9300 mg/kg)				
Small Mammal	**Body Weight in Grams**	**% of Weight Eaten Per Day**	**Food Consumed Per Day in Grams**	**Estimated LC_{50} Per Day in PPMs**
Meadow vole	46 gms	61 %	28.1 gms	15,224 ppm
Adult field mouse	13 gms	16 %	2.1 gms	57,571 ppm
Least shrew	5 gms	110 %	5.5 gms	8,455 ppm

The above table is based on information contained in Principles of Mammology by D. E. Davis and F. Golly, published by Reinhold Corporation, 1963.

The estimated LC_{50} is then compared to the residues listed above (for avian species) to calculate a risk quotient (EEC/LC_{50}). The table below indicates the risk quotients for each of the application rates:

Mammalian Dietary Risk Quotients (based on Dietary RQ = EEC/Lowest LC_{50})		
Small Mammal	Application Rates in lbs. a.i./A	
	7.86	3.93
Meadow vole	0.12	0.06
Adult field mouse	0.02	0.009
Least shrew	0.01	0.007

The only current uses for which the RQs exceed the LOC for possible adverse effects to small endangered mammals are cranberries, citrus fruits, and hops when used on fine-textured soils. The arguments posed above for birds also apply to the small endangered mammals. The Agency thus concludes that the use of norflurazon will not harm endangered species of birds and mammals through acute toxicity.

A separate chronic risk assessment for mammals could not be conducted due to the lack of chronic mammalian toxicity data. An examination of the chronic risk quotients for birds, however, as derived above shows that chronic risk quotients for all food items other than fruits and pods exceed the LOC for high risk (1). As noted above, norflurazon is generally persistent in the

terrestrial environment, which increases concern for possible chronic effects. Therefore, the Agency concludes that the application of liquid norflurazon on all crops poses a high risk of chronic effects on birds and mammals, and may cause adverse chronic effects to endangered species of these groups.

(c) Risk Characterization for Cranberry Use

LD_{50}/ft^2 Method: The use of norflurazon on cranberries has been determined to be applied solely as a granular formulation at a maximum use rate of 8.0 lb ai/A. The Agency typically assesses the risk of granular formulations using the exposure index of mg ai/ft^2. The risk quotient is calculated by dividing this value by the $LD_{50.}$ With a maximum use rate of 8.0 lb a.i./A, the exposure index is calculated as follows:

8 lb ai/A x 453,600 mg/lb x 1/43,560 A/ft^2 = 83.3 mg ai/ft^2.

Since avian LD_{50} is >2510 mg ai/kg body weight (bw), the acute risk quotient for birds and small mammals is:

RQ = Exposure (mg ai/ft^2) / (LD_{50} x kg of body weight)

or:

RQ = 83.3/(2510 x kg of body weight)

For birds with body weights of 20, 180, and 1000 g, the RQ would be 1.7, 0.18, and 0.033, respectively.

Since the acute rat LD_{50} is 9300 mg ai/kg bw, the acute risk quotient for birds and small mammals is:

RQ = 83.3/(9300 x kg of body weight)

For small mammals with body weights of 15, 35, and 1000 g, the RQ would be 0.60, 0.26, and 0.0090, respectively.

According to this analysis, use of granular norflurazon at the rate of 8 lb ai/A is expected to pose minimal risk of acute toxicity to birds and mammals with

the exception of possible harm to small birds. Since some of the risk quotients exceed the LOC of 0.1; however, the possibility that endangered species of birds and mammals may be affected, cannot be ruled out.

Number of granules method: The registrant determined the weight of a single granule of Evital to be approximately 0.43 g. Since Evital contains 5.0% ai, a single granule contains 0.43 x 0.05 = 0.0215 mg of ai. Taking the inverse of this value determines that there are 46.5 granules per gram of ai.

The number of granules that an animal must consume to reach the LD_{50} can now be calculated with the following formula:

# of granules = granules/mg ai x LD_{50} (mg ai/kg bw) x BW (kg)

The number of granules that must be consumed to reach the LD_{50} of norflurazon for birds (2510 mg/kg) is shown below for birds of various weights:

Body Weight	# of Granules
20 g	2340
180 g	21000
1000 g	117,000

The number of granules that must be consumed to reach the LD_{50} of norflurazon for mammals (9300 mg/kg) is shown below for small mammals of various weights:

Body Weight	# of Granules
15 g	6488
35 g	15140
1000 g	432,558

The Agency concludes that it is highly unlikely that an individual bird or small mammal would consume this many granules of product in one day. Examining similar arguments based on the percentage of body weight consumed, the Agency concludes that it is unlikely that birds or mammals would consume the percentage of their body weights necessary to reach the LD50.

The above assessments show that birds and mammals are not likely to consume enough granular norflurazon product to approach an **acutely** toxic dose. The Agency therefore concludes that the use of granular norflurazon on cranberries will pose minimal acute risk to birds and mammals, and is not expected to cause adverse effects on endangered birds and small mammals.

In considering chronic risk,the Agency notes that several special factors are associated with the cranberry use that may reduce the level of risk to birds and mammals:

1. Cranberries require either weekly rainfall or irrigation. This would likely wash much of the active ingredient off the granules and into the soil. Granules on the surface would therefore likely contain high concentrations of norflurazon for only a few days.

2. The cranberry plants create a dense cover which would restrict access of birds to norflurazon granules lying on the soil surface.

3. The granules are composed of sand. Since a layer of sand is often put over the peat soil in cranberry bogs, the granules may be indistinguishable from the surrounding substrate, and thus less likely to be selected by birds as grit.

Considering these factors, the Agency concludes that the use of granular norflurazon on cranberries will pose minimal chronic risk to birds. There is a high uncertainty associated with these factors, however, and the potential exists for norflurazon to cause reproductive effects in birds. Because of this and because the Agency is more protective of endangered species, possible effects on endangered species of birds and mammals cannot be ruled out.

(d) Insects

Norflurazon is practically non-toxic to honeybees. Therefore, insects are not likely to be adversely affected by the use of norflurazon.

(2) Exposure and Risk to Nontarget Aquatic Animals

Expected Aquatic Concentrations: Norflurazon displays slight to moderate toxicity to most aquatic organisms tested to date. The Agency calculated generic EECs for norflurazon application to citrus (7.86 and 3.93 lbs a.i./A) and to cranberries (8.0 lbs a.i./A). These EECs are designed as a screen and estimate expected concentrations from a few basic chemical parameters and pesticide label application information.

The GENeric Expected Environmental Concentration Program (GENEEC) is the model used to estimate runoff from a ten hectare field into a one hectare by two meter deep pond. GENEEC calculates both acute and chronic generic expected environmental concentration (GEEC) values. It considers reduction in dissolved pesticide concentration due to adsorption of pesticide to soil or sediment, incorporation, degradation in soil before washoff to a water body, direct deposition of spray drift into the water body, and degradation of the pesticide within the water body. It is designed to mimic a PRZM-EXAMS simulation. Risk quotients based on refined EECs would likely be less conservative than those based on GENEEC, while those based on the available monitoring data may be under-protective.

The most current usage information indicates that, for citrus, the maximum rate of 7.86 lbs a.i./A is only made using ring drench practices and the maximum rate of 3.93 lb a.i./A is only made using banded applications. Although these banded applications are allowed by the labels, and may even be the typical practice, nothing on the product labels prohibits the product from being applied at the 3.93 lbs ai/A rate over the entire field (i.e. a broadcast application) using a boom sprayer. Based on the most recent usage information, risk assessments were thus performed using three scenarios: ring drench applications at 7.86 lbs a.i./A, banded applications at 3.93 lbs a.i./A, and broadcast spray applications at 3.93 lbs a.i./A.

The most recent usage information indicates that no more than about 30% of the total field is treated when using a ring drench application, and no more than 50% of the field is treated when using a banded application. These assumptions appear to be a reasonable for the citrus and other fruit and nut crops on which norflurazon is used. The area of the field treated does not affect the terrestrial EECs, which are based on concentrations in the treated areas, but it does affect aquatic EECs, which are based on the total amount of active ingredient applied per acre of field. The product labels do not allow the rate applied on any point of land to exceed the maximum label rate, no matter what the application method is. The maximum use rates therefore have been multiplied by 0.3 and 0.5 when calculating aquatic EECs for ring drench and banded applications, respectively.

Norflurazon may be applied on citrus and other fruit and nut crops using a low volume irrigation system. The area of the field that is treated will vary depending on the type of irrigation system and the age of the trees. The Agency has made the estimate that no more than 30% of the total area of the field will be treated by these chemigation applications.

GENEEC Inputs for Citrus and Other Fruit and Nut Crops: The GENEEC model was used to calculate generic EECs (GEECs) for application to citrus and several other crops. The maximum rate for a ring drench application to citrus is equivalent to 7.86 x 0.3 = 2.36 lb ai/A and 3.93 x 0.3 = 1.18 lb ai/A for low volume chemigation. The maximum rate for banded applications is equivalent to 3.93 x 0.5 = 1.97 lb ai/A since no more than 50% of the field is treated. Norflurazon could conceivably be applied as a broadcast spray over the entire field at the rate of 3.93 lbs a.i./A. The input data for the GENEEC model for these crops were as follows:

Rate (lb ai/A):	2.36 (citrus, ring drench) 1.18 (citrus, chemigation) 1.97 (banded) 3.93 (broadcast)
Soil K_{OC}:	625
Solubility (ppm):	28
Aerobic Soil $T_{1/2}$ (d):	130
Aerobic Aquatic $T_{1/2}$ (d):	240
Photolysis $T_{1/2}$ (d):	3

Wetted-In?	Yes
Incorporation Depth	0
Spray Drift	1.0% (Ground spray)

Cranberries: The GENEEC model also was used to estimate GEECs for cranberries. Since it is actually applied as a sand granule, negligible spray drift should occur. The input data for the GENEEC model for these crops were as follows:

Rate (lb ai/A):	8.0
Soil K_{OC}:	1080
Solubility (ppm):	28
Aerobic Soil $T_{1/2}$ (d):	130
Aerobic Aquatic $T_{1/2}$ (d):	240
Photolysis $T_{1/2}$ (d):	3
Wetted-In?	No
Incorporation Depth	0
Spray Drift	0% (Granular)

Cotton: GEECs were also determine for use of norflurazon on cotton using the following input values:

Rate (lb ai/A):	1.97
Soil K_{OC}:	625
Solubility (ppm):	28
Aerobic Soil $T_{1/2}$ (d):	130
Aerobic Aquatic $T_{1/2}$ (d):	240
Photolysis $T_{1/2}$ (d):	3
Wetted-In?	No
Incorporation Depth	0
Spray Drift	5% (Aerial spray)

The following table outlines the Generic EECs which were calculated for norflurazon application to citrus, cranberries, and to cotton:

ESTIMATED ENVIRONMENTAL CONCENTRATIONS (EECs) FOR NORFLURAZON							
Crop	**Application Method**	**Application Rate (lbs a.i./A)**	**Number of Applications**	**Peak GEEC (ppb)**	**4-day GEEC (ppb)**	**21-day EEC (ppb)**	**56-day EEC (ppb)**
Citrus	Ring drench	2.36[a]	1	42.1	41.1	36.2	29.4
Citrus	Low volume chemigation	1.18	1	21.0	20.5	18.1	14.7
Cranberries	Granular	8.00	1	94.2	91.0	76.3	58.4
Cotton	Aerial spray	1.97	1	37.5	36.6	32.3	26.2
Citrus and other crops	Banded spray	1.97[b]	1	35.0	34.2	30.1	24.5
Other crops	Broadcast ground spray	3.93	1	70.1	68.4	60.3	49.0

[a] The application rate in the wetted area is 7.86 lb ai/A.
[b] The application rate in the wetted area is 3.93 lb ai/A.

(a) Freshwater Fish

The table below provides both acute and chronic risk quotients for freshwater fish.

Risk Quotients (RQs) for Freshwater Fish				
Crop	**Application Method**	**Application Rate (lbs a.i./A)**	**Acute RQ (Peak EEC/LC_{50})**	**Chronic RQ (56-day EEC/NOEC)**
Citrus	Ring drench	2.36[a]	0.0052	0.038
Citrus	Low volume chemigation	1.18[b]	0.0026	0.019
Cranberries	Granular	8.00	0.012	0.076
Cotton	Aerial spray	1.97	0.0046	0.034
Citrus and other crops	Banded spray	1.97[b] (typical)	0.0043	0.032
Other crops	Broadcast ground spray	3.93 (typical)	0.0087	0.064

[a] The application rate in the wetted area is 7.86 lb ai/A.
[b] The application rate in the wetted area is 3.93 lb ai/A.

No acute or chronic LOCs have been exceeded for freshwater fish. Therefore, the use of norflurazon is not likely to adversely affect freshwater fish.

(b) Freshwater Invertebrates

The table below provides both acute and chronic RQs for freshwater invertebrates.

Risk Quotients (RQs) for Freshwater Invertebrates

Crop	Application Method	Application Rate (lbs a.i./A)	Acute RQ (Peak EEC/LC_{50})	Chronic RQ (21-day EEC/NOEC)
Citrus	Ring drench	2.36[a]	0.0028	0.036
Citrus	Low volume chemigation	1.18[b]	0.0014	0.018
Cranberries	Granular	8.00	0.0063	0.076
Cotton	Aerial spray	1.97	0.0025	0.032
Citrus and other crops	Banded spray	1.97[b] (typical)	0.0023	0.030
Other crops	Broadcast ground spray	3.93 (typical)	0.0047	0.060

[a] The application rate in the wetted area is 7.86 lb ai/A.
[b] The application rate in the wetted area is 3.93 lb ai/A.

No acute or chronic LOCs have been exceeded for freshwater invertebrates. Therefore, the use of norflurazon is not likely to adversely affect freshwater invertebrates.

(c) Estuarine and Marine Animals

The following table provides acute risk quotients for estuarine and marine animals.

Risk Quotients (RQs) for Estuarine and Marine Animals					
Crop	**Application Method**	**Application Rate (lbs a.i./A)**	**Acute RQ (Peak EEC/LC_{50})**		
			Fish	Mollusk	Shrimp
Citrus	Ring drench	2.36[a]	0.0044	0.011	0.0076
Citrus	Low volume chemigation	1.18[b]	0.0022	0.0055	0.0038
Cranberries	Granular	8	0.0098	0.025	0.017
Cotton	Aerial spray	1.97	0.0039	0.0099	0.0068
Citrus and other crops	Banded spray	1.97[b] (typical)	0.0037	0.0092	0.0063
Other crops	Broadcast ground spray	3.93 (typical)	0.0073	0.018	0.013

[a] The application rate in the wetted area is 7.86 lb ai/A.
[b] The application rate in the wetted area is 3.93 lb ai/A.

No acute LOCs have been exceeded for estuarine and marine organisms. Therefore, the use of norflurazon is unlikely to adversely impact estuarine/marine endangered or non-endangered species. Data were not available to assess the chronic risk to estuarine and marine organisms; however, because the freshwater chronic studies and the acute estuarine and marine studies indicate that norflurazon has general low toxicity to aquatic organisms, chronic testing on estuarine and marine organisms is not required.

(3) Exposure and Risk to Nontarget Plants

(a) Terrestrial and Semi-aquatic

Non-target terrestrial plants are those which inhabit non-aquatic areas. Non-target semi-aquatic plants are plants that usually inhabit low-lying wet areas that may or may not be dry in certain times of the year. These plants are not obligatory aquatic plants in that they do not live in a continuously aquatic environment. These terrestrial and "semi-aquatic" plants are exposed to pesticides from runoff, drift or volatilization.

Runoff exposure is determined from a generic EEC. This runoff is characterized as a one acre to one acre sheet runoff to an adjacent area that impacts terrestrial plants, or a

channelized runoff from 10 acres to low lying areas some distance away that impacts semi-aquatic plants.

Like aquatic EEC's, EEC's for terrestrial and semi-aquatic plants are based on the average rate (lbs ai/A) applied over the entire field, not just the area wetted. The application rates for ring drench and banded applications were reduced by 70% and 50%, respectively, to account for the limited amount of the field that is treated. Also, no spray drift component was included in the EEC's for crops other than cotton. Applications on citrus and other fruit and nut crops are made by boom sprayers or low-volume "micro sprinkler" or drip irrigation systems. None of these application methods are expected to result in significant spray drift. Aerial application of granular norflurazon on cranberries is also not expected to result in significant spray drift becauseit is applied as a granule. Aerial application to cotton may result in significant spray drift. The table below provides risk quotients for nonendangered and endangered terrestrial and semi-aquatic plants.

Risk Quotients (RQs) for Terrestrial and Semi-Aquatic Plants

Crop	**Application Method**	**Application Rate (lbs a.i./A)**	Terrestrial Plants Adjacent to Use Site		Semi-aquatic Plants in Wet Areas	
			EEC (lbs ai/A)	RQ	EEC (lbs ai/A)	RQ
Citrus	Ring drench	2.36[a]	0.047	24	0.47	240
Citrus	Low volume chemigation	1.18[b]	0.024	12	0.24	120
Cranberries	Granular	8	0.16	80	1.6	800
Cotton	Aerial spray	1.97	0.12[c] 0.99[d]	61 1.7	0.33 0.099	170 1.7
Citrus and other crops	Banded spray	1.97[b] (typical)	0.039	20	0.39	200
Other crops	Broadcast ground spray	3.93 (typical)	0.079	40	0.79	400

[a] The application rate in the wetted area is 7.86 lb ai/A.
[b] The application rate in the wetted area is 3.93 lb ai/A.
[c] The EEC and corresponding RQ are for effects on emerging seedlings from exposure to a combination of runoff and spray drift.
[d] The EEC and corresponding RQ are for effects on foliage from exposure to spray drift only.

All risk quotients exceed the LOCs for terrestrial and semi-aquatic plants. Therefore, use of norflurazon on all

sites, except cranberries (see below), may adversely affect nontarget terrestrial and semi-aquatic plants, including endangered species.

The special condition of cranberry bogs, as discussed below, reduces the risk of norflurazon to nontarget plants when used on this site. Use of norflurazon on cranberry bogs is not expected to result in significant exposure to dry land terrestrial plants. Under some circumstances, however, nontarget semi-aquatic plants may be exposed to norflurazon from water being discharged from cranberry bogs. The Agency therefore concludes that use of norflurazon on cranberries will not adversely affect nontarget terrestrial plants growing in adjacent dry land areas, but under some circumstances may adversely affect semiaquatic plants, including endangered species, growing in wet areas.

(b) Aquatic

Nontarget aquatic plants may be exposed to norflurazon through runoff from terrestrial sites or from drift. In order to estimate the risk to nontarget aquatic plants, EECs calculated using EFED's GENEEC program were used to calculate risk quotients.

In addition, the risk to aquatic plants was based on the results for *Kirchneria subcapitata* because this is the most sensitive aquatic plant tested. The table below provides risk quotients for nonendangered and endangered aquatic plants.

Risk Quotients (RQs) for Aquatic Plants				
Crop	**Application Method**	**Application Rate (lbs a.i./A)**	**RQ for Nonendangered Species (Peak EEC/EC_{25})**	**RQ for Endangered Species (Peak EEC/NOEC)**
Citrus	Ring drench	2.36[a]	3.2	6.7
Citrus	Low volume chemigation	1.18[b]	1.6	3.3
Cranberries	Granular	8.00	7.3	15.0
Cotton	Aerial spray	1.97	2.9	6.0
Citrus and other crops	Banded spray or low volume chemigation	1.97[b] (typical)	2.7	5.6
Other crops	Broadcast ground spray	3.93 (typical)	5.4	11.1

[a] The application rate in the wetted area is 7.86 lb ai/A.
[b] The application rate in the wetted area is 3.93 lb ai/A.

The LOCs for nontarget aquatic plants, including endangered species, have been exceeded for aquatic plants for all use sites. Therefore, all uses of norflurazon may adversely impact aquatic plants, including endangered species.

The special condition of cranberry bogs, as discussed below, reduces the risk to aquatic plants for this use site. Under some circumstances, however, some nontarget aquatic plants may be exposed to norflurazon from water being discharged from cranberry bogs. The Agency cannot therefore dismiss this risk.

Cranberry Use and Effects on Nontarget Plants

The Agency has determined that runoff from a cranberry bog into adjacent terrestrial areas will likely be minimal in most cases. The most important factor responsible for this is that cranberries are normally grown in a flat area that is surrounded by a dike or dam. Rainfall and irrigation therefore would not normally result in runoff from the cranberry bog. The high organic content of the peat soils of cranberry bogs would greatly enhance the binding of the herbicide to the soil. The Environmental Fate and Effects Division determined that norflurazon

would not be mobile in these soils. This would further decrease norflurazon potential for leaving cranberry bogs via runoff.

Under some conditions, cultivation practices used for cranberries would likely reduce the potential for contamination of surface water where aquatic plants may be affected. For example, water discharged from a flooded cranberry bog is often retained in a pond or reservoir to be reapplied to the bog. This practice would prevent norflurazon from leaving the water management system and entering natural water. However, in Wisconsin some cranberry growers use a gravity-feed system without pumps (Shoemaker, 1983). With this system, water discharged from a flooded cranberry field may contaminate natural streams and wetlands lying downstream. Also, even when pumps are used to recycle water, heavy rains may necessitate that water be released from the retaining pond. There is thus some potential for exposure to aquatic and semi-aquatic plants from runoff. This potential is reduced somewhat by the high degree of binding of norflurazon to the peat soils of cranberry bogs.

The Agency also determined that exposure to nontarget areas from drift from applications on cranberry fields would be minimal. Norflurazon is applied to cranberries in a sand granule formulation which would not drift an appreciable distance from the site of applications. Furthermore, applications are made by ground broadcast or by helicopter. With liquid formulations, these application methods result in less spray drift compared to application from a fixed winged aircraft. With a sand granular formulation, these methods would be expected to result in negligible drift.

In conclusion, use of norflurazon on cranberries should not result in any appreciable exposure to nontarget terrestrial and semiaquatic plants, either via spray drift or runoff. The Agency therefore concludes minimal risk to these plants. Under some circumstances, such as heavy rainfall, some nontarget aquatic plants may be exposed to norflurazon from water being discharged from cranberry bogs, although in most cases there will be little exposure.

(4) Endangered Species

The following endangered species LOCs have been exceeded: chronic effects on birds and mammals, and aquatic, semi-aquatic and terrestrial plants. The discussions above examine various factors that may affect exposure in characterizing the risk to these species.

When the Endangered Species Protection Program becomes final, limitations in the use of norflurazon may be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. A consultation with the Fish and Wildlife Service may be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

b. Water Resources Risk Implication for Human Health

(1) Surface Water

Norflurazon is not currently regulated under the Safe Drinking Water Act (SDWA). Therefore, no MCL has been established for it and water supply systems are not required to sample and analyze for it. Norflurazon is not on the OPP Health Effects Division's list of "apparent exceeders (chronic effects and cancer)". For these reasons, the Agency is not recommending surface water monitoring at this time.

(2) Ground Water

Data exist showing that norflurazon leaches to ground water as a result of normal agricultural use, causing concern for the impact of norflurazon on ground water quality. For this reason, norflurazon product labels carry a ground water advisory. Norflurazon has been detected in ground water in Florida at concentrations that approach or exceed the estimated HAL 30 ppb. OPP has determined an estimated HAL of 30 ppb for comparison with levels potentially found in ground water. The registrant has

begun work on monitoring programs for both the State of Florida and the EPA. These studies should further clarify the extent to which norflurazon can leach to ground water. The need for further mitigation for ground water concerns will be evaluated as the results of these studies become available.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing norflurazon as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing norflurazon pending acceptance of the risk mitigation measures described in this document. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of norflurazon, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of norflurazon and to determine that norflurazon can be used without resulting in unreasonable adverse effects to humans and the environment when label directions, including the mitigation measures described in this document are followed. To ensure that the potential risks of norflurazon are not unreasonable, the Agency is requiring the registrant to implement certain risk mitigation measures. Provided that these risk mitigation measures are implemented, the Agency finds that all products containing norflurazon as the active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although, the Agency has found all uses of norflurazon are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing norflurazon, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient norflurazon, the Agency has sufficient information on the health effects of norflurazon and on its potential for causing adverse effects in fish and wildlife and the environment. Although, the current uses of norflurazon exceed levels of concern for avian and mammalian species - chronic, and terrestrial, semi-aquatic and aquatic plants, the Agency concludes that all uses of products containing norflurazon as the active ingredient, once amended to reflect the risk mitigation measures imposed in this RED, are eligible for reregistration.

2. Eligible and Ineligible Uses

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

C. Regulatory Position

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

1. Tolerance Reassessment

Tolerances Listed under 40 CFR §180.356:

The tolerances listed in 40 CFR §180.356 are for the combined residues of norflurazon and its desmethyl metabolite.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.356 for the following commodities: almonds, apples, apricots, asparagus, avocados, blackberries, blueberries, cherries, citrus, cottonseed, cranberries, filberts, grapes, hops, nectarines, peaches, peanuts, pears, pecans, plums, raspberries, soybeans, soybean forage and hay, walnuts, milk, and the fat, meat, and meat-by-products of cattle, hogs, horses, and sheep.

The tolerance for hops, green listed under 40 CFR §180.356 should be revoked and a tolerance for the RAC (hops, green and dried) should be appropriately listed under a separate section for regional registrations (40 CFR §180.356(x)).

Tolerances Listed under 40 CFR §185.4450:

The tolerance listed in 40 CFR §185.4450 is for the combined residues of norflurazon and its desmethyl metabolite in dried hops. Sufficient data are available to ascertain the adequacy of this established tolerance. However, according to PR Notice 93-12 (12/23/93), for regulatory purposes, hops is considered as a RAC in both the fresh (green) and dried forms. The Agency concludes that this tolerance should be revoked and a tolerance for the RAC (hops, green and dried) should be cited under tolerances with regional registrations [40 CFR §180.356(x)].

Tolerances Listed under 40 CFR §186.4450:

The tolerances listed in 40 CFR §185.4450 are for the combined residues of norflurazon and its desmethyl metabolite in citrus molasses and dried citrus pulp. Citrus molasses is no longer considered a significant animal feed item and therefore no tolerances are necessary on this commodity: the current tolerance can be revoked. Norflurazon does not concentrate in dried citrus pulp: the RAC tolerance is therefore considered adequate to cover expected residues in dried citrus pulp and the current tolerance for dried citrus pulp can be revoked.

New Tolerances Needed:

Table II indicates that data on cotton gin byproducts (cotton gin trash) are required. The data should reflect three cropfield trials on stripped cotton and three on picked cotton and represent the major U.S. cotton growing regions. The registrant must propose a tolerance for this commodity once adequate data have been submitted and evaluated.

Residues of norflurazon and its metabolite concentrate in citrus oil. The Agency has recommended that a maximum residue limit of 0.7 ppm for citrus oil be proposed.

A summary of the norflurazon tolerance reassessment and modifications in commodity definitions are presented in Table C.

Table C. Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.356:			
Almond, hulls	1	1	
Almond, meat	0.1	0.1	*Almond*
Apricot	0.1	0.1	
Apple	0.1	0.1	
Asparagus	0.05	0.05	
Avocado	0.2	0.2	
Blackberry	0.1	Revoke	Once the 0.2 ppm tolerance for caneberries is established, tolerances on blackberries and raspberries should be revoked.
Blueberry	0.2	0.2	
Cattle, fat, meat, and mbyp	0.1	0.1	
Cherry	0.1	0.1	
Citrus fruit	0.2	0.2	
Cottonseed	0.1	0.1	*Cotton, undelinted seeds*
Cranberry	0.1	0.1	
Filberts	0.1	0.1	
Goats, fat, meat, and meat by-products (mbyp)	0.1	0.1	
Grape	0.1	0.1	
Hogs, fat, meat, and mbyp	0.1	0.1	
Hops, green	1.0	Revoke	As hops are now considered a RAC in both the fresh (green) and dried forms, the 1.0 ppm tolerance for hops, green and the 3 ppm tolerance for hops, dried (§185.4550) should be revoked, and a regional 2 ppm tolerance for hops (green and dried) should be established in §180.356(x).
Horses, fat, meat, and mbyp	0.1	0.1	
Milk	0.1	0.1	
Nectarine	0.1	0.1	
Pecan	0.1	0.1	
Peach	0.1	0.1	
Peanut	0.05	0.05	*Peanuts, nutmeat*
Peanut, hay	5.5	5.5	
Peanut, hulls	1.5	1.5	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Peanut, vines	1.5	Revoke	Peanut vines are no longer considered to be animal feed items
Pear	0.1	0.1	
Plum (fresh prune)	0.1	0.1	
Poultry, fat, meat, and mbyp	0.1	Revoke	The Agency concluded that poultry commodities are a 40 CFR 180.6(a)(3) situation and the tolerances on poultry commodities should therefore be revoked.
Raspberry	0.2	Revoke	Once the 0.2 ppm tolerance for caneberries is established, tolerances on blackberries and raspberries should be revoked.
Sheep, fat, meat, and mbyp	0.1	0.1	
Soybean	0.1	0.1	
Soybean forage	1	1	
Soybean hay	1	1	
Walnut	0.1	0.1	
Tolerances listed under 40 CFR §185.4450:			
Hops, dried	3	Revoke	As hops are now considered a RAC in both the fresh (green) and dried forms, the 1.0 ppm tolerance for hops, green and the 3 ppm tolerance for hops, dried (§185.4550) should be revoked, and a regional 2 ppm tolerance for hops (green and dried) should be established in §180.356(x).
Tolerances listed under 40 CFR §186.4450:			
Citrus molasses	1	Revoke	Citrus molasses is no longer considered a significant feed item.
Citrus pulp, dried	0.4	Revoke	Concentration does not occur in dried citrus pulp, and the RAC tolerance therefore adequately covers the processed feed.
New Tolerances Required under 40 CFR §180.356 :			
Caneberry	None	0.2	Must be established

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Cotton gin by-products	None	To be determined	Data are required
New Regional Tolerances Required under 40 CFR §185.356(x):			
Hops, green and dried	None	2	As hops are now considered a RAC in both the fresh (green) and dried forms, the 1.0 ppm tolerance for hops, green and the 3 ppm tolerance for hops, dried (§185.4550) should be revoked, and a regional 2 ppm tolerance for hops (green and dried) should be established in §180.356(x).
New Food Additive Tolerances Required under 40 CFR §185.4450:			
Citrus, oil	None	--	A Section 701 MRL of 0.7 ppm must be proposed.

CODEX HARMONIZATION

No maximum residue limits (MRLs) for norflurazon have been established by Codex for any agricultural commodity. Therefore, no compatibility issues exist with respect to U.S. tolerances.

2. Summary of Risk Management Decisions

a. Human Health

(1) Dietary

Acute Dietary

The Agency has evaluated the acute dietary risk associated with the use of norflurazon based on established and proposed tolerance levels and assuming 100% of each crop is treated. The endpoint used is a developmental NOEL of 30 mg/kg/day, skeletal variations observed at 60 mg/kg/day, in a rabbit developmental toxicity study. The MOE is 5000 for females of child-bearing age, the most sensitive subpopulation. MOE's of 100 or greater are generally considered acceptable.

Chronic Dietary (including cancer)

The Agency has evaluated the chronic dietary risk associated with the use of norflurazon based on the same residue values (tolerances) and percent crop treated levels (100%) used for the acute dietary risk. The RfD was established at 0.015 mg/kg/day based upon a chronic toxicity (6 month) study in dogs with a NOEL of 1.58 mg/kg/day. The chronic dietary risk is considered to be minimal. The chronic exposure analysis results in a TMRC which is 10% of the RfD for the U.S. general population. The subpopulation exposed the greatest is non-nursing infants (<1 year old). This subpopulation's TMRC utilizes 47% of the RfD. The Agency considers exposures which utilize 100% or less of the RfD to be adequately protective.

(2) Worker (Mixer/Loader/Applicator)

Acute (Short-Term) and Intermediate Term

The Agency has determined that there is a potential dermal exposure to pesticide handlers. The endpoint used is a systemic NOEL of 375 mg/kg/day based on a 21-day dermal toxicity study in rabbits. The MOEs for short and intermediate-term occupational exposure subchronic systemic effects to norflurazon are greater than 100 for the exposure scenarios considered. For example, during mixing/loading, the MOEs range from 240 - 6800; these MOEs assume the use of long pants, long-sleeve shirts, and chemical-resistant gloves. During groundboom and aerial applications, the MOEs range from 330 - 4100 and during flagging, the MOEs range from 1400 - 1700. These MOES assume the use of long pants and long-sleeve shirts (no gloves). And, during the mixer/loader/applicator using hand held equipment, the MOEs are 1,339 for low pressure handwand and 2,206 for the backpack sprayer. These MOEs assume the use of long pants, long-sleeve shirt, and chemical-resistant gloves.

Post-Application

The Agency concludes that the risks from post-application exposures to norflurazon would be acceptable, provided entry does not occur immediately following application. Therefore, post-application exposure data are not required at this time.

The Agency is requiring PPE which include long-sleeved shirt and long pants, chemical-resistant gloves, and shoes plus socks, as well as, requiring a REI of 12 hours. These measures should be sufficient to mitigate the potential exposure to workers.

b. Environmental

(1) Avian

Acute

The Agency has evaluated data to determine the acute effects of norflurazon to birds. At the use rate of 3.93 lb a.i./A, the risk quotients were determined to be less than 0.1, the LOC for presuming adverse effects to avian endangered species. The Agency concludes there will be no adverse effects to endangered birds by uses of norflurazon which have a maximum label rate of 3.93 lb a.i./A or less. This rate includes the use of norflurazon on cotton, soybeans, and peanuts. The use of norflurazon at rates of 7.86 lb a.i./A may cause adverse effects to endangered species of birds due to acute toxicity. This is supported by the risk quotients of <0.19 and <0.11 which are greater than the LOC of 0.1. Several reasons why risk to terrestrial birds and mammals would not be as great as predicted by the RQ method could be: (1) with the ring drench and banded applications used on citrus, only 30% to 80% of the field is exposed to norflurazon; (2) growth of weeds is normally prevented around the base of trees where this herbicide would be applied; and (3) residues on all wildlife food items are predicted to be well below the avian dietary LC_{50} and the mammalian dietary LC_{50}'s estimated from the rat LD_{50}. Considering these factors, it is safe to conclude that the use of norflurazon on citrus will not harm any endangered species of birds and mammals through acute toxicity.

Norflurazon is applied to cranberries solely as a granular formulation. In evaluating the risk of norflurazon use on cranberries, the Agency concludes that it is highly unlikely that an individual bird or small mammal would consume enough granules of norflurazon product in one day so that the percentage of their body weights necessary to reach the LD50 would be reached. The Agency concludes that the use of granular norflurazon on cranberries will pose minimal acute risk to birds and mammals,

and is not expected to cause adverse effects to endangered birds and small mammals.

Chronic

The Agency has evaluated data on the chronic effects of norflurazon to birds. The chronic risk quotients for birds range from 3 - 47 for the 7.86 lb ai/A rate and 1 - 24 for the 3.93 lb ai/A rate. The Agency concludes that application of liquid norflurazon as currently labeled on all sites, except cranberries, poses a high chronic risk to birds and may affect avian endangered species. Several special factors are associated with the cranberry use that reduces the level of risk to birds: 1) the dense cover of cranberry plants restricts the access of birds to norflurazon granules lying on the soil surface; 2) only granular formulations of norflurazon are applied to cranberries and granules are composed of sand which would make them indistinguishable from the surrounding substrate and unlikely to be selected by birds as grit; and 3) cranberries require either weekly rainfall or irrigation, this would wash much of norflurazon off granules and into the soil. Considering these factors, the Agency concludes that the use of granular norflurazon on cranberries will pose minimal chronic risk to birds.

Although, risk reduction measures including reduced application rates, and use precaution statements already appear on norflurazon product labels, a chronic risk to birds still exists. The registrant has agreed to further mitigate the chronic risk to birds by implementing the following measures: 1) clarifying the soil incorporation statements on the Solicam DF and Zorial product labels by making them more conspicuous and adding them to the specific use directions for each crop; and 2) simplifying the use directions of the Solicam DF and Zorial product labels in banded treatments by clearly stating that no part of a field receives more than the equivalent of the maximum broadcast rate. These measures should reduce exposure to norflurazon for birds on both an immediate and long term basis.

(2) Mammals

Acute

At the application rate of 7.86 lb ai/A, the acute risk quotients for norflurazon were determined to be 0.01, 0.02, and

0.12 for the least shrew, adult field mouse and meadow vole, respectively. At the use rate of 3.93 lb ai/A, the acute risk quotients were determined to be less than 0.1. The Agency concludes that the use of norflurazon will not harm mammals, including endangered species through acute toxicity.

Chronic

The Agency could not conduct a separate chronic risk assessment for mammals due to the lack of chronic mammalian toxicity data. An examination of the chronic risk assessment for birds shows that chronic risk quotients for all food items other than fruits and pods exceed the LOC for high risk (1). Norflurazon is generally persistent in the terrestrial environment, which increases concern for possible chronic effects. Therefore, the Agency concludes that the application of liquid norflurazon on all crops poses a high risk of chronic effects on mammals, and may cause adverse chronic effects to endangered species of these groups. For the application of granular norflurazon on cranberries, the conclusions posed above on the chronic effects to birds also apply to mammals. Likewise, the risk mitigation measures proposed above for birds should also reduce the exposure of norflurazon to mammals.

(3) Insects

Norflurazon is practically non-toxic to honeybees. Therefore, insects are not likely to be adversely affected by the use of norflurazon.

(4) Freshwater Fish

No acute or chronic LOCs have been exceeded for freshwater fish. Therefore, the use of norflurazon is not likely to adversely affect freshwater fish.

(5) Aquatic invertebrates

No acute or chronic LOCs have been exceeded for freshwater invertebrates. Therefore, the use of norflurazon is not likely to adversely affect freshwater invertebrates.

(6) Estuarine and Marine Organisms

No acute LOCs have been exceeded for estuarine and marine organisms. Therefore, the use of norflurazon is unlikely to adversely impact estuarine/marine endangered or non-endangered species. Data were not available to assess the chronic risk to estuarine and marine organisms. Because the freshwater chronic studies and the acute estuarine and marine studies indicate that norflurazon has general low toxicity to aquatic organisms, chronic testing on estuarine and marine organisms is not required.

(7) Nontarget Plants (Terrestrial, Semi-Aquatic, and Aquatic)

The Agency has evaluated data which indicate that LOCs are exceeded for terrestrial, semi-aquatic, and aquatic plants. Depending on the crops, application method and application rates, the risk quotients for terrestrial plants range from 1.7 - 80. The semi-aquatic plant risk quotient for cotton is 1.7 (this is the effect on foliage from exposure to spray drift only). The other risk quotients for semi-aquatic plants range from 120 - 800 depending on the crop, application method and application rates. The risk quotients for aquatic plants, nonendangered species range from 1.6 - 7.3, and the endangered species risk quotients range from 3.3 - 11.1. Therefore, use of norflurazon on all sites, except cranberries, may adversely affect nontarget terrestrial and semi-aquatic plants, including endangered species. Considering the special conditions of cranberry bogs, the Agency concludes that use of norflurazon on cranberries will not adversely affect nontarget terrestrial plants growing in adjacent dry land areas, but under some circumstances may adversely affect semiaquatic plants, including endangered species, growing in wet areas.

The use of norflurazon on cranberries should not result in any appreciable exposure to nontarget terrestrial and semiaquatic plants, either via spray drift or runoff. The Agency therefore concludes minimal risk to these plants. The special condition of cranberry bogs reduces the risk to aquatic plants for this use site because under some conditions cultivation practices used for cranberries would likely reduce the potential for contamination of surface water where aquatic plants may be affected. Also, exposure to nontarget areas from drift from applications on cranberry fields would be minimal because norflurazon is applied

to cranberries as a sand granule formulation which would not drift an appreciable distance from the site of applications.

Due to the phytotoxic nature of norflurazon and its method of application, a spray drift advisory is being required on all norflurazon product labels. The Agency believes that this advisory should reduce the risk of norflurazon to nontarget plants via drift. In addition, spray drift studies are being required to evaluate the exposure and risk to nontarget plants.

(8) Endangered Species

The Agency has concerns about the exposure of threatened and endangered plant and animal species to norflurazon as discussed above in the science assessment chapter. Endangered species LOCs have been exceeded for chronic effects on birds, mammals, and aquatic, semi-aquatic and terrestrial plants.

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

(9) Surface Water

There is a concern for norflurazon contaminating surface water at application via spray drift and runoff. Substantial amounts of applied norflurazon could be available for runoff several months postapplication. The Agency is not requiring surface water monitoring studies at this time; however, due to the mobility and persistence of norflurazon and desmethyl norflurazon, a surface

water label advisory is required. The Agency believes that this advisory will reduce the risk of norflurazon contaminating surface water through spray drift and runoff.

(10) Ground Water

Norflurazon exhibits some of the properties and characteristics of chemicals that have been detected in ground water. Environmental fate data suggest that norflurazon leaches to ground water as a result of normal agricultural use.

The registrant has already placed a ground water advisory on product labels. The Agency is requiring that the ground water label adivsory be maintained. Previously the Agency required the registrant to conduct ground water monitoring studies which are currently in progress. These studies will provide a better evaluation of the leaching potential of norflurazon, as well as, determine if any appropriate risk mitigation measures will be necessary.

3. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Agency completes its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, the Agency may impose further refinements in spray drift management practices to further reduce off-target drift and risks associated with this drift.

4. Labeling Rationale

Occupational/Residential Labeling Rationale/Risk Mitigation

The Worker Protection Standard (WPS)

Scope of the WPS

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of

the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in.

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

- on pastures or rangelands,

- in a manner not directly related to the production of agricultural plants, including, for example, control of vegetation in noncrop areas.

Compliance With The WPS

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7, 93-11, and 95-5. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

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

- After October 23, 1995, except as otherwise provided in PR Notices 93-7, 93-11, and 95-5, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person.

Personal Protective Equipment/Engineering Controls for Handlers

At this time there are no engineering control requirements, such as closed systems, currently required on labeling for end-use products containing norflurazon.

Occupational-Use Products

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

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If EPA determines that *regulatory action on an active ingredient must be taken* as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most end-use products containing that active ingredient.
- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of the end-use product.
- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

EPA has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for occupational handlers must be taken for norflurazon. The exposure and risk assessments for occupational mixers and loaders, and occupational mixer/loader/applicators were based on exposure data in which the handlers wore chemical-resistant gloves. Therefore, EPA is requiring chemical-resistant gloves as the baseline (minimum) PPE requirements for such handlers.

Post-Application/Entry Restrictions

Occupational-Use Products (WPS Uses)

Restricted-Entry Interval:

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

The WPS interim REI for norflurazon in effect is 12 hours. EPA notes that the 12-hour interim WPS REI was established because EPA data indicates that norflurazon is classified as toxicity category IV for acute dermal toxicity, eye irritation potential, and skin irritation potential. After reviewing the probable exposures and risks from post-application exposures to norflurazon, EPA has determined that a 12-hour restricted-entry interval (REI) is appropriate. Due to the lack of post-application exposure data and the systemic dermal NOEL, EPA has determined that norflurazon is not a candidate for an REI below 12 hours.

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

EPA also notes that if norflurazon has been correctly incorporated, the WPS permits workers to enter the treated area during the restricted-entry interval without personal protective equipment or any other restriction if they are performing tasks that do not involve contact with the soil subsurface.

Early-Entry PPE:

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

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

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

Since EPA has determined that no regulatory action must be taken due to the acute effects or other adverse effects of norflurazon, it is establishing PPE for dermal protection on the basis of the acute toxicity of the active ingredient. Norflurazon is classified as toxicity category IV for acute dermal toxicity and skin irritation potential. Since norflurazon is classified as toxicity category IV for eye irritation potential, no protective eyewear is required.

WPS Notification Statement

EPA has determined that double notification is not required for norflurazon end-use products.

Occupational-Use Products (NonWPS Uses)

Since EPA has concerns about post-application, immediate (before sprays have dried) exposures to persons after nonWPS occupational uses of norflurazon, it is establishing entry restrictions for all nonWPS occupational uses of norflurazon end-use products. For specific requirements, refer to Section V of this document.

Additional Labeling Requirements

The Agency is requiring additional labeling statements to be located on all end-use products containing norflurazon. For the specific labeling statements, refer to Section V of this document.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of norflurazon for the above eligible uses has been reviewed and determined to be substantially complete.

The following confirmatory data are required to support reregistration of norflurazon:

Product Chemistry
Acute Inhalation for Technical and 78.6% DF
Dermal Sensitization
Gene Mutation (Ames Salmonella)

Directions for Use - Label Amendment to include PHIs
Residue Analytical Methods - Animal (Radiovalidation data)
Cropfield Trials - Cotton Gin By-products
Field Rotational Crops (in progress)

Tier II Aquatic Plant Growth
Batch Equilibrium Study (Degradate)
Spray Drift
Small Scale Ground Water Monitoring (in progress)

2. Labeling Requirements for Manufacturing-Use Products

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

> "Only for formulation into an herbicide for the following use(s): ....."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under

> "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

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

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

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

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

2. Labeling Requirements for End-Use Products

a. Worker Protection

(1) Personal Protective Equipment/Entry Restrictions; Labeling

PPE Requirements for Pesticide Handlers

Sole-active-ingredientend-use products that contain norflurazon must be revised to adopt the handler personal protective equipment requirements set forth in this section. Any conflicting PPE requirements on their current labeling must be removed.

Multiple-active-ingredientend-use products that contain norflurazon must compare the handler personal protective equipment requirements set forth in this section to the PPE requirements on their current labeling and retain the more protective. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Products Intended Primarily for Occupational Use

WPS and nonWPS uses

Minimum (baseline) PPE requirements --The minimum (baseline) PPE for all WPS and nonWPS uses of norflurazon end-use products is:

Applicators and other handlers must wear:
--long-sleeved shirt and long pants, and
--shoes plus socks.

In addition, chemical-resistant gloves* must be worn by all mixers** and loaders and by applicators using hand-held equipment, such as handwands, hoses, or nozzles.

* For the glove statement, use the statement established for norflurazon through the instructions in Supplement Three of PR Notice 93-7.

** The word "mixer" may be removed if the product is formulated as "ready-to-use."

Actual end-use product PPE requirements --"The PPE that would otherwise be established based on the acute toxicity of each end-use product must be compared to the minimum (baseline) personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7."

Placement in labeling --The personal protective equipment must be placed on the end-use product labeling in the location specified in PR Notice 93-7 and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Entry Restrictions

Sole-active-ingredientend-use products that contain norflurazon must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on their current labeling must be removed.

Multiple-active-ingredientend-use products that contain norflurazon must compare the entry restrictions set forth in this section to the entry restrictions on their current labeling and retain the more protective. A specific time-period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

Products Intended Primarily for Occupational Use

WPS uses

Restricted-entry interval --A 12-hour restricted entry interval (REI) is required for uses within the scope of the WPS (see PR Notice 93-7) on all end-use products (see tests in PR Notices 93-7 and 93-11). This REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7.

Early-entry personal protective equipment (PPE) --

The PPE required for early entry is:

--coveralls,
--chemical-resistant gloves,
--shoes plus socks

Placement in labeling --The REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7. The PPE required for early entry must be inserted into the standardized early entry PPE statement required by Supplement Three of PR Notice 93-7.

NonWPS uses

Entry restrictions --The Agency is establishing the following entry restrictions for all nonWPS occupational uses of norflurazon end-use products:

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

For granular applications:
"Do not enter or allow others to enter the treated area until dusts have settled. In addition, if the granules are watered-in, do not enter or allow others to enter until the treated area is dry, following the watering-in."

(2) Other Labeling Requirements

Products Intended Primarily for Occupational Use

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

Application restrictions

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

Engineering controls

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User safety requirements

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

User safety recommendations

■"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

■"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

■"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Optional soil incorporation statement

"Exception: if the product is soil-injected, soil-incorporated or watered-in, the Worker Protection Standard, under certain circumstances, allows

workers to enter the treated area if there will be no contact with anything that has been treated."

b. End-Use Labeling Requirements

Soil Incorporation

The following soil incorporation label statement must be added to the specific use directions for **each crop** on the Solicam DF® product label:

"Solicam must be moved into the weed seed germination zone to be effective. If no rainfall occurs within 4 weeks after application, the product must be incorporated by flood or sprinkler irrigation."

The following soil incorporation label statement must be added to the specific use directions for **each crop** on the Zorial Rapid 80® product label:

"Zorial Rapid 80 must be applied and incorporated by tillage, irrigation or rainfall before weeds germinate."

Banded Treatments

The following label statement must be added in the "Application Equipment" section of the norflurazon Solicam DF® and Zorial® labels to clarify the formulas for the row (banded) treatment calculation:

"The solution should be mixed to the maximum label rate and **at no point on the field**should the solution be applied at a concentration any lower or higher than this rate."

c. Environmental Hazard Statements

The following labeling statements must be added to the "Environmental Hazards" section on all norflurazon end-use products:

Labeling for Wetlands

"Do not contaminate water when disposing of equipment washwaters. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not allow this material to drift onto neighboring crops or noncrop areas or use in a manner or at a time other than in accordance with label directions because animal, plant or crop injury, illegal residues or other undesirable results may occur."

Labeling for Surface Water

"Norflurazon can contaminate surface water through spray drift. Under some conditions, norflurazon may also have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several months post-application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water."

Labeling for Ground Water

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

d. Spray Drift Labeling

The following language must be placed on each product label that can be applied aerially:

"Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related

factors determine the potential for spray drift. The applicator is responsible for considering all these factors when making decisions.

The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.

2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they should be observed.

The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.

The following aerial drift reduction advisory information must be contained in the product labeling:

[This section is advisory in nature and does not supersede the mandatory label requirements.]

Information on Droplet Size

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

Controlling Droplet Size

- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

Boom Length

For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

Application Height

Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

Swath Adjustment

When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)

Wind

Drift potential is lowest between wind speeds of 3-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 3 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

Temperature and Humidity

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

Temperature Inversions

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

Sensitive Areas

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g., when wind is blowing away from the sensitive areas)."

C. Existing Stocks

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

The Agency has determined that registrants may distribute and sell norflurazon products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from

the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES													
ALMOND				**Use Group: TERRESTRIAL FOOD+FEED CROP**									
Soil treatment, Preharvest, Boom sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			.9825 lb A	C									
Soil treatment, Preharvest, Low volume sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			.9825 lb A	C									
APPLE				**Use Group: TERRESTRIAL FOOD+FEED CROP**									
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									
Soil treatment, Foliar, Low volume ground sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									
APRICOT				**Use Group: TERRESTRIAL FOOD CROP**									
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									
Soil treatment, Foliar, Low volume sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									
ASPARAGUS				**Use Group: TERRESTRIAL FOOD CROP**									
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									
Soil treatment, Foliar, Low volume sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									

USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
AVOCADO				**Use Group: TERRESTRIAL FOOD CROP**									
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									
Soil treatment, Foliar, Low volume sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									
BLACKBERRY				**Use Group: TERRESTRIAL FOOD CROP**									
Soil treatment, Dormant, Boom sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									
Soil treatment, Dormant, Low volume sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									
BLUEBERRY				**Use Group: TERRESTRIAL FOOD CROP**									
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									
Soil treatment, Foliar, Low volume sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									
CHERRY				**Use Group: TERRESTRIAL FOOD CROP**									
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
Soil treatment, Foliar, Low volume sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. Dose /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
CITRUS FRUITS			Use Group: TERRESTRIAL FOOD+FEED CROP										
Chemigation, Foliar, Drip irrigation	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			3.93 lb A	M									
			3.93 lb A	C									
Chemigation, Foliar, Sprinkler irrigation	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			3.93 lb A	M									
			3.93 lb A	C									
Low volume spray (concentrate), Foliar, Low volume ground sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			3.93 lb A	M									
			3.93 lb A	C									
Soil broadcast treatment, Foliar, Boom sprayer	DF	NA	7.86 lb A	F	NS	NS	NS	NS	NS	.5	FL, TX		C92
			7.86 lb A	M									
			7.86 lb A	C									
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			3.93 lb A	M									
			3.93 lb A	C									
	FlC	NA	UC	*	NS	NS	12 lb	NS	NS	.5			CAU, G96
Soil treatment, Foliar, Low volume sprayer	FlC	NA	UC	*	NS	NS	12 lb	NS	NS	.5			CAU, G96
COTTON (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil broadcast treatment, Preemergence, Aircraft	FlC	NA	UC	*	NS	NS	NS	NS	NS	.5	CA		C13, C46, C92, GH4
			UC	F									
			UC	M									
			UC	C									
Soil broadcast treatment, Preemergence, Boom sprayer	FlC	NA	UC	*	NS	NS	NS	NS	NS	.5	CA		C13, C46, C92, GH4
			UC	F									
			UC	M									
			UC	C									

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	*	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION														
FOOD/FEED USES (con't)														
COTTON (UNSPECIFIED) (con't)				**Use Group: TERRESTRIAL FOOD+FEED CROP (con't)**										
Soil incorporated treatment, Preplant, Aircraft	FlC	NA	UC	*	NS	NS	NS	NS	NS	.5		CA		C13, C46, C92, GH4
			UC	F										
			UC	M										
			UC	C										
Soil incorporated treatment, Preplant, Boom sprayer	FlC	NA	UC	*	NS	NS	NS	NS	NS	.5		CA		C13, C46, C92, GH4
			UC	F										
			UC	M										
			UC	C										
CRANBERRY			**Use Group: TERRESTRIAL FOOD CROP**											
Low volume spray (concentrate), Early spring, Aircraft	G	NA	8 lb A	*	NS	1/1 yr	NS	8 lb	NS	.5	NJ, MA, OR, WA, WI			
Spray, Early spring, Sprayer	G	NA	8 lb A	*	NS	1/1 yr	NS	8 lb	NS	.5	NJ, MA, OR, WA, WI			
Spray, Fall, Aircraft	G	NA	8 lb A	*	NS	1/1 yr	NS	8 lb	NS	.5	NJ, MA, OR, WA, WI			
Spray, Fall, Sprayer	G	NA	8 lb A	*	NS	1/1 yr	NS	8 lb	NS	.5	NJ, MA, OR, WA, WI			
FILBERT (HAZELNUT)			**Use Group: TERRESTRIAL FOOD CROP**											
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5				C92
			2.9475 lb A	M										
			1.965 lb A	C										
Soil treatment, Foliar, Low volume sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5				C92
			2.9475 lb A	M										
			1.965 lb A	C										

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
GRAPES			**Use Group: TERRESTRIAL FOOD+FEED CROP**										
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									
Soil treatment, Foliar, Low volume sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									
HOPS			**Use Group: TERRESTRIAL FOOD+FEED CROP**										
Soil treatment, Fall, Sprayer	FlC	NA	UC	*	NS	NS	NS	NS	NS	NS	OR		C46
			UC	F									
			UC	M									
			UC	C									
	FlC	NA	UC	*	NS	NS	NS	NS	NS	NS	WA		C46
Soil treatment, Spring, Sprayer	FlC	NA	UC	*	NS	NS	NS	NS	NS	NS	OR		C46
			UC	F									
			UC	M									
			UC	C									
	FlC	NA	UC	*	NS	NS	NS	NS	NS	NS	WA		C46
NECTARINE			**Use Group: TERRESTRIAL FOOD CROP**										
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									
Soil treatment, Foliar, Low volume sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									
PEACH			**Use Group: TERRESTRIAL FOOD CROP**										
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A	F	NS	NS	NS	NS	NS	.5			C92
			2.9475 lb A	M									
			1.965 lb A	C									

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
PEACH (con't)				**Use Group: TERRESTRIAL FOOD CROP (con't)**								
Soil treatment, Foliar, Low volume sprayer	DF	NA	3.93 lb A 2.9475 lb A 1.965 lb A	F M C	NS NS	NS NS	NS NS	NS NS	NS NS	.5 .5		C92
PEANUTS				**Use Group: TERRESTRIAL FOOD+FEED CROP**								
Soil treatment, Preemergence, Sprayer	FlC	NA	UC	*	NS	NS	NS	NS	NS	NS	GA	C46
PEANUTS (UNSPECIFIED)				**Use Group: TERRESTRIAL FOOD+FEED CROP**								
Soil broadcast treatment, Preemergence, Aircraft	FlC	NA	UC	*	NS	1/1 yr	NS	NS	NS	.5	AL, NC, SC, FL, GA, TX, OK, VA, 013	C13, C46, C92
Soil broadcast treatment, Preemergence, Boom sprayer	FlC	NA	UC	*	NS	1/1 yr	NS	NS	NS	.5	AL, NC, SC, FL, GA, TX, OK, VA, 013	C13, C46, C92
PEAR				**Use Group: TERRESTRIAL FOOD CROP**								
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A 2.9475 lb A 1.965 lb A	F M C	NS NS	NS NS	NS NS	NS NS	NS NS	.5 .5		C92
Soil treatment, Foliar, Low volume sprayer	DF	NA	3.93 lb A 2.9475 lb A 1.965 lb A	F M C	NS NS	NS NS	NS NS	NS NS	NS NS	.5 .5		C92
PECAN				**Use Group: TERRESTRIAL FOOD CROP**								
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A 2.9475 lb A 1.965 lb A	F M C	NS NS	NS NS	NS NS	NS NS	NS NS	.5 .5		C92

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
PECAN (con't)				**Use Group: TERRESTRIAL FOOD CROP (con't)**									
Soil treatment, Foliar, Low volume sprayer	DF	NA	3.93 lb A 2.9475 lb A 1.965 lb A	F M C	NS	NS	NS	NS	NS	.5			C92
PLUM				**Use Group: TERRESTRIAL FOOD CROP**									
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A 2.9475 lb A 1.965 lb A	F M C	NS	NS	NS	NS	NS	.5			C92
Soil treatment, Foliar, Low volume sprayer	DF	NA	3.93 lb A 2.9475 lb A 1.965 lb A	F M C	NS	NS	NS	NS	NS	.5			C92
PRUNE				**Use Group: TERRESTRIAL FOOD CROP**									
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A 2.9475 lb A 1.965 lb A	F M C	NS	NS	NS	NS	NS	.5			C92
Soil treatment, Foliar, Low volume sprayer	DF	NA	3.93 lb A 2.9475 lb A 1.965 lb A	F M C	NS	NS	NS	NS	NS	.5			C92
RASPBERRY (BLACK, RED)				**Use Group: TERRESTRIAL FOOD CROP**									
Soil treatment, Dormant, Boom sprayer	DF	NA	3.93 lb A 2.9475 lb A 1.965 lb A	F M C	NS	NS	NS	NS	NS	.5			C92
Soil treatment, Dormant, Low volume sprayer	DF	NA	3.93 lb A 2.9475 lb A 1.965 lb A	F M C	NS	NS	NS	NS	NS	.5			C92
SOYBEANS (UNSPECIFIED)				**Use Group: TERRESTRIAL FOOD+FEED CROP**									
Soil broadcast treatment, Preemergence, Aircraft	FlC	NA	UC UC UC	* F M	NS	NS	NS	NS	NS	.5	AL, AR, FL, GA, 013, NM KY, LA, MS, MO, NC, OK, SC, TN,		C13, C46, C92, GE8

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
SOYBEANS (UNSPECIFIED) (con't)				**Use Group: TERRESTRIAL FOOD+FEED CROP (con't)**								
Soil broadcast treatment, Preemergence, Boom sprayer	FlC	NA		UC	* NS NS NS NS NS .5					AL, AR, FL, GA, 013, NM KY, LA, MS, MO, NC, OK, SC, TN, TX, VA		C13, C46, C92, GE8
				UC	F							
				UC	M							
Soil broadcast treatment, Preplant, Aircraft	FlC	NA		UC	* NS NS NS NS NS .5					AL, AR, FL, GA, 013, NM KY, LA, MS, MO, NC, OK, SC, TN, TX, VA		C13, C46, C92, GE8
				UC	F							
				UC	M							
Soil broadcast treatment, Preplant, Boom sprayer	FlC	NA		UC	* NS NS NS NS NS .5					AL, AR, FL, GA, 013, NM KY, LA, MS, MO, NC, OK, SC, TN, TX, VA		C13, C46, C92, GE8
				UC	F							
				UC	M							
Soil incorporated treatment, Preplant, Aircraft	FlC	NA		UC	* NS NS NS NS NS .5					AL, AR, FL, GA, 013, NM KY, LA, MS, MO, NC, OK, SC, TN, TX, VA		C13, C46, C92, GE8
				UC	F							
				UC	M							
Soil incorporated treatment, Preplant, Boom sprayer	FlC	NA		UC	* NS NS NS NS NS .5					AL, AR, FL, GA, 013, NM KY, LA, MS, MO, NC, OK, SC, TN, TX, VA		C13, C46, C92, GE8
				UC	F							
				UC	M							
WALNUT (ENGLISH/BLACK)				**Use Group: TERRESTRIAL FOOD CROP**								
Soil treatment, Foliar, Boom sprayer	DF	NA	3.93 lb A	F	NS NS NS NS NS .5							C92
			2.9475 lb A	M								
			1.965 lb A	C								
Soil treatment, Foliar, Low volume sprayer	DF	NA	3.93 lb A	F	NS NS NS NS NS .5							C92
			2.9475 lb A	M								
			1.965 lb A	C								

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED											
INDUSTRIAL AREAS (OUTDOOR)				Use Group: TERRESTRIAL NON-FOOD CROP							
Soil treatment, Preemergence, Boom sprayer	DF	NA	3.93 lb A	*	NS	NS	NS	NS	NS	.5	C92
Soil treatment, Preemergence, Low volume sprayer	DF	NA	3.93 lb A	*	NS	NS	NS	NS	NS	.5	C92
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS				Use Group: TERRESTRIAL NON-FOOD CROP							
Soil treatment, Preemergence, Boom sprayer	DF	NA	3.93 lb A	*	NS	NS	NS	NS	NS	.5	C92
Soil treatment, Preemergence, Low volume sprayer	DF	NA	3.93 lb A	*	NS	NS	NS	NS	NS	.5	C92
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS				Use Group: TERRESTRIAL NON-FOOD CROP							
Soil treatment, Preemergence, Boom sprayer	DF	NA	3.93 lb A	*	NS	NS	NS	NS	NS	.5	C92
Soil treatment, Preemergence, Low volume sprayer	DF	NA	3.93 lb A	*	NS	NS	NS	NS	NS	.5	C92

LEGEND
444444

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate, Maximum Number of Applications at Maximum Rate, Maximum Dose per Crop Cycle or per Year, Minimum Interval Between Applications (Days), Restricted Entry Interval (Days), Allowed/Disallowed Geographical Areas, Use Limitations Codes.

HEADER ABBREVIATIONS

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

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

DF	: WATER DISPERSIBLE GRANULES (DRY FLOWABLE)
FlC	: FLOWABLE CONCENTRATE
G	: GRANULAR

ABBREVIATIONS

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

APPLICATION RATE

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

LEGEND (con't)
444444

USE LIMITATIONS CODES
C13 : Groundwater restriction.
C46 : Do not apply through any type of irrigation system.
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
CAU : Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.
G96 : Do not graze livestock in treated areas or cut treated crops for feed.
GE8 : Do not graze or harvest for forage or hay.
GH4 : Do not graze or feed for forage.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
013 : Other
AL : Alabama
AR : Arkansas
CA : California
FL : Florida
GA : Georgia
KY : Kentucky
LA : Louisiana
MA : Massachussets
MO : Missouri
MS : Mississippi
NC : North Carolina
NJ : New Jersey
NM : New Mexico
OK : Oklahoma
OR : Oregon
SC : South Carolina
TN : Tennessee
TX : Texas
VA : Virginia
WA : Washington
WI : Wisconsin

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Norflurazon covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to norflurazon in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

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

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Norflurazon

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	00111653, 00079434, 00149768, 42056301, GS-0229-1,2,3
61-2A	**Start. Mat. & Mnfg. Process**	All	00079434, 00111653, 00149768, 42056301, GS-0299-1,2,3
61-2B	**Formation of Impurities**	All	00149768
62-1	**Preliminary Analysis**	All	00149768, 42056301, 42080401 - **DATA GAP**
62-2	**Certification of limits**	All	00149768, 42056301
62-3	**Analytical Method**	All	00149768, 42056301
63-2	**Color**	All	00079434, 00111653, 00149768
63-3	**Physical State**	All	00079434, 00111653, 00149768
63-4	**Odor**	All	00079434, 00111653, 00149768
63-5	**Melting Point**	All	00079434, 00111653, 00149768
63-6	**Boiling Point**	N/A	
63-7	**Density**	All	00149768
63-8	**Solubility**	All	00079434, 00111653, 00149768, 40587901
63-9	**Vapor Pressure**	All	00079434, 00111653, 00149768, 00152751
63-10	**Dissociation Constant**	All	00149768
63-11	**Octanol/Water Partition**	All	00149768
63-12	**pH**	All	00149768

Data Supporting Guideline Requirements for the Reregistration of Norflurazon

REQUIREMENT		USE PATTERN	CITATION(S)
63-13	**Stability**	All	00079434, 00111653, 00149768, 41986902, 43366901
63-14	**Oxidizing/Reducing Action**	All	00149768
63-15	**Flammability**	N/A	
63-16	**Explodability**	N/A	
63-17	**Storage stability**	All	**DATA GAP**
63-18	**Viscosity**	N/A	
63-19	**Miscibility**	N/A	
63-20	**Corrosion characteristics**	All	**DATA GAP**
63-21	**Dielectric breakdown volt**	N/A	
64-1	**Submittal of Samples**	N/A	
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	A,B	00048362, 00063622, 00092234
71-1B	**Acute Avian Oral - Quail/Duck TEP**	N/A	
71-2A	**Avian Dietary - Quail**	A,B	00037051
71-2B	**Avian Dietary - Duck**	A,B	00077292
71-3	**Wild Mammal Toxicity**	N/A	
71-4A	**Avian Reproduction - Quail**	A,B	00039222, 00052172, 42615301
71-4B	**Avian Reproduction - Duck**	A,B	00037051, 42615302
71-5A	**Simulated Field Study**	N/A	
71-5B	**Actual Field Study**	N/A	

Data Supporting Guideline Requirements for the Reregistration of Norflurazon

REQUIREMENT		USE PATTERN	CITATION(S)
72-1A	**Fish Toxicity Bluegill**	A,B	00087862
72-1B	**Fish Toxicity Bluegill - TEP**	N/A	
72-1C	**Fish Toxicity Rainbow Trout**	A,B	00087863
72-1D	**Fish Toxicity Rainbow Trout- TEP**	N/A	
72-2A	**Invertebrate Toxicity**	A,B	00035709
72-2B	**Invertebrate Toxicity - TEP**	N/A	
72-3A	**Estuarine/Marine Toxicity - Fish**	A,B	42080403
72-3B	**Estuarine/Marine Toxicity - Mollusk**	A,B	00045704, 43041802
72-3C	**Estuarine/Marine Toxicity - Shrimp**	A,B	42080402
72-3D	**Estuarine/Marine Toxicity Fish- TEP**	N/A	
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**	N/A	
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**	N/A	
72-4A	**Early Life Stage Fish**	A,B	00118047, 00118048, 00248828, 00248839
72-4B	**Life Cycle Invertebrate**	A,B	00118049, ACC#FA0N0R03
72-5	**Life Cycle Fish**	N/A	
72-6	**Aquatic Organism Accumulation**	N/A	
72-7A	**Simulated Field - Aquatic Organisms**	N/A	

Data Supporting Guideline Requirements for the Reregistration of Norflurazon

REQUIREMENT		USE PATTERN	CITATION(S)
72-7B	**Actual Field - Aquatic Organisms**	N/A	
122-1A	**Tier I: Seed Germination/Seedling Emergence**	N/A	
122-1B	**Tier I: Vegetative Vigor**	N/A	
122-2	**Tier I: Aquatic Plant Growth**	N/A	
123-1A	**Tier II: Seed Germination/Seedling Emergence**	A,B,C	42080404, 43312501
123-1B	**Tier II: Vegetative Vigor**	A,B,C	42080405
123-2	**Aquatic Plant Growth**	A,B,C	42080406, 42080407 - **DATA GAP**
124-1	**Tier III: Terrestrial Field**	N/A	
124-2	**Tier III: Aquatic Field**	N/A	
141-1	**Honey Bee Acute Contact**	A,B	00146168
141-2	**Honey Bee Residue on Foliage**	N/A	
141-5	**Field Test for Pollinators**	N/A	
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	A,B	00111612
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	A,B	00090786, 00111612
81-3	**Acute Inhalation Toxicity - Rat**	A,B	**DATA GAP**
81-4	**Primary Eye Irritation - Rabbit**	A,B	00111612
81-5	**Primary Dermal Irritation - Rabbit**	A,B	00111612

Data Supporting Guideline Requirements for the Reregistration of Norflurazon

REQUIREMENT		USE PATTERN	CITATION(S)
81-6	**Dermal Sensitization - Guinea Pig**	A,B	00111615 - **DATA GAP**
81-7	**Acute Delayed Neurotoxicity - Hen**	N/A	
82-1A	**90-Day Feeding - Rodent**	A,B	00091055
82-1B	**90-Day Feeding - Non-rodent**	A,B	00092290
82-2	**21-Day Dermal - Rabbit/Rat**	A,B	00063617
82-3	**90-Day Dermal - Rodent**	N/A	
82-4	**90-Day Inhalation - Rat**	N/A	
82-5A	**90-Day Neurotoxicity - Hen**	N/A	
82-5B	**90-Day Neurotoxicity - Mammal**	N/A	
83-1A	**Chronic Feeding Toxicity - Rodent**	A,B	00041015, 00041016, 00082019, 00111649
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	A,B	00111618
83-2A	**Oncogenicity - Rat**	A,B	00082019, 00091056, 00111617
83-2B	**Oncogenicity - Mouse**	A,B	000041015, 00041016, 00111649
83-3A	**Developmental Toxicity - Rat**	A,B	00063621
83-3B	**Developmental Toxicity - Rabbit**	A,B	00131151, 00131152
83-4	**2-Generation Reproduction - Rat**	A	00080750, 00080751, 43522301
84-2A	**Gene Mutation (Ames Test)**	A,B	00072974 - **DATA GAP**
84-2B	**Structural Chromosomal Aberration**	A,B	00155734
84-4	**Other Genotoxic Effects**	A,B	00155375
85-1	**General Metabolism**	A	00260490, 00047765, 43081501

Data Supporting Guideline Requirements for the Reregistration of Norflurazon

REQUIREMENT		USE PATTERN	CITATION(S)
85-2	**Dermal Penetration**	N/A	
86-1	**Domestic Animal Safety**	N/A	
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**	N/A	
132-1B	**Soil Residue Dissipation**	N/A	
133-3	**Dermal Passive Dosimetry Exposure**	N/A	
133-4	**Inhalation Passive Dosimetry Exposure**	N/A	
231	**Estimation of Dermal Exposure at Outdoor Sites**	N/A	
232	**Estimation of Inhalation Exposure at Outdoor Sites**	N/A	
233	**Estimation of Dermal Exposure at Indoor Sites**	N/A	
234	**Estimation of Inhalation Exposure at Indoor Sites**	N/A	
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**	N/A	
161-1	**Hydrolysis**	A,B,C	00146165
161-2	**Photodegradation - Water**	A,B,C	00148311
161-3	**Photodegradation - Soil**	A,B	00148311
161-4	**Photodegradation - Air**	N/A	

Data Supporting Guideline Requirements for the Reregistration of Norflurazon

REQUIREMENT		USE PATTERN	CITATION(S)
162-1	**Aerobic Soil Metabolism**	A,B,C	40079601
162-2	**Anaerobic Soil Metabolism**	A,B,C	40079601
162-3	**Anaerobic Aquatic Metabolism**	A	40079601
162-4	**Aerobic Aquatic Metabolism**	A	40079601
163-1	**Leaching/Adsorption/Desorption**	A,B,C	00148312, 41986904, 43681001, 42710901 - **DATA GAP**
163-2	**Volatility - Lab**	N/A	Not required because of the low vapor pressure.
163-3	**Volatility - Field**	N/A	
164-1	**Terrestrial Field Dissipation**	A,B,C	**WAIVED**
164-2	**Aquatic Field Dissipation**	A	**WAIVER PENDING**[1]
164-3	**Forest Field Dissipation**	N/A	
164-5	**Long Term Soil Dissipation**	N/A	
165-3	**Accumulation - Irrigated Crop**	A	**WAIVER PENDING**[1]
165-4	**Bioaccumulation in Fish**	A,B,C	41986905
165-5	**Bioaccumulation - Aquatic NonTarget**	N/A	
166-1	**Ground Water - Small Prospective**	A,B,C	**DATA GAP** - Study in progress; due 1/98.
166-2	**Ground Water - Small Retrospective**	N/A	

[1] Guidelines 164-2 and 165-3 may be waived provided acceptable batch equilibrium studies on peat soils are submitted to the Agency.

Data Supporting Guideline Requirements for the Reregistration of Norflurazon

REQUIREMENT		USE PATTERN	CITATION(S)
166-3	**Ground Water - Irrigated Retrospective**	N/A	
201-1	**Droplet Size Spectrum**	A,B,C	**DATA GAP**
202-1	**Drift Field Evaluation**	A,B,C	**DATA GAP**
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**		00037055, 00047763, 00047764, 00092285, 00095845, 00104774, 00111625, 00150191, 40012008, 41107201, 41762503, 41762504, 42471201, 43041801 - Additional data in Review
171-4B	**Nature of Residue - Livestock**		00025638, 00047765, 00111607, 40012006, 40012009, 41762501, 43081502, 43081503, 43395801, 43395802
171-4C	**Residue Analytical Method - Plants**		00129332, 00152752, 40012007, 40429302, 40765001, 00027375, 00031642, 00085081, 00092294, 00092296, 00106025, 00111625, 00111648, 00111651, 00111667, 00111669, 41770701, 41986903, 42754901, 43672301
171-4D	**Residue Analytical Method - Animal**		42754901
171-4E	**Storage Stability**		00111625, 40079603, 42880802, 43859901 - **DATA IN REVIEW**
171-4F	**Magnitude of Residues - Potable H2O**	N/A	
171-4G	**Magnitude of Residues in Fish**	N/A	

Data Supporting Guideline Requirements for the Reregistration of Norflurazon

REQUIREMENT		USE PATTERN	CITATION(S)
171-4H	**Magnitude of Residues - Irrigated Crop**	N/A	
171-4I	**Magnitude of Residues - Food Handling**	N/A	
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**		
	- Cattle, goat, sheep, hogs, horses, fat, meat and mbyp		00111648, 00111669
	- Milk		00111648, 00111669
	- Poultry, fat, meat and mbyp		00111648, 00111669
171-4K	**Crop Field Trials**		
	Legume Vegetables (Succulent or Dried) Group		
	- Soybeans		00031634, 00079435, 00111625, 00111651, 00111667
	Foliage of Legume Vegetables Group		
	- Soybeans, forage and hay		00031634, 00079435, 00111651
	Citrus Fruits Group		
	- Citrus Fruit		00106025
	Pome Fruits Group		
	- Apples		00106025, 00111648
	- Pears		00111648
	Stone Fruits Group		
	- Apricots		00111655
	- Cherries		00111641

REQUIREMENT	USE PATTERN	CITATION(S)
- Nectarines		00111641
- Peaches		00106025, 00111641
- Plums (fresh prunes)		00111641, 40157701
Small Fruits and Berries Group		
- Blackberries		00131238
- Blueberries		00129332
- Caneberries		PP#4E4383
- Cranberries		00037052, 00111625
- Grapes		00111645, 00128129
- Raspberries		00131238
Tree Nuts Group		
- Almond, hulls		00111648
- Almond, meat		00111648
- Filberts		00106025, 00111641
- Pecans		00106036
- Walnuts		00111641
Miscellaneous Commodities		
- Asparagus		00150867
- Avocados		00150867
- Cottonseed		0009299, 00092300, 00111625
- Cotton, gin by-products		**DATA GAP**
- Peanuts		00111651, PP#6G3319, PP#9F3702

Data Supporting Guideline Requirements for the Reregistration of Norflurazon

REQUIREMENT		USE PATTERN	CITATION(S)
	- Peanuts hay, hulls, vines		00111651, PP#6G3319, PP#9F3702
	- Hops, green		00111648, 42378301
171-4L	**Processed Food**		
	- Citrus, molasses		00106025, 40012007, 42764901,
	- Citrus pulp, dried		00106025, 42764901
	- Citrus, oil		42764901,
	- Cottonseed		00092300, 42495801
	- Hops, dried		00111648
	- Raisin waste		00111645, 00128129, 42663701
	- Soybeans, hulls, meal, crude and refined oil, and soapstock		00031634, 00079435, 00111651, 00111667, 40429302, 42625101
171-5	**Reduction of Residues**	N/A	
171-6	**Proposed Tolerance**	N/A	
171-7	**Support for Tolerance**	N/A	
171-13	**Analtyical Reference Standard**	N/A	
165-1	**Confined Rotational Crop**	A,B	40012005
165-2	**Field Rotational Crop**	A,B	42880801, 42909301

GUIDE TO APPENDIX C

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

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

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

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

   c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

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

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

BIBLIOGRAPHY

MRID	CITATION
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 7; or

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

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

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

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-96).

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

Section I - Why You are Receiving this Notice
Section II - Data Required by this Notice
Section III - Compliance with Requirements of this Notice
Section IV - Consequences of Failure to Comply with this Notice
Section V - Registrants' Obligation to Report Possible Unreasonable Adverse Effects
Section VI - Inquiries and Responses to this Notice

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes provided.

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

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

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

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

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

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

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

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

b. Use Deletion -

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

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

c. Generic Data Exemption -

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

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

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

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

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption

you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

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

d. Satisfying the Generic Data Requirements of this Notice

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

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data Requirements

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

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form,

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

a. Voluntary Cancellation

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

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

b. Satisfying the Product Specific Data Requirements of this Notice.

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

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any

other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide you to additional instructions provided in this Section. The options are:

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

Option 1. Developing Data

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

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

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

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data

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

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

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

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant normally will be subject to initiation of suspension proceedings, unless you commit to submit, and do submit, the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study

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

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

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

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

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

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

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

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

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

Option 5. Upgrading a Study

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

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

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

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

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core-minimum." For ecological effects studies, the

classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option, you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

2. Product Specific Data

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

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

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

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

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

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

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

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

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

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

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

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

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

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

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

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

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

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

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

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its

benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

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

b. Request for Waiver of Data

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

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

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You

should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

iii. Otherwise take appropriate steps to meet the requirements stated in this Notice,

unless you commit to submit and do submit the required data in the specified time frame.

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

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

NORFLURAZON DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Veronica Dutch at (703) 308-8585.

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

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

RE: **NORFLURAZON**

NORFLURAZON DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for norflurazon are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional product chemistry, acute toxicity, residue chemistry, environmental fate, and plant protection data on norflurazon are needed. These data are needed to fully complete the reregistration of all eligible norflurazon products.

INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

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

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Data Call-In Response Forms." Only registrants responsible for generic data have been sent the generic data response form. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

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

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

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

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

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

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

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

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

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

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

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

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

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources

are registered), you may not claim a Generic Data Exemption and you may not select this item.

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

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

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

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

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

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

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

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

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

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

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

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

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Requirements Status and Registrant's Response Forms." Only registrants responsible for generic data have been sent the generic data response forms. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

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

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

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

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

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

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

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

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

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

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

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

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

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

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

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

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical GradeActive Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Indredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites

TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

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

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

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

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

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

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

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

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

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

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

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core

minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

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

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

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

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

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

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant

EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

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

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

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

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

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

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

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

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

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

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

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

Eight products were found which contain norflurazon as an active ingredient. The products have been divided into two batches. One batch consists solely of the technical product, EPA Registration No. 55947-55. As there is currently no acceptable inhalation LD50 or dermal sensitization test for norflurazon, these tests must be conducted on this product. The other batch consists of all other currently registered norflurazon products. There are acceptable data on EPA Registration No. 55947-154. The toxicity profile for this product is as follows:

Acute oral	Category III
Acute dermal	Category III
Acute inhalation	Category III
Eye irritation	Category IV
Skin irritation	Category IV
Dermal sensitization	Non-sensitizer

None of the other products in this batch are expected to be more toxic than this product. Therefore, labeling associated with this toxicity profile is acceptable for all of these products. Should the registrant wish to lower the toxicity category to IV for acute oral, dermal, or inhalation toxicity, the appropriate tests are required on the end-use product.

Table 1 (Batch 1)

EPA Reg. No.	% Active Ingredient	Formulation Type
55947-55	97.8	Solid

Table 2 (Batch 2)

EPA Reg. No.	% Active Ingredient	Formulation Type
55947-57	05.0	Solid
55947-77	78.6	Solid
55947-78	78.6	Solid
55947-154	52.7 norflurazon 26.66 diuron	Solid
GA95000100	78.6	Solid
OR90002400	78.6	Solid
WA90003200	78.6	Solid

Attachment 5. List of All Registrants Sent This Data Call-In (insert) Notice

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			
18. Signature of Approving Official		19. Title		20. Phone No. *(Include Area Code)*		21. Date		

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

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

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date

Name and Title (Please Type or Print)

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

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

APPENDIX E - LIST OF AVAILABLE RELATED DOCUMENTS

The following is a list of available documents for norflurazon that my further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Veronica Dutch at (703)-308-8585.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for norflurazon.

The following documents are part of the Administrative Record for norflurazon and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria