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Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

EPA 738-R-04-003
September 2003

Reregistration Eligibility Decision for Oxadiazon

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the risk assessment for the oxadiazole pesticide, oxadiazon (Ronstar[®]). Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of oxadiazon. The EPA is now publishing its reregistration eligibility and risk management decisions for the current uses of oxadiazon, and its associated human health and environmental risks. The enclosed "Reregistration Eligibility Decision for Oxadiazon," which was approved on September 15, 2003, contains the Agency's decision on the individual chemical oxadiazon.

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

This document and the process used to develop it are the result of a pilot process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions for pesticides. 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 for these chemicals. The human health and environmental risk assessments were placed in the public docket and an invitation for public comment was announced in the *Federal Register* on February 19, 2003.

Please note that the oxadiazon risk assessments and the attached RED concern only this particular chemical. Oxadiazon is a member of the oxadiazole class of herbicides. While current data are limited, EPA has evidence that compounds within a class may share a common mechanism of toxicity. At this time, the

Agency does not have sufficient data concerning common mechanism issues to determine whether or not oxadiazon shares a common mechanism of toxicity with other substances, including other oxadiazoles or other probable human carcinogens. Therefore, for the purposes of this risk assessment, the Agency has assumed that oxadiazon does not share a common mechanism of toxicity with any other chemicals.

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

If you have questions on this document or the proposed label changes, please contact the Special Review and Reregistration Division representative, Mark Seaton, at (703) 306-0469. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Bentley Gregg at (703) 308-8178.

Betty Shackleford, Acting Director
Special Review and
Reregistration Division

Attachment

Reregistration Eligibility Decision

for

Oxadiazon

List B

Case 2485

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration.
EP	End-Use Product
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC ₅₀	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.

LD ₅₀	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MUP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PCA	Percent Crop Area
PAD	Population Adjusted Dose
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/	
EXAMS	Tier II Surface Water Computer Model
Q ₁ *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision

REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Oxadiazon Reregistration Eligibility Decision Team

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Executive Summary

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

Oxadiazon is a herbicide registered for use on golf course and commercial turf, and on ornamental plants and shrubs by horticultural nurseries. There are no registered homeowner uses. EPA estimates that approximately 250,000 pounds of active ingredient are used annually, about 80% of which is applied to golf course turf.

Overall Risk Summary

EPA's human health risk assessment for oxadiazon suggests dietary (drinking water) and occupational risks of concern. Risk estimates based on refined (Tier II) models indicate a chronic cancer risk of concern from exposure to drinking water from surface water sources. To further assess the risk from drinking water exposure, the Agency is requiring the registrant to submit three years of drinking water monitoring data collected from sites determined by the Agency to be likely to result in upper-bound exposures.

In addition, there is a cancer risk of concern for handlers who mix/load/apply wettable powder formulations. To mitigate the cancer risk to handlers, the Agency is requiring changes to packaging, as well as changes to the required personal protective equipment for handlers who mix/load/apply wettable powder formulations.

The ecological risk assessment suggests potential chronic risks of concern to aquatic organisms from application of oxadiazon at the maximum application rate of 8 lbs ai/A/year to golf courses. In order to further assess the risk to fish and invertebrates from oxadiazon exposure, the Agency is requiring that the registrant submit additional early stage fish toxicity data and invertebrate life cycle toxicity data.

Dietary Risk

Acute, chronic and cancer dietary risk from food are not of concern since there are no food tolerances and no registered food uses. Acute and chronic (non-cancer) risks from oxadiazon in groundwater and surface water are also not of concern. Cancer risks from surface water are potentially of concern for the general population based on modeled estimates of environmental concentrations of oxadiazon in surface water from use on golf courses. To address potential drinking water risks associated with estimated surface water concentrations resulting from the use of oxadiazon on golf course turf, the registrant has agreed to reduce the maximum annual application rate at 6 lbs ai/A, with the exception that areas heavily infested with weeds may be treated with up to 8 lbs ai/A. The registrant has agreed to provide additional water monitoring data to refine exposure estimates.

Occupational Risks

Risks for occupational handlers of oxadiazon are of concern. Exposures of concern include mixing/loading/applying wettable powder formulations. To mitigate the cancer risk to handlers, the registrant has agreed that wettable powder formulations of oxadiazon be packaged in water-soluble packaging. In addition, wettable-powder product labels will require that handlers wear chemical-resistant gloves in addition to long pants and a long-sleeved shirt during mixing/loading/applying activities.

Occupational post-application scenarios assessed for oxadiazon include golf course and sod farm workers engaged in turf maintenance. There are no risks of concern from occupational post-application exposure scenarios.

Residential Risk

There were no exposure scenarios of concern for residential risk.

Ecological Risks

Oxadiazon use on golf course turf is of concern given the maximum application rates for turf and the likelihood of golf course runoff to move toward surface water. Acute risks for birds, mammals, fish, aquatic invertebrates and aquatic plants at the typical application rates for golf course turf are not of concern. Chronic risks are not a concern for birds or mammals, but are potentially of concern for aquatic organisms at the maximum application rate of 6 lbs ai/A/year for turf. In order to further assess the risk to fish and invertebrates from oxadiazon exposure, the Agency is requiring that the registrant submit additional toxicity data including early-stage estuarine fish studies and life cycle estuarine/marine invertebrate studies. Also, enhanced toxicity through exposure to high levels of solar radiation may increase risk to aquatic organisms that inhabit small, shallow water bodies. Therefore, EPA is requiring a study on the phototoxicity of oxadiazon in fathead minnows.

Reregistration Eligibility Decision

As required under Section 4(g)(2)(A) of FIFRA, the Agency has completed its review of oxadiazon-specific data, and has determined that the data are sufficient to support reregistration of all products containing oxadiazon provided that certain data gaps are addressed, the risk reduction measures outlined in this document are adopted and labels are amended to implement these measures. The reviewed data were sufficient to allow the Agency to determine that oxadiazon can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency, therefore, finds that all products containing oxadiazon as the active ingredient are eligible for reregistration, provided specified changes are made to the label. Actions needed to reregister particular products are addressed in Section V of this document. The

Agency concludes that these label changes address the current risk estimates and reflect the use of all acceptable data available at this time together with uncertainty factors where data gaps exist.

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 or not the pesticide meets the “no unreasonable adverse effects” criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act (FQPA) was signed into law. This Act amends FIFRA to require 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. FQPA also amends the Federal Food, Drug, and Cosmetic Act (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.

With respect to tolerances for oxadiazon, there have been no active food-use registrations since 1991. The tolerance for rice straw was revoked as of the July 1, 2001 revision to 40 CFR 180.346. In a confirmatory letter to EPA, dated January 24, 2001, the registrant maintained its previous position that it would not support the sixteen remaining oxadiazon tolerances. Therefore, effective April 24, 2003, EPA revoked all the tolerances in 40 CFR 180.346 for the combined residues of the herbicide oxadiazon and its metabolites in the following commodities: in or on milk; cattle, fat; cattle, meat; cattle, meat byproducts; goats, fat; goats, meat; goats, meat byproducts; hogs, fat; hogs, meat; hogs, meat byproducts; horses, fat; horses, meat; horses, meat byproducts; sheep, fat; sheep, meat; and sheep, meat byproducts. In addition, because EPA determined on April 21, 2002 that there is no reasonable expectation of finite residues of oxadiazon and its metabolites in or on meat, milk, poultry, and egg commodities, the sixteen associated tolerances for livestock commodities were considered by the Agency to no longer be needed under 40 CFR 180.6(a)(3). Therefore, on June 3, 2002, the Agency considered the FQPA safety finding to be met and counted the sixteen oxadiazon livestock tolerances as reassessed.

Given that all tolerances for oxadiazon have been revoked, this pesticide no longer falls under the scope of FQPA. As such, no quantitative aggregate assessment of risk from dietary and residential exposures was completed as part of the reregistration process. EPA has evaluated the likelihood of concurrent exposures to oxadiazon for the general population, including children. Because of the relatively low volume of use of oxadiazon on sites other than golf courses, its specialized use pattern, and its relatively high cost, concurrent exposures are not likely.

At this time, the Agency has not made a decision as to whether oxadiazon shares a common mechanism of toxicity with other oxadiazoles, or any other pesticide. A careful evaluation of all the available data is still

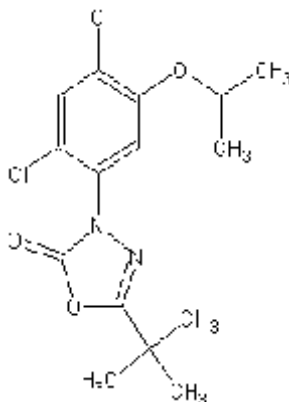
needed, as well as peer review by the FIFRA Scientific Advisory Panel, before a formal decision is made. Therefore, for the purposes of this risk assessment, the Agency has assumed that oxadiazon does not share a common mechanism of toxicity with other pesticides. After a decision is made regarding common 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 presents the Agency's decision regarding the reregistration eligibility of the registered uses of oxadiazon, including the consideration of risk to infants, children and adults for any potential food, drinking water, dermal, inhalation or oral exposures. In an effort to simplify the RED, the information presented herein is summarized. More detailed information can be found in the technical supporting documents for oxadiazon referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page at www.epa.gov/pesticides, and in the Public Docket.

This document consists of six sections. Section I is the introduction. Section II provides a profile of the use and usage of oxadiazon, and its regulatory history. Section III gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV presents the reregistration eligibility and risk management decisions. Section V summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all related documents and how to access them, and Data Call-In (DCI) information.

II. Chemical Overview

A. Chemical Identification



- **Common name:** Oxadiazon
- **Chemical name:** [2-tert-butyl-4-(2,4-dichloro-5-isopropoxyphenyl) -2-1,3,4-oxadiazoline-5-one]
- **Empirical formula:** C₁₅H₁₈Cl₂N₂O₃
- **CAS Registry No.:** 19666-30-9
- **Case number:** 2485
- **OPP Chemical Code:** 109001
- **Molecular weight:** 345.2
- **Trade name:** Ronstar
- **Basic manufacturer:** Bayer Environmental Science

Technical oxadiazon is a white, crystalline powder with a melting point of 90 °C. Oxadiazon is stable for 30 days at 55 °C, and is stable in the presence of aluminum, iron and tin powders (but not ferric chloride). The water solubility of oxadiazon is 0.7 mg/L at 20 °C. Oxadiazon has a vapor pressure of 7.76 x 10⁻⁷ mm Hg.

B. Use Profile

Oxadiazon is labeled for professional use only. The label indicates that the purchase, storage and application of this pesticide are limited to commercial nursery, turf and landscape personnel. The product is not available to homeowners. The following is information on the currently registered uses of oxadiazon. A detailed table of the uses of oxadiazon eligible for reregistration is contained in Appendix A.

- **Type of Pesticide and Target Pests:** Oxadiazon is a pre-emergent or early post-emergent oxadiazole herbicide used to control grassy weeds (e.g., goosegrass and crabgrass) and broadleaf weeds in turf and ornamentals. Oxadiazon works by interfering with the pathway for chlorophyll production, and results in a breakdown of plant tissue on exposure to light.
- **Use Sites:** Oxadiazon is registered for commercial use on residential turf (i.e., apartment/condominium complexes, parks, athletic fields, playgrounds, and cemeteries) and on golf courses (predominant use). In addition, oxadiazon is used on sod farms and on conifer nurseries and landscapes (i.e., industrial sites, ornamental, roadside plantings, woody, ornamental shrubs, vines and trees, and herbaceous ornamentals). Oxadiazon use sites are classified as non-food sites (i.e., primarily golf course fairways), residential outdoor use, roadsides and nurseries.
- **Formulation Types Registered:** Oxadiazon is formulated as a granular (predominant formulation, ~90% of total use) and wettable powder.
- **Method and Rates of Application**

Equipment: Granular formulas are applied using mechanical spreaders, manual spreaders (i.e., belly grinder, push type spreader) or tractor-drawn spreaders. Methods of application associated with the other formulation and use-patterns of oxadiazon include: groundboom, rights-of-way sprayer, handgun sprayer, backpack sprayer, low pressure handwand, high pressure handwand, and lawn handgun.

Rates: The frequency of application ranges from 1 to 3 applications per season. Oxadiazon can be applied at a minimum single application rate of 2.0 pounds active ingredient per acre (ai/A) up to a maximum single application rate of 4.0 pounds ai/A to turf and ornamentals. The annual maximum application rate is 8 lbs ai/A/year.

Use Classification: Not classified.

C. Estimated Usage of Pesticide

Approximately 250,000 pounds of oxadiazon are applied to approximately 50,000 acres annually. Oxadiazon is used primarily in southern states and predominantly on golf courses. Table 1 summarizes the EPA's best available estimates for the pesticide uses of oxadiazon. These estimates are derived from a variety of published and proprietary sources available to the Agency.

Table 1. Oxadiazon Usage Summary

Crop	Lbs. Active Ingredient Applied (Wtd. Avg.)¹	Percent Crop Treated (Likely Maximum)	Percent Crop Treated (Wtd. Avg.)¹
Turf:			
Golf Courses	160,000	6%	3%
Landscape, Rights-of-way, Parks	28,000	---	---
Horticultural Nurseries	56,000	---	---

¹Wtd Avg (weighted average): the most recent years and more reliable data are weighted more heavily.

---: missing information or lack of confidence in the data.

D. Regulatory History

Oxadiazon was registered in 1978. A Phase Four generic data call-in (DCI) was issued in May of 1991. Due to additional data required under FIFRA as amended in 1988, the oxadiazon registrant decided to no longer support food uses of oxadiazon. With respect to tolerances for oxadiazon, there have been no active food-use registrations since 1991. The tolerance for rice straw was revoked as of the July 1, 2001 revision to 40 CFR 180.346. In a confirmatory letter to EPA, dated January 24, 2001, the registrant maintained its previous position that it would not support the sixteen remaining oxadiazon tolerances. Therefore, effective April 24, 2003, EPA revoked all the tolerances in 40 CFR 180.346 for the combined residues of the herbicide oxadiazon and its metabolites in the following commodities: in or on milk; cattle, fat; cattle, meat; cattle, meat byproducts; goats, fat; goats, meat; goats, meat byproducts; hogs, fat; hogs, meat; hogs, meat byproducts; horses, fat; horses, meat; horses, meat byproducts; sheep, fat; sheep, meat; and sheep, meat byproducts. In addition, because EPA determined on April 21, 2002 that there is no reasonable expectation of finite residues of oxadiazon and its metabolites in or on meat, milk, poultry, and egg commodities, the sixteen associated tolerances for livestock commodities were considered by the Agency to no longer be needed under 40 CFR 180.6(a)(3). Therefore, on June 3, 2002, the Agency considered the FQPA safety finding to be met and counted the sixteen oxadiazon livestock tolerances as reassessed. There are no CODEX, Canadian, or Mexican tolerances for oxadiazon residues.

III. Summary of Oxadiazon Risk Assessments

A. Human Health Risk Assessment

1. Toxicity of Oxadiazon

Details of the hazard assessment of oxadiazon can be found in the revised Human Health Risk Assessment for Oxadiazon, dated June 6, 2003 (McCarroll, 2003). Major features of the toxicology profile are presented below. In acute studies, oxadiazon was only slightly toxic to rats and rabbits. In rabbits, oxadiazon was mildly irritating to ocular tissue and negligibly irritating to the skin, and in guinea pig studies, oxadiazon was not a dermal sensitizer (Table 2).

Guideline No./ Study Type	MRID No.	Results	Toxicity Category
870.1100 Acute oral toxicity (rat)	41866501 (97.5% a.i.)	LD ₅₀ >5000 mg/kg %, & combined	IV
870.1200 Acute dermal toxicity (rabbit)	41866502 (97.5% a.i.)	LD ₅₀ >2000 mg/kg, %, & combined	III
870.1300 Acute inhalation toxicity (rat)	41866503 (93.7% a.i.)	LC ₅₀ >1.94 mg/L %, & combined	III
870.2400 Acute eye irritation (rabbit)	41866504 (97.5% a.i.)	Mild irritant to ocular tissues	III
870.2500 Acute dermal irritation (rabbit)	41866505 (97.5% a.i.)	Negligibly irritating to skin	III
870.2600 Skin sensitization (guinea pig)	41230401 (93.7% a.i.)	Not a dermal sensitizer (Buehler test)	--

In both subchronic and chronic studies, the major target organ of oxadiazon toxicity was the liver. Effects were consistent among the species tested (rat, dog, mouse) and typically included enlarged livers along with increases in serum clinical chemistry parameters associated with hepatotoxicity such as alkaline phosphatase and serum aspartate or alanine aminotransferase.

Following long-term dietary administration, oxadiazon caused an increased incidence of hepatocellular adenoma and carcinoma in rats and mice. Consistent findings were reported in a total of four acceptable studies in two species (two mouse and two rat studies). A third mouse study was unacceptable, although increased hepatocellular tumors were also observed in mice of both sexes. A classification of "likely to be carcinogenic to humans" was assigned by the Cancer Assessment Review Committee (CARC). A quantitative risk (Q_1^*) of $7.11 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$ was calculated as the most potent unit risk, based on the incidence of male mouse liver adenoma and/or carcinoma combined tumor rates in the ICR-JCL mouse.

In a special submitted mechanistic study in rats and a published study in rats, mice and dogs, oxadiazon induced peroxisomal proliferation (based on liver enlargement, peroxisomal enzyme induction and electron microscopy) after a 14-day dietary administration. Some peroxisomal proliferator compounds are known to be liver carcinogens, but the Health Effects Division Mechanism of Toxicity Assessment Review Committee (MTARC) concluded that there is insufficient evidence to support peroxisome proliferation as a mechanism of carcinogenicity for oxadiazon due to insufficient data showing hepatocellular proliferation, lack of concordance between the enzyme induction dose-response and tumor formation, and an unexplained decrease in catalase, which is normally significantly increased by peroxisomal proliferator compounds.

Oxadiazon did not show mutagenic potential in any in vitro assays with bacteria (*S. typhimurium* and *E. coli*) or mammalian cells (TK +/-mouse lymphoma cells), did not show clastogenic potential in the *in vitro* Chinese hamster ovary cell chromosomal aberration assays and did not induce unscheduled DNA synthesis in cultured primary rat hepatocytes. However, a dose-related increase in transformation frequencies was observed in an in vitro Syrian hamster kidney BHK21 C13/HRC1 cell transformation assay.

Significant fetal toxicity (fetal loss due to resorptions and post-implantation loss, decreased fetal weight, skeletal variations) was observed in developmental toxicity studies in both rats and rabbits. These fetal effects occurred at the same dose levels at which slight maternal toxicity (decreased weight gain/weight loss) were observed. Offspring survival effects were also observed in the rat two-generation reproduction study. No toxicity was reported at the lowest dose tested; however, in the range-finding phase of the reproduction study at higher dose levels, fetal and neonatal survival were also sharply reduced. The decreased neonatal survival was due at least in part to effects on lactation, based on findings of inactive mammary glands in the dams at necropsy. Neonatal loss may have resulted from starvation and would, therefore, be an effect of direct maternal toxicity. Inactivity of the mammary tissue as a possible effect of endocrine disruption was considered by the Hazard Identification Assessment Review Committee (HIARC) but was not found to be likely since there was no evidence from any other study in the database suggesting endocrine disruption. No fetal malformations were observed in the rat or rabbit developmental toxicity studies; however, some skeletal variations (delayed ossification, asymmetric pelvis) were reported. The above findings indicate that there is no quantitative evidence of increased susceptibility of rats or rabbits following *in utero* or postnatal exposure to oxadiazon.

Neurotoxicity studies are not required for oxadiazon because no clinical signs of toxicity suggestive of neurobehavioral alterations nor evidence of neuropathological effects were observed in any of the available toxicity studies. There was no evidence of neurotoxicity of oxadiazon in the rat and rabbit developmental toxicity studies, nor in the rat two-generation reproduction toxicity study.

Based on the available data, the Metabolism Assessment Review Committee (MARC) concluded that the only residue of concern is the parent compound, oxadiazon, because major degradation products would only be minor components in the environment and are not likely to be significantly more toxic than the parent.

The only toxicity data gap that has been identified at this time is a 28-day inhalation study (OPPTS No. 870.3465). This study is being required by the Agency because some currently registered products of oxadiazon include spray formulations which could result in exposure via the inhalation route.

2. Dose Response Assessment and Toxicity Endpoints

The HIARC concluded that neither an acute nor a chronic reference dose (RfD) was required for oxadiazon because there are no food or feed uses. A short-term oral endpoint was selected for incidental oral exposure in children, using a No Observed Adverse Effect Level (NOAEL) of 12 mg/kg/day based on a statistically significant decrease in maternal body weight gains at 40 mg/kg/day (LOAEL) in a developmental study in rats (Table 3). The same endpoint was selected for short-term and intermediate dermal exposure.

In the absence of food or feed uses, HIARC did not select an acute RfD for oxadiazon. In order to estimate acute drinking water risk, EPA has used the same study and endpoint described above for short-term incidental exposure. For the acute drinking water assessment an uncertainty factor of 100 was applied, based on a 10X for intraspecies variation and a 10X for interspecies extrapolation. Therefore, the “theoretical acute RfD” would be 0.12 mg/kg/day. When maternal toxicity can be attributed to a single dose (e.g, body weight loss in the early dosing period), the developmental studies can be selected for the acute RfD, the short-term (1-7 days) incidental oral exposure and/or the intermediate (7 days to several months) because the critical effect (in the case of oxadiazon, body weight loss at days 16-20 which was possibly due to resorption of fetuses) occurred during the treatment period which encompasses both exposure periods of concern. It is reasonable to assume that effects were possibly manifested by exposure to a single dose and the resulting body weight loss did not become apparent until after 7 days.

A chronic RfD was not selected by HIARC because the lack of food or feed uses. However, for the purpose of assessing potential risks from drinking water, EPA has used the chronic/oncogenicity feeding study. For the chronic drinking water assessment, an uncertainty factor of 100 was applied based on a 10x factor for intraspecies variation and a 10x factor for interspecies extrapolation. This chronic oral endpoint was based on increased incidence of swollen cells in the central lobe of the livers of male rats observed at the LOAEL of 3.5 mg/kg/day. The NOAEL in this study was 0.36 mg/kg/day. Therefore, the “theoretical chronic RfD” would be 0.0036 mg/kg/day. For long-term dermal exposure, this same endpoint was selected. The HIARC recommended that a dermal absorption factor of 9% be used in the calculations, based on a dermal penetration study.

Due to a lack of inhalation studies, the HIARC selected an endpoint from oral studies for inhalation risk assessments. For short and intermediate-term inhalation exposure, the same oral study was chosen as for dermal exposure of these durations, with a NOAEL of 12 mg/kg/day. The same chronic/oncogenicity feeding

study in rats chosen for dermal exposure of this duration was selected for the long-term inhalation exposure, with a NOAEL of 0.36 mg/kg/day. An absorption factor of 100% was applied for inhalation exposures.

A level of concern, referred to as a Margin Of Exposure or MOE, of 100 for occupational and residential exposure scenarios was calculated using a 10x factor for intraspecies variation and a 10x factor for interspecies extrapolation. Because the effects from dermal and inhalation exposure are the same, the doses for these routes and duration were combined. Dermal and incidental oral exposures for toddlers were also combined to reflect a total exposure burden.

Table 3: Endpoints for Oxadiazon Risk Assessment

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Incidental Oral, Short-Term and Intermediate Term	NOAEL= 12 Maternal effects	Reduced body weight/body weight gain at 40 mg/kg/day (LOAEL).	Developmental Toxicity - Rat MRID No. 40470202
Dermal, Short-Term and Intermediate-Term	NOAEL= 12 Maternal effects/ Developmental effects	Reduced body weight/body weight gain at 40 mg/kg/day (LOAEL) / Increased fetal resorptions/postimplantation loss, increased incidence of incomplete ossification at 40 mg/kg/day (LOAEL). For this risk assessment, the dermal absorption rate of 9% is applied.	Developmental Toxicity - Rat MRID No. 40470202
Dermal, Long-Term	NOAEL=0.36	Increased centrilobular swelling in male livers at 3.5 mg/kg/day (LOAEL). For this risk assessment, the dermal absorption rate of 9% is applied.	Combined Chronic Feeding/ Oncogenicity - Rat MRID Nos. 40993401, 00149003/00157780
Inhalation, Short-Term and Intermediate-Term	NOAEL= 12 Maternal effects/ Developmental effects	Reduced body weight/body weight gain at 40 mg/kg/day (LOAEL) / Increased fetal resorptions/postimplantation loss, increased incidence of incomplete ossification at 40 mg/kg/day (LOAEL). For this risk assessment, a 100% absorption rate is applied	Developmental Toxicity - Rat MRID No. 40470202
Dietary, Long-term	NOAEL=0.36	Increased centrilobular swelling in male livers at 3.5 mg/kg/day (LOAEL).	Combined Chronic Feeding/ Oncogenicity - Rat MRID Nos. 40993401, 00149003/00157780
Inhalation, Long-Term	NOAEL= 0.36	Increased centrilobular swelling in male livers at 3.5 mg/kg/day (LOAEL). A 100% absorption rate applied.	Combined Chronic Feeding/ Oncogenicity - Rat MRID Nos. 40993401, 00149003/00157780

Table 3: Endpoints for Oxadiazon Risk Assessment

Cancer	Q ₁ * of 7.11 x 10 ⁻² (mg/kg/day) ⁻¹	Significant increase (pair-wise and trend, p<0.01) in liver adenomas and/or carcinomas combined in males at \$9.3 mg/kg/day).	Combined Chronic Feeding/ Carcinogenicity - Mouse MRID Nos. 40993301
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3. FQPA Considerations

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. With respect to tolerances for oxadiazon, there have been no active food-use registrations since 1991. Effective April 24, 2003, EPA revoked all the tolerances in 40 CFR 180.346 for the combined residues of the herbicide oxadiazon and its metabolites. In addition, the Agency considered the FQPA safety finding to be met and counted the sixteen oxadiazon livestock tolerances as reassessed.

Given that there are no remaining food/feed uses for oxadiazon, and given that all food tolerances have been revoked, this pesticide no longer falls under the scope of FQPA. As such, no quantitative aggregate assessment of risk from dietary and residential was conducted. EPA has qualitatively evaluated the likelihood of concurrent exposures from different sources of oxadiazon for the general population, including children. Because of the relatively low volume of oxadiazon use on sites other than golf courses, its specialized use pattern, and its relatively high cost, concurrent exposures are not expected.

Only 15% (or about 28,000 pounds) of the oxadiazon that is applied each year is used on parks, landscapes, rights-of-way, etc., and this use is distributed across five or more states. An even smaller portion of the 28,000 pounds is used on sites where people, including children could be exposed, such as parks. Because of its comparatively high cost, oxadiazon is not routinely used in residential lawn care. Furthermore, the exposure assumption in both the residential and drinking water assessments are sufficiently protective to account for the unlikely event of exposure from more than one source.

With respect to sensitivity in children, there is no evidence of either a qualitative or quantitative increase in susceptibility of rats or rabbits to *in utero* and/or postnatal oxadiazon exposure. Although significant fetal toxicity was observed in developmental toxicity studies in both rats and rabbits (i.e., fetal loss due to resorptions and post-implantation loss) and in a two-generation reproduction study (i.e., reduced neonatal survival), these fetal/neonatal effects occurred at the same doses that caused maternal toxicity. It is also likely that neonatal losses resulted from starvation and could, thus, be a possible direct maternal toxic effect. Inactivity of the mammary tissue as a possible endocrine disruption effect was considered but was found to be unlikely since there was no evidence from any other study in the database suggesting endocrine disruption.

4. Dietary Risk from Drinking Water

Since there are no food/feed uses of oxadiazon and no tolerances exist, dietary risk from oxadiazon can only result through exposure in drinking water. Drinking water exposure to pesticides can occur through ground and surface water contamination. EPA considers acute, chronic non-cancer, and chronic cancer drinking water risks and uses modeling and monitoring data, if available, to estimate those risks. To determine the maximum contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a “drinking water level of comparison” (DWLOC) to ascertain whether or not modeled or monitored concentrations exceed this level. In the case of oxadiazon, there is no contribution from food. Estimated environmental concentrations (EECs) that are above the corresponding DWLOC exceed the Agency’s level of concern.

Based on its review of submitted studies, the EPA has concluded that oxadiazon would be stable and persistent under typical terrestrial environmental conditions. In the absence of measured environmental concentrations of oxadiazon from monitoring studies, and based on environmental fate characteristics, potential oxadiazon concentrations in unfinished drinking water were estimated using Tier 2 PRZM/EXAMS (surface water) and Tier 1 SCIGROW (ground water) models. The PRZM/EXAMS model as used here is a standard turf scenario that includes a two-centimeter layer of thatch, and is referred to as the Florida Turf Scenario.

The combined (“linked”) PRZM/EXAMS model is typically used by EPA in estimating pesticide concentrations in surface waters. The PRZM model estimates the amount of pesticide that reaches a body of surface water as a result of runoff. The EXAMS model estimates pesticide concentrations by taking into account different mechanisms for dissipation, weather patterns, and periodic application of pesticide, for several years. The PRZM/EXAMS model generates concentration estimates of acute (one in ten year peak concentration), non-cancer chronic (one in ten year mean concentration) and chronic cancer (36-year mean concentration).

As used here, the PRZM/EXAMS estimates of pesticide concentrations in surface water generated by this linked model can be considered to be upper-bound estimates. Several conservative parameter values have been incorporated into the mathematical formulas, including a calculated factor for the half-life of oxadiazon in water. The Florida Turf Scenario introduces a two-inch thatch layer as an intercept to incorporation of oxadiazon with soil particles. As typically applied, oxadiazon granules are watered into the soil surface, thereby mediating the potential effects of the thatch layer. Also, an assumption in the current model is that oxadiazon is applied as a wettable powder formulation (i.e., applied as a spray), and therefore the model includes a value for spray drift into water bodies.

An additional conservative parameter incorporated into the model is the value for percent crop area (PCA). The term PCA refers to the area of land around a watershed that is planted with crops to which a specific pesticide will be applied. In the example of oxadiazon, the primary application site is golf course turf. In the present model, a PCA value of 94% was used to account for the land area of a typical golf course that is greens, tees, fairway (27%) and rough (67%). The EPA makes the protective assumption that 94% of land area around a particular watershed might possibly be made up of golf course, and that 100% of the golf courses in the watershed apply oxadiazon at the maximum application rate and frequency. Registrants have

submitted a GIS analysis suggesting that the upper-bound limit of PCA for turf (including golf courses and other recreational turf) in south Florida is substantially less than 94%. Model-derived surface water EECs and DWLOCs are summarized in Table 4.

The SCIGROW model is typically used for Tier 1 screening purposes for pesticides applied to soils. The SCIGROW model is based on leaching studies conducted in sandy soils above shallow aquifers, and estimates likely groundwater concentration. In areas with those characteristics, groundwater is particularly vulnerable to contamination. The SCIGROW model estimated environmental concentration for oxadiazon in groundwater is 0.59 ppb.

Table 4. Surface Water DWLOC and EEC Comparisons						
	Acute DWLOC (ppb)	Acute EEC (ppb)	Chronic (non-cancer) DWLOC (ppb)	Chronic (non-cancer) EEC (ppb)	Chronic (cancer) DWLOC (ppb)	Chronic (cancer) EEC (ppb)
Infants (<1 year)	1200	181	36	65	0.49	56
Children (1-6 years)	1200		36			
Females (13-50 years)	3600		108			
U.S. population	4200		126			
Ground Water DWLOC and EEC Comparisons						
Infants (<1 year)	1200	0.59	36	0.59	0.49	0.59
Children (1-6 years)	1200		36			
Females (13-50 years)	3600		108			
U.S. population	4200		126			

a. Acute Drinking Water Risk

Acute DWLOCs were calculated for oxadiazon based on results of a developmental toxicity study. The No Observable Adverse Effect Level (NOAEL) was 12 mg/kg/day, with the toxicity endpoint being a reduction in maternal body weight gain at the Lowest Observable Adverse Effect Level (LOAEL) of 40 mg/kg/day. The rationale for selection of this endpoint is provided in the “Dose Response and Toxicity Endpoint” section of this document. Based on a comparison of DWLOCs to the corresponding PRZM/EXAMS (surface water) and SCIGROW (groundwater) estimates (EECs), the EECs for surface water (181 ppb) and groundwater (0.59 ppb) were less than the DWLOCs calculated for all populations (1200 - 4200 ppb) and, thus, the Agency concludes that acute exposure to residues of oxadiazon in surface and groundwater-sourced drinking water is not of concern.

b. Chronic Drinking Water Risk

Chronic DWLOCs were calculated based on a chronic toxicity/carcinogenicity study. The NOAEL was 0.36 mg/kg/day, based on the endpoint of centrilobular swelling in male rats, observed at the LOAEL of 3.5 mg/kg/day. The rationale for selection of this endpoint is provided in the “Dose Response and Toxicity Endpoint” section of this document. Using the PRZM/EXAMS model estimates, the EECs for surface water (65 ppb) were higher than the DWLOCs calculated for infants and children (36 ppb) (Table 4) and thus, potentially of concern. The chronic ground water EEC of 0.59 ppb was less than the chronic (noncancer) DWLOC of 36 for the most sensitive subpopulations (children less than 1, and children 1-6 years) and is not a concern.

c. Cancer Drinking Water Risk

For the cancer exposure calculations, the Agency used multi-year mean water concentration values. The DWLOC_{cancer} is the concentration in drinking water that results in a negligible cancer risk of one in a million (1.0×10^{-6}). The cancer ground water EEC of 0.59 ppb slightly exceeds the DWLOC of 0.49. However, given the protective exposure assumptions, this slight exceedence is not of concern. The cancer EEC for surface water (56 ppb) exceeds the cancer DWLOC (0.49 ppb) (Table 4) and thus, is potentially of concern.

5. Residential and Other Non-occupational Post-application Risks

Since oxadiazon is only available to professional turf, landscape, and nursery personnel, there are no residential handler scenarios. Although oxadiazon is not available for homeowner use, the Agency has determined that there are potential postapplication exposures to residents entering oxadiazon treated turf and lawns. A complete discussion of potential residential exposures, including the sources of exposure data and toxicity information is found in the document “Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Oxadiazon” dated June 7, 2003 (Tadayan, 2003) on the Agency's web page at www.epa.gov/pesticides, and in the Public Docket.

The scenarios likely to result in postapplication exposures in non-occupational situations are presented below. The duration of postapplication dermal exposure is expected to be either short-term or intermediate-term, based on oxadiazon turf residue dissipation data. Oxadiazon has a half-life on turf of up to 1.4 days (irrigated) and 1.7 days (non-irrigated) after spraying, requiring several days to dissipate to non detectable levels of transferable residues (MRID # 435178-01). Because the label prohibits application more than 3 times per year, and even with the slow dissipation rates, it is not expected that individual residential exposure duration would exceed 30 days in duration. Exposure on a residential lawn would diminish continuously with time, while exposure through recreation turf contact would more likely be random intermittent events of varying doses, all less than the dose predicted in this assessment. Residential postapplication exposure assessments assume that residents wear the following attire: short sleeved shirt, short pants, shoes and socks, and no gloves or respirator. The scenarios likely to result in postapplication exposures are as follows:

- dermal postapplication risks to adults and toddlers when entering oxadiazon treated turf and lawns;

- oral postapplication risks to toddlers from “hand-to-mouth” (i.e., ingestion of grass, soil, granular pellets, or hand-to-mouth contact) exposure when reentering lawns treated with granular and wettable powder formulations.

Representative turf reentry activities include, but are not limited to:

- Adults involved in a low exposure activity, such as golfing or walking on treated turf.
- Toddlers involved in a low exposure activity, such as walking on treated turf.
- Adults mowing or other moderate contact activity, for 1-2 hours.
- Adults involved in a high exposure activity, such as heavy yard work (doses similar to occupational scenarios for cutting and harvesting sod).
- Toddlers involved in high exposure activities on turf.

For risk assessment purposes, Margins of Exposure (MOEs) compare the estimated exposure concentration to a No Observed Adverse Effect Level (NOAEL) from an animal study. In the case of oxadiazon, the Agency’s level of concern for residential post-application risk is exceeded if MOEs fall below 100. The target MOE of 100 for non-occupational exposure scenarios was selected based on the uncertainty factors of 10x for intraspecies variation and 10x for interspecies extrapolation.

The registrant submitted a study on turf-transferable residues (TTR) in response to an occupational/residential exposure Data Call-In, and in support of oxadiazon re-registration requirements. *Ronstar® 50 WP* a wettable powder product containing ~ 50 % oxadiazon, was applied to turf in North Carolina. The study was conducted in order to quantify the dermal exposure associated with re-entry onto oxadiazon treated turf. *Ronstar® 50 WP* which is labeled for use on dormant, Bermuda grass, St. Augustine grass and *Zoisia* turf in areas such as fairways, parks, and lawns was used at a maximum label rate of 3 .0 lb ai/A. Two different exposure scenarios were monitored:

- Application at the maximum label rate followed by re-entry as soon as the turf was dry.
- Application followed within 30 minutes by sprinkler irrigation of 1/10 inch of water with re-entry occurring as soon as the turf is dry.

Utilizing the transferable residue data and revised residential SOPs, all of the non-cancer risk scenarios developed for adults and children had short-term and intermediate-term dermal MOEs greater than 100. The cancer risks for all adult, non-occupational, dermal, post-application exposures ranged from 6×10^{-6} to 8×10^{-7} . Although the estimated cancer risk slightly exceeds the Agency’s level of concern (1.0×10^{-6}), that estimate is conservative given that the risk assessment was performed with a spray application, whereas approximately 90% of oxadiazon is applied as a granular formulation. The granule size for a typical end-use product, *Ronstar G*, is 20/50 Mesh, or 300-850 microns. In all instances, the granules are designed to fall below the grass canopy and into the thatch layer. If used according to label directions, it is unlikely that oxadiazon granules would be accessible to a child or adult. According to the registrant, for best results oxadiazon granules should

be watered-in as soon as is practical following application. Watering-in the granules will carry them further into the thatch layer, and will further decrease the likelihood of dermal exposure.

Estimated incidental oral short-term exposures ("hand-to-mouth") for children had an MOE of 100 using the TTR default values from the residential SOP; when the TTR data from a submitted oxadiazon study were used, the MOEs were 240 and 90 for irrigated and non-irrigated turf, respectively.

MOEs were not calculated for the incidental ingestion of oxadiazon granules because, as discussed above, the very small granules would not be available on the lawn surface and thus not accessible to children. It is thought, therefore, that the incidental ingestion of granules is not likely to be a cause for concern.

6. Occupational Risk

a. Occupational Toxicity

For risk assessment purposes, Margins of Exposure (MOEs) compare the estimated exposure concentration to a No Observed Adverse Effect Level (NOAEL) from an animal study. In the case of oxadiazon, the Agency's level of concern for occupational risk is exceeded if MOEs fall below 100. The target MOE of 100 for occupational exposure scenarios was selected based on the uncertainty factors of 10x for intraspecies variation and 10x for interspecies extrapolation. The short-term and intermediate-term MOEs for occupational risk were calculated based on a NOAEL of 12 mg/kg/day from a rat developmental toxicity study. The LOAEL in this study was 40 mg/kg/day; the endpoint is reduced bodyweight gain.

The short-term and intermediate-term MOEs for dermal and inhalation exposures were calculated using an oral NOAEL of 12 mg/kg/day for both exposure durations (see Human Health Risk Assessment Section 3.3 Dose Response Assessment). The Agency also used route-to-route extrapolations to convert this oral dose to dermal and inhalation doses. A dermal absorption rate of 9% was applied to the dermal exposure assessments and an inhalation absorption rate of 100% was applied to the inhalation exposure assessments. Since the effects from dermal and inhalation exposure are based on the same oral study (i.e. rat developmental toxicity study), the exposures for these routes and durations were combined.

b. Occupational Handler Exposure

Occupational exposure to oxadiazon via the dermal and inhalation routes may occur during mixing, loading and applying through the use of ground spray, granular and other turf application methods. Based on the use patterns, 14 major occupational exposure scenarios were identified for oxadiazon:

- (1a) mixing/loading wettable powders for chemigation application;
- (1b) mixing/loading wettable powders for groundboom application;
- (1c) mixing/loading wettable powders for rights-of-way sprayer;

- (2) loading granular formulations;
- (3) applying sprays with a groundboom;
- (4) applying sprays with a rights-of-way sprayer;
- (5) applying wettable powder sprays with handgun sprayer;
- (6) applying granules with a tractor drawn spreader;
- (7) mixing/loading/applying sprays with a backpack sprayer;
- (8) mixing/loading/applying sprays with a low pressure handwand (wetable powder formulations);
- (9) mixing/loading/applying sprays with a high pressure-handwand (wetable powder formulations);
- (10) mixing/ loading/ applying sprays with a lawn handgun (wetable powder formulations);
- (11) mixing/ loading/ applying granules with a push type spreader; and,
- (12) mixing/loading/applying granules with a bellygrinder.

Maximum single application rates for oxadiazon range from 3 to 4 lb. ai/acre, with the higher rate being applied to golf courses, roadside turf, lawns, parks, recreational areas and woody ornamentals.

The exposure scenarios are of short-term (1-30 days) and intermediate-term (30 days to several months). Since the use patterns for oxadiazon do not suggest any long term use, exposure scenarios of a longer duration were not considered. The estimated exposures considered:

- baseline protection (long pants, long shirts and no gloves - dermal; no respirator - inhalation),
- additional PPE (long pants, long shirts and chemical resistant gloves and/or double layer of clothing - dermal; plus 80% protection from dust/mist respirator - inhalation), and
- engineering controls (use of water soluble packages for wettable powder formulations).

EPA completed handler exposure assessments first assuming the baseline level of protection and, if required, increasing levels of risk mitigation (PPE and engineering controls) to achieve an MOE of 100 or more for non-cancer risks. The Agency's assumptions for specific categories of handlers and equipment are as follows:

- all occupational handlers are wearing footwear (socks plus shoes or boots)
- occupational mixers and loaders using open mixing techniques are wearing long-sleeved shirts and long pants and gloves; this represents **minimum PPE**
- occupational mixers and loaders using open mixing techniques are wearing long-sleeved shirts and long pants, coveralls and gloves; this represents **maximum PPE**
- occupational applicators who use open cab tractor-driven application equipment are wearing long-sleeved shirts and long pants and gloves; this represents **minimum PPE**.

- Also, if necessary, dust/mist respirator represented by 5-fold protection factor or an organic vapor respirator represented by a 10-fold protection factor are added to mitigate the risks.

Engineering control assumptions are as follows:

- engineering controls are not available for occupational handlers (mixers, loaders, and applicators) who use hand-held application equipment.
- occupational mixers and loaders handling liquid formulations using a closed system are wearing chemical-resistant gloves plus long-sleeved shirts and long pants.
- occupational mixers and loaders handling wettable powders using a closed system (water-soluble packages) are wearing long-sleeved shirts and long pants, and chemical-resistant gloves.
- occupational applicators who use tractor-driven application equipment are located in enclosed cabs are wearing long-sleeved shirts and long pants, and no gloves.

Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted to the Agency in support of the reregistration of oxadiazon. In such instances, it is the policy of the EPA to use data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available. EPA's level of confidence in these data are explained in detail in the "Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Oxadiazon" dated June 7, 2003 (Tadayon, 2003).

c. Occupational Risk (noncancer)

The results of the short- and intermediate-term handler assessments are presented in Table 5 and indicate that potential non-cancer exposure scenarios have MOE(s) greater than or equal to 100 at either the baseline (i.e., long pants, long sleeved shirts, no gloves), PPE (i.e., long pants, long sleeved shirts, and chemical resistant gloves while using open systems) or using engineering controls (i.e., water-soluble packages). The only exception, for which engineering controls are not feasible, is scenario 8 (low pressure handwand-wettable powder formulations), with a total MOE of 46 with maximum PPE. The low-pressure hand wand applicator is likely to be used in non-turf areas of golf courses, such as landscaping.

Table 5: Exposure Variables (Noncancer) and MOEs for Uses of Oxadiazon						
Exposure Scenario (Scenario #)	Crop Type	App Rates (lb ai/acre)	Daily Acres Treated	Total MOEs		
				Base line	PPE	Eng. Control
Mixer/Loader						

Table 5: Exposure Variables (Noncancer) and MOEs for Uses of Oxadiazon

Exposure Scenario (Scenario #)	Crop Type	App Rates (lb ai/acre)	Daily Acres Treated	Total MOEs		
				Base line	PPE	Eng. Control
Mixing/Loading Wettable Powders for Chemigation Application (1a)	sod farms	3	350	2	35	610
Mixing/Loading Wettable Powders for Groundboom Application (1b)	conifer nurseries, woody ornamentals	4	40	12	220	NA
	herbaceous ornamentals	3	40	16	300	NA
	sod farms	3	80	8	150	NA
	golf courses	4	40	12	220	NA
Mixing/Loading Wettable Powders for Rights-of-Way Sprayer (1c)	r o a d s i d e t u r f , ornamentals	4	40	12	220	NA
Loading Granular formulations (2)	sod farms, conifers forest	4	80	920	NA	NA
	golf course turf, parks, recreational areas	4	40	1800	NA	NA
	woody ornamentals	4	40	1800	NA	NA
Applicator						
Applying with a Groundboom (3)	sod farms	3	80	1500	NA	NA
	herbaceous ornamentals	3	40	3000	NA	NA
	golf courses	4	40	2300	NA	NA
	conifer nurseries, woody ornamentals	4	40	2300	NA	NA
Applying with a Rights-of-Way Sprayer (4)	roadsides	4	40	37	120	NA
Applying Wettable-Powders for Handgun Applicators (ORETF) (5)	l a w n s , p a r k s , recreational areas	4	5	See PPE	540	NA
Applying Granular with a Tractor Drawn Spreader (6)	sod farms	4	80	1100	NA	NA
	golf courses	4	40	2200	NA	NA
Mixer/Loader/Applicator						
Backpack Sprayer (LCO) (7)	l a w n s , g o l f c o u r s e s , ornamentals nurseries	4	5	See PPE	140	NA
Low Pressure Handwand - Wettable Powder Formulations (LCO) (8)	lawns, golf courses, nursery stock	4	5	10	46	NF

Table 5: Exposure Variables (Noncancer) and MOEs for Uses of Oxadiazon

Exposure Scenario (Scenario #)	Crop Type	App Rates (lb ai/acre)	Daily Acres Treated	Total MOEs		
				Base line	PPE	Eng. Control
High Pressure Handwand -- (Wettable Powder Formulations) (9)	woody ornamentals, conifer nurseries.	4	5	See PPE	100	NA
Lawn Handgun (Wettable Powder Formulations) (ORETF) (10)	ornamentals, lawns, parks rec areas	4	5	280	NA	NA
Granulars with a Push Type Spreader (ORETF) (11)	lawns, golf courses, parks, recreational areas, ornamentals	4	5	1100	NA	NA
Granulars with a Bellygrinder (LCO) (12)	golf courses, parks, rec areas.	4	1	190	NA	NA

Baseline dermal unit exposure scenarios includes long pants, long shirts and no gloves.

Baseline inhalation unit exposure represents no respirator

PPE dermal unit exposure includes long pants, long shirts and gloves for scenarios 5, 7, and 9.

PPE dermal unit exposure includes long pants, long shirts gloves and double layer (50% protection) for scenarios 1a, 1b, 1c, and 8.

PPE inhalation unit exposure represents dust/ mist respirator (80 % protection) for scenarios 1a, 1b, 1c, and 8.

Engineering Control dermal unit exposure scenarios includes long pants, long shirts, gloves and water soluble packages for scenario 1a.

Engineering inhalation unit exposure represents no respirator.

NA = Not applicable.

NF = Not Feasible. No engineering controls are available to mitigate risk.

d. Occupational Handler Risk (cancer)

The cancer risk assessments for handlers used baseline PPE and, as needed, increasing levels of risk mitigation (PPE and engineering controls) to achieve cancer risks below EPA's level of concern. As noted previously, the Agency's level of concern for cancer risks for occupational exposure to pesticides ranges from 1.0×10^{-4} to 1.0×10^{-6} , depending on the feasibility, availability, and cost of various mitigation options.

Potential cancer risks to handlers were assessed using the following assumptions:

- an average typical adult body weight of 70kg;
- typical working lifetime of 35 years;
- 70 year lifetime;
- dermal absorption of 9% and inhalation absorption of 100% of the oral dose.

Based on the scenarios identified above, the Agency estimates that cancer risks from occupational dermal and inhalation exposures to oxadiazon range from 1.7×10^{-2} to 4.7×10^{-7} during "baseline" conditions (i.e. long pants, long-sleeves, no gloves). Cancer risk ranges from 1.0×10^{-3} to 1.4×10^{-7} when PPE was used. The Agency estimates that cancer risk decreases to a range of 5×10^{-5} to 1×10^{-8} with engineering controls. Engineering controls included the use of chemical-resistant gloves along with water soluble packaging for wettable powder formulations. Overall these estimates suggest that when PPE and/or engineering controls are used, none of the evaluated scenarios have cancer risks that exceed 1.0×10^{-4} , but most are in the range where further consideration is warranted.

e. Occupational Exposure and Risk, Post-application (non-cancer)

EPA uses the term "post-application" to describe those individuals who can be exposed to pesticides after entering areas previously treated with pesticides and performing certain tasks or activities (also often referred to as reentry exposure). Most of the oxadiazon used is applied either pre-plant or when the crops are quite small (early post-emergence). This fact, and the degree of mechanization, minimizes the post-application contact of workers with oxadiazon. However, the Agency has determined that there are potential post-application exposures to individuals re-entering oxadiazon treated areas for the purpose of:

- *Roadsides*: mowing
- *Bermuda grass rights-of-way*: mowing
- *Sod farms*: mowing and harvesting
- *Golf-course turf*: mowing

Based on usage information provided by the registrants for reregistration, the most common post-application exposures for oxadiazon will occur for workers on turf. Based on label restrictions and pattern of use, oxadiazon is applied early in the season, either pre-plant or before weeds emerge (pre-emergence).

Mowing would be a common post-application activity after either spraying method. Treated turf or grasses will routinely require reentry activities, such as mowing and watering, and eventually harvesting in the case of sod farms.

Because oxadiazon has a low vapor pressure (1.0×10^{-6} mm Hg) and is only used outdoors, the inhalation component of post-application exposure is anticipated to be negligible. Therefore, all calculations of post-application risk estimates have been done for dermal exposure only.

For short-and intermediate-term non-cancer risks, mowing (e.g., golf courses, roadsides, and sod farms) and harvesting (e.g., sod farms) scenarios were considered. Transfer coefficients of 500 and 16,500 cm^2/hr were used, based on the Agricultural Re-entry Task Force data (refer to EPA Exposure SAC Policy guidance 3.1, 8/00). Occupational post-application activities had MOEs of 30-1000 at day 0. This information is summarized below in Table 6.

f. Occupational Risk, Post-application (cancer)

Cancer risks for occupational post-application scenarios were estimated not to exceed EPA's level of concern (i.e. $\# 1.0 \times 10^{-4}$; Table 6).

Crop/Use Pattern	Application Rate (lb ai/acre)	Postapplication Activity	Transfer Coefficient ^a	Cancer Risk		
				MOE ^b	LADD ^c mg/kg/day	Risk ^d
Golf Course Turf	4	Mow, seed, scout, mechanical weed, aerate, fertilize, prune	500	1000	4.23e-5	3.01e-6
		Transplant, hand weed	16,500	30	1.39e-3	9.92e-5
Sod Farms	4	Mow, scout, mechanical weed, irrigate	500	1000	4.23e-5	3.01e-6
		Transplant, hand weed, harvest (hand or mechanical)	16,500	30	1.39e-3	9.92e-5
Bermuda Grass Rights of Way	4	Mow, seed, scout, mechanical weed, aerate, fertilize	500	1000	4.23e-5	3.01e-6

^aTransfer coefficient from Science Advisory Council for Exposure: Policy Memo # 003 .1 "Agricultural Transfer Coefficients," Revised - August 7, 2000.

^bMOE = Short-term NOAEL (12 mg/kg/day; based on a dermal study) / dermal dose where absorbed dose = TTR ($\mu\text{g}/\text{cm}^2$) x TC (cm^2/hr) x conversion factor (1 mg/1,000 μg) x exposure time(8hrs/day)x dermal absorption (9 %) / body weight (60 kg; adult).

^cAbsorbed dermal dose where absorbed dose = TTR ($\mu\text{g}/\text{cm}^2$) x TC (cm^2/hr) x conversion factor (1 mg/1,000 μg) x exposure time (8 hrs/day) x dermal absorption (9 %) / body weight (70 kg) x (Number of days (3) exposure per year applicator) /365 days per year) x 35 years worked/70 year lifetime

^dCancer Risk = LADD (mg/kg/day) x (Q_1^*), where $Q_1^* = 7.11 \times 10^{-2}$ (mg/kg/day)⁻¹.

7. Incident Data

Oxadiazon has not been reported to cause life-threatening illness or death in humans. On the list of the top 200 chemicals for which National Pesticide Information Center (NPIC, formerly National Pesticide Telecommunications Network) received calls from 1984-1991 inclusively, oxadiazon was ranked 192nd with 12 incidents in humans reported and five incidents in animals (mostly pets). Most of the cases appear to be related to irritation to the skin, eyes and mucous membranes.

B. Environmental Risk Assessment

A summary of the Agency's environmental fate and effects risk assessment is presented below. More detailed information on the environmental and ecological risks associated with the use of oxadiazon may be found in the "EFED Revised Risk Assessment for the Reregistration Eligibility Decision of Oxadiazon," dated June 11, 2003. Since that document was completed, the Agency made changes to refine its assessment of the chronic surface water concentrations of oxadiazon associated with the use on turf. Specifically, the Tier 1 model simulations were refined using the Tier 2 PRZM/EXAMS model simulation with a turf scenario. The linked PRZM/EXAMS models are typically used by EPA in estimating pesticide concentrations in surface waters. The PRZM model estimates the amount of pesticide that reaches a body of surface water as a result of runoff. The EXAMS model estimates pesticide concentrations by taking into account different mechanisms for dissipation, weather patterns, and periodic application of pesticide, for several years. The complete environmental fate and effects risk assessment and related addenda are not included in this document, but are available on the Agency's web page at www.epa.gov/pesticides, and in the Public Docket.

1. Environmental Fate and Transport

Based on the fate studies reviewed, oxadiazon would be stable and persistent under typical terrestrial environment conditions. Soil photolysis and hydrolysis under acidic and basic conditions do not appear to be an important dissipation mechanism. However, direct aqueous photolysis half-life of about three days (summer sunlight conditions in Florida) suggests that in clear and shallow surface water bodies where sunlight penetration can be significant, photolytic degradation of oxadiazon is possible. The photolytic effect may substantially diminish in turbid and deeper water bodies.

Microbial metabolism in soil and aquatic environments under either aerobic and anaerobic conditions is not expected to cause any significant transformation of oxadiazon, although a number of degradates have been reported from the different chemical and biological fate studies.

Studies on equilibrium sorption and aged/unaged oxadiazon indicate that the pesticide has low environmental mobility (K_d 's ranged from 8.17 to 22.83; K_{oc} 's ranged from 1409 to 3268). Thus, oxadiazon is likely to be transported, via surface runoff, bound to erodible soil particles, to nearby surface water bodies. Leaching from surficial soils to groundwater is expected to be low or negligible, unless the soil is very porous or has some cracks that favor preferential flow. Oxadiazon exhibited slow dissipation in two terrestrial field studies conducted in California and North Carolina.

2. Water Resources

The potential impact to water quality from the use of oxadiazon on turf is essentially due to the parent (as opposed to possible degradates). Oxadiazon appears to be persistent under most environmental conditions making the chemical available for surface runoff. The remaining factor which affects the impact of oxadiazon on water quality is mobility in soils. A soil column leaching study, and supplemental batch equilibrium studies, indicate that oxadiazon has low mobility in the various soils tested. Ordinarily this would mean that the chemical would remain soil bound and would be transported to a water body on eroded soil. Turf scenarios, however, offer different challenges than typical agricultural crops. The turf itself offers a vegetative interception layer (including thatch) that prevents rapid deposition of the oxadiazon on the surface of the soil. Both liquid and granular formulation labels of oxadiazon recommend mowing the grass prior to application. Also, both liquid and granular formulation labels of oxadiazon specify that the chemical's effectiveness is improved if it is wetted in after application. Oxadiazon is more likely to bind to soil particles if the turf is watered after application of the pesticide.

The models used for the Tier 1 determination of the water exposures were FIRST, GENECC 2.0 for surface waters, and SCIGROW for ground waters. The models are screening tools designed to provide upper-bound estimates of the concentrations that might be found due to the use of oxadiazon. For drinking water, a Tier II refinement was performed, using PRZM/EXAMS. In the Tier II refinement, a scenario that incorporates three applications (1 @ 4 lb a.i./A and 2 @ 2 lb ai/A) was used. Surface water monitoring data for oxadiazon is limited and has not been used to represent possible concentrations of oxadiazon in surface waters. The chemical is not included in the NAWQA monitoring studies. The STORET database contained only two samples taken from the same location within an interval of only four days. The estimated recommended acute and long term drinking water concentrations are detailed in Chapter 6 of the document "EFED Revised Risk Assessment for the Reregistration Eligibility Decision of Oxadiazon," dated June 11, 2003.

3. Ecological Risk

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The Agency calculates risk quotients (RQs) by dividing exposure estimates by acute and chronic ecotoxicity values:

$$RQ = \text{EXPOSURE} / \text{TOXICITY}$$

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by EPA to indicate potential risk to nontarget organisms. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. The exposure and effects inputs to a screening-level assessment are by design assumed to overestimate likely exposures and effects of pesticides. Exceedence of an LOC indicates that risks of concern are possible, but the likelihood, magnitude, and/or severity of the risk cannot be quantified. Risk presumptions, along with the corresponding LOCs, are given in Table 7 below.

Risk Presumption	LOC terrestrial animals	LOC aquatic animals
Acute Risk -there is potential for acute risk; mitigation 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,	0.1	0.05
Chronic Risk -there is potential for chronic risk; regulatory action may be warranted.	1	1

Aquatic and terrestrial risk assessments were conducted by using standard ecotoxicity endpoints (*i.e.*, LD₅₀ and LC₅₀ values, and NOAEC values). The toxicity endpoints chosen for use in the ecological risk assessment are summarized below in Table 8.

Type Of Toxicity	Organism	Species	Toxicological Endpoint
Oral Acute	Bird	Mallard	1040 mg/kg
Dietary		Bobwhite/Mallard	>5000 ppm

Type Of Toxicity	Organism	Species	Toxicological Endpoint
Chronic		Bobwhite	500 ppm ¹
Oral Acute	Mammal	Rat	>5000 mg/kg
Chronic		Rat	200 ppm ²
Acute	Freshwater Fish	Rainbow trout/Bluegill	0.88 ppm
Chronic		Rainbow trout	0.88 ppb ³
Acute	Freshwater Invertebrates	Daphnid	2.18 ppm
Chronic		Daphnid	0.03 ppm
Acute	Estuarine Fish	Sheepshead Minnow	1.5 ppm
Chronic		Sheepshead Minnow	0.0015 ppm ⁴
Acute	Estuarine Invertebrates	Mysid	0.27 ppm
Chronic		Mysid	0.0037ppm ⁴
Acute	Aquatic Plants (vascular)	duckweed	EC ₅₀ =41 ppb NOAEC = <8 ppb
	(Nonvascular)	marine diatom	EC ₅₀ = 5.2 ppb

¹ No effects on any reproductive parameter or viability of F₁ offspring at the highest dose tested, 1000 ppm; however due to excessive mortality (33%) of adult female birds in that dose level, a NOAEC for chronic effects was set at 500 ppm.

² LOAEL of ≥38 mg/kg/ day for inactive mammary tissue and fetal/pup death observed in the one year range-finding test of a rat reproduction study. NOAEC >200 ppm.

³ Rainbow trout was more sensitive than the fathead minnow (fathead minnow NOAEC= 33 ppb).

⁴ Extrapolation from acute/chronic ratio.

a. Risks to Birds

Table 9 provides avian acute and chronic RQs from exposure to multiple applications of oxadiazon EC to turf for the maximum three application rates (4.0, 3.0 and 2.0 lbs ai/A) and two split applications (1.0 lb ai/A, 4 times/6 months; 1.3 lbs ai/A, 3 times/6 months). The maximum three applications have the potential for chronic exposure to birds that feed on plants and grass (e.g., ducks, geese) and may result in risk to these birds (RQ = 1.0 - 2.0). The split application appears to lower this chronic exposure and risk (RQ = ≤1). The EC formulation was evaluated because it

presents an upper-bound estimate of risk. The majority of oxadiazon is applied as a granular formulation. Exposure from the granular formulation was evaluated because birds may be exposed to granular pesticides through ingestion when foraging for food or grit. RQ values were calculated for three weight classes of birds (1000g waterfowl, 180g upland game bird, and 20g songbird). All scenarios for the granular resulted in no acute risk to birds (RQ < 0.5). However, the potential chronic concern noted for non-endangered birds suggest that oxadiazon may present a risk to endangered species (RQ > 0.1).

Pesticide dissipation from foliar surfaces is primarily due to degradation or dissipation by one or more processes including photolysis, hydrolysis, microbial degradation and volatilization. Since adequate foliar dissipation data are not available for oxadiazon, a default half-life of 35 days was used in the EEC calculations.

Site Application Rate lbs ai/A (# appl)	Food Item	Maximum EECs (ppm)	Acute RQ (EEC/LC₅₀)	Chronic RQ (Max. EEC/NOAEC)
Turf (EC) 4.0 (2)	Short grass	984.1	< 0.2	2.0
	Tall grass	451.1	< 0.1	1.0
	Broadleaf plants/insects	553.6	< 0.1	0.1
	Seeds	61.5	< 0.0	0.1
Turf (EC) 3.0 (2)	Short grass	739.6	<0.1	1.5
	Tall grass	339.0	0.0	1.0
	Broadleaf plants/insects	416.0	<0.1	1.0
	Seeds	46.2	0.0	0.1
Turf (EC) 2.0 (2)	Short grass	493.1	<0.1	1.0
	Tall grass	226.0	0.0	0.4
	Broadleaf plants/insects	277.3	0.0	0.5
	Seeds	30.8	0.0	0.1
Turf (EC) 1.0 (split 4 applications/ 6 months)	Short grass	424.4	<0.1	1.0
	Tall grass	194.5	0.0	0.4
	Broadleaf plants/insects	238.7	0.0	0.5
	Seeds	26.5	0.0	0.1

Crop	Food Items	EEC (ppm)	Chronic RQ (Max. EEC/NOAEC) ^b
Turf (EC) 1.3 (split 3 applications/ 6 months)	Short grass	257.0	<0.1
	Tall grass	117.8	0.0
	Broadleaf plants/insects	144.6	0.0
	Seeds	16.1	0.0

^aAvian acute and chronic risk quotients (RQ's) as generated through ELL-FATE for broadcast ground spray applications for oxadiazon. RQ's are based on mallard duck LC₅₀ > 5,000 ppm and NOAEC = 500 ppm. The EEC reflects the turf use with the three highest use rate (4.0, 3.0 and 2.0 lbs ai/A, 2 applications) and two split applications (1.0 lb ai/A, 4 times/6 months; 1.3 lbs ai/A, 3 times/6 months).

b. Risks to Mammals

The Agency has concluded that for the EC formulation of oxadiazon the assessed single application rates (4.0, 3.0 and 2.0 lbs ai/A), as well as the split use rates (1.0 and 1.3 lbs ai/A) should not result in acute risk to mammals (RQ ≤ 0.2). However, these application scenarios can result in chronic exposure and risk to mammalian herbivores and insectivores (15g, 35g, and 1000g) with RQ values ranging from 0.1 to 4.9 (Table 10). This chronic risk to non-endangered mammalian species also suggests the potential for impact to endangered species.

Crop Application Rate lbs ai/A (# of applications)	Food Items	Max. EEC (ppm)	Chronic RQ (Max. EEC/NOAEC) ^b
Turf (EC) 4.0 (2)	Short Grass	986.1	4.9
	Tall Grass	452.0	2.3
	Broadleaf plant/ Insects	554.7	2.8
	Seeds	61.6	0.3
Turf (EC) 3.0 (2)	Short Grass	739.6	3.7
	Tall Grass	339.0	1.7
	Broadleaf plant/ Insects	416.0	2.1
	Seeds	46.2	0.2
Turf (EC) 2.0 (2)	Short Grass	493.1	2.4
	Tall Grass	226.0	1.1
	Broadleaf plant/ Insects	227.3	1.4
	Seeds	30.8	0.1

Turf (EC) 1.0 (split 4 applications/ 6 months)	Short Grass	424.4	2.4
	Tall Grass	194.5	1.1
	Broadleaf plant/ Insects	238.7	1.3
	Seeds	26.5	0.1
Turf (EC) 1.3 (split 3 applications/ 6 months)	Short Grass	257.0	1.6
	Tall Grass	117.8	1.0
	Broadleaf plant/ Insects	144.6	1.0
	Seeds	16.1	0.1

^aMammalian chronic risk quotients as generated through ELL-FATE for ground application of an emulsifiable concentrate of oxadiazon are based on rat (*Rattus norvegicus*) NOAEC = 200 ppm. The EEC reflects the three highest assessed application rates (4.0, 3.0 and 2.0 lbs ai/A, 2 applications) and two split applications (1.0 lb ai/A, 4 times/6 months; 1.3 lbs ai/A, 3 times/6 months).

^bChronic risk (LOC \geq 1)

c. Risks to Fish and Aquatic Invertebrates

Tables 11 and 12 provide acute and chronic RQ values for oxadiazon exposure to freshwater and estuarine/marine species for turf use patterns (application rates for EC at 2.0 - 4.0 lbs ai/A and 4.0 lbs ai/A for granular). Although our assessment suggests that oxadiazon acute exposure may result in low acute risk to fish (RQ = 0.1 - 0.2) and invertebrates (RQ = 0.3 - 0.5), there is uncertainty regarding the potential for enhanced risk that may occur through phototoxicity. Since oxadiazon is a light-dependent peroxidizing herbicide (LDPH), enhanced toxicity through exposure to high levels of solar radiation is a possible concern regarding aquatic organisms that inhabit small, shallow water bodies.

EPA's Tier I (GENEEC) risk assessment suggests that chronic exposure to this compound can result in risk to freshwater and estuarine/marine fish (RQ = 39.3 - 131.8) and aquatic invertebrates (RQ = 3.9 - 36.7). Endangered species concerns are also suggested, as acute RQs exceeded the level of concern (0.1). Also, enhanced toxicity through exposure to high levels of solar radiation may increase toxic risk to aquatic organisms that inhabit small, shallow water bodies. Therefore, EPA is requiring a study on the phototoxicity of oxadiazon in fathead minnows.

The Tier I GENEEC model 60-day EEC for oxadiazon in surface water following 2-4 lb applications of granular oxadiazon was 142 ppb. However, the conservative Tier I model does not account for the effect of established golf course turf on reducing sediment run-off. Tier II PRZM/EXAMS estimates of EECs for drinking water, although not directly applicable to the risk assessment for aquatic organisms, suggest that the golf course scenario greatly reduces run-off. Tier II estimates of oxadiazon concentrations in surface-sourced drinking water were approximately six-fold lower than the Tier I GENEEC estimate described above. It is reasonable to assume that Tier II EECs for a pond scenario would likewise be reduced.

Table 11. Acute and Chronic RQ's for Oxadiazon Exposure to Fish^a							
Crop App. Rate (lbs ai/A; # App.)	Organism	Acute (LC₅₀, ppm)	Chronic (NOAEC, ppm)	EEC Peak (ppm)	EEC 60-Day Avg. (ppm)	Acute RQ (EEC/LC₅₀)	Chronic RQ^d (EEC/NOAEC)
Turf (EC) 4.0 (2)	Freshwater	0.88	0.00088	0.143	0.116	0.2^c	131.8
	Estuarine/ Marine	1.5	0.0015 ^b	0.143	0.116	0.1^c	77.3
Turf (EC) 3 (2)	Freshwater	0.88	0.00088	0.130	0.122	0.1^c	139.0
	Estuarine/ Marine	1.5	0.0015 ^b	0.130	0.122	0.1^c	81.3
Turf (EC) 2 (2)	Freshwater	0.88	0.00088	0.088	0.083	0.1^c	94.3
	Estuarine/ Marine	1.5	0.0015 ^b	0.088	0.083	0.0	55.3
Turf (Granular) 4.0 (2)	Freshwater	0.88	0.00088	0.122	0.099	0.1^c	112.5
	Estuarine/ Marine	1.5	0.0015 ^b	0.122	0.099	0.1^c	66.0

^aAcute and chronic RQ's for evaluating toxic risk of oxadiazon exposure to fish (freshwater and estuarine/marine). RQ's are based on the bluegill (*Lepomis macrochirus*) LC₅₀ = 0.88 ppm, rainbow trout (*Oncorhynchus mykiss*) NOAEC = 0.00088 ppm and sheepshead minnow (*Cyprinodon variegatus*) LC₅₀ = 1.5 ppm., NOAEC = 0.0015 ppm¹. EEC values are generated from GENEEC and reflect three of the highest assessed EC application rates, and the maximum assessed granular use rate (4.0, 3.0, and 2.0 lbs ai/A, 2 applications each; 4.0 lbs ai/A, 2 applications, respectively) for turf use.

^b Extrapolated chronic value using acute/chronic freshwater toxicity ratio

^c Acute restricted use (≥ 0.1), acute species

^d Chronic concern (≥ 1.0)

Table 12. Acute and Chronic Risk Quotients for Aquatic Invertebrates^a							
Crop App. Rate (lbs ai/A) # App. (days)	Organism	Acute (EC₅₀, ppm)	Chronic (NOAEC, ppm)	EEC Peak (ppm)	EEC 21-Day Ave. (ppm)	Acute RQ (EEC/LC₅₀)	Chronic RQ (EEC/NOAEC)
Turf (EC) 4.0 (2)	Freshwater	2.18	0.03	0.143	0.136	0.1²	4.5¹
	Estuarine/ Marine	0.27	0.0037	0.143	0.136	0.5²	36.7¹
Turf (EC) 3.0 (2)	Freshwater	2.18	0.03	0.130	0.127	0.5²	4.2¹
	Estuarine/ Marine	0.27	0.0037	0.130	0.127	0.5²	34.3³
Turf (EC) 2.0 (2)	Freshwater	2.18	0.03	0.088	0.086	0.0	2.9³
	Estuarine/ Marine	0.27	0.0037	0.088	0.086	0.3²	23.2³
Turf (Granular) 4.0 (2)	Freshwater	2.18	0.03	0.122	0.116	0.0	3.9¹
	Estuarine/ Marine	0.27	0.0037	0.122	0.116	0.4²	31.3¹

^aAcute and chronic risk RQ's for evaluating toxic risk of oxadiazon exposure to aquatic invertebrates (freshwater and estuarine / marine). RQ's are based on Daphnia (*Daphnia magna*) EC₅₀ = 2.18 ppm, NOAEC = 0.03 ppm and the Mysid shrimp (*Americamysis bahia*) EC₅₀ = 0.27 ppm, NOAEC = 0.0037 ppm¹. EEC values are generated from GENEEC and reflect three of the highest proposed EC application rates, and the maximum granular use rate (4.0, 3.0, and 2.0 lbs ai/A, 2 applications each; 4.0 lbs ai/A, 2 applications, respectively) for turf use.

¹ Extrapolated chronic value using acute/chronic freshwater toxicity ratio

² Acute restricted use (≥ 0.1)

³ Chronic concern (≥ 1.0)

d. Risk to Benthic Organisms

Oxadiazon residues can accumulate in sediments and may increase the risk from chronic exposure of benthic and epibenthic organisms--aquatic organisms that live in or on the sediment. In order to better understand this potential risk, EPA is requiring appropriate acute and chronic sediment toxicity testing on this compound.

e. Risks to Aquatic Plants

Exposure to non-target aquatic plants may occur through runoff or spray drift from adjacent treated sites. An aquatic plant acute risk assessment is usually made for aquatic vascular plants from the surrogate duckweed *Lemna gibba*. Non-vascular acute aquatic plant risk assessments are performed using either algae or a diatom, whichever is the most sensitive species. Runoff and drift exposure are computed from GENEEC2 and the risk quotient is determined by dividing the pesticide's initial or peak concentration in water by the plant EC₅₀ value. Acute risk quotients for vascular and non-vascular plants are tabulated in Table 13.

Aquatic plant acute risk levels of concern are exceeded (Table 13) for both vascular and nonvascular plants. The RQs range from 1.1 to 4.2 for vascular plants and from 8.5 - 33 for non-vascular plants. The acute plant risk level of concern is exceeded for vascular plants with RQs ranging of 5.5 -22. Currently, EPA does not perform assessments for chronic risk to aquatic plants.

The Tier I GENEEC model 60-day EEC of oxadiazon in surface water following 2-4 lb applications of granular oxadiazon was 142 ppb. However, the conservative Tier I model does not account for the effect of established golf course turf on reducing sediment run-off. Tier II PRZM/EXAMS estimates of EECs for drinking water, although not directly applicable to the risk assessment for aquatic organisms, suggest that the golf course scenario greatly reduces run-off. Tier II estimates of oxadiazon concentrations in surface-sourced drinking water were approximately six-fold lower than the Tier I GENEEC estimate described above. It is reasonable to believe that Tier II EECs for a pond scenario would likewise be reduced.

Table 13. Acute Risk Quotients for Aquatic Plants ^a				
Turf/ Rate of Application in lbs ai/A (Number of Applications).	Species	EC ₅₀ (ppm)	EEC (ppm)	Non-target plant RQ (EEC/EC ₅₀)
4 (2)	duckweed	0.041	0.173	4.2
4 (1)	“	0.041	0.089	2.2
3 (1)	“	0.041	0.067	1.6
2 (1)	“	0.041	0.044	1.1
4 (2)	diatom	0.0052	0.173	33.3
4 (1)	“	0.0052	0.089	17.1
3 (1)	“	0.0052	0.067	12.9
2 (1)	“	0.0052	0.044	8.5

^aAcute risk quotients for aquatic plants are based upon a duckweed (*Lemna gibba*) EC₅₀ of 41 ppb and a nonvascular plant (marine diatom) EC₅₀ of 5.2 ppb.

4. Endangered Species Risk Assessment

Endangered species LOCs for liquid and granular formulations of oxadiazon are exceeded for acute risks to birds, mammals, freshwater and estuarine fish and invertebrates and aquatic vascular plants. Although the terrestrial plant data are outstanding, it is assumed that endangered terrestrial plants are at risk since oxadiazon is an herbicide. Although the endangered species LOC for estuarine invertebrates has been exceeded, there are no listed species in this group.

The Agency is currently engaged in a Proactive Conservation Review with the Fish and Wildlife Service (FWS) and the National Marine Fisheries Service under section 7(a)(1) of the Endangered Species Act. The objective of this review is to clarify and develop consistent processes for endangered species risk assessments and consultations. Subsequent to the completion of this process, the Agency will reassess the potential effects of oxadiazon use to federally listed threatened and endangered species. At that time the Agency will also consider any regulatory changes recommended in the RED that are being implemented. Until such time as this analysis is completed, the overall environmental effects mitigation strategy articulated in this document and any County Specific Pamphlets described in section IV of the RED which address oxadiazon, will serve as interim protection measures to reduce the likelihood that endangered and threatened species may be exposed to oxadiazon at levels of concern.

IV. Risk Management, Reregistration and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing oxadiazon as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing oxadiazon provided that certain data gaps are addressed, the risk reduction measures outlined in this document are adopted and labels are amended to implement these measures. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of oxadiazon.

These data were sufficient to allow the Agency to determine that oxadiazon can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency, therefore, finds that all products containing oxadiazon as the active ingredient are eligible for reregistration, provided specified changes are made to the label. Actions needed to reregister particular products are addressed in Section V of this document. Those actions are the result of risk management steps summarized in Chapter 4. The Agency concludes that these label changes address the current risk estimates and reflect the use of all acceptable data available at this time together with uncertainty factors where data gaps exist.

The Agency may take appropriate regulatory action if new information comes to the Agency's attention regarding the reregistration of oxadiazon. The Agency may also require the submission of additional data (1) to support the registration of products containing oxadiazon, (2) if the data requirements for registration change, or (3) if the guidelines for generating such data change.

B. Tolerance Reassessment

With respect to tolerances for oxadiazon, there have been no active food-use registrations since 1991. The tolerance for rice straw was revoked as of the July 1, 2001 revision to 40 CFR 180.346. In a confirmatory letter to EPA, dated January 24, 2001, the registrant maintained its previous position that it would not support the sixteen remaining oxadiazon tolerances. Therefore, effective April 24, 2003, EPA revoked all the tolerances in 40 CFR 180.346 for the combined residues of the herbicide oxadiazon and its metabolites in the following commodities: in or on milk; cattle, fat; cattle, meat; cattle, meat byproducts; goats, fat; goats, meat; goats, meat byproducts; hogs, fat; hogs, meat; hogs, meat byproducts; horses, fat; horses, meat; horses, meat byproducts; sheep, fat; sheep, meat; and sheep, meat byproducts. In addition, because EPA determined on April 21, 2002 that there is no reasonable expectation of finite residues of oxadiazon and its metabolites in or on meat, milk, poultry, and egg commodities, the sixteen associated tolerances for livestock commodities were considered by the Agency to no longer be needed under 40 CFR 180.6(a)(3). Therefore, on June 3, 2002, the Agency considered the FQPA safety finding to be met and counted

the sixteen oxadiazon livestock tolerances as reassessed. There are no CODEX, Canadian, or Mexican tolerances for oxadiazon residues.

C. Regulatory Position

1. FQPA and Aggregate Risk

Given that all tolerances for oxadiazon have been revoked, this pesticide no longer falls under the scope of FQPA. As such, no quantitative aggregate assessment of risk from dietary and residential exposures was completed as part of the reregistration process. EPA has qualitatively evaluated the likelihood of combined exposures for the general population, including children. Because of the relatively low volume of use of oxadiazon on sites other than golf courses, its specialized use pattern, and its relatively high cost, neither concurrent nor aggregate exposures from different sources of oxadiazon are likely. If EPA receives a petition for food/feed uses and/or tolerances, EPA will perform an FQPA evaluation at that time.

2. 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 such 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 effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

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

3. Cumulative Risks

For the purposes of this risk assessment, the Agency has assumed that oxadiazon does not share a common mechanism of toxicity with other oxadiazoles or carcinogenic chemicals.

4. Benefits Assessment

The EPA has concluded that there are no suitable selective pre-emergence alternatives to oxadiazon currently available. Oxadiazon is expensive in comparison to other goosegrass controls, but those controls are not as selective, as they kill non-target plants as well. Because oxadiazon is expensive (estimated \$100 - \$200 per acre in 2003), it is expected that mainly high-end golf courses are going to use the herbicide.

D. Tolerance Summary

All tolerances for oxadiazon have been revoked. No maximum residue limits for oxadiazon have been established by Codex for any agricultural commodities. Therefore, there are no issues regarding compatibility with respect to U.S. tolerances.

E. Human Health Risk Mitigation

1. Dietary (Drinking Water) Risk Mitigation

Screening-level estimates (EECs) of potential drinking water exposure from ground water sources do not exceed the acute or chronic (non-cancer and cancer) DWLOC values, and therefore, are not of concern. However, exposure from surface water sources after application to golf courses is potentially of concern for chronic non-cancer and chronic cancer dietary risk.

The Tier II modeled estimate of average concentrations in surface water associated with the use of oxadiazon on golf courses is 56 ppb. That value exceeds the Agency's level of concern by 100-fold. However, it should be noted that this estimate was derived using an assumption that oxadiazon is applied as a wettable powder formulation (i.e., applied as a spray), and therefore includes a value for spray drift into water bodies. However, the predominant formulation for oxadiazon applied to golf course turf is granular, and typically the herbicide is encapsulated in a granular fertilizer.

Additionally, the Tier II assessment of EECs used an annual application rate of 8 lbs ai/A. Discussions with the oxadiazon registrant and golf course personnel indicate that the cost of oxadiazon limits the frequency of use of the 8 lbs ai/A annual rate to areas with heavy weed infestation, as might be encountered during the first year during which golf course turf is being established. Following the first year at the 8 lbs ai/A rate, more typical rates of 2-6 lbs ai/A/yr are used on established turf. The registrant has agreed to set the maximum application rate at 6 lbs a.i./A/yr (typically applied in multiple applications) except in areas of heavy weed infestation. In areas with heavy weed infestation, the maximum application rate will be 8 lbs a.i./A/yr. The maximum single application rate is 4 lbs ai/A.

When the typical annual maximum application rate (6 lbs ai/A) and the impact of a granular formulation versus a wettable-powder formulation are considered, the surface water EEC decreases

to approximately 25 ppb. This value is below the level of concern for chronic non-cancer risk, but is still 50-fold greater than the chronic cancer DWLOC.

Limited water monitoring data from three states indicate that oxadiazon, though detected in surface water bodies, is present at concentrations below the Agency's level of concern. Additionally, preliminary data from a study designed to measure pesticide concentrations in golf course runoff, and performed under an EPA grant, suggest that oxadiazon concentrations in surface-sourced drinking water will not exceed the Agency's level of concern (DWLOC = 0.49 ppb).

One factor that may be contributing to the apparent discrepancy between model estimates and measured concentrations is the percent crop area (PCA) value. This value is used in the PRZM/EXAMS models as the percentage of land area, within a specific watershed, that is made up of the crop of interest, in this case golf course turf. In characterizing oxadiazon, the Agency has used a PCA value of 94% to account for the land area of a typical golf course that is tees and greens (4%), fairway (23%) and rough (67%). Using the 94% PCA value results in an upper-bound estimate of the potential environmental concentrations of oxadiazon if 94% of a watershed was golf course turf, and on each golf course 100% of available turf was treated with oxadiazon at the maximum application rate.

The registrant has submitted Geographic Information System (GIS) data that localizes golf courses in Florida, along with watershed boundary information. That data suggests that the upper bound PCA for golf course turf in Florida is substantially less than 94%. The Agency took that information into account when it concluded that although oxadiazon is eligible for reregistration, water monitoring studies are required.

As noted above, the currently supported maximum rate of 8 lbs ai/A/year might be applied to turf with heavy weed infestation during the first year in which a golf course is being established. Thereafter, because of the expense of treating with oxadiazon, typical application rates of 2-6 lbs ai/A would be used, depending on location. For most locations, a single 2-4 lb ai application per year is sufficient to control goosegrass. However, in the extreme southern locations (e.g., south Florida) where the growing season is continuous, two applications of 3 lbs ai/A are typical. Similarly, economic factors limit the use of oxadiazon on golf course roughs. Since roughs make up approximately 67% of golf course turf area, the limited use on roughs can have a great impact on the total pounds applied.

The estimated EECs in surface water were derived using the high-end values discussed above, in addition to others that, when combined, lead to an upper-bound estimate of risk. For example, when estimating the chronic cancer risk, the assumption is made that an individual drinks from the same water source every day for a 70-year lifetime. After characterizing the assumptions used to derive the estimates of oxadiazon concentrations in drinking water, the Agency has concluded that the actual concentrations of oxadiazon in drinking water are likely to be below the Agency's level of concern. To confirm the absence of chronic exposure to oxadiazon in drinking water at concentrations that exceed the Agency's cancer level of concern, the Agency is requiring the registrant to submit three years of drinking water monitoring data collected from sites determined by the Agency to be likely to result in upper-bound exposures, with interim reporting after the first season. In addition to providing real-world measures of oxadiazon concentrations in drinking water, the monitoring data may prove to be useful in on-going efforts to validate a refined PCA value for

turf. In the event that interim data indicate concentrations of oxadiazon in drinking water do exceed the Agency's level of concern, registrants have agreed to consider further mitigation measures, such as, further rate reductions and limitations on the areas of golf courses that can be treated. Regardless of the outcome of the water monitoring study, the registrant has agreed to establish a 15 foot "no apply" zone around bodies of water that may serve as sources of drinking water.

2. Non-occupational Post-application Risk Mitigation

a. Non-cancer risk mitigation

Because oxadiazon is not available for sale to homeowners, residential handler scenarios do not exist. All of the non-cancer post-application risk scenarios for adults and toddlers had short-term and intermediate-term dermal MOEs greater than 100. Therefore, no mitigation measures are needed.

Estimated incidental, oral short-term exposures ("hand-to-mouth") for children had an MOE of 100 using the TTR default values from the residential SOP. When the TTR data from the submitted oxadiazon study were used, the MOEs were 90 and 240 for non-irrigated and irrigated dormant grass, respectively. The MOE of 90 for non-irrigated grass does not meet or exceed the target value of 100, and is therefore potentially of concern. However, the risk estimate can be considered to be an upper-bound for several reasons: 1) the submitted TTR study data were obtained using the wettable powder formulation, whereas the formulation more likely to be used on residential turf is granular oxadiazon. The granule size for a typical end-use product, Ronstar G, is 20/50 Mesh, or 300-850 microns. In all products, the formulated granules are designed to fall below the grass canopy into the thatch layer. If used according to label directions, it is unlikely that oxadiazon granules would be accessible to a child. According to the registrant, for best results oxadiazon granules should be watered-in as soon as is practical following application. Watering-in the granules will carry them further into the thatch layer, and will further decrease the likelihood for exposure. When compared to values for granular formulations, TTR values are generally 10-100 fold greater for liquid formulations; 2) the highest mean residues from the Jazzercise study described above were used to estimate exposures between zero and one days after treatment, and the hand-to-mouth risk estimates were generated at those high-end exposure levels; and 3) the risk estimates were generated assuming 20 hand-to mouth events per hour for a two hour duration. That value was taken from observations of children in an indoors setting, and is likely an overestimate when considering an outdoor scenario.

Given that the estimate of risk from incidental, oral short-term exposures ("hand-to-mouth") for children resulted from the combined use of these high-end exposure assumptions, the EPA concludes that the risk estimate that results in an MOE of 90 for non-irrigated dormant grass is likely to be an overestimate and not a cause for concern. No mitigation measures are required to address the non-cancer chronic risk from non-occupational post-application exposure.

MOEs were not calculated for the incidental ingestion of oxadiazon granules because, as discussed above, the very small granules would not be available on the lawn surface and thus not

accessible to children. It is thought, therefore, that the incidental ingestion of granules is not likely to be a cause for concern.

b. Cancer risk mitigation

The cancer risks for all adult post-application exposures were between 6.22×10^{-6} and 7.51×10^{-7} . Exposure scenarios ranged from adults involved in low exposure activities on turf such as mowing with a push mower (Transfer Coefficient = $500 \text{ cm}^2/\text{hour}$; cancer risk = 7.51×10^{-7}) and golfing (Transfer Coefficient = $500 \text{ cm}^2/\text{hour}$; cancer risk = 1.50×10^{-6}) to adults involved in high exposure activities on turf such as heavy yard work (Transfer Coefficient = $14,500 \text{ cm}^2/\text{hr}$; cancer risk = 6.22×10^{-6} on non-irrigated turf). The cancer risk estimates were based on several upper-bound assumptions, including: 1) the maximum application rate of 4 lbs ai/A; 2) an exposure concentration based on the residue concentration at day 0-1 after treatment with a wettable powder formulation; and 3) three exposures to oxadiazon-treated turf per year for 35 years.

Those assumptions are thought to be upper-bound, since: 1) although the maximum single application rate is 4 lbs ai/A, the typical application rate for residential and golf course turf is 2-3 lbs ai/A; 2) based on residue data, the dissipation half-life for oxadiazon on turf is approximately 1.5 days. As such, it is unlikely that an individual would golf or perform heavy yard work, and thereby be exposed to the maximum residue concentration, each time oxadiazon is applied over a 35 year period; and 3) typically oxadiazon is applied once per year to residential turf, and twice per year to golf course turf in areas with extended growing seasons (e.g. south Florida).

Given the combination of upper-bound assumptions, as described above, the Agency concludes that the cancer risk equation, as used in the assessment of cancer risk from post-application, non-occupational exposure to oxadiazon, is likely to result in an overestimate of risk. No mitigation measures are required to address the risk of cancer from post-application, non-occupational exposure to oxadiazon.

3. Occupational Risk Mitigation

a. Handlers

(1.) Non-cancer risk mitigation

The results of the short and intermediate-term handler assessments are presented in Table 5 and indicate that all, but one, potential non-cancer exposure scenarios provide at least one application rate with a total MOE(s) greater than or equal to 100 at either the baseline (i.e., long pants, long sleeved shirts, no gloves) using open systems, PPE (i.e., long pants, long sleeved shirts, and chemical resistant gloves while using open systems), or using engineering controls (i.e., closed systems). The only exception, with the feasible level of mitigation, is application of wettable powder formulations with a low pressure handwand, with an MOE of 46.

This scenario assumes that a worker would treat five acres per day using a low-pressure hand wand. The highest volume use of a low-pressure hand wand applicator is likely to be on non-turf areas of golf courses (e.g., in areas under and around trees, shrubs, and ornamentals). According to golf course personnel, a typical worker would likely cover a maximum of one acre a day when applying oxadiazon with a low-pressure hand wand. The total area on a golf course likely to be treated with a low-pressure handwand is approximately two acres. Using a conservative assumption that in a worst-case scenario a worker might treat three acres in a day, and considering PPE, the MOE for this scenario would increase to the target MOE of 100. The Agency concludes that the non-cancer risk does not exceed the Agency's level of concern, therefore, no mitigation is required to address the non-cancer risks from occupational handler exposures to oxadiazon.

(2.) Cancer risk mitigation

The cancer risk assessments for handlers used baseline exposure scenarios and, as needed, increasing levels of risk mitigation (PPE and engineering controls) to achieve cancer risks that would be considered of no concern. According to Agency policy, the level of concern for cancer risks from occupational exposure to pesticides ranges from 1.0×10^{-4} to 1.0×10^{-6} , depending on the feasibility, availability, and cost of various mitigation options.

Based on the scenarios identified previously, the Agency estimates that the risk of developing cancer from occupational dermal and inhalation exposures to oxadiazon ranges from 1.7×10^{-2} to 4.7×10^{-7} during "baseline" conditions (i.e., long pants, long-sleeves, no gloves). Cancer risk ranges from 1×10^{-3} to 1×10^{-7} when personal protective equipment (PPE) (i.e., long pants, long-sleeved shirt, and chemical-resistant gloves) was used. The Agency estimates that cancer risk decreases to a range of 5×10^{-5} to 1×10^{-8} with engineering controls. Engineering controls included the use of chemical-resistant gloves along with water-soluble packaging for wettable powder formulations. Overall these data suggest that when PPE and engineering controls are used, none of the evaluated scenarios have cancer risks that exceed 1.0×10^{-4} . Therefore, the Agency is requiring that wettable powder formulations of oxadiazon be packaged in water-soluble packaging. In addition, wettable-powder product labels will require that handlers wear chemical-resistant gloves in addition to long pants and a long-sleeved shirt during mixing/loading/applying scenarios.

b. Post-application

The Agency uses the term "post-application" to describe those individuals who can be exposed to pesticides when entering areas previously treated with pesticides and performing certain jobs, tasks or activities. This is also often referred to as reentry exposure. The Agency has determined that there are potential post-application exposures to individuals re-entering oxadiazon treated areas for the purpose of:

Roadsides: mowing

Bermuda grass rights-of-way: mowing

Sod farms: mowing, hand-weeding, and harvesting

Golf-course turfgrass: mowing and hand-weeding

For short-and intermediate-term non-cancer risks, mowing (e.g., golf courses, roadsides, and sod farms) and harvesting (e.g., sod farms) scenarios were considered for post-application occupational exposure. Calculations for mowing activities resulted in MOEs of 1000.

Calculations for hand-weeding and harvesting activities on golf courses and sod farms resulted in MOEs of 30, less than the target MOE of 100 for post-application occupational exposures. However, the values used to calculate the hand-weeding and harvesting MOEs likely result in an over-estimate of risk. For example, the calculation for hand-weeding on golf courses assumes that a worker would perform that activity for 8 hours/day on the day following application of oxadiazon at the maximum application rate. Based on the quality of turf present on high-end golf courses most likely to apply oxadiazon, it is unlikely that golf course personnel would spend more than one or two hours per day performing hand-weeding activities. The Agency concludes that the risk from post-application hand-weeding of golf courses does not exceed the level of concern. No mitigation measures will be required.

With respect to risk concerns from post-application activities on sod farms, while the oxadiazon label does not prohibit its use, the cost of treating with oxadiazon is prohibitive. Due to its cost, less than 20% of sod farmers are using oxadiazon. Those sod farmers that are using oxadiazon apply it as a wettable powder formulation at 2-3 lbs ai/A immediately after planting (aka sprigging) to control weeds during sod establishment. Harvesting activities occur six to nine months following application, depending on the variety of grass being grown. As noted above, the scenario with respect to hand-weeding assumes an 8-hour workday, which is unlikely. The foliar dissipation half life for oxadiazon (approximately 1.5 days) is such that after three days post-application, the MOE would rise above 100. Therefore, the Agency concludes that the risk from post-application harvesting on sod farms does not exceed the level of concern. No mitigation measures will be required.

Cancer risks for occupational postapplication scenarios were estimated not to exceed EPA's level of concern.

4. Inhalation Toxicity and Exposure Uncertainties

The Agency is concerned about potential inhalation risk to applicators using wettable powder formulations.

The following confirmatory data are required:

- 870.3465 28-day inhalation toxicity study

F. Environmental Risk Mitigation

1. Terrestrial Organism Risk Mitigation

Using the EC formulation, at application rates of 2.0 - 4.0 lbs ai/A (2 applications/6 months) and two split applications (1.0 lbs ai/A applied 4 times/6 months and 1.3 lbs ai/A applied 3 times/6 months), model estimates indicate that oxadiazon may pose a chronic risk to mammals that eat plants and insects. RQs range from 1 to 5.

The Agency does not currently perform screening-level assessments of chronic risk to birds and mammals from granular formulations. Here, the emulsifiable concentrate (EC) formulation was used to estimate chronic risk to birds and mammals. The emulsifiable concentrate formulation likely represents an upper-bound scenario in terms of oxadiazon exposure to birds and mammals that might feed on grasses and insects on golf course turf. Approximately 90% of oxadiazon is applied as a granular formula. Unlike the residue that would remain on grass and foliage following a spray application, granules of oxadiazon would settle to the thatch or soil layer. This is especially true when the turf is watered following application, as many end-product labels currently recommend. The granule size for a typical end-use product, Ronstar G, is 20/50 Mesh, or 300-850 microns. In all products, the formulated granules are designed to fall below the grass canopy. If used according to label directions, it is unlikely that oxadiazon granules would be accessible to birds and mammals that feed on grasses. According to the registrant, for best results oxadiazon granules should be watered-in as soon as is practical following application. Watering-in the granules will carry them further into the thatch layer, and will further decrease the likelihood for exposure. As such, the amount of oxadiazon available for ingestion by birds and mammals is likely to be less than was used in calculating the RQ values, and it is likely that the actual exposures would result in RQ values significantly less than the range of 1 to 5 obtained by assessing the emulsifiable concentrate formulation. The Agency concludes that the chronic risk to terrestrial organisms from exposure to oxadiazon does not exceed the level of concern. No mitigation measures will be required.

2. Aquatic Organism Risk Mitigation

a. Fish and Invertebrates

Tier 1 model estimates of oxadiazon concentrations in water suggest that acute exposures pose low risk to fish (RQ = 0.1-0.2) and invertebrates (RQ= 0.3 - 0.5); however, there is some uncertainty about the role of sunlight on oxadiazon toxicity in clear, shallow bodies of water. GENECC model outputs suggest that chronic exposure to oxadiazon may result in risk to freshwater and estuarine/marine fish. RQs range from 94 to 139 (freshwater) and 55 to 81 (estuarine/marine), depending on application rate and formulation. Likewise, model estimates indicate that chronic exposure to oxadiazon may result in chronic risk to freshwater and estuarine/marine invertebrates. RQs range from 2.9 to 4.5 (freshwater) and 23 to 37 (estuarine/marine), depending on application rate and formulation.

The Tier I GENEEC model 60-day EEC of oxadiazon in surface water following two four-pound applications of granular oxadiazon was 142 ppb. However, the conservative Tier I model does not account for the effect of established golf course turf on reducing run-off. Tier II PRZM/EXAMS estimates of EECs for drinking water, although not directly applicable to the risk assessment for aquatic organisms, suggest that the golf course scenario greatly reduces run-off. Tier II estimates of oxadiazon concentrations in surface-sourced drinking water were approximately six-fold lower than the Tier I GENEEC estimate described above. It is reasonable to believe that Tier II EECs for a pond scenario would likewise be reduced.

In order to further assess the risk to fish and invertebrates from oxadiazon exposure, the Agency is requiring that the registrant submit toxicity data from early-stage estuarine fish studies and life cycle estuarine/marine invertebrate studies. Also, enhanced toxicity through exposure to high levels of solar radiation may increase toxic risk to aquatic organisms that inhabit small, shallow water bodies. Therefore, EPA is requiring a study on the phototoxicity of oxadiazon in fathead minnows.

b. Benthic Organisms

Oxadiazon residues can accumulate in sediments and may increase the risk from chronic exposure of benthic and epibenthic organisms (aquatic organisms that live in or on the sediment) to the pesticide. In order to better understand this potential risk, EPA is requiring appropriate sediment toxicity testing, both acute and chronic, on this compound.

c. Aquatic Plants

For aquatic plants, RQs for acute exposure are relatively high, ranging from 1.1 to 4.2 for duckweed, and 8.5 to 33 for diatoms, depending on application rates and formulation.

The Tier I GENEEC model 60-day EEC of oxadiazon in surface water following two four-pound applications of granular oxadiazon was 142 ppb. However, the conservative Tier I model does not account for the effect of established golf course turf on reducing sediment run-off. Tier II PRZM/EXAMS estimates of EECs for drinking water, although not directly applicable to the risk assessment for aquatic organisms, suggest that the golf course scenario greatly reduces run-off. Tier II estimates of oxadiazon concentrations in surface-sourced drinking water were approximately six-fold lower than the Tier I GENEEC estimate described above. It is reasonable to assume that Tier II EECs for a pond scenario would likewise be reduced.

Currently, the Agency does not have sufficient data with respect to the toxic effects of oxadiazon on aquatic organisms on which to base an effective risk management strategy. To help clarify the risks to aquatic plant species, the Agency is requiring that the registrant submit the following studies: aerobic aquatic metabolism, seedling germination/emergence, vegetative vigor, and aquatic phototoxicity.

G. Other Labeling Requirements

1. 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 pesticide 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 this 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. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at www.epa.gov/espp. A final Endangered Species Protection Program, which may be altered from the interim program, has been proposed for public comment in the Federal Register (67 FR #231, December 2, 2002; edocket OPP-2002-0311.)

2. Spray Drift Management

Approximately 90% of oxadiazon is applied as a granular formulation, for which spray drift is not a concern. The approximately 10% of oxadiazon that is applied as a spray using a wettable powder formulation is applied to nursery stock and non-turf areas of golf courses using handheld sprayers and to sod farms using tractor-drawn boom sprayers. The wettable powder formulation is not typically used around bodies of water, so that the risk of contamination of water with oxadiazon as a result of spray drift is not of concern. No label language is required to address ecological or drinking water concerns that arise from off-target drift from spray applications of oxadiazon.

To address the risk to human health associated with off-target drift from spray applications, the following label language is required for oxadiazon wettable-powder products: "Do not apply this product in a way that will contact workers or other persons either directly or through drift."

The Agency is currently working with stakeholders to develop appropriate generic label statements to address off-target drift risk. Once this process has been completed, oxadiazon products may need to be revised to include this additional language.

V. Actions Required of Registrants

In order to be eligible for reregistration, registrants need to implement the risk mitigation measures outlined in Section IV, which include, among other things, submission of the following:

For oxadiazon 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 Mark Seaton at 703/306-0469 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)
Mark Seaton
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:

Document Processing Desk (DCI/SRRD)
Mark Seaton
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

For products containing the active ingredient oxadiazon, 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) Complete 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 15 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 database supporting the reregistration of oxadiazon for the eligible uses has been reviewed and determined to be substantially complete. The following confirmatory data are required:

Guideline Test Name	OPPTS Guideline No.	Old Guideline No.
28-day inhalation toxicity	870.3465	82-4
Aerobic Aquatic Metabolism	835.4300	162-4
Early-stage Estuarine Fish	850.1400	72-4(a)
Life Cycle Estuarine/Marine Invertebrate	850.1300 850.1350	72-4(b)
Seedling Germination/Emergence	850.4100	122-1(a)
Vegetative Vigor	850.4150	122-1(b)
Seedling Germination/Emergence	850.4225	123-1(a)
Vegetative Vigor	850.4250	123-1(b)
Aquatic Phototoxicity Studies (Fathead minnow)	--	70-1
Acute and Chronic Sediment Toxicity Testing	--	70-1
Water Monitoring Study		70-1

2. Labeling for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MUP labeling should bear the labeling contained in the table at the end of this section. The MUP label will explicitly prohibit use of products that do not conform to Section V.B.2 of this document.

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.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section V above. Specific language to implement these changes is specified in Table 14 at the end of this section. To remain in compliance with FIFRA, end-use product (EUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies.

C. Labeling Changes Summary Table

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

Table 14: Summary of Labeling Changes for Oxadiazon		
Description	Amended Labeling Language	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) [fill blank only with those uses that are being supported by MP registrant]. This product may not be formulated into products intended for residential consumer use.”	Directions for Use
	<p>“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).”</p> <p>“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p>	Directions for Use
Packaging statement required by the RED for wettable-powder formulations	“All wettable-powder formulations must be packaged in water-soluble packaging.”	Directions for Use

Description	Amended Labeling Language	Placement on Label
Environmental Hazards Statements Required by the RED and Agency Label Policies	<p>"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."</p> <p>"Do not apply this product within 15 feet of bodies of water that may serve as sources of drinking water."</p>	Directions for Use
End Use Products		
Front Panel Statement for Granular and Wettable Powder Products	"For sale to and use by professional applicators only. Not for sale to or use by homeowners/consumers."	Insert in a prominent position associated with the Brand name on the front panel of the pesticide label

Description	Amended Labeling Language	Placement on Label
<p>PPE Requirements Established by the RED for wettable powders formulations</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> -Long-sleeved shirt and long pants, -Shoes plus socks, and -Chemical resistant gloves, such as (<i>registrant insert correct chemical-resistant materials</i>), <p>In addition, mixers and loaders must wear a chemical-resistant apron.</p> <p>See engineering controls for additional requirements.”</p>	<p>Immediately following/below</p> <p>Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>PPE Requirements Established by the RED for granular formulations</p>	<p>“Personal Protective Equipment (PPE)</p> <p>Loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> - Long-sleeved shirt and long pants, and - Shoes plus socks.” 	<p>Immediately following/below</p> <p>Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>User Safety Requirements for Wettable Powder Formulations and Granular Formulations</p>	<p>“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.”</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements</p>

Description	Amended Labeling Language	Placement on Label
<p>Engineering Controls for Wettable Powder Formulations</p> <p>(Wettable powders products must be contained in water soluble packaging to be eligible for reregistration)</p>	<p>“Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must :</p> <ul style="list-style-type: none"> - wear the personal protective equipment required above for mixers/ loaders, and - be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: chemical-resistant footwear and a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N, R, P, or HE filter.” 	<p>Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)</p>
<p>User Safety Recommendations</p>	<p>“User Safety Recommendations</p> <p>Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>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.”</p>	<p>Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls</p> <p>(Must be placed in a box.)</p>
<p>Restricted-Entry Interval for WPS uses</p>	<p>“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.”</p>	<p>Directions for Use, Agricultural Use Requirements Box</p>

Description	Amended Labeling Language	Placement on Label
Early Entry Personal Protective Equipment established by the RED.	<p>“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:</p> <ul style="list-style-type: none"> - coveralls, - shoes plus socks, and - chemical-resistant gloves made of any waterproof material.” 	
General Application Restrictions	<p>“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.”</p>	Place in the Directions for Use directly above the Agricultural Use Box.
Application Restrictions for Granular and Wettable Powder Formulations	<p>The label must be revised to specify a maximum application rate of .xxx {registrant to provide value} pounds of product per acre per year (equivalent to 6 pounds ai/A/year), except in areas where there is heavy weed infestation. In areas of heavy weed infestation, the maximum application rate is .xxx {registrant to provide value} pounds of product per acre per year (equivalent to 8 pounds ai/A/year) .</p> <p>The label must be revised to specify a maximum single application rate of .xxx {registrant to provide value} pounds of product per acre (equivalent to 4 pounds ai/A)</p> <p>The label must be revised to read “Not for use on home lawns.”</p>	Directions For Use under General Precautions and Restrictions
Application Restrictions for Granular Formulations	<p>“The label must be revised to read “For best results, water-in the product as soon as practical after application.”</p>	

¹ PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. 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.

² If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” designation must be dropped.

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

Instructions in the Labeling section not in quotes represents actions that the registrant should take to amend their labels or product registrations.

D. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. Refer to “Existing Stocks of Pesticide Products; Statement of Policy”; *Federal Register*, Volume 56, No. 123, June 26, 1991.

Appendix A. Table of Oxadiazon Use Patterns Eligible for Reregistration

Appendix A
OXADIAZON (CASE 2485) USE PATTERNS ELIGIBLE FOR
REREGISTRATION

Site Application Equipment	Formulation	Maximum Single Application Rate	Max No of Appl per/y	Restrictions
Turf: golf course, ornamental				
Groundboom Application, Handgun Application, Tractor Drawn Spreader, Backpack Sprayer, Low Pressure Handwand, Push Type Spreader, Bellygrinder.	Granular Water-soluble powder	4 lb ai/acre	3	Maximum 6 lbs ai/A/yr except in cases of heavy weed infestation (8 lb ai/A/yr) Do not apply through any type of irrigation system. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not store or use in or around the home or home garden. Do not graze livestock in treated areas.
Turf: sod farms				
Chemigation Application Groundboom Application	Granular Water-soluble powder	4 lb ai/acre	3	Maximum 6 lbs ai/A/yr except in cases of heavy weed infestation (8 lb ai/A/yr) Do not apply through any type of irrigation system. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not store or use in or around the home or home garden.

Site Application Equipment	Formulation	Maximum Single Application Rate	Max No of Appl per/y	Restrictions
				Do not graze livestock in treated areas.
Nursery: woody ornamental shrubs, vines and trees				
Groundboom Application Handgun Applicators Tractor Drawn Spreader Backpack Sprayer Low Pressure Handwand Push Type Spreader Bellygrinder	Granular Water-soluble powder	4 lb ai/acre	3	Maximum 6 lbs ai/A/yr except in cases of heavy weed infestation (8 lb ai/A/yr) Do not apply through any type of irrigation system. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not store or use in or around the home or home garden. Do not graze livestock in treated areas.
Roadsides, rights-of-way				
Rights-of-way sprayer	Granular Water-soluble powder	4 lb ai/acre	3	Maximum 6 lbs ai/A/yr except in cases of heavy weed infestation (8 lb ai/A/yr) Do not apply through any type of irrigation system. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not store or use in or around the home or home garden. Do not graze livestock in treated areas.

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Oxadiazon

REQUIREMENT		USE PATTERN	CITATION(S)
<u>PRODUCT CHEMISTRY</u>			
New Guideline Number	Old Guideline Number		
830.1550	61-1	Product Identity and Composition	All 40968001
830.1600	61-2A	Start. Mat. & Mnfg. Process	All 40968001
830.1670	61-2B	Formation of Impurities	All 40968001
830.1700	62-1	Preliminary Analysis	All 41863601
830.1750	62-2	Certification of limits	All 41863601
830.1800	62-3	Analytical Method	All 41863601
830.6302	63-2	Color	All 41842801
830.6303	63-3	Physical State	All 41842801
830.6304	63-4	Odor	All 41842801
830.7050	None	UV/Visible Absorption	All Data gap
830.7200	63-5	Melting Point	All 41842801
830.7300	63-7	Density	All 41565701
830.7840	63-8	Solubility	All 41474201
830.7860			
830.7950	63-9	Vapor Pressure	All 41230301
830.7550	63-11	Octanol/Water Partition Coefficient	All 41230302
830.6313	63-13	Stability	All 41877601
<u>ECOLOGICAL EFFECTS</u>			
850.2100	71-1	Avian Acute Oral Toxicity	C 41610101
850.2200	71-2	Avian Dietary Toxicity	C 41610102 41610103
850.2300	71-4	Avian Reproduction	C 41993201 41993202
850.1075	72-1A	Fish Toxicity	C 42330401 42350601
850.1010	72-2	Freshwater Invertebrate Toxicity	C 42331801
850.1075	72-3(a)	Estuarine/Marine Toxicity - Fish	C 42615801
850.1025	72-3(b)	Estuarine/Marine Toxicity - Mollusk	C 42570301
850.1035	72-3(c)	Estuarine/Marine Toxicity - Shrimp	C 42615802
850.1045			

Data Supporting Guideline Requirements for the Reregistration of Oxadiazon

REQUIREMENT			USE PATTERN	CITATION(S)
850.1400	72-4(a)	Estuarine Fish- Early Life Stage	C	Data gap
850.1300	72-4(b)	Estuarine/Marine Invertebrate Life Cycle	C	Data gap
850.1350				
850.4100	122-1(a)	Seed Germ./ Seedling Emergence Tier I	C	Data gap
850.4150	122-1(b)	Vegetative Vigor Tier I	C	Data gap
850.4400	122-2	Aquatic Plant Growth	C	41610105 41610106 41610107 41610108 42659001
850.4225	123-1(a)	Seed Germ./ Seedling Emergence Tier II	C	Data gap
850.4250	123-1(b)	Vegetative Vigor Tier II	C	Data gap
850.4400	123-2	Aquatic Plant Growth	C	41610105-41610108
850.3020	141-1	Honey Bee Acute	C	42468301
	70-1	Aquatic Phototoxicity Studies (Fathead minnow)	C	Data gap
	70-1	Acute and Chronic Sediment Toxicity Testing	C	Data gap
	70-1	Water Monitoring Study	C	Data gap
<u>TOXICOLOGY</u>				
870.1100	81-1	Acute Oral Toxicity-Rat	C	41866501
870.1200	81-2	Acute Dermal Toxicity-Rabbit	C	41866502
870.1300	81-3	Acute Inhalation Toxicity-Rat	C	41866503
870.2400	81-4	Primary Eye Irritation-Rabbit	C	41866504
870.2500	81-5	Primary Skin Irritation	C	41866505
870.2600	81-6	Dermal Sensitization	C	41230401
870.3100	82-1A	90-Day Feeding - Rodent	C	00111804
870.3150	82-1B	90-Day Feeding - Dog	C	00111805
870.3200	82-2	21-Day Dermal - Rabbit	C	41863602
870.3465	82-4	28-day inhalation toxicity	C	Data gap
870.3700a	83-3A	Prenatal development (rat)	C	40470202
870.3700b	83-3B	Prenatal development (rabbit)	C	40470201
870.3800	83-4	Reproduction and fertility effects (rat)	C	41239801
870.4100a	83-1A	Chronic Feeding Toxicity - Rodent	C	see 870.4300
870.4100b	83-1B	Chronic Feeding Toxicity - Dog	C	41326401
870.4200	83-2B	Oncogenicity - Mouse	C	00115733 40993301

Data Supporting Guideline Requirements for the Reregistration of Oxadiazon

REQUIREMENT			USE PATTERN	CITATION(S)
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity-Rat	C	00149003 00157780 40993401
870.5100- 870.5500	84-2A-84-2B	Gene mutation studies	C	00069893 41871701 00115726 00115729
870.5375		Cytogenetics In vitro mammalian cell chromosomal aberration assay	C	00115728 00115730
870.5550	84-4	Other Effects	C	00115723 00115727 00115703
870.7485	85-1	General Metabolism	C	42324701 42663601
870.7600		Dermal penetration-Rat	C	44588101 42310001
	Special Study			
<u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u>				
875.2100	132-1A	Transferable Residue Dissipation: Lawn and Turf	C	43517801
<u>ENVIRONMENTAL FATE</u>				
835.2120	161-1	Hydrolysis	C	41863603
835.2240	161-2	Photodegradation - Water	C	41897201
835.2410	161-3	Photodegradation - Soil	C	41898201
835.4100	162-1	Aerobic Soil Metabolism	C	42772801
835.4400	162-3	Anaerobic Aquatic Metabolism	C	42773802
835.4300	162-4	Aerobic Aquatic Metabolism	C	Data gap
835.1230	163-1	Leaching/Adsorption/Desorption	C	41898202
835.1240				41889601
835.6100	164-1	Terrestrial Field Dissipation	C	41767401
None	165-4	Bioaccumulation in Fish	C	42226701

Appendix C. Technical Support Documents

Appendix C. TECHNICAL SUPPORT DOCUMENTS

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 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 February 19, 2003. Sixty days later the first public comment period closed.

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:

<http://www.epa.gov/edocket/>

These documents include:

HED Documents:

1. OXADIAZON: Response to the 30-day Error Only Comments on the HED Chapter of the Reregistration Eligibility Decision Document (RED). PC Code: 109001, Case #819425, Submission No. S610158, DP Barcode: D280876 [49 pages]
2. Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Oxadiazon. DP Barcode: D276360 [62 pages]
3. Oxadiazon. Reregistration Case No. 2680. Toxicology Chapter for the Reregistration Eligibility Decision (RED) Document for Oxadiazon. DP Barcode: D266361 [45 pages]
4. Oxadiazon-Report of the Hazard Identification Assessment Review Committee. (HED Doc. No. 014469) [30 pages]
5. Cancer Assessment Document Evaluation of the Carcinogenic Potential of Oxadiazon (Third Review) (HED Doc. No. 014555) [28 pages]
6. Oxadiazon: Assessment of Mode of Action on Liver Carcinogenicity. DP Barcode: D266361 [15 pages]
7. Revised Oxadiazon Quantitative Risk Assessment (Q1*) Based On ICR-JCL Mouse and SPF Wistar Rat Dietary Studies With 3/4's Interspecies Scaling Factor (HED Doc. No. 014465) [3 pages]
8. Oxadiazon. (List B, Case No. 2485) The Outcome of the HED Metabolism Assessment Review Committee Meeting Held on 1/30/01. DP Barcode 272425. Chemical 109001. [4 pages]

9. Oxadiazon. List B Reregistration Case 2485. PC Code 109001. Product Chemistry and Residue Chemistry Chapter for the Reregistration Eligibility Decision [RED] Document. DP Barcode D273740. [3 pages]
10. Oxadiazon. List B Reregistration Case 2485. PC Code 109001. Product Chemistry and Residue Chemistry Chapter for the Reregistration Eligibility Decision [RED] Document. DP Barcode D273740. [12 pages]

EFED Documents:

1. EFED Risk Assessment for the Reregistration Eligibility Decision of Oxadiazon. DP Barcode: D280320 [83 pages]
2. Tier I Estimated Environmental Concentration of Oxadiazon. DP Barcode: D273599 [4 pages]
3. Tier II Estimated Drinking Water Concentrations (EDWCs) for Human Health Risk for oxadiazon on Florida Golf Course (PC Code 1090001, DP Code: D281176) [7 pages]

Appendix D. Citations Considered to be Part of the Database Supporting the Reregistration Decision (Bibliography)

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

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
 - a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

- b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.
- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
 - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

PRODUCT CHEMISTRY

- 40968001 Brocahard, M. (1988) Oxadiazon Manufacturing Process and Discussion of Formation of Impurities. Unpublished compilation prepared by Rhone-Poulenc Sante. 54 p.
- 41230301 Citation: Hoffman, M. (1989) Vapor Pressure Determination of Oxadiazon: Final Report: HLA 6001-372. Unpublished study prepared by Hazleton Laboratories Americas, Inc. 71 p.
- 41230302 Seymour, R., Hall, L. (1988) Octanol/Water Partition Coefficient Determination for Oxadiazon. Unpublished study prepared by Rhone-Poulenc Ag Co. 12 p.
- 41474201 Pruitt, P. (1987) Solubility of Oxadiazon (R. P.-17623) in Selected Solvents: Lab Project Number: 40207. Unpublished study prepared by Rhone-Poulenc Ag Co. 8 p.
- 41565701 Chabassol, Y. (1990) Oxadiazon-Specific Gravity and Density at 20 (degree) C: Lab Project Number: 89-15. Unpublished study prepared by Rhone-Poulenc Secteur Agro. 16 p.
- 41842801 Chabassol, Y. (1991) Oxadiazon Technical Grade Physical Properties: Lab Project Number: 90-26. Unpublished study prepared by Rhone-Poulenc Secteur Agro. 40 p.
- 41863601 Chabassol, Y.; Chabert, M.; Hunt, G. et al. (1991) Oxadiazon Technical Grade: Analysis and Certification of Product Ingredients. Lab Project Number: 90-12: 9115221. Unpublished study prepared by Rhone-Poulenc, Secteur Agro. 462 p.
- 41877601 Sanders, J. (1991) Oxadiazon, Technical: Determination of Stability: Lab Project Number: 4053-91-0061-AS. Unpublished study prepared by Ricerca, Inc. 102 p.

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- 41610101 Pedersen, C. (1990) Oxadiazon Technical: 21-Day Acute Oral LD50 Study in bobwhite Quail: Lab Project Number: BLAL/NO/89 QD 139. Unpublished study prepared by Bio-Life Associates, Ltd. 35 p.

- 41610102 Pedersen, C. (1990) Oxadiazon Technical: 8-Day Acute Dietary LC50 Study in bobwhite Quail: Lab Project Number: BLAL/NO/89 QC 141. Unpublished study prepared by Bio-Life Associates, Ltd. 82 p.
- 41610103 Pedersen, C. (1990) Oxadiazon Technical: 8-Day Acute Dietary LC50 Study in Mallard Ducklings: Lab Project Number: BLAL/NO/89 DC 137. Unpublished study prepared by Bio-Life Associates, Ltd. 80 p.
- 41610105 Giddings, J. (1990) Oxadiazon Technical-Toxicity to the Marine Diatom *Skeletonema costatum*: Lab Project Number: 90-7-3384: 10566-1089-6137-450. Unpublished study prepared by Springborn Laboratories, Inc. 55 p.
- 41610106 Giddings, J. (1990) Oxadiazon Technical-Toxicity to the Freshwater Diatom *Navicula pelliculosa*: Lab Project Number: 90-8-3423; 10566-1089-6137-440. Unpublished study prepared by Springborn Laboratories, Inc. 52 p.
- 41610107 Giddings, J. (1990) Oxadiazon Technical-Toxicity to the Duckweed Lemma *gibba* G3: Final Report: Lab Project Number: 90-7-3389; 10566.1089.6137.410. Unpublished study prepared by Springborn Laboratories, Inc. 48 p.
- 41610108 Giddings, J. (1990) Oxadiazon Technical-Toxicity to the Freshwater Green Alga *Selenastrum capricornutum*: Amended Report: Lab Project Number: 90-8-3422; 10566.1089.6137.437. Unpublished study prepared by Springborn Laboratories, Inc. 52 p.
- 41784301 Blakemore, G.; Burgess, D. (1991) Chronic Toxicity of Oxadiazon Technical to *Daphnia magna* under Flow-thru Conditions: Final Report: Lab Project Number: 38369. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 349 p.
- 41993201 Fletcher, D.; Pedersen, C. (1991) Oxadiazon Technical: Toxicity and Reproduction Study in Mallard Ducks: Lab Project Number: 89 DR 35. Unpublished study prepared by Bio-Life Associates, Ltd. 138 p.
- 41993202 Fletcher, D.; Pedersen, C. (1991) Oxadiazon Technical: Toxicity and Reproduction Study in bobwhite Quail: Lab Project Number: 89 QR 39. Unpublished study prepared by Bio-Life Associates, Ltd. 145 p.
- 42330401 Sword, M.; Northup, R. (1992) Acute Flow-Through Toxicity of Oxadiazon to Rainbow Trout (*Oncorhynchus mykiss*): Lab Project Number: 39729. Unpublished study prepared by ABC Laboratories, Inc. 211 p.

- 42331801 Blasberg, J.; Bowman, J. (1992) Acute Toxicity of Oxadiazon to *Daphnia magna* under Flow-through Conditions: Amended Final Report: Lab Project Number: 39730. Unpublished study prepared by ABC Labs, Inc. 254 p.
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Appendix E. Generic Data Call-in

Appendix F. Product-specific Data Call-in

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

EPA'S BATCHING OF OXADIAZON 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 **Oxadiazon** the primary 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 the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should 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 in a batch, or to generate all the required acute toxicological studies for each of their own products. If the 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 the 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 to-days 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, the 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 the registrant supplies the data to support a batch of products, he/she must select the 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). 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.

Forty six products were found which contain **Oxadiazon** as the active ingredient. These products have been placed into *five batches and a No batch* in accordance with the active and inert ingredients and type of formulation.

Batch 1	EPA Reg. No.	Percent active ingredient	Formulation Type
	264-502	50.0	Solid
	432-887	50.0	Solid
	432-893	50.0	Solid

Batch 2	EPA Reg. No.	Percent active ingredient	Formulation Type
	8660-36	1.0	Solid
	35512-44	1.0	Solid

Batch 3	EPA Reg. No.	Percent active ingredient	Formulation Type
	961-379	1.0	Solid
	8378-61	1.0	Solid

	8660-17	1.0	Solid
	10404-63	1.0	Solid
	34704-833	1.0	Solid
	52287-1	0.95	Solid
	52287-14	1.20	Solid
	67508-1	1.0	Solid

Batch 4	EPA Reg. No.	Percent active ingredient	Formulation Type
	52287-10	Oxadiazon - 0.500 Benefin - 0.375 Trifluralin - 0.375	Solid
	52267-11	Oxadiazon - 0.75 Benefin - 0.25 Trifluralin - 0.25	Solid
	52287-12	Oxadiazon - 1.00 Benefin - 0.25 Trifluralin - 0.25	Solid

Batch 5	EPA Reg. No.	Percent active ingredient	Formulation Type
	961-371	Oxadiazon - 0.50	Solid
	961-382	Oxadiazon - 0.69	Solid
	10404-93	Oxadiazon - 0.63	Solid
	34704-834	Oxadiazon - 0.67	Solid
	52287-3	Oxadiazon - 0.67	Solid
	52287-9	Oxadiazon - 0.75	Solid

No Batch	EPA Reg. No.	Percent active ingredient	Formulation Type
	264-450	94.0	Solid
	432-886	2.0	Solid
	432-898	2.0	Solid
	538-146	4.0	Solid
	538-147	8.0	Solid
	538-164	Oxadiazon - 1.31 Bensulide - 5.25	Solid
	538-257	Oxadiazon - 2.0 Pendimethalin - 0.62	Solid
	961-340	1.73	Solid
	961-380	1.50	Solid
	8378-62	1.50	Solid
	9198-75	1.38	Solid
	9198-154	Oxadiazon - 1.0 Dithiopyr - 0.125	Solid
	9198-155	Oxadiazon - 1.0 Dithiopyr - 0.1875	Solid
	9198-176	Oxadiazon - 1.31 Bensulide - 5.25	Solid
	9198-185	2.75	Solid
	9198-203	1.5	Solid
	10404-97	Oxadiazon - 1.0 Dithiopyr - 0.15	Solid

	34704-771	Oxadiazon - 2.0 Napropamide - 4.0	Solid
	35512-43	2.0	Solid
	48234-1	Oxadiazon - 1.0 Balfin - 0.5	Solid
	48234-2	2.0	Solid
	48234-10	Oxadiazon - 1.0 Oxyfluorfen - 2.0	Solid
	48234-14	1.0	Solid
	48234-15	Oxadiazon - 1.0 Prodiamine - 0.2	Solid

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

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

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

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

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

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

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

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

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf

8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit

www.epa.gov/pesticides/registrationkit/

Dear Registrant:

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

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

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

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

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).
 - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
 - b. EPA Form No. 8570-4, Confidential Statement of Formula
 - c. EPA Form No. 8570-27, Formulator's Exemption Statement
 - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
 - e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).
 - a. Registration Division Personnel Contact List
 - b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
 - c. Antimicrobials Division Organizational Structure/Contact List
 - d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
 - e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
 - f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
 - g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

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

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

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

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

- Date of receipt;
- EPA identifying number; and
- 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.