United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

EPA 738-R-04-012
July 2004

Reregistration Eligibility Decision for Benfluralin

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the risk assessment for the dinitroaniline pesticide, benfluralin (Balan®). Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of benfluralin. The EPA is now publishing its reregistration eligibility and risk management decisions for the current uses of benfluralin, and its associated human health and environmental risks. The enclosed "Reregistration Eligibility Decision for Benfluralin," which was approved on July 30, 2004, contains the Agency's decision on the individual chemical benfluralin.

A Notice of Availability for this Reregistration Eligibility Decision (RED) for benfluralin is published in the *Federal Register*. To obtain a copy of the RED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the RED and all supporting documents are available on the Internet. See http://www.epa.gov/pesticides/reregistration/status.htm.

This document and the process used to develop it are the result of EPA's program to facilitate greater public involvement and participation in the Agency's pesticide reregistration and tolerance reassessment decision making. Since the enactment of the Food Quality Protection Act of 1996 (FQPA), EPA has undertaken special efforts to increase transparency, consult with stakeholders, and engage the public in developing pesticide reregistration and tolerance reassessment decisions. The human health and environmental risk assessments for benfluralin were placed in the public docket and issued for public comment through a *Federal Register* notice on February 25, 2004.

At this time, the Agency does not have sufficient data concerning common mechanism issues to determine whether or not benfluralin shares a common mechanism of toxicity with other substances, including other dinitroaniline or other pesticides. Therefore, for the purposes of this action, the Agency has assumed that benfluralin does not share a common mechanism of toxicity with any other chemicals.

End-use product labels should be revised by the manufacturer to adopt the changes set forth in Section V of this document. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in Section V of this document.

If you have questions on this document or the proposed label changes, please contact the Special Review and Reregistration Division representative, Katie Hall, at (703) 308-0166. For questions about product reregistration and/or the Product data call-in (DCI) that accompanies this document, please contact Moana Appleyard at (703) 308-8175.

Debra Edwards, Ph.D.
Director, Special Review and Reregistration Division

Attachment

Reregistration Eligibility Decision

for

Benfluralin

List B
Case 2030

Approved By:

_____
Debra Edwards, Ph.D.
Director, Special Review and
Reregistration Division

_____
Date

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration.
EP	End-Use Product
EPA	Environmental Protection Agency
ESA	Endangered Species Act
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
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.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MUP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate

OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PCA	Percent Crop Area
PAD	Population Adjusted Dose
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/ EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Benfluralin Reregistration Eligibility Decision Team
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Executive Summary

This document presents the Environmental Protection Agency's (the Agency or EPA) decision regarding the reregistration eligibility of the registered uses of benfluralin. The Agency made its reregistration eligibility determination based on the required data, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that currently registered uses of benfluralin are eligible for reregistration, provided the changes specified in this document are made to the label.

Benfluralin is a pre-emergent herbicide registered for use on residential and commercial turf, alfalfa, clover, birdsfoot trefoil, lettuce, non-bearing fruit and nut trees, non-bearing berries, non-bearing vineyards, ornamentals, non-cropland areas, fence rows/hedgerows, and Christmas tree plantations. There are tolerances for benfluralin on alfalfa, birdsfoot trefoil, clover, and lettuce. A use site for peanuts has been voluntarily cancelled from the technical label by the registrant, and the peanut tolerance will be proposed for revocation by EPA. The Agency estimates that approximately 700,000 pounds of active ingredient are used annually, with approximately 80% used on turf.

Risks summarized in this document are those that result only from the use of benfluralin. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect at would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for benfluralin. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative.

Dietary Risk from Food

Benfluralin's dietary risk assessment considered both acute and chronic risks from residues in food based on field trials. The acute and chronic dietary (food) risks are less than 100% of the Acute Population Adjusted Dose (aPAD) and Chronic Population Adjusted Dose (cPAD) for all population subgroups and are not of concern.

Dietary Risk from Drinking Water

Benfluralin has at least 26 identified degradates, but none were of significant toxicity. One degradate, 2,6-dinitro-4-trifluoromethyl-phenol, was found at a level of 0.133 ppm in an aerobic soil study, and environmental fate data indicate that this degradate is more mobile than parent benfluralin, and has a higher potential to leach to ground water than parent. On this basis, it is considered in the drinking water assessment.

The Agency estimates potential surface water and ground water pesticide contamination using models. All modeled surface water EECs (< 3.5) and ground water EECs (< 0.07) are less than the DWLOCs (50 or greater) and therefore are not of concern. The available monitoring data indicates that benfluralin is found at a lower level in surface water than the modeling estimates indicate. All detections are well below the DWLOCs and are not of concern.

Residential Risk

Residential handlers may be exposed to benfluralin during and after application on home lawns and ornamental plants; or after applications at golf courses, parks, and schools. Benfluralin products are marketed for homeowner use on residential lawns and landscape ornamental plants. Benfluralin containing products are also marketed for use by professional applicators (Lawn Control Operators, or LCOs) on residential turf, on golf courses, other turf such as recreational or commercial areas, and on ornamental plantings. Based on these uses, benfluralin has been assessed for the residential applicator (or "handler") and for children's post-application exposure that may occur from turf contact and hand to mouth transfer.

Benfluralin is not assessed for systemic dermal toxicity (because no systemic toxicity was observed from a dermal toxicity study in rats), but is assessed for systemic inhalation toxicity. All residential handler MOEs are greater than 100 and therefore risks to residential handlers are not of concern.

Benfluralin uses in the residential setting include applications to ornamentals and to lawns. Although the type of use site for benfluralin varies from golf courses to ornamental gardens, the scenario chosen for risk assessment (residential turf use) represents what the Agency considers the likely upper-end estimate of possible exposure. For this assessment, children are the population group most likely to be significantly exposed. Since systemic toxicity was not observed in a dermal toxicity study, up to a dose level of 1,000 mg/kg/day, the only risk addressed in the assessment is the possible oral exposure of small children from treated turf, or from treated soil (i.e., soil ingestion, granule ingestion, and hand-/object-to-mouth transfer). A Margin of Exposure of 100 (or more) is considered protective for this assessment. The oral MOE from all ingestion exposures to children is above 100, and therefore these risks are not of concern. Postapplication inhalation exposure is expected to be minimal.

Benfluralin Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water pathways) as well as exposures from non-occupational sources (e.g., residential uses). Drinking water exposure to pesticides can occur through ground water and surface water contamination. In assessing drinking water risks, EPA considers acute (one day), chronic (long-term) and cancer (overall mean) exposure, and uses either modeling or monitoring data if available, to estimate those risks. To determine the maximum contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then calculates a "drinking water level of comparison" (DWLOC) to determine whether modeled or monitoring

exposure estimates exceed the allowable risk level. Estimated environmental concentrations (EECs) that are above the corresponding DWLOC exceed the Agency's level of concern.

Acute Aggregate Risk. There are no adverse effects expected from a single exposure to benfluralin; therefore, an acute aggregate risk assessment was not conducted.

Short-term Aggregate Risk. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water. Short-term aggregate risk from residential inhalation, incidental oral exposure to children, and chronic exposure to food and drinking water are not of concern.

Chronic Aggregate Risk. The chronic aggregate risk assessment addresses only exposure to benfluralin residues in food and water, since there are no benfluralin uses that would result in chronic residential exposure. Chronic aggregate risk is not of concern.

Occupational Risk

The Agency has identified 13 handler scenarios resulting from mixing/loading and applying benfluralin for crop and non-crop uses. Of the 13 scenarios, all short- and intermediate-term exposures resulted in an MOE above 100 and are therefore not of concern.

Ecological Risk

Available data indicates that benfluralin is of variable soil persistence with different mechanisms of degradation. Benfluralin has low mobility in soils, according to available mobility studies (K_{oc} values range from 9840 to 11,660 L/kg). Acceptable field dissipation studies observed in three different locations indicate moderate half-lives of 22 to 79 days. Benfluralin volatilizes rapidly, as indicated in laboratory volatility studies.

Parent benfluralin is not expected to leach into ground water, based on its low mobility in soil. However, degradate 2,6 dinitro-4-trifluoromethyl-phenol was formed at 6% of parent in the soil metabolism study. Based on limited environmental fate information, it has the potential to contaminate groundwater. Trifluoroacetic acid (TFA) was not found in environmental fate studies, but was noted as a plant metabolite.

Based on its measured bioaccumulation factor in whole fish (1580), parent benfluralin is considered to be bioaccumulative. The depuration rate was 0.54 per day for whole fish.

Most ecological risk quotient (RQ) values are 9 and below, including RQ values for acute risk to freshwater fish, freshwater invertebrates, and estuarine invertebrates, and for chronic risk to birds, mammals, and freshwater fish. The highest RQ value for non-cropland areas at the maximum application rate of 12 lb ai/A per year is 24 for chronic risk to mammals. The RQs for non-target terrestrial and aquatic plants have not been calculated due to lack of toxicity data.

Endangered Species

EPA has reviewed ecotoxicity and fate data for benfluralin to assess potential effects on endangered species. This limited analysis indicates that some of the previously allowed uses are likely to have no effects on certain taxa of listed species, but other uses might potentially be affecting listed species. On the basis of that analysis, we have decided that some generally applicable risk mitigation measures (e.g., reduced application rates) would be appropriate. We expect such measures will reduce risks for non-target wildlife in general, and threatened and endangered species, in particular. EPA anticipates refining its assessment of the potential risks to listed species and critical habitat in the future, after additional data are submitted as required under the RED. EPA will follow the approach for ecological risk assessment described in the Overview of the Benfluralin Risk Assessments, dated December 15, 2003, available on the e-docket website at www.epa.gov/edocket. To the extent the refined assessments indicate that benfluralin is harming listed species or critical habitat, we will take appropriate steps to ensure compliance with FIFRA and the Endangered Species Act (ESA). Such actions may include initiating consultation with the Services and/or site-specific risk mitigation measures, consistent with the Endangered Species Protection Program.

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at www.epa.gov/espp. A final Endangered Species Protection Program, which may be altered from the interim program, was proposed for public comment in the Federal Register December 2, 2002.

Risk Mitigation Summary

To mitigate the risks of concern posed by the use of benfluralin, EPA considered the mitigation proposed by the technical registrant, as well as risk mitigation ideas from other interested parties, and has decided on a number of label amendments to address ecological concerns. A summary of the risk mitigation is listed below. A complete discussion of the risks, and the label amendments necessary to mitigate them are presented in Chapter IV of this RED.

- Reduction in application rate and limitation in the number of applications for non-cropland areas, landscape ornamentals, field-grown ornamentals, container-grown ornamentals, non-bearing vineyards, non-bearing fruit and nut trees, non-bearing berries, and Christmas tree farm use sites.

- For granule applications to turf, watering in will be required.

- Peanut use site has been voluntarily cancelled from the technical labels and the peanut tolerance will be proposed for revocation by the Agency.

Conclusions

The Agency is issuing this Reregistration Eligibility Decision (RED) for benfluralin, as announced in a Notice of Availability published in the *Federal Register*. This RED document includes guidance and time frames for complying with any required label changes for products containing benfluralin. With the addition of the label restrictions and amendments detailed in this document, the Agency has determined that all currently registered uses of benfluralin are eligible for reregistration.

The risk assessments for benfluralin are based on the best scientific data currently available to the Agency and are adequate for regulatory decision making.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 and amended again by the Pesticide Registration Improvement Act of 2003 to set timeframes for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or the Agency). Reregistration involves a thorough review of the scientific database 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 or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act (FQPA) was signed into law. This Act amends FIFRA to require that by 2006, EPA must reassess all tolerances in effect at the time of the enactment. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity.

Benfluralin is a pre-emergent dinitroaniline herbicide used to control grasses on commercial and residential turf. Benfluralin also has four food/feed use sites that include lettuce, alfalfa, clover, and birdsfoot trefoil. Other nonfood/nonfeed sites include non-bearing fruit and nut trees, non-bearing berries, non-bearing vineyards, turf, ornamentals, rights of way, fence rows/hedgerows, and Christmas tree plantations.

The Agency has concluded that the FQPA Safety Factor for benfluralin should be removed (equivalent to 1X) based on a complete database for FQPA consideration and a conclusion that there is no increased susceptibility following pre- and/or postnatal exposure. The FQPA Safety Factor recommendation assumes that the exposure databases (food, drinking water, and residential) are complete, the risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern, and does not underestimate the potential risk for infants and children. These criteria have been met in the benfluralin risk assessment.

Risks summarized in this document are those that result only from the use of benfluralin. The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for benfluralin and any other substances and benfluralin does not appear to produce a toxic metabolite produced by other substances. For the

purposes of this action, therefore, EPA has assumed that benfluralin does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of benfluralin, including the consideration of risk to infants, children and adults for any potential food, drinking water, dermal, inhalation or oral exposures from residential uses. In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting documents for benfluralin referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page at *www.epa.gov/pesticides*, and in the Public Docket at http://www.epa.gov/edocket.

This document consists of six sections. Section I is the introduction. Section II provides a chemical overview, a profile of the use and usage of benfluralin, and its regulatory history. Section III, Summary of Benfluralin Risk Assessment, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management, Reregistration, and Tolerance Reassessment Decision, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

II. Chemical Overview

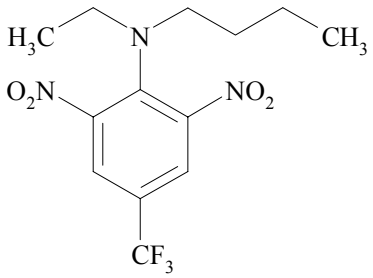
A. Regulatory History

Benfluralin has been registered in the United States since l970 for use as a pre-emergent dinitroaniline herbicide. During the second phase of reregistration, the Agency conducted a review of the scientific data base underlying pesticide registrations and identified missing or inadequate studies. Subsequent Data Call-Ins (DCIs) were issued in 1991, and 1995 for benfluralin. This Reregistration Eligibility Decision (RED) reflects a reassessment of all data submitted to date.

There are approximately 120 products containing benfluralin, registered under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Currently, there are no Section 18 (Emergency Exemption) uses, or Section 24(c) (Special Local Needs) uses registered for benfluralin. This Reregistration Eligibility Decision document evaluates risks from all currently registered uses, including agricultural food and non-food crops; non-bearing fruit and nut trees; non-bearing berries; non-bearing vineyards; Christmas tree plantations; non-agricultural use areas such as rights-of-way, and turf.

A close-out conference call was conducted on July 28, 2004, with EPA, USDA, and the registrants to discuss the risk management decisions and resultant changes to the benfluralin labels.

B. Chemical Identification



- **Common name:** Benfluralin, Benefin
- **Chemical name:** [N-butyl-n-ethyl-alpha-alpha-alpha-tri-fluoro-2,6-dinitro-p-toluidine]
- **Chemical Family:** Dinitroaniline
- **Empirical formula:** $C_{13}H_{16}F_3N_3O_4$
- **CAS Registry No.:** 1861-40-1
- **Case number:** 2030
- **OPP Chemical Code:** 084301
- **Molecular weight:** 335.3
- **Trade name:** Balan
- **Basic manufacturer:** Dow AgroSciences LLC, Loveland Products LLC

Technical benfluralin is a yellowish-orange, crystalline solid with a melting point of 65-68 °C. The water solubility of benfluralin is 0.1 ppm at pH 7.00 and 25 °C. Benfluralin has a vapor pressure of 6.57 x 10^{-5} mm Hg at 25 °C.

C. Use Profile

The following is information on the currently registered uses of benfluralin products and an overview of use sites and application methods. A detailed table of the uses of benfluralin eligible for reregistration is contained in Appendix A.

Type of Pesticide: Herbicide

Summary of Use: Benfluralin is a pre-emergent dinitroaniline herbicide used to control grasses and other weed species. Benfluralin is used alone and is also commonly formulated with trifluralin and oryzalin.

Food: Benfluralin is used on a single food crop (pre-plant on lettuce), and on several feed crops (pre-plant on alfalfa, clover, trefoil). There are tolerances for benfluralin on alfalfa, birdsfoot trefoil, clover, and lettuce. The use for peanuts has been voluntarily canceled by the registrant and the tolerance for peanuts will be proposed for revocation by the Agency.

Non-Food: Benfluralin is registered for use on non-bearing fruit and nut trees, non-bearing berries, non-bearing vineyards, turf, ornamentals, rights of way (including industrial sites, utility substations, highway guardrails, sign posts, and delineators), fence rows/hedgerows, and Christmas tree plantations.

Residential: Benfluralin is used on residential turf and ornamental plants.

Target Pests: Target pests include Johnsongrass seedlings, chickweed, lambsquarters, purslane, knotweed, clover, pigweed, plantain, crabgrass, foxtail, goosegrass, and *Poa annua*, barnyardgrass and fescue. Benfluralin works by inhibiting growth (mitotic disruptor).

Formulation Types: Formulated as emulsifiable concentrate, granules, soluble concentrate/liquid, water dispersible granules (dry flowable).

Method and Rates of Application:

Equipment: Benfluralin is applied as band treatment, broadcast, golf course treatment, soil incorporated treatment, and spray with ground or sprinkler irrigation systems. Equipment used to apply benfluralin include groundboom, push spreader, bellygrinder, shaker can, low

pressure hand wand, tractor/ATV drawn spreader, pump-feed and gravity-feed backpack sprayer, handgun sprayer, and bucket and spoon.

Application Rates: Current maximum labeled agricultural rates per application are 1.2 - 3.0 lbs ai/A. Current maximum labeled non-agricultural rate per application is 1.5 - 6.0 lbs ai/A. The current maximum agricultural rate per year is 6 lbs ai/acre. The current maximum non-agricultural rate per year is 12 lbs ai/A.

Timing: Applied pre-emergent for all use sites.

Use Classification: General Use

Registrants: Dow AgroSciences LLC (formerly DowElanco), United Phosphorus, Inc., and Loveland Products, (formerly Platte Chemical Company).

D. Estimated Usage of Pesticide

Table 1 summarizes the best estimates available for the uses of benfluralin. The estimate for total domestic use (annual average) is approximately 700,000 pounds of active ingredient, with the majority of use in the following sectors: lawn care operator, landscape, other turf, alfalfa, and lettuce.

Table 1. Benfluralin Usage Summary

Site	Lbs. Active Ingredient Applied (Weighted Average)[1]	Percent Crop Treated (Likely Maximum)	Percent Crop Treated (Weighted Average)[1]
Lawn Care Operator	430,000	---	---
Landscape	85,000	---	---
Other Turf	100,000	---	---
Alfalfa	50,000	< 2%	< 1%
Lettuce	35,000	12%	9%

[1]Weighted Average: the most recent years and more reliable data are weighted more heavily.

III. Summary of Benfluralin Risk Assessments

The following is a summary of EPA's human health and ecological effects risk findings and conclusions for the pre-emergent dinitroaniline pesticide benfluralin, as presented fully in the documents: "Benfluralin: Human Health Risk Assessment (Revised)," dated October 30, 2003 (including addendum, dated June 8, 2004); "Response to Dow AgroSciences' Comments on EFED RED Chapter for Benfluralin," (including as an attachment, the Environmental Fate and Effects Risk Assessment), dated June 4, 2004; here after referred to as the Environmental Fate and Effects Risk Assessment.

The purpose of this section is to summarize the key features and findings of the risk assessments in order to help the reader better understand the conclusions reached in the assessments. Risks summarized in this RED document are those that result only from the use of benfluralin. While the risk assessments and related addenda are not included in this RED, they are available from the OPP Public Docket and may also be accessed on the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

A. Human Health Risk Assessment

1. Dietary Risk from Food

A brief overview of the toxicity studies used for endpoints in the dietary risk assessments is outlined below in Table 2. Further details on the toxicity of benfluralin can be found in the "Human Health Risk Assessment (Revised)," dated October 30, 2003 (including addendum, dated June 8, 2004).

a. Toxicity of Benfluralin

The Agency has reviewed all toxicity studies submitted for benfluralin and has determined that the toxicological database is sufficient for reregistration. The studies have been submitted to support guideline requirements.

Major features of the toxicology profile are presented below. In acute studies, benfluralin has low acute toxicity (Toxicity Category IV) by the oral and dermal routes. For primary skin and eye irritation, benfluralin was placed in Toxicity Category III. In guinea pig studies, technical benfluralin was found to be a dermal sensitizer. The acute toxicity data table is listed below.

Table 2. Acute Toxicity Data on Benfluralin

Guideline No./ Study Type	MRID Number	Results	Toxicity Category
870.1100 Acute Oral Toxicity	00024255 (rat, 1965)	LD50 > 10 g/kg (adults) 0 out of 10 died at 5 and 10 g/kg	IV
870.1200 Acute Dermal Toxicity	41751701 (rabbit, 1990)	LD50 > 5 g/kg	IV
870.1300 Acute Inhalation Toxicity	41613807 (rat, 1989)	LC50 > 2.3 mg/L	IV
870.2400 Acute Eye Irritation	00024265 (rabbit, 1976)	Slightly irritating, reversible within 7 days	III
870.2500 Acute Dermal Irritation	41751702 (rabbit, 1990)	Moderate erythema and edema at day 7, which cleared by day 11.	III
870.2600 Skin Sensitization	00144283 (guinea pig, 1990)	7 out of 12 guinea pigs tested positive in the Beuhler test	Skin Sensitizer

In longer-term studies, benfluralin is toxic to the kidneys and liver (20 mg/kg/day, female rats, MRID 44050001), and is toxic to the thyroid at high dose levels (136.3 mg/kg/day, male rats). Rats show a lowest observed adverse effect level (LOAEL) based on kidney toxicity. Dogs show a LOAEL based on liver toxicity and mice show a LOAEL based on liver and kidney toxicity. Other dinitroaniline pesticides show a mixture of kidney, liver, hematological, and thyroid toxicity at their respective LOAELs.

No appropriate endpoints (effects) attributable to a single exposure (dose) were identified in any study including developmental studies in rabbits or rats. Therefore, an acute RfD was not established and EPA has not assessed acute dietary risk for benfluralin.

Risk assessment for chronic dietary exposure is based on a no observed adverse effect level (NOAEL) of the combined chronic toxicity/oncogenicity study in rats. The NOAEL for chronic toxicity was 0.5 mg/kg/day for males and 0.7 mg/kg/day for females, based on an increased incidence of histologic lesions of the kidney in males and females at the LOAEL of 5.4 mg/kg/day for males and 6.8 mg/kg/day for females.

The short-term incidental oral exposure endpoint is used to assess oral exposure for a duration up to 30 days. In a rabbit developmental study, the maternal NOAEL was determined to be 100 mg/kg/day and the LOAEL 225 mg/kg/day, based on dose related nominal body weight gain decrement, few feces, and reduced food consumption. Intermediate-term incidental oral exposure is not expected based on current use patterns and labeling.

In a 21-day dermal toxicity (rabbit) study conducted with benfluralin, the LOAEL was found to be 100 mg/kg/day, the lowest dose tested. In this study, a NOAEL was not established. Dose-related dermal effects included epidermal hyperplasia, hyperkeratosis, parakeratosis, chronic-active

inflammation, edema, and hyperplasia of the sebaceous glands. No systemic effects were seen with technical benfluralin (95.8%) at the highest dose tested (1000 mg/kg/day), but severe dermal effects were seen in the study 3 days after starting treatment with benfluralin.

In a modified Beuhler topical patch test for skin sensitization (guinea pig), several test animals responded with a typical delayed hypersensitivity reaction to a challenge with technical benfluralin at 5% in 95% ethanol. Formulated products showed no evidence of sensitization in Beuhler's assays when tested concentrations ranged from 19% to 60% benfluralin. Further testing of benfluralin products will be conducted during product reregistration.

There are no dermal adsorption studies for benfluralin. However, the Agency estimated a 3% dermal absorption factor for benfluralin based on the results of the dermal adsorption study for ethalfluralin, a structurally related compound.

Risk assessment for short-term inhalation exposure is based on an oral study. The Agency selected the developmental study in rabbits to be the basis for short-term inhalation risk assessment. Also, an assumption is made that 100% of the estimated inhalation dose will be absorbed. Risk estimates are based on the NOAEL dose of 100 mg/kg/day. The maternal LOAEL in the study is 225 mg/kg/day based on decreases in food consumption.

Intermediate-term inhalation risk assessment is based on the two-generation rat reproduction study, where liver and kidney toxicity were observed at the LOAEL of 68 mg/kg/day. The NOAEL is 7.2 mg/kg/day. As in the short-term inhalation risk assessment, an assumption is made that 100% of the estimated inhalation dose will be absorbed. All toxicological endpoints used for risk assessment are presented in Table 3 below.

Table 3: Endpoints for Benfluralin Risk Assessment

Exposure Scenario	Dose used in Risk Assessment (mg/kg/day)	FQPA Safety Factor*, Level of Concern for Risk Assessment, Uncertainty Factor, Absorption Rate	Study and Toxicological Effects
Acute Dietary	An appropriate endpoint attributable to single dose was not identified; therefore, an acute RfD / aPAD was not established.		
Chronic Dietary (All populations)	NOAEL = 0.5	FQPA SF = 1 X UF = 100 Chronic RfD = 0.005 mg/kg/day cPAD = 0.005/1 = 0.005 mg/kg/day	Chronic /carcinogenicity-Rat LOAEL = 5.4 mg/kg/day based on increased histopathologic lesions of the kidneys seen in males (5.4 mg/kg/day for males and 6.8 mg/kg/day for females).
Dermal, Short, Intermediate and Long-Term	None	There was no systemic toxicity in the 21-day dermal study and dermal toxicity showed no NOAEL.	
Inhalation, Short-Term (1-30 days)	NOAEL= 100	Residential Level of Concern (LOC) for MOE = 100 Occupational Level of Concern (LOC) for MOE = 100 absorption rate = 100%	Oral Developmental toxicity - Rabbits LOAEL = 225 mg/kg/day based on decreases in maternal body weight gain over a 13 day dosing period.

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

In accord with the Agency's Draft Guidelines for Cancer Risk Assessment (July, 1999), the Agency Cancer Assessment Review Committee (CARC) classified benfluralin into the category "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential" by the oral route based on the following weight of evidence considerations: 1) The two highest doses resulted in an increase in tumors of the liver and thyroid. However, these doses were considered excessive by the Agency review committee and no tumors were seen at lower doses, which were considered adequate for cancer testing. This study contributes little to the overall weight of evidence for a positive finding of carcinogenicity for benfluralin. 2) Female mice had a borderline statistically significant increase in liver tumors by both trend and pairwise tests at doses that were adequate. No tumors were seen in the male mice, but after considering additional new data, the Agency determined that the doses tested in the males were not high enough and this part of the mouse cancer testing should be repeated. 3) There was a lack of carcinogenic potential in rats, a lack of mutagenic potential in a battery of tests, and structurally related pesticides were classified as "C" carcinogens with their respective mutagenicity studies showing no uniform pattern of mutagenicity.

Suggestive evidence of neuropathy occurring only in rats and only at study termination was evaluated by the Agency. This neuropathy was considered to be due to normal age related neuropathy in aging rats at excessive dose levels. The Agency concluded that acute and subchronic

neurotoxicity studies are not required because the neuropathy effects would not likely occur at the doses that would be tested in these studies.

Benfluralin shows no developmental toxicity in two studies (in the rat and rabbit) at maternally toxic doses. The 2-generation rat reproduction study showed pup weight decrement at parentally toxic dose levels and decreased live pups at the highest dose level tested. Thus, there was no evidence for quantitative or qualitative increased susceptibility of fetuses or offspring.

No obvious endocrine related effects were noted on the organs of reproduction. Thyroid toxicity in rats was seen at the highest dose, but whether or not these thyroid effects were directly related to endocrine modulation by benfluralin can not be determined based on the data submitted.

b. FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide up to an additional 10-fold safety factor (10x), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. The Agency has concluded that the FQPA Safety factor should be removed (equivalent to1X) based on a conclusion of no increased susceptibility and no residual uncertainty. The FQPA Safety Factor assumes that the exposure databases (food, drinking water, and residential) are complete, the risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern, and does not underestimate the potential risk for infants and children. These criteria have been met in the benfluralin risk assessment. The food (dietary) assessment for benfluralin is a Tier 1, or screening type assessment, because it is based on tolerance level residues and assumes 100% of considered crops are treated with benfluralin. The drinking water (dietary) assessment is based on an adequate environmental fate database for parent benfluralin and, in the absence of complete fate data for all degradates of concern, upper-bound estimates were made using data on the parent compound such that the estimated environmental concentrations (EECs) are not underestimated. The benfluralin residential risk assessment is also considered an upper-bound assessment since it is based on maximum use rates, the Agency's Residential SOPs (which tend to be conservative) and more recent data from the Outdoor Residential Exposure Task Force (ORETF).

c. Population Adjusted Dose

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor (SF). This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern.

1) Acute PAD

As discussed in Section III.A.1.a, EPA has not assessed acute dietary risk for benfluralin because no appropriate endpoint attributable to a single exposure (dose) could be identified. As a result, an acute dietary RfD was not established.

2) Chronic PAD

Dietary risk for benfluralin is assessed by comparing chronic dietary exposure estimates (in mg/kg/day) to the benfluralin cPAD. Dietary risk is expressed as a percent of the cPAD. The cPAD is the chronic Population Adjusted Dose, which is the chronic Reference Dose (0.005 mg/kg/day) modified by the FQPA safety factor. The benfluralin cPAD is 0.005 mg/kg/day based on a RfD of 0.005 mg/kg/day, and incorporating the FQPA safety factor of 1x (no special factor) for the overall U.S. population or any populations subgroups. The cPAD was derived from a combined rat chronic/carcinogenicity study, in which benfluralin was administered to Fischer 344 rats (60/sex/dose) in the diet at dose levels at 0.5, 5.0, 125, and 250 mg/kg/day for up to two years, with a NOAEL of 0.5 mg/kg/day as noted in Table 3 above.

d. Exposure Assumptions

The benfluralin chronic dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), Version 1.3, which incorporates consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The CSFII data are based on the reported food consumption by more than 20,000 individuals over two nonconsecutive survey days. For the chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups. Exposure estimates are reported in mg per kg of body weight per day, and risk is expressed as a percent of the cPAD.

e. Dietary (Food) Risk Assessment

1) Acute Dietary Risk

Acute risk is not a concern for benfluralin since no appropriate endpoint attributable to a single dose has been identified.

2) Chronic (Noncancer) Dietary Risk

Benfluralin food and feed use sites currently include alfalfa, birdsfoot trefoil, clover, lettuce, and peanuts at 0.05 ppm. The use on peanuts was not included in the dietary risk assessment since the peanut use site is not being supported by the registrants. The voluntary cancellation notice was published in the *Federal Register* Notice on June 25, 2003 and became effective on December 22, 2003. The established tolerance for peanuts will be proposed for revocation. Feeding studies in ruminants and poultry demonstrated that, based on the expected residue levels in treated feed items

(alfalfa, birdsfoot trefoil, clover), there would in turn be no expectation of finite residue in the livestock commodities of milk, meat, poultry, and eggs.

The remaining food use for benfluralin is on lettuce. An upper-bound (tier 1) chronic dietary risk assessment was conducted for benfluralin. The residue estimate for lettuce, the only direct food use for benfluralin, is based on the level set for tolerance (0.05 ppm). Also, an assumption is made that 100% of the U.S. lettuce crop is treated with benfluralin. Estimated chronic dietary risk estimates for all population subgroups are less than 1% of the benfluralin cPAD (0.005 mg/kg/day) and do not indicate a concern for this route of exposure.

For more information on chronic dietary risk assessment, please refer to the Dietary Exposure and Risk Analysis sections of the "Human Health Risk Assessment (Revised)," dated October 30, 2003 (including addendum, dated June 8, 2004).

2. Dietary Risk from Drinking Water

Benfluralin has at least 26 identified degradates, but none were of significant toxicity. One degradate 2,6-dinitro-4-trifluoromethyl-phenol was found at a level of 0.133 ppm in an aerobic soil study, and environmental fate data indicate that this degradate is more mobile than parent benfluralin, and has a higher potential to leach to ground water than parent. On this basis, it is considered in drinking water assessment. For a listing of all identified degradates, see the Environmental Fate and Effects Risk Assessment.

Drinking water exposure to pesticides can occur through ground and surface water contamination. In assessing drinking water risks, EPA considers acute (one day), chronic (long-term) and, if applicable, cancer (overall mean) exposure, and uses either modeling or monitoring data if available, to estimate those risks. To determine the maximum contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then calculates a "drinking water level of comparison" (DWLOC) to determine whether modeled or monitoring exposure estimates exceed the allowable risk level. Estimated environmental concentrations (EECs) that are above the corresponding DWLOC exceed the Agency's level of concern.

a. Surface Water

Modeling: Estimated surface water (drinking water) concentrations are based on two models coupled together, PRZM and EXAMS. The PRZM/EXAMS combined model is a Tier II assessment that includes refined assumptions. The Estimated Environmental Concentrations (EECs) have been calculated for two types of dietary risk assessment: 1) acute or peak concentration; 2) non-cancer chronic concentration. Since acute dietary risk is not a concern, the only EECs of interest for benfluralin are the chronic (non-cancer) concentrations, which are defined as the highest (90^{th} percentile) in a ten-year span. All modeled surface water EECs are less than the DWLOCs and therefore are not of concern.

Monitoring: At the present time, the Agency has limited monitoring data on the concentrations of benfluralin and/or degradates in surface water. The available monitoring data indicates that benfluralin is found at a lower level in surface water than the modeling estimates indicate. The U.S. Geological Survey (USGS) has performed monitoring for parent benfluralin under the NAWQA program. Of over 5000 samples, benfluralin was detected in 92 samples at a maximum concentration of 0.097 ppb. All detections are well below the DWLOCs and are not of concern.

b. Ground Water

Modeling: The SCI-GROW model was used to estimate potential ground water concentrations. SCI-GROW is a screening tool, or tier 1 model for ground water. It is based on a regression approach which relates the concentrations found in ground water in Prospective Ground Water studies to aerobic soil metabolism rate and soil-water partitioning properties of the chemical. The SCI-GROW EECs for benfluralin were 0.009 ppb for alfalfa, 0.020 ppb for turf, and 0.07 ppb for rights of way use sites. These estimates are below the DWLOCs for all populations.

Monitoring: The Pesticides in Ground Water Database ((EPA 734-12-92-001, Sept. 1992) shows that benfluralin was looked for in 83 wells in Arkansas in 1986-1987, 1 well in California in 1984-1989, and 22 wells in Oregon in 1985-1987. There were no detections of benfluralin.

For more information on drinking water risks and the calculations of the DWLOCs, see the Water Exposure section of the "Human Health Risk Assessment (Revised)," dated October 30, 2003 (including addendum, dated June 8, 2004).

3. Residential and Other Nonoccupational Exposure

Residential risk assessment considers all potential pesticide exposure, other than exposure due to residues in foods or in drinking water. Exposure may occur during and after application on home lawns and ornamental plants; or after applications at golf courses, parks, schools, etc. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE), which is the ratio of estimated exposure to an appropriate No Observed Adverse Effect Level (NOAEL) dose. Benfluralin products are marketed for homeowner use on residential lawns and landscape ornamental plants. Benfluralin containing products are also marketed for use by professional applicators (Lawn Control Operators, or LCOs) on residential turf, on golf courses, other turf such as recreational/commercial areas, and on ornamental plantings. Based on these uses, benfluralin has been assessed for the residential applicator (or "handler") and for children's post-application exposure that may occur from turf contact and hand to mouth transfer.

a. Residential Applicator (Handler)

1) Exposure, Scenarios, Data, and Assumptions

Homeowners (or others) may be exposed to benfluralin while treating their lawns. All homeowner-use products are in granular form with the active ingredient (ai) comprising up to 1.25% of total formulation. Benfluralin is applied by typical push-type spreaders or bellygrinders before seasonal weed emergence, at a rate up to 3 lbs. ai/acre. A number of assumptions, or estimates, such as adult body weight and area treated per application, are made by the Agency for residential risk assessment. Also, note that residential handlers are addressed somewhat differently than occupational handlers in that homeowners are assumed to complete all elements of an application (mix/load/apply) without use of protective equipment (assessments are based on an assumption that individuals will be wearing short pants and short-sleeved shirts).

The quantitative exposure/risk assessment developed for residential handlers is based on these scenarios:

Granular formulation: loading/applying with bellygrinder spreader
Granular formulation: loading/applying with push-type spreader
Granular formulation: loading/applying with shaker can.

Benfluralin-specific data to assess the above exposure scenarios were not submitted to the Agency in support of reregistration. Instead, exposure estimates for these scenarios are taken from the Pesticide Handlers Exposure Database (PHED, Version 1.1 August 1998) which is used to assess handler exposures when chemical-specific monitoring data are not available. In addition to PHED data, this risk assessment relies on data from the Outdoor Residential Exposure Task Force (ORETF) and proprietary studies. For more information, see the "Human Health Risk Assessment (Revised)," dated October 30, 2003 (including addendum, dated June 8, 2004).

The following assumptions were used in the exposure calculations:

- Average body weight of an adult handler is 70 kg;
- Area treated estimate of 0.5 acres for lawn and ornamental treatments using granular formulations with a bellygrinder spreader or push-type spreader;
- Area treated estimate of 1000 square feet for ornamental treatments using a shaker can; and
- Exposure frequency - The residential handler exposure is expected to be of a short-term duration (less than 30 days).

2) Benfluralin Residential Handler Risk Estimates

Benfluralin is not assessed for systemic dermal toxicity (because no systemic toxicity was observed from a dermal toxicity study in rats), but is assessed for systemic inhalation toxicity. Risk assessment for inhalation exposure is based on a rabbit developmental toxicity oral study NOAEL of 100 mg/kg/day. An assumption is made that 100% of the estimated inhalation dose will be absorbed. A Margin of Exposure (MOE) greater than or equal to 100 (10x for interspecies extrapolation and 10x for intraspecies variation) is considered adequately protective for this assessment. Since all

residential handler MOEs are greater than 100, risk to residential handlers is not of concern. The benfluralin risk estimates are presented in Table 4 below.

Table 4. Benfluralin Risk Estimates for Residential Handlers

Exposure Scenario (Data Source)	Crop or Target	Application Rate[a]	Area Treated Daily[b]	Baseline Inhalation MOE[c]
Mixer/Loader/Applicator				
Loading/Applying Granulars with a Belly Grinder	residential turf	3 lb ai/acre	0.5 acres	75,000
	ornamentals: outdoor	3 lb ai/acre	0.5 acres	75,000
	ornamental bulbs	1.5 lb ai/acre	0.5 acres	150,000
Loading/Applying Granulars with a Push Type Spreader (ORETF)	residential turf	3 lb ai/acre	0.5 acres	5,300,000
	ornamentals: outdoor	3 lb ai/acre	0.5 acres	5,300,000
	ornamental bulbs	1.5 lb ai/acre	0.5 acres	11,000,000
Loading/Applying Granulars with a Bucket and Spoon (MRID 452507-01)	ornamentals: outdoor	0.689 lb ai/1000 sq ft	1000 sq ft	230,000
	ornamental bulbs	0.0344 lb ai/1000 sq ft	1000 sq ft	4,500,000
Loading/Applying Granulars with a Shaker Can (PHED)	ornamentals: outdoor	0.689 lb ai/1000 sq ft	1000 sq ft	22,000
	ornamental bulbs	0.0344 lb ai/1000 sq ft	1000 sq ft	440,000

a Application rates are the maximum application rates determined from EPA registered labels for benfluralin.
b Amount handled per day values are EPA estimates of acreage treated or gallons applied based on Exposure SAC Policy #9 "Standard Values for Daily Acres Treated in Agriculture".
c Baseline inhalation MOE = short-term NOAEL (100 mg/kg/day) / baseline inhalation dose (mg/kg/day), where baseline inhalation dose = baseline inhalation unit exposure (µg/lb ai) x application rate x amount handled per day x 1mg / 1000µg) / body weight (70 kg).

b. Residential Postapplication Risk

1) Exposure, Scenarios, Data, and Assumptions

Benfluralin uses in the residential setting include applications to ornamentals and to lawns. Although the type of site that benfluralin may be used on varies from golf courses to ornamental gardens, the scenario chosen for risk assessment (residential turf use) represents what the Agency considers the likely upper-end estimate of possible exposure. For this assessment, children are the population group most likely to be significantly exposed. Since systemic toxicity was not observed in a dermal toxicity study, up to a dose level of 1,000 mg/kg/day, the only scenario addressed in the assessment is the possible oral exposure of small children from treated turf, or from treated soil (i.e., soil ingestion, granule ingestion, and hand-/object-to-mouth transfer). A Margin of Exposure of 100 (or more) is considered protective for this assessment.

The quantitative exposure/risk assessment for benfluralin postapplication risk to children is based on these scenarios:

- *Hand-to-mouth activity from treated turf:* Postapplication exposure to children from the "incidental" ingestion of pesticide residues on treated turf from hand-to-mouth transfer (i.e., those residues that end up in the mouth from children touching turf and then putting their hands in their mouth).
- *Object-to-mouth activity from treated turf:* Postapplication exposure to children from incidental ingestion of pesticide residues on treated turf from object-to-mouth transfer (i.e., those residues that end up in the mouth from a child mouthing a handful of treated turf).
- *Soil ingestion activity:* Postapplication exposure to children from incidental ingestion of soil in a treated area.
- *Ingestion of benfluralin granules from treated turf:* Postapplication exposure to children from the "episodic" (infrequent to very infrequent) ingestion of pesticide granules picked up from treated turf. This assessment is not needed for benfluralin since an endpoint and dose for acute oral risk assessment was not identified.

2) Benfluralin Postapplication Risk Estimates

Risk assessment for oral exposure is based on a NOAEL of 100 mg/kg/day from a rabbit developmental toxicity study. A Margin of Exposure (MOE) of 100 (10x for interspecies extrapolation and 10x for intraspecies variation) is considered adequately protective for this assessment. Table 5 below presents the MOEs for Post-Application Oral Exposure in Children.

Table 5. Post-Application Oral Exposure to Benfluralin in Children

Exposure Scenario Applied at 3.0 lb ai/acre	Margin of Exposure
Outdoor Exposure	
Hand to Mouth Activity on Turf	2,200
Object to Mouth Activity on Turf	8,900
Soil Ingestion	670,000
Ingestion of Pellets	N/A

The combined postapplication risk from all oral ingestion exposures to children is presented below in Table 6. The total oral MOE is above 100, and thus not of concern.

Table 6. Oral Ingestion and Combined Exposure to Benfluralin in Children

Exposure Scenario				Margins of Exposure (MOEs) (UF=100)			
				Dermal	Inhalation	Oral MOE	Total Oral MOE
Child	Turf (3.0 lb ai/acre)	Postapplication	Hand to Mouth	N/A	N/A	2,200	1,800
			Object to Mouth	N/A	N/A	8,900	
			Soil Ingestion	N/A	N/A	670,000	

4. Aggregate Risk

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure.

For benfluralin, aggregate risk assessments were conducted for short-term (up to 30 days) and chronic (one year or more) exposures. The routes of exposure assessed are oral (food, water, and incidental) and inhalation (residential handlers). Intermediate term and chronic residential exposures are not expected and therefore, are not included in this aggregate assessment. Generally, combined risks from chronic exposures that are less than 100% of the cPAD are not a risk concern.

a. Short-term Aggregate Risk

Short-term aggregate risk was considered by aggregating exposure to adult male or female handlers, or children who may be orally exposed following application to residential turf, chronic food exposure, and drinking water exposure.

The calculated short-term DWLOCs for benfluralin and degradates are all greater than the EECs. Therefore, EPA expects that no adverse toxicological effect will occur due to aggregate short-term exposure. See Table 7 below for a comparison of EECs to DWLOCs.

The surface water EECs (ranging from 0.17 - 3.5 ug/L), and groundwater EECs (ranging from 0.009 - 0.07 ug/L) are less than the estimated DWLOC of more than 100 ppb; therefore no adverse toxicological effect will occur due to aggregate short-term exposure. Table 7 below presents a comparison of EECs to DWLOCs.

b. Chronic Aggregate Risk

Chronic aggregate risk was considered by aggregating chronic food and drinking water exposure. The calculated chronic DWLOCs for benfluralin and degradates are 50 parts per billion (ppb) for children, and greater than 100 for adult females and males. Therefore no adverse toxicological effect will occur due to aggregate chronic exposure.

The surface water EECs (ranging from 0.17 - 3.5 ug/L), and groundwater EECs (ranging from 0.009 - 0.07 ug/L) are less than the estimated DWLOCs of 50 ppb for exposure to children, and over 100 ppb for adult males and females; therefore no adverse toxicological effect will occur due to aggregate chronic exposure. Table 7 below presents a comparison of EECs to DWLOCs.

Table 7. Short-Term and Chronic DWLOC Calculations

Short-Term DWLOC Calculation			
Population Subgroup	**Groundwater EEC (µg/L)**	**Surface Water EEC (µg/L)**	**DWLOC (µg/L)**
Children	≤ 0.07	≤ 3.5	>100
Females	≤ 0.07	≤ 3.5	>100
Males	≤ 0.07	≤ 3.5	>100
Chronic DWLOC Calculations			
Children	≤ 0.07	≤ 3.5	50
Females	≤ 0.07	≤ 3.5	>100
Males	≤ 0.07	≤ 3.5	>100

5. Cumulative Assessment

Risks summarized in this document are those that result only from the use of benfluralin. The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for benfluralin and any other substances . For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating

effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

6. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of benfluralin include: workers in agricultural areas, workers in rights-of-way areas, and workers applying benfluralin on commercial or residential lawns or ornamental plants. Occupational risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL). In the case of benfluralin MOEs greater than 100 do not exceed the Agency's level of concern. For workers entering a treated site, MOEs are calculated for each day after application to determine the minimum length of time required before workers can safely reenter.

Occupational risk estimates are expressed as MOEs, which are the ratio of estimated exposure to an established dose level (NOAEL). Benfluralin MOEs are determined by a comparison of specific exposure scenario estimates to the inhalation NOAEL of 100 mg/kg/day (from the oral rabbit developmental toxicity study) for short-term assessment, or 7.2 mg/kg/day (from the oral rat reproduction toxicity study) for intermediate-term assessment. Since no dermal endpoint was identified, only inhalation risk was assessed. For benfluralin users an MOE of 100 has been determined to be adequately protective (for both short- and intermediate-term exposure) based on the standard uncertainty factors of 10x for interspecies extrapolation and 10x for intraspecies variability. Long-term worker exposure is not expected for benfluralin.

Occupational risk is assessed for exposure at the time of application (termed "handler" exposure) and assessed for exposure following application, or post-application exposure. Application parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site, and by the application rate required to achieve an efficacious dose. Post-application risk is assessed for activities such as scouting, irrigating, pruning, and harvesting and is based primarily on dermal exposure estimates. Note that occupational risk estimates are intended to represent pesticide workers, and on this basis assumptions are made concerning acres treated per day and the seasonal duration of exposure.

For more information on the assumptions and calculations of potential risk of benfluralin to workers, see the Occupational Exposure Assessment (Section 7.0) in the "Human Health Risk Assessment (Revised)," dated October 30, 2003 (including addendum, dated June 8, 2004).

a. Occupational Toxicity

Table 8 below provides a listing of the toxicological endpoints used in the benfluralin occupational risk assessment.

Table 8: Toxicological Endpoints for the Benfluralin Occupational Risk Assessment

Exposure Scenario	Dose used in Risk Assessment (mg/kg/day)	Margin of Exposure (MOE) for Risk Assessment	Study and Toxicological Effects
Short-Term (1-30 days) Inhalation	NOAEL= 100	MOE = 100	Developmental Toxicity-Rabbits LOAEL = 225 mg/kg/day based on decreases in maternal body weight gain over a 13 day dosing period.
Intermediate-Term (1-6 months) Inhalation	NOAEL= 7.2	MOE = 100	Reproduction and Fertility Effects-Rats LOAEL = 68.1 mg/kg/day based on progressive chronic nephropathy in adult males and females and pup weight decrement.

For more occupational toxicity information, see the benfluralin "Human Health Risk Assessment (Revised)," dated October 30, 2003 (including addendum, dated June 8, 2004).

b. Occupational Handler Exposure

Occupational handler risk estimates have been assessed for both short- and intermediate-term exposure durations. For most benfluralin handlers, exposure for more than 30 days are unlikely since it is used pre-plant, or timed specifically for the seasonal emergence of weeds. However, since the duration of exposure is uncertain, intermediate-term risk estimates are provided as an upper-bound assessment.

Occupational handler assessments are conducted using increasing levels of protection. The Agency typically evaluates all exposures with minimal protection and then considers additional protective measures using a tiered approach (going from minimal to maximum levels of protection) in an attempt to obtain an adequate MOE. The lowest tier is represented by the baseline clothing scenario (i.e., single layer clothing, socks, and shoes), followed by, if MOEs are of concern, increasing levels of risk mitigation such as personal protective equipment (PPE) and engineering controls (EC). In the case of benfluralin, MOEs for every occupational exposure scenario are above 100 at baseline PPE (long-sleeved shirt, long pants, socks, and shoes). While the generic assessment for benfluralin does not indicate a need for additional PPE, evaluation of end-use product toxicity data may. End-use product PPE will be assessed on a product-by-product basis.

c. Occupational Handler Risk Summary

The Agency has determined that there are potential exposures to individuals who mix, load, apply, and otherwise handle benfluralin during the usual use patterns associated with the pesticide's use. Based on the use patterns, 13 major occupational handler exposure scenarios were identified as follows:

(1) mixing/loading dry flowables to support ground applications;
(2) mixing/loading granulars to support ground applications;
(3) applying sprays with groundboom equipment;

(4) applying granules with a tractor/ATV-drawn spreader;
(5) mixing/loading/applying dry flowables with a low pressure handwand;
(6) mixing/loading/applying dry flowables with a backpack sprayer;
(7) mixing/loading/applying dry flowables with a low pressure, high volume turf/handgun sprayer;
(8) mixing/loading/applying granules with a pump-feed backpack spreader;
(9) mixing/loading/applying granules with a gravity-feed backpack spreader;
(10) mixing/loading/applying granules with a bellygrinder spreader;
(11) mixing/loading/applying granules with a push-type spreader;
(12) mixing/loading/applying granules with a bucket and spoon; and
(13) mixing/loading/applying granules with a shaker can.

Occupational Handler Exposure Assumptions

When possible, the assumptions for daily areas treated are taken from the Health Effects Division Science Advisory Committee on Exposure *Policy 9: Standard Values for Daily Acres Treated in Agriculture* (July 5, 2000). In other instances, the daily areas to be treated were defined for each handler scenario by best scientific judgement.

Chemical-specific data to assess the above exposure scenarios were not available for benfluralin. Analyses were completed using acceptable surrogate exposure data for the scenario assessed. Several handler assessments were completed using data from the Pesticide Handler Exposure Database (version 1.1). No data were available to assess mixing/loading/applying dry flowable formulations with a low-pressure handwand sprayer, therefore PHED data for mixing/loading/applying liquid formulations with a low-pressure handwand sprayer were used as a reasonable surrogate. Some handler assessments (i.e., handheld handgun equipment, push-type spreader) were completed using data from the Outdoor Residential Exposure Task Force (ORETF).

The following assumptions and factors were used in order to complete the exposure and risk assessments for occupational handlers and applicators:

- Average body weight of an adult handler is 70kg;
- Average occupational workday is 8 hours;
- Non-crop land and rights-of-way treatments are assessed at the maximum labeled single application rate of 6.0 pounds active ingredient per acre;
- Christmas trees are assessed at the maximum labeled application single rate of 4.0 pounds active ingredient per acre;
- Landscape ornamentals, field/container grown ornamentals, residential and golf course turfgrass (dry flowable formulations) are assessed at the maximum labeled single application rate of 3.0 pounds active ingredient per acre;
- Residential and golf course turfgrass (granular formulations) are assessed at the application rate of 2.0 pounds active ingredient per acre;
- Alfalfa, birdsfoot trefoil, clover, lettuce, and ornamental bulbs are assessed at the maximum labeled single application rate of 1.5 pounds active ingredient per acre;
- For alfalfa, birdsfoot trefoil, and clover, the area treated daily is 200 acres for ground applications;

- For lettuce, non-crop lands, and rights-of-way, the area treated daily is 80 acres for ground applications;
- For Christmas tree and ornamental (other than bulb) applications, the area treated daily is 40 acres for tractor- or ATV-drawn spreaders; 10 acres for backpack spreaders; 5 acres for push-type spreaders, 1 acre for bellygrinder spreaders, and 5,000 square feet for shaker cans;
- For turf applications, the area treated daily is 40 acres for ground applications (golf courses); 5 acres for ground applications (commercial areas), 5 acres for low-pressure handwand sprayers, handgun sprayers, and push-type spreaders; and 1 acre for bellygrinders; and
- For ornamental bulb applications, the area treated daily is 5 acres for tractor- or ATV-drawn spreaders; 10 acres for backpack spreaders; 5 acres for push-type spreaders, 1 acre for bellygrinder spreaders, and 5,000 square feet for shaker cans.

Summary of Risk Concerns and Data Gaps for Handlers

Short- and intermediate-term inhalation Margin of Exposure estimates for occupational handler scenarios are greater than 100 at the baseline level of protection (i.e., long-sleeved shirt, long pants, shoes plus socks, no respirator). Short-term MOEs range from 4,000 to 900,000, and intermediate-term MOEs range from 290 to 65,000. Therefore, short- and intermediate-term occupational risk is not of concern.

There is a data gap identified for evaluating exposure when mixing/loading/applying benfluralin using backpack equipment. However, estimates based on low pressure handwand is considered a reasonable surrogate to evaluate this risk. Table 9 provides a listing of the short- and intermediate-term risk estimates for handlers.

Table 9. Occupational Handler Short and Intermediate-Term Risk Summary

Exposure Scenario	Crop or Use Site	Application Rate[a]	Area Treated Daily[b]	Baseline Short-term Inhalation MOE[c]	Baseline Intermediate-term Inhalation MOE[c]
Mixer/Loader					
Mixing/Loading Dry Flowables for Groundboom Application	alfalfa, birdsfoot trefoil, clover	1.5 lb ai/acre	200 acres	30,000	2,200
	lettuce	1.5 lb ai/acre	80 acres	76,000	5,500
	turf: golf courses	3 lb ai/acre	40 acres	76,000	5,500
	turf: residential and commercial areas	3 lb ai/acre	5 acres	610,000	44,000
Loading Granulars for Drop Type Tractor (or ATV) Drawn Spreader Application	turf: commercial areas and golf courses; and ornamentals: container grown, field grown and landscape	3 lb ai/acre	40 acres	34,000	2,500
	Christmas trees	4 lb ai/acre	40 acres	26,000	1,900
	non-crop land, rights-of-way	6 lb ai/acre	80 acres	8,600	620

Exposure Scenario	Crop or Use Site	Application Rate[a]	Area Treated Daily[b]	Baseline Short-term Inhalation MOE[c]	Baseline Intermediate-term Inhalation MOE[c]
	ornamental bulbs	1.5 lb ai/acre	5 acres	550,000	40,000
Applicator					
Applying Sprays with Groundboom Application	alfalfa, birdsfoot trefoil, clover	1.5 lb ai/acre	200 acres	32,000	2,300
	lettuce	1.5 lb ai/acre	80 acres	79,000	5,700
	turf: golf courses	3 lb ai/acre	40 acres	79,000	5,700
	turf: residential and commercial areas	3 lb ai/acre	5 acres	630,000	45,000
Applying Granulars with Drop Type Tractor (or ATV) Drawn Spreader	turf: commercial areas and golf courses; and ornamentals: container grown, field grown and landscape	3 lb ai/acre	40 acres	49,000	3,500
	Christmas trees	4 lb ai/acre	40 acres	36,000	2,600
	non-crop land, rights-of-way	6 lb ai/acre	80 acres	12,000	880
	ornamental bulbs	1.5 lb ai/acre	5 acres	780,000	56,000
Mixer/Loader/Applicator					
Mixing/Loading/Applying Dry Flowables with a Low Pressure Handwand	turf	3 lb ai/acre	5 acres	16,000	1,100
Mixing/Loading/Applying Dry Flowables with a Backpack Sprayer	turf	3 lb ai/acre	5 acres	16,000	1,100
Mixing/Loading/Applying Dry Flowables with a Handheld Handgun (ORETF)	turf	3 lb ai/acre	5 acres	210,000	15,000

Exposure Scenario	Crop or Use Site	Application Rate[a]	Area Treated Daily[b]	Baseline Short-term Inhalation MOE[c]	Baseline Intermediate-term Inhalation MOE[c]
Loading/Applying Granulars with a Pump Feed Backpack Granular Spreader (MRID 451672-01)	Christmas trees	4 lb ai/acre	10 acres	42,000	3,000
	container grown, field grown and landscape ornamentals	3 lb ai/acre	10 acres	56,000	4,000
	ornamental bulbs	1.5 lb ai/acre	10 acres	110,000	8,000
Loading/Applying Granulars with a Gravity Feed Backpack Granular Spreader (MRID 452507-01)	Christmas trees	4 lb ai/acre	10 acres	4,000	290
	container grown, field grown and landscape ornamentals	3 lb ai/acre	10 acres	5,300	380
	ornamental bulbs	1.5 lb ai/acre	10 acres	11,000	760
Loading/Applying Granulars with a Belly Grinder	Christmas trees	4 lb ai/acre	1 acres	28,000	2,000
	turf	3 lb ai/acre	1 acres	38,000	2,700
	container grown, field grown and landscape ornamentals	3 lb ai/acre	1 acres	38,000	2,700
	ornamental bulbs	1.5 lb ai/acre	1 acres	75,000	5,400
Loading/Applying Granulars with a Push Type Spreader (ORETF)	Christmas trees	4 lb ai/acre	5 acres	48,000	3,500
	turf: residential areas, commercial areas, and golf courses; and ornamentals: container grown, field grown, and landscape	3 lb ai/acre	5 acres	64,000	4,600
	ornamental bulbs	1.5 lb ai/acre	5 acres	130,000	9,200
Loading/Applying Granulars with a Bucket and Spoon (MRID 452507-01)	Christmas trees	0.0918 lb ai/ 1000 sq ft	5000 sq ft	340,000	24,000
	ornamentals: container grown, field grown and landscape	0.0689 lb ai/ 1000 sq ft	5000 sq ft	450,000	33,000

Exposure Scenario	Crop or Use Site	Application Rate[a]	Area Treated Daily[b]	Baseline Short-term Inhalation MOE[c]	Baseline Intermediate-term Inhalation MOE[c]
	ornamental bulbs	0.0344 lb ai/ 1000 sq ft	5000 sq ft	900,000	65,000
Loading/Applying Granulars with a Shaker Can (PHED)	Christmas trees	0.0918 lb ai/1000 sq ft	5000 sq ft	32,000	2,300
	ornamentals: container grown, field grown and landscape	0.0689 lb ai/ 1000 sq ft	5000 sq ft	43,000	3,100
	ornamental bulbs	0.0344 lb ai/ 1000 sq ft	5000 sq ft	87,000	6,200

Footnotes

a Application rates are the maximum application rates determined from EPA registered labels for benfluralin.

b Amount handled per day values are EPA estimates of acreage treated or gallons applied based on Exposure SAC Policy #9 "Standard Values for Daily Acres Treated in Agriculture".

c Baseline inhalation MOE = short-term NOAEL (100 mg/kg/day) / baseline inhalation dose (mg/kg/day), where baseline inhalation dose = baseline inhalation unit exposure (µg/lb ai) x application rate x amount handled per day x 1mg / 1000µg) / body weight (70 kg).

For more information, see the Occupational Exposure Assessment (Section 7.0) in the "Human Health Risk Assessment (Revised)," dated October 30, 2003 (including addendum, dated June 8, 2004).

d. Occupational Postapplication Risk Summary for Benfluralin

Benfluralin uses are varied, since it is used in agriculture, rights-of-way, on ornamentals, and on turf (lawns, golf courses). As a result, a wide array of individuals can potentially be exposed by working in areas that have been previously treated. However, since no dermal endpoint has been identified for systemic toxicity, and post-application inhalation exposure is expected to be negligible, no occupational post-application exposure and risk assessment is warranted. As a result, the general 12 hour REI, as established by the Worker Protection Standard, applies to all benfluralin agricultural use products.

e. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from the National Poison Control Centers (PCC), the Agency's Office of Pesticide Program's Incident Data System (IDS), and the California Pesticide Illness Surveillance Program.

Relatively few incidents of illness have been reported due to benfluralin. There was some evidence of dermal effects, but these cases may be due to not wearing required personal protective equipment (PPE) (long-sleeved shirt, long pants, shoes plus socks, gloves, and other PPE dependent on end-use product formulation). The following data bases have been consulted for the poisoning incident data on the active ingredient benfluralin.

The PCC database contained 47 occupational and non-occupational cases of benfluralin exposure. Three of the cases required medical attention due to flushing, skin irritation or pain, and itching sufficient to require medical attention. The other exposures resulted in minor irritation or no irritation, and did not require attention in a health care facility. None of the exposures required hospitalization.

In the IDS and California Pesticide Illness Surveillance Program databases, there were a total of 7 cases of benfluralin exposure reported to Poison Control Centers for the years 1982-2001. Of these, 6 cases occurred in a single residential incident, and 1 case occurred in a occupational incident. None of these cases reported hospitalization as an outcome.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. Benfluralin has several registered use sites: turf, non-bearing fruit and nut trees, non-bearing vineyards, citrus, non-bearing berries, Christmas tree plantations, non-cropland sites, alfalfa, clover, birdsfoot trefoil, and lettuce. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for benfluralin use sites and any associated uncertainties.

For detailed discussions of all aspects of the environmental risk assessment, see the "Revised Environmental Risk Assessment for Benfluralin", dated June 4, 2004, the "Drinking Water Estimates for Benfluralin," dated January 31, 2003, the "Addendum to Drinking Water Estimates for Benfluralin, Multiple Applications to Turf, Christmas Tree Farms, Rights-of-Way," dated March 5, 2003, the "Second Addendum to Drinking Water Estimates for Benfluralin, Non-Bearing Vineyards, Fruit Trees, Nut Trees, and Berries" dated April 25, 2003, and the Environmental Fate and Effects Risk Assessment. These documents are also available in the OPP public docket and on the Agency's website at: *http://www.epa.gov/pesticides/reregistration/status.htm.*

1. Environmental Fate and Transport

The environmental fate database for benfluralin is sufficient to conduct a preliminary assessment for benfluralin use.

Available data indicates that benfluralin is of variable soil persistence with different mechanisms of degradation. Based on acceptable studies, benfluralin is metabolized with a half-life of 20 to 86 days under aerobic soil conditions. This represents a variable soil metabolism pattern. In anaerobic soils, benfluralin laboratory studies indicate a half-life of 12 days. A soil photolysis study showed that benfluralin has a half-life of 12.5 days. Benfluralin is stable to hydrolysis and has a half-life of 5.5 to 9.9 hours in aqueous photolysis studies. In an anaerobic aquatic metabolism study benfluralin was determined to have a half-life of 38 hours. No major degradates were formed in soil metabolism studies.

Benfluralin has low mobility in soils, according to available mobility studies (K_{oc} values range from 9840 to 11,660 L/kg). Acceptable field dissipation studies observed in three different locations

indicate moderate half-lives. At one turf site in CA where benfluralin was applied as a granular broadcast the half-life was determined to be 22 days. At two sites where benfluralin was applied as an incorporated spray the half-lives were determined to be 62 days in a field dissipation trial in GA on peanuts, and 79 days in a lettuce field dissipation trial in CA.

Benfluralin volatilizes rapidly, as indicated in laboratory volatility studies. Oxidation by hydroxyl radicals in the atmosphere has the potential to be a dissipation pathway for benfluralin. However, benfluralin is formulated and applied to minimize volatilization. For example, spray formulations are incorporated into the soil before planting or at the time of planting because of the volatile nature of benfluralin, and granular formulations are manufactured to slow volatilization. Benfluralin has a short estimated half-life in air (less than half a day) which indicates that it may not be persistent in air.

Parent benfluralin is not expected to leach into ground water, based on its low mobility in soil. However, degradate 2,6 dinitro-4-trifluoromethyl-phenol was formed at 6% of parent in the soil metabolism study. Based on limited environmental fate information, it has the potential to contaminate groundwater. Trifluoroacetic acid (TFA) was not found in environmental fate studies, but was noted as a plant metabolite.

Based on its measured bioaccumulation factor in whole fish (1580), parent benfluralin is considered to be bioaccumulative. The depuration rate was 0.54 per day for whole fish.

2. Ecological Risk

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to nontarget organisms from the use of benfluralin products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the EEC to the most sensitive toxicity endpoint values, such as the median lethal dose (LD_{50}) or the median lethal concentration (LC_{50}). These RQ values are then compared to the Agency's levels of concern (LOCs) which indicate whether a chemical, when used as directed, has the potential to cause adverse effects on nontarget organisms. When the RQ exceeds the LOC for a particular category, the Agency presumes a risk of concern to that category of organisms. The LOCs and the corresponding risk presumptions are presented in Table 10.

Table 10. LOCs and Associated Risk Presumptions

IF...	THEN the Agency presumes...
Mammals and Birds	
The acute RQ > LOC of 0.5	Acute risk
The acute RQ >LOC of 0.2	Risk that may be mitigated through restricted use
The acute RQ > LOC of 0.1	Acute effects may occur in Endangered Species
The chronic RQ > LOC of 1	Chronic risk *and* Chronic effects may occur in Endangered Species
Fish and Aquatic Invertebrates	
The acute RQ > LOC of 0.5	Acute risk
The acute RQ > LOC of 0.1	Risk that may be mitigated through restricted use
The acute RQ >LOC of 0.05	Acute effects may occur in Endangered Species
The chronic RQ > LOC of 1	Chronic risk *and* Chronic effects may occur in Endangered Species
Terrestrial and Aquatic Plants	
The acute RQ > LOC of 1	Acute risk *and* Acute effects may occur in Endangered Species

For a more detailed explanation of the ecological risks posed by the use of benfluralin, please refer to the Revised Environmental Fate and Effects Risk Assessment for Benfluralin.

a. Risk to Birds

1) Toxicity (Hazard) Assessment

Because there are no mortalities at the highest concentration tested (LD50 greater than 2000 mg/kg, LC50 greater than 4360 ppm), benfluralin is considered to be practically non-toxic to birds on an acute and subacute basis. The likelihood of acute or subacute risk to non-endangered and endangered species of birds is low.

Benfluralin caused reproductive effects in chronic avian studies. Avian reproductive toxicity was assessed in two studies that are presented in Table 11 below. The bobwhite quail endpoint cannot be assumed conservative, as effects were observed at the lowest dose tested of 96 ppm. Another quail study is needed to establish a No Observed Adverse Effect Concentration (NOAEC) for reproductive effects since a NOAEC was not established in this test.

At the Lowest Observed Adverse Effect Concentration (LOAEC) the reproductive toxicity study with the Northern Bobwhite Quail, showed developmental effects that included a decrease in the number of surviving hatchlings, decreased egg set, and decrease in 14-day hatchling survivor weight. At the LOAEC, of the reproductive toxicity study with the Mallard Duck showed an increase in the percentage of eggs that cracked.

Table 11. Reproductive Toxicity to Birds

Test Species	% a.i.	NOAEC (ppm ai)	LOAEC (ppm ai)	LOAEC Endpoints	MRID	Study Classification
Northern Bobwhite Quail *(Colinus virginianus)*	95.6	< 96	96	fewer survivors, egg set and 14 day survivors weight	42145502	Supplemental
Mallard Duck *(Anas platyrhynchos)*	95.6	288	975	percentage eggs cracked	42145501	Core

2) Exposure and Risk

Acute

As no acute endpoint was determined, risk quotients (RQs) were not calculated for benfluralin. The likelihood of acute or subacute risk to non-endangered and endangered species of birds is low.

Chronic

Chronic risks to birds are expected from both spray and granular formulations of benfluralin. Benfluralin is typically incorporated into the soil for application to alfalfa, birdsfoot trefoil, clover, and lettuce. Exposure at these use sites could occur at the end of field rows where bordering plants could potentially be food for birds. A foliar half-life of 12.5 days was assumed for chronic assessments of spray applications. Table 12 below summarizes the Level of Concern (LOC) exceedances for birds associated with benfluralin residues in plants at the edge of the field that may be incidentally sprayed during application to the crop. The avian chronic LOC is exceeded on all food items except seeds at lettuce and alfalfa use sites.

Table 12. Avian Chronic Risk Quotients for Use on Lettuce and Alfalfa Based on a Bobwhite NOAEC of < 96 ppm.

Use Sites	Maximum Residue on Short Grass	Maximum Residue on Tall Grass	Maximum Residue on Broadleaf Plants/Insects	Maximum Residue on Seeds
Alfalfa (3 lbs ai/A)	**7.5**	**3.44**	**4.22**	< 1
Lettuce (1.5 lbs ai/A)	**3.75**	**1.72**	**2.11**	< 1

Risk quotients (RQs) in **bold print** signify an exceedance of the level of concern (LOC) for risk to birds including endangered species.

The Agency believes that chronic risk to birds from granular formulations is likely for the following reasons. First, a NOAEC was not found in the bobwhite quail avian reproduction study. For the risk assessment, the current endpoint for reproductive effects is the LOAEC of less than 96 ppm. Also, calculations based on average granule size and weight plus the results from the avian reproduction study on bobwhite quail indicate that for the benfluralin fertilizer blend, 5 to 6 granules contain the equivalent amount of benfluralin to represent 96 ppm in the bobwhite quail reproduction study. It is also reasonable to assume that a bobwhite quail consumes at least 6 granules per day as a daily intake of grit since several bird species are known to consume up to 18 granules per day.

Smaller avian species such as passerines and songbirds may be affected by smaller amounts of pesticide than the bobwhite quail due to lower body weight.

Currently the Agency does not have a standard procedure for assessing chronic risk to avian species from granular products. Estimating long term exposure from granular applications is difficult, since the granules are not expected to remain intact over extended periods. Over a period of time, the granular formulation will break down in the soil. The chemical is expected to become distributed in the soil as the granules dissipate. The Hoerger-Kenaga nomogram could not be used for estimating environmental concentrations of residues since it was used only with spray applications. Therefore, a fugacity model was used to estimate exposure in the soil to birds.

A fugacity model is designed to estimate exposure in the soil to organisms after the granule has degraded and distributed through the soil column to a certain depth. Many of the inputs for the fugacity model, such as food ingestion rates, fraction of diet, weight of animals, and amount of food eaten per day, were derived from the Wildlife Exposure Factors Handbook, (EPA, 1993). The Wildlife Exposure Factors Handbook was also used to scale exposure estimates from quail to robin, and from rat to mouse. For more information on fugacity model inputs, refer to the Environmental Fate and Effects Risk Assessment, dated June 4, 2004.

The estimated concentrations for the fugacity model used to estimate exposure in the soil to birds are measured from the top 1.0 cm and top 7.6 cm of the soil. The top 1 cm is to represent turf use sites which have a thatch and the top 7.6 cm will represent other bare soil use sites at time of application. The fugacity model used for the top 7.6 cm of soil assumes that an average residue level is distributed evenly throughout the top 7.6 cm.

Table 13 below shows the avian risk quotient results when exposures are estimated with the fugacity model.

Table 13. Avian Fugacity Exposure (for Granular Applications) and Risk Quotient.

Application Rate	Robin				Quail			
	1 cm soil depth		7.5 cm soil depth		1 cm soil depth		7.5 cm soil depth	
	exposure (mg/kg/day)	RQ	exposure (mg/kg/day)	RQ	exposure (mg/kg/day)	RQ	exposure (mg/kg/day)	RQ
3 lb ai/A (turf, non-bearing berries, non-bearing fruit trees, ornamentals, Christmas trees, non-bearing nut trees, non-bearing vineyards, non-cropland areas)	217	**2.3**	26.7	< 1	84.5	< 1	10.4	< 1

Application Rate	Robin				Quail			
	1 cm soil depth		7.5 cm soil depth		1 cm soil depth		7.5 cm soil depth	
	exposure (mg/kg/day)	RQ	exposure (mg/kg/day)	RQ	exposure (mg/kg/day)	RQ	exposure (mg/kg/day)	RQ
6 lb ai/A (turf, non-bearing berries, non-bearing fruit trees, ornamentals, Christmas trees, non-bearing nut trees, non-bearing vineyards, non-cropland areas)	425	**4.4**	49.4	< 1	169	**1.8**	19.3	< 1
9 lb ai/A (non-bearing berries, non-bearing fruit trees, non-bearing nut trees, non-bearing vineyards, non-cropland areas)	642	**6.7**	74.1	< 1	254	**2.6**	29.0	< 1
12 lb ai/A (non-cropland areas)	850	**8.9**	99.0	**1.0**	338	**3.5**	38.7	< 1

Risk quotients (RQs) in **bold print** signify an exceedance of the level of concern (LOC) for risk to birds including endangered species.

b. Risk to Mammals

1) Toxicity (Hazard) Assessment

Benfluralin is classified as practically nontoxic to small mammals on an acute oral basis with an LD50 value of greater than 10,000 mg/kg. Mammalian toxicity data indicate that the use of benfluralin is of concern for chronic risk to mammals. Chronic toxicity from the 2-generation rat reproduction study indicate decreased body weight, body weight gains and food consumption, liver and kidney enlargement, progressive chronic nephropathy, dead pups, and decreased pup size at the LOAEL of 1000 ppm. The endpoint for chronic risk assessment to mammals is the NOAEL of 100 ppm. Table 16 discusses the data that support the chronic endpoint used in assessing the risks to mammals.

2) Exposure and Risk

Acute

Since the acute rat LD50 (10,000 mg/kg-bw) is greater than the highest dose tested and there was no mortality observed at the highest concentration dose, it is assumed that unacceptable acute risk to mammals is not likely. Therefore, no risk quotients (RQs) were calculated for acute risk to mammals.

Chronic

There is potential for exposure to mammals from soil-incorporated spray applications and granular applications. The mammalian chronic LOC exceedance from exposure to soil-incorporated spray applications follow the same pattern as for birds (Table 14). A foliar half-life of 12.5 days was assumed for chronic assessments of spray applications. LOCs are exceeded for all food items except for seeds.

Table 14. Mammalian Chronic Risk Quotients for Spray-Incorporated Benfluralin Based on a Rat Chronic NOAEC of 100 ppm (7.2 mg/kg/day, males).

Crop	Short Grass	Tall Grass	Broadleaf Plants/Insects	Seeds
Alfalfa (3 lbs ai/A)	**7.2**	**3.30**	**4.05**	< 1
Lettuce (1.5 lbs ai/A)	**3.6**	**1.65**	**2.03**	< 1

RQS in **bold print** signify an exceedance of the LOC for risk to birds including endangered species.

For an explanation of how chronic risk was assessed for granular exposure to mammals using a fugacity model see discussion preceding Table 13 presented previously.

Table 15. Fugacity Exposure and Risk Quotient with Mammalian Chronic Endpoint = 5 mg/kg-body weight

Application Rate	Deer Mouse (21 grams)			
	1 Cm Soil Depth		7.5 cm Soil Depth	
	Exposure	RQ	Exposure	RQ
3 lb ai/A	31	**6.2**	3.7	< 1
6 lb ai/A	61	**12.2**	7.0	**1.4**
9 lb ai/A	91	**18.2**	10.5	**2.1**
12 lb ai/A	120	**24.0**	14.0	**2.8**

RQs in **bold print** signify an exceedance of the LOC for risk to mammals including endangered species.

c. Risk to Fish and Aquatic Invertebrates

1) Toxicity (Hazard) Assessment for Freshwater Species

Freshwater Species

The available acute toxicity data on benfluralin, outlined in Table 16 below, indicate that it is very highly toxic to freshwater fish on an acute basis, based on typical end-use product (TEP) LC50 values of less than 100 ppb ai in bluegill sunfish.

Based on TEP data, benfluralin is moderately toxic to freshwater aquatic invertebrates on an acute basis with a daphnid LC50 of 2.18 ppm active ingredient. This study is for a formulated product

however, and there are currently no adequate daphnid acute data using technical grade benfluralin. Table 19 displays the acute toxicity endpoints for freshwater fish and invertebrates.

Table 16. Acute Toxicity Endpoints for Freshwater Fish/Invertebrates.

Test Species	Test Type	% a.i.	Toxicity Value (ppm of a.i.)	Toxicity Category	MRID or Accession Number
Rainbow Trout (*Oncorhynchus mykiss)*	Fish Toxicity	19.9 (End Use Product	(96-hour LC50) 0.288	Highly Toxic	42419201
Bluegill Sunfish *(Lepomis macrochirus)*	Fish Toxicity	96.4 (Technical Grade Active Ingredient)	(96-hour LC50) 0.0317	Very Highly Toxic	Acc. No. 234214
Water Flea *(Daphnia magna)*	Invertebrate Toxicity	20.1 (End Use Product	(48-hour LC50) 2.18	Moderately Toxic	42390802

Chronic data for freshwater fish show that growth and development was the most sensitive endpoint for benfluralin. Test results indicate that benfluralin may affect fish length and survival at concentrations greater than 1.9 ppb. The chronic toxicity endpoint for freshwater fish is listed in Table 17.

Table 17. Early Life-Stage Toxicity to Freshwater Fish

Test Species	Test Type	% a.i.	NOAEL (ppm ai)	LOAEL (ppm ai)	MRID or Accession Number.
Rainbow Trout (*Oncorhynchus mykiss)*	Fish - Early Life Stage	95.9	0.0019	0.005 larval length	41613805

A freshwater aquatic invertebrate life-cycle study using technical grade benfluralin was conducted (MRID 41613806). The NOAEL for this study was 15.5 ppb a.i. It is classified as supplemental and not upgradable because the negative control appears to have far less neonates due to loss of neonates, which could have been the result of the unusual test design. This creates much uncertainty with the control population. Since the controls were affected, there may be more chronic sensitivity of Daphnids exposed to benfluralin than the faulty test study indicated. It is worthwhile to note that the Daphnia NOAEC for trifluralin is 2.4 ppb, which may indicate that potentially, the benfluralin chronic NOAEC may also be very low. Uncertainties in the Daphnia life cycle study appear to underestimate the potential chronic risk to aquatic invertebrates. An updated Daphnia life-cycle study will reduce much of this uncertainty.

2) Toxicity (Hazard) Assessment for Estuarine/Marine Species

Estuarine/Marine Species

Although initially considered acceptable, the acute toxicity data for estuarine fish were found to be invalid upon reexamination. The study exceeds the Agency's guidance of a 1.5 variability limit for test concentrations as recommended by the Rejection Rate Analysis and ASTM E-729, p. 392, 11.9.3.4(2). The measured concentrations ranged from 6% to 8% of the nominal concentrations. Precipitation was observed at the three highest concentration levels, resulting in an LC50 that is uncertain since actual test concentrations and time of exposure are not well understood. The Agency is unable to provide a risk assessment for estuarine fish because of the lack of adequate data.

Available acute toxicity data on technical benfluralin indicate that it is very highly toxic to estuarine/marine invertebrates. The 96-hour flow-through study yielded an EC50 of 0.043 ppm a.i. And NOAEC of 16 ppb. Table 18 below lists the acute toxicity endpoint for estuarine/marine invertebrates.

Table 18. Acute Toxicity to Estuarine/Marine Invertebrates

Test Species	Test Type	% a.i.	96-hour EC50 (ppm a.i.)	Toxicity Category	MRID or Accession No.
Mysid *(Americamysis bahia)*	Invertebrate Toxicity	96.6	0.043	Very Highly Toxic	41613804

No data are available to assess chronic toxicity endpoints for estuarine/marine fish and invertebrates. An estuarine/marine invertebrate life-cycle toxicity study using the TGAI is required for benfluralin because the end-use product is expected to be transported to the estuarine environment from the intended use sites (turf and non-bearing fruit trees), the mysid LC50 is less than 1 mg/L, the EEC in water is equal to or greater than 0.01 of the acute mysid LC50 of 43 ppb, and studies of birds and mammals indicate the reproductive physiology may be affected. The preferred test species is mysid shrimp.

3) Exposure and Risk

Because of uncertain aquatic toxicity data, alternative methods were used to ascertain the potential for acute and chronic risk to aquatic species. One method was to analyze the data from other very similar dinitroaniline herbicides, trifluralin and ethalfluralin. There are some similarities in aquatic toxicity data between trifluralin, ethalfluralin, and benfluralin. However, there are uncertainties in this approach, as the solubility for benfluralin (100 ppb) is one-third that of trifluralin and ethalfluralin (300 ppb). This may affect the amount of exposure in water bodies and perhaps the toxicity of the chemical to the organisms. Another uncertainty is that the toxicity of the other dinitroaniline herbicides may not accurately reflect similar trends of toxicity of benfluralin.

Chronic data for the three herbicides are similar, particularly for the trout early life stage study. The supplemental daphnia chronic toxicity test for benfluralin (NOAEC 15.5 ppb) appears to be between that of trifluralin (2.4 ppb) and ethalfluralin (24 ppb). This would indicate the need for chronic data to assess chronic risk.

The Estimated Environmental Concentrations (EECs) used to determine the risk quotients (RQS) were estimated by modeling for surface water in a farm pond scenario. Benfluralin's high organic carbon partitioning coefficient (K_{oc} = 10,750), indicates that it has a strong tendency to bind to soil rather than dissolve in water. Thus, any transport to water from the soil to which it is applied is probably due to transport of suspended soil particles. Benfluralin may also be transported from soil to water by volatilization and re-condensation, but this phenomenon cannot be quantified at this time.

Volatility from soil was not modeled in the farm pond analysis, because incorporation of spray applications and use of granular formulations are both intended to suppress volatilization. Table 19 below lists the EECs for all modeled scenarios. The EECs are then used to determine the risk that a benfluralin application might pose in the given scenario.

Table 19. Estimated Environmental Concentrations (EECs) for Benfluralin (Farm Pond scenario) in Parts-Per-Billion (ppb)

Scenario Application Rate (lbs ai/A)	Peak	96-hr	21-day	60-day
Alfalfa				
Alfalfa, All Sites (Range in Ppb)[1] (1.5)	0.74 - 0.96	0.56 - 0.76	0.20 - 0.32	0.11 - 0.23
Turf				
Florida Turf, 1 Application (3)	2.4	1.8	0.73	0.41
Florida Turf, 2 Applications (3)	5.6	4.0	1.8	1.1
Pennsylvania Turf, 1 Application (3)	1.7	1.2	0.47	0.29
Pennsylvania Turf, 2 Applications (3)	3.7	2.6	1.0	0.57
Christmas Tree Farms				
Oregon Christmas Trees (4)	1.5	1.3	0.47	0.27
Non-bearing Fruit Trees, Nut Trees, Vineyards & Berries				
North Carolina Apples (3)	30.3	24.0	9.6	5.6
GENEEC				
Non-agricultural Areas - 1 Application (6)	30.4	29.0	22.5	13.9
Non-agricultural Areas - 2 Applications (12)	50.2	47.9	37.2	23.0

[1] The EEC values for lettuce will be approximately one-half of the alfalfa values since lettuce is applied at one-half rate of alfalfa and California alfalfa scenarios appear to reflect lettuce scenarios.

The PRZM-EXAMS model was used to calculate acute and chronic exposure concentrations for uses of benfluralin on turf, alfalfa, Christmas tree farms, and non-bearing agricultural areas. Acute risk assessments are performed using peak estimated environmental concentration (EEC) values for single and multiple applications. Chronic risk assessments are performed using the 21-day EECs for invertebrates and 60-day EECs for fish.

GENEEC, a Tier 1 screening exposure program, was used to calculate acute and chronic exposure concentrations for benfluralin use on non-agricultural land such as rights-of-way, because there is no PRZM-EXAMS scenario for these uses. These estimates are considered to be conservative. Acute

risk assessments are performed using peak EEC values for single and multiple applications. Chronic risk assessments are performed using the 21-day EECs for invertebrates and 56-day EECs for fish.

There are no acute risks expected to fish and aquatic invertebrates from soil-incorporated applications of benfluralin. No acute LOC is exceeded at use sites where soil-incorporated applications of benfluralin are made (lettuce and alfalfa). Also, no LOC is exceeded for granular applications to Christmas tree use sites.

Acute risks to aquatic species are of concern for many use sites where there are granular applications of benfluralin. For freshwater fish, the LOC for acute risk (0.5) was exceeded for non-cropland areas (two applications). Presumption of restricted use LOC (0.1), as well as the endangered species LOC (0.05) was exceeded in non-agricultural areas, non-bearing fruit trees, nut trees, vineyards, berries, and turf.

For freshwater invertebrates, the LOC for acute risk (0.5) was exceeded in non-agricultural areas (two applications). Presumption of restricted use LOC (0.1) was exceeded at non-cropland areas, non-bearing fruit trees, nut trees, vineyards, and berries. The endangered species LOC (0.05) was exceeded in non-agricultural areas, non-bearing fruit trees, nut trees, vineyards, berries, and turf.

For estuarine invertebrates, the LOC for acute risk (0.5) was exceeded for non-cropland areas, non-bearing fruit trees, nut trees, vineyards, and berries. Presumption of risk LOC (0.1) and endangered species LOC (0.05) was exceeded in non-agricultural areas, non-bearing fruit trees, nut trees, vineyards, berries, and turf.

The risk quotients (RQs) and LOCs for acute risk from benfluralin for both freshwater and estuarine organisms are outlined in Table 20.

Table 20. Acute Risk Quotients for Freshwater Fish (bluegill LC_{50} = 69.7 ppb), Freshwater Invertebrates (*Daphnia magna* LC_{50} > 100 ppb), and Estuarine Invertebrates (mysid shrimp LC_{50} = 43 ppb).

Use Site Application Rate (lbs ai/A)	Type of Application	Acute RQ Freshwater Fish	Acute RQ Freshwater Invertebrate[2]	Acute RQ Estuarine Invertebrate
Non-agricultural Areas (GENEEC)				
Non-cropland Areas (6)	broadcast (1x)	0.44	0.29	0.71
	broadcast (2x)	0.72	0.48	1.17
Alfalfa				
Alfalfa - All Sites (1.5)	incorporated	< 0.05	< 0.05	< 0.05
Christmas Tree Farms				
Christmas Trees - Oregon (4)	broadcast (2x)	< 0.05	< 0.05	< 0.05

Use Site Application Rate (lbs ai/A)	Type of Application	Acute RQ Freshwater Fish	Acute RQ Freshwater Invertebrate[2]	Acute RQ Estuarine Invertebrate
Turf				
Turf - Florida (3)	broadcast (1x)	< 0.05	< 0.05	0.06
	broadcast (2x)	0.08	< 0.06	0.13
Turf - Pennsylvania (3)	broadcast (1x)	< 0.05	< 0.05	< 0.05
	broadcast (2x)	0.05	< 0.05	0.09
Non-bearing Fruit Trees, Nut Trees, Vineyards & Berries				
Peaches - Georgia (3)	broadcast	0.26	0.18	0.43
Almonds - California (3)	broadcast	< 0.05	< 0.05	0.06
Citrus - Florida (3)	broadcast	0.19	0.13	0.30
Apples - North Carolina (3)	broadcast	0.43	0.30	0.70
Apples - Oregon (3)	broadcast	0.06	< 0.05	0.09
Berries - Oregon (3)	broadcast	0.05	< 0.05	0.08
Filberts - Oregon (3)	broadcast	0.05	< 0.05	0.09

As stated previously, the chronic level of concern (LOC) is 1.0. Risk quotients for chronic risk to freshwater fish are presented below in Table 21. The chronic LOC is exceeded for non-cropland areas, non-bearing fruit trees, nut trees, vineyards, and berries when compared to the 60-day average EEC. No chronic LOCs were exceeded for alfalfa or turf use sites.

Table 21. Chronic Risk Quotients for Freshwater Fish Early Life Stage Toxicity using Rainbow Trout (*Oncorhynchus mykiss*) (NOAEC 1.9 ppb) Based on 56-day EEC.

Site	Chronic RQ Freshwater Fish[1]
Christmas Trees - Oregon - 2	< 1
Non-agricultural Areas - 1	**7.3**
Non-agricultural Areas - 2	**12.1**
Alfalfa - All Sites	< 1
Turf - Pennsylvania - All Sites	< 1
Peaches - Georgia	**1.2**
Almonds - California	< 1
Citrus - Florida	**1.4**
Apples - North Carolina	**2.9**
Apples - Oregon	< 1
Berries - Oregon	< 1
Filberts - Oregon	< 1

[1] **Bold Type** indicates that the Chronic LOC of 1.0 was exceeded.

d. Risk to Nontarget Insects

Available data from a honey bee acute toxicity study indicated that technical benfluralin is practically non-toxic to the honey bee (with an LD50 is greater than 10 micrograms per bee; MRID 00018842, 41613812). Based on benfluralin use patterns, minimal risk is expected to nontarget insects.

e. Risk to Nontarget Terrestrial Plants

The Agency is unable to assess risk to non-target plants due to a lack of plant toxicity data. Terrestrial plant phytotoxicity data were submitted for technical benfluralin only. These data showed that non-target plants will not be at risk from spray drift or runoff. However, there is uncertainty in this conclusion because the data were based on the technical active ingredient and not the formulated product, which contains the adjuvants that are necessary for the chemical to be biologically available to nontarget terrestrial plants. Adjuvants, such as surfactants and other chemicals, are frequently used so that penetration of the active ingredient into the plant can take place. Phytotoxicity data using the typical end use product are needed to assess risk to nontarget plants.

Plant toxicity data from two closely related dinitroaniline herbicides, ethalfluralin and trifluralin, were examined and found to be incomplete. As in the case with benfluralin, the plant species were tested with the technical active ingredient, not a typical end use product. The results show that plant species are tolerant of the non-formulated herbicides. There are outstanding plant data requirements for trifluralin and ethalfluralin. The severity and spectrum of non-target plant risk from benfluralin is

uncertain without additional data. Table 22 below outlines the terrestrial plant seedling emergence toxicity EC25s and NOAECs determined from a study administered with technical benfluralin.

Table 22. Nontarget Terrestrial Plant Seedling Emergence Toxicity (Tier II)

Species	Percent Active Ingredient	EC_{25} (lb ai/A)	NOAEC (lb ai/A)	MRID No. Author/Year
Monocot- Corn	95.6 Technical	>3	0.375	43599201 Schwab, 1995
Monocot- Sorghum		1.3	0.75	
Monocot- Onion		>3	3	
Monocot- Wheat		>3	3	
Sunflower		>3	3	
Cabbage		>3	3	
Cotton		>3	3	
Cucumber		>3	3	
Radish		>3	3	
Soybean		>3	3	

Table 23 below outlines the results of a vegetative vigor study completed with technical benfluralin.

Table 23. Nontarget Terrestrial Plant Vegetative Vigor Toxicity (Tier II)

Species	Percent Active Ingredient	EC_{25} (lbs ai/A)	EC_{05} (lb ai/A)	MRID No. Author/Year
Corn	95.6	>3	3	43599201 Schwab, 1995
Onion		>3	3	
Sorghum		>3	0.05	
Wheat		>3	3	
Cabbage		>3	1.5	
Cotton		>3	3	
Cucumber		>3	0.38	
Radish		>3	3	
Soybean		2.3	0.38	
Sunflower		>3	0.05	

f. Risk to Nontarget Aquatic Plants

The Agency is unable to assess risk to non-target aquatic plants due to a lack of toxicity data. Only data on green algae (*Selenastrum capricornutum)* were submitted, which showed the EC_{50} to be greater than the solubility limit. Data on four additional species are needed to complete the data set for a screening level risk assessment.

The level of concern (LOC) for acute risk to endangered aquatic plant species is 1.0. Using the 96-hour environmental effect concentration (EEC) as the exposure concentration, and 100 ppb (solubility limit) as the concentration causing 49% growth inhibition in a green algae, there are no LOC exceedances. A new study of all four recommended aquatic plant species would clarify what concentration is toxic to aquatic plants. The results of a study on the toxicity of technical benfluralin to green algae are outlined in Table 24 below.

Table 24. Toxicity to Aquatic Plants (Tier I)

Species	Percent Active Ingredient	Concentration (ppm)	Percent Response	MRID Number Author/Year
Green algae (formerly *Selenastrum capricorntum) Kirchneria subcapitata*	95.9	0.100	49	41613809 Cocke, 1990

g. Food-Chain Effects

Benfluralin residues may bioconcentrate (Bioconcentration Factor (BCF) = 1,580) in fish near high benfluralin use areas such as non-cropland sites or orchards. Fish-eating birds that consume fish containing 30 to 48 ppm (North Carolina apple scenario) benfluralin residues may suffer chronic effects (NOAEC < 96 ppm). The risk quotient (0.3 to 0.5) for birds eating benfluralin-contaminated fish is uncertain, due to the uncertainty in the chronic no-effect concentration for birds (NOAEC < 96 ppm), and due to the uncertainty of the water concentrations estimated by PRZM-EXAMS. The RQ may be lower if actual water concentrations are lower, but may be higher if the NOAEC proves to be much lower when new data are submitted. Based on the data currently available to the Agency, it is reasonable to conclude that benfluralin exposure in fish-eating birds (in use areas such as non-cropland areas or orchards) may approach levels causing chronic toxicity. An avian reproduction study is needed to reduce the uncertainty of this risk.

Fugacity calculations (see Appendix VII of the Environmental Fate and Effects Risk Assessment dated, June 4, 2004) indicate that earthworms may accumulate concentrations of benfluralin approximately fifteen (15) times what is found in the soil. For instance, the earthworm will accumulate 180 ppm of benfluralin from soil containing 12 ppm (Table VII-B). These concentrations are well above the concentrations that cause chronic effects in mammals and birds that consume earthworms.

h. Risk to Endangered Species

As shown in Table 25, the Agency's screening level risk assessment for benfluralin concluded that there is a potential for risk to endangered species. Additional information, including the Preliminary Benfluralin Endangered Species Risk Assessment, dated July 12, 2004, can be found in Agency's e-docket website, www.epa.gov/e-docket.

Reductions in application rates and/or number of applications will reduce overall risk. As indicated in Table 29, rates for non-cropland sites, ornamentals, and Christmas tree farms are being reduced. The use of benfluralin on alfalfa and lettuce is limited in terms of application rate, frequency of application and the states that use it for these crops. The endangered species assessment on all use sites will be refined using data that will be submitted as a result of this RED. A list of required studies is shown in Section V of this document. After the new data are reviewed, the risk assessment will be refined, and exceedences of the levels of concern for risks for endangered species will be addressed.

Table 25. Potential Risks of Concern for Endangered Species Per Use Site

Use Site *(Maximum Use Rate on Current Labels)*	**Risk of Concern** *(Target RQ)*	**Species Group of Concern** *(RQ exceedance range)*
Non-cropland Areas: Industrial Sites, Utility Substations, Highway Guardrails, Sign Posts, and Delineators *(12 lb ai/A per year)*	Acute Risk *(0.05)*	Freshwater Fish *(0.72)*
		Freshwater Invertebrates *(0.48)*
		Estuarine Invertebrates *(1.17)*
	Chronic Risk *(1.0)*	Freshwater Fish *(12.1)*
		Birds *(1.0 - 8.9)*
		Mammals *(2.8 - 24.0)*
Turf *(6 lbs ai/A per year)*	Acute Risk *(0.05)*	Freshwater Fish *(0.05 - 0.08)*
		Freshwater Invertebrates *(less than 0.06)*
		Estuarine Invertebrates *(0.06 - 0.13)*
	Chronic Risk *(1.0)*	Birds *(1.8 - 4.4)*
		Mammals *(1.4 - 12.2)*

Use Site *(Maximum Use Rate on Current Labels)*	**Risk of Concern** *(Target RQ)*	**Species Group of Concern** *(RQ exceedance range)*
Landscape Ornamentals, Field-grown and Container-grown Ornamentals, Non-Bearing Vineyards, Fruit Trees, Nut Trees, and Berries *(9 lbs ai/A per year)*	Acute Risk *(0.05)*	Freshwater Fish *(0.05 - 0.43)*
		Freshwater Invertebrates *(0.13 - 0.30)*
		Estuarine Invertebrates *(0.06 - 0.70)*
	Chronic Risk *(1.0)*	Freshwater Fish *(1.2 - 2.9)*
		Birds *(2.6 - 6.7)*
		Mammals *(2.1 - 18.2)*
Christmas Tree Farms *(8 lbs ai/A per year)*	Chronic Risk *(1.0)*	Birds *(less than 2.6 - 6.7)*
		Mammals *(less than 2.1 - 18.2)*
Alfalfa, Lettuce (spray) *(1.5 lbs ai/A per year)*	Chronic Risk *(1.0)*	Birds *(1.72 - 3.75)*
		Mammals *(1.65 - 3.6)*

Note: While risks to endangered estuarine invertebrates are potentially of concern, there are currently no federally listed endangered or threatened estuarine invertebrate species.

i. Ecological Incident Reports

There are three incidents reported for benfluralin in the Ecological Incident Information System (EIIS) data base. The first was a 1997 incident associated with adverse effects (damage) to freshwater fish. Benfluralin was applied to a lawn up to the edge of a pond. A rainfall occurred, and the resulting wash of benfluralin to the pond resulted in a fish kill.

There were two plant incidents in 1994 that occurred with benfluralin mixed with sulfonylurea herbicides. The compound drifted over non-target plants and caused plant damage.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing benfluralin 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 benfluralin.

The Agency has completed its assessment of the dietary, occupational, residential, and ecological risk associated with the use of pesticide products containing the active ingredient benfluralin. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient benfluralin, the Agency has sufficient information on the human health and ecological effects of benfluralin to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that benfluralin containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in SectionV. Appendix A summarizes the uses of benfluralin that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of benfluralin, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of benfluralin, the Agency has determined that benfluralin products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of benfluralin. If all changes outlined in this document are incorporated into the product labels, then all current risks for benfluralin will be adequately mitigated for the purposes of this determination.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for benfluralin. During the public comment period on the risk assessments, which closed on April 26, 2004, the Agency received comments from two commentors, Dow AgroSciences and the U.S. Fish and Wildlife Service. These comments in their entirety are available in the public docket, www.epa.gov/.edocket, (OPP-2003-0381). An individual response to these comments is being prepared by EPA and will be made available in the public docket, www.epa.gov/.edocket, (OPP-2004-0210).

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. EPA has determined that risk from dietary (food sources only) exposure to benfluralin is within its own "risk cup." An aggregate assessment was conducted for exposures through food, drinking water, and residential uses. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances for benfluralin meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food, water, and residential uses.

b. Determination of Safety to U.S. Population

The Agency has determined that the established tolerances for benfluralin, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of benfluralin. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of benfluralin. As discussed in Chapter 3, the total acute dietary (food alone) risk was not assessed as no acute oral endpoint was observed. Further, the chronic dietary (food alone) risk from benfluralin is not of concern.

Acute and chronic risks from drinking water exposures are not of concern. Models have been used to estimate ground and surface water concentrations. The DWLOC calculated to assess the surface water contribution to chronic (noncancer) dietary exposure is a range of less than 0.07 to less than 3.5 for the U.S. general population (all population subgroups). The surface water EECs are below the DWLOC for all population subgroups (see Table 8). Drinking water monitoring data from the U.S. Geological Survey National Water Quality Assessment (NAWQA) Program confirm that concentrations of benfluralin are less than modeled estimates.

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerances for benfluralin, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors on the toxicity, use practices and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of benfluralin residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from benfluralin residues, the Agency considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for benfluralin because: 1) there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* or postnatal exposure; 2) a

DNT study with benfluralin is not required; and 3) the dietary (food and drinking water) and non-dietary (residential) exposure assessments will not underestimate the potential exposures to infants and children.

d. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

One study showed that benfluralin is toxic to the thyroid at high dose levels (136.3 mg/kg/day, male rats). However, these doses were considered excessive by the Agency review committee and no tumors were seen at lower doses. When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, benfluralin may be subject to additional screening and/or testing.

e. Cumulative Risks

Risks summarized in this document are those that result only from the use of benfluralin. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for benfluralin. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

2. Tolerance Summary

Tolerances are established for "negligible" residues of the herbicide benfluralin (N-butyl-N-ethyl-α,α,α- trifluoro-2,6-dinitro-p-toluidine) in/on the raw agricultural commodities (RACs) of alfalfa, birdsfoot trefoil, clover, lettuce, and peanuts at 0.05 ppm [40 CFR §180.208]. Because there is no

expectation of residues of benfluralin in poultry or cattle, tolerances are not required for animal and processed food/feed commodities.

a. Tolerances Currently Listed Under 40 CFR §180.208

Sufficient field trial data have been submitted (or were translated when appropriate) to reassess the established tolerances for the following plant commodities, as defined: alfalfa, birdsfoot trefoil, clover, and lettuce.

For the peanut use, the technical registrant has requested voluntary cancellation of that use. A *Federal Register* Notice was published on June 25, 2003, announcing the receipt of this voluntary use cancellation request. The cancellation was effective on December 22, 2003 (68 FR 37811). The tolerance will be proposed for revocation. Table 26 provides a listing of the tolerances currently registered for benfluralin.

Table 26. Tolerance Reassessment Summary for Benfluralin.

Commodity	Current Tolerance (ppm)	Maximum Residue Value (ppm)	Reassessed Tolerance (ppm)	Comment
Tolerance Listed Under 40 CFR §180.208				
Alfalfa, forage	0.05(N)[1]	alfalfa forage = <0.01 alfalfa hay = 0.014	0.05	
Afalfa, hay	0.05(N)[1]		0.05	
Clover, forage	0.05(N)[1]	alfalfa forage = <0.01 alfalfa hay = 0.014	0.05	The available data for alfalfa may be translated.
Clover, hay	0.05(N)[1]		0.05	
Lettuce	0.05(N)[1]	head lettuce with wrapper leaves = 0.014 leaf lettuce = 0.02	0.05	
Peanuts	0.05(N)[1]	--	Revoke	The peanut use has been voluntarily canceled in a *Federal Register* Notice dated June 25, 2003.
Trefoil, birdsfoot, forage	0.05(N)[1]	alfalfa forage = <0.01 alfalfa hay = 0.014	0.05	The available data for alfalfa may be translated.
Trefoil, birdsfoot, hay	0.05(N)[1]		0.05	

[1] EPA expects to remove the "(N)" designation from all entries to conform with current administrative practice ("(N)" designation means negligible residues).

b. Codex Harmonization

No Codex maximum residue levels (MRLs) have been established for benfluralin.

c. Residue Analytical Methods - Plants and Livestock (GLN 860.1340)

The reregistration requirements for residue analytical methods are fulfilled. Adequate methods are available for data collection and for the enforcement of tolerances for residues of benfluralin *per se* in/on plant commodities. Since no tolerances exist, or are required for milk, eggs, and edible livestock tissues, enforcement methods for the determination of benfluralin residues in livestock commodities are not needed.

The Pesticide Analytical Manual (PAM, Vol. II, Section 180.208) lists two methods, designated as Methods I and A, for determination of benfluralin *per se* in/on plant commodities. Method I lists the PAM, Vol. I multiresidue methods for organochlorine compounds. Method A is a GC/ECD method with detection limits of 0.005-0.01 ppm. Because ethalfluralin may interfere with determination of benfluralin, PAM Vol. II also includes references to methods for ethalfluralin and trifluralin, which may be used for confirmation of benfluralin residues.

Samples of alfalfa and lettuce from more recent study submissions were analyzed using the Dow AgroSciences GC/ECD Method Am-AA-CA-R027-AA-755 in a study titled *"Determination of Benefin in Agricultural Crops and Soil."* A brief description of the method follows: residues were extracted with methanol, diluted with 10% sodium chloride, and the extract was partitioned into dichloromethane (DCM). Decane was added as a keeper, and the DCM was evaporated under vacuum. The concentrated DCM phase was subjected to Florisil column chromatography; residues were eluted with hexane. Decane was added again, the hexane was evaporated, and residues were re-dissolved in toluene for quantitation by GC/ECD. The reported Limit of Quantitation was 0.01 ppm. This method is similar to Method A in PAM Vol. II.

The Agency notes that Method A in PAM Vol. II requires the use of benzene (as the solvent for GC/ECD determination). Since benzene is known to be a hazardous substance, the registrants should propose the data-collection Method Am-AA-CA-R027-AA-755 as a replacement for Method A. Because the two methods are similar, no independent laboratory validation of the method would be required.

D. Regulatory Rationale

The Agency has determined that benfluralin is eligible for reregistration provided that: additional data that the Agency intends to require confirm this decision; and the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures.

The following is a summary of the rationale for managing risks associated with the use of benfluralin. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document. Some application rates have been reduced, and other measures are needed to reduce risks to wildlife. The risk reduction by these actions have not been completely quantified but will reduce exposure to benfluralin. Table 29 lists all the use sites that have revised application rates and label requirements.

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

Benfluralin is not acutely toxic. No adverse effects attributed to a single exposure were identified in any available study including developmental studies in rabbits or rats. Therefore, no acute dietary assessment was conducted and no mitigation is needed.

The chronic non-cancer dietary analysis indicates all risk estimates are below the Agency's level of concern for all population subgroups for benfluralin. The highest chronic dietary risk estimates are less than 1% of the chronic population adjusted dose (PAD). Therefore, the chronic dietary (food) risk estimate is not of concern, and no risk reduction measures are necessary.

b. Drinking Water Risk Mitigation

Estimated environmental concentrations (EECs) of benfluralin and its degradates for both groundwater and surface water sources of drinking water are below the Agency's drinking water levels of concern (DWLOCs). Therefore, no mitigation is needed for drinking water.

c. Residential Risk Mitigation

Residential exposure to benfluralin may occur during and after application at homes; or after applications at golf courses, parks, schools, or other areas where benfluralin may be applied to turf or ornamental plants. Since systemic toxicity was not observed in a dermal toxicity study up to a dose level of 1000 mg/kg/day, the only risk addressed is the possible inhalation exposure to residential handlers. For residential lawn uses, the short-term inhalation risk from exposure to the granular formulation of benfluralin indicates that inhalation MOEs are not of concern. Therefore, the short-term risks to homeowners from residential exposure are not of concern and no residential handler mitigation is needed.

Post-application residential exposure to benfluralin is anticipated to include applications to ornamental plants and to lawns. Although the type of site that benfluralin may be used on varies from golf courses to ornamental gardens, the scenario chosen for risk assessment represents what the Agency considers to be the likely upper-end of possible exposure. For this assessment, children are the population group of concern. Since systemic toxicity was not observed in a dermal toxicity study, the only potential risk considered is the possible oral exposure of small children from treated turf, or from treated soil (i.e., soil ingestion, granule ingestion, and hand/object to mouth). The Total Oral MOE for post-application exposure to a child from all three turf scenarios is 1800, well above 100, and is thereby not of concern. Therefore, no mitigation is needed.

d. Aggregate Risk Mitigation

1) Acute Aggregate Risk

There are no adverse effects expected from a single exposure to benfluralin; therefore, an acute aggregate risk assessment was not conducted.

2) Short-term Aggregate Risk

Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water. Short-term aggregate risks from food, residential inhalation, and drinking water are not of concern; therefore, no mitigation is required.

3) Chronic (Non-Cancer) Aggregate Risk

The chronic aggregate risk assessment addresses only exposure to benfluralin residues in food and water; since there are no benfluralin uses that could result in chronic residential exposure. The estimated environmental concentrations (EECs) do not exceed the drinking water level of comparison (DWLOC). Chronic dietary (food + water) risk and chronic aggregate risk are below the Agency's level of concern and therefore no mitigation is required.

e. Occupational Risk Mitigation

1) Handler Exposure

Handler exposure assessments are completed by EPA using a baseline (long-sleeved shirt and long pants) exposure scenario and, if required, increasing levels of mitigation (Personal Protective Equipment (PPE) and engineering controls) to achieve and adequate margin of exposure (MOE). For benfluralin the target MOE for workers is 100. Analyses for handler/applicator exposures were performed using PHED, ORETF, and available studies. The calculations indicate that the MOEs for all occupational handler scenarios are above 100 at the baseline level and are not of concern. Therefore, no mitigation is needed.

2) Post-application Risk Mitigation

Dermal exposure is the only significant exposure for benfluralin. Since no dermal endpoint was identified, no re-entry risk assessment was undertaken for benfluralin. These risks are not of concern; therefore, no mitigation is needed.

2. Environmental Risk Mitigation

EPA's screening level ecological risk assessment shows some exceedance of the acute and chronic levels of concern for risk to birds, small mammals, freshwater fish, freshwater invertebrates, and estuarine invertebrates. The levels of concern are also exceeded for risk to endangered birds, mammals, freshwater fish, freshwater invertebrates, and estuarine invertebrates. Table 27 details the revised application rates and application intervals that were agreed upon by the registrants.

Table 27. Revised Use Site Parameters and Requirements for Benfluralin.

Crop	Range of Single Application Rates (lb ai/A)		Minimum Retreatment Interval	Maximum Number of Applications Per Year		Yearly Maximum Rate (lb ai/A)		Current REI (hours)
Turf	Previous	Revised	56 - 70 days/ 70 - 84 days	Previous	Revised	Previous	Revised	12

Crop	Range of Single Application Rates (lb ai/A)		Minimum Retreatment Interval	Maximum Number of Applications Per Year		Yearly Maximum Rate (lb ai/A)		Current REI (hours)
	1.5 - 3	1.5 - 3		1 - 2	1 - 2	6	6	
Alfalfa	1.2 - 1.5	1.2 - 1.5	none	1	1	1.5	1.5	12
Clover	1.2 - 1.5	1.2 - 1.5	none	1	1	1.5	1.5	12
Bird's Foot Trefoil	1.2 - 1.5	1.2 - 1.5	none	1	1	1.5	1.5	12
Lettuce	1.2 - 1.5	1.2 - 1.5	none	1	1	1.5	1.5	12
Non-bearing Berries	2 - 3	3	2 - 4 months	3	2	9	6	24[1]
Non-bearing Fruit Trees	2 - 3	3	2 - 4 months	3	2	9	6	24[1]
Ornamentals	2 - 3	2	2 - 4 months	2	2	6	4	24[1]
Christmas Trees	2 - 4	2	2 months	2	2	8	4	24[1]
Warm Season Turf	1 - 1.5	1 - 1.5	60 - 90 days	2	2	3	3	24[1]
Non-bearing Nut Trees	2 - 3	3	2 - 4 months	3	2	9	6	24[1]
Non-bearing Vineyards	2 - 3	3	2 - 4 months	3	2	9	6	24[1]
Non-cropland Areas	2 - 6	2 - 4	2 - 8 months	3	2	12	4	24[1]

[1]The 24-hour REI is for products that also contain oryzalin; other products with only benfluralin or benfluralin combined with trifluralin have a 12-hour REI.

The tables below outline the species group of concern and risk of concern per use site for species of concern other than endangered species and endangered species. Tables 28 and 29 also provide a characterization of the risk and risk mitigation strategies employed.

Table 28. Risk Characterization and Mitigation Strategies for Ecological Risks of Benfluralin.

Use Site *(Maximum Use Rate)*	Risk of Concern *(Target RQ)*	Species Group of Concern *(Current RQ range)* (Approx. Revised RQ Range)	Characterization and Mitigation
Non-cropland Areas: Industrial Sites, Utility Substations, Highway Guardrails, Sign Posts, and Delineators *(4 lbs ai/A per year)*	Acute Risk *(0.5)*	Freshwater Fish *(0.72)* (0.24)	The maximum rate for non-cropland areas has been reduced from 12 lbs ai/A per year to a yearly maximum application rate of 4 lbs ai/A. The risk assessment was calculated with the maximum use rate, which has been reduced. Also, the target RQ for acute risk to freshwater fish is only slightly exceeded. The Agency has received significant information from non-cropland area stakeholders, including utilities companies, and the registrant that this is a minor use with very little acreage. Since there is very little usage the Agency has determined that this reduction in label rate and limited use will reduce potential ecological impacts. The approximate revised RQ s for acute risk indicate that when rate reductions are implemented, acute risk for freshwater fish and estuarine invertebrates will not be of concern.
		Estuarine Invertebrates *(1.17)* (0.4)	
	Chronic Risk *(1.0)*	Freshwater Fish *(12.1)* (4.0)	
		Birds *(1.0 - 8.9)* (0,33 - 3.0)	
		Mammals *(2.8 - 24.0)* (0.9 - 8)	
Turf *(6 lbs ai/A per year)*	Chronic Risk *(1.0)*	Birds *(1.8 - 4.4)* (same)	All labels with turf use sites will recommend watering in of the granule as a mitigation measure. Since the concern in this scenario is for birds and mammals eating the granules, watering after application will reduce the granule availability, promote degradation, and reduce exposure.
		Mammals *(1.4 - 12.2)* (same)	
Landscape Ornamentals, Field-grown and Container-grown Ornamentals, Non-Bearing Vineyards, Fruit Trees, Nut Trees, and Berries *(6 lbs ai/A per year)*	Acute Risk *(0.5)*	Estuarine Invertebrates *(0.06 - 0.7)* (0.03 - 0.35 for Landscape Ornamentals) (0.04 - 0.46 for Field-grown Ornamentals, Non-bearing)	The maximum use rate for landscape ornamentals has been reduced from 8 lbs ai/A per year to 4 lbs ai/A per year. The maximum use rate for field-grown and container-grown ornamentals, and non-bearing fruit trees, nut trees, vineyards, and berries has been reduced from 9 lbs ai/A per year to 6 lbs ai/A per year. These reduction in label rates will reduce potential ecological impacts. The approximate revised RQ s indicate that when rate reductions are implemented, acute risk to estuarine invertebrates will not be of concern.
	Chronic Risk *(1.0)*	Freshwater Fish *(1.2 - 2.9)* (0.6 - 1.45 for Landscape Ornamentals) (0.8 - 1.9 for Field-grown Ornamentals, Non-bearing)	
		Birds *(2.6 - 6.7)* (1.3 - 3.35 for Landscape Ornamentals) (1.7 - 4.5 for Field-grown Ornamentals, Non-bearing)	

Use Site *(Maximum Use Rate)*	**Risk of Concern** *(Target RQ)*	**Species Group of Concern** *(Current RQ range)* (Approx. Revised RQ Range)	**Characterization and Mitigation**
		Mammals *(2.1 - 18.2)* (1.1 - 9.1 for Landscape Ornamentals) (1.4 - 12.1 for Field-grown Ornamentals, Non-bearing)	
Christmas Tree Farms *(4 lbs ai/A per year)*	Chronic Risk *(1.0)*	Birds *(approx. 2.6 - 6.7)* (1.3 - 3.35)	The maximum use rate for Christmas tree farms has been reduced from 8 lbs ai/A per year to 4 lbs ai/A per year. This reduction in label rates will reduce potential ecological impacts.
		Mammals *(approx. 2.1 - 18.2)* (1.1 - 9.1)	
Alfalfa, Lettuce (Spray) *(1.5 lbs ai/A per year)*	Chronic Risk *(1.0)*	Birds *(1.72 - 3.75)* (same)	The Agency has received significant comments from stakeholders, including USDA, and the registrant, that benfluralin is used on alfalfa and lettuce use sites in CA, AZ, and TX. Also, benfluralin liquid spray is soil incorporated at alfalfa and lettuce use sites. This application method should minimize exposures to birds and mammals. Additionally, benfluralin is only applied once per year at these use sites, which will reduce the likelihood and duration of exposure to birds and mammals.
		Mammals *(1.65 - 3.6)* (same)	

Note: While risks to endangered estuarine invertebrates are potentially of concern, there are currently no federally listed endangered or threatened estuarine invertebrate species.

Table 29. Potential Risks of Concern for Endangered Species and Risk Characterization and Mitigation Strategies for Ecological Risks of Benfluralin.

Use Site *(Maximum Use Rate)*	Risk of Concern *(Target RQ)*	Species Group of Concern *(RQ exceedance range)* (Approx. Revised RQ Range)	Characterization and Mitigation
Non-cropland Areas: Industrial Sites, Utility Substations, Highway Guardrails, Sign Posts, and Delineators *(4 lb ai/A per year)*	Acute Risk *(0.05)*	Freshwater Fish *(0.72)* (0.24)	Further evaluation of endangered species will be conducted by the Agency at a later date. The future assessment will be built upon the data and use patterns from this risk assessment. The maximum rate for non-cropland areas has been reduced from 12 lbs ai/A per year to a maximum yearly application rate of 4 lbs ai/A. The Agency has received significant information from non-cropland stakeholders, including utilities companies and the registrant that this is a minor use with very little acreage. Since there is very little usage the Agency has determined that this reduction in label rate and limited use will reduce potential exposure to listed species. Data on fish and aquatic invertebrate life cycle, avian reproduction, and other studies are being required as a result of the reregistration of benfluralin. These data will further inform EPA's endangered species analysis.
		Freshwater Invertebrates *(0.48)* (0.16)	
		Estuarine Invertebrates *(1.17)* (0.4)	
	Chronic Risk *(1.0)*	Freshwater Fish *(12.1)* (4.0)	
		Birds *(1.0 - 8.9)* (0.3 - 3.0)	
		Mammals *(2.8 - 24.0)* (0.9 - 8.0)	
Turf *(6 lbs ai/A per year)*	Acute Risk *(0.05)*	Freshwater Fish *(0.05 - 0.08)* (same)	Further evaluation of endangered species will be conducted by the Agency at a later date. The future assessment will be built upon the data and use patterns from this risk assessment. All labels with turf use sites will recommend watering in of the granule as a mitigation measure. Since the concern in this scenario is for birds and mammals eating the granules, watering after application will begin to degrade the granule on the ground and reduce the exposure to birds and mammals which will reduce potential exposure to listed species. Data on fish and aquatic invertebrate life cycle, avian reproduction, and other studies are being required as a result of the reregistration of benfluralin. These data will further inform EPA's endangered species analysis.
		Freshwater Invertebrates *(less than 0.06)* (same)	
		Estuarine Invertebrates *(0.06 - 0.13)* (same)	
	Chronic Risk *(1.0)*	Birds *(1.8 - 4.4)* (same)	
		Mammals *(1.4 - 12.2)* (same)	

Use Site *(Maximum Use Rate)*	**Risk of Concern** *(Target RQ)*	**Species Group of Concern** *(RQ exceedance range)* (Approx. Revised RQ Range)	**Characterization and Mitigation**
Landscape Ornamentals, Field-grown and Container-grown Ornamentals, Non-Bearing Vineyards, Fruit Trees, Nut Trees, and Berries (6 lbs ai/A per year)	Acute Risk *(0.05)*	Freshwater Fish *(0.05 - 0.43)* (0.03 - 0.2 for Landscape Ornamentals) (0.03 - 0.3 for Field-grown Ornamentals and Non-bearing)	Further evaluation of endangered species will be conducted by the Agency at a later date. The future assessment will be built upon data and use patterns from this risk assessment. The maximum use rate for landscape ornamentals has been reduced from 8 lbs ai/A per year to 4 lbs ai/A per year. The maximum use rate for field-grown and container-grown ornamentals has been reduced from 9 lbs ai/A per year to 6 lbs ai/A per year. These reduction in label rates will reduce potential exposure to listed species. Data on fish and aquatic invertebrate life cycle, avian reproduction, and other studies are being required as a result of the reregistration of benfluralin. These data will further inform EPA's endangered species analysis.
		Freshwater Invertebrates *(0.13 - 0.30)* (0.07 - 0.15 for Landscape Ornamentals) (0.09 - 0.2 for Field-grown Ornamentals and Non-bearing)	
		Estuarine Invertebrates *(0.06 - 0.70)* (0.03 - 0.35 for Landscape Ornamentals) (0.04 - 0.5 for Field-grown Ornamentals and Non-bearing)	
	Chronic Risk *(1.0)*	Freshwater Fish *(1.2 - 2.9)* (0.6 - 1.45 for Landscape Ornamentals) (0.8 - 1.9 for Field-grown Ornamentals and Non-bearing)	
		Birds *(2.6 - 6.7)* (1.3 - 3.4 for Landscape Ornamentals) (1.73 - 4.5 for Field-grown Ornamentals and Non-bearing)	
		Mammals *(2.1 - 18.2)* (1.1 - 9.1 for Landscape Ornamentals) (2.1 - 12.1 for Field-grown Ornamentals and Non-bearing)	

Use Site *(Maximum Use Rate)*	Risk of Concern *(Target RQ)*	Species Group of Concern *(RQ exceedance range)* (Approx. Revised RQ Range)	Characterization and Mitigation
Christmas Tree Farms *(4 lbs ai/A per year)*	Chronic Risk *(1.0)*	Birds *(less than 2.6 - 6.7)* (less than 1.3 - 3.4)	Further evaluation of endangered species will be conducted by the Agency at a later date. The future assessment will be built upon the data and use patterns used in this risk assessment. The maximum use rate for Christmas tree farms has been reduced from 8 lbs ai/A per year to 4 lbs ai/A per year. This reduction in label rates will reduce potential exposure to listed species. Data on fish and aquatic invertebrate life cycle, avian reproduction, and other studies are being required as a result of the reregistration of benfluralin. These data will further inform EPA's endangered species analysis.
		Mammals *(less than 2.1 - 18.2)* (less than 1.1 - 9.1)	
Alfalfa, Lettuce (spray) *(1.5 lbs ai/A per year)*	Chronic Risk *(1.0)*	Birds *(1.72 - 3.75)* (same)	Further evaluation of endangered species will be conducted by the Agency at a later date. The future assessment will be built upon the data and use patterns used in this risk assessment. The Agency has received significant comments from stakeholders, including USDA, and the registrant, that benfluralin is used on alfalfa and lettuce use sites in CA, AZ, and TX. Also, benfluralin liquid spray is soil incorporated at alfalfa and lettuce use sites. This application method should minimize exposures to birds and mammals. Additionally, benfluralin is only applied once per year at these use sites, which may reduce the likelihood and duration of chronic exposure to birds and mammals. Data on fish and aquatic invertebrate life cycle, avian reproduction, and other studies are being required as a result of the reregistration of benfluralin. These data will further inform EPA's endangered species analysis.
		Mammals *(1.65 - 3.6)* (same)	

Note: While risks to endangered estuarine invertebrates are potentially of concern, there are currently no federally listed endangered or threatened estuarine invertebrate species.

As an herbicide, benfluralin has the potential to affect federally listed threatened and endangered vascular plants. Until additional data are submitted and a determination made whether a species specific assessment needs to be conducted for listed species, the mitigation strategy articulated in this document will serve to reduce the likelihood that listed plant species will be exposed to benfluralin.

3. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing benfluralin. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

4. Endangered Species Considerations

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. This analysis will consider the risk mitigation measures that are being implemented as a result of this RED.

A determination that there is a likelihood of potential impact to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries Service as necessary. EPA is not requiring specific label language at the present time relative to threatened and endangered species. The general risk mitigation required through this RED will serve to reduce exposure to listed species of potential concern until such time as the agency refines its risk assessment for plants and for chronic effects to fish, avian and mammalian species and acute risks to fish and invertebrates. If in the future specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at www.epa.gov/espp. A final Endangered Species Protection Program, which may be altered from the interim program, was proposed for public comment in the Federal Register December 2, 2002.

5. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, we will continue to work with all interested parties on this important issue.

From its assessment of benfluralin, as summarized in this document, the Agency concludes that certain drift mitigation measures are needed to address the risks from off-target drift for benfluralin. Label statements implementing these measures are listed in the "spray drift management" section of the label table (Table 31) in Chapter V of this RED document. In the future, benfluralin product labels may need to be revised to include additional or different drift label statements.

V. What Registrants Need to Do

The Agency has determined that benfluralin is eligible for reregistration provided that: (i) additional data are submitted that the Agency intends to require, confirming this decision; and (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Summary Table in Section D below. The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

A. For benfluralin technical grade active ingredient products, the registrant needs to submit the following items:

Within 90 days from receipt of the generic data call in (DCI):

1. completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and
2. submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Katie Hall at (703) 308-0166 with questions regarding generic reregistration.

By US mail:
Document Processing Desk (DCI/SRRD)
Katie Hall
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Katie Hall
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1801 S. Bell Street
Arlington, VA 22202

B. For end-use products containing the active ingredient benfluralin, the registrant needs to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and
2. submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. two copies of the confidential statement of formula (EPA Form 8570-4);
2. a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";
3. five copies of the draft label incorporating all label amendments outlined in Table 31 of this document;
4. a completed form certifying compliance with data compensation requirements (EPA Form 8570-34); and
5. if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and
6. the product-specific data responding to the PDCI.

Please contact Moana Appleyard at (703) 308-8175 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PDCI/PRB)
Moana Appleyard
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PDCI/PRB)
Moana Appleyard
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of benfluralin for the above eligible uses has been reviewed and determined to be substantially complete. However, the following data requirements listed below are necessary to confirm the reregistration eligibility decision documented in this RED.

Table 30. Data Requirements for the Reregistration Eligibility Decision on Benfluralin

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
UV/Visible Absorption	830.7050	None
90-Day Inhalation - Rat (The Agency should be contacted prior to conducting the study)	870.3465	82-4
Carcinogenicity - Mouse	870.4200	83-2B
Directions for Use	860.1200	171-3
Residue Analytical Method - Plants (propose new method)	860.1340	171-4C
Confined Accumulation in Rotational Crops	860.1850	165-1
Field Accumulation in Rotational Crop Study (Reserved) (Data gap for Trifluoroacetic Acid)	860.1900	165-2
Avian Reproduction - Quail	850.2300	71-4A
Acute Fish Toxicity Bluegill	850.1075	72-1A
Acute Fish Toxicity Rainbow Trout	850.1075	72-1C
Acute Aquatic Invertebrate Toxicity	850.1010	72-2A
Acute Estuarine/Marine Toxicity - Fish	850.1075	72-3A
Acute Estuarine/Marine Toxicity - Mollusk	850.1025	72-3B
Life Cycle Fish	850.1500	72-5
Life Cycle Aquatic Invertebrate	850.1350	72-4B
Aquatic Plant Growth	850.5400	122-2
Seedling Germination and Seedling Emergence	850.4225	123-1A
Vegetative Vigor	850.4250	123-1B
Aquatic Plant Growth	850.4400	123-2
Aerobic Aquatic Metabolism	835.4300	162-4
Droplet Size Spectrum (Reserved)	840.1100	201-1
Drift Field Evaluation (Reserved)	840.1200	202-1

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 31.

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 Registrant 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 the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. A product-specific data call-in, outlining specific data requirements, will be issued separately.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 31.

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 document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in 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.

C. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table (Table 31) describes how language on the labels should be amended.

Table 31. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 31: Summary of Labeling Changes for Benfluralin		
Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
For all Manufacturing Use Products	"Only for formulation into an herbicide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"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)." "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)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements
For Manufacturing Use Products with ≥60% active ingredient benfluralin	"Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."	Precautionary Statements: Hazards to Humans and Domestic Animals

End Use Products Intended for Occupational Use		
PPE Requirements Established by the RED[1] for granular formulations	"Personal Protective Equipment (PPE) All loaders, applicators, and other handlers must wear: - long sleeved shirt and long pants, - socks plus shoes."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED[1] for liquid and dry flowable formulations	"Personal Protective Equipment (PPE) All mixers, loaders, applicators, and other handlers must wear: - long sleeved shirt and long pants, - socks plus shoes."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations for all Occupational Use Products	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE 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."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

Environmental Hazards	"This pesticide is toxic to fish and aquatic invertebrates. 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 contaminate water when disposing of equipment washwater or rinsate. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas."	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval for products with directions for use within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.	Directions for Use Inside the Agricultural Use Requirements Box
Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: * coveralls, * shoes plus socks * chemical-resistant gloves made of any waterproof material."	Directions for Use Inside the Agricultural Use Requirements Box
Entry Restrictions for Granular Formulations with direction for use only on turfgrass (no other crops or use-patterns)	"Except for those people involved in the watering-in, do not enter or allow other people (or pets) to enter the treated area until dusts have settled and until the watering-in is complete and the surface is dry.	If no WPS uses on the product, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions If the product also contains WPS uses (i.e., sodfarm uses), then create a NonAgricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.

Entry Restrictions for Granular Formulations with nonWPS uses, but no turfgrass uses	"Do not enter or allow other people (or pets) to enter the treated area until dusts have settled."	If no WPS uses on the product, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions If the product also contains WPS uses, then create a NonAgricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.
Entry Restrictions for Granular Formulations with directions for use on turfgrass and other nonWPS sites.	"Do not enter or allow other people (or pets) to enter the treated area until dusts have settled. If watering in is required after the application – except for those people involved in the watering-in – do not enter or allow other people (or pets) to enter the treated areas until the watering-in is complete and the surface is dry."	If no WPS uses on the product, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions. If the product also contains WPS uses, then create a NonAgricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.
Entry Restrictions for Liquid and Dry Flowable Formulations with directions for use outside the scope of the WPS	"Do not enter or allow other people (or pets) to enter the treated areas until sprays have dried."	If no WPS uses on the product, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions If the product also contains WPS uses, then create a NonAgricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.

General Application Restrictions for liquid or dry flowable products	"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."	Place in the Direction for Use directly above the Agricultural Use Box.
General Application Restrictions for granular products with directions for use within the scope of the WPS *or* for granular products primarily intended for occupational (professional) use	"Do not apply this product in a way that will contact workers or other persons (or pets), either directly or through drift. Only protected handlers may be in the area during application."	Directions for Use under General Precautions and Restrictions
Application Restrictions for products with directions for use on food or feed crops	Other than the crops listed on this labeling, do not plant or transplant crops in the treated area for at least 12 months following an application of this product.	Directions for Use under General Precautions and Restrictions

Use-Specific Application Restrictions (Note: the maximum allowable application rate and maximum allowable rate per year must be listed as pounds or gallons of formulated product per acre, not just as pounds active ingredient per acre.)	**Alfalfa, Clover, Bird's Foot Trefoil** "Maximum of 1.5 pounds active ingredient per acre per application." "Maximum of 1 application per year." **Lettuce** "Maximum of 1.5 pounds active ingredient per acre per application." "Maximum of 1 application per year." **Field-Grown Ornamentals; Container-Grown Ornamentals; Non-bearing Berries, Non-bearing Fruit Trees, Non-bearing Nut Trees, Non-bearing Vineyards** "Maximum of 3 pounds active ingredient per acre per application." "Maximum of 2 applications per year." "Maximum of 6 pounds active ingredient per acre per year." "Applications to plants that will bear fruits, berries, or nuts within 12 months are prohibited."	Directions for Use Associated with the Specific Use Pattern

Use-Specific Application Restrictions (Note: the maximum allowable application rate and maximum allowable rate per year must be listed as pounds or gallons of formulated product per acre, not just as pounds active ingredient per acre.)	**Landscape Ornamentals** "Maximum of 2 pounds active ingredient per acre per application." "Maximum of 2 applications per year." "Maximum of 4 pounds active ingredient per acre per year." **Ornamental Bulbs** **>Fall Application, Coarse Soils** "Maximum of 0.75 pounds active ingredient per acre per application." "Maximum of 2 applications per year." "Maximum of 1.5 pounds active ingredient per acre per year." >**Fall Application, Medium and Fine Soils** "Maximum of 1.5 pounds active ingredient per acre per application." "Maximum of 2.25 pounds active ingredient per acre per year." >**February Through March Application, All Soils** "Maximum of 0.75 pounds active ingredient per acre per application." "Maximum of 3 applications per year." "Maximum of 2.25 pounds active ingredient per acre per year." **Christmas Trees** "Maximum of 2 pounds active ingredient per acre per application." "Maximum of 2 applications per year." "Maximum of 4 pounds active ingredient per acre per year."	Directions for Use Associated with the Specific Use Pattern

Use-Specific Application Restrictions (Note: the maximum allowable application rate and maximum allowable rate per year must be listed as pounds or gallons of formulated product per acre, not just as pounds active ingredient per acre.)	**Turfgrass** "This product must be watered in as soon as possible after application. Watering-in must be performed by the commercial applicator or the commercial applicator must provide the following instructions to the resident or owner in writing: > "This product must be watered in as soon as possible. > "Do not enter or allow others (including children or pets) to enter the treated areas (except those involved in the watering) until the watering-in is complete and the surface is dry." **>Cool Season Turf** "Maximum of 3 pounds active ingredient per acre per application." "Maximum of 2 applications per year." "Maximum of 6 pounds active ingredient per acre per year." **>Warm Season Turf** "Maximum of 1.5 pounds active ingredient per acre per application." "Maximum of 2 applications per year." "Maximum of 3 pounds active ingredient per acre per year." **Noncropland Areas (Industrial Sites, Utility Substations, Highway Guardrails, Sign Posts, and Delineators)** "Maximum of 2 pounds active ingredient per acre per application." "Maximum of 2 applications per year." "Maximum of 4 pounds active ingredient per acre per year."	Directions for Use Associated with the Specific Use Pattern

Spray Drift	"Apply with nozzle height no more than 2 feet above the ground. Use hooded sprayer to direct spray toward the soil when wind speed is 10 mph or more at the application site. Use standard nozzles and apply as a medium or coarser spray (according to ASAE standard 572)."	Directions for Use
End Use Products Intended for Residential Use		
Application Restrictions	"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application."	Directions for Use under General Precautions and Restrictions
Entry Restrictions	"Do not allow people or pets to enter the treated area until dusts have settled. If watering in is required after the application – except for those people involved in the watering-in – do not enter or allow other people (or pets) to enter the treated areas until the watering-in is complete and the surface is dry."	Directions for use under General Precautions and Restrictions
Environmental Hazards	"Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate." .	Precautionary Statements immediately following the User Safety Recommendations

VI. Appendicies

Appendix A. Use Patterns Subject to Reregistration for Benfluralin (Case 2030)

Appendix A. Food/Feed Use Patterns Subject to Reregistration for Benfluralin (Case 2030)

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Year	Maximum Yearly Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations [1, 2]
Food/Feed Uses						
Alfalfa						
Preplant Soil incorporated Ground	60% DF [34704-746]	1.5 lb/A for fine soils 1.2 lb/A for coarse or medium soils	1	Not specified (NS)	Not applicable (NA)	Applications may be made in 5-40 gallons of water or liquid fertilizer per acre. Application may be made alone or as a tank mix with other pesticides. Application 3 weeks prior to planting is recommended.
Birdsfoot trefoil						
Preplant Soil incorporated Ground	60% DF [34704-746]	1.5 lb/A for fine soils 1.2 lb/A for coarse or medium soils	1	NS	NA	See "Alfalfa."
Clover						
Preplant Soil incorporated Ground	60% DF [34704-746]	1.5 lb/A for fine soils 1.2 lb/A for coarse or medium soils	1	NS	NA	See "Alfalfa."
Lettuce						
Before seeding or transplanting Soil incorporated Ground	60% DF [34704-746]	1.5 lb/A for fine soils 1.2 lb/A for coarse or medium soils	1	NS	NA	Applications may be made in 5-40 gallons of water or liquid fertilizer per acre. Application may be made alone or as a tank mix with other pesticides.
Non-food/non-feed Uses						
Non-bearing fruit and nut trees and non-bearing vineyards [including almond, apple, apricot, avocado, cherry (sweet and sour), fig, filbert, grape (American and European), grapefruit, kiwi, kumquat, lemon, macadamia nut, nectarine, olive, orange, peach, pear, pecan, pistachio, plum, pomegranate, prune, and walnut (black and English)]						

Appendix A. Food/Feed Use Patterns Subject to Reregistration for Benfluralin (Case 2030)						
Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Year	Maximum Yearly Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations [1, 2]
Broadcast application Ground	1% G [70506-45]	3.0 lb/A	2	6.0 lb/A	NA	Use limited to nonbearing fruit and nut trees and nonbearing vineyards comprised of plants that will not bear fruit for at least one year after treatment.
Nonbearing berries [including blackberry, blueberry, boysenberry, currant, dewberry, elderberry, gooseberry, loganberry, and raspberry]						
Broadcast application Ground	1% G [70506-45]	3.0 lb/A	2	6.0 lb/A	NA	Use limited to nonbearing berries comprised of plants that will not bear berries for at least one year after treatment.
Turf: golf course						
Broadcast or spray application Low-pressure handwand, backpack, handgun, groundboom	60% DF [62719-127]	Cool season turf: 3.0 lb/A Warm season turf: 1.5 lb/A	2 per year	Cool season turf: 6.0 lb/A Warm season turf: 3.0 lb/A	NA	Minimum retreatment interval 56 to 70 days for cool season established turf, 70 to 84 days for warm season established turf.
Broadcast or spray application Push-type spreader, bellygrinder, tractor-drawn spreader	0.92% G [62719-146]	Cool season turf: 3.0 lb/A	2 per year	Cool season turf: 6.0 lb/A	NA	Minimum retreatment interval 56 to 70 days for cool season established turf, 70 to 84 days for warm season established turf.

Appendix A. Food/Feed Use Patterns Subject to Reregistration for Benfluralin (Case 2030)						
Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Year	Maximum Yearly Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations [1, 2]
		Warm season turf: 1.5 lb/A		Warm season turf: 3.0 lb/A		
Turf: residential						
Broadcast application Push-type spreader, bellygrinder	0.92% G [62719-146]	3.0 lb/A	2 per year	6.0 lb/A	NA	Minimum retreatment interval 56 to 70 days for cool season established turf, 70 to 84 days for warm season established turf.
Broadcast application Push-type spreader, bellygrinder,	0.82% G [62719-327]	2.0 lb/A	2 per year	6.0 lb/A	NA	Minimum retreatment interval 56 to 70 days for cool season established turf, 70 to 84 days for warm season established turf.
Noncropland Areas (Industrial Sites, Utility Substations, Highway Guardrails, Sign Posts, and Delineators)						
Broadcast application Push-type spreader, bellygrinder, tactor-drawn spreader	1.0% G [70506-45]	2.0 lb/A	2 per year	4.0 lb/A	NA	Minimum retreatment interval 2 to 8 months.
Christmas trees						
Broadcast application Push-type spreader, bellygrider, shaker can, backpack granular spreader, tractor-drawn spreader	1.0% G [70506-45]	2.0 lb/A	2 per year	4.0 lb/A	NA	Minimum retreatment interval 2 months.
Container and Field Grown Ornamentals						

Appendix A. Food/Feed Use Patterns Subject to Reregistration for Benfluralin (Case 2030)						
Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Year	Maximum Yearly Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations [1, 2]
Broadcast application Push-type spreader, bellygriner, shaker can, backpack granular spreader	1.0% G [70506-45]	3.0 lb/A	2 per year	6.0 lb/A	NA	Minimum retreatment interval 2 to 4 months.
Ornamental Bulbs						
Broadcast application Push-type spreader, bellygriner, tractor-drawn spreader	1.0% G [70506-45]	Fall Application, Coarse Soil; 0.75 lb/A	2 per year	1.5 lb/A	NA	Minimum retreatment interval 2 to 4 months.
		Fall Application, Medium and Fine Soil; 1.5 lb/A	NS	2.25 lb/A		
		February through March Application, All Soils; 0.75 lb/A	3 per year	2.25 lb/A		
Landscape Ornamentals						
Broadcast application Push-type spreader, bellygriner, shaker can, backpack granular spreader	0.575% G [70506-45]	2.0 lb/A	2 per year	4.0 lb/A	NA	Minimum retreatment interval 2 to 4 months.

[1]The restricted entry interval (REI) for the 60% DF formulation (EPA Reg. No. 34704-746) is 12 hours; the REI for the 1% G formulation (EPA Reg. No. 62719-136) is 24 hours.

[2]The following rotational crop restrictions are established for the 60% DF formulation (EPA Reg. No. 34704-746): wheat, barley, oats, rye, other grasses, onions, corn, milo (grain sorghum), spinach, red beets, sugar beets, or other root crops should not be planted for 10 months following application of the 60% DF formulation in arid, irrigated areas of the Western U.S. (AZ, CA, ID, MT, NV, OR, UT, WA, and WY).

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Benfluralin

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Data Supporting Guideline Requirements for the Reregistration of Benfluralin

REQUIREMENT			Use Patterns	CITATION(S)
PRODUCT CHEMISTRY				
New Guideline Number	**Old Guideline Number**			
830.1550	**61-1**	**Product Identity and Composition**	All	42039401, 42340801, 44258001
830.1600	**61-2A**	**Description of materials used to produce the product**	All	42039401, 42779101, 44258001
830.1620	**61-2B**	**Description of production process**		42039401, 44258001
830.1670	**61-2B**	**Formation of Impurities**	All	42039401, 44258001
830.1700	**62-1**	**Preliminary Analysis**	All	42340801, 43548701, 43548702, 44258002
830.1750	**62-2**	**Certification of limits**	All	42340801, 44258001,
830.1800	**62-3**	**Analytical Method**	All	42340801, 43548702, 44258003, 44258004
830.6302	**63-2**	**Color**	All	00160844
830.6303	**63-3**	**Physical State**	All	00160844
830.6304	**63-4**	**Odor**	All	00160844
830.6313	**63-13**	**Stability to normal and elevated temperatures, metals, and metal ions**	All	42066201
830.700	**63-12**	**pH**	All	N/A
830.7050	**None**	**UV/Visable Absorption**	All	Data gap
830.7200	**63-5**	**Melting Point**	All	00160844
830.7220	**63-6**	**Boiling Point**	All	N/A
830.7300	**63-7**	**Density**	All	00160844
830.7370	**63-10**	**Dissociation constants in water**	All	N/A
830.7550	**63-11**	**Partition coefficient, shake flask method**	All	42039402

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REQUIREMENT			Use Patterns	CITATION(S)
830.7840	**63-8**	**Solubility**	All	00160844
830.7950	**63-9**	**Vapor Pressure**	All	42785301
ECOLOGICAL EFFECTS				
850.2100	**71-1A**	**Avian Acute Oral Toxicity**	A, B	160875, 24273, 160000
850.2200	**71-2A**	**Avian Dietary Toxicity - Quail**	A, B	24635, 234214
850.2200	**71-2B**	**Avian Dietary Toxicity - Duck**	A, B	26954, 234214
850.2300	**71-4A**	**Avian Reproduction - Quail**	A, B	42145502, Data gap
850.2300	**71-4B**	**Avian Reproduction - Duck**	A, B	42145501
850.1075	**72-1A**	**Fish Toxicity Bluegill**	A, B	Data gap, 41613801, 145756, 257844, 26955, 234214
850.1075	**72-1B**	**Fish Toxicity Bluegill - TEP**	A, B	42390801
850.1075	**72-1C**	**Fish Toxicity Rainbow Trout**	A, B	Data gap, 145756, 257844
850.1075	**72-1D**	**Fish Toxicity Rainbow Trout - TEP**	A, B	42419201
850.1010	**72-2A**	**Invertebrate Toxicity**	A, B	Data gap, 42390802, 257844, 00415757
850.1010	**72-2B**	**Invertebrate Toxicity - TEP**	A, B	42390802
850.1075	**72-3A**	**Estuarine/Marine Toxicity - Fish**	A, B	Data gap, 41613802
850.1025	**72-3B**	**Estuarine/Marine Toxicity - Mollusk**	A, B	Data gap, 41613803
850.1035	**72-3C**	**Estuarine/Marine Toxicity - Shrimp**	A, B	41613804
850.1300	**72-4A**	**Fish Early Life Stage - Daphnid**	A, B	41613805, 41613806
850.1350	**72-4B**	**Estuarine/Marine Invertebrate Life Cycle**	A, B	Data gap, 41613806
850.1400	**72-4C**	**Freshwater Fish- Acute Toxicity**	A, B	41613805
850.1500	**72-5**	**Life Cycle Fish**	A, B	Data gap
850.4100	**122-1A**	**Terrestrial Plant Toxicity, Seedling Emergence**	A, B	41613808

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REQUIREMENT			Use Patterns	CITATION(S)
850.5400	**122-2**	**Aquatic Plant Growth**	A, B	41613809, Data gap for *Lemna gibba, Skeletonema costatum, Anabaena flos-aquae*, and a freshwater diatom.
850.4225	**123-1A**	**Seedling Germination and Seedling Emergence**	A, B	Corn, sorghum, onion, wheat, sunflower, cabbage, cotton, cucumber, radish, soybean: 43599201 Data gap (TEP)
850.4250	**123-1B**	**Vegetative Vigor**	A, B	Corn, sorghum, onion, wheat, sunflower, cabbage, cotton, cucumber, radish, soybean: 43599201 Data gap (TEP)
850.4400	**123-2**	**Aquatic Plant Growth**	A, B	Data gap
850.3020	**141-1**	**Honey Bee Acute Contact**	A, B	41613812, 00018842
TOXICOLOGY				
870.1100	**81-1**	**Acute Oral Toxicity-Rat**	A, B	00024255, 243848,. 249554,. 257099,. 249185, 251206, 24255, 243848, 257847, 245611
870.1200	**81-2**	**Acute Dermal Toxicity-Rabbit/Rat**	A, B	41751701
870.1300	**81-3**	**Acute Inhalation Toxicity-Rat**	A, B	41613807
870.2400	**81-4**	**Primary Eye Irritation-Rabbit**	A, B	00024265
870.2500	**81-5**	**Primary Skin Irritation**	A, B	41751702
870.2600	**81-6**	**Dermal Sensitization**	A, B	00144283
870.3100	**82-1A**	**Subchronic Oral Toxicity: 90-Day Study Rodent**	A, B	44050001
870.3150	**82-1B**	**Subchronic Oral Toxicity: 90-Day Study Non-rodent**	A, B	43072301
870.3200	**82-2**	**21-Day Dermal - Rabbit/Rat**	A, B	43020201
870.3465	**82-4**	**90-Day Inhalation-Rat**	A, B	Data gap
870.4100	**83-1B**	**Chronic Feeding Toxicity - Non-Rodent**	A, B	43628702
870.3700	**83-3A**	**Developmental Toxicity - Rat**	A, B	00147535

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Data Supporting Guideline Requirements for the Reregistration of Benfluralin

REQUIREMENT			Use Patterns	CITATION(S)
870.3700	**83-3B**	**Developmental Toxicity - Rabbit**	A, B	42039101
870.3800	**83-4**	**2-Generation Reproduction - Rat**	A, B	43628701
870.4300	**83-5**	**Combined Chronic Toxicity/ Carcinogenicity: Rats**	A, B	44050002, 44545501
870.4200	**83-2B**	**Carcinogenicity Mice**	A, B	Data gap, 41021501
870.5100	**84-2**	**Bacterial Reverse Gene Mutation**	A, B	00160863
870.5375	**84-2B**	**Cytogenetics**	A, B	00160866
870.7485	**85-1**	**General Metabolism**	A, B	40693201, 40693207, 00132820
870.7600	**85-3**	**Dermal Penetration and Absorption**	A, B	92062028
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2400	**133-3**	**Dermal Passive Dosimetry Exposure**	A, B	45167201, 45250701
875.2500	**133-4**	**Inhalation Passive Dosimetry Exposure**	A, B	45250701
ENVIRONMENTAL FATE				
835.2120	**161-1**	**Hydrolysis**	A, B	257843
835.2240	**161-2**	**Photodegradation - Water**	A, B	257843, 41613814
835.2410	**161-3**	**Photodegradation - Soil**	A, B	41613815
835.4100	**162-1**	**Aerobic Soil Metabolism**	A, B	41751703, 257843
835.4200	**162-2**	**Anaerobic Soil Metabolism**	A, B	41751704
835.4400	**162-3**	**Anaerobic Aquatic Metabolism**	A, B	43106001
835.4300	**162-4**	**Aerobic Aquatic Metabolism**	A, B	Data gap
835.1240	**163-1**	**Leaching/Adsorption/Desorption**	A, B	41613816, 41866201
835.1410	**163-2**	**Laboratory Volatilization**	A, B	43915701
835.6100	**164-1**	**Terrestrial Field Dissipation**	A, B	Turf CA - 41778901 Lettuce CA, peanuts GA - 41778902

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REQUIREMENT			Use Patterns	CITATION(S)
None	**165-4**	**Bioaccumulation in Fish**	A, B	40278401
RESIDUE CHEMISTRY				
860.1200		**Directions for Use**	A, B	Data Gap
860.1300	**171-4A**	**Nature of Residue - Plants**	A, B	Lettuce - 42338501, 43039901, 43624501 Alfalfa - 42370101, 42409801 Peanut - 43064801
860.1300	**171-4B**	**Nature of Residue - Livestock**	A, B	Ruminant - 42128201 Poultry - 42204801, 42854601
860.1340	**171-4C**	**Residue Analytical Method - Plants**	A, B	Data gap, 00024254, 00024258, 00024496, 00124776
860.1380	**171-4E**	**Storage Stability - Plants**	A, B	43831901, 43831902
860.1500	**171-4K**	**Crop Field Trials (Leafy Vegetables)**	A, B	43831902
860.1500	**171-4K**	**Crop Field Trials (Alfalfa, forage and hay)**	A, B	43831901
860.1500	**171-4K**	**Crop Field Trials (Clover, forage and hay)**	A, B	43831901
860.1500	**171-4K**	**Crop Field Trials (Trefoil, forage and hay)**	A, B	43831901
860.1850	**165-1**	**Confined Accumulation in1 Rotational Crops**	A, B	Data gap, 44019801
860.1900	**165-2**	**Field Accumulation in Rotational Crop Study**	A, B	Reserved., Data Gap for trifluoroacetic acid
OTHER				
840.1100	**201-1**	**Droplet Size Spectrum**	A, B	Reserved
840.1200	**202-1**	**Drift Field Deposition Evaluation**	A, B	Reserved

Appendix C. Technical Support Documents

Appendix C. TECHNICAL SUPPORT DOCUMENTS

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 South Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The docket initially contained preliminary risk assessments and related documents as of August 10, 1998. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on June 16, 1999.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

www.epa.gov/pesticides/reregistration

These documents include:

HED Documents:

1. Benfluralin: Human Health Risk Assessment (Revised) 30-Oct-2003.
2. Benfluralin: Residue Chemistry Chapter for the Reregistration Eligibility Decision. 28-May-2003.
3. Benfluralin. Case 2030. PC Code 084301. Product Chemistry Chapter for the Reregistration Eligibility Decision Document. 27-Mar-2003.
4. Third Report of the Hazard Identification Assessment Review Committee 03-Apr-2003.
5. Second Report of the Hazard Identification Assessment Review Committee 27-Jan-2003.
6. Report of the Hazard Identification Assessment Review Committee 10-Apr-2001.
7. Benfluralin: Health Effects Decision (HED) Metabolism Assessment Review Committee (MARC) Decision Document 29-Apr-2003.
8. Benflluralin: Confined Rotational Crop Data on Lettuce, Mustard, Radishes, and Wheat. 20-Mar-2003.
9. Drinking Water Estimates for Benfluralin - PRZM/EXAMS data 12-Oct-2002.
10. Second Addendum to Drinking Water Estimates for Benfluralin: Non Bearing Vineyards, Fruit, Trees, Nut Trees, and Berries 25-Apr-2003.
11. Drinking Water Estimates for Benfluralin 31-Jan-2003.
12. Benfluralin: Health Effects Division Response to Corrections and Comments Submitted by Dow AgroSciences for the Phase One Human Health Risk Assessment 30-Oct-2003.
13. Evaluation of Carcinogenic Potential of Benfluralin 27-Dec-2003.
14. Benfluralin: HED Response to Comments Submitted by the Registrant (Dow Agrosciences) on April 26, 2004. 08-June-2004.

EFED Documents:

1. "Response to Dow AgroSciences' Comments on EFED RED Chapter for Benfluralin," (including as an attachment, the Environmental Fate and Effects Risk Assessment), dated June 4, 2004.
2. Benfluralin: Environmental Fate and Ecological Effects Risk Assessment 22-Oct-2003.

3. Benfluralin: EFED's Response to 30-Day Error Comment 22-Oct-2003.
4. Dissipation of 14-C Benefin in Soils Maintained Under Aerobic Conditions, D.F. Berard, ABC-0289, Lilly Research Laboratories, March 1985 Guideline Number: 162-1 28-Jul-2003.
5. Anaerobic Metabolism of 14-C Benefin on Sandy Loam Soil Guideline Number: 162-2 28-Jul-2003.
6. Aerobic Metabolism of 14-C Benefin on Sandy Loam Soil Guideline Number: 162-1 28-Jul-2003.
7. Field Dissipation of Benefin Following Application of Balan to Bare Soil and Seeded with Lettuce or Peanuts, O.D. Decker, DowElanco 28-Jul-2003.
8. Field Dissipation of Benefin Following One or Two Applications to Turf 28-Jul-2003.
9. DER Addenda for the Benfluralin Reregistration Eligibility Document.28-Jul-2003.
10. Response to Dow AgroSciences' Phase 3 Comments on EFED RED Chapter for Benfluralin 04-June-2004.
11. Revised Benfluralin Environmental Fate and Ecological Effects Risk Assessment 04-June-2004.

Other Documents:

1. Quantitative Usage Analysis for Benfluralin 14-May-2002.

Appendix D. Citations Considered to Be Part of the Data Base Supporting the Reregistration Decision (Bibliography)

Appendix D. CITATIONS CONSIDERED TO BE PART OF THE DATA BASE SUPPORTING THE INTERIM REREGISTRATION DECISION (BIBLIOGRAPHY)

GUIDE TO APPENDIX D

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 (1999), 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.

Acree, W.E., Jr. Thermochim. Acta, 1991, 37.

Balcomb, R. C.A. Bowen II, D. Wright, and M. Law. 1984 Effects on Wildlife of at-planting corn applications of granular carbofuran.

Belfroid, A., M. Sikkenk, W. Seinen, K.V. Gestel, J. Hermens. 1994. The toxicokinetic behavior of chlorobenzenes in earthworm (Eisenia andrei) experiments in soil. Environ. Toxicol. Chem. 13: 93-99

Beyer, W.N., E.E. Connor, S. Gerould. 1994. Estimates of soil ingestion by wildlife. J.Wildl. Manage. 58: 375-382.

Carmo, A.M., Hundal. L.S., and Thompson, M.L., "Sorption of Hydrophobic Organic Compounds by Soil Materials: Application of Unit Equivalent Freundlich Coefficients," Environmental Science & Technology, 2000, 34, 4363-4369.

Degradates Identified in Benfluralin Fate Studies, Memorandum to file, WP Eckel, Jan. 22, 2003.

Determination of Benefin in Agricultural Crops and Soil, OD Decker and RD Griggs, Lilly Research Laboratories, 1980. EPA Acc. No. 255775.

Dissipation of 14C Benefin in Soils Maintained Under Aerobic Conditions, DF Berard, 1985. Lilly Research Laboratories, Greenfield, IN. Report No. ABC-0289. EPA Acc. No. 257843.

Drinking Water Estimates for Benfluralin (PC# 084301), Jan. 31, 2003 memorandum from WP Eckel, EFED to M. Rice, SRRD. DP Barcode 288082

Dunning, J.B. 1984. Body Weights of 686 Species of North American Birds. Monograph Number 1. Western Bird Banding Association.

Farm Chemicals Handbook, vol. 86, 2000. Meister Publishing Company, Willoughby, OH. Page C47, Benefin.

Fisher, D.L. and L.B. Best. 1995. Avian Consumption of Blank Pesticide Granules Applied at Planting to Iowa Cornfields. Environ. Tox. Chem. 14:1543-1549.

Hansch, C., A Leo, D Hoekman, Exploring QSAR - Hydrophobic, Electronic, and Steric Constants. Washington, DC: American Chemical Society, 1995.

Mackay, D. And S. Paterson. 1981. Calculating fugacity. Environ. Sci. Technol. 15: 1006-1014.

The Merck Index, 10th Ed., M. Windholz, ed., 1983. Merck & Co., Inc., Rahway, NJ. Monograph 1038: Benfluralin.

Nagy, K.A. 1987. Field metabolic rate and food requirement scaling in mammals and birds. Ecol. Monogr. 57: 111-128.

Processes of Retention and Loss of Benefin in Soil, BJ Simoneaux, 1969. Ph.D. dissertation, Auburn University, Auburn, Alabama.

Schwarzenbach, RP, Gschwend, PM, and Imboden, DM, Environmental Organic Chemistry, John Wiley & Sons, New York, 1993.

Soil Degradation of Three Dinitroanilines, RL Zimdahl and SM Gwynn, 1977. Weed Science, vol. 25, no. 3, pp. 247-251.

Tomlin, CDS (ed.) The Pesticide Manual- World Compendium 10th ed. Surrey, UK:The British Crop Protection Council, 1994.

Trapp, S. And J.C McFarlane (eds.). 1995. Plant Contamination Modeling and Simulation of Organic Chemical Processes. Lewis Publishers. Boca Raton, Florida.

United States Environmental Protection Agency (EPA). 1993. Wildlife Exposure Factors Handbook. EPA/600/9-93/187a. Office of Research and Development. Washington, DC.

Upgrading Benfluralin Photolysis Studies, July 9, 2002 memorandum from I. Kennedy, EFED to R. Kendall, SRRD

Wauchope RD et al., Rev Environ Contam Toxicol 123: 1-155 (1992)

Weed Science Society of America. Herbicide Handbook, 5th ed. Champaign, IL., 1983.

Woodrow, JE, Crosby, DG and Seiber, JN, "Vapor-Phase Photochemistry of Pesticides," Res. Rev., 85, 111 (1983).

Product Chemistry MRID References

00160844	West, S.; Casell, R. (1985) Physical and Chemical Properties of Technical Benefin: EWD8514. Unpublished study prepared by Lilly Research Laboratories. 7 p.
42039401	Handy, P.; Reinhart, R. (1991) Product Composition of Technical Benefin: Lab Project Number: PRH9103. Unpublished study prepared by DowElanco. 20p.
42039402	Day, E.; Saunders, D.; Loh, A. (1983) Octanol/Water Partition Coefficient of Benefin: Lab Project Number: I0EWD-93-29. Unpublished study prepared by Lilly Research Labs. 9 p.
42066201	Handy, P. (1991) Stability of Technical Benefin to Metals and Metal Ions: Lab Project Number: FOR91062. Unpublished study prepared by DowElanco, Formulation and Environ. Chem. Lab. 13 p.
42340801	DowElanco (1992) Analysis and Certification of Benefin Technical Grade Active Ingredient (T2A CHEPHY US 89-139). 20 p.
42779101	Linscott, D. (1993) Techinical Benefin–Beginning materials Specification Sheets: Lab Project Number: DJL040793. Unpublished study prepared by Lilly Research Labs. 13 p.
43548701	Hamilton, T. (1995) Series 62-1: Preliminary Analysis of Product Sample of Benefin Technical for Nitrosamines: Lab Project Number: FOR93097. Unpublished study prepared by DowElanco. 22 p.

43548702	Hamilton, T. (1995) Validation of an Analytical Method for the Determination of N-Nitroso Compounds in Benefin Technical Grade Active Ingredient: Lab Project Number: FOR93120.01. Unpublished study prepared by DowElanco. 35 p.
44258001	Linscott, D.; Owen, J.; Cook, J. (1997) Series 61: Product Identity and Compostion f Balan Technical: Lab Project Number: GH-C 4268. Unpublished study prepared by DowElanco. 123 p. (Relates to L0000159).
44258002	Hanselman, D.; Yeh, L. (1997) Preliminary Analysis of Product Samples for Active Ingredient and Impurities in Technical Grade Benefin: (Final Report): Lab Project Number: FOR96137. Unpublished study prepared by DowElanco. 77 p.
44258003	Hanselman, D.; Yeh, L. (1997) Analytical Method and Validation for the Determination of Benefin in Benefin Technical by Gas Chromatography with Flame Ionization Detection: Lab Project Number: NA-AM-96-006. Unpublished study prepared by DowElanco. 22 p.
44258004	Hanselman, D. (1997) Analytical Method and Validation for the Determination of Process Impurities in Benefin Technical by Gas Chromatography with Flame Ionization Detection: Lab Project Number: NA-AM-96-007. Unpublished study prepared by DowElanco. 81 p. (Relates to L0000159).

Occupational and Residential MRID References

00024255	Worth, H.M.; Anderson, R.C., eds. (1965) Toxicological Studies with N-Butyl-N-ethyl-alpha,alpha,alpha-trifluoro-2,6-dinitro-?~p~?- toluidine, Benefin. (Unpublished study received Jul 16, 1965 under 1471-55; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006278-A)
00024265	Arthur, B.H.; Broddle, W.D.; Gibson, W.R.; et al. (1976) Acute Tox- icity Studies of Benefin Technical: Supplement. (Unpublished study received Nov 4, 1976 under 1471-55; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:226802-A)
00024275	Worth, H.M. (1964) ?Toxicity Studies on Mice, Dogs, Rats and Rab- bits|. (Unpublished study received Oct 1, 1965 under 1471-50; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006275-C)
00132820	Bridge, T.; van Lier, R.; Adams, E.; et al. (1982) Percutaneous Absorption of 14C-Ethalfluralin (EL-161, Compound 94961) in Monkeys: Studies M-6162 and P03282. (Unpublished study received Dec 2, 1983 under 4F3006; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL:072180-B)
00144283	Mattingly, C. (1984) A Guinea Pig Sensitization Study of Benefin, Compound 54521: Study G01183. Unpublished study prepared by Lilly Research Laboratories. 46 p.
00147535	MacKenzie, K. (1985) Rat Teratology Study with Benefin: Study No. 6180-101. Unpublished study prepared by Hazleton Laboratories America, Inc. 141 p.
00160863	Rexroat, M. (1985) The Effect of Benefin (EL-110, Compound 54521) on the Induction of Reverse Mutations in Salmonella typhimurium Using the Ames Test: Studies 850624AMS2598 and 850708AMS2598. Unpublished study prepared by Lilly Research Laboratories. 36 p.

00160866	Bewsey, B. (1985) The Effect of Benefin (EL-110, Compound 54521) on the Induction of Forward Mutation at the Thymidine Kinase Locus of L5178Y Mouse Lymphoma Cells: Studies 850612MLA2598 and 850724MLA2598. Unpublished study prepared by Lilly Research Laboratories. 42 p.
40693201	Berard, D. (1988) Characterization and Identification of Radio- activity in Urine and Feces of Rats Dosed with ?Carbon 14| Bene- fin: Project ID. ABC-0389. Unpublished study prepared by Lilly Research Laboratories. 48 p.
40693207	Koenig, G.; Pohland, R. (1988) An Overview of Radiocarbon Disposi- tion Studies Conducted in Male and Female Fischer 344 Rats Given ?Carbon 14|-Benefin ...: Project ID's. R06087, R16687, R09887, R23887, R09987, R03588. Unpublished study prepared by Lilly Research Laboratories. 19 p.
41021501	Koenig, G.; Jordan, W. (1988) A Chronic Toxicity and Oncogenicity Study in B6C3F, Mice Given Benefin (EL-110, Compound 54521) in the Diet for Two Years: Laboratory Project ID M02785: M02885. Unpublished study prepared by Lilly Research Laboratories. 1178 p.
41613807	Koenig, G.; Allen, D.; Wolff, R. (1989) The Acute Inhalation Toxi- city of Technical Benefin (EL-110, Compound 05421) in Fischer 344 Rat: Lab Project Number: R-H-048-85. Unpublished study pre- pared by Lilly Research Laboratories. 37 p.
41751701	Koenig, G.; Rock, G.; Laska, D.; et al. (1990) The Acute Dermal Toxicity of Benefin (El-110, Compound 054521) in New Zealand White Rabbits: Lab Project Number: B04990. Unpublished study prepared by Lilly Research Laboratories. 28 p.
41751702	Koenig, G.; Rock, G.; Laska, D.; et al. (1990) The Primary Dermal Irritation of Benefin (El-110, Compound 054521) in New Zealand White Rabbits: Lab Project Number: B09690. Unpublished study prepared by Lilly Research Laboratories. 25 p.
42039101	Mercieca, M. (1991) Teratology Study in Rabbits with Benefin: Final Report: Lab Project Number. Unpublished study prepared by Springborn Labs, Inc. 265 p.
43020201	McGuirk, R.; Stebbins, K. (1993) Benefin: Probe and 21-Day Repeated Dose Dermal Toxicity Study in New Zealand White Rabbits: Lab Project Number: DR-0097-3397-002. Unpublished study prepared by The Dow Chemical Co. 198 p.
43072301	Dalgard, D. (1993) Benefin: 13--Week Oral Toxicity Study in Beagle Dogs: Lab Project Number: HWA 174-135: DR-0097-3397-003. Unpublished study prepared by Hazleton Washington, Inc. 273 p.
43628701	Trutter, J. (1995) Two-Generation Reproduction Study in Rats with Benefin: Final Report: Lab Project Number: HWA 174-136. Unpublished study prepared by Hazleton Washington, Inc. 1788 p.
43628702	Walker, M. (1995) Benefin: One-Year Oral Chronic Toxicity Study in Beagle Dogs: Final Report: Lab Project Number: CHV 174-143: DR-0097-3397-004. Unpublished study prepared by Corning Hazleton Inc. 381 p.

44050001	Adams, E.; Jordan, W. (1996) Subchronic Toxicity Studies of Benefin (Compound 054521) Administered Orally in the Diet to Fischer 344 Rats for 3 Months: Lab Project Number: R33989: R44089: R29990. Unpublished study prepared by Lilly Research Labs. 702 p.
44050002	Moore, M. (1996) Benefin: Two-Year Dietary Chronic Toxicity/Oncogenicity Study in Fischer 344 Rats: Final Report: Lab Project Number: CHV 174-133: DR-0097-3397-005. Unpublished study prepared by Corning Hazleton Inc. 3247 p.
44545501	Moore, M. (1998) Benefin: Two-Year Dietary Chronic Toxicity/Oncogenicity Study in Fischer 344 Rats: Final Report: Lab Project Number: CHV 174-133: DR-0097-3397-005. Unpublished study prepared by Covance Labs., Inc. 111 p.
45167201	Urtizberea, M. (1999) Worker Exposure Study During Application in Banana Plantation with Temik 10G: Lab Project Number: SA 98337: RPS/ALD/98072. Unpublished study prepared by ADME Bioanalyses. 156 p. {OPPTS 875.1000}
45250701	Leffingwell, J. (1986) An Exposure Study of Mixer/Loader-Applicators Working with MOCAP EC. Unpublished study. 140 p. {OPPTS 875.1000}
45250702	Pontal, P. (1996) Fipronil: Worker Exposure Study During Application of Regent 20GR in Banana Plantation: Lab Project Number: 338/95/0072: 94/136: 94002 HI. Unpublished study prepared by Rhone-Poulenc Agrochemie. 196 p. {OPPTS 875.1000}
46082401	Tiu, C.; Hanley, T. (2003) Dow AgroSciences Response to the U.S. EPA's Benfluralin: Human Risk Assessment. Project Number: KSG092603. Unpublished study prepared by Dow AgroSciences LLC. 15 p.
92062028	Environ Corp. (1990) Dowelanco Phase 3 Summary of MRID 00132820. Percutaneous Absorption of (Carbon-14) - Ethalfluralin in Monkeys: M-6162 and P03282. Prepared by LILLY RESEARCH LABS. 7 p.

Environmental Fate MRID References

00148874	Hydrolysis of the Herbicide Benefin in Aqueous Buffer Solution, DG Sanders, SK Smith, and JW Mosier, 1985. Lilly Research Laboratories, Greenfield, IN. EPA Acc. No. 257843.
40287401	Laboratory Studies of 14C Benefin Accumulation in Fish, JD Magnussen and DP Rainey, 1987. Lilly Research Laboratories, Greenfield, IN.
40457201	Moran, J.; Saunders, D. (1986) Photolysis of Benefin in Aqueous Solution: Laboratory Project I.D.: AAC8518. Unpublished study prepared by Lilly Research Laboratories. 44 p.
41613814	Determination of photolysis rate of 14C-Benefin in aqueous solution, M Carpenter, and M Fennesey, 1988. Analytical Bio-Chemistry Laboratories, Columbia, MO. Second amended report No. 36866.
41613815	Determination of the Photolysis rate of Benefin on the surface of soil, J Dykes, 1989. Analytical Bio-Chemistry laboratories, Columbia, MO. Amended final report No. 36867.

41613816	Adsorption and Desorption of Benefin on Soil, DG Saunders and FL Powers, 1987. Eli Lilly, Greenfield, IN. Project ID No. EWD8724.
41751703	Aerobic metabolism of 14C Benefin on Sandy loam Soil, LK Graper, 1991. DowElanco, Greenfield, IN.
41751704	Anaerobic metabolism of 14C Benefin on Sandy Loam Soil, LK Graper, 1991. DowElanco, Greenfield, IN.
41778901	Field Dissipation of Benefin Following One or Two Applications of Balan to Turf, OD Decker, 1991. DowElanco, Greenfield, IN.
41778902	Field Dissipation of Benefin Following Application of Balan to Bare Soil and Seeded with Lettuce or Peanuts, OD Decker, 1991. DowElanco, Greenfield, IN.
41866201	Benefin Aged Soil Leaching Study, DG Saunders and FL Powers, 1991. DowElanco, Greenfiled, IN. Project ID No. AAC908.
43106001	Anaerobic Aquatic Metabolism of 14C Benefin, BL Lawrence, A Kesterson and RH Atkins, 1994. PTRL East, Richmond, KY. Laboratory project Nos. 651, 1540.
43374901	Supplemental Report for MRID 41778902 Titled "BenefinTerrestrial Lettuce and Peanut Field Dissipation Studies" and MRID 41778901 Titled "Benefin Terrestrial Turf Dissipation Study, OD Decker, 1994, DowElanco Indianapolis, IN.
43915701	Laboratory Volatility of [14C]-Trifluralin formulated as an emulsifiable concentrate and as Granules, W Skinner, 1996. PTRL West, Richmond, CA. Laboratory project ID No. 552W. Submitted by DowElanco, Indianapolis, IN.
470208027	Photolysis of Benefin in Aqueous Solution, JW Moran and DG Saunders, 1985. Lilly Research Laboratories, Greenfield, IN. Laboratory report No. AAC8518. EPA Acc. No. 257843.

Ecological Effects MRID References

00018842	Study Record Deleted. Study Is a Duplicate of MRID 9181.
00024273	Broddle, W.D.; Kehr, C.C.; West, H.C.; et al. (1973) The Safety of Balan^(R)I to the Mallard and Quail. (Unpublished study re- ceived Dec 3, 1973 under 6735-201; prepared by Elanco Products Co., Div. of Eli Lilly and Co., submitted by Tide Products, Inc., Edinburg, Tex.; CDL:010110-A)
00024635	West, H.C.; Hamelink, J.L.; Broddle, W.D.; et al. (1978) The Toxic- ity of Compound 54521 (Benefin) in Bobwhites (?~Colinus Vir~?- ?~ginianus~?) Eight Day Dietary Study: Study No. 7008-77. (Un- published study received Jun 29, 1978 under 1471-71; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:kd-A)
00026954	West, H.C.; Hamelink, J.L.; Broddle, W.D.; et al. (1978) The Toxic- ity of Compound 54521 (Benefin) in Mallards (?~Anas Platy~?- ?~rhynchos~?) Eight Day Dietary Study: Study No. 7011-77. (Un- published study received Jun 29, 1978 under 1471-71; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:234214-B)

00026955	Kehr, C.C.; West, H.C.; Hamelink, J.L.; et al. (1978) The Toxicity of Benefin in Bluegills (?~Lepomis Macrochirus~?): A Twenty- Eight Day Continuous Flow-Through Study: Study No. 2057-77. (Unpublished study received Jun 29, 1978 under 1471-71; submit- ted by Elanco Products Co., Div. of Eli Lilly and Co., Indiana- polis, Ind.; CDL:234214-C)
00094769	Hamelink, J.L.; Kehr, C.C.; Adams, E.R.; et al. (1978) The Toxicity of Compound 94961 (El-161) to Bluegills in a 96 Hour Soil-water Static Test: Study No. 2111-78. Includes procedure no. 5801633 dated Sep 24, 1976. (Unpublished study received Feb 4, 1982 under 1471-122; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:070677-N)
00094770	Karnak, R.E.; Kehr, C.C.; Hamelink, T.L.; et al. (1980) The Toxic- ity of Compound 94961 (Ethalfluralin) to~Daphnia magna~in a 48- hour Static Study: Study No. 5044-78. Includes procedure no. 5801633 dated Sep 24, 1976. (Unpublished study received Feb 4, 1982 under 1471-122; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:070677-O)
00135183	Sleight, B. (1973) Acute Toxicity of 94961 to Bluegill ..., Rainbow Trout ..., and Goldfish (Carassius auratus). (Unpublished study received Aug 24, 1978 under 1471-EX-63; prepared by Bionomics, Inc., submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL:097325-F)
00145756	Hamelink, J. (1985) The Acute Toxicity of Benefin (EL-110, Compound 54521) to Rainbow Trout (Salmo gairdneri) in a Static-renewal Test System: Study F00185. Unpublished study prepared by Eli Lilly and Co. 38 p.
00160000	Hudson, R.; Tucker, R.; Haegele, M. (1984) Handbook of toxicity of pesticides to wildlife: Second edition. US Fish and Wildlife Service: Resource Publication 153. 91 p.
00160875	Seacat, J.; Cochrane, R. (1985) The Toxicity of Benefin (Compound 54521) to Bobwhite in a Fourteen-day Acute Oral Study: Study A01085. Unpublished study prepared by Lilly Research Laborato- ries. 27 p.
00234214	West, H.C.; Hamelink, J.L.; Broddle, W.D.; et al. (1978) The Toxic- ity of Compound 54521 (Benefin) in Bobwhites (?~Colinus Vir~?- ?~ginianus~?) Eight Day Dietary Study: Study No. 7008-77. (Un- published study received Jun 29, 1978 under 1471-71; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:234214-A) West, H.C.; Hamelink, J.L.; Broddle, W.D.; et al. (1978) The Toxic- ity of Compound 54521 (Benefin) in Mallards (?~Anas Platy~?- ?~rhynchos~?) Eight Day Dietary Study: Study No. 7011-77. (Un- published study received Jun 29, 1978 under 1471-71; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:234214-B) Kehr, C.C.; West, H.C.; Hamelink, J.L.; et al. (1978) The Toxicity of Benefin in Bluegills (?~Lepomis Macrochirus~?): A Twenty- Eight Day Continuous Flow-Through Study: Study No. 2057-77. (Unpublished study received Jun 29, 1978 under 1471-71; submit- ted by Elanco Products Co., Div. of Eli Lilly and Co., Indiana- polis, Ind.; CDL:234214-C)

00243848 Dean, W.P.; Myer, J.R.; Olafsson, A.; et al. (1980) Acute Oral Toxicity (LDI50^) Study in Rats (FIFRA): IRDC No. 446-005. (Un- published study received Dec 4, 1980 under 9198-56; prepared by International Research and Development Corp., submitted by Anderson Lawn Fertilizer, Div. of Free Flow Fertilizer Co., Maumee, Ohio; CDL:243848-A)
Dean, W.P.; Rajasekaran, D.; Myer, J.R.; et al. (1980) Acute Dermal Toxicity (LDI50^) Study in Rabbits (FIFRA): IRDC No. 446-003. (Unpublished study received Dec 4, 1980 under 9198-56; prepared by International Research and Development Corp., submitted by Anderson Lawn Fertilizer, Div. of Free Flow Fertilizer Co., Maumee, Ohio; CDL:243848-B)

00243848	Ralston Purina Company (1980) Turf Care Balan Concentrate-25: RT Lab No. 584711. (Compilation; unpublished study received Oct 28, 1980 under 9198-56; submitted by Anderson Lawn Fertil- izer, Div. of Free Flow Fertilizer Co., Maumee, Ohio; CDL: 243848-C)
00245611	Koenig, G.R.; Ansley, A.D.; Gomez, S.R.; et al. (1981) The Acute Oral, Dermal, Ocular and Inhalation Toxicity Testing of Balan EC, an Emulsifiable Concentrate Formulation (AT-0270) Containing Benefin, Lot X-29293: Study Nos. R-O-287-79; R-O-288-79; B-D-84- 79; B-E-85-79; R-H-46-79. (Unpublished study received Jul 22, 1981 under 1471-55; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:245611-A)
00249185	Ansley, A.; Koenig, G.; Arthur, B.; et al. (1982) The Acute Oral, Dermal, and Ocular Toxicity Testing of Balan Dry Flowable, a Granular Formulation (FN-3045) Containing Benefin: Studies R-0- 21-82; B-D-25-82; B-E-28-82. (Unpublished study received Dec 16, 1982 under 1471-138; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL:249185-B) Decker, O. (1982) Benefin Residues in Peanuts and Lettuce following Application of Balan 60 DF for Weed Control: I-ODD-82-08. (Un- published study received Dec 16, 1982 under 1471-138; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL:249185-A)
00249554	Ansley, A.; Quarles, J.; Gomez, S. (1982) The Acute Oral, Dermal, Ocular and Inhalation Toxicity Testing of Balan LC, a Liquid Concentrate Formulation (FN-5014) Containing 1.5 Lbs/Gal Com- pound 54521 (Benefin): Studies R-0-133-82, B-D-91-82, B-E-93-82, and R-H-56-82. (Unpublished study received Feb 17, 1983 under 1471-114; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL:249554-A) MRID 125865
00251206	Negilski, Q.; Quarles, J.; Gomez, S.; et al. (1983) The Acute Oral, Dermal, Ocular and Inhalation Toxicity of an Aqueous Suspension Formulation (FN-7035) Containing Benefin at a Concentration of 1.5 Pounds per Gallon: Studies R-O-101-83, B-D-92-83, B-E-99-83 and R-H-53-83. Final rept. (Unpublished study received Sep 9, 1983 under 10404-46; prepared by Lilly Research Laboratories, submitted by Lakeshore Equipment & Supply Co., Elyria, OH; CDL: CDL:251206-A)
00257099	Negilski, D.; Bridge, T.; Markey, T. (1985) The Acute Oral, Dermal, Ocular, and Inhalation Toxicity Assessment of a Granular Formu- lation (FN-9023) Containing Benefin at a Concentration of 2.0% on Fertilizer. Unpublished study prepared by Eli Lilly & Co. 37 p.
00257843	Saunders, D. (1985) Hydrolysis of the Herbicide Benefin in Aqueous Buffer Solution: EWD8447. Unpublished study prepared by Lilly Research Labs. 7 p. Berard, D. (1985) Dissipation of [Carbon-14] Benefin in Soils Maintained under Aerobic Conditions: ABC-0289. Unpublished study prepared by Lilly Research Labs. 26 p. Berard, D. (1985) Dissipation of [Carbon-14] Oryzalin in Soils Maintained under Aerobic Conditions: ABC-0290. Unpublished study prepared by Lilly Research Labs. 28 p.
00257844	Hamelink, J. (1985) The Acute Toxicity of Benefin (EL-110, Compound 54521) to Rainbow Trout (Salmo gairdneri) in a Static-renewal Test System: Study F00185. Unpublished study prepared by Eli Lilly and Co. 38 p. Francis, P.; Grothe, D. (1985) The Acute Toxicity of Benefin (El- 110, Compound 54521) to Daphnia magna in a Static-renewal Test System: Study C00185. Unpublished study prepared by Eli Lilly and Co. 37 p.
00257847	Sabol, E. (1985) Rat Acute Inhalation Toxicity [of Benefin]: Pro- ject No. 3606-85. Unpublished study prepared by Stillmeadow, Inc. 15 p.

00249554	Ansley, A.; Quarles, J.; Gomez, S. (1982) The Acute Oral, Dermal, Ocular and Inhalation Toxicity Testing of Balan LC, a Liquid Concentrate Formulation (FN-5014) Containing 1.5 Lbs/Gal Com- pound 54521 (Benefin): Studies R-0-133-82, B-D-91-82, B-E-93-82, and R-H-56-82. (Unpublished study received Feb 17, 1983 under 1471-114; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL:249554-A) MRID 125865
00415757	Miles Inc. (1990) Submission of Data To Support Registration of Cutter Insect Repellent - Tick Repellent - Formula MMII: Product Chemistry and Toxicology Studies. Transmittal of 3 studies. 41575701 Spagnoli, J. (1990) Product Chemistry for Cutter Insect Repellent-- Tick Repellent Foprmula MMII. Unpublished study prepared by Miles Inc. 18 p. Kowalski, R.; Hartangel, R. (1990) Ocular Irritation of Cutter Tick Repellent Aerosol CTR-002 in the Rabbit: Lab Project Number: MTD0164. Unpublished study prepared by Miles Inc. 23 p. Kowalski, R.; Hartnagel, R. (1990) Dermal Irritation of Cutter Tick Repellent Concentrate CTR-002 in the Rabbit: Lab Project Number: MTD0146. Unpublished study prepared by Miles Inc. 20 p.
05008271	Macek, K.J.; Lindberg, M.A.; Sauter, S.; Buxton, K.S.; Costa, P.A. (1976) Toxicity of Four Pesticides to Water Fleas and Fathead Minnows. Duluth, Minn.: U.S. Environmental Protection Agency, Environmental Research Laboratory. (EPA report no. EPA-600/3-76-099; available from: NTIS, Springfield, VA; PB-262 912)
40278401	Magnussen, J.; Rainey, D. (1987) Laboratory Studies of [Carbon 14] Benefin Accumulation in Fish: Laboratory Project Identification ABC-0362, ABC-0365. Unpublished study prepared by Lilly Research Laboratories. 53 p.
40094602	Johnson, W.; Finley, M. (1980) Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates: Resource Publi- cation 137. US Fish and Wildlife Service, Washington, D.C. 106 p.
40098001	Mayer, F.; Ellersieck, M. (1986) Manual of Acute Toxicity: Inter- pretation and Data Base for 410 Chemicals and 66 Species of Freshwater Animals. US Fish & Wildlife Service, Resource Pub- lication 160. 579 p.
41386202	Adams, E.; Cocke, P. and Gunnoe, M. (1990) The Toxicity of Triflu- ralin to Rainbow Trout (Salmo gairdneri) in a 48-Day Early Life- stage Study: Lab Project Number: FO2489. Unpublished study pre- pared by Lilly Research Laboratories. 86 p.
41613801	Cocke, P.; Koenig, G. (1990) The Acute Toxicity of Benefin to Blue- gill (Lepomis macrochirus) in a Static-Renewal Test System: Lab Project Number: F00990. Unpublished study prepared by Lilly Research Laboratories. 41 p.
41613802	Sousa, J. (1990) Benefin--Acute Toxicity to Sheepshead Minnow (Cyprinodon variegatus) Under Flow-through Conditions: Lab Pro- ject Number: 90-08-3416; 1982.1289.6104.505. Unpublished study by Springborn Laboratories, Inc. 60 p.
41613803	Dionne, E. (1990) Benefin--Acute Toxicity to Eastern Oysters (Cras- sstrea virginica) Under Flow-through Conditions: Lab Project Nu- mber: 90-07-3355; 1982.1289.6103.504. Unpublished study prepar- ed by Springborn Laboratories, Inc. 55 p.
41613804	Sousa, J. (1990) Benefin-Acute Toxicity to Mysid Shrimp (Mysidopsis bahia) Under Flow-through Conditions: Lab Project Number: 90-06- -3343; 1982.1289.6102.515. Unpublished study prepared by Spring born Laboratories, Inc. 55 p.

41613805	Cocke, P.; Gunnoe, M.; Koenig, G. (1990) The Toxicity of Benefin to Rainbow Trout (Salmo gairdneri) in a 49-Day Early Life-Stage Study: Lab Project Number: F00690. Unpublished study prepared by Lilly Research Laboratories. 88 p.
41613806	Mohr, R.; Cocke, P.; Koenig, G. (1990) The Chronic Toxicity of Benefin to Daphnia magna in a Flow-through Life-Cycle Test: Lab Project Number: C01090. Unpublished study prepared by Lilly Research Laboratories. 67 p.
41613808	Waldrep, T. (1989) Influence of Benefin on the Germination of Seeds of Ten Crop Plants: Tier I: Lab Project Number: 61989010. Unpublished study prepared by DowElanco. 13 p.
41613809	Cocke, P.; Koenig, G. (1990) Toxicity of Benefin to a Freshwater Green Alga (Selenastrum capricornutum) in a Static Test System: Lab Project Number: J00790. Unpublished study prepared by Lilly Research Laboratories. 43 p.
41613812	Hoxter, K.; Jaber, M. (1990) The Acute Contact Toxicity of Benefin to the Honey Bee: Lab Project Number: 151-115. Unpublished study prepared by Wildlife International Ltd. 30 p.
41613904	Sousa, J. (1990) Ethalfluralin--Acute Toxicity to Sheepshead Min- now (Cyprinodon variegatus) under Flow-through Conditions: Lab Project Number: SLI 90-7-3404: 1982. 1289. 6108. 505. Unpub- lished study prepared by Springborn Labs, Inc. 56 p.
41613905	Dionne, E. (1990) Ethalfluralin--Acute Toxicity to Eastern Oysters under Flow-through Conditions: Lab Project Number: SLI 90-07-338 1: 1982. 1289. 6107. 504. Unpublished study prepared by Spring born Labs, Inc. 54 p.
41613906	Sousa, J. (1990) Ethalfluralin--Acute Toxicity to Mysid Shrimp (Mysidopsis bahia) under Flow-through Conditions: Lab Project Number: SLI 90-7-3405: 1982. 1289. 6106. 515. Unpublished study prepared by Springborn Labs, Inc. 56 p.
41994901	Murray, A.; Meyerhoff, R.; Adams, E. (1991) The Toxicity of Ethal- fluralin to Rainbow Trout (Salmo gairdneri) in a 50-Day Early Life-Stage Study: Lab Project Number: F02690. Unpublished study prepared by Lilly Research Labs. 108 p.
42145501	Murray, A.; Smith, J.; Grothe, D. (1991) The Toxicity of Benefin to Mallards in a One-Generation Reproduction Study: Lab Project Number: A01090. Unpublished study prepared by Lilly Research Labs. 437 p.
42145502	Murray, A.; Seacat, J.; Grothe, D. (1991) The Toxicity of Benefin to Bobwhite in a One-Generation Reproduction Study: Lab Project Number: A00690. Unpublished study prepared by Lilly Research Labs. 470 p.
42176401	Murray, A.; Grothe, D.; Adams, E. (1992) The Acute Toxicity of Sonalan (FN 0802), a Formulation Containing Ethalfluralin (EL-161, Compound 094961), to Bluegill (Lepomis macrochirus) in a Static Renewal Test System: Lab Project Number: FO2391. Unpublished study prepared by Lilly Research Labs. 46 p.
42176402	Grothe, D.; Adams, E. (1992) The Acute Toxicity of Sonalan EC (FN 0802), a Formulation Containing Ethalfluralin (EL-161, Compound 094961), to Daphnia magna in a Static-Renewal Test System: Lab Project Number: CO1191. Unpublished study prepared by Lilly Research Labs. 37 p.

42390801	Brock, D. (1992) The Acute Toxicity of Balan EC (FN 0270) a Formulation Containing Benefin (EL-110, Compound 054521), to Bluegill (Lepomis macrochirus) in a Static Renewal Test System: Lab Project Number: F00692. Unpublished study prepared by Lilly Research Labs. 35 p.
42390802	Newstead, J.; Brock, D. (1992) The Acute Toxicity of Balan EC (FN 0270) a Formulation Containing Benefin (EL-110, Compound 054521), to Daphnia magna in a Static Renewal Test System: Lab Project Number: C01692. Unpublished study prepared by Lilly Research Labs. 36 p.
42419201	Brock, D. (1992) The Acute Toxicity of Balan EC (FN 0270), A Formulation Containing Benefin (EL-110, Compound 054521), to Rainbow Trout (Oncorhynchus mykiss) in a Static-Renewal Test System: Lab Project Number: F01892. Unpublished study prepared by Lilly Research Labs. 37 p.
42449901	Parrish, P.; Dyer, E.; Enos, J.; et al. (1978) Chronic Toxicity of Chlordane, Trifluralin, and Pentachlorophenol to Sheepshead Minnows (Cyprinodon variegatus): Lab Project Number: EPA-600/3-78-010. Unpublished study prepared by EG&G Bionomics 69 p.
42785301	Decker, O. (1987) Vapor Pressure of Benefin: Lab Project Number: ODD8720. Unpublished study prepared by Lilly Research Labs. 13 p.
42449902	Liu, D.; Lee, J. (1975) Toxicity of Selected Pesticides to the Bay Mussel (Mytilus edulis): Lab Project Number: EPA-660/3-75-016. Unpublished study prepared by Stanford Research Institute. 114 p.
42930101	Milazzo, D.; Servinski, M.; Kirk, H.; et al. (1993) Ethalfluralin: Evaluation of the Chronic Toxicity to the Daphnid, Daphnia magna Straus: Lab Project Number: 0233-3655: DECO-ES-2666. Unpublished study prepared by Dow Chemical Co. 49 p.

Residue Chemistry MRID Referneces

00024254	Eli Lilly and Company (1966) Determination of Benefin Residues in Agricultural Crops. Method 5801230 dated Mar 12, 1965. (Unpublished study received Feb 16, 1966 under 1471-55; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092800-I)
00024258	Eli Lilly and Company (1965) [Determination of Benefin Residues in Agricultural Crops]. Method # 5800820 dated Mar 17, 1964; method # 5801110 dated Oct 15, 1964; method # 5801230 dated Mar 12, 1965. (Unpublished study received Jul 16, 1965 under 1471-55;CDL:006278-D)
00024496	Johnson, W.S.; Macy, T.; Bewley, G. (1974) Determination of Benefin in Agricultural Crops and Soil. Undated method no. 5801620. (Unpublished study received Feb 13, 1975 under 464-322; prepared by Eli Lilly and Co., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:028471-F)
00124776	Decker, O. (1982) Benefin Residues in Peanuts and Lettuce following Application of Balan 60 DF for Weed Control: I-ODD-82-08. (Unpublished study received Dec 16, 1982 under 1471-138; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL:249185-A)

42128201	Berard, D. (1991) Nature of Carbon 14-Benefin Residues in Bovine Tissues and Milk: Lab Project Number: MET91002. Unpublished study prepared by DowElanco North American Environmental Chemistry Lab. 68 p.
42204801	Dalidowicz, J. (1991) Carbon 14-Benefin Chicken Tissue and Egg Residue Study: Lab Project Number: ABC0448. Unpublished study prepared by Lilly Research Labs. 41 p.
42338501	Rainey, D. (1992) Benefin [carbon 14] Nature of Residue Studyin Lettuce: Lab Project Number: MET 91004. Unpublished study prepared by DowElanco. 37 p.
42370101	Rainey, D. (1992) Carbon 14 Benefin Nature of Residue Study in Alfalfa: Lab Project Number: MET 91005. Unpublished study prepared by DowElanco. 39 p.
42409801	Rainey, D. (1992) Nature of Residue in Peanuts Treated with [carbon 14] Benefin: Lab Project Number: ABC 0456. Unpublished study prepared by DowElanco. 52 p.
42854601	Rainey, D. (1993) Response to EPA Review of Benefin Nature of Residue Study in Poultry: Lab Project Number: DPR072093. Unpublished study prepared by DowElanco. 13 p.
43039901	Rainey, D. (1992) (Carbon-14) Benefin Nature of Residue Study in Lettuce: Lab Project Number: MET91004: MET91004R. Unpublished study prepared by N. American Environmental Chemistry Laboratory, DowElanco. 33 p.
43064801	Rainey, D. (1992) (Carbon-14) Benefin Nature of Residue Study in Alfalfa: Lab Project Number: MET91005: MET91005R. Unpublished study prepared by North American Environmental Chemistry Lab., DowElanco. 43 p.
43624501	Rainey, D. (1995) (Carbon 14) Benefin: Nature of Residue Study in Lettuce: (Supplement): Lab Project Number: MET91004: MET91004R2. Unpublished study prepared by DowElanco. 31 p.
43831901	Singer, G. (1995) Magnitude of the Residue of Benefin in Alfalfa Raw Agricultural Commodities Following Ground Application: Final Report: Lab Project Number: AA940005:94-0047: AA940005.CA2. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs, Inc. 277 p.
43831902	Singer, G. (1995) Magnitude of the Residue of Benefin in Lettuce Following Ground Application: Final Report: Lab Project Number: 94-011: AA940004: AA940004.AZ. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs, Inc. 244 p.
44019801	Singer, G. (1996) Confined Accumulation Study on Rotational Crops with (carbon 14)-Benefin: Final Report: Lab Project Number: AA930005: SC980240: XBL 94121. Unpublished study prepared by American Agricultural Services, Inc.; Battelle Labs; and XenoBiotic Labs, Inc. 443 p.

Appendix E. Generic Data Call-In

Appendix E. GENERIC DATA CALL-IN

The Generic Data Call-In will be posted at a later date. See Chapter V of the Benfluralin RED for a list of studies required.

Appendix F. Product Specific Data Call-In

Appendix F. PRODUCT SPECIFIC DATA CALL-IN

A Product Specific Data Call-In will be posted at a later date.

Appendix G. EPA's Batching of Benfluralin Products for Meeting Acute Toxicity Data Requirements for Reregistration

Appendix G. EPA'S BATCHING OF BENFLURALIN PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

2. 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 **BENFLURALIN** as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

One hundred twenty three products were found which contain **Benfluralin** as the active ingredient. These products have been placed into fifteen batches and a "No Batch" category in accordance with the active and inert ingredients and type of formulation. Furthermore, the following bridging strategies are deemed acceptable for this chemical:

- Batch 11: testing should be conducted with EPA Reg. No. 52287-12.
- Batch 12: testing should be conducted with EPA Reg. No. 62719-280.

- Batch 14: EPA Reg. Nos. 70506-45 & 56 may not cite data generated with EPA Reg. No. 70506-49
- Batch 15: Since these products have already undergone reregistration with the Trifluralin RED that data will be acceptable to cite to satisfy this RED. However, any new products in this batch should conduct an eye study using the highest levels of nitrogen in the fertilizer used by the registrant.
- No Batch: Each product in this Batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch 1	EPA Reg. No.	% Active Ingredient
	62719-100	96.6
	68156-1	96.6

Batch 2	EPA Reg. No.	% Active Ingredient
	34704-746	60.0
	62719-127	60.0

Batch 3	EPA Reg. No.	% Active Ingredient
	228-158	10.0
	8660-107	10.0

Batch 4	EPA Reg. No.	% Active Ingredient
	961-268	2.5
	8660-8	2.3
	34704-101	2.5
	62719-96	2.5

Batch 5	EPA Reg. No.	% Active Ingredient
	228-174	2.5
	9198-83	2.5
	10404-36	2.5
	32802-7	2.5

Batch 6	EPA Reg. No.	% Active Ingredient
	7401-298	2.5
	8660-130	2.5

Batch 7	EPA Reg. No.	% Active Ingredient
	7401-46	2.5
	8378-35	2.5
	8660-37	2.5
	8660-96	2.5
	8660-243	2.0

Batch 8	EPA Reg. No.	% Active Ingredient
	228-172	1.175
	961-284	1.720
	961-321	1.220
	8378-10	1.500
	8660-6	1.150
	8660-27	1.720
	8660-39	1.200
	8660-42	1.280
	8660-74	1.300
	8660-112	1.130
	8660-113	1.650
	9198-66	1.280
	32802-10	1.175
	32802-11	1.300
	34704-751	1.200
	62719-147	1.150
	62719-148	1.250

Batch 9	EPA Reg. No.	% Active Ingredient
	228-159	0.92
	961-228	0.86
	8378-11	0.92
	8660-26	0.55
	8660-30	0.78
	8660-38	0.86
	8660-40	1.02
	8660-99	0.78
	8660-186	0.96
	8660-192	0.43
	8660-235	0.70
	8660-236	0.87
	8660-237	0.62
	8660-238	1.15
	8780-57	1.15
	9198-30	0.92
	32802-8	0.92
	32802-9	1.02
	34704-750	0.29
	38167-30	1.00
	62719-146	0.92

Batch 10	EPA Reg. No.	% Active Ingredient
	961-390	Benfluralin: 0.82 Clopyralid: 0.18 Triclopyr: 0.50 Trifluralin: 0.43

Batch 10	EPA Reg. No.	% Active Ingredient
	961-391	Benfluralin: 0.82 Clopyralid: 0.18 Triclopyr: 0.50 Trifluralin: 0.43

Batch 11	EPA Reg. No.	% Active Ingredient
	52287-10	Benfluralin: 0.375 Oxadiazon: 0.500 Trifluralin: 0.375
	52287-11	Benfluralin: 0.250 Oxadiazon: 0.750 Trifluralin: 0.250
	52287-12	Benfluralin: 0.250 Oxadiazon: 1.000 Trifluralin: 0.250

Batch 12	EPA Reg. No.	% Active Ingredient
	62719-192	Benfluralin: 0.53 Isoxaben: 0.29 Trifluralin: 0.27
	62719-280	Benfluralin: 0.76 Isoxaben: 0.38 Trifluralin: 0.39

Batch 13	EPA Reg. No.	% Active Ingredient
	7401-413	Benfluralin: 1.00 Oryzalin: 1.00
	7401-415	Benfluralin: 1.00 Oryzalin: 1.00
	8660-16	Benfluralin: 0.86 Oryzalin: 0.86
	8660-139	Benfluralin: 0.86 Oryzalin: 0.86
	8660-146	Benfluralin: 0.86 Oryzalin: 0.86
	32802-30	Benfluralin: 0.85 Oryzalin: 0.85

Batch 14	EPA Reg. No.	% Active Ingredient
	70506-45	Benfluralin: 1.000 Oryzalin: 1.000
	70506-49	Benfluralin: 0.575 Oryzalin: 0.575
	70506-56	Benfluralin: 1.000 Oryzalin: 1.000

Batch 15	EPA Reg. No.	% Active Ingredient
	228-207	Benfluralin: 0.58 Trifluralin: 0.29
	228-208	Benfluralin: 0.77 Trifluralin: 0.38
	228-209	Benfluralin: 1.00 Trifluralin: 0.50
	228-254	Benfluralin: 0.59 Trifluralin: 0.29
	228-255	Benfluralin: 0.74 Trifluralin: 0.37
	228-256	Benfluralin: 0.89 Trifluralin: 0.44
	228-257	Benfluralin: 0.45 Trifluralin: 0.22
	961-346	Benfluralin: 0.77 Trifluralin: 0.39
	961-348	Benfluralin: 1.03 Trifluralin: 0.52
	8378-17	Benfluralin: 0.76 Trifluralin: 0.38
	8378-18	Benfluralin: 0.84 Trifluralin: 0.43
	8378-19	Benfluralin: 1.00 Trifluralin: 0.50
	8378-20	Benfluralin: 0.62 Trifluralin: 0.30
	8378-37	Benfluralin: 0.93 Trifluralin: 0.49

Batch 15	EPA Reg. No.	% Active Ingredient
	8660-19	Benfluralin: 0.85 Trifluralin: 0.43
	8660-143	Benfluralin: 0.90 Trifluralin: 0.45
	8660-149	Benfluralin: 0.90 Trifluralin: 0.45
	8660-151	Benfluralin: 0.76 Trifluralin: 0.38
	8660-207	Benfluralin: 0.77 Trifluralin: 0.38
	9198-79	Benfluralin: 0.77 Trifluralin: 0.38
	9198-91	Benfluralin: 0.38 Trifluralin: 0.19
	9198-94	Benfluralin: 0.62 Trifluralin: 0.30
	9198-101	Benfluralin: 0.59 Trifluralin: 0.28
	9198-130	Benfluralin: 1.00 Trifluralin: 0.50
	10404-53	Benfluralin: 0.67 Trifluralin: 0.33
	10404-56	Benfluralin: 0.77 Trifluralin: 0.38
	10404-57	Benfluralin: 0.84 Trifluralin: 0.41
	32802-24	Benfluralin: 0.77 Trifluralin: 0.38
	32802-33	Benfluralin: 1.00 Trifluralin: 0.50
	32802-35	Benfluralin: 0.58 Trifluralin: 0.29
	32802-40	Benfluralin: 0.39 Trifluralin: 0.19
	62719-137	Benfluralin: 1.33 Trifluralin: 0.67

Batch 15	EPA Reg. No.	% Active Ingredient
	62719-150	Benfluralin: 0.76 Trifluralin: 0.39
	62719-151	Benfluralin: 0.61 Trifluralin: 0.31
	62719-152	Benfluralin: 0.82 Trifluralin: 0.43
	62719-289	Benfluralin: 0.50 Trifluralin: 0.50
	62719-290	Benfluralin: 0.83 Trifluralin: 0.42
	62719-327	Benfluralin: 0.82 Trifluralin: 0.43
	62719-331	Benfluralin: 0.76 Trifluralin: 0.39
	62719-332	Benfluralin: 0.61 Trifluralin: 0.31

No Batch	EPA Reg. No.	% Active Ingredient
	829-211	Benfluralin: 2.0
	5905-496	Benfluralin: 19.1
	8660-104	Benfluralin: 1.15 2,4-D: 1.50 Benzoic acid: 0.28
	8660-225	Benfluralin: 0.725
	48234-1	Benfluralin: 0.50 Oxadiazon: 1.00
	62719-117	Benfluralin: 16.30
	62719-317	Benfluralin: 64.30 Trifluralin: 32.20
	62719-318	Benfluralin: 48.20 Trifluralin: 48.20

Appendix H. List of Registrants Sent this Data Call-In

Appendix H. LIST OF REGISTRANTS SENT THIS DATA CALL-IN.

A list of registrants sent this data call-in will be posted at a later date.

Appendix I. List of Available Related Documents and Electronically Available Forms

Appendix I. LIST OF AVAILABLE RELATED DOCUMENTS AND ELECTRONICALLY AVAILABLE FORMS

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet:
at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product_	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing_	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf

8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).

   a. Registration Division Personnel Contact List
   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
   c. Antimicrobials Division Organizational Structure/Contact List
   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' website.

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

   The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: ace.orst.edu/info/nptn.

   The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

   1. Date of receipt;
   2. EPA identifying number; and
   3. Product Manager assignment.

   Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

   To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may be 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 respective Chemical Status Sheet.

1. Health Effects Division and Environmental Fate and Effects Division Science Chapters, which include the complete risk assessments and supporting documents.
2. Detailed Label Usage Information System (LUIS) Report.