United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

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Reregistration Eligibility Decision (RED)

OXYFLUORFEN

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F02-013 October, 2002

EPA R.E.D. FACTS

Oxyfluorfen

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet the safety standard of the FQPA and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 2670, oxyfluorfen.

Use Profile

Oxyfluorfen is a diphenyl-ether herbicide used for broad spectrum pre- and post-emergent control of annual broadleaf and grassy weeds in a variety of tree fruit, nut, vine, and field crops. The largest agricultural markets in terms of total pounds active ingedient are wine grapes and almonds. There are also non-agricultural ornamental and forestry uses. Oxyfluorfen is also used for weed control in landscapes, patios, driveways, and similar areas in residential sites.

Regulatory History

Oxyfluorfen was first registered in the United States in 1979 to control pre-emergent and post-emergent broadleaf and grassy weeds in a variety of field, fruit, and vegetable crops, ornamentals, as well as non-crop sites. It is manufactured by Dow AgroSciences and Makhteshim-Agan under the trade names Goal and Galigan. Data call-ins were issued in 1991, 1993, and 1995. In January 2002, the risk assessments were made publicly available for comment and a close-out conference call was conducted on July 25, 2002, to discuss the risk management decisions and resultant changes to the oxyfluorfen labels.

Human Health Assessment

Toxicity

Oxyfluorfen is of low acute oral, dermal, and inhalation toxicity. The primary toxic effects are alterations in blood parameters (anemia) and in the liver. Oxyfluorfen is classified as a possible human carcinogen based on combined hepatocellular adenomas/carcinomas in the mouse carcinogenicity study. A cancer potency factor (Q1*) was used to estimate human risk. The FQPA Safety Factor for protection of infants and children was reduced to 1X for all population subgroups as there was no increased susceptibility in animals due to pre- or post-natal exposure to oxyfluorfen.

Dietary Exposure

No adverse effects reflecting a single dose were identified in toxicological studies; therefore, no acute endpoint was selected and an acute dietary risk assessment was not conducted. EPA's dietary risk analysis for oxyfluorfen evaluated chronic (non-cancer) and cancer risk. For these chronic food risk assessments, anticipated residues were calculated using either USDA Pesticide Data Program (PDP) monitoring data or field trial data. Both data sets are consistent in that they show all non-detectable residues.

Based on this analysis, the percentage of cPAD utilized is expected to be less than 1 percent for the U.S. population and all subpopulations. Therefore, the chronic (non-cancer) dietary risk estimate from food alone is not of concern. Cancer risk from food is calculated by using a linear low-dose risk model ("Q_1*") to determine the lifetime cancer risk estimate. The Agency generally considers risks greater than 1×10^{-6} (1 in 1 million) to exceed its level of concern for cancer dietary exposure. Using the Q_1* of 7.32×10^{-2} results in a maximum estimated lifetime cancer risk to the U.S. general population of 3.8×10^{-7}. Therefore, the cancer risk from food alone is also not of concern.

People may be exposed to residues of oxyfluorfen through the diet. Tolerances or maximum residue limits have been established for 33 fruits, vegetables and nut trees as well as meat commodities (please see 40 CFR 180.381). EPA has reassessed the oxyfluorfen tolerances and found that the majority are acceptable. New tolerances must be proposed/established for cotton gin byproducts, soybean forage, soybean hay, and grass forage, grass hay, and grass seed screenings.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to oxyfluorfen during and after normal use of liquid and granular formulations in agricultural and other settings. Oxyfluorfen is used in the residential environment by homeowners to kill weeds on patios, driveways and similar surfaces. Oxyfluorfen homeowner products are intended solely for spot treatment; they are not used for broadcast treatment of lawns because they kill grass.

FQPA Considerations

Chronic (non-cancer) Aggregate Risk - This assessment addresses exposure to oxyfluorfen residues in food and water only, as there are no chronic residential scenarios identified. Comparison of the chronic DWLOCs with the environmental concentrations of oxyfluorfen shows that estimated surface and groundwater concentrations are substantially less than the DWLOCs for all populations. Consequently, the Agency concludes that residues of oxyfluorfen in food and drinking water do not result in a chronic aggregate risk of concern.

Short-term Aggregate Risk - Short-term DWLOCs were calculated based upon average food residues, and the residential handler exposure which resulted in the greatest risk (spot treatment of weeds using a RTU trigger pump sprayer). DWLOC calculations are for adults only since the residential exposure is to applicators. Surface and ground water concentrations estimated using conservative modeling are less than the short-term DWLOCs for oxyfluorfen. Consequently, there are no short-term aggregate risk concerns from food, drinking water and residential exposures.

Cancer Aggregate Risk - The chronic food cancer risk estimate of 3.8×10^{-7}, combined with the highest residential cancer risk estimate of 8.7×10^{-7}, results in a food + residential cancer risk of 1.3×10^{-6}. Since the Agency's level of concern is 1.0×10^{-6}, cancer risk slightly exceeds EPA's level of concern when considering both food and residential exposures. However, since PDP monitoring and field trial data showed all residues on food were non-detects, the food risk estimate is considered upper-bound. Screening-level surface water modeling indicates that there may be a concern for oxyfluorfen in drinking water, but this water modeling is also considered upper-bound.

Occupational and Residential Risk

Cancer risk to workers is of greater concern than non-cancer risk. Occupational cancer risks, when calculated without personal protective equipment or engineering controls, can range up to 1×10^{-3}. With the protection specified on several current labels, most scenarios result in cancer risks in the 10^{-5} range.

The residential assessment for oxyfluorfen only addresses the applicator, because negligible postapplication exposure is anticipated from spot treatment of weeds. None of the residential applicator scenarios are of concern because the short-term MOEs are greater than 100 and the cancer risks are less than 1.0×10^{-6}.

Environmental Assessment

Oxyfluorfen has the potential to affect terrestrial plants and aquatic ecological systems at all levels, as it is toxic to plants, invertebrates, and fish, and has been shown to drift from application sites to nearby areas. Birds and mammals may also experience subchronic and chronic effects from oxyfluorfen use.

Environmental Fate

Oxyfluorfen is persistent and relatively immobile in soil. The most likely route of dissipation is soil binding. Laboratory data suggest that once the soil-bound oxyfluorfen reaches deep or turbid surface water it will persist since it is stable to hydrolysis and since light penetration would be limited; however, it may degrade by photolysis in clear, shallow water. Oxyfluorfen can contaminate surface water through spray drift and runoff; however, it is unlikely to contaminate ground water because it is relatively immobile in the soil column; therefore, the likelihood of leaching is small. No degradates were identified, and therefore, only the parent, oxyfluorfen, is of toxicological concern for risk assessment.

Ecological Effects

For acute exposures, oxyfluorfen is practically non-toxic to birds, mammals, and bees, and the Agency has no risk concerns. However, subchronic and chronic risks to terrestrial birds and mammals do present a concern. These toxic effects may be manifested as reproductive, developmental, and hemolytic consequences. Assuming maximum residue values, the chronic level of concern is exceeded when oxyfluorfen is applied to crops at application rates greater than or equal to 0.25 lbs ai/acre/year for birds and greater than or equal to 2.0 lbs ai/acre for mammals. In addition, the potential of oxyfluorfen (as a light-dependent peroxidizing herbicide) to be more toxic in the presence of intense light may lead to the occurrence of more serious environmental effects that are not predicted by standard guideline toxicity tests. Oxyfluorfen is highly toxic to very highly toxic to fish and aquatic invertebrates. However, concentrations predicted by the Agency's surface water models from normal use are generally not high enough to cause an acute concern for fish. Chronic risk to fish and acute and chronic risk to aquatic invertebrates may occur from some uses of oxyfluorfen.

There are acute concerns for freshwater algal plants for all uses of oxyfluorfen. The risk to vascular aquatic plants cannot be assessed due to lack of data. Oxyfluorfen is expected and has been shown to negatively impact seedling emergence and vegetative vigor of terrestrial plants. Non-target terrestrial plants are exposed to oxyfluorfen as a result of spray drift and runoff and most incidents reported to the Agency are related to plants affected by spray drift. Acute levels of concern are exceeded for all uses of oxyfluorfen for terrestrial plants and semi-aquatic plants adjacent to treated areas.

Ecological Effects Risk Assessment

Generally, the Agency believes that oxyfluorfen presents the greatest risks to terrestrial plants and to aquatic organisms through spray drift of liquid formulations and runoff of dissolved and soil entrained oxyfluorfen.

Risk Mitigation

To lessen the risks of cancer from drinking water, occupational risks, and risks to wildlife posed by oxyfluorfen, EPA is requiring the following risk mitigation measures:

- Lower the maximum rate to 1.5 lbs ai/broadcast acre/season for food crops and 2 lbs ai/acre/season for conifer seedlings.
- For liquid formulations and granulars applied to field-grown ornamentals, registrants have agreed to lower this seasonal maximum rate to 4.5 lbs ai/A (1.5 lbs ai/A/application). For granulars applied to containerized ornamentals, the rate will be lowered to a seasonal maximum of 6 lbs ai/A (2 lbs ai/A/application).
- Label language will be added to require 25 foot, no-spray, vegetative buffer zones around surface water bodies such as rivers, lakes, streams, and ponds.
- To minimize oxyfluorfen drift, only use of a coarse, very coarse, or extremely coarse spray will be allowed according to the ASAE 572 definitions for standard nozzles, or a volume median diameter (VMD) of 385 microns or larger for spinning atomizer nozzles.
- The maximum application rate on residential products will be reduced to 3 lbs ai/A or less unless efficacy data support the need for higher rates.
- Closed mixing/loading systems to support applications to corn, cotton, soybeans, and aerial applications to fallow land.
- Enclosed cab for applications to corn, and closed cockpit aircraft for applications to fallow land.
- Double layer Personal Protective Equipment (PPE) for all other mixers, loaders, and applicators.

Additional Data Required

EPA is requiring the following additional generic studies for oxyfluorfen to confirm its regulatory assessments and conclusions: 21-day Dermal Toxicity Study in Rats; Crop Field Trials in Bananas and Cacao Beans; Estuarine/marine Fish Early-life Stage; Whole Sediment Invertebrate Freshwater Acute Toxicity; Whole Sediment Invertebrate Estuarine/marine Acute Toxicity; Seed Germination/Seedling Emergence; Vegetative Vigor; Aquatic Plant Growth; Dislodgeable Foliar Residue Study in Conifers; Fish Phototoxicity Study; and Edge of Field Water and Sediment Monitoring.

Product Labeling Changes Required

All oxyfluorfen end-use products must comply with EPA's current pesticide product labeling requirements. For a comprehensive list of labeling requirements, please see the oxyfluorfen RED document. The labeling requirements table is available as a separate document.

Regulatory Conclusion

The use of currently registered products containing oxyfluorfen in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

All products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for oxyfluorfen during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet are available on the Internet. See http://www.epa.gov/REDs.

Printed copies of the RED and fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the oxyfluorfen RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 1-800-553-6847, or 703-605-6000.

For more information about EPA's pesticide reregistration program, the oxyfluorfen RED, or reregistration of individual products containing oxyfluorfen, please contact the Special Review and Reregistration Division (7508C), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Information Center (NPIC). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. Their internet address is http://npic.orst.edu.

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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 preliminary risk assessment for the herbicide oxyfluorfen. The Agency has revised the human health and environmental effects risk assessments based on the comments received during the public comment period and additional data received from the registrant. Based on the EPA's revised risk assessments for oxyfluorfen, 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 oxyfluorfen. EPA is now publishing its reregistration eligibility, risk management, and tolerance reassessment decisions for the current uses of oxyfluorfen, and its associated human health and environmental risks. The Agency's decision on the individual chemical oxyfluorfen can be found in the attached document entitled, "Reregistration Eligibility Decision for Oxyfluorfen" which was approved on August 2, 2002.

A Notice of Availability for the Reregistration Eligibility Decision for Oxyfluorfen is being published in the *Federal Register*. To obtain copies of the RED document, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), USEPA, 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.

As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets and to engage the public in the reregistration and tolerance reassessment processes. During the public comment period, comments on the risk assessment were submitted by Dow AgroSciences, the technical registrant. EPA also received letters from approximately 65 growers, extension agents, and commodity organizations testifying to the importance of oxyfluorfen to their weed control programs for commodities such as forest seedlings, wine grapes, artichokes, raspberries, blackberries, strawberries, garbanzo beans, onions, garlic, and almonds. The Confederated Tribes of the Warm Springs Reservation of Oregon raised concern that the dietary risk assessment for oxyfluorfen is not protective, because estimated fish consumption was based on an amount representative of the general public rather than subpopulations which may consume higher levels of fish. A close-out conference call with interested stakeholders was conducted on July 25, 2002 to discuss the risk management decisions and resultant changes to the oxyfluorfen labels.

Please note that the oxyfluorfen risk assessment and the attached RED concern only this particular pesticide. The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, 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." Oxyfluorfen is a diphenyl ether herbicide structurally related to lactofen, fomesafen and acifluorfen. At this time, the Agency has not made a decision as to whether oxyfluorfen shares a common mechanism of toxicity with these other diphenyl ethers or any other pesticide. A careful evaluation of all the available data is still needed, as well as peer review by the FIFRA Science Advisory Panel, before a formal decision is made. Therefore, for the purposes of this risk assessment, the Agency has assumed that oxyfluorfen does not share a common mechanism of toxicity with other pesticides. After a decision is made regarding common mechanism of toxicity, and if the Agency has determined that a cumulative assessment is necessary, the Agency will address any outstanding risk concerns at that time.

This document contains a generic and/or a product-specific Data Call-In(s) (DCI) that outline(s) further data requirements for this chemical. Note that registrants of oxyfluorfen must respond to DCIs issued by the Agency within 90 days of receipt of this letter. This RED also contains labeling requirements for oxyfluorfen products. End-use product labels must be revised by the manufacturer to adopt the changes set forth in Section IV 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.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by oxyfluorfen. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency’s action.

There will be a 60-day public comment period for this document, commencing on the day the Notice of Availability publishes in the Federal Register.

If you have questions on this document or the proposed label changes, please contact the Special Review and Reregistration Division representative, John Leahy (703) 305-6703. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Bonnie Adler at (703) 308-8523.

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

Reregistration Eligibility Decision
(RED)
for
Oxyfluorfen
Case No. 2490

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARC	Anticipated Residue Contribution
BCF	Bioconcentration Factor
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated to occur.
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization
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
GLC	Gas Liquid Chromatography
GLN	Guideline Number
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
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.
LEL	Lowest Effect Level
LOC	Level of Concern

LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
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
PRN	Pesticide Registration Notice
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
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product

TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

Executive Summary

EPA has completed its review of public comments on the preliminary risk assessments and is issuing its risk management decision for oxyfluorfen. The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and additional information received. After considering the risks identified in the revised risk assessment and comments and mitigation suggestions from interested parties, EPA developed its risk management decision for uses of oxyfluorfen that pose risks of concern. This decision is discussed fully in this document.

Oxyfluorfen is a broad spectrum pre- and postemergent herbicide used on a variety of tree and vine crops, selected annual and perennial crops, as well as fallow bed and non-crop uses (e.g. roadsides), to control annual broadleaf and grassy weeds. Residential homeowners may use oxyfluorfen products for spot treatment of weeds. It was first registered in 1979. Approximately 761,000 pounds of oxyfluorfen active ingredient are applied annually. Sites on which oxyfluorfen has the highest percent of crop treated include wine grapes, almonds, cotton, walnuts, and table grapes.

The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, 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." Oxyfluorfen is structurally related to other diphenyl ethers including lactofen, acifluorfen, and fomesafen. The Agency has not determined whether or not oxyfluorfen shares a common mechanism of toxicity with these pesticides or any other pesticide. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment. After a decision is made regarding common mechanism of toxicity, and if the Agency has determined that a cumulative assessment is necessary, the Agency will address any outstanding concerns at that time.

Overall Risk Summary

Acute risks were not evaluated for oxyfluorfen because adverse effects reflecting a single dose were not identified in toxicological studies at the highest dose tested. EPA's human health risk assessment for oxyfluorfen indicates that chronic food risk is not of concern (<1% of cPAD). Oxyfluorfen is classified in group C (possible human carcinogen) based on combined hepatocellular adenomas/carcinomas in the mouse carcinogenicity study. The cancer dietary risk from food alone is 3.8×10^{-7} for the general U.S. population, and is not a concern for the Agency ($< 1 \times 10^{-6}$). The drinking water risk estimates for chronic (non-cancer) exposures are below EPA's level of concern for ground or surface waters. However, cancer risk estimates from modeling for surface water sources of drinking water indicate a concern based on conservative assumptions for model inputs. Residential risks are below EPA's level of concern, however, there is a concern for aggregate risk when considering exposures from food, drinking water, and residential uses. There are cancer risk concerns for workers who mix, load, and apply oxyfluorfen to agricultural sites, as well as workers who re-enter treated sites. Finally,

EPA has identified risks of concern to plant and aquatic species and chronic concerns to birds and mammals.

To mitigate risks of concern posed by the uses of oxyfluorfen, EPA considered the comments and mitigation ideas from interested parties, and has decided on a number of label amendments to address the drinking water, aggregate, worker, and ecological concerns. Results of the risk assessments, and required label amendments to mitigate those risks, are presented in this RED.

Dietary Risk – Food

No adverse effects reflecting a single dose were identified in toxicological studies; therefore, no acute endpoint was selected and an acute dietary risk assessment was not conducted. EPA's dietary risk analysis for oxyfluorfen evaluated chronic (non-cancer) and cancer risk. For these chronic food risk assessments, anticipated residues were calculated using either USDA Pesticide Data Program (PDP) monitoring data or field trial data. Both data sets are consistent in that they show all non-detectable residues.

Based on this analysis, the percentage of cPAD utilized is expected to be less than 1 percent for the U.S. population and all subpopulations. Therefore, the chronic (non-cancer) dietary risk estimate from food alone is not of concern. Cancer risk from food is calculated by using a linear low-dose risk model ("Q_1*") to determine the lifetime cancer risk estimate. The Agency generally considers risks greater than 1×10^{-6} (1 in 1 million) to exceed its level of concern for cancer dietary exposure. Using the Q_1* of 7.32×10^{-2} results in a maximum estimated lifetime cancer risk to the U.S. general population of 3.8×10^{-7}. Therefore, the cancer risk from food alone is also not of concern.

Dietary Risk – Drinking Water

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. For oxyfluorfen, EPA considered chronic (lifetime) drinking water risk and used modeling to estimate those risks. To determine the maximum allowable contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a "drinking water level of comparison" (DWLOC) to determine whether modeled or monitoring estimated environmental concentration (EEC) levels exceed this level. EECs that are above the corresponding DWLOC exceed the Agency's level of concern.

Since the chronic EECs for surface water and groundwater are less than the lowest DWLOC, chronic non-cancer dietary risk from food and drinking water is not of concern. However, modeling does indicate a possible concern for cancer risk, as the EEC in surface water exceeds the cancer DWLOC. To address surface water concerns, the technical registrants have agreed to implement measures to reduce the potential for oxyfluorfen to reach surface water, including a reduction in maximum seasonal rates and implementation of vegetative buffers between treated areas and natural water bodies. Actual drinking water exposure to oxyfluorfen

from surface water sources is expected to be less than the DWLOCs and the registrants have also agreed to conduct an edge of field monitoring study to confirm that drinking water exposure will not exceed the level of concern.

Residential Risk

Oxyfluorfen is used in the residential environment by homeowners to kill weeds on patios, driveways and similar surfaces. Oxyfluorfen homeowner products are intended solely for spot treatment; they are not used for broadcast treatment of lawns because they kill grass. The residential assessment for oxyfluorfen only addresses the applicator, because negligible postapplication exposure is anticipated from spot treatment of weeds. None of the residential applicator scenarios are of concern because the short-term MOEs are greater than 100 and the cancer risks are less than 1.0×10^{-6}.

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). Generally, all risks from these exposures must have MOEs greater than 100 to not be of concern to the Agency.

Chronic (Non-cancer) Aggregate Risk. The chronic (non-cancer) aggregate risk assessment addresses exposure to oxyfluorfen residues in food and water only, as there are no chronic residential scenarios identified. As discussed previously, comparison of the chronic DWLOCs with the environmental concentrations of oxyfluorfen shows that estimated surface and groundwater concentrations are substantially less than the DWLOCs for all populations. Consequently, the Agency concludes that residues of oxyfluorfen in food and drinking water do not result in a chronic aggregate risk of concern.

Short-term Aggregate Risk. Short-term DWLOCs were calculated based upon average food residues, and the residential handler exposure which resulted in the greatest risk (spot treatment of weeds using a RTU trigger pump sprayer). DWLOC calculations are for adults only since the residential exposure is to applicators. Surface and ground water concentrations estimated using conservative modeling are less than the short-term DWLOCs for oxyfluorfen. Consequently, there is no short-term aggregate risk concerns from food, drinking water and residential exposures.

Cancer Aggregate Risk. The chronic food cancer risk estimate of 3.8×10^{-7}, combined with the highest residential cancer risk estimate of 8.7×10^{-7}, results in a food + residential cancer risk of 1.3×10^{-6}. Since the Agency's level of concern is 1.0×10^{-6}, cancer risk slightly exceeds EPA's level of concern when considering both food and residential exposures. However, since PDP monitoring and field trial data showed all residues on food were non-detects, the food risk estimate is considered upper-bound. Screening-level surface water modeling indicates that there

may be a concern for oxyfluorfen in drinking water, but this water modeling is also considered upper-bound.

Occupational Risk

Cancer risk to workers is of greater concern than non-cancer risk. Occupational cancer risks, when calculated without personal protective equipment or engineering controls, can range up to 1×10^{-3}. With the protection specified on several current labels, most scenarios result in cancer risks in the 10^{-5} range. EPA believes these risks can be mitigated to an acceptable level with the following label restrictions: (1) requiring additional personal protective equipment or engineering controls for certain scenarios, and (2) increasing restricted entry intervals for certain uses.

Ecological Risk

Ecological risks are of concern to the Agency. Based on toxicity studies submitted by the registrant, oxyfluorfen has the potential to result in adverse effects to birds, mammals, aquatic organisms and plants. To address these ecological risks, the registrants have agreed to decrease seasonal maximum rates for certain crops, add label statements prohibiting application of oxyfluorfen within 25 feet of aquatic areas, and require coarse droplet size for all spray applications. The registrants will also conduct additional ecological effects and environmental fate studies to better characterize exposure to non-target species.

Conclusions

The Agency is issuing this Reregistration Eligibility Document (RED) for oxyfluorfen, 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 oxyfluorfen. With the addition of the label restrictions and amendments detailed in this document, the Agency has determined that all currently registered uses of oxyfluorfen are eligible for reregistration.

The risk assessments for oxyfluorfen are based on the best scientific data currently available to the Agency and are adequate for regulatory decision making. Registrants have committed to provide additional data that may remove some of the uncertainties associated with exposures and risks posed by oxyfluorfen, including studies to define the cancer mechanism and efficacy studies to determine an appropriate rate for residential uses. If data are provided which enable EPA to refine the exposure or risk conclusions presented in this document, EPA will evaluate the risk mitigation measures identified above, and if appropriate, will amend this RED to reflect any new risk conclusions.

There is a 60-day public comment period for this document.

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. 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 the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment during reregistration. It also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA, which was August 3, 1996. FQPA also amends the FFDCA to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity.

Oxyfluorfen is a diphenyl ether herbicide structurally related to lactofen, fomesafen and acifluorfen. At this time, the Agency has not made a decision as to whether oxyfluorfen shares a common mechanism of toxicity with these other diphenyl ethers or any other pesticide. A careful evaluation of all the available data is still needed, as well as peer review by the FIFRA Science Advisory Panel, before a formal decision is made. Therefore, for the purposes of this risk assessment, the Agency has assumed that oxyfluorfen does not share a common mechanism of toxicity with other pesticides. After a decision is made regarding common mechanism of toxicity, and if the Agency has determined that a cumulative assessment is necessary, the Agency will address any outstanding risk concerns at that time.

The implementation of FQPA has required the Agency to revisit some of its existing policies relating to the determination and regulation of dietary risk, and has also raised a number of new issues for which policies need to be created. These issues were refined and developed through collaboration between the Agency and the Tolerance Reassessment Advisory Committee (TRAC), which was composed of representatives from industry, environmental groups, and other interested parties. The TRAC identified the following science policy issues it believed were key to the implementation of FQPA and tolerance reassessment:

- Applying the FQPA 10-fold safety factor
- Whether and how to use probabilistic analyses in dietary exposure assessments
- How to interpret "no detectable residues" in dietary exposure assessments
- Refining dietary (food) exposure estimates
- Refining dietary (drinking water) exposure estimates
- Assessing residential exposure

- Aggregating exposure from all non-occupational sources
- How to conduct a cumulative risk assessment for organophosphate or other pesticides with a common mechanism of toxicity
- Selection of appropriate toxicity endpoints for risk assessments of organophosphates
- Whether and how to use data derived from human studies

The process developed by the TRAC calls for EPA to provide one or more documents for public comment on each of the policy issues described above. Each of these issues is evolving and in a different stage of refinement. Some issue papers have already been published for comment in the Federal Register and others will be published shortly.

This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes required label changes based on the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list Data Call-In (DCI) information. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page www.epa.gov/pesticides, and in the Public Docket.

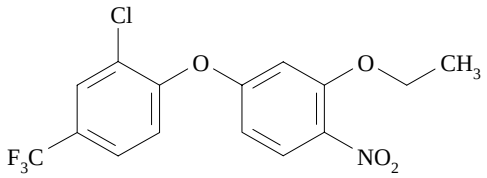
II. Chemical Overview

A. Regulatory History

Oxyfluorfen was first registered in the United States in 1979 to control pre-emergent and post-emergent broadleaf and grassy weeds in the culture of a variety of field, fruit, and vegetable crops, ornamentals, as well as non-crop sites. It is manufactured by Dow AgroSciences and Makhteshim-Agan under the trade names Goal and Galigan. Data call-ins were issued in 1991, 1993, and 1995.

In an effort to promote transparency of the reregistration process and public understanding of regulatory decisions, the Agency, in cooperation with the U.S. Department of Agriculture (USDA) modified the reregistration and tolerance reassessment process in 1998. This modified process provides opportunities for stakeholders to ask questions about and provide input to the risk assessment and risk mitigation strategies, via conference calls and other formats. Consistent with this process, the January 2002 risk assessments were made publicly available for comment and a close-out conference call was conducted on July 25, 2002 to discuss the risk management decisions and resultant changes to the oxyfluorfen labels.

B. Chemical Identification



- **Common Name:** Oxyfluorfen
- **Chemical Name:** 2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene
- **Chemical family:** Diphenyl ether herbicide
- **Case number:** 2490
- **CAS registry number:** 42874-03-3
- **OPP chemical code:** 111601
- **Empirical formula:** $C_{15}H_{11}ClF_3NO_4$
- **Molecular weight:** 361.72 g/mole
- **Trade and other names:** Goal, Galigan
- **Basic manufacturer:** Dow AgroSciences

Oxyfluorfen is an orange to deep red brown crystalline solid with a melting point of 65-84 °C, density of 1.49 g/mL, octanol/water partition coefficient of >20, and vapor pressure of 2.5×10^{-7} Torr at 25° C. Oxyfluorfen is practically insoluble in water (0.1 ppm), but is readily soluble in most organic solvents.

C. Use Profile

The following information is based on the currently registered uses of oxyfluorfen:

Type of Pesticide: Contact herbicide used for pre- or post-emergence control of monocotyledenous and broad-leaved weeds.

Mode of Action: Oxyfluorfen targets a specific enzyme, protoporphyrinogen oxidase, in the chlorophyll biosynthetic pathway. Inhibiting protoporphyringen oxidase in plants leads to an accumulation of phototoxic chlorophyll precursors which, in the presence of light, produce activated oxygen species which rapidly disrupt cell membrane integrity. Oxyfluorfen must contact plant foliage to cause effects. Plants that are actively growing are most susceptible to oxyfluorfen. By forming a chemical barrier on the soil surface, oxyfluorfen affects plants at emergence. This barrier is formed with adequate spray coverage or irrigation following granule application (to partially dissolve granules and promote dispersion of oxyfluorfen over the soil surface). Because of the length of oxyfluorfen soil half-life, this barrier may last up to three months. All plants attempting to emerge through the soil surface will be affected through contact. Oxyfluorfen also affects plants through direct contact of spray or granules to exposed tissues.

Summary of Use Sites:

<u>Food</u>:

Treefruit/Nut/Vine Crops:
Almonds, apple, apricot, avocado, banana, beechnut, brazil nut, butternut, cashew, cherry, chestnut, chinquapin, citrus (non-bearing), crab apple, dates, feijoa, fig, filbert, grapes, hickory nut, kiwi, loquat, macadamia nut, mango, mayhaw, nectarine, olives, papaya, peach, pear, pecan, persimmon, pistachio, plum, pomegranates, prune, quince, and walnut.

Field Crops:
Artichokes (globe), blackberries, broccoli, cabbage, cacao, cauliflower, clary sage, clover, coffee, corn, cotton, garbanzo beans, garlic, guava, horseradish, jojoba, mint, onions, raspberries, soybeans and taro.

Fallow Bed:
Broccoli, cabbage, cauliflower, cotton, garlic, grapes, kiwi, onion, potato, soybeans, tree fruit/nut/citrus, dry beans.

Fallow Bed (non-food, no tolerance):
Cantaloupe, carrot, cereal grains, celery, conifers, dry beans, peanut (other legumes), pepper, safflower, squash, strawberries, sugarbeet (other root/tuber crops), tomato (other fruiting vegetables), watermelon (other cucurbits).

Non-food Uses:
Ornamental plants/trees/shrubs, conifer seed beds and transplants, cut flowers, forest trees, Christmas tree plantations, rights-of-way/fencerows and non-crop areas (nonagricultural uncultivated areas, roadsides, industrial areas, storage yards, non-grazed meadows and farmsteads.)

Residential Uses: Landscape, curbs/gutters, patios, brick walls, sidewalks/walkways and driveways.

Formulation Types Registered: Oxyfluorfen is formulated for agricultural uses as an emulsifiable liquid concentrate containing 0.2 to 4 pounds active ingredient (ai) per gallon and as a granular product containing 2% oxyfluorfen by weight. Oxyfluorfen is most frequently used in a liquid formulation for food crops and as a granular formulation for ornamental nursery crops. There are also several ready-to-use products and a liquid concentrate available for residential use. Residential formulations contain 0.25% to 0.70% oxyfluorfen by volume and are packaged in a ready-to-use (RTU) sprinkler jug, a RTU trigger sprayer or as a liquid to be mixed in a sprinkler can or tank sprayer.

Application Methods and Equipment: Agricultural liquid formulations of oxyfluorfen are applied using large, small or ATV groundboom rigs. Aerial application is used mainly for fallow fields and bulb vegetables. Backpack sprayers can be used in Christmas tree plantations and right-of-way areas. Chemigation is used for over the top application to bulb vegetables and for drip application to some orchard trees, however, chemigation is often prohibited per the product labels. Right-of-way sprayers are used in right-of-way areas. Granular oxyfluorfen is applied to field- and container-grown ornamentals with broadcast spreaders.

Application Rates and Frequency: 0.25 - 2.0 lbs ai/acre/application. Typically one or two applications are made in the growing season to prevent weed growth (pre emergent) and/or to kill small weeds (post emergent). Some crops allow a greater number of applications/season, including tropical commodities (e.g. guava, coffee, macadamia nut) in Hawaii and ornamentals.

Use Classification: General use pesticide

D. Estimated Usage of Pesticide

A full listing of all uses of oxyfluorfen, with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Use Analysis" document, which is available in the public docket. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Based on available pesticide survey usage information for the years 1990 through 1999, an annual estimate of oxyfluorfen's total domestic usage averaged approximately 761,000 pounds a..i. for 1,167,000 acres treated. Use of oxyfluorfen is increasing. From 1992 to 1997 the use of oxyfluorfen increased by 54%, from an estimated 458,000 pounds active ingredient in 1992 to an estimated 705,000 lbs active ingredient in 1997. The largest markets in terms of total pounds active ingredient are wine grapes (32%), almonds (23%), cotton (7%), walnuts (6%), and table grapes (4%). The remaining usage is primarily on apples, corn, raisin grapes, mint, dry

onion, ornamentals, peaches, pistachios, prunes, and artichokes. Crops with a high percentage of the total U.S. planted acres treated include wine grapes (54%), artichokes (53%), pistachios (44%), almonds (43%), table grapes and nectarines (35% each), and figs (33%). Most of the usage is in CA, OR, WA and the cotton growing regions along the Mississippi River.

Table 1. Oxyfluorfen Estimated Usage for Representative Sites[1]

Crop	Lbs. Active Ingredient Applied (Wt. Avg.)[2]	Percent Crop Treated (Wt. Avg.)	Percent Crop Treated (Likely Maximum)
Almonds	170,000	43%	86%
Artichokes	4,000	53%	78%
Blackberries	1,000	18%	29%
Corn	7,000	.02%	0.1%
Cotton	54,000	1%	3%
Figs	3,000	33%	69%
Table grapes	30,000	35%	61%
Wine grapes	240,000	54%	84%
Kiwifruit	1,000	9%	29%
Mint	10,000	18%	26%
Nectarines	5,000	35%	61%
Olives	5,000	13%	21%
Onions, dry	15,000	29%	57%
Peaches	24,000	14%	23%
Pistachios	26,000	44%	76%
Plums	6,000	24%	52%
Pomegranates	1,000	26%	54%
Raspberries	1,000	28%	56%
Walnuts	48,000	28%	42%
Total non-agricultural (pasture, ornamentals, right-of-way, rangeland, etc.)	41,000	N/A	N/A

[1] Uses with more than 5,000 lbs applied (weighted average) and/or over 20% crop treated were selected as representative sites.

[2] Weighted Average is based on data for 1990 through 1999; the most recent years and more reliable data are weighted more heavily.

III. Summary of Oxyfluorfen Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the herbicide oxyfluorfen, as fully presented in the documents, "Oxyfluorfen. Revised Human Health Risk Assessment" dated April 29, 2002, and "Environmental Fate and Effects Division Science Chapter for Reregistration Eligibility Document for Oxyfluorfen," dated May 2, 2002. The purpose of this summary is to assist readers by identifying the key

features and findings of these risk assessments, so that they may better understand the conclusions reached in the assessments.

The original risk assessments for oxyfluorfen were made available in the public docket and on the Internet on January 30, 2002. The Agency reviewed and addressed all comments on the risk assessment documents. There is a discussion of these comments in Section IV, later in this document.

A. Human Health Risk Assessment

In response to comments and studies submitted, the risk assessments were updated and refined. The conclusions of the risk assessment are summarized below.

1. Dietary Risk from Food

a. Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is sufficiently complete, and that it supports a reregistration eligibility determination for all currently registered uses. The Agency Metabolism Assessment Review Committee has concluded that the residue of concern in plants and animals is oxyfluorfen *per se* and not its metabolites or degradate products.

It should be noted that older toxicity studies with oxyfluorfen used technical material of approximately 71% or 85% purity. The newer toxicity studies used a technical material of approximately 98% purity, which is the basis for the current registrations of oxyfluorfen. The newer technical material has similar impurities to the older technical material, but in reduced concentrations. Toxicity was less severe for studies with the 98% product than for the 71% product; however, one mammal developmental study with the 98% technical was submitted in which animals experienced the most severe anemia and related hematologic effects of any of the mammalian studies. When there were studies with both the new and old technical material, preference for an endpoint for risk assessment purposes was generally given to the newer, 98% technical material (current registrations).

Oxyfluorfen is of low acute toxicity and is in toxicity category IV for acute oral, dermal, and inhalation toxicity. It is a slight eye and dermal irritant and is not a dermal sensitizer.

Toxicity was similar for subchronic and chronic rat, mouse, and dog studies in both sexes. Oxyfluorfen inhibits heme production, which results in a variety of anemias. Heme is the part of the hemoglobin molecule that contains iron and binds oxygen. In the 1997 subchronic rat study which used the current 98% a.i. formulation, the red blood cell count was normal, but the red blood cell mass was decreased due to the small size of the red blood cells, presumably because of inhibition of the protoporphyrinogen oxidase enzyme. The anemia was generally mild in other studies, with varying hematologic abnormalities described in the rat, mouse, and dog studies.

Mild liver toxicity was described in the 1997 subchronic rat study which used the current 98% formulation. Increased liver weight was accompanied by very slight increases in liver enzyme activities and minimal histopathologic changes. Similar effects also occurred in the other subchronic and chronic rat, mouse, and dog studies. There were typically few histopathological lesions seen in the liver, although hepatocyte necrosis did occur in the mouse and dog studies. Renal toxicity was most severe in the 2-generation reproduction study in rats, in which pelvic mineralization occurred.

Developmental studies using the current 98% technical material found no developmental toxicity in rats whereas an increase in late resorptions occurred in the rabbit study (principally in 1 litter). A developmental study in rats using the older 71% technical material found increased early resorptions, decreased fetal weight, and increased incidence of fetal visceral and skeletal variations and malformations. A developmental study in rabbits with formulation manufactured from the older technical material found increased early resorptions and decreased litter size. A reproduction study with 71% technical material reported decreased live pups per litter and decreased pup body weights.

The newer technical material (96-99% a.i.) was tested in 12 genetic toxicology studies, which included assessments of gene mutation, chromosomal aberrations, and DNA damage. All assays were negative, except for one Ames assay which was positive only at high, insoluble levels. A subsequent Ames assay with 96% material was negative. The older 72% technical material and a polar fraction were tested in eight genetic toxicology studies. Both Ames assays and a mouse lymphoma study were positive for the 72% technical material. The polar fraction of the 72% technical material was also positive in an Ames assay.

Oxyfluorfen is classified as a category C, possible human carcinogen based upon combined hepatocellular adenomas/carcinomas in the mouse carcinogenicity study. The Cancer Peer Review Committee recommended a linear, low dose extrapolation for human risk assessments, with a Q_1^* of 7.32×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents.

Lactofen, a compound that is structurally related to oxyfluorfen, has recently been identified as a non-genotoxic hepatocarcinogen with a mechanism of action due to peroxisome proliferation. Peroxisome proliferator compounds are known to cause an increased number of peroxisomes in rodent liver cells. Peroxisomes are membrane-bound vesicles of enzymes in liver cells which produce hydrogen peroxide. The increased peroxisomes leak hydrogen peroxide which cause DNA effects and act as promoters for cancer in rodent livers. Dow AgroSciences has committed to undertake mechanistic studies to determine whether or not oxyfluorfen acts via a mechanism involving peroxisome proliferation. If oxyfluorfen is shown to be a peroxisome proliferator, an MOE approach (indicative of a non-linear dose response), rather than a Q* approach would be more appropriate to quantify cancer risks. If oxyfluorfen is determined to be a peroxisome proliferator, EPA will re-evaluate cancer risks and risk mitigation decisions for oxyfluorfen.

Further details on the toxicity of oxyfluorfen can be found in the April 29, 2002, Human Health Risk Assessment, and the August 8, 2001 memo entitled, "Oxyfluorfen: Toxicology Chapter for the RED". A brief overview of the studies used for the human health risk assessment and other relevant information is outlined in Table 2 .

b. FQPA Safety Factor

The FQPA Safety Factor was removed (i.e. reduced to 1X) based on the following factors: 1) There does not appear to be any increased susceptibility in animals due to pre- or postnatal exposure to oxyfluorfen based upon the developmental and reproductive toxicity studies reviewed. Although two does in the high-dose group of the 98% ai rabbit developmental study aborted, these abortions were considered secondary to the debilitating condition (generalized, systemic toxicity) of the mothers and occurred at the same dose that cause maternal toxicity; 2) Although neurotoxicity studies were not performed, there was no indication of neurotoxicity in the submitted developmental and reproductive studies or in the published literature. A developmental neurotoxicity study was not required; and 3) The dietary (food and drinking water) and non-dietary (residential) exposure assessments will not underestimate the potential exposures for infants and children. The FQPA safety factor is applicable to the dietary and residential risk assessments for all population subgroups.

c. Population Adjusted Dose (PAD)

Dietary exposure estimates are expressed in mg/kg body weight/day and as a percent of the acute/chronic Population Adjusted Dose (a/cPAD) which is the RfD taking into account the FQPA safety factor. This procedure is performed for each population subgroup. There are no aPADs for oxyfluorfen because an appropriate acute endpoint was not identified. Resorptions seen in the rabbit developmental study were not used as an acute endpoint because they were not considered indicative of a one-time exposure; rather, they were considered secondary to the debilitating condition of the mothers.

The cPAD is a risk expression reflecting the Reference Dose that has been adjusted to account for the FQPA safety factor (i.e., RfD/FQPA safety factor). In the case of oxyfluorfen, the FQPA safety factor is 1; therefore, the chronic RfD equals the chronic PAD. A risk estimate that is less than 100% of the chronic PAD does not exceed the Agency's risk concern.

d. Endpoints and Doses for Risk Assessment

All doses for risk assessment purposes were assessed along with the uncertainty factors of 10X for interspecies extrapolation and 10X for intraspecies variability. An additional uncertainty factor of 3X was applied to intermediate-term exposures because the dose was derived from the LOAEL. No short- or immediate-term oral endpoints are necessary due to negligible postapplication residential exposure. Long-term endpoints are also not needed, as all exposures are expected to be of short- or intermediate-term duration.

Table 2. Summary of Toxicological Endpoints and Other Factors Used in the Human Health Risk Assessment for Oxyfluorfen

Assessment	Dose (mg/kg/day)	Endpoint	UF[c]	Study
Chronic Dietary	NOAEL = 3.0	Liver toxicity occurring in dogs and mice at the LOAEL of 33 mg/kg/day (♂) and 42 mg/kg/day (♀) mice.	100	Chronic dog and mouse carcinogenicity studies
Cancer	$Q_1^* = 7.32 \times 10^{-2}$ $(mg/kg/day)^{-1}$	Combined hepatocellular adenomas and carcinomas.	n/a	Mouse carcinogenicity study
Dermal, Short-Term[a]	NOAEL= 30	Clinical signs seen at the maternal LOAEL of 90 mg/kg/day	100	Developmental rabbit study (1998)
Dermal, Intermediate-Term[a]	LOAEL = 32	Liver toxicity and anemia seen at the LOAEL of 32 mg/kg/day.	300	90-day mouse
Inhalation, Short-Term[b]	NOAEL = 30	Clinical signs seen at the maternal LOAEL of 90 mg/kg/day.	100	Developmental rabbit study (1998)
Inhalation, Intermediate-Term[b]	LOAEL = 32	Liver toxicity and anemia seen at the LOAEL of 32 mg/kg/day.	300	90-day mouse

NOAEL = no observed adverse effect level; LOAEL = lowest observed adverse effect level; UF=uncertainty factor; RfD = reference dose.

a. An oral endpoint was used for dermal exposure: a dermal absorption factor of 18% of oral exposure was selected from a dermal absorption study in rats.
b. An oral endpoint was used for inhalation exposure: inhalation exposure is assumed equivalent to oral exposure.
c. Uncertainty factors of 10x for intraspecies variability, 10x for interspecies extrapolation and 3x for lack of a NOAEL

e. Exposure Assumptions

Oxyfluorfen chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model (DEEM™) software Version 7.73, which incorporates consumption data from USDA's Continuing Surveys of Food Intake by Individuals (CSFII), 1989-1992. The 1989-92 data are based on the reported consumption of more than 10,000 individuals over three consecutive days, and therefore represent more than 30,000 unique "person days" of data. Foods "as consumed" (e.g., apple pie) are linked to raw agricultural commodities and their food forms (e.g., apples-cooked/canned or wheat-flour) by recipe translation files internal to the DEEM software. Consumption data are averaged for the entire US population and within population subgroups for chronic exposure assessment.

For chronic exposure and risk assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange-juice) on the commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total estimated exposure. Exposure estimates are expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

Anticipated residues were calculated using either USDA Pesticide Data Program (PDP) monitoring data or field trial data. Both data sets are consistent in that they show essentially all non-detectable residues, with the same limit of detection (0.01 ppm). Monitoring data for

oxyfluorfen generated through the USDA PDP were from the years 1996 to 1999 (total of 3,720 samples analyzed). These data were used for the following crops: apple juice, apples, carrots, grapes, green beans (canned and fresh), high fructose corn syrup, oranges, peaches, spinach (fresh and canned), sweet corn, sweet peas, tomatoes (fresh and canned), sweet potatoes, orange juice, pears, winter squash (fresh and canned), cantaloupe, grape juice, strawberries (fresh and frozen) and sweet bell peppers. There were no residues detected on these commodities. In addition, estimates of percent crop treated (% CT) generated by the Biological and Economic Analysis Division (BEAD), Office of Pesticide Programs, were used to refine the assessment.

Although a Tier 2/3 dietary risk assessment was conducted and is the most refined assessment to date for oxyfluorfen, there are some uncertainties associated with the exposure estimates as follows: (i) the use of ½ LOQs instead of ½ LODs for field trial residue values will tend to overestimate the residue values from the field trial studies (all of the field trial studies were non-detects; therefore, this assessment is an upper bound and the real residues are somewhere between this estimate and zero); (ii) no cooking studies were used; (iii) tolerance level residues for bananas and cacao beans and 100% crop treated for cacao beans were used; and (iv) DEEM default processing factors were used in the assessment.

f. Dietary Risk from Food

In general, a non-cancer chronic dietary (food) risk estimate of less than 100% of the chronic PAD is not of concern to the Agency. Cancer risks less than 1×10^{-6} are also not of concern to the Agency. Oxyfluorfen is classified as a category C, possible human carcinogen based upon combined hepatocellular adenomas/carcinomas in the mouse carcinogenicity study. A cancer dietary (food) risk assessment using a low-dose linear extrapolation was conducted. As shown in Table 3, chronic dietary risk is <1% of the chronic PAD for the U.S. general population and all population subgroups. Using the Q_1* of 7.32×10^{-2} results in a maximum estimated lifetime cancer risk to the U.S. general population of 3.8×10^{-7}. Neither the non-cancer or the cancer risk estimates pose a dietary risk concern for food for any population subgroup.

Table 3. Summary of Dietary Exposure and Risk for Oxyfluorfen

Population Subgroup	Chronic Dietary		Cancer
	Dietary Exposure (mg/kg/day)	% cPAD	Risk
U.S. Population	0.000005	<1	3.8×10^{-7}
Infants (<1 year old)	0.000011	<1	
Children 1-6 years	0.000012	<1	

2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground water and surface water contamination. For oxyfluorfen, EPA considered chronic (lifetime) drinking water risks and used modeling to estimate those risks. The PRZM-EXAMS/IR model was used to estimate

surface water concentrations, and SCI-GROW was used to estimate groundwater concentrations. Both of these models are considered to be screening tools, with the PRZM-EXAMS model being somewhat more refined than SCI-GROW.

Oxyfluorfen in the environment is expected to be very persistent with low mobility. In general, oxyfluorfen degrades very slowly in both soil and water and binds strongly to soil containing organic matter. Oxyfluorfen contaminates surface water through spray drift and runoff; the latter is considered a much larger contributor to surface water contamination. Oxyfluorfen is unlikely to contaminate ground water because it is relatively immobile in the soil column; therefore, the likelihood of leaching is small.

Some samples have been collected and analyzed for oxyfluorfen in water and sediments in the Columbia River basin of Oregon and Washington as a result of an August, 2000 oxyfluorfen (Goal 2XL) spill into the Fifteen Mile Creek near its mouth into the Columbia River. Of 35 background sediment measurements made in nearby rivers and streams which were reportedly unaffected by the spill, 2 detections of oxyfluorfen in sediment were noted. The higher detection, 541 ppb, was downstream of orchards.

Except for the data collected near the spill site in Fifteen Mile Creek (near the Columbia River), no targeted water monitoring data are available for dissolved phase oxyfluorfen. The U.S. Geological Survey (USGS) monitored oxyfluorfen concentrations in suspended sediment at one site in the San Joaquin River in central California during several years in the 1990's. The highest average concentration of oxyfluorfen in sediment was 27.2 ppb. Assuming partitioning between water and sediment is reversible and at equilibrium, the dissolved oxyfluorfen concentration was estimated to by 0.27 µg/L (calculated using the average K_d partitioning coefficient of 100.) Additionally, the USGS-EPA pilot reservoir monitoring program did not detect oxyfluorfen concentrations in raw and finished drinking water. However, due to the limited geographic range of these data and the uncertainties in estimating the dissolved concentration, these data are insufficient for use in the drinking water assessment.

The monitoring data are not adequate to perform a quantitative drinking water assessment for the following reasons: 1) The majority of the data are limited to sediment levels, whereas dissolved phase concentrations are more useful for estimating drinking water exposure; and 2) Oxyfluorfen use is widespread but the monitoring data are limited to a few locations. The monitoring data are temporally limited.

a. Surface Water

PRZM/ EXAMS, a Tier II model with index reservoir (IR) scenarios and a percent cropped area (PCA) adjustment factor, was used. For Tier II surface water screening assessments, OPP uses the PRZM-EXAMS model which accommodates the specific characteristics of the chemical and which include site-specific information regarding the application method and impact of daily weather on the treated field over a period of 30 more years. The PRZM-EXAMS model was developed to provide ‘best estimates’ of chemical concentrations in the modeled water bodies based on the fate characteristics of the chemical. The

input values specific to each of the modeled cropping scenarios and the fate parameter inputs for a given chemical are intended to be conservative.

Apples in Oregon (2 lbs ai/acre, 1X/season) was chosen to estimate the concentration of oxyfluorfen in surface drinking water. This scenario was selected after evaluating results from additional scenarios chosen to represent areas where oxyfluorfen is heavily used or has the potential for heavy use.

b. Ground Water

The SCI-GROW model, a Tier I model, was used to estimate the concentration of oxyfluorfen in drinking water from shallow ground water sources. Currently, there is no Tier II assessment tool for groundwater. Since SCI-GROW, unlike the PRZM/EXAMS surface water model, does not require a specific crop scenario, EFED used the highest use rate of four applications at 2.0 lbs ai/acre as allowed for ornamentals to estimate the concentration of oxyfluorfen in drinking water from shallow groundwater sources.

c. Drinking Water Levels of Comparison (DWLOCs)

To determine the maximum allowable contribution of pesticide residues in water, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a "drinking water level of comparison"(DWLOC) to determine whether modeled or monitoring levels exceed this level. The Agency uses the DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary exposure, does not exceed a level of concern.

The results of the Agency's drinking water analysis are summarized here. Details of the drinking water analysis are found in the Revised Human Health Risk Assessment for Oxyfluorfen, dated April 29, 2002.

(1) DWLOCs for Chronic (Cancer and Non-cancer) Exposure

Chronic and cancer DWLOCs for oxyfluorfen were calculated based on anticipated residues in food only; DWLOCs calculated from food + residential exposure are presented in the aggregate risk section of this document. Comparisons made between DWLOCs and the estimated concentrations of oxyfluorfen in surface water and ground water are presented in Table 4. If model estimates are less than the DWLOC, there is generally no dietary (food + water) concern.

Table 4. Oxyfluorfen Summary of Chronic (Non-cancer) DWLOC Calculations

Population Subgroup	DWLOCs (ppb)[1]		EECs (ppb)		
	Chronic	Cancer	Surface Water (PRZM/EXAMS)		Ground Water (SCI-GROW)
			Chronic [2]	Cancer [3]	Chronic and Cancer
U.S. Population	1050	0.315	7.1	5.7	0.08
All Infants (< 1Year)	900	N/A			
Children (1-6 years)	300	N/A			
Females (13-50 years)	300	N/A			

[1] DWLOCs based on food exposure only.
[2] Chronic risk based on the 1 in 10 yearly concentration
[3] Cancer risk based on the 36 year annual mean concentration

(2) Chronic Dietary Risk

As shown in Table 4, the chronic DWLOCs, ranging from 300 - 1050 for all populations, are substantially higher than the estimated environmental concentrations (EECs) of oxyfluorfen in surface and groundwater (7.1 ppb and 0.08 ppb respectively) based on conservative modeling. Consequently, chronic drinking water risk from surface or groundwater sources is below EPA's level of concern.

(3) Cancer Dietary Risk

The cancer DWLOC is the concentration of a pesticide in drinking water that results in a negligible cancer risk when considered together with estimated food exposure (1×10^{-6} or less). Upon comparison of the cancer DWLOC with the environmental concentrations of oxyfluorfen estimated using conservative modeling, the surface water concentration (5.7 ppb) is greater than the cancer DWLOC (0.315 ppb). Thus, there appears to be a potential concern for oxyfluorfen residues in surface water.

However, the estimated drinking water concentrations are considered to be conservative. First, the 2 lb ai/broadcast acre/season maximum labeled rate used in the drinking water modeling assessment is not typically applied as a broadcast spray but rather as a banded application between rows of perennial crops such as fruit/nut trees and artichokes, which leaves approximately 50-75% of the actual land area untreated. Careful targeting of the spray is required because oxyfluorfen is non-selective and will damage crops. The use rate for the perennial crops *per acre of total land area* is generally around 0.5 to 1.0 lbs ai/acre. Although there are oxyfluorfen use sites that are broadcast treated, such as bulb vegetables or fallow land, these sites have a lower maximum rate, typically 0.5 lbs ai/acre.

The drinking water assessment also assumes that the maximum labeled rate of 2 lbs ai/acre is applied *every year for 70 years* when it is known that the average reported use rate (regardless of application method) is less than ½ of the maximum labeled rate (< 1 lb ai/acre). Based on information provided by growers, extension service, and industry, the higher 2 lb rate

is used more during the first couple of establishment years or when a poorly managed orchard/field is purchased; after which lower rates are generally used to manage weeds at a maintenance level.

3. Non-dietary Risk from Residential Uses

Oxyfluorfen is used in the residential environment by homeowners to kill weeds on patios, driveways and similar surfaces. Oxyfluorfen homeowner products are intended solely for spot treatment; they are not used for broadcast treatment of lawns because they kill grass.

Residential formulations contain 0.25% to 0.70% oxyfluorfen by weight and are packaged in a RTU sprinkler jug, a RTU trigger sprayer or as a liquid to be mixed in a sprinkler can or tank sprayer.

Table 5. Residential Use Product Information for Oxyfluorfen

Product/Registrant	Formulation and Application Method	Application Rate (lbs ai/acre)
Kleenup Super Edger/Platte Chemical Corp	Contains 0.25% oxyfluorfen in pre-mixed one pint to one gallon containers. Applied from a RTU trigger sprayer, a RTU sprinkler jug or from a tank sprayer.	4.8
Ortho GroundClear SuperEdger/ Scotts Company	Ready to use liquid containing 0.25% oxyfluorfen. Applied directly from the jug which has an applicator spout.	4.8
Ortho GroundClear Triox Total Vegetation Killer A /Scotts Company	Concentrate containing 0.70% oxyfluorfen. Mixed with water and applied from a sprinkler can.	8.9

a. Exposure

The assessment evaluated four methods of application: 1) low pressure tank sprayer, 2) “mix your own” sprinkler can, 3) ready-to-use (RTU) invert sprayer, and 4) RTU trigger sprayer. The residential assessment for oxyfluorfen only addresses the applicator, because negligible postapplication exposure is anticipated from spot treatment of weeds.

Exposure data for scenarios 1 and 4 were taken from an Outdoor Residential Exposure Task Force (ORETF) mixer/loader/applicator exposure study with carbaryl. Exposure data for scenarios 2 and 3 were derived from an ORETF proprietary study that was conducted during the application of diazinon to lawns using “Mix Your Own” and “Ready to Use” hose end sprayers.

Dermal and inhalation exposures are combined in this assessment. MOEs were calculated for short-term (1-30 day) exposure scenarios only based on the use pattern.

General assumptions used in the residential handler risk assessment are as follows:

- Clothing consisted of a short-sleeved shirt, short pants and no gloves.

- An area of 200 sq ft per application was treated with one gallon of the "ready to use" product or 2.67 quarts of the "mix your own" product in an invert jug or sprinkler can. An area of 300 sq ft per application was treated with one gallon of product in a low pressure hand carried tank sprayer.
- Two applications are made per year.
- Applicators are assumed to have 50 years of potential exposure over a 70 year life span.

b. Residential Handler Risk Estimates

Residential handler *non-cancer* risk is measured as a Margin of Exposure (MOE), which determines how closely the exposure comes to a NOAEL. Since the FQPA safety factor was reduced to 1X, the Agency's level of concern (i.e., target MOE) is 100. As with dietary risk, residential *cancer* risk estimates less than 1.0×10^{-6} do not exceed the Agency's level of concern. As shown in Table 6, none of the residential applicator scenarios alone are of concern because the MOEs for non-cancer effects are greater than 100 and the cancer risks are less than 1.0×10^{-6}. The highest residential applicator cancer risk is 8.7×10^{-7} for the trigger pump sprayer scenario; however, this risk estimate is considered conservative because it is not anticipated that homeowners would use two gallons of product/year if applying with a trigger sprayer. Assuming one gallon/year, the cancer risk estimate for the trigger pump sprayer is 4.4×10^{-7}.

Table 6. Residential Risk Estimates for Non-cancer and Cancer Effects

Spot Treatment Scenarios	Combined Absorbed Daily Dose (mg/kg/day)	Non-Cancer Short-term Risk (MOE)	Lifetime Absorbed Daily Dose (mg/kg/day)	Cancer Risk
Low Pressure Tank Sprayer	2.5×10^{-3}	12,000	8.5×10^{-6}	6.2×10^{-7}
"Mix Your Own" Sprinkler Can	1.4×10^{-3}	22,000	4.6×10^{-6}	3.3×10^{-7}
RTU Invert Sprayer	1.8×10^{-4}	170,000	5.9×10^{-7}	4.3×10^{-8}
RTU Trigger Pump Sprayer	3.5×10^{-3}	8,500	1.2×10^{-5}	8.7×10^{-7}

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 for establishing a pesticide tolerance, "that there is 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 oxyfluorfen, aggregate risk assessments were conducted for short-term (one to thirty days) and chronic (cancer/non-cancer) exposure. Occupational exposure is not considered in any aggregate exposure assessment. As noted previously, no acute dietary/aggregate risks were assessed for oxyfluorfen because no adverse effects reflecting a single dose were identified.

a. Chronic (Non-Cancer) Aggregate Risk

The chronic aggregate risk assessment addresses exposure to oxyfluorfen residues in food and water only, as there are no chronic residential scenarios identified. As shown previously in Table 4, comparison of the chronic DWLOCs with the estimated environmental concentrations of oxyfluorfen shows that estimated surface and groundwater concentrations are substantially less than the DWLOCs for all populations. Consequently, the Agency concludes that residues of oxyfluorfen in food and drinking water do not result in a chronic aggregate risk of concern.

b. Short-term Aggregate Risk

Short-term DWLOCs were calculated based upon average food residues, and the residential handler exposure which resulted in the greatest risk estimate (spot treatment of weeds using a RTU trigger pump sprayer). DWLOC calculations are for adults only since the residential exposure is to adult handlers. The DWLOC calculation was done using standard body weight and daily water consumption, i.e., 70 kg/2L (adult male) and 60 kg/2L (adult female).

As shown in Table 7, surface and ground water concentrations (7.1 ppb and 0.08 ppb respectively), estimated using modeling, are below the short-term DWLOCs of 8900 ppb (females) and 10400 ppb (males). Consequently, there are no short-term aggregate risk concerns from food, drinking water and residential exposures.

Table 7. Short-Term Aggregate Risk and DWLOC Calculations

Population	Aggregate Risk MOE (food + residential)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC[1] (ppb)
Adult Male	8600	7.1	0.08	10400
Adult Female	8600	7.1	0.08	8900

c. Aggregate Risk for Cancer

Cancer DWLOCs were calculated using average food residues together with residential exposure estimates. The handler exposure scenario which resulted in the greatest risk estimate (spot treatment of weeds using a RTU Trigger Pump Sprayer) was used in the calculation. DWLOC calculations were done for adults only using standard body weight and daily water consumption, i.e., 70 kg/2L (adult male). The chronic food cancer risk estimate of 3.8×10^{-7}, combined with the residential cancer risk estimate of 8.7×10^{-7}, results in a food + residential cancer risk of 1.3×10^{-6}. Since the Agency's level of concern is 1.0×10^{-6}, the DWLOC is effectively zero and any additional water exposure will further contribute to potential risks of concern.

Table 8. Cancer Aggregate Risk (Food and Residential) and DWLOC Calculations

Population	Chronic Food Risk	Residential Risk	Aggregate Cancer Risk (food and residential)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Cancer DWLOC (ppb)
U.S. Pop	3.8×10^{-7}	8.7×10^{-7}	1.3×10^{-6}	5.7	0.08	0

The estimated food risk is considered highly conservative. First, PDP analyzed 3,700 samples on approximately 20 different commodities from 1996-1999 and found zero detects. This is not surprising considering the fact that, except for bulb vegetables, oxyfluorfen is not directly applied to crops due to damage to the foliage. Secondly, field trial data also showed all residues were non-detects at an LOD of 0.01 ppm. Third, ½ LOQ (0.01 ppm) was used in the dietary assessment instead of ½ LOD (0.003 ppm), which over-estimates the residue values. EPA used ½ LOQ rather than ½ LOD for field trial residue values because of the possibility of an occasional residue of oxyfluorfen greater than 0.01 ppm, and the registrant's intention to propose a new single analyte enforcement method for oxyfluorfen with a quantitation limit of 0.02 ppm. Actual residues are expected to be somewhere in between the calculated estimates and zero.

In addition, the residential cancer risk estimate of 8.7×10^{-7} is believed to be an over-estimate since residential applicators are not likely to apply two gallons/year of a ready-to-use product with a trigger sprayer. Assuming one gallon/year, the cancer risk estimate for the trigger pump sprayer is 4.4×10^{-7}. Therefore, the cancer risk of 6.2×10^{-7} from use of the low pressure tank sprayer can be considered "worst-case".

Regardless of food and residential exposure, estimated cancer risk from drinking water alone is of concern based on the surface water EEC of 5.7 ppb. As noted previously, the Agency believes that the surface water modeling overestimates the concentration of oxyfluorfen that may be present in drinking water. Targeted drinking water monitoring data would allow refinement of the EECs.

5. Occupational Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of oxyfluorfen include: individual farmers or growers who mix, load, and/or apply pesticides, and professional or custom agricultural applicators. Non-cancer 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 oxyfluorfen, dermal/inhalation MOEs greater than 100 for short-term and 300 for intermediate-term do not exceed the Agency's level of concern. Cancer risks greater than 1.0×10^{-4} (one in ten thousand) for the occupational population exceeds the Agency's level of concern. EPA closely examines occupational cancer risks in the 1×10^{-4} to 1×10^{-6} range and seeks cost effective ways to reduce occupational cancer risks to the greatest extent feasible, preferably 10^{-6} or less.

a. Toxicity

The toxicological endpoints, and other factors used in the occupational risk assessment for oxyfluorfen are listed previously in Table 2. The acute toxicity profile for technical oxyfluorfen is listed below in Table 9. Oxyfluorfen is of low acute toxicity and is in toxicity category IV for acute oral and inhalation toxicity and is category III for acute dermal toxicity. Oxyfluorfen is a slight eye and dermal irritant and is not a dermal sensitizer.

Table 9. Acute Toxicity of Technical Oxyfluorfen

Study Type	Test Material	MRID	Results	Toxicity Category
Acute Oral	96%	44712010	LD_{50} > 5000 mg/kg	IV
	97.1%	44828903	LD_{50} > 5000 mg/kg	IV
Acute Dermal	96%	44712011	LD_{50} > 2000 mg/kg	III
	97.1%	44828904	LD_{50} > 5000 mg/kg	IV
Acute Inhalation	96%	44712012	LC_{50} > 3.71 mg/L	IV
Primary Eye Irritation	96%	44712013	slight irritant	IV
	96%	44828906	negative	IV
Primary Skin Irritation	96%	44712014	slight irritant	IV
	96%	44828905	negative	IV
Dermal Sensitization	96%	44712015	negative	---
	23%	44814901	negative	---

b. Handler Exposure

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with oxyfluorfen. Agricultural liquid formulations of oxyfluorfen are applied using large, average or all-terrain vehicle (ATV) groundboom rigs. Aerial application is generally used only for fallow fields and bulb vegetables. Chemigation is mainly used for over-the-top application to bulb vegetables and for drip application to some orchard trees, however, chemigation is often prohibited on product labels. Granular oxyfluorfen is applied to field and container grown ornamentals with broadcast spreaders. Based upon the application methods, the following exposure scenarios were developed:

Application Method	Exposure Scenario
1. Large Groundboom (can treat 200 acres/day)	1A - Mix/Load Liquids - Large Groundboom 1B - Spray Application - Large Groundboom
2. Average Groundboom (can treat 80 acres/day)	2A - Mix/Load Liquids - Average Groundboom 2B - Spray Application - Average Groundboom
3. ATV Groundboom	3A - Mix/Load Liquids - ATV Groundboom 3B - Spray Application - ATV Groundboom

4. Fixed Wing Aircraft	4A - Mix/Load Liquids for Aerial Application 4B - Spray Application - Fixed-Wing Aircraft 4C - Flag Aerial Applications
5. Chemigation	5 - Mix/Load Liquids - Chemigation
6. Right-of- Way (ROW) Sprayer	6A - Mix/Load Liquids - ROW Sprayer 6B - Spray Application - ROW Sprayer
7. Backpack Sprayer	7 - Mix/Load/Apply Liquids - Backpack
8. Tractor Drawn Broadcast Spreader	8A - Load Granules into Broadcast Spreader 8B - Apply Granules with Broadcast Spreader
9. Push Type Broadcast Spreader	9 - Broadcast Spreader (Load/Apply)

EPA has adopted a methodology to present the risks separately for some scenarios and combine others. Most of the hand-held equipment such as backpack sprayers and push type granular spreaders are assessed as a combined function. With these types of small operations the mixing, loading, and applying are almost always carried out by the same individual and there are data available to estimate exposure from these activities. For equipment such as fixed-wing-aircraft or groundboom tractors, the applicators are assessed separately from the individual who mixes and loads the formulated product. EPA assumes that the pilots are rarely involved in mixing/loading procedures. By separating the two job functions, EPA can determine the most appropriate PPE or engineering controls without requiring the handler to wear PPE throughout the entire workday or to use engineering controls that are not needed.

Handler Data Sources

With the exception of the push-type broadcast spreader scenario, which relied upon a high-quality Outdoor Residential Exposure Task Force (ORETF) study with DCPA, exposure analyses were performed with The Pesticide Handlers Exposure Database (PHED). PHED was designed by a task force of representatives from the US EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. It is a software system consisting of two parts – a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates). The quality of the data and exposure factors represents the best sources of data currently available to the Agency for completing these kinds of assessments.

Handler Exposure Assumptions

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

- The average work day was 8 hours.

- Maximum application rates and daily acreage were used to evaluate non-cancer occupational risk.
- Average application rates and daily acreage were used to evaluate cancer occupational risk.
- A body weight of 60 kg was assumed for short term exposures because the short term endpoint relates to females 13-50 years of age.
- A body weight of 70 kg was assumed for intermediate term exposures because the intermediate term endpoint is not gender specific.
- A body weight of 70 kg was assumed for cancer scenarios.
- A private grower is assumed to mix, load and apply liquid formulation of oxyfluorfen 5 days per year. This is based upon the 90^{th} to 95^{th} percentile farm size (taken from the 1997 Census of Agriculture) divided by the assumed acres treated per day. It is also assumed that approximately one or two applications are made per year as listed in the National Agricultural Statistics Service (NASS) data.
- A private grower is assumed to load and apply granular formulations of oxyfluorfen 10 days per year because the granular labels allow up to 4 applications of 2 lb/ai per year.
- A custom applicator mixes, loads and applies oxyfluorfen 30 days per year.
- Baseline PPE includes long sleeve shirts, long pants and no gloves or respirator.
- Single Layer PPE includes baseline PPE with gloves.
- Double Layer PPE includes coveralls over single layer PPE .
- Double Layer PPE PF5 includes a dust/mist respirator.
- Double Layer PPE PF10 includes a cartridge respirator.

Anticipated use patterns and application methods, range of application rates, and daily amount of acres treated were derived from current product labeling. With the exception of some tropical commodities, application rates specified on oxyfluorfen labels range from 0.5 to 2.0 pounds of active ingredient per acre in agricultural settings. The Agency typically uses acres treated per day values that are thought to represent 8 hours of application work for specific types of application equipment.

c. Handler (Non-cancer) Risk

Since the endpoint of concern was the same for dermal and inhalation, the exposures and risks were combined. The target MOEs are 100 for short term exposures and 300 for intermediate term exposures. Scenarios with MOEs greater than the target MOEs are not of concern for the occupational population.

Table 10 summarizes the ranges of the combined MOEs for the various exposure scenarios. A brief summary of the specific exposure scenarios with risks of concern (i.e. combined MOEs less than 100 or 300) is presented in Table 11.

Table 10. Non-Cancer Combined MOEs for Occupational Exposure to Oxyfluorfen

Endpoint	Baseline MOEs	Single Layer MOEs[1]
Short Term	6 - 14000	490 - 14000
Intermediate Term	7 - 17000	520 - 15000

[1] Single layer = baseline clothing + gloves

Table 11. Oxyfluorfen Handler Exposure Scenarios of Concern[a]

Mitigation Level	Scenarios of Concern (MOE = Short Term, Intermediate Term)
Baseline PPE	1A - Mix/load liquids - Large Groundboom (MOE =23 to 34, 29 to 43) 2A - Mix/load liquids - Average Groundboom (MOE = 22 to 85, 27 to 110) 3A - Mix/load liquids - ATV Groundboom (MOE = 43, 54) 4A - Mix/load liquids - Aerial (MOE = 6, 7) 5 - Mix/load liquids - Chemigation (MOE =20, 24) 6A - Mix/load liquids - Right-of-Way Sprayer (MOE = 69, 86) 6B - Spray Application - Right-of- Way (MOE = 150, 190)
Single layer PPE (without respirators)	None

a. Scenarios are of concern when the MOE <100 for short term exposures or the MOE <300 for intermediate term exposures

The calculations of occupational handler/applicator non-cancer risk indicate that, at the single layer PPE level (which includes baseline PPE + chemical resistant gloves) none of the scenarios are of concern for short or intermediate term non-cancer risks. Currently, PPE requirements on labels ranges from baseline to double layer with most of the labels requiring waterproof or chemical-resistant gloves.

d. Handler Cancer Risk

For occupational risks between 1×10^{-6} and 1×10^{-4}, the Agency will pursue risk mitigation where feasible and cost effective to manage the risks to 1×10^{-6}. The cancer risks were calculated starting with the PPE level (single layer) that achieved acceptable MOEs for non-cancer risks. As shown in Table 12, the cancer risks for all of the custom applicator scenarios are less than 1×10^{-4} at the single layer PPE level and some of the applicator scenarios are less than 1×10^{-6}. At the highest level of mitigation (engineering controls) the risks for most of the custom applicator scenarios are reduced to less than 1×10^{-5} and some are reduced to less than 1×10^{-6}. In general, cancer risks to private growers were three to six times less than those for custom applicators due to the assumption that they handle oxyfluorfen fewer number of days per year (30 days/year = custom applicators, 10 days/year = private grower [granular], 5 days/year = private grower [liquid]). Cancer risk estimates for private growers can be found in the May 1, 2002 Revised Occupational and Residential Exposure and Risk Assessment for oxyfluorfen.

Table 12. Summary of Oxyfluorfen Cancer Risks for Custom Applicators (30 Exposure Days per Year)

Exposure Scenario	Crops	Average Application Rate (lb ai/Acre)	Treated Area (Acres/day)	Single Layer Cancer Risk	Double Layer Cancer Risk	Double Layer PF5 Cancer Risk	Double Layer PF10 Cancer Risk	Engineering Controls Cancer Risk
1A - Mix/Load Liquids - Large Groundboom	Corn	0.5	200	2.3e-05	1.9e-05	1.5e-05	1.4e-05	7.0e-06
1B - Spray Application - Large Groundboom				1.4e-05	1.2e-05	9.2e-06	8.8e-06	4.1e-06
1A - Mix/Load Liquids - Large Groundboom	Cotton, Soybeans	0.25	200	1.1e-05	9.3e-06	7.3e-05	7.2e-06	3.5e-06
1B - Spray Application - Large Groundboom				7.0e-06	5.8e-06	4.6e-06	4.4e-06	2.0e-06
2A - Mix/Load Liquids - Average Groundboom	Orchards/ Vineyards Nursery Trees, Mint	1.0	80	1.8e-05	1.5e-05	1.2e-05	1.1e-05	5.6e-06
2B - Spray Application - Average Groundboom				1.1e-05	9.4e-06	7.3e-06	7.1e-06	3.2e-06
2A - Mix/Load Liquids - Average Groundboom	Onions, Brassica	0.25	80	4.6e-06	3.7e-06	2.9e-06	2.8e-06	1.4e-06
2B - Spray Application - Average Groundboom				2.8e-06	2.3e-06	1.8e-06	1.8e-06	8.1e-07
3A - Mix/Load Liquids - ATV Groundboom	Artichokes	1.0	40	9.2e-06	7.5e-06	5.8e-06	5.6e-06	2.8e-06
3B - Spray Application - ATV Groundboom				5.6e-06	4.7e-06	3.7e-06	3.5e-06	1.6e-06
4A - Mix/Load Liquids for Aerial Application	Fallow Fields	0.25	350	2.0e-05	1.6e-05	1.3e-05	1.2e-05	6.1e-06
4B - Spray Application - Aerial				Not applicable (N/A)	N/A	N/A	N/A	3.6e-06
4C - Flag Aerial Applications				9.4e-06	8.8e-06	7.7e-06	7.6e-06	1.8e-07
5 - Chemigation	Onions, Garlic, Horseradish	0.25	350	2.0e-05	1.6e-05	1.3e-05	1.2e-05	6.1e-06
6A - Mix/Load Liquids - Right of Way Sprayer	Right of Ways	1.0	50	5.7e-05	4.7e-06	3.6e-06	3.5e-06	1.8e-06
6B - Spray Application - Right of Way Sprayer				8.0e-05	6.0e-05	5.7e-05	5.7e-05	N/A
7 - Mix/Load/Apply Liquids - Backpack	Conifers	1.0	2	4.1e-05	2.7e-05	2.5e-05	2.5e-05	N/Aa
7 - Mix/Load/Apply Liquids - Backpack	Conifers	0.375	2	1.5e-05	1.0e-05	9.5e-06	9.4e-06	N/A
8A - Tractor Drawn Broadcast Spreader - Load	Ornamentals	1.0	40	5.1e-06	4.0e-06	1.6e-06	1.3e-06	1.1e-07
8B - Tractor Drawn Broadcast Spreader - Apply	Ornamentals	1.0	40	4.3e-06	3.4e-06	1.7e-06	1.5e-06	1.0e-06
9 - Load and Apply Using Broadcast Spreader	Ornamentals	1.0	5	1.0e-05	5.9e-06	4.6e-06	4.4e-06	N/A

(1) Post-Application Occupational Risk

The post-application occupational risk assessment considered exposures to workers entering treated sites. Oxyfluorfen is a non-selective herbicide that can cause leaf damage to most of the labeled crops. With the exception of bulb vegetables and conifers, which have more tolerance to oxyfluorfen, over the top applications are not recommended. Therefore, it was determined that significant postapplication exposure is only anticipated following applications of oxyfluorfen to conifer seedlings, conifer trees and bulb vegetables.

Only dermal exposures were evaluated in the postapplication worker assessment; inhalation exposures are not anticipated due to the low vapor pressure of oxyfluorfen (2.0×10^{-7} torr at 20 C). Because oxyfluorfen is typically applied only a few times per season and because the agricultural scenarios generally occur for only a few months per year, it was determined that oxyfluorfen exposures would be in the range covered by the short and intermediate term toxicological endpoints.

In the Worker Protection Standard (WPS), a restricted entry interval (REI) is defined as the duration of time which must elapse before residues decline to a level so entry into a previously treated area and engaging in any task or activity would not result in exposures which are of concern. Typically, the activity with the highest risk will drive the selection of the appropriate REI for the crop. The restricted entry interval for oxyfluorfen is currently set at 24 hours.

(2) Data Sources

The registrant submitted a chemical specific Dislodgeable Foliar Residue (DFR) study for postapplication worker exposure. This study measured dislodgeable foliar residues following groundboom application of oxyfluorfen (Goal) to control weeds in conifer seedling beds at a nursery in Oregon. This study is of marginally sufficient quality for use in risk assessment. The lack of validation data, high fortification levels and low recovery during the study are the most significant deficiencies. In the absence of acceptable chemical-specific DFR data, standard Agency assumptions were also used for comparative purposes: the initial percent of application rate assumed to be available as DFR was 20% for bulb vegetables and conifers, and the dissipation rate per day was assumed to be 10%.

The transfer coefficients are based on proprietary data from the Agricultural Re-entry Task Force (ARTF). These coefficients range from 300 for low contact activities such as scouting, irrigating and thinning fields of bulb vegetables to 3000 for higher contact activities such as shearing Christmas trees. The exact transfer coefficient for a given scenario also depends upon the crop height and foliage development. Currently there are no transfer coefficients for conifer seedlings and a value of ~1000 cm^2/hr was chosen for conifer seedling irrigation/scouting based upon professional judgement, transfer coefficients for similar activities on other low crops, and preliminary ARTF data that is being collected for a variety of related crops.

(3) Assumptions

The following assumptions were made regarding post application occupational exposure:

- Occupational post application cancer risks were calculated using a 30 day rolling average DFR that was predicted using the default dissipation rate of 10 percent per day. These calculations are based upon the assumption that post application exposure would only occur on one particular farm. This assumption is considered valid for conifer seedling nurseries and Christmas tree farms, because these industries are less likely to employ migrant labor that would move from one farm to the next. This assumption is less valid for bulb vegetable farms that use migrant labor.
- Non-Cancer short term risks were assessed using the maximum label rates. Intermediate term and cancer risks were assessed using average application rates. Risks for conifer trees were also assessed at the rate of 0.375 lbs ai/acre, which can be used for "chemical mowing[1]" around Christmas trees.
- It was assumed that a private grower has ten days of post application exposure per year and a commercial re-entry worker has thirty days of post application exposure per year.

e. Reentry Worker (Non-cancer) Risk

The length of time for non-cancer risks to decline to levels that are not of concern (i.e., MOEs $\geq$ 300) was shorter than the current REI of 24 hours for all activities except for Christmas tree shearing, which required 3 days.

f. Reentry Worker Cancer Risk

A summary of the cancer risks for commercial re-entry workers is presented in Table 13. Risks for conifer tree activities exceed $1.0x10^{-4}$ on day of treatment. These risks decline to less than $1.0x10^{-4}$ in 3 days for all activities. All of the scenarios have cancer risks in excess of $1.0x10^{-6}$ on day zero and the time for these risks to decline to $1.0x10^{-6}$ ranges from 12 to 47 days. Cancer risks for private growers are three times less than commercial workers due to the assumption that they work fewer days per year.

[1] Chemical mowing is a term used to describe the practice of applying post-emergent herbicides at low rates to stunt or suppress weeds, which is cost-effective and promotes soil conservation. Chemical mowing can be used as a broadcast application or as a treatment for row middles.

Table 13. Post Application Cancer Risks for Commercial Workers (Default Data)

Crops	Average Application Rate (lbs ai/acre)	Activities	Cancer Risk on Day Zero After Treatment	Day After Treatment When Cancer Risk is Less Than:		
				$1.0x10^{-4}$	1.0×10^{-5}	$1.0x10^{-6}$
Bulb Vegetables	0.25	Irrigating, scouting, hand weeding	3.3e-06	0	0	12
Tree Seedlings, Conifer	0.5	Irrigation, Scouting, Hand Weeding	2.2e-05	0	8	30
Trees, Conifer	1.0	Irrigation, Scouting	4.5e-05	0	15	37
		Shearing	1.3e-04	3	25	47
Trees, Conifer	0.375 (chemical mowing)	Irrigation, Scouting	1.7e-05	0	5	27
		Shearing	5.0e-05	0	16	38

Although the chemical-specific study data on conifer seedlings has serious deficiencies, the study is useful for characterizing oxyfluorfen-specific DFR levels on conifers, as the study suggests dissipation is faster than default assumptions. Cancer risk using a 30-day rolling average could not be calculated using the conifer DFR data because the conifer DFR dissipated to the LOD by DAT 5. When using the study data, reentry risks for conifer tree activities decline to less than $1.0x10^{-4}$ in one day and the time for these risks to decline to $1.0x10^{-6}$ ranges from 6 to 11 days.

Table 14. Postapplication Cancer Risks for Commercial Workers (Conifer Study Data)

Crops	Application Rate (lbs ai/acre)	Activities	Cancer Risk on Day Zero After Treatment	Day After Treatment When Cancer Risk is Less Than:	
				$1.0x10^{-4}$	$1.0x10^{-6}$
Tree Seedlings, Conifer	0.5	Irrigation, Scouting, Hand Weeding	6.9e-05	0	6
Trees, Conifer	1.0	Irrigation, Scouting	1.4e-04	1	8
		Shearing	4.2e-04	1	11
Trees, Conifer	0.375	Irrigation, Scouting	5.2e-05	0	6
		Shearing	1.6e-04	1	8

6. Human Incident Data

The Agency consulted and reviewed sources of information on health incidents involving human exposure. Oxyfluorfen cases mostly relate to handler and worker exposure. The four sources of information are OPP's Incident Data System (IDS), American Association of Poison Control Centers (PCC), California Department of Pesticide Regulation (CDPR), and the National Pesticides Telecommunication Network. CDPR and OPP data tend to provide the most insight into oxyfluorfen's association with human health incidents. A total of 66 incidents connected with oxyfluorfen were reported in the OPP Incident Data System (IDS) from 1994 to 2000. Most of these incidents involved irritant effects to the eyes, skin and occasionally respiratory

passages. There were 25 cases reported in the California Pesticide Illness Surveillance Program and the majority of these cases involved minor symptoms of systemic illness such as headache, dizziness and nausea. During one of these incidents, nine of 15 field workers developed symptoms while transplanting cauliflower plants in a field that was sprayed about 30 minutes earlier. The reentry interval required on the label was 24 hours. These illnesses included symptoms of chemical conjunctivitis, eye irritation, tingling and itching of the skin, nausea, dizziness, headache, and vomiting. The incident report recommends that measures be taken to enforce the reentry interval and that skin and eye protection be worn by handlers and those who are likely to have substantial contact with oxyfluorfen products. Both PCC and CDPR data indicate that incidents rarely result in hospitalization or prolonged absences from work, which is expected due to the low acute toxicity profile for oxyfluorfen. However, in the case of oxyfluorfen, the Agency does not have as great a concern for acute poisoning as for cancer risk, which is not covered by incident data.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Fate and Effects Division Science Chapter for the Oxyfluorfen Reregistration Eligibility Decision, dated May 2, 2002, available in the public docket.

1. Environmental Fate and Transport

Except for the photolysis in water study (which indicates relatively rapid degradation), laboratory data indicate that oxyfluorfen is persistent (aerobic soil metabolism half-lives of 291 and 294 days in a clay loam soil and 556 and 596 days in a sandy loam soil; and anaerobic soil metabolism half-lives between 554 and 603 days). Adsorption/desorption studies suggest oxyfluorfen is relatively immobile, except perhaps when used on very sandy soils. The most likely route of dissipation is soil binding. Laboratory data suggest that once the soil-bound oxyfluorfen reaches deep or turbid surface water it will persist since it is stable to hydrolysis and since light penetration would be limited; however, it may degrade by photolysis in clear, shallow water. Oxyfluorfen can contaminate surface water through spray drift and runoff; however, it is unlikely to contaminate ground water because it is relatively immobile in the soil column; therefore, the likelihood of leaching is small.

The major degradate found in the environmental fate studies was 2-chloro-1-(3-ethoxy-4-hydroxyphenol)-4-(trifluoromethyl) benzene, which was identified in the aqueous photolysis study at $\geq$10 % of the applied radioactivity. Other degradates were identified in the aqueous photolysis study but not quantified. In the hydrolysis study, 2-chloro-1-(3-hydroxy-4-nitrophenoxy)-4-(trifluoromethyl) benzene was identified at a maximum concentration of 1.2-1.7% of the applied radioactivity. There were no degradates identified in the anaerobic soil metabolism, leaching adsorption/desorption and soil photolysis studies. The Health Effects Division has determined that only parent oxyfluorfen is of toxicological concern for human health risk assessment.

2. Ecological Risk

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations based on environmental fate characteristics, pesticide use, and/or monitoring data. To evaluate the potential risk to nontarget organisms from the use of oxyfluorfen products, EPA calculates a Risk Quotient (RQ), which is the ratio of the estimated exposure concentration to the toxicity endpoint values, such as the LC_{50} (the concentration of a substance which causes death to 50% of the test animals). The RQ is simply a means of integrating the results of ecological exposure and ecological toxicity. These RQ values are compared to levels of concern (LOCs), given in Table 15 which provide an indication of the relative risk the particular pesticide and/or use may pose for nontarget organisms. If the RQ does not exceed the LOC, it is unlikely that the pesticide will pose a significant risk. Similarly, when RQs are equal to or greater than the LOC, then the Agency does have concerns. These concerns may be addressed by further refinements of the risk assessment or by mitigation. Use, toxicity, fate, and exposure are considered to characterize the risk as well as the level of certainty and uncertainty in the assessment. EPA further characterizes ecological risk based on any reported aquatic or terrestrial incidents to nontarget organisms in the field (e.g., fish or bird kills).

Table 15. Risk Presumptions for Terrestrial and Aquatic Animals

Risk Presumption	LOC terrestrial animals	LOC aquatic animals
Acute Risk there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification,	0.5	0.5
Acute Restricted Use -there is potential for acute risk, but may be mitigated through restricted use classification,	0.2	0.1
Acute Endangered Species -endangered species may be adversely affected; regulatory action may be warranted,	0.1	0.05
Chronic Risk -there is potential for chronic risk; regulatory action may be warranted.	1	1

Specific uses chosen for modeling include non-bearing citrus, apples, grapes, walnuts, cotton, and cole crops. Although this only represents a portion of the crops for which oxyfluorfen has a labeled use, it does represent crops with higher application rates and crops which have a large percentage of their total acreage treated with oxyfluorfen. By encompassing crops with large percentages of acreage treated with oxyfluorfen and a large geographic area, some crops with lower maximum application rates were also included in the set of scenarios.

3. Risk to Terrestrial Organisms

a. Toxicity (Hazard) Assessment

Toxicity values for risk calculations for all terrestrial assessments are given in Table 16. Toxicity tests with terrestrial species show that oxyfluorfen is "practically non-toxic" to birds and mammals exposed for short periods; however, adverse effects were demonstrated in one of

the two avian reproduction toxicity studies and in the mammalian sub-chronic, chronic, developmental, and 2-generation toxicity studies. Guideline toxicity tests show oxyfluorfen is "practically non-toxic" to honeybees; however, a non-guideline study demonstrated that an oxyfluorfen end-use product caused almost 100% mortality of predaceous mites at an application rate of 1.28 lbs ai/acre/application. In general, toxicity tests demonstrate that oxyfluorfen negatively impacts seedling emergence and vegetative vigor of terrestrial plants.

Table 16. Summary of toxicity values for terrestrial risk assessments

Test Species	% a.i.	Endpoint	Toxicity Category and/or Most Sensitive Endpoint	MRID
Acute Avian and Mammalian				
Bobwhite quail (oral)	70.1	LD_{50} > 2150 mg ai/kg-bw	practically nontoxic	921361-02[a]
Bobwhite quail (dietary)	70.2	LC_{50} > 5000 mg ai/kg-diet	practically nontoxic	921361-03
Laboratory rat (dietary)	97.1	LD_{50} > 5000 mg ai/kg-bw	practically nontoxic	447120-10
Chronic (reproductive) Avian and Mammalian				
Bobwhite quail	72.5	NOAEC <50 mg ai/kg-diet LOAEC = 50 mg ai/kg-diet	Reduced body weight of 14-day chicks	4153012-06
Laboratory rat	71.4	NOAEC = 400 mg ai/kg-diet LOAEC = 1600 mg ai/kg-diet	Parental = mortality, decreased BW and liver and kidney histopathology Reproductive = decreased BW and decreased number of live pups/litter	420149-01
Non-Target Insects				
Honey bee	71.4	LD_{50} > 100 μg/bee	practically non-toxic	423681-01
Terrestrial Plants				
Seedling Emergence-Monocot	71.5	EC_{25} = 0.0058 lbs ai/acre	shoot length (ryegrass)	416440-01
Seedling Emergence - Dicot	71.5	EC_{25} = 0.0026 lbs ai/acre	shoot length (cabbage)	416440-01
Vegetative Vigor - Monocot	71.5	EC_{25} = 0.0062 lbs ai/acre	shoot weight (onion)	416440-01
Vegetative Vigor - Dicot	71.5	EC_{25} = 0.00043 lbs ai/acre	shoot weight (tomato)	416440-01

[a] Also reviewed under MRID 422559-01.

b. Exposure and Risk

For pesticides applied as liquids, the estimated environmental concentrations (EECs) on food items following product application are compared to LC50 values to assess risk with a Risk Quotient (RQ) method. For birds and mammals, estimates of maximum residue levels of oxyfluorfen on wildlife food was based on the model of Hoerger and Kenega (1972), as modified by Fletcher et al. (1994). EECs resulting from multiple applications are calculated from the maximum number of applications, minimum application interval, and foliar half-life data. The Agency does not calculate assess chronic risk from granular applications. For terrestrial and semi-aquatic plants, the exposure model incorporates runoff and spray drift.

RQs were not calculated to evaluate the potential acute risks to birds and mammals because no adverse effects reflecting a single dose were identified at the highest dose. For the current labeled application rates, minimal acute risks to birds and mammals are anticipated.

Subchronic and chronic risks to terrestrial birds and mammals do present a concern. Assuming maximum residue values, the chronic LOC of 1.0 is exceeded for birds consuming short grass when oxyfluorfen is applied to crops at application rates greater than or equal to 0.25 lbs ai/acre/year. The chronic RQs are lower for birds consuming other food stuffs, but there are chronic exceedences at higher application rates. Since the NOEC in the chronic avian toxicity study was not determined (< 50 mg ai/kg-diet), the RQs represent a lower bound. Consumption of short grass leads to the highest chronic risk estimates for birds.

Table 17. Summarized Chronic Avian Risk Quotients for Spray Applications [a]

Crop (Site)	Max Single App. Rate (lbs ai/A)	Max No. of Apps.	Chronic RQs for Predicted Max Residue Levels			
			Fruits, pods, seeds, large insects	Broadleaf forage, small insects	Tall grass	Short grass
Citrus (Florida)	2.0	2	>0.9	>8.4+	>6.8+	>14.9+
Apples (Oregon) Walnut (California) Grapes (New York)	2.0	1	>0.6	>5.4+	>4.4+	>9.6+
Cotton (Mississippi) Cole crops (California)	0.5	1	>0.2	>1.4+	>1.1+	>2.4+
Cole crops (California)	0.25	1	>0.1	>0.7	>0.6	>1.2+

+ indicates an exceedence of Chronic LOC

[a] Chronic toxicity threshold (NOEC) was <50 mg ai/kg-diet; Chronic LOC = 1.0.

For mammals, chronic risk quotients are estimated to exceed the Chronic LOC of 1.0 for the citrus scenario with the highest application rate (2 lbs ai/acre, 2 applications/season) and for all scenarios with a 2 lb ai/acre/year application rate (chronic RQs $\leq$2). Multiple applications of a pesticide may raise the risk to an organism by increasing the concentration of residues on food items and by extending the period during which these residues may be present.

Table 18. Summarized Chronic Mammalian Risk Quotients for Spray Applications [a]

Crop (Site)	Max Single App. Rate (lbs ai/A)	Max No. of Apps.	Chronic RQs for Predicted Max Residue Levels		
			Seeds	Broadleaf forage, small insects	Short grass
Citrus (Florida)	2.0	2	0.12	1.05	1.86+
Apples (Oregon) Walnut (California) Grapes (New York)	2.0	1	0.08	0.68	1.20+
Cotton (Mississippi) Cole crops (California)	0.5	1	0.02	0.17	0.30
Cole crops (California)	0.25	1	0.01	0.09	0.15

+ indicates an exceedence of the Chronic Risk LOC.

[a] Chronic toxicity threshold (NOEC) was 400 mg ai/kg-diet.

The Agency currently does not quantify risks to terrestrial non-target insects; therefore, risk quotients are not calculated for these organisms.

As a herbicide, oxyfluorfen is expected and has been shown to negatively impact seedling emergence and vegetative vigor of terrestrial plants. For nearly all modeled scenarios, the acute risk LOC of 1.0 for terrestrial plants adjacent to treated areas and plants in semi-aquatic areas is exceeded. The RQs range from 1 to 169. The risk assessment for terrestrial plants was based on RQs calculated from toxicity studies using the technical grade of oxyfluorfen instead of a typical end-use product (TEP). Often the TEPs include surfactants or adjuvants to increase the herbicide's adsorption into the plant, thereby increasing its efficacy. If the toxicity tests were conducted using a TEP of oxyfluorfen (e.g., Goal 2XL) at the same rates as the technical grade, the toxicity endpoints may be much lower. Furthermore, if the toxicity endpoints were reduced with the TEP, the RQs and the risks would be higher than currently estimated.

Table 19. Summarized Acute Non-endangered Terrestrial Plant Risk Quotients

Crop	Application Rate (lbs ai/acre)	Acute RQs	
		Adjacent to treated sites	Semi-aquatic areas
Citrus	2 lbs ai/acre, 2 applications/year	6-93	6-169
Apples, Walnuts, Grapes	2 lbs ai/acre, 1 application/year	3-47	3-85
Cotton (aerial)	0.5 lbs ai/acre, 1 application/year	4-58	4-58
Cole crops (aerial)	0.25 lbs ai/acre, 1 application/year	2-30	2-30

4. Uncertainties in Terrestrial Risk Assessment

There are a number of areas of uncertainty in the terrestrial risk assessment. Sensitivity differences between species can be considerable (even up to two orders of magnitude) for some chemicals. The rank of the tested species relative to the distribution of all species' sensitivities to oxyfluorfen is unknown. In addition, the toxicity of oxyfluorfen to wild (non-laboratory) species relative to laboratory species is unknown.

The risk assessment only considered a subset of possible use scenarios. It is possible that some of the labeled uses that were not modeled will have a greater risk to the environment than those included in this risk assessment. For example, coffee, cacao, and ornamentals have a higher seasonal maximum application rate than those modeled. There is uncertainty in the Chronic RQ estimates for birds because a NOEC was not established in the study used for risk assessment. The true magnitude of the RQs for chronic avian toxicity is unknown, as these represent lower bound estimates. Only dietary exposure is included in the exposure assessment. Other exposure routes are possible for animals in treated areas. These routes include ingestion of contaminated drinking water, ingestion of contaminated soils, preening/grooming, dermal contact, and inhalation.

5. Risk to Aquatic Animals

a. Toxicity (Hazard) Assessment

Toxicity values for risk calculations for all aquatic assessments are given in Table 20. Based on toxicity studies with aquatic species submitted by the registrant, oxyfluorfen is "highly toxic" to fish exposed for short or extended periods of time, "very highly toxic" to "moderately toxic" to aquatic invertebrates exposed for short or extended periods of time, and "highly toxic" to aquatic plants.

Table 20. Summary of toxicity values for aquatic risk assessments.

Test Species	% a.i.	Endpoint	Toxicity Category and/or Most Sensitive Endpoint	MRID
Acute Freshwater				
Bluegill Sunfish	94.0	96-hr LC_{50} = 200 µg/L	Highly toxic	Acc. 95583
Daphnia magna	23.2	48-hr EC_{50} = 80 µg/L	Very highly toxic	Acc. 96881
Acute Estuarine/Marine				
Sheepshead Minnow	71.4	96-hr LC_{50} > 170 µg/L	Highly toxic	416988-01
Grass shrimp	74.0	96-hr LC_{50} = 32 µg/L	Very highly toxic	309701-17
Chronic Freshwater				
Fathead Minnow	71	NOAEC = 38 µg/L LOAEC = 74 µg/L	Survival, larval length and weight	921360-57[a]
Daphnia magna	71.8	NOAEC = 13 µg/L LOAEC = 28 µg/L	growth (length), reproduction	421423-05[b]
Aquatic Plants				
Selenastrum capricornutum	23.2	96-hr EC_{50} = 0.29 µg/L	reduction in growth	452713-02

[a] Also reviewed under Acc. 99270.
[b] Raw data submitted under MRID 455502-01.

b. Exposure and Risk

For exposure to aquatic animals, EPA considers surface water only since most organisms are not found in ground water. Surface water models are used to estimate exposure to freshwater

aquatic animals since monitoring data are generally not targeted studies on small water bodies and primary streams where many aquatic animals are found. The modeling results used in risk calculations are detailed in the EFED chapter.

The Agency used PRZM-EXAMS to calculate refined EECs. The Pesticide Root Zone Model (PRZM, version 3.12) simulates pesticides in field runoff and erosion, while the Exposure Analysis Modeling System (EXAMS, version 2.7.95) simulates pesticide fate and transport in an aquatic environment (one hectare body of water, two meters deep). EECs were calculated for surface water using the highest application rate on non-bearing citrus, apples, grapes, walnuts, cotton, and cole crops. Although this only represents a portion of the crops for which oxyfluorfen has a labeled use, it does represent crops with higher application rates and crops which have a large percentage of their total acreage treated with oxyfluorfen. By encompassing crops with large percentages of acreage treated with oxyfluorfen and a large geographic area, some crops with lower maximum application rates were also included in the set of scenarios.

For freshwater and estuarine fish, the acute and chronic risk LOCs are not exceeded. For freshwater invertebrates, the acute risk LOC of 0.5 is exceeded for two citrus scenarios with higher application rates (RQs $\leq$0.62). For estuarine invertebrates, the acute risk LOC of 0.5 is exceeded for all citrus scenarios (RQs $\leq$1.56). Though oxyfluorfen is highly toxic to all fish and invertebrate species tested, the RQs calculated from EECs derived from Tier II simulations suggest little potential for acute risk to fish or invertebrates.

Of the scenarios modeled, there were no Chronic Risk LOC exceedences for freshwater fish. For freshwater invertebrates, the Chronic LOC was exceeded in all Florida citrus scenarios and for the maximum application rate on New York grapes.

Table 21. Acute/Chronic Risk Quotients for Aquatic Species

Crop (Site)	Max Single App. Rate (lbs ai/A)	Max No. of Apps./ Method Type	Freshwater				Estuarine/ Marine
			Acute RQ		Chronic RQ		Acute RQ
			Fish	Invert.	Fish	Invert.	Invert.
Citrus (Florida)	2.0	2/ground	0.25**	0.62***	0.67	2.35+	1.56***
Apples (Oregon)	2.0	1/ground	0.04	0.10**	0.10	0.38	0.25**
Grapes (New York)	2.0	1/ground	0.10**	0.25**	0.33	1.11+	0.61***
Walnut (California)	2.0	1/ground	0.02	0.04	0.11	0.82	0.10*
Cotton (Mississippi)	0.5	1/aerial 1/ground	0.02	0.06* 0.06*	0.08 0.09	0.29 0.27	0.15** 0.14**
Cole crops (California)	0.25	1/aerial 1/ground	0.01	0.02	0.02	0.08 0.06	0.05* 0.04

* indicates an exceedence of Endangered Species LOC
** indicates an exceedence of Acute Restricted Use LOC
*** indicates an exceedence of Acute Risk LOC
+ indicates an exceedence of Chronic LOC

Limited monitoring data provide further information for the evaluation of environmental risk to aquatic organisms. Based on sampling during February 1992 in the San Joaquin River, oxyfluorfen concentrations in water were estimated to be between 0.1 and 1.0 µg/L. Using 1.0 µg/L as an EEC, the Acute Risk LOC was exceeded for aquatic plants (RQ = 3.45), but there were no acute LOC exceedences for freshwater fish (RQ < 0.01) and invertebrates (RQ = 0.01), and estuarine fish (RQ < 0.01) and invertebrates (RQ = 0.03). Long term sampling at four sites had estimated average concentrations of oxyfluorfen in water ranging from 0.01 to 0.27 µg/L, indicating a lower risk to aquatic organisms; however, localized high concentrations of oxyfluorfen have been observed. As a result of the Goal 2XL spill in the Columbia River Basin (Fifteen Mile Creek) on August 24, 2000, focused sediment and water sampling was conducted. Water and sediment samples were collected as background measures from areas thought not to be impacted by the spill. The few background water samples did not have detectable amounts of oxyfluorfen, but 2 of the 35 background sediment samples did have detectible amounts of oxyfluorfen (the highest was 541 ppb). It is important to note that these background samples were collected seven months after most oxyfluorfen applications would have occurred (oxyfluorfen is primarily applied during the dormant winter season).

6. Risk to Aquatic Plants

The RQs for all modeled scenarios currently exceed the acute risk LOC of 1.0 for freshwater algal plants, and range from 5 to 172. Risks to aquatic vascular plants cannot be assessed at this time since no data have been submitted.

Table 22. Acute Risk Quotients for Aquatic Plants*

Crop (Site)	Max Single App. Rate (lbs ai/A)	Max No. of Apps./ Method Type	Freshwater algae (Nonvascular)
			Acute RQ
Citrus (Florida)	2.0	2/ground	171.59
Apples (Oregon)	2.0	1/ground	28.38
Grapes (New York)	2.0	1/ground	67.59
Walnut (California)	2.0	1/ground	44.72
Cotton (Mississippi)	0.5	1/aerial 1/ground	16.72 15.31
Cole crops (California)	0.25	1/aerial 1/ground	5.45 4.59

* Acute toxicity for Aquatic Plants (The plant growth study on *Selenastrum capricornutum* (MRID 452713-02*)* with Goal 2XL indicated a 96-hr EC_{50} of 0.29 ppb at 23.2 % ai, classifying oxyfluorfen as "highly toxic")

a. Uncertainties in the Aquatic Assessment

There are a number of areas of uncertainty in the aquatic organism risk assessment. The risk assessment only considers the most sensitive species tested. The position of the tested species relative to the distribution of all species' sensitivities to oxyfluorfen is unknown. The aquatic plant risk assessment is based on only one species, a freshwater algae. There is a large uncertainty because the response of non-vascular plants to oxyfluorfen may be different than the response of the vascular plants to oxyfluorfen. The risk assessment only considered a subset of

possible use scenarios. Some of the labeled uses that were not modeled may have a greater risk to the environment than those included in this risk assessment. No chronic toxicity studies for estuarine fish or invertebrates were submitted to the Agency, so the toxicity of oxyfluorfen to these organisms is unknown.

Aquatic risks have not been assessed for a myriad of aquatic habitats (e.g., marshes, streams, intermittent aquatic areas) which are more extensive and are frequently more productive than 2-meter deep ponds. The benthic environment (aquatic soil environment) provides habitat to many invertebrates that provide important food sources to fish and other aquatic organisms. Based on toxicity data to invertebrates, oxyfluorfen may pose long term effects to benthic organisms. Because of oxyfluorfen's high affinity to soil, soil eroding from application areas is likely to carry bound oxyfluorfen to aquatic areas. Guideline studies for aerobic and anaerobic soil metabolism suggest oxyfluorfen is highly persistent on soil and would likely accumulate in depositing sediments. This information, combined with oxyfluorfen measurements in river suspended sediment and aquatic toxicity data, suggests benthic organisms may be impacted and aquatic habitat degraded as a result of oxyfluorfen usage. EPA is requesting a 10-day survival and growth toxicity test for sediments using freshwater sediment toxicity organisms.

Oxyfluorfen may pose risks to animals not conveyed by standard guideline toxicity studies because oxyfluorfen's mode of action suggests it may be more toxic in the presence of light (phototoxic). Oxyfluorfen, and other light-dependent peroxidizing herbicides, act in plants by producing phototoxic compounds. Toxicity studies with oxyfluorfen and other similar herbicides suggest the same phototoxic compounds may occur in animals as a result of herbicide exposure. Because guideline toxicity studies are normally conducted under relatively low, artificial light conditions, the effects of being exposed simultaneously to oxyfluorfen and sunlight are not known. To provide information on the magnitude of this effect, EPA is requesting fish phototoxicity studies be conducted for oxyfluorfen.

7. Endangered Species

The preliminary risk assessment for endangered species indicates that oxyfluorfen exceeds the endangered species LOCs for the following combinations of analyzed uses and species:

- terrestrial plants for all uses;
- avian chronic for non-bearing citrus and all applications with rates greater than 0.5 lb ai/acre/application (such as rights-of-way, apples, walnuts and grapes) based on both maximum and mean residue levels;
- mammalian chronic for non-bearing citrus, and applications with rates of 2 lbs ai/acre (such as rights-of-way, apples, walnuts and grapes) based on maximum residues;
- freshwater fish for non-bearing citrus and grapes (of those scenarios modeled); and
- estuarine fish for non-bearing citrus, apples and grapes (of those scenarios modeled); and
- freshwater invertebrates for non-bearing citrus, apples, grapes and cotton (of those scenarios modeled).

Although the endangered species LOC for estuarine invertebrates has been exceeded, there are no federally listed species in this group. Risks to endangered aquatic vascular plants cannot be assessed at this time since no acceptable toxicity test for *Lemna gibba* has been submitted to the Agency. Further analysis regarding the overlap of individual species and their behavior with each use site is required prior to determining the likelihood of potential impact to listed species.

The Agency had a consultation in 1985 (amended in 1986) with the US Fish and Wildlife Service (FWS or the Service) on oxyfluorfen (Goal 1.6E and Goal 2E) regarding its use on noncrop areas including rights-of ways, fence rows, roadsides, and levee banks. The Service found jeopardy to 76 species of endangered plants, 54 species of endangered fish, 23 species of endangered mussels (clams), two species of snails, eleven species of endangered insects, four endangered amphibians and one endangered bird (piping plover). The Service proposed a Reasonable and Prudent Alternatives (RPA) to avoid jeopardy to these species. The RPA prohibited the application of Goal within a quarter mile of the habitat of the listed plants and terrestrial invertebrates and within a quarter mile of the streams or bodies of water where the aquatic species occur.

Oxyfluorfen was included in the corn cluster consultation in 1983, and it's uses on crops and forests were also included in the "reinitiation" of clusters in 1988. The resulting 1989 opinion found jeopardy to one amphibian (the Wyoming toad which is extirpated in the wild except on FWS refuges), five fish species, two species of crustaceans and one bird species (the wood stork). The Service proposed Reasonable and Prudent Alternatives (RPA) for each of these jeopardized species. In addition, the Service had Reasonable and Prudent Measures (RPM) to reduce incidental take of 34 aquatic and three bird species. The details of the RPM recommendations are provided in the FWS 1989 biological opinion.

Acute risks to endangered birds is no longer a concern for oxyfluorfen, as the study used as the basis for the earlier findings of jeopardy to birds has since been determined to be invalid. However, many additional species, especially aquatic species, have been federally listed as endangered/threatened since the biological opinion of 1989 was written, and determination of potential effect to these species has not been assessed for oxyfluorfen. In addition, endangered plants, which were considered in the 1985 and 1986 biological opinions for the rights-of-way uses, were not considered in the 1989 opinion and need to be addressed. Finally, not only are more refined methods to define ecological risks of pesticides being used but also new data, such as that for spray drift, are now available that did not exist in 1989. The RPAs and RPMs in the 1989 opinion may need to be reassessed and modified based on these new approaches.

The Agency is currently engaged in a Proactive Conservation Review with FWS and the National Marine Fisheries Service under section 7(a)(1) of the Endangered Species Act to clarify and develop consistent processes for endangered species risk assessments and consultations. Subsequent to the completion of this process, the Agency will reassess both those species listed since the completion of the biological opinion and those not considered in the opinion. The Agency will also consider regulatory changes implemented in this RED when the reassessment is undertaken.

8. Ecological Incidents

There is one reported incident in the EIIS database with an aquatic organism effect. On August 22, 2000, Fifteen Mile Creek near the Dalles Dam in Oregon was the site of an oxyfluorfen spill. A truck carrying formulated oxyfluorfen (Goal 2XL) crashed on a bridge spilling approximately 20,000 gallons of herbicide into the creek yards from where the creek enters the Columbia River. Two weeks after the spill, samples of filtered and unfiltered water near the spill site contained an average of 32 µg/L and 340 µg/L, respectively. This spill was estimated to cause a 35% decrease in the numbers of adult chinook salmon and a 26% decrease in the numbers of steelhead passing over the Dalles Dam the day immediately following the spill, relative to the day prior to the spill. The spill was also reported to kill thousands of young lampreys. An extensive cleanup operation (removal of water and sediment) removed a majority of the chemical, and the estimated quantity of oxyfluorfen not recovered was less than 1000 gallons.

There are several reported plant incidents in the Environmental Incident Information System (EIIS) database. One incident occurred on March 7, 1996, when a pest control operator in Madera County, California, applied Roundup (glyphosate) and Goal (oxyfluorfen) to an unspecified site. These herbicides drifted to 40 acres of plums and 90-100 acres of almonds with total damage estimated at $520,000 to $760,000. A similar incident occurred in 1996 in Arkansas. A grower stated that aerial drift of Roundup Ultra and Goal damaged 160 acres of rice, and 80 acres had to be replanted. Another aerial drift incident occurred in 1996 in California. A grower stated that aerial drift of Roundup Ultra and Goal damaged 10 acres of oranges. Investigation by Monsanto representatives revealed that adequate buffer zones had not been employed. In these cases, either of these compounds may have contributed to the damage of these crops. There are 2 reported incidents of damage attributed to a home use product (Ortho GroundClear Triox). Both incidents involved damage and death to small numbers of ornamentals and juniper trees. The damage may have been caused by oxyfluorfen and/or the other active ingredient in Triox, isopropylamine salt.

The lack of reported incidents to birds, mammals, and aquatic species cannot be considered as evidence of lack of risk. For example, the major concerns for risks to birds and mammals are chronic effects. If oxyfluorfen is having a chronic impact to bird and mammal populations in the wild, observance of these effects is much less likely than if the risks of concern were acute effects (e.g., mortality).

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submissions of relevant data concerning an active ingredient, whether products containing the active ingredient

are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., an active ingredient specific) data required to support reregistration of products containing the active ingredient oxyfluorfen.

The Agency has completed its assessment of the occupational, non-occupational, and ecological risks associated with the use of pesticide products the active ingredient oxyfluorfen, as well as an oxyfluorfen-specific dietary risk assessment. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient oxyfluorfen, EPA has sufficient information on the human health and ecological effects of oxyfluorfen 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 oxyfluorfen products are eligible for reregistration provided that: (i) current data gaps and additional 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 Section V. Appendix A summarizes the uses of oxyfluorfen 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 oxyfluorfen, 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 oxyfluorfen, the Agency has determined that oxyfluorfen 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 use of oxyfluorfen. If all changes outlined in this document are incorporated into the product labels, then all current risks for oxyfluorfen will be adequately mitigated for the purposes of this determination.

B. Public Comments and Responses

When making its reregistration decision, the Agency took into account all comments received after opening of the public docket. These comments in their entirety are available in the docket (OPP #34252). Comments on the risk assessment were submitted by two registrants, Dow AgroSciences and the Scotts Company. EPA also received letters from approximately 65 growers, extension agents, and commodity organizations attesting to the importance of oxyfluorfen to their weed control programs for commodities such as forest seedlings, grapes, artichokes, various brassica and crucifer crops, Christmas trees, raspberries, blackberries, garbanzo beans, onions, ornamentals, various orchard crops, garlic, walnuts, and almonds. The majority of comments were submitted by the forestry and nursery industries, which point out that oxyfluorfen is one of the most important, if not the most important, pesticides used for weed control based on its cost effectiveness and efficacy. The Oregon Strawberry Commission submitted a comment regarding their pending Section 3 petition for use of oxyfluorfen on strawberries. Strawberry growers have used oxyfluorfen (Goal 2XL) under the Section 18 Emergency Exemption Program from 1997-2001.

The Confederated Tribes of the Warm Springs Reservation of Oregon raised concern that the dietary risk assessment for oxyfluorfen is not protective, because estimated fish consumption was based on an amount representative of the general public rather than subpopulations which may consume higher levels of fish. EPA did not address this comment in the Response to Comments documents, so this comment is being addressed here. The fish bioconcentration study suggests that accumulation would occur, but residues would depurate rapidly when fish move to clean water. In contrast, the fish monitoring data from the Columbia river (gathered as a part of the oxyfluorfen spill incident) suggests a slower depuration period. The fish in the Columbia River were not sediment dwelling but frequently contained residues greater than 10 ppb and a couple of instances over 100 ppb. It is uncertain whether or not residues were caused by the spill because the fish were collected either upstream or many miles downstream. These measurements in the Columbia River are useful in defining bioaccumulation potential since they were collected in the field and represent a variety of fish (including those eaten by tribes and recreational anglers). The Columbia River results do suggest that oxyfluorfen has the potential to accumulate in fish in the environment to a certain extent. The Office of Pesticide Programs has provided the information relevant to potential oxyfluorfen accumulation in fish to the Office of Water who will determine if state advisory actions and/or additional monitoring programs are needed. The Office of Pesticide Programs will continue to work with the Office of Water to ensure that potential exposures and risks are appropriately assessed.

Formal Agency responses to comments related to the risk assessments can be found in the following documents, which are available in the public docket: "Oxyfluorfen: Response to Public Comments to the Human Health Risk Assessment" dated May 1, 2002; "Oxyfluorfen: Response to the Occupational/Residential Exposure (ORE) Comments Submitted in Response to the 60 Day Public Comment Period" dated May 2, 2002; and "Environmental Fate and Effects Division Response to Public Comments Made by Dow AgroSciences and the California Almond Board on EFED's Risk Assessment for Oxyfluorfen" dated May 2, 2002.

C. Regulatory Position

1. FQPA Assessment

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 oxyfluorfen is within its own "risk cup." In other words, EPA has concluded that the tolerances for oxyfluorfen meet the FQPA safety standards. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the acute and chronic food exposure. An aggregate assessment was conducted for exposures through food, drinking water, and residential uses. The Agency has determines that the human health risks from these combined exposures are within acceptable levels.

Therefore, there are no changes in oxyfluorfen tolerances due to risk concerns and most tolerances will remain in effect; however, the following tolerance changes and data are necessary:

Tolerances for field corn fodder and forage are not warranted because oxyfluorfen's registered use on field corn is limited to the states of NC and SC in conjunction with a USDA program to eradicate "witchweed" (*Striga asiatica*); the treated forage and fodder of field corn are not fed to livestock to avoid the spread of the weed. With respect to animal commodities, the established oxyfluorfen tolerances for milk, fat, meat, and meat by-products of cattle, goats, hogs, horses, and sheep should be lowered from 0.05 to 0.01 ppm based on the reviewed cattle feeding study. Similarly, adjustments in the tolerance levels of the following poultry commodities are required based on the results of the poultry feeding study: eggs (from 0.05 to 0.03 ppm); meat and meat by-products (from 0.05 to 0.01 ppm); and fat (from 0.05 to 0.2 ppm). The registrant may impose label restrictions on the feeding of oxyfluorfen-treated soybean forage and hay in lieu of submitting field residue data and proposing tolerances for these soybean commodities. The Agency will establish tolerances for cotton gin byproducts, and citrus oil. Tolerances with regional registration for grass forage, grass hay, and grass seed screenings at 0.05 ppm each should also be established. The need to modify tolerances for bananas and cacao beans will be determined upon receipt of confirmatory data.

b. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for oxyfluorfen, 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, that there is a reasonable certainty of no harm for the general population. In reaching this determination, EPA has considered all available information on the toxicity, use practices, and scenarios, and the environmental behavior of oxyfluorfen. As discussed in chapter 3, the chronic dietary (food alone) risk is below the level of concern, as is the cancer dietary risk from food alone. Risks from residential exposures alone are also below the level of concern. Regarding risks from drinking water exposures, chronic risks from drinking water are not of concern for surface or groundwater supplies. Although the projected surface water concentrations exceed the Agency’s cancer concern level, the Agency believes that those projections are conservative and over-estimate the human exposure to oxyfluorfen that will result from drinking water sources from surface water (See Regulatory Rationale under Drinking Water in section IV.D.1.a.iv.).

c. Determination of Safety for Infants and Children

EPA has determined that the established tolerances for oxyfluorfen, 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 the factors 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 oxyfluorfen residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from oxyfluorfen residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. An FQPA safety factor is not required for oxyfluorfen because: 1) There does not appear to be any increased susceptibility in animals due to pre- or postnatal exposure to oxyfluorfen based upon the developmental and reproductive toxicity studies reviewed. Although two does in the high-dose group of the rabbit developmental study aborted, these abortions are considered secondary to the debilitating condition (generalized, systemic toxicity) of the mothers; 2) Although neurotoxicity studies were not performed, there was no indication of neurotoxicity in the submitted developmental and reproductive studies or in the published literature. A developmental neurotoxicity study was not required; and 3) the dietary (food and drinking water) and non-dietary (residential) exposure assessments will not underestimate the potential exposures for 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 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 effects in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allows, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, oxyfluorfen may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

e. Cumulative Risks

The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, 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." Oxyfluorfen is a diphenyl ether herbicide structurally related to lactofen, fomesafen and acifluorfen. Although chemical class is not necessarily synonymous

with a common mechanism of toxicity, structurally similar chemical substances do frequently exhibit common modes of toxicity. At this time, the Agency has not made a decision as to whether oxyfluorfen shares a common mechanism of toxicity with these other diphenyl ethers or any other pesticide. A careful evaluation of all the available data, as well as additional data on the cancer mechanism of the diphenyl ether herbicides are still needed. A peer review by the FIFRA Science Advisory Panel is also necessary before a formal decision is made. Therefore, for the purposes of this risk assessment, the Agency has assumed that oxyfluorfen does not share a common mechanism of toxicity with other pesticides. After a decision is made regarding common mechanism of toxicity, and if the Agency has determined that a cumulative assessment is necessary, the Agency will address any outstanding risk concerns at that time.

f. Tolerances Summary

A summary of the oxyfluorfen tolerance reassessments is presented in Table 23. In the assessment, tolerances for residues of oxyfluorfen in/on plant commodities [40 CFR §180.381] are presently expressed in terms of the parent only.

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

The majority of data indicate that oxyfluorfen residues in/on most plant commodities were below the LOQ (<0.01 ppm) of the data-collection method following application of oxyfluorfen formulation(s) according to maximum registered uses. At this time, EPA is reassessing most plant commodity tolerances at the established level of 0.05 ppm until an adequate single analyte enforcement method becomes available.

The need to modify tolerances for bananas and cacao beans will be determined upon receipt of confirmatory data. The reassessed tolerance for broccoli is based on residue data translated from cabbage and cauliflower. As per 40 CFR §180.1 a separate tolerance for garlic is not needed because the established tolerance for dry bulb onions will apply to garlic.

Tolerances for field corn fodder and forage are not warranted because oxyfluorfen's registered use on field corn is limited to the states of NC and SC in conjunction with a USDA program to eradicate "witchweed" (*Striga asiatica*); the treated forage and fodder of field corn are not fed to livestock to avoid the spread of the weed.

With respect to animal commodities, the established oxyfluorfen tolerances for milk, fat, meat, and meat by-products of cattle, goats, hogs, horses, and sheep should be lowered from 0.05 to 0.01 ppm based on the reviewed cattle feeding study. Similarly, adjustments in the tolerance levels of the following poultry commodities are required based on the results of the poultry feeding study: eggs (from 0.05 to 0.03 ppm); meat and meat by-products (from 0.05 to 0.01 ppm); and fat (from 0.05 to 0.2 ppm).

An oxyfluorfen tolerance for cotton gin byproducts must be proposed once adequate field residue data, reflecting the maximum registered use pattern, have been submitted and evaluated. The registrant may impose label restrictions on the feeding of oxyfluorfen-treated soybean forage and hay in lieu of submitting field residue data and proposing tolerances for these soybean commodities.

Adequate data are available to reassess the established tolerances with regional registrations for the following commodities, **as defined**: blackberry, garbanzo beans, guava, papaya, raspberry, and taro (corms and leaves).

Table 23. Tolerance Reassessment Summary for Oxyfluorfen.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.381 (a):			
Almond hulls	0.1	0.1	*[Almond, hulls]*
Artichokes	0.05	0.05	*[Artichoke, globe]*
Avocados	0.05	0.05	*[Avocado]*
Bananas (including plantain)	0.05	TBD [1]	*[Banana (including plantain)]*
Broccoli	0.05	0.05	The registrant may wish to propose a crop group tolerance of 0.05 ppm for Head and stem Brassica subgroup.
Cabbage	0.05	0.05	
Cauliflower	0.05	0.05	
Cattle, fat	0.05	0.01	
Cattle, mbyp	0.05	0.01	
Cattle, meat	0.05	0.01	
Cocoa beans	0.05	TBD [1]	*[Cacao bean]*
Coffee	0.05	0.05	*[Coffee bean, green]*
Corn, grain	0.05	0.05	*[Corn, field, grain]*
Cottonseed	0.05	0.05	*[Cotton, undelinted seed]*
Dates	0.05	0.05	*[Date]*
Eggs	0.05	0.03	
Feijoa	0.05	0.05	*[Feijoa (pineapple guava)]*
Figs	0.05	0.05	*[Fig]*
Garlic	--	0.05	
Goat, fat	0.05	0.01	
Goat, mbyp	0.05	0.01	
Goat, meat	0.05	0.01	
Grapes	0.05	0.05	*[Grape]*
Hogs, fat	0.05	0.01	
Hogs, mbyp	0.05	0.01	
Hogs, meat	0.05	0.01	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Horseradish	0.05	0.05	
Horses, fat	0.05	0.01	
Horses, mbyp	0.05	0.01	
Horses, meat	0.05	0.01	
Kiwifruit	0.05	0.05	
Olives	0.05	0.05	*[Olive]*
Onions (dry bulb)	0.05	0.05	*[Onion, dry bulb (only)]*
Milk	0.05	0.01	
Mint hay (peppermint and spearmint)	0.1	0.05	Separate tolerances should be established, each at 0.05 ppm for: *[Peppermint, tops] [Spearmint, tops]*
Persimmons	0.05	0.05	*[Persimmon]*
Pistachios	0.05	0.05	*[Pistachio]*
Pome fruits group	0.05	0.05	*[Fruit, Pome, Group]*
Pomegranates	0.05	0.05	*[Pomegranate]*
Poultry, fat	0.05	0.2	
Poultry, mbyp	0.05	0.01	
Poultry, meat	0.05	0.01	
Sheep, fat	0.05	0.01	
Sheep, mbyp	0.05	0.01	
Sheep, meat	0.05	0.01	
Soybeans	0.05	0.05	*[Soybean]*
Stone fruits group	0.05	0.05	*[Fruits, Stone, Group]*
Tree nuts group (except almond hulls)	0.05	0.05	*[Nuts, Tree, Group]* For tolerance reassessment counting purposes walnut was counted separately because it had been listed separately in the Tolerance Index System .
Tolerances To Be Proposed Under 40 CFR §180.381 (a):			
Cotton, gin byproducts	None	TBD [1]	New RAC according to Table 1 (OPPTS 860.1000).
Soybean forage	None	TBD [1]	A feeding restriction may be established in lieu of proposing tolerances.
Soybean hay	None	TBD [1]	
Tolerances Listed Under 40 CFR §180.381 (c):			
Blackberry	0.05	0.05	Recently established under PP#5E04429 (60 FR 62330, 12/6/95)
Garbanzo beans	0.05	0.05	*[Chickpea (bean, garbanzo)]*
Guava	0.05	0.05	
Papaya	0.05	0.05	
Raspberry	0.05	0.05	Recently established under PP#5E04429 (60 FR 62330, 12/6/95)

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Taro (corms and leaves)	0.05	0.05	Separate tolerances should be established, each at 0.05 ppm for: *[Taro, corm]*, *[Taro, foliage]*
Tolerances To Be Proposed Under 40 CFR §180.381 (c)			
Grass Forage, Grass Hay, and Grass Seed Screenings	None	0.05	Separate tolerances should be established, each at 0.05 ppm for grass forage, grass hay and grass seed screenings

TBD = To be determined. This term means the tolerance to be set will be safe. However, additional confirmatory data are needed to be able to set the tolerance level.

Residue Analytical Methods

The Pesticide Analytical Manual (PAM) Vol. II lists two GLC/electron capture detector (ECD) methods, designated as Methods I and II, for the enforcement of tolerances for oxyfluorfen residues in/on plant and animal commodities, respectively. Both methods determine levels of oxyfluorfen and its reduced metabolites by a common moiety (as heptafluorobutyryl derivatives of oxyfluorfen). The tolerance expression for oxyfluorfen was amended (60 FR 62330, 12/6/95) to delete the metabolites of oxyfluorfen containing the diphenyl ether linkage. The established tolerances for plant and animal commodities [40 CFR §180.381 (a), (b), and (c)] are now expressed in terms of oxyfluorfen *per se* [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene]. Because oxyfluorfen *per se* is now the residue of concern, the PAM Vol. II methods are no longer suitable for enforcement purposes.

EPA recommends that FDA's Multiresidue Methods for oxyfluorfen *per se* be utilized as the primary enforcement method for plant commodities until the registrant submits a proposed enforcement method for plants to determine oxyfluorfen *per se*. An enforcement method for the determination of oxyfluorfen *per se* in animal commodities is required as FDA's Multiresidue Methods are not suitable for animal commodities.

New single analyte methods are being proposed for determination of residues of oxyfluorfen *per se* for enforcement and data collection purposes. In conjunction with a pending tolerance petition (PP#3F4229/FAP#3H5674) on peanut, the registrant proposed a GC/ECD method (Method TR 34-94-150, renamed as Method TR-34-95-111) including a confirmatory GC/MS method for the enforcement of oxyfluorfen tolerances on plant commodities. The stated limits of quantitation (LOQ) and detection (LOD) for Method TR-34-95-111 are 0.01 ppm and 0.003 ppm, respectively, except on peanut vine, shell, and hay for which the reported LOQ and LOD are 0.02 ppm and 0.007 ppm, respectively. Method TR 34-95-111 was adequately validated by the registrant using a wide array of plant matrices and by an independent laboratory using peanut nutmeat. The method will be forwarded to the Biological and Economic Analysis Division's Analytical Chemical Laboratory for a petition method validation trial to ensure that the procedures are appropriate for tolerance enforcement.

Also in conjunction with PP#3F4229/FAP#3H5674, the registrant proposed a GC/ECD method (Method TR 34-95-110) including a confirmatory GC/MS method for the enforcement of oxyfluorfen tolerances on animal commodities. The stated LOQ and LOD for Method TR-34-95-110 are 0.01 ppm and 0.003 ppm, respectively, for all animal commodities. Method TR 34-95-110 was adequately validated by the registrant using a variety of animal matrices and by an independent laboratory using milk and chicken fat. The method was also successfully radiovalidated using aged samples from the hen and goat metabolism studies. EPA will forward Method TR 34-95-110 to the Biological and Economic Analysis Division's Analytical Chemical Laboratory (ACL) for a petition method validation trial.

D. Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the current use of oxyfluorfen. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

No adverse effects reflecting a single dose were identified; therefore, no acute endpoint was selected and an acute dietary risk assessment was not conducted. A refined Tier 3 dietary risk assessment using the Dietary Exposure Evaluation Model (DEEM^{TM}) was completed for chronic food exposure. The DEEM^{TM} analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-91 Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. For all analyses, anticipated residues and percent of crop treated data were used.

(1) Chronic Dietary (Food)

The chronic dietary analysis utilized USDA Pesticide Data Program (PDP) monitoring data, field trial data, and percent crop treated information. Based on that analysis, the percentage of cPAD utilized is expected to be less than 1 percent for the U.S. population and all subpopulations. Therefore, the chronic dietary (food) risk estimate is not of concern, and no mitigation measures are needed.

(2) Cancer Dietary (Food)

A cancer dietary exposure and risk analysis was performed based upon revised cancer Q_1* of 7.32×10^{-2} derived from a mouse carcinogenicity study and upon Agency analyses of anticipated residues in food. Based on that analysis, which yielded a cancer risk of 3.8×10^{-7}, the Agency has concluded that the cancer dietary risk from food alone is not of concern ($< 1 \times 10^{-6}$), and that no mitigation measures are needed to address the cancer food risk.

(3) Drinking Water

As previously mentioned, acute endpoints were not established for oxyfluorfen and an acute drinking water assessment was not performed. The Agency has determined that there are no chronic (non-cancer) drinking water concerns, as the chronic EECs are substantially less than the DWLOCs for all populations (see Section III.A.2). However, the Agency risk assessment shows potential dietary cancer risks of concern for drinking water derived from surface waters. This assessment was based on modeling simulations which predict that oxyfluorfen residues in surface waters have a 36-year annual mean concentration of 5.7 ppb. In comparison, the cancer DWLOC based on food exposure is 0.315 ppb.

EPA believes that the DWLOC based on food exposure is upper-bound because PDP and field trial residue data show all non-detectable residues, and ½ the LOQ was used in the dietary (food) assessment which overestimates residue values. EPA used ½ LOQ rather than ½ LOD for field trial residue values because of the possibility of an occasional residue of oxyfluorfen greater than 0.01 ppm, and the registrant's intention to propose a new single analyte enforcement method for oxyfluorfen with a quantitation limit of 0.02 ppm. Actual residues are expected to be somewhere in between the calculated estimates and zero.

The Agency also believes that the modeling simulations over-estimate exposures through drinking water. First, the model input variables assumed maximum use rates and frequencies. Usage data indicate that typical use rates are below maximum use rates by approximately 50%. Secondly, the modeling assumed that the 2 lb ai/acre application rate was being applied as a broadcast treatment; however, oxyfluorfen is typically applied as a banded application between rows of crops. Careful targeting of the spray is required because oxyfluorfen is non-selective and will damage crops. The maximum use rate for crops *per acre of total land area treated* is generally around 1.0 lb ai/acre. There are oxyfluorfen use sites that are broadcast treated rather than banded, such as bulb vegetables or fallow land, but these sites have a lower maximum rate, typically 0.5 lbs ai/acre/season. Nut trees may also require broadcast treatment to clear the orchard floor before harvest, but typically at a rate of 0.5 lbs ai/acre.

Monitoring data also indicate that concentrations may be lower than what was estimated with the PRZM/EXAMS model. For example, USGS conducted monitoring of oxyfluorfen bound to suspended sediment for several years in central California, within an area of high usage. The highest average concentration of oxyfluorfen associated with the suspended sediment was 27.2 ppb. From this monitoring, it is estimated that approximately 0.27 ppb of oxyfluorfen may be available in the water, assuming reversible partitioning with an average Kd partitioning coefficient of 100.

These water monitoring results are useful, but do not negate the need for targeted water monitoring. The monitoring data available are not adequate because the data are mainly limited to sediment levels, they are limited to only a few locations, and the data are temporally limited; samples were often taken outside the major use season. Also, the samples collected as a result of the August 24, 2000 spill in Oregon indicated that a sediment detection of 541 ppb was found in

a nearby creek believed to be unaffected by the spill and downstream from orchards. EPA needs additional information to ascertain whether this detection was actually related to the spill or due to the presence of the upstream orchards.

In response to potential dietary cancer risks from drinking water derived from surface waters, the registrants have agreed to several measures which are expected to decrease the amount of oxyfluorfen reaching surface water:

- The maximum seasonal application rate for oxyfluorfen use on food crops is currently 2 lbs ai/broadcast acre/season[2]. Registrants have agreed to lower this maximum rate to 1.5 lbs ai/broadcast acre/season and 2 lbs ai/acre/season for conifer seedlings. The time interval of the total chemical applied is inconsistent and unclear on some labels, and for some uses the maximum poundage to be applied per year or the maximum number of applications per year is not specified (e.g. right-of-way). The maximum poundage of the chemical applied per acre must be given on a calendar year basis for all uses, or the terms "season" and "growing season" must be clearly defined on the labels.

- The maximum seasonal application rate for oxyfluorfen use on ornamentals is currently 8 lbs ai/A. For liquid formulations and granulars applied to field-grown ornamentals, registrants have agreed to lower this seasonal maximum rate to 4.5 lbs ai/A (1.5 lbs ai/A/application). For granulars applied to containerized ornamentals, the rate will be lowered to a seasonal maximum of 6 lbs ai/A (2 lbs ai/A/application).

- Labeling will clearly limit the seasonal maximum rate for conifer seedlings to 2 lbs ai/acre. Information provide by conifer seedling growers indicate the need for greater than 1.5 lbs ai/acre, particularly in the South. Since conifer seedling nurseries tend to be relatively small operations (20 to 40 acres) and only about 2,500 acres are in U.S. production, EPA concludes that the 2 lb ai/acre/season rate is appropriate and will add negligible risk.

- Label language will be added to require 25 foot, no-spray, vegetative buffer zones around surface water bodies such as rivers, lakes, streams, and ponds.

- Spray requirements will be added to labels to minimize oxyfluorfen drift. Only use of a coarse, very coarse, or extremely coarse spray will be allowed according to the ASAE 572 definitions for standard nozzles, or a volume median diameter (VMD) of 385 microns or larger for spinning atomizer nozzles.

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[2] Use rates are higher (up to 6 lbs ai/broadcast acre/season) for some Hawaiian commodities such as guava, coffee, and macadamia nuts because high humidity, heat, and rain require a higher single application rate and more frequent applications. EPA is not concerned with surface water contamination for drinking water risk purposes because drinking water sources are predominately groundwater in Hawaii. The higher rates are addressed in more detail in the ecological risk mitigation section.

The registrant (Dow AgroSciences) has further agreed to conduct a tiered surface water monitoring study to provide additional information on potential drinking water contamination. The initial tier consists of an edge-of-field water and sediment monitoring in a limited number of vulnerable sites around the country. Vulnerability would be based on soil types, historical precipitation levels, and/or other relevant factors. Study sites as well as the monitoring study protocol would be agreed upon by the registrant and the Agency in advance of study initiation. Higher tiers (e.g., full scale monitoring study at drinking water treatment plants) would be initiated based on the results of the initial monitoring.

(4) Aggregate Risk Mitigation (short-term, chronic, and cancer)

The short-term aggregate risk assessment considers exposures from food, drinking water, and residential exposures. As shown in Section III.A.4, surface and ground water concentrations (7.1 ppb and 0.08 ppb respectively), estimated using modeling, are below the short-term DWLOCs of 8900 ppb (females) and 10400 ppb (males). Consequently, there are no short-term aggregate risks of concern.

The chronic (non-cancer) aggregate risk assessment addresses exposure to oxyfluorfen residues in food and water only, as there are no chronic residential scenarios identified. The lowest DWLOC of 300 is substantially higher than the estimated environmental concentrations of oxyfluorfen in surface and groundwater (7.1 ppb and 0.08 ppb respectively). Consequently, the Agency concludes that residues of oxyfluorfen in food and drinking water do not result in a chronic aggregate risk of concern.

To evaluate cancer aggregate risk, the chronic food cancer risk estimate combined with the highest residential cancer risk estimate results in a food + residential cancer risk of 1.3×10^{-6}. Since the Agency's level of concern is 1.0×10^{-6}, this cancer risk exceeds EPA's level of concern when considering just food and residential exposures combined. As stated previously, the exposure and risk estimate from food is upper-bound as all field trial and PDP samples contained non-detectable residues of oxyfluorfen. Therefore, no mitigation measures are necessary to address dietary risk from food due to aggregate risk concerns.

Although residential cancer risk alone is not of concern ($< 1.0 \times 10^{-6}$), it contributes to aggregate risk. It is realistic to assume that residential applicators are only applying 1 gallon/year with a trigger sprayer; therefore, the highest residential cancer risk is 6×10^{-7} for spot treatment of weeds using a low pressure tank sprayer. Currently, residential rates (4.5 to 8.9 lbs ai/acre) are considerably higher than agricultural rates (2 lbs ai/acre). The Scotts Company, a registrant of two oxyfluorfen residential products, has stated that a 4.5 lb ai/acre rate is necessary to control perennial grassy weeds and for effective residual control. The registrant is conducting efficacy trials to support appropriate residential use rates. In response to the residential/aggregate cancer risks, the registrants have agreed to several measures which are expected to decrease the amount of oxyfluorfen used in residential settings:

- The maximum application rate on residential products will be reduced to 3 lbs ai/A or less unless efficacy data support the need for higher rates. This measure will bring the residential rates in line with the highest rate (2 lb ai/A/season) needed for efficacy in agricultural use scenarios. EPA will consider the results of the efficacy studies to determine whether the data support a different rate.

Notwithstanding the food + residential risk estimate, aggregate cancer risk is still of concern because surface water modeling indicates that there may be a risk exceedence from oxyfluorfen in drinking water alone. The Agency believes this risk can be reduced by implementing the risk mitigation actions previously mentioned under drinking water risk management. The modeled drinking water concentrations are believed to be high-end estimates that may not represent levels that people actually consume in finished drinking water (for reasons discussed earlier in the drinking water sections of this document). However, the extent to which the modeling may overestimate surface water concentrations is not known and additional information is necessary. The registrants of oxyfluorfen must submit edge-of-field water and sediment monitoring. Pending review of these studies, no additional mitigation measures are necessary to address drinking water concerns at this time.

b. Occupational Risk Mitigation

(1) Handler Risks

Handler exposure assessments are completed by EPA using a baseline exposure scenario and, if required, increasing levels of mitigation (PPE and engineering controls) to achieve an adequate margin of exposure (MOE). For oxyfluorfen the target MOE is 100 or greater for short-term risks and 300 or greater for intermediate-term risks. Analyses for handler/applicator exposures were performed using PHED. These calculations indicate that the MOEs for most mixing/loading scenarios and the Right-of-Way application scenario are below 100 at the baseline level and exceed EPA's level of concern. At the single layer PPE level (which includes chemical resistant gloves), all of the scenarios have MOEs of 490 or greater. Cancer risks to handlers are of greater concern than non-cancer risks; therefore, risk mitigation measures will be determined based on the cancer risk assessment for occupational handlers.

Occupational cancer risks greater than 1×10^{-4} are of concern. For risks between 10^{-6} and 10^{-4}, EPA carefully evaluates exposure scenarios to seek cost effective ways to reduce cancer risks to the greatest extent feasible, preferably to a risk of 1×10^{-6} or less.

At baseline and single-layer PPE, cancer risks for all handler scenarios are greater than 1×10^{-6}, but less than 1×10^{-4}. Assuming the use of double layer protective clothing currently on some oxyfluorfen labels, most cancer risks are in the 10^{-5} range.

To address cancer risks to agricultural handlers, EPA has determined that the following mitigation measures are necessary, reasonable, and cost-effective:

- closed mixing/loading systems to support applications to corn, cotton, soybeans, and aerial applications to fallow land;
- enclosed cab for applications to corn, and closed cockpit aircraft for applications to fallow land; and
- double layer PPE for all other mixers, loaders, and applicators.

For high-acreage crops such as corn, cotton, and soybeans, engineering controls for mixing and loading, and closed cabs are increasingly common for exposure reduction as well as for comfort and increased efficiency of mixing and transferring high volumes of chemicals necessary to treat large fields. Also, EPA understands that virtually all agricultural aviators currently use closed-cockpit aircraft. As such, EPA believes that these requirements are cost effective and appropriate.

Likewise, EPA has determined that the use of engineering controls for additional handler scenarios would further reduce exposure to handlers, but for some scenarios, such as mixing/loading and applying with handheld (backpack) equipment and applying with Right-of-Way spray equipment, engineering controls are not currently available. For other scenarios, such as mixing/loading to support applications to perennials including tree fruit, nut, and vine crops, while some engineering controls may be available they are not common with the equipment typically used to make ground-directed herbicide applications in these crops. Such equipment tends to be smaller and less sophisticated than the equipment used for foliar sprays of fungicides and insecticides. EPA encourages the use of engineering controls in all settings where practical and feasible, and allows for handlers to reduce PPE when engineering controls are used. But EPA concludes that the risk-reduction potential of requiring engineering controls for additional scenarios would not be commensurate with the costs and difficulties associated with implementing the requirement.

(2) Post-application Exposure

Oxyfluorfen is a non-selective herbicide that can cause leaf damage to most of the labeled crops. For this reason, the liquid product labels specify that it should be applied to the ground in such a manner as to minimize crop damage and the granular product labels specify that it should be watered in to rinse the granules off of the foliage. With the exceptions of bulb vegetables and conifers, which have more tolerance to oxyfluorfen, over the top applications are not recommended. Based upon these factors it was determined that re-entry workers would only have significant post-application exposure following applications of oxyfluorfen to conifer seedlings, conifer trees and bulb vegetables.

The Restricted Entry Interval (REI) represents the amount of time required for residues to dissipate in treated areas prior to beginning a job or task in that area such that the resulting exposures do not exceed the Agency's level of risk concern. In order to determine the REI for a crop, EPA calculates the number of days that must elapse after pesticide application until residues dissipate and risk to a worker falls below the target risk estimate. For a specific crop/pesticide combination, the duration required to achieve the target risk estimate can vary depending on the activity assessed.

To address potential risks to post-application workers, the Agency is modifying the REIs for oxyfluorfen as described in Table 24 below. Since the conifer REIs are based on the chemical-specific DFR study which has serious deficiencies, a confirmatory DFR study on conifers is necessary.

For all post-application commercial worker exposure scenarios, the proposed REIs provide estimated dermal MOEs greater than the target MOE of 300. Although the estimated cancer risks for some of the scenarios are slightly above the 1×10^{-6} target value, they are still in the 10^{-6} range, and the Agency believes these REIs provide an acceptable level of protection without disruption to needed cultural practices.

Table 24. Restricted Entry Intervals (REIs) for Oxyfluorfen

Crop	Pre-harvest Interval (days)	REI (days)	Comments
Bulb vegetables	45 (dry bulb onion) 60 (onions grown for seed) 60 (dry bulb garlic) 6 months (taro)	2	A two day REI results in a cancer risk estimate of 2.7×10^{-6}.
Conifer seedlings	N/A	3	A three day REI results in a cancer risk estimate of 3.1×10^{-6}.
Conifer trees	N/A	6	An REI of 6 days results in a cancer risk estimate of 1.8×10^{-6} for low exposure activities (e.g. irrigation, scouting, hand weeding) and 5.4×10^{-6} for medium exposure activities (shearing). Since oxyfluorfen is applied to weeds in Christmas tree plantations in a semi-directed manner to reduce tree contact, only the lower branches typically receive overspray. Therefore, the risk estimates for Christmas tree shearing are probably conservative.
All other crops	N/A	24 hours	Current Labeling

Scouting is a handler activity under the WPS, so anyone performing this activity may legally enter the treated field during the REI provided they use the handler personal protective equipment (PPE) specified on the label. In addition, if the scout is a certified crop advisor as defined in the WPS [40 CFR 170.204(b)], the individual can determine the appropriate PPE to be used. For many of these crops, irrigation equipment is not routinely moved by hand. For these methods, the primary activity involves entering the field to turn the watering equipment on and off. This activity is allowed during the REI under the no contact exception to WPS [40 CFR 170.112(b)]. Should irrigation equipment need unexpected repairs during the REI, WPS allows workers to enter a treated field provided early entry PPE is used [40 CFR 170.112(c)]. This exception also usually applies to mechanical harvesting and tree shaking for nut crops in enclosed cabs.

2. Environmental Risk Mitigation

a. Risk Characterization

(1) Aquatic Organisms

Oxyfluorfen has the potential to affect aquatic ecological systems at all levels, as it is toxic to plants, invertebrates, and fish, and exceeds the LOCs based on modeled EECs. For freshwater invertebrates, the chronic level of concern was exceeded in all Florida citrus scenarios, as well as for the maximum application rate on New York grapes. For estuarine invertebrates, the acute risk level of concern is exceeded for all citrus scenarios. Based on toxicity data to invertebrates, oxyfluorfen may pose long term effects to benthic (soil dwelling) aquatic organisms; however, data on persistence and toxicity in the benthic environment is poor. Dissolved oxyfluorfen concentrations are expected to be relatively low in runoff water. However, because of oxyfluorfen's high affinity to soil, soil eroding from application areas is likely to carry bound oxyfluorfen to aquatic areas.

The RQs for all modeled scenarios exceed the acute risk level of concern for freshwater algal plants. The risk to vascular aquatic plants cannot be assessed due to lack of data.

(2) Terrestrial Organisms

For acute exposures, oxyfluorfen is practically non-toxic to birds, mammals, and bees, and the Agency has no risk concerns. However, subchronic and chronic risks to terrestrial birds and mammals do present a concern. These toxic effects may be manifested as reproductive, developmental, and hemolytic consequences. Assuming maximum residue values, the chronic level of concern is exceeded when oxyfluorfen is applied to crops at application rates greater than or equal to 0.25 lbs ai/acre/year for birds and greater than or equal to 2.0 lbs ai/acre for mammals.

Oxyfluorfen is expected and has been shown to negatively impact seedling emergence and vegetative vigor of terrestrial plants. Non-target terrestrial plants are exposed to oxyfluorfen as a result of spray drift and runoff and most incidents reported to the Agency are related to plants affected by spray drift. Acute levels of concern are exceeded for all uses of oxyfluorfen for terrestrial plants and semi-aquatic plants adjacent to treated areas.

(3) Endangered Species

The preliminary risk assessment for endangered species indicates that oxyfluorfen exceeds the endangered species LOCs for the following combinations of analyzed uses and species:

- terrestrial plants for all uses;

- avian chronic for non-bearing citrus and all applications with rates greater than 0.5 lb ai/acre/application (such as rights-of-way, apples, walnuts and grapes) based on both maximum and mean residue levels;
- mammalian chronic for non-bearing citrus, and applications with rates of 2 lbs ai/acre such as rights-of-way, apples, walnuts and grapes) based on maximum residues;
- freshwater fish for non-bearing citrus and grapes (of those scenarios modeled); and
- freshwater invertebrates for non-bearing citrus, apples, grapes and cotton (of thosescenarios modeled).

Based on the available data, oxyfluorfen acute toxicity, RQs, and LOC exceedences for estuarine/marine fish were assumed to be similar to that of freshwater fish. Although the endangered species LOC for estuarine invertebrates has been exceeded, there are no federally listed species in this group. Risks to endangered aquatic vascular plants cannot be assessed at this time since no acceptable toxicity test for *Lemna gibba* has been submitted to the Agency.

(4) Mitigation Measures

Those same mitigation measures that will reduce drinking water exposure will also reduce exposure to non-target organisms. A reduction in maximum seasonal rates from 2.0 lbs ai/broadcast acre to 1.5 lbs ai/broadcast acre will protect both aquatic and terrestrial organisms. The maintained 25 foot vegetative buffer strip is designed to reduce the potential for oxyfluorfen to contaminate water through runoff. The buffer strips in combination with use of only coarse, very coarse, or extremely coarse spray will also reduce exposure to aquatic organisms through spray drift. The water and sediment monitoring will further refine the exposure potential for aquatic and sediment-dwelling species.

3. Other Label Statements

In order to be eligible for reregistration, various use and safety information must also be placed on the labeling of all end-use products containing oxyfluorfen. For the specific labeling statements, refer to Section V of this document.

a. Endangered Species Statement

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 to affect any particular species, EPA puts basic toxicity and exposure data developed for REDs into context for individual listed species and their locations by evaluating important ecological parameters, pesticide use information, the geographic relationship between specific pesticides uses and species locations, and biological requirements and behavioral aspects of the particular species. This analysis will take into consideration any regulatory changes

recommended in this RED that are being implemented at that time. 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.

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. These Pamphlets are available for voluntary use by pesticide applicators, on EPA's web site at www.EPA.gov/espp . A final Endangered Species Protection Program, which may be altered from the interim program, is scheduled to be proposed for public comment in the Federal Register in 2002.

b. Spray Drift Management

The Agency is in the process of developing more appropriate label statements for spray, and dust drift control to ensure that public health, and the environment is protected from unreasonable adverse effects. In August 2001, EPA published draft guidance for label statements in a pesticide registration (PR) notice ("Draft PR Notice 2001-X" http://www.epa.gov/ PR_Notices/#2001). A *Federal Register* notice was published on August 22, 2001, 66 FR 44141 (http://www.epa.gov/fedrgstr) announcing the availability of this draft guidance for a 90-day public comment period. After receipt, and review of the comments, the Agency will publish final guidance in a PR notice for registrants to use when labeling their products.

Until EPA decides upon, and publishes the final label guidance for spray, and dust drift, the registrant for oxyfluorfen has agreed to add the following spray drift related language, in part to address concerns of surface water runoff of oxyfluorfen.

> A 25 ft. vegetative buffer strip must be maintained between all areas treated with this product and lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds.
>
> "Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, non-target crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals.
>
> For groundboom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy and when wind speed is 10 mph or less at the application site as measured by an anemometer.
>
> Use coarse spray according to ASAE 572 definition for standard nozzles or VMD of 475 microns for spinning atomizer nozzles.
>
> The applicator also must use all other measures necessary to control drift."

V. What Registrants Need to Do

The Agency has determined that oxyfluorfen is eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this interim decision; and (ii) the risk mitigation measures outlined in this document are adopted, and 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 V.D below. The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

A. For oxyfluorfen technical grade active ingredient products, registrants need 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 John Leahy at (703) 305-6703 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed:

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

By express or courier service:
Document Processing Desk (DCI/SRRD)
John Leahy
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

B. For products containing the active ingredient oxyfluorfen registrants need 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 25 of this document;

(4) a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

(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 Bonnie Adler at (703) 308-8523 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

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

By express or courier service only:
Document Processing Desk (PDCI/PRB)
Bonnie Adler
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

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

OPPTS GLN 870.3200: 21-day Dermal Toxicity Study in Rats
OPPTS GLN 870.3465: 90-day Subchronic Inhalation Toxicity
OPPTS GLN 860.1200: (Directions for Use) - Label revisions are required
OPPTS GLN 860.1500: Crop Field Trials in Bananas and Cacao Beans
OPPTS GLN 850.1400: Estuarine/marine Fish Early-life Stage
OPPTS GLN 850.1735: Whole sediment acute toxicity invertebrates, Fresh Water
OPPTS GLN 850.1740: Whole sediment acute toxicity invertebrates, Estuarine/marine
OPPTS GLN 850.1300: Daphnid Chronic Toxicity
OPPTS GLN 850.2300: Avian Reproduction Studies, Quail and Duck
OPPTS GLN 850.4225: Seed Germination/seedling Emergence
OPPTS GLN 850.4250: Vegetative Vigor
OPPTS GLN 850.4400: Aquatic Plant Growth
OPPTS GLN 875.2100: Dislodgeable Foliar Residue Study in Conifers

Non-Guideline Studies:

Fish Phototoxicity Study. Oxyfluorfen has a light dependent peroxidase and may be more toxic to fish in clear natural waters than the guideline fish acute toxicity study would indicate. This study should quantify any additional toxicity which is light induced.

Edge of Field Water and Sediment Monitoring. Simple initial tier study to determine oxyfluorfen residues in drinking water. Monitoring of drinking water is reserved pending the results of this study.

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 MP labeling should bear the labeling contained in Table 25 at the end of this section.

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. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then 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, accompanies this RED.

2. Labeling for End-Use Products

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 25.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 12 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 24 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; *Federal Register*, Volume 56, No. 123, June 26, 1991.

D. Required Labeling Changes Summary Table

Table 25 Summary of Required Labeling Changes for Oxyfluorfen

Description	Required Labeling	Placement on Label
Manufacturing Use Products		
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	"Only for formulation into an herbicide for the following use(s): artichokes (globe), broccoli, cabbage, cauliflower, cacao, citrus (non-bearing), coffee, conifers (seedbeds, transplants, container stock) and selected deciduous trees, corn, cotton, cottonwood, eucalyptus, fallow bed (cotton/soybeans), fallow land, garbanzo beans, garlic, guava (Hawaii only), horseradish, jojoba, mint, onions, onions grown for seed, papayas (Hawaii only), soybeans, taro, and tree fruit, nuts, and vines (which includes almond, apple, avocado, beechnut, brazil nut, butternut, cashew, cherry, chestnut, chinquapin, crabapple, date, feijoa, fig, filbert, grapes, hickory nut, kiwi, loquat, macadamia nut, mayhaw, nectarines, olives, peach, pear, pecan, persimmon, pistachio, plum, pomegranates, prune, quince, walnut).	Directions for Use
	"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)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	This pesticide is toxic to fish. Do not discharge effluent into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant 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 sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.	Directions for Use
Handler PPE Guidelines (all formulations)	Note the following information when preparing labeling for all end use products: For **sole-active-ingredient** end-use products that contain oxyfluorfen, the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current label must be removed. For **multiple-active-ingredient** end-use products that contain oxyfluorfen, the handler PPE/engineering control requirements set forth in this section must be compared with the requirements on the current label, and the more protective language must be retained. For guidance on which requirements are considered to be more protective, see PR Notice 93-7. PPE that will be established on the basis of Acute Toxicity testing on end-use products undergoing product reregistration must be compared with the active ingredient PPE specified below by the RED. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.	Handler PPE Statements

Description	Required Labeling	Placement on Label
End Use Products Intended for Occupational Use (WPS and Non-WPS Uses)		
PPE Requirements Established by the RED for liquid products	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category [*registrant inserts A,B,C,D,E,F,G,or H*] on an EPA chemical-resistance category selection chart." Mixers, loaders and applicators using engineering controls (see engineering controls requirements below), must wear: Long-sleeved shirt and long pants Shoes plus socks Chemical-resistant gloves when mixing and loading Chemical-resistant apron when mixing and loading All other mixers, loaders, applicators and other handlers must wear: Coveralls over long-sleeved shirt and long pants Chemical-resistant footwear plus socks Chemical-resistant gloves Chemical-resistant headgear when exposed overhead Chemical-resistant apron when exposed to the concentrate	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED for Granular product formulations.	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category [*registrant inserts A,B,C,D,E,F,G,or H*] on an EPA chemical-resistance category selection chart." Mixers, loaders, applicators and other handlers must wear: Coveralls over long-sleeved shirt and long pants Chemical-resistant footwear plus socks Chemical-resistant gloves Chemical-resistant apron for mixers and loaders.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Required Labeling	Placement on Label
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." "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls Established by the RED for liquid products	"Engineering Controls "Mixers and loaders supporting aerial applications to fallow land or ground applications to corn, cotton, or soybeans must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)], and must: -- wear the personal protective equipment required above for mixers/loaders using engineering controls, -- wear protective eyewear if the system operates under pressure, and -- be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: coveralls, and chemical-resistant footwear ." "Handlers performing applications to corn must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, such applicators must: -- wear the personal protective equipment required above for applicators using engineering controls, -- be provided and must have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant headgear, if overhead exposure, -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab." "Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]; "When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
Engineering Controls Established by the RED for Granular Formulations.	"Engineering controls" "When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)

Description	Required Labeling	Placement on Label
User Safety Recommendations	"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 product is toxic to aquatic invertebrates and wildlife. Do not apply directly to water, or areas where surface water is present or to intertidal areas below the mean high water mark. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. See Directions for Use for additional restrictions. Do not contaminate water when disposing of equipment wash water."	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval	In the Agricultural Use Requirements box, place the following statements: "Do not enter or allow workers to enter during the restricted-entry interval (REI).	Directions for Use, Agricultural Use Requirements Box and Application Instructions for Appropriate Crop
	In the Directions for Use under Application Instructions for each crop, specify the following REIs: The REI is 24 hours for all crops except for the following: Onions, garlic and horseradish: The REI is 48 hours. Conifer seedlings: The REI is three days. Conifer trees: The REI is six days.	
Early Re-entry Personal Protective Equipment established by the RED.	" 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, -- chemical-resistant gloves made of any waterproof material, -- shoes plus socks	Directions for Use, Agricultural Use Requirements Box

Description	Required Labeling	Placement on Label
REI Statements required if non-WPS uses are on the label	Liquid Formulations: “Do not enter or allow others to enter until sprays have dried.” Granular formulations: “Do not enter or allow others to enter until dusts have settled.”	Directions for Use Non-Agricultural Use Requirements Box
General Application Restrictions	Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Direction for Use directly above the Agricultural Use Box.
Other Application Restrictions	The following risk mitigation measures must be reflected in the directions for use: New Maximum Annual Application Rates Restrictions: All Food/Feed Crops (except tropical commodities grown in HI): 1.5 lbs ai/A All ornamentals: liquid application rate of 1.5 lbs/ai/application (4.5 lbs ai/season) Container-grown ornamentals: granular application rate of 2 lbs ai/A/application (6 lbs ai/season). Conifer seedlings: 2 lbs/ai/A.	Directions for Use

Description	Required Labeling	Placement on Label
Spray Drift Buffer Restrictions	The following spray drift statement is required. "A 25 ft. vegetative buffer strip must be maintained between all areas treated with this product and lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds." "Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, non-target crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals. For groundboom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use coarse spray according to ASAE 572 definition for standard nozzles or VMD of 475 microns for spinning atomizer nozzles. The applicator also must use all other measures necessary to control drift."	Directions for Use under General Application Instructions and/or Restrictions
End Use Products Intended for Residential Consumer Use		
Environmental Hazards	**"Environmental Hazards**" "Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate."	Precautionary Statements
Entry Restrictions	"Do not allow people or pets to enter treated area until spays have dried."	Directions for Use
General Application Restrictions	"Do not apply this product in a way that will contact people or pets"	Directions for Use
Other Application Restrictions/Risk Mitigation	The application instructions must be revised to reflect the maximum consumer product (residential) rate of 3 lbs ai/A.	Directions for Use

Instructions in the Labeling Required section appearing in quotations represent the exact language that must appear on the label.

Instructions in the Labeling Required section not in quotes represent actions that the registrant must take to amend their labels or product registrations.

VI. APPENDICES

This Reregistration Eligibility Document is supported by documents that are presently maintained in the OPP docket. The OPP docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays from 8:30 am to 4 pm.

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/oxyfluorfen.

Appendix A: Use Patterns Eligible for Reregistration

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Almonds (See also "Tree nuts")						
Directed spray application Nondormant Ground equipment	1.6 lb/gal EC [CA890012] 2 lb/gal EC [CA960020]	1.5 lb/A	Not specified (NS)	1.5 lb/A (nondormant season)	30	Use limited to CA. Application may be made in a minimum of 20 gal of water/A (minimum of 10 gal/A for certain tank mix applications). Application may be made alone or as a tank mix with other herbicides.
Chemigation Nondormant Flood (basin) irrigation, low-volume sprinkler (microsprinkler) or drip trickle irrigation	2 lb/gal EC [CA960020]	1.5 lb/A	NS	1.5 lb/A (nondormant season)	30	Use limited to CA.
Apples (See "Pome fruits")						
Apricots (See "Stone fruits")						
Artichokes, Globe						
Directed spray application Postemergence Ground equipment	1.6 lb/gal EC [62719-400]	1.5 lb/A	1	1.5 lb/A	5	Applications may be made in a minimum of 40 gal of water/A. The use of any treated plants for feed or forage and the feeding or grazing of any treated area are prohibited for the 1.6 lb/gal EC formulation only.
	2 lb/gal EC [62719-424]	1.0 lb/A	2	1.5 lb/A	5	The first application is made to susceptible weed seedlings and the second application is made 8-10 weeks later. Applications may be made in a minimum of 40 gal of water/A. The use of any treated plants for feed or forage and the feeding or grazing of any treated area are prohibited for the 1.6 lb/gal EC formulation only.

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Avocados						
Directed spray application Dormant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424]	1.5 lb/A	NS	1.5 lb/A	NS	Applications may be made in a minimum of 40 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. The use of any treated plants for feed or forage, the feeding or grazing of any treated area, and application after buds start to swell or when foliage or fruit are present are prohibited.
Beech nut (See "Tree nuts")						
Blackberries						
Directed spray application Early season (primocane growth 4 to 6 inches) or dormant Ground equipment	1.6 lb/gal EC [OR960005] 2 lb/gal EC [OR960036] [OR000028]	0.8 lb/A (early season) 1.0 lb/A (dormant)	4	1.5 lb/A	15	Use limited to OR. Applications may be made in a minimum of 50 gal water/A.
Brazil nut (See "Tree nuts")						
Broccoli						
Broadcast application Pretransplant (preplant) Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.5 lb/A	NS	0.5 lb/A	NS	Applications may be made in a minimum of 20 gal of water/A.
Butternut (See "Tree nuts")						
Cabbage						
Broadcast application Pretransplant (preplant) Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.5 lb/A	NS	0.5 lb/A	NS	See "Broccoli."

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Cacao beans (bearing and nonbearing)						
Directed spray application Postemergence Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	2.0 lb/A	NS	6.0 lb/A	1	Applications may be made in a minimum of 15 gal of water/A.
Directed spray application Pretransplant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	1.0 lb/A	NS	6.0 lb/A	1	
Cashew (See "Tree nuts")						
Cauliflower						
Broadcast application Pretransplant (preplant) Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.5 lb/A	NS	0.5 lb/A	NS	See "Broccoli."
Cherries (See "Stone fruits")						
Chestnut (See "Tree nuts")						
Chickpea (Garbanzo bean)						
Broadcast application Preemergence Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.25 lb/A	NS	NS	NS	Use limited to CA. Applications may be made in a minimum of 25 gal of water/A. Feeding of bean, vines, or hay is prohibited.

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Chickpea (Garbanzo bean) (continued)						
Broadcast application Preemergence Ground equipment	1.6 lb/gal EC [CA920029] 2 lb/gal EC [AZ000001] [CA960022]	0.25 lb/A	NS	NS	NS	Use limited to AZ and CA. Applications may be made in a minimum of 20 gal of water/A.
Chinquapin (See "Tree nuts")						
Coffee (bearing and nonbearing)						
Broadcast application (over the top) Dormant transplants Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	2.0 lb/A	NS	6.0 lb/A	1	Use limited to HI. Applications may be made in a minimum of 30 gal of water/A. Applications may be made alone or as a tank mix with other herbicides.
Directed spray application Postemergence Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	2.0 lb/A	NS	6.0 lb/A	1	
Directed spray application Pretransplant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	1.0 lb/A	NS	6.0 lb/A	1	

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Corn, field						
Directed spray application Foliar/postemergence Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424] [NC990007] [SC000002]	0.75 lb/A (first application) 0.5 lb/A (subsequent applications)	NS	1.25 lb/A	30 [62719-395] [62719-400] 60 [62719-424] [NC990007] [SC000002]	Use in conjunction with the USDA "witchweed" eradication program in NC and SC. Applications may be made in a minimum of 10 gal of water/A. The use of any plants from a treated field for green chop, ensilage, forage, or fodder is prohibited. PHI is 60 days.
Broadcast application Fallow bed Ground or aerial equipment	1.6 lb/gal EC [LA930011] 2 lb/gal EC [AR960009] [LA960012] [MS960015]	0.5 lb/A	NS	0.5 lb/A (per fallow season)	Not applicable (NA)	Use limited to AR, LA, and MS. Application may be made in a minimum of 20 gal of water/A using ground equipment or 5 gal/A by air. Applications may be made alone or as a tank mix with other herbicides. A 7-day interval from treatment to planting is specified. The use of any plants from a treated field for green chop, ensilage, forage or fodder or the feeding or grazing of animals on any treated area is prohibited. PHI is 60 days.
Cotton						
Directed spray application Postemergence Ground equipment	1.6 lb/gal EC [62719-400] [VA930010] 2 lb/gal EC [62719-395] [62719-424]	0.5 lb/A	NS	0.5 lb/A (single or multiple applications)	90 [62719-400] [62719-424] [VA930010] NS [62719-395]	Use limited to AL, AR, GA, LA, MS, MO, NM, NC, OK, SC, TN, TX, and VA (Southern cotton). Applications may be made in a minimum of 20 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. Application after initiation of bloom is prohibited.
				1.0 lb/A (multiple applications) 0.5 lb/A (single application)	75 [62719-400] [62719-424] NS [62719-395]	Use limited to AZ and CA (Western cotton). Applications may be made in a minimum of 20 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. Application after initiation of bloom is prohibited.

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Cotton (continued)						
Broadcast application Fallow bed Aerial equipment	2 lb/gal EC [62719-395]	0.5 lb/A	NS	0.5 lb/A (per fallow season)	NA	Use limited to AZ and CA. Applications may be made in a minimum of 10 gal of water/A (minimum of 5 gal/A for certain tank mix applications). Applications may be made alone or as a tank mix with other herbicides. A 14-day interval from treatment to incorporation and planting is specified.
Broadcast application Fallow bed Ground equipment	2 lb/gal EC [62719-395]	0.5 lb/A	NS	0.5 lb/A (per fallow season)	NA	Applications may be made in a minimum of 20 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. A 14-day interval from treatment to incorporation and planting is specified.
Broadcast application Fallow bed Ground or aerial equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.5 lb/A	NS	0.5 lb/A (per fallow season)	NA	Applications may be made in a minimum of 20 gal of water/A using ground equipment or 5 gal/A by air (minimum of 10 gal/A by air in CA). Applications may be made alone or as a tank mix with other herbicides. A 7-day interval from treatment to planting is specified.
Crabapples (See "Pome fruits")						
Dates						
Directed spray application Dormant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424]	1.5 lb/A	NS	1.5 lb/A	NS	Applications may be made in a minimum of 40 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. The use of any treated plants for feed or forage, the feeding or grazing of any treated area, and application after buds start to swell or when foliage or fruit are present are prohibited.
Fallow land						
Broadcast application Fallow bed Ground or aerial equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.5 lb/A	NS	0.5 lb/A	NA	Applications may be made in a minimum of 20 gal of water/A using ground equipment or 10 gal/A by air. Applications may be made alone or as a tank mix with other herbicides.

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Fallow land (continued)						
Broadcast application Fallow bed Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424]	0.5 lb/A	NS	NS	NA	Use limited to ID, OR, and WA. Use is restricted to summer fallow land that will be planted back the following year to barley, oats, or winter wheat. Applications may be made in a minimum of 20 gal of water/A. Applications may be made alone or as a tank mix with other herbicides.
Feijoa						
Directed spray application Dormant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	1.5 lb/A	NS	1.5 lb/A	NS	Applications may be made in a minimum of 40 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. The use of any treated plants for feed or forage, the feeding or grazing of any treated area, and application after buds start to swell or when foliage or fruit are present are prohibited.
Figs						
Directed spray application Dormant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424]	1.5 lb/A	NS	1.5 lb/A	NS	Applications may be made in a minimum of 40 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. The use of any treated plants for feed or forage, the feeding or grazing of any treated area, and application after buds start to swell or when foliage or fruit are present are prohibited.
Filberts (See "Tree Nuts")						
Garbanzo bean (see "Chickpea")						
Garlic						
Broadcast or band application Postemergence to seeded garlic (at least 2 true leaves) Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.25 lb/A	NS	0.5 lb/A	60	Use limited to direct-seeded garlic in Western states of AZ, CA, CO, ID, NV, NM, OR, TX, UT, and WA. Applications may be made in a minimum of 40 gal of water/A. For use on dry bulb garlic only; use on garlic grown for seed is prohibited.

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Garlic (continued)						
Broadcast or band application Postemergence to seeded garlic (at least 3 true leaves) Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.06 lb/A	NS	0.5 lb/A	60	Use limited to direct-seeded garlic in Northeastern states of CT, ME, MA, NH, NJ, NY, RI, and VT. Applications may be made in a minimum of 40 gal of water/A. For use on dry bulb garlic only; use on garlic grown for seed is prohibited.
Broadcast or band application Postemergence to seeded garlic (at least 2 true leaves) Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.12 lb/A	NS	0.5 lb/A	60	Use limited to direct-seeded garlic in all other states not listed above. Applications may be made in a minimum of 40 gal of water/A. For use on dry bulb garlic only; use on garlic grown for seed is prohibited.
Broadcast or band application After transplanting Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.5 lb/A	NS	0.5 lb/A	60	Use limited to transplanted garlic for all states except the Northeastern states listed above. Applications may be made in a minimum of 40 gal of water/A. For use on dry bulb garlic only; use on garlic grown for seed is prohibited.
		0.06 lb/A	NS	0.5 lb/A	60	Use limited to transplanted garlic in the Northeastern states listed above. Applications may be made in a minimum of 40 gal of water/A. For use on dry bulb garlic only; use on garlic grown for seed is prohibited.
Broadcast application Preemergence Ground or aerial equipment	1.6 lb/gal EC [CA920018] 2 lb/gal EC [CA960021]	0.25 lb/A	NS	0.5 lb/A	60	Use limited to CA. Applications may be made in a minimum of 20 gal of water/A using ground equipment or 10 gal/A by air. For use on dry bulb garlic only.

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Garlic (continued)						
Directed spray application Postemergence Ground equipment	1.6 lb/gal EC [CA920018] 2 lb/gal EC [CA960021] [NV990001]	0.25 lb/A	NS	0.5 lb/A	60	Use limited to CA and NV. Applications may be made in a minimum of 20 gal of water/A. For use on dry bulb garlic only.
Chemigation Preemergence or postemergence Sprinkler irrigation	1.6 lb/gal EC [CA920018] 2 lb/gal EC [CA960021]	0.25 lb/A	NS	0.5 lb/A	60	Use limited to CA. For use on dry bulb garlic only.
Grapes						
Directed spray application Dormant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424]	1.5 lb/A	NS	1.5 lb/A	NS	Applications may be made in a minimum of 40 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. The use of any treated plants for feed or forage, the feeding or grazing of any treated area, and application after buds start to swell or when foliage or fruit are present are prohibited.
Directed spray or broadcast (over the top) application Dormant (nonbearing) Ground equipment	1.6 lb/gal EC [CA950008] 2 lb/gal EC [CA960023] [WA970023]	1.5 lb/A	NS	NS	NS	Use limited to CA and WA. Applications may be made in a minimum of 40 gal of water/A. Application after buds start to swell is prohibited.

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Grapes (continued)						
Directed spray application Nondormant Ground equipment	2 lb/gal EC [CA970026]	0.5 lb/A	NS	1.5 lb/A	14	Use limited to CA as a nondormant application to wine grapes and raisin grapes only. Applications may be made in a minimum of 20 gal of water/A (minimum of 10 gal/A for certain tank mix applications). Application may be made alone or as a tank mix with other herbicides.
	2 lb/gal EC [OR000001] [WA970013]	0.5 lb/A	NS	1.5 lb/A	60	Use limited to OR and WA as a nondormant application to wine and processing grapes only. Applications may be made in a minimum o f 50 gal of water/A. Application may be made alone or as a tank mix with other herbicides.
Chemigation Nondormant Low-volume sprinkler (microsprinkler) or drip trickle irrigation	2 lb/gal EC [CA970026] [WA970024]	0.5 lb/A	NS	1.5 lb/A	14	Use limited to CA and WA as a nondormant application to grapes grown for processing (includes juice, wine, and raisin grapes only).
Grasses grown for seed						
Broadcast application Ground equipment	2 lb/gal EC [OR990006] [WA990035]	0.125-0.375 lb/A	2	0.375 lb/A	150	Use limited to OR and WA for grass grown for seed (including Kentucky bluegrass, tall fescue, orchardgrass, bentgrass, and perennial ryegrass). Applications may be made in a minimum of 20 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. A 150-day pregrazing interval (PGI) has been established.
	2 lb/gal EC [OR990006]	0.12 lb/A	1	0.12 lb/A	150	Use limited to OR for grass grown for seed (including fine fescues: chewing, creeping red, and hard types). Applications may be made in a minimum of 20 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. A 150-day pregrazing interval (PGI) has been established.

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
	2 lb/gal EC [OR990036]	0.0375 lb/A	1	NS	150	Use limited to OR for grass grown for seed (including perennial ryegrass and tall fescue). Applications may be made in a minimum of 20 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. A 150-day pregrazing interval (PGI) has been established.
Guavas (bearing and nonbearing)						
Directed spray application Postemergence (after new foliage has hardened off) Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	2.0 lb/A	NS	4.0 lb/A	1	Use limited to HI. Applications may be made in a minimum of 15 gal of water/A. Applications may be made alone or as a tank mix with other herbicides.
Hickory Nut (See "Tree Nuts")						
Horseradish						
Broadcast application Preemergence Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.5 lb/A	NS	1.5 lb/A	NS	Applications may be made in a minimum of 20 gal of water/A.
Kiwifruit						
Directed spray application Dormant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424]	1.5 lb/A	NS	1.5 lb/A	NS	Applications may be made in a minimum of 40 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. The use of any treated plants for feed or forage, the feeding or grazing of any treated area, and application after buds start to swell or when foliage or fruit are present are prohibited.
Loquat (See "Pome fruits")						

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Macadamia Nut (bearing and nonbearing; see also "Tree nuts")						
Directed spray application Postemergence (after new foliage has hardened off) Ground equipment	2 lb/gal EC [HI960010]	2.0 lb/A 1.0 lb/A (lava soil)	NS	4.0 lb/A	7	Use limited to HI. Applications may be made in a minimum of 15 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. Feeding or grazing of animals on any treated area is prohibited.
Mayhaws (See "Pome fruits")						
Nectarines (See "Stone fruits")						
Olive						
Directed spray application Dormant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424]	1.5 lb/A	NS	1.5 lb/A	NS	Applications may be made in a minimum of 40 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. The use of any treated plants for feed or forage, the feeding or grazing of any treated area, and application after buds start to swell or when foliage or fruit are present are prohibited.
Onions, bulb						
Broadcast or band application Postemergence to seeded onions (at least 2 true leaves) Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.25 lb/A	NS	0.5 lb/A	45	Use limited to direct-seeded onions in Western states of AZ, CA, CO, ID, NV, NM, OR, TX, UT, and WA. Applications may be made in a minimum of 40 gal of water/A.
Broadcast or band application Postemergence to seeded onions (at least 3 true leaves) Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.06 lb/A	NS	0.5 lb/A	45	Use limited to direct-seeded onions in Northeastern states of CT, ME, MA, NH, NJ, NY, RI, and VT. Applications may be made in a minimum of 40 gal of water/A.

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Onions, bulb (continued)						
Broadcast or band application Postemergence to seeded onions (at least 2 true leaves) Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.12 lb/A	NS	0.5 lb/A	45	Use limited to direct-seeded onions in all other states not listed above. Applications may be made in a minimum of 40 gal of water/A.
Broadcast or band application After transplanting Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.5 lb/A	NS	0.5 lb/A	45	Use limited to transplanted onions for all states except the Northeastern states listed above. Applications may be made in a minimum of 40 gal of water/A.
		0.06 lb/A	NS	0.5 lb/A	45	Use limited to transplanted onions in the Northeastern states listed above. Applications may be made in a minimum of 40 gal of water/A.
Broadcast or band application Pre-transplanting Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.5 lb/A	NS	0.5 lb/A	45	Use prohibited in Northeastern and Western states listed above, except if specifically directed on other approved supplemental labeling. Applications may be made in a minimum of 40 gal of water/A.
Broadcast application Pre-transplanting Ground equipment	1.6 lb/gal EC [GA890006]	0.5 lb/A	NS	0.5 lb/A	NS	Use limited to GA. Applications may be made in a minimum of 40 gal of water/A. The use of any treated plants for feed or forage and the feeding or grazing of any treated area are prohibited.
Chemigation Postemergence (at least 2 true leaves) or after transplanting Sprinkler irrigation	1.6 lb/gal EC [CA880034] [OR910026] 2 lb/gal EC [OR970008]	0.25 lb/A	NS	0.5 lb/A	45 (OR) 60 (CA)	Use limited to CA and OR.

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Onions, bulb (continued)						
Chemigation Postemergence (at least 2 true leaves) Sprinkler irrigation	2 lb/gal EC [CA960026] [WA960033]	0.25 lb/A	NS	0.5 lb/A	45	Use limited to CA and WA.
Chemigation After transplanting Sprinkler irrigation	2 lb/gal EC [WA960033]	0.5 lb/A	NS	0.5 lb/A	45	Use limited to WA.
Onions Grown for Seed						
Broadcast application Postemergence (at least 4 true leaves) Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.03 lb/A	NS	0.5 lb/A	60	Use limited to onions grown for seed in Northeastern states of CT, ME, MA, NH, NJ, NY, RI, & VT. Applications may be made in a minimum of 40 gal/A.
Broadcast application Postemergence (at least 3 true leaves) Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.12 lb/A	NS	0.5 lb/A	60	Use limited to onions grown for seed in all other states not listed above. Applications may be made in a minimum of 40 gal/A.
Ornamental Plants						
Field grown ornamentals and Containerized ornamentals Broadcast application Postemergence (at least 4 true leaves) Ground equipment	2% Granular [538-172] 2 lb/gal EC [62719-424]	1.5 lb/A	NS	4.5 lb/A	NA	

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Ornamental Plants (continued)						
Containerized ornamentals Broadcast application Postemergence (at least 4 true leaves) Ground equipment	2% Granular [538-172]	2.0 lb/A	NS	6.0 lb/A	NA	
Residential ornamentals Broadcast application Ground equipment	0.25% Solution [239-2356]	1.5 lb/A	NS	3.0 lb/A	NA	
Papayas						
Directed spray application Postemergence Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	1.0 lb/A	NS	3.0 lb/A	1	Use limited to HI. Initial application should occur no earlier than 4 months after transplanting or 6 months after direct seeding. Applications may be made in minimum of 15 gal of water/A and repeated at 4-month intervals.
Peaches (See "Stone fruits")						
Pears (See "Pome fruits")						
Pecans (See "Tree nuts")						

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Peppermint						
Broadcast or band application Dormant Ground equipment	1.6 lb/gal EC [62719-400]	1.5 lb/A	1	NS	NA	Use limited to OR and WA (East of Cascades) and western ID. Application may be made in a minimum of 20 gal of water/A.
	2 lb/gal EC [62719-395]	0.75 lb/A	1	NS	NA	Use limited to western OR (Willamette Valley). Application may be made in a minimum of 20 gal of water/A.
	1.6 lb/gal EC [CA930014] [NV930002] [SD940001] 2 lb/gal EC [MT960003] [ND980001]	1.5 lb/A	NS	1.5 lb/A	NA	Use limited to CA, MT, ND, NV, and SD. Applications may be made in a minimum of 20 gal of water/A.
Broadcast application Dormant Ground equipment	2 lb/gal EC [62719-424]	1.5 lb/A	1	NS	NA	Use limited to OR and WA (East of Cascades) and CA, ID, MT, NV, SD, and UT. Application may be made in a minimum of 20 gal of water/A.
		0.75 lb/A	1	NS	NA	Use limited to western OR (Willamette Valley). Application may be made in a minimum of 20 gal of water/A.
Broadcast application Dormant Ground equipment	2 lb/gal EC [SD960007]	1.5 lb/A	1	NS	NA	Use limited to SD. Application may be made in a minimum of 20 gal of water/A.

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Peppermint (continued)						
Broadcast application Preemergence (dormant) Ground equipment	1.6 lb/gal EC [IN840003] [WI950001] 2 lb/gal EC [IN960004] [MI970002] [WI960009]	1.5 lb/A	NS	NS	NA	Use limited to IN, MI, and WI for mint grown in muck soil (≥20% organic matter). Applications may be made in a minimum of 20 gal of water/A. The use of any treated plants for feed or forage and the feeding or grazing of any treated area are prohibited.
Persimmons						
Directed spray application Dormant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	1.5 lb/A	NS	2.0 lb/A	NS	Applications may be made in a minimum of 40 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. The use of any treated plants for feed or forage, the feeding or grazing of any treated area, and application after buds start to swell or when foliage or fruit are present are prohibited.
Pistachios (See also "Tree Nuts")						
Directed spray application Nondormant Ground equipment	1.6 lb/gal EC [CA950007] 2 lb/gal EC [CA960019]	1.5 lb/A	NS	1.5 lb/A (nondormant season)	7	Use limited to CA. Application may be made in a minimum of 20 gal of water/A (minimum of 10 gal/A for certain tank mix applications). Application may be made alone or as a tank mix with other herbicides.
Chemigation Nondormant Flood (basin) irrigation	1.6 lb/gal EC [CA950007]	1.5 lb/A	NS	1.5 lb/A (nondormant season)	7	Use limited to CA.
Chemigation Nondormant Flood (basin) irrigation, low-volume sprinkler (microsprinkler) or drip trickle irrigation	2 lb/gal EC [CA960019]					

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Plums (See "Stone fruits")						
Pome fruits (including apple, crabapple, loquat, mayhaws, pear, and quince)						
Directed spray application Dormant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424]	1.5 lb/A	NS	1.5 lb/A	NS	Applications may be made in a minimum of 40 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. The use of any treated plants for feed or forage, the feeding or grazing of any treated area, and application after buds start to swell or when foliage or fruit are present are prohibited.
Pomegranates						
Directed spray application Dormant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424]	1.5 lb/A	NS	1.5 lb/A	NS	Applications may be made in a minimum of 40 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. The use of any treated plants for feed or forage, the feeding or grazing of any treated area, and application after buds start to swell or when foliage or fruit are present are prohibited.
Prunes (See "Stone fruits")						
Quince (See "Pome fruits")						
Raspberries						
Directed spray application Early season (primocane growth 4 to 6 inches) Ground equipment	1.6 lb/gal EC [OR960006]	0.8 lb/A	2	1.2 lb/A	50	Use limited to OR and WA. Applications may be made in a minimum of 50 gal water/A.
	2 lb/gal EC [OR960037] [WA960034]	0.75 lb/A	2	1.25 lb/A	50	

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Soybeans						
Broadcast application (Conservation tillage) Early preplant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424]	0.75 lb/A	2	0.75 lb/A (all uses)	NS	Use prohibited in CA. Application should be made approximately 14 days prior to planting.
Broadcast application (No-till) Preemergence Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424]	0.5 lb/A	2	0.75 lb/A (all uses) 0.5 lb/A (preemergent uses)	NS	Use prohibited in CA. Application should be made within 1 day of planting. Application may be made in a minimum of 20 gal of water/A. Application may be made alone or as a tank mix with other herbicides.
Broadcast application (Conventional till) Preemergence Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424]	0.38 lb/A	2	0.75 lb/A (all uses) 0.5 lb/A (preemergent uses)	NS	
Directed spray application (Conventional-till) Postemergence Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424]	0.25 lb/A	2	0.75 lb/A (all uses) 0.5 lb/A (preemergent uses)	NS	Use prohibited in CA. Application should be made when soybean plants are a minimum of 8 inches tall and before blooms appear. Application may be made in a minimum of 20 gal of water/A. Application may be made alone or as a tank mix with other herbicides.

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Soybeans (continued)						
Broadcast application Fallow bed Ground or aerial equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.5 lb/A	NS	0.5 lb/A (per fallow season)	NA	Use prohibited in CA. Applications may be made in a minimum of 20 gal of water/A using ground equipment or 5 gal/A by air. Applications may be made alone or as a tank mix with other herbicides. A 7-day interval from treatment to planting is specified.
Spearmint						
Broadcast or band application Dormant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395]	1.5 lb/A	1	NS	NA	See "Peppermint."
Broadcast application Dormant Ground equipment	2 lb/gal EC [62719-424] [SD960007]	1.5 lb/A	1	NS	NA	See "Peppermint."
Broadcast or band application Dormant Ground equipment	1.6 lb/gal EC [CA930014] [NV930002] [SD940001] 2 lb/gal EC [MT960003] [ND980001]	1.5 lb/A	NS	NS	NA	See "Peppermint."

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Spearmint (continued)						
Broadcast application Preemergence (dormant) Ground equipment	1.6 lb/gal EC [IN840003] [WI950001] 2 lb/gal EC [IN960004] [MI970002] [WI960009]	1.5 lb/A	NS	NS	NA	See "Peppermint."
Stone fruits (including apricot, cherry, nectarine, peach, plum, and prune)						
Directed spray application Dormant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424]	1.5 lb/A	NS	1.5 lb/A	NS	Applications may be made in a minimum of 40 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. The use of any treated plants for feed or forage, the feeding or grazing of any treated area, and application after buds start to swell or when foliage or fruit are present are prohibited.
Taro						
Broadcast or band application Preemergence (within one week after transplanting) Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.5 lb/A	NS	1.0 lb/A (all uses)	6 (months)	Use limited to HI. Applications may be made in a minimum of 15 gal of water/A.
Directed spray application Postemergence Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-424]	0.25 lb/A	NS	1.0 lb/A (all uses) 0.5 lb/A (multiple post-direct applications) 0.5 lb/A (preemergent uses)	6 (months)	Use limited to dryland taro grown in HI. Applications may be made in a minimum of 20 gal of water/A.

Site Application Type Application Timing Application Equipment	Formulation Example [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum No. of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Limitations [1]
Tree nurseries and plantations, right of ways, irrigation systems, uncultivated non-agricultural land, industrial sites						
Directed spray application Postemergence Ground equipment	2 lb/gal EC [62719-424]	2.0 lb/A	NS	2.0 lb/A	NA	
Tree nuts (including almond, beech nut, Brazil nut, butternut, cashew, chestnut, chinquapin, filbert, hickory nut, macadamia nut, pecan, pistachio, and walnut)						
Directed spray application Dormant Ground equipment	1.6 lb/gal EC [62719-400] 2 lb/gal EC [62719-395] [62719-424]	1.5 lb/A	NS	1.5 lb/A	NS	Applications may be made in a minimum of 40 gal of water/A. Applications may be made alone or as a tank mix with other herbicides. The use of any treated plants for feed or forage, the feeding or grazing of any treated area, and application after buds start to swell or when foliage or fruit are present are prohibited.
Walnuts (See also "Tree nuts")						
Directed spray application Nondormant Ground equipment	1.6 lb/gal EC [CA890012] 2 lb/gal EC [CA960020]	1.5 lb/A	NS	1.5 lb/A (nondormant season)	7	Use limited to CA. Application may be made in a minimum of 20 gal of water/A (minimum of 10 gal/A for certain tank mix applications). Application may be made alone or as a tank mix with other herbicides.
Chemigation Nondormant Flood (basin) irrigation, low-volume sprinkler (microsprinkler) or drip trickle irrigation	2 lb/gal EC [CA960020]	1.5 lb/A	NS	1.5 lb/A (nondormant season)	7	Use limited to CA.

Appendix B:Data Supporting the Reregistration of Oxyfluorfen

Data Supporting Guideline Requirements for the Reregistration of Oxyfluorfen

REQUIREMENT			USE PATTERN	CITATION(S)
New Guideline Number	**Old Guideline Number**	**Description**		
	PRODUCT CHEMISTRY			
830.1550	61-1	Product Identity and Composition	All	44828901, CSF 11/17/99 44720201, CSF 12/4/98
830.1600 830.1200	61-2A	Start. Mat. & Mnfg. Process	All	44828901, 44720201
830.1670	61-2B	Formation of Impurities	All	44828901, 44720201
830.1700	62-1	Preliminary Analysis	All	44828901, 44720201, 44720202
830.1750	62-2	Certification of limits	All	44828901, CSF 11/17/99, 44712001, 44712002, CSF 12/4/98
830.1800	62-3	Analytical Method	All	44828901, 44720201, 44720202
830.6302	63-2	Color	All	44828902, 44720203
830.6303	63-3	Physical State	All	44828902, 44720203
830.6304	63-4	Odor	All	44828902, 44720203
830.7050	None	UV/Visable Absorption	All	44828902, 44720203
830.7200	63-5	Melting Point	All	44828902, 44720203
830.7300	63-7	Density	All	44828902, 44720203
830.7840 830.7860	63-8	Solubility	All	44828902, 44712004, 44712005
830.7950	63-9	Vapor Pressure	All	44828902, 44712006
830.7550	63-11	Octanol/Water Partition Coefficient	All	44828902, 44712007
	ECOLOGICAL EFFECTS			
850.2100	71-1	Avian Acute Oral Toxicity	All	92136102
850.2200	71-2A	Avian Dietary Toxicity - Quail	All	92136103
850.2200	71-2B	Avian Dietary Toxicity - Duck	All	92136104
850.2300	71-4A	Avian Reproduction - Quail	All	**Data Gap**
850.2300	71-4B	Avian Reproduction - Duck	All	**Data Gap**
850.1075	72-1A	Fish Toxicity Bluegill	All	42129801
850.1075	72-1C	Fish Toxicity Rainbow Trout	All	42129802
850.1010	72-2A	Invertebrate Toxicity	All	45271301
850.1075	72-3A	Estuarine/Marine Toxicity - Fish	All	41698801
850.1025	72-3B	Estuarine/Marine Toxicity - Mollusk	All	42378901
850.1035 850.1045	72-3C	Estuarine/Marine Toxicity - Shrimp	All	30970117
850.1400	72-4A	Fish- Early Life Stage	All	92136057 (99270), **Data Gap**

Data Supporting Guideline Requirements for the Reregistration of Oxyfluorfen

REQUIREMENT			USE PATTERN	CITATION(S)
New Guideline Number	**Old Guideline Number**	**Description**		
850.1300 850.1350	72-4B	Estuarine/Marine Invertebrate Life Cycle	All	**Data Gap**
850.1735	None	Fresh Water Whole Sediment Acute Toxicity	All	**Data Gap**
850.1740	None	Estruarine/marine Whole Sediment Acute Toxicity	All	**Data Gap**
850.1500	72-5	Life Cycle Fish	All	Reserved
850.4225	123-1A	Seed Germ./ Seedling Emergence	All	41644001, **Data Gap**
850.4250	123-1B	Vegetative Vigor	All	41644001, **Data Gap**
850.4400	123-2	Aquatic Plant Growth	All	45271302
	TOXICOLOGY			
870.1100	81-1	Acute Oral Toxicity-Rat	All	44712010, 44828903
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	All	44712011, 44828904
870.1300	81-3	Acute Inhalation Toxicity-Rat	All	44712012
870.2400	81-4	Primary Eye Irritation-Rabbit	All	44712013, 44828906
870.2500	81-5	Primary Skin Irritation	All	44712014, 44828905
870.2600	81-6	Dermal Sensitization	All	44712015, 44814901
870.3100	82-1A	90-Day Feeding - Rodent	All	44933101, 00117601, 92136011, 42142317, 00117603, 0017602, 92136012, 42142316
870.3200	82-2	21-Day Dermal - Rabbit/Rat	All	**Data Gap**
870.3465	82-4	90-Day Inhalation-Rat	All	**Data Gap**
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent	All	00078767, 92136062, 92136016
870.4200	83-2B	Oncogenicity - Mouse	All	00037939, 92136017
870.3700	83-3A	Developmental Toxicity - Rat	All	44933103
870.3700	83-3B	Developmental Toxicity - Rabbit	All	44933102, 00094052, 00094051, 92136018, 92136019
870.3800	83-4	2-Generation Reproduction - Rat	All	42014901
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity	All	00083445, 00135072, 92136061
870.5140	84-2A	Gene Mutation (Ames Test)	All	00098421, 44942801, 44933104, 40992201, 00098420, 00098422, 44947205
870.5375	84-2B	Structural Chromosomal Aberration	All	00098419, 44933105, 44933106, 44947204, 44947203, 41873801, 00098418, 00109283, 00098423
None	84-4	Other Genotoxic Effects	All	44947201, 00098424
870.7485	85-1	General Metabolism	All	42374201, 42652401
870.7600	85-2	Dermal Penetration	All	42142306, 92136095

Data Supporting Guideline Requirements for the Reregistration of Oxyfluorfen

REQUIREMENT			USE PATTERN	CITATION(S)
New Guideline Number	**Old Guideline Number**	**Description**		
	OCCUPATIONAL/RESIDENTIAL EXPOSURE			
875.2100	132-1A	Foliar Residue Dissipation	ABC	42098301
875.2400	133-3	Dermal Passive Dosimetry Exposure	ABC	42098301
None	231	Estimation of Dermal Exposure at Outdoor Sites	ABC	44972201, 444598-01
	ENVIRONMENTAL FATE			
835.2120	161-1	Hydrolysis	All	96882
835.2240	161-2	Photodegradation - Water	All	42142307, 42129101
835.2410	161-3	Photodegradation - Soil	All	41999901
835.4100	162-1	Aerobic Soil Metabolism	All	42142309
835.4200	162-2	Anaerobic Soil Metabolism	All	42142310
835.1240	163-1	Leaching/Adsorption/Desorption	All	94336, 42142311
835.6100	164-1	Terrestrial Field Dissipation	All	43840101
None	165-4	Bioaccumulation in Fish	All	96883
840.1200	202-1	Drift Field Evaluation	ABC	144894
	RESIDUE CHEMISTRY			
None	171-2	Chemical Identity	AB	**Data Gap**
860.1300	171-4A	Nature of Residue - Plants	AB	00160143, 42865001, 42873301, 42913201, 92136027, 92136101, 92136114, 92136121
860.1300	171-4B	Nature of Residue - Livestock	AB	42634701 , 42670601, 43317701
860.1340	171-4C	Residue Analytical Method - Plants	AB	00149622, 40223201, 92136028, 92136029, 92136065, 44400202, 44400203
860.1340	171-4D	Residue Analytical Method - Animals	AB	00135077, 43307502 , 43307503, 43346401, 92136030, 92136060, 44400204, 44407801, 44506601
860.1380	171-4E	Storage Stability	AB	43424201, 43424202, 43813201, 43859801
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	AB	43152201, 43152202
		Root and Tuber Vegetables Group		
860.1500	171-4K	Crop Field Trials (Horseradish)	AB	43973701
860.1500	171-4K	Crop Field Trials (Taro Corm)	AB	40940301
		Leaves of Root and Tuber Vegetables Group		
860.1500	171-4K	Crop Field Trials (Taro Foliage)	AB	40940301
		Bulb Vegetables Group		
860.1500	171-4K	Crop Field Trials (Garlic)	AB	No additional data required

Data Supporting Guideline Requirements for the Reregistration of Oxyfluorfen

REQUIREMENT			USE PATTERN	CITATION(S)
New Guideline Number	**Old Guideline Number**	**Description**		
860.1500	171-4K	Crop Field Trials (Onions, dry bulb)	AB	00126583, 43965501, 92136049, 92136083
		Brassica Leafy Vegetables Group		
860.1500	171-4K	Crop Field Trials (Broccoli)	AB	00148291, 40007203, 92136034, 92136070
860.1500	171-4K	Crop Field Trials (Cabbage)	AB	00148291, 40007201, 43986301, 92136035, 92136071
860.1500	171-4K	Crop Field Trials (Cauliflower)	AB	00148291, 40007202, 43986302, 92136036, 92136072
		Legume Vegetables (Succulent or Dried) Group		
860.1500	171-4K	Crop Field Trials (Chickpea)	AB	41622701
860.1500	171-4K	Crop Field Trials (Soybean seed and aspirated grain fractions)	AB	00125632, 00136873, 92136053, 92136086
		Foliage of Legume Vegetables Group		
860.1500	171-4K	Crop Field Trials (Soybean forage and hay)	AB	**Data Gap**
		Pome Fruits Group		
860.1500	171-4K	Crop Field Trials (All)	AB	00079475, 00141092, 40223206, 43794001, 44575901, 92136050, 92136051, 92136084
		Stone Fruits Group		
860.1500	171-4K	Crop Field Trials (All)	AB	00036704, 00036705, 00036708, 00079475, 00110745, 00146340, 43794008, 44025401, 92136054, 92136087
		Berries Group		
860.1500	171-4K	Crop Field Trials (Blackberries)	AB	43424201
860.1500	171-4K	Crop Field Trials (Raspberries)	AB	43424202 , 43424203
		Tree Nuts Group		
860.1500	171-4K	Crop Field Trials (All)	AB	00036707, 00071290, 00071291, 00071292, 00071293, 00110745, 00141093, 40223206, 92136055, 92136088
860.1500	171-4K	Crop Field Trials (Pistachios)	AB	00071290, 00071291, 00071292, 00071293, 92136056, 92136089
		Cereal Grains Group		
860.1500	171-4K	Crop Field Trials (Corn, field, grain and aspirated grain fractions)	AB	00135077, 43944801, 92136038, 92136074
		Forage, Fodder, Hay, and Straw of Cereal Grains Group		
860.1500	171-4K	Crop Field Trials (Corn, field, forage and fodder)	AB	00135077, 92136038, 92136074

Data Supporting Guideline Requirements for the Reregistration of Oxyfluorfen

REQUIREMENT			USE PATTERN	CITATION(S)
New Guideline Number	**Old Guideline Number**	**Description**		
		Miscellaneous Commodities		
860.1500	171-4K	Crop Field Trials (Artichokes)	AB	00145973, 43794007, 92136031, 92136067
860.1500	171-4K	Crop Field Trials (Avocado)	AB	00145972, 40223202, 43794002, 92136032, 92136068
860.1500	171-4K	Crop Field Trials (Bananas)	AB	00102529, 92136033, 92136069, **Data Gap**
860.1500	171-4K	Crop Field Trials (Cacao beans)	AB	PP#0E3898
860.1500	171-4K	Crop Field Trials (Coffee)	AB	00102529, 92136037, 92136073
860.1500	171-4K	Crop Field Trials (Cotton, seed, and gin byproducts)	AB	00071290, 00071291, 00071292, 00071293, 00110747, 92136039, 92136040, 92136075
860.1500	171-4K	Crop Field Trials (Dates)	AB	00145972, 40223205, 92136041, 92136076
860.1500	171-4K	Crop Field Trials (Fallow land)	AB	40567001
860.1500	171-4K	Crop Field Trials (Feijoa)	AB	PP#9E3779
860.1500	171-4K	Crop Field Trials (Figs)	AB	00079475, 43794003 , 92136042, 92136077
860.1500	171-4K	Crop Field Trials (Grapes)	AB	00036703, 00110745, 00146340, 92136043, 92136078, 44385401, 44385402
860.1500	171-4K	Crop Field Trials (Guavas)	AB	00158014, 92136044, 92136079
860.1500	171-4K	Crop Field Trials (Kiwifruits)	AB	00145972, 40223203, 43794005, 92136045, 92136080
860.1500	171-4K	Crop Field Trials (Mint, tops)	AB	00071290, 00071291, 00071292, 00071293, 92136046, 92136047, 92136081
860.1500	171-4K	Crop Field Trials (Olives)	AB	00145972, 40223204, 43794006, 92136048, 92136082
860.1500	171-4K	Crop Field Trials (Papayas)	AB	40783201
860.1500	171-4K	Crop Field Trials (Persimmons)	AB	PP#9E3718
860.1500	171-4K	Crop Field Trials (Pomegranates)	AB	00145972, 43794004 , 92136052, 92136085
860.1500	171-4K	Crop Field Trials (Strawberries)	AB	IR-4 Project PR-3443
		Processed Commodities		
860.1520	171-4L	Processed Food (Apples)	AB	00141092, 92136051
860.1520	171-4L	Processed Food (Coffee)	AB	44172301
860.1520	171-4L	Processed Food (Corn, field, grain)	AB	43944801
860.1520	171-4L	Processed Food (Cottonseed)	AB	00071290, 00071291, 00071292, 00071293, 00110747, 92136040, 92136075
860.1520	171-4L	Processed Food (Figs)	AB	No additional data required

Data Supporting Guideline Requirements for the Reregistration of Oxyfluorfen

REQUIREMENT			USE PATTERN	CITATION(S)
New Guideline Number	**Old Guideline Number**	**Description**		
860.1520	171-4L	Processed Food (Grapes)	AB	No additional data required
860.1520	171-4L	Processed Food (Mint)	AB	00071290, 00071291, 00071292, 00071293, 92136046, 92136047
860.1520	171-4L	Processed Food (Olives)	AB	No additional data required
860.1520	171-4L	Processed Food (Plums)	AB	No additional data required
860.1520	171-4L	Processed Food (Soybeans)	AB	43764901
860.1850	165-1	Rotational Crops (Confined)	AB	40567001

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, 1921 Jefferson Davis Highway, 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/op

These documents include:

HED Documents:

1. Revised Human Health Risk Assessment for Oxyfluorfen, 4-29-02, Felicia Fort, OPP/HED
2. Second Revised Occupational and Residential Risk Assessment for Oxyfluorfen, 5-01-02, Timothy Dole, OPP/HED
3. Report of the HIARC for Oxyfluorfen, Kit Farwell, OPP/HED
4. Toxicity Chapter for Oxyfluorfen, 4-08-02, Kit Farwell, OPP/HED
5. FQPA Safety Factor Report, 4-30-01, Kit Farwell, OPP/HED
6. Product and Residue Chemistry Chapter for Oxyfluorfen, 6-06-01, Jose Morales, OPP/HED
7. Dietary Risk Assessment for Oxyfluorfen, 7-12-01, Jose Morales, OPP/HED

EFED Documents:

1. Water Estimates for Oxyfluorfen, 8-30-01, Amer Al-Mudallal, OPP/EFED
2. Revised EFED Risk Assessment, 5-02-02, Christine Hartless, OPP/EFED

Appendix D. Citations Considered to be Part of the Database 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.

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Appendix E. Generic Data Call-In

See the following table for a list of generic data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

Appendix F. Product Specific Data Call-In

See attached table for a list of product-specific data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

Appendix G: EPA'S Batching of Oxyfluorfen Products for Meeting Acute Toxicity Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing **Oxyfluorfen** 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. Not-with-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.

Fourteen products were found which contain **Oxyfluorfen** as the active ingredient. These products have been placed into four 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:

- 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
	11603-29	97.4
	62719-399	99.0

Batch 2	EPA Reg. No.	% Active Ingredient
	62719-395	23.5
	62719-400	19.4

Batch 3	EPA Reg. No.	% Active Ingredient
	62719-424	23.0
	66222-28	22.2

Batch 4	EPA Reg. No.	% Active Ingredient
	4-432	Oxyfluorfen: 0.25 Glyphosate: 0.25
	239-2516	Oxyfluorfen: 0.25 Glyphosate: 0.25

No Batch	EPA Reg. No.	% Active Ingredient
	239-2622	Oxyfluorfen: 0.70 Imazapyr: 0.08
	524-520	Oxyfluorfen: 2.50 Glyphosate: 40.00
	538-172	Oxyfluorfen: 2.00 Pendimethalin: 1.00
	48234-10	Oxyfluorfen: 2.00 Oxadiazon: 1.00
	58185-27	Oxyfluorfen: 2.00 Oryzalin: 1.00
	62719-447	41.00

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

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 Information Center (NPIC) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPIC by telephone at (800) 858-7378 or through their website: http://npic.orst.edu..

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:

a. Date of receipt;
b. EPA identifying number; and
c. 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.