OVERVIEW OF
OXADIAZON RISK ASSESSMENTS

Introduction

This document summarizes EPA's human health and ecological risk findings and conclusions for the selective, pre-emergent and early post-emergent herbicide, oxadiazon, as presented fully in the documents, "Human Health Risk Assessment for Oxadiazon," dated March 5, 2002, and "EFED Risk Assessment for the Reregistration Eligibility Decision of Oxadiazon," dated March 5, 2002.

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments and to better understand the conclusions reached in the assessments. References to relevant sections in the complete documents are provided to allow the reader to find the place in these assessments where a more detailed explanation is provided. This summary was developed in response to comments and requests from the public which indicated that the risk assessments were difficult to understand, that they were too lengthy and that it was not easy to compare the assessments for different chemicals due to the use of different formats.

Tolerances

The Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requires EPA (the Agency) to review the allowable food residue concentrations ("tolerances") for registered chemicals in effect on or before the date of the enactment of FQPA. In reviewing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. The tolerances are considered reassessed once the safety finding has been made or a revocation occurs.

There are no food or feed, or anticipated food or feed uses for oxadiazon. The Registrant is not supporting any tolerances for oxadiazon in the United States. Likewise, there are no Canadian or Mexican tolerances for oxadiazon. Revocation of tolerances for residues of oxadiazon on food and feed has been proposed (Federal Register: August 1, 2001, Vol. 66, Number 148) and tolerances will be revoked in FY2003. Consequently, dietary exposure from food is not a concern for this product.

Cumulative Risk Assessment

EPA did not perform a cumulative risk assessment as part of the Reregistration Eligibility Decision (RED) for oxadiazon because the Agency has not yet initiated a comprehensive review to determine if there are any other chemical substances that have a mechanism of toxicity common with that of oxadiazon. For purposes of this risk assessment, EPA has assumed that oxadiazon

does not have a common mechanism of toxicity with other substances. In the future, the registrant may be asked to submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether oxadiazon shares a common mechanism of toxicity with any other substance. The Agency has developed a framework for conducting cumulative risk assessments on substances that have a common mechanism of toxicity. This guidance was issued on January 16, 2002 (67 FR 2210-2214) and is available from the Office of Pesticide Programs (OPP) Website at: http://www.epa.gov/pesticides/trac/science/cumulative_guidance.pdf.

Availability of Documents

The risk assessments and associated documents for oxadiazon are available on the Internet at http://www.epa.gov/pesticides/reregistration/status.htm and in the public docket, located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, for viewing. Public comments will be invited and welcomed for 60 days. The Agency's report on the risk management decision for oxadiazon will also be announced in the Federal Register once public comments are considered, and any revisions to the risk assessments have been completed.

Use Profile

- **Herbicide:** 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. 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.

- **Uses:** Oxadiazon is registered for commercial use on turf grown on golf courses (~77% of total use) and in apartment/condominium complexes, parks, athletic fields, playgrounds, and cemeteries (~12% of total 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 and roughs), residential outdoor use, roadsides and nurseries.

- **Annual Poundage:** Approximately 249,000 pounds are used on 52,000 acres annually. Oxadiazon is used primarily in southern states (~71%) and predominantly on golf courses (~77%).

- **Formulations:** Granular (predominant formulation, ~90% of total use), wettable powder,

soluble concentrate, and emulsifiable concentrate.

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

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

- **Registrant:** Bayer Environmental Science (formerly Aventis Environmental Science USA), a business group of Bayer Crop Science, Inc.

Human Health Risk Assessment

In acute studies, oxadiazon is only slightly toxic. Oxadiazon is classified as "likely to be carcinogenic to humans" based on studies that showed an increase in the incidence of liver tumors in two species (mice and rats) following exposure to oxadiazon. In both subchronic and chronic studies, the primary target organ is the liver.

Dietary (Food) Risk:

There are no, nor are there anticipated to be, food or feed uses for oxadiazon. The registrant is not supporting any tolerances for oxadiazon in the United States. Likewise, there are no Canadian or Mexican tolerances for oxadiazon. A request for revocation of tolerances for residues of oxadiazon on food and feed has been granted, and tolerances will be revoked in FY2003. Consequently, dietary exposure from food is not a concern for this product.

Drinking Water Dietary Risk:

(For a complete discussion, see section 4.2.2 and 5.0 of the Human Health Risk Assessment)

Drinking water sources include groundwater and surface water. The transfer and accumulation of chemicals in drinking water can result in acute and/or chronic exposures in humans. The Agency uses a drinking water level of concern (DWLOC) as a benchmark in making a determination of the risk associated with exposure from pesticides in drinking water. The DWLOCs represent the maximum contribution to the human diet (in ppb or μg/L) that may be attributed to residues of a pesticide in drinking water. Risks from drinking water are assessed by comparing the DWLOCs to the estimated drinking water concentrations (EDWCs) of a chemical

in surface water and groundwater.

The Metabolism Assessment Review Committee (MARC) concluded that the only residue of concern with respect to oxadiazon is the parent compound, because major degradates would be minor components in the environment. Moreover, those degradates are not likely to be significantly more toxic than the parent. Leaching of oxadiazon from surface soil to groundwater is expected to be low or negligible, unless the soil is very porous or has cracks that enhance flow. Since this stable compound can be adsorbed to particulate and organic matter, oxadiazon residues can persist in soil and sediments.

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 II PRZM/EXAMS (surface water) and Tier I SCIGROW (ground water) models. The PRZM/EXAMS model as used here includes a standard citrus grove scenario that has been modified in an attempt to account for the use of oxadiazon on turf. The modified scenario includes a two-inch layer of thatch, and is referred to as the Florida Turf Scenario.

The 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 SCIGROW model is typically used for Tier 1 screening purposes for pesticides applied to soils. The SCIGROW model estimates likely groundwater concentration if the pesticide is used at the maximum allowable rate in areas where groundwater is exceptionally vulnerable to contamination.

- Using the PRZM/EXAMS model, the contribution of surface water to the EDWC for oxadiazon was estimated to be 181 ppb (µg/L) for an acute exposure, and 65 ppb (µg/L) for a chronic (non-cancer) exposure.
- Using the SCIGROW model, the contribution of groundwater to the EDWC for oxadiazon was estimated to be 0.59 ppb (µg/L).
- These values generally depict worst-case scenarios, and represent the upper-bound estimates of the concentration of oxadiazon that might be found in surface and ground water due to the application of oxadiazon to turf.

Acute Drinking Water Risk

- Acute DWLOCs were calculated for oxadiazon based on results of a developmental toxicity study in which pregnant rats were administered oxadiazon via gavage on Gestation Days six through 15.
- 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. For risk assessment purposes, an uncertainty factor of 100 was applied (based on a 10x for interspecies extrapolation and a 10x for intraspecies variation), resulting in a theoretical acute Population Adjusted Dose (aPAD) of 0.12 mg/kg/day.
- Based on a comparison of DWLOCs to the corresponding PRZM/EXAMS and SCIGROW values (Table 1), the Agency concludes that acute exposure to residues of oxadiazon in surface and ground drinking water is not a concern.

Table 1. Summary of Acute DWLOC Calculations for Oxadiazon

Population Subgroup[1]	Acute Scenario					
	Theoretical aPAD mg/kg/day	Acute Food Exp mg/kg/day	Max Acute Water Exp mg/kg/day[2]	PRZM/EXAMS Surface Water EDWC (μg/L)	SCIGROW Ground Water EDWC (μg/L)	Acute DWLOC (μg/L)[3]
U.S. Population	0.12	0.00	0.12	181	0.59	4200
Females 13-50 years old	0.12	0.00	0.12	181	0.59	3600
Infants <1 year old	0.12	0.00	0.12	181	0.59	1200
Children 1-6 years old	0.12	0.00	0.12	181	0.59	1200

[1] Default body weights and consumption values for calculation of the DWLOCs were: 2L/70 kg (adult male), 2L/60 kg (adult female) and 1L/10 kg (child), respectively.
[2] Maximum acute water exposure (mg/kg/day) = [(acute PAD (mg/kg/day) - acute food exposure (mg/kg/day)]
[3] Acute DWLOC(μg/L) = $\frac{\text{[maximum chronic water exposure (mg/kg/day) x body weight (kg)]}}{\text{[water consumption (L) x } 10^{-3} \text{ mg/}\mu\text{g]}}$

Chronic Drinking Water Risk

- Chronic DWLOCs were calculated based on a chronic toxicity/carcinogenicity study, in which rats were administered oxadiazon in their feed for 104 weeks.
- The NOAEL was 0.36 mg/kg/day, with the endpoint being adverse liver effects in male rats at a LOAEL of 3.5 mg/kg/day. For risk assessment purposes, an uncertainty factor of 100 was applied (10x for intraspecies variation and 10x for interspecies extrapolation). Therefore, the theoretical chronic Population Adjusted Dose (cPAD) was taken to be

0.0036 mg/kg/day.

- Using the PRZM/EXAMS model estimates, the EDWCs for surface water (65 μg/L) were higher than the DWLOCs calculated for infants and children (36 μg/L) (Table 2) and thus, potentially of concern.

Table 2. Summary of Chronic DWLOC Calculations for Oxadiazon

Population Subgroup[1]	Chronic Scenario					
	Theoretical cPAD mg/kg/day	Chronic Food Exp mg/kg/day	Max Chronic Water Exp mg/kg/day[2]	PRZM/EXAMS Surface Water EDWC ($\mu g/L$)	SCIGROW Ground Water EDWC ($\mu g/L$)	Chronic DWLOC (μg/L)
U.S. Population	0.0036	0.00	0.0036	65	0.59	126
Females 13-50 years old	0.0036	0.00	0.0036	65	0.59	108
Infants <1year old	0.0036	0.00	0.0036	65	0.59	36
Children 1-6 years old	0.0036	0.00	0.0036	65	0.59	36

[1] Default body weights and consumption values for calculation of the DWLOCs were: 2L/70 kg (adult male), 2L/60 kg (adult female) and 1L/10 kg (child), respectively.

[2] Maximum Chronic Water Exposure (mg/kg/day) = [Chronic PAD (mg/kg/day) - Chronic Dietary Exposure (mg/kg/day)]

[3] Chronic DWLOC(μg/L) = $\frac{\text{[maximum chronic water exposure (mg/kg/day) x body weight (kg)]}}{\text{[water consumption (L) x } 10^{-3} \text{ mg/}\mu\text{g]}}$

Cancer Drinking Water Risk

In accordance with the EPA Draft Guidelines for Carcinogen Risk Assessment (July, 1999), the Cancer Assessment Review Committee (CARC) classified oxadiazon into the category **"Likely to be Carcinogenic to Humans"** based on the following weight-of-the-evidence considerations:

- Treatment-related benign and malignant liver tumors were observed in two species. There was clear evidence that oxadiazon induced a statistically significant increase in liver tumors in male Wistar rats and male and female ICR-JCL mice. The findings of liver tumors are consistent with the results of earlier studies in male F-344 rats and male and female CD mice. The positive results from an *in vitro* cell transformation assay are in concordance with the results of *in vivo* rodent bioassays.
- Oxadiazon was not mutagenic. However, it causes cell transformation *in vitro;* these results are in concordance with the carcinogenicity seen in *in vivo* rodent studies.

The Committee recommended a low dose linear extrapolation approach for the quantification of human cancer risk based on the most potent liver tumors in rats and mice. The Q_1* is 7.11 x 10^{-2}. Data submitted by registrants was inadequate to demonstrate the mode of action for oxadiazon-induced liver tumors in rodents.

- For the cancer exposure calculations, the Agency used multi-year mean water

concentration values. The $DWLOC_{cancer}$ is the concentration in drinking water as a part of the aggregate chronic exposure that results in a negligible cancer risk (1.0×10^{-6}).

- Using the PRZM/EXAMS and SCIGROW model estimates, EDWCs for both surface (56 μg/L) and ground water (0.59 μg/L) were higher than the cancer DWLOC (0.49 μg/L) (Table 3) and thus, potentially of concern.

Table 3. Summary of Cancer DWLOC Calculations for Oxadiazon

Population	Q*	Negligible Risk Level[1]	Target Max Exposure[2] mg/kg/day	Chronic Food Exposure mg/kg/day	Max Water Exposure[3] mg/kg/day	PRZM/EXAMS Surface Water EDWC ($\mu g/L$)	SCIGROW Ground Water EDWC ($\mu g/L$)	Cancer DWLOC[4] (μg/L)
U.S. Pop	7.11e-02	0.000001	0.000014	0.000000	0.00001400	56	0.59	0.490000

[1] $DWLOC_{CANCER}$ was calculated for U.S. population only. Default body weights and consumption values for calculation of the DWLOCs were: 2L/70 kg

[2] Target Maximum Exposure (mg/kg/day) = [negligible risk/Q*]

[3] Maximum Water Exposure (mg/kg/day) = [Target Maximum Exposure - (Chronic Food Exposure + Residential Exposure (Lifetime Average Daily Dose))]

[4] Cancer DWLOC(μg/L) = $\frac{\text{[maximum water exposure (mg/kg/day) x body weight (kg)]}}{\text{[water consumption (L) x } 10^{-3} \text{ mg/}\mu\text{g]}^{2}}$

As noted above, the Tier II PRZM/EXAMS model for estimating surface water exposure incorporates a standard citrus scenario that has been modified to include a two-inch layer of thatch. The linked PRZM/EXAMS model is typically used by EPA in estimating pesticide concentrations in surface waters. The SCIGROW model for estimating groundwater exposures is typically used for Tier 1 screening purposes for pesticides applied to soils. The SCIGROW model estimates likely groundwater concentration if the pesticide is used at the maximum allowable rate in areas where groundwater is exceptionally vulnerable to contamination. The Agency feels that taken together, these models provides a conservative, high-end estimate of exposure from drinking water.

Residential Exposure and Hazard:

(For a complete discussion, see section 4.3.3 of the Human Health Risk Assessment)

- The short-term and intermediate-term margins of exposure (MOEs) for dermal exposures were calculated based on a NOAEL of 12 mg/kg/day from a developmental toxicity study in which pregnant rats were administered oxadiazon via gavage on Gestation Days six through 15. The toxicity endpoints were a reduction in maternal body weight gain, increased fetal resorptions, postimplantation loss, and increased incidence of incomplete ossification at 40 mg/kg/day. Based on results of a dermal penetration study, the dermal absorption rate of 9% was used.
- The unit risk value for cancer ($Q_1^* = 7.11 \times 10^{-2}$ mg/kg/day^{-1}) was calculated from studies in which male mouse liver adenomas and/or carcinoma tumor rates were determined.
- The target MOE of 100 for residential exposure scenarios was selected based on the

uncertainty factors of 10x for intraspecies variation and 10x for interspecies extrapolation.

- Oxadiazon is registered for commercial use on lawns and turf grown in apartment/condominium complexes, parks, and playgrounds; therefore, the potential for post-application residential exposure exists during activities such as mowing the lawn, doing yard work, and playing golf.
- Negligible inhalation exposure is anticipated in those exposure scenarios, due to the low chemical vapor pressure of oxadiazon and the dilution of the vapor outdoors. Dermal absorption is the route of exposure that is a concern.
- Residential postapplication dermal exposure assessments assumed residents wear the following attire: short sleeved shirt, short pants, shoes and socks, and no gloves or respirator.
- The duration of exposures range from two to four hours per day, and the frequency of exposures was three per year for 35 years.
- Data used to develop residential exposure estimates were conservative in that the highest mean postapplication turf transferable residue value from the Jazzercize study (MRID No. 43517801) along with the data from the wettable powder formulation, instead of the more commonly used granular formulation, were used.
- Other assumptions and all equations used for the assessment of each exposure scenario can be found in the Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision document for Oxadiazon, dated July 15, 2001.

Residential Risk, Postapplication (noncancer):

Utilizing wettable powder application study data, all of the non-cancer risk scenarios developed for adults and toddlers had short-term and intermediate-term dermal MOEs greater than 100, and thus are not of concern.

Residential Risk, Postapplication (cancer):

The Agency's level of concern for non-occupational cancer risk is 1.0×10^{-6}. The cancer risks for adult residential, dermal, postapplication exposures to oxadiazon were between 6.22×10^{-6} to 7.51×10^{-8}, indicating that for some exposure scenarios the cancer risk slightly exceeds the EPA's level of concern.

Aggregate Risk:

Because there are no remaining food tolerances for oxadiazon, the EPA has not assessed this pesticide with respect to the FQPA. Additionally, EPA did not perform an aggregate risk assessment as part of this reregistration review for oxadiazon, for the reasons outlined below.

The DWLOC values for oxadiazon that were calculated as part of the human health risk assessment are based on conservative default values since no monitoring data were available on oxadiazon. As noted previously, data used to develop residential exposure estimates were also conservative. The highest mean postapplication turf transferable residue values, along with the data from the wettable powder formulation (instead of the granular formulation) were used to derive those estimates. Thus, combining a conservative estimate of oxadiazon in drinking water with a conservative residential exposure estimate would only result in an even more conservative expression of aggregate risk.

Worker Exposure and Hazard:

(For a complete discussion, see Section 4.3 of the Human Health Risk Assessment).

EPA has determined that there are potential exposures to occupational mixers, loaders, applicators, or other occupational handlers during standard use-patterns associated with oxadiazon.

- Fourteen major exposure scenarios were identified for occupational exposure of handlers.
- These scenarios include mixing, loading and applying through the use of ground spray, granular and lawn application methods.
- The exposure scenarios are of short-term (1-7 days) and intermediate-term (1 week to several weeks); use patterns do not indicate any long-term use.
- The short-term and intermediate-term MOEs were calculated based on a NOAEL of 12 mg/kg/day from a developmental toxicity study in which pregnant rats were administered oxadiazon via gavage on Gestation Days six through 15. The toxicity endpoints were a reduction in maternal body weight gain, increased fetal resorptions, postimplantation loss, and increased incidence of incomplete ossification at 40 mg/kg/day.
- The EPA's Cancer Assessment Review Committee has classified oxadiazon as "Likely to be Carcinogenic to Humans". The cancer unit risk value ($Q_1^* = 7.11 \times 10^{-2}$ mg/kg/day^{-1}) was calculated from studies in which male mouse liver adenomas and/or carcinoma tumor rates were determined.
- For risk assessment purposes, inhalation and dermal exposure estimates were made using the following criteria: a career duration of 35 years; a lifetime of 70 years; exposure frequencies of three (representing the maximum number of applications per season) and thirty (representing applications to multiple sites per season).
- 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.

- Since the effects from dermal and inhalation exposure are based on the same oral study (i.e. rat development study), the doses for these routes and durations were aggregated.

- The percent absorbed following dermal exposure was taken to be 9%.

Worker Risk (noncancer):

- Calculation of non-cancer occupational risk based on combined dermal and inhalation exposure indicates that only one scenario (i.e. low-pressure handwand-wettable powder formulations) had an MOE of 46 with the highest feasible level of mitigation.
- All other potential exposure scenarios provide at least one application rate with total MOEs $\geq$100 at baseline, or with PPE or engineering controls.
- Dermal exposure, rather than inhalation exposure, appears to be the main contributor to the total MOE for the low-pressure handwand-wettable powder formulation scenario as well as the majority of occupational exposures.

Worker Risk (cancer):

The Agency's level of concern for cancer risk begins at $\leq 1.0 \times 10^{-4}$. The Agency attempts to put additional safeguards in place to decrease the risk (i.e. mitigate) to $\leq 1.0 \times 10^{-6}$, when possible.

- With respect to oxadiazon, the Agency developed a number of scenarios for potential occupational exposure, ranging from mixing and loading wettable-powder formulations to applying granular formulations.
- Based on those scenarios, the Agency estimates that the risk of developing cancer from occupational dermal and inhalation exposures to oxadiazon ranges from 1.65×10^{-2} to 4.66×10^{-7} during "baseline" conditions (i.e. long pants, long-sleeves, no gloves).
- Cancer risk ranges from 1.05×10^{-3} to 1.38×10^{-7} when personal protective equipment (PPE; i.e. long pants, long-sleeved shirt, with chemical-resistant gloves) was used.
- The Agency estimates that cancer risk decreases to a range of 4.92×10^{-5} to 1.10×10^{-8} with engineering controls. Engineering controls included the use of PPE 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} (the Agency's level of concern).

Worker Risk, Postapplication (noncancer):

- For short-and intermediate-term non-cancer risks, mowing (e.g. golf courses, roadsides, and sod farms) and harvesting (e.g. sod farms) activities were considered for post-application occupational exposure.
- All occupational postapplication activities had MOEs of 300-10000.

Worker Risk, Postapplication (cancer):

Cancer risks for occupational postapplication scenarios, including the current minimum12 hour period in which reentry is prohibited, were estimated to range from 9.92×10^{-6} to 3.01×10^{-7} .

Ecological Risk Characterization

To estimate potential ecological risk, the Agency integrates the results of exposure and ecotoxicity studies using the quotient method. Risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic, for various wildlife species. RQs are then compared to the levels of concern (LOCs). Generally, the higher the RQ, the greater the potential risk. The potential risks identified below can be further characterized by considering when, where and how a specific pesticide is used.

Environmental Fate and Transport

- Environmental fate studies indicate that oxadiazon persists in the environment bound to organic matter.
- In clear, shallow bodies of water, oxadiazon not bound to organic matter may be degraded by sunlight. Alternatively, oxadiazon is defined as a light-dependent peroxidizing herbicide (LDPH), which suggests that toxicity is greater in the presence of light.
- Studies indicate that after application to soil, oxadiazon remains near the surface, and can be transported via runoff to nearby surface water bodies.
- Leaching from surface soils to groundwater is expected to be low or negligible, unless the soil is very porous.
- Since this stable compound can bind to particulate and organic matter, oxadiazon residues can accumulate in sediments at the bottom of bodies of water.
- Oxadiazon may accumulate in aquatic organisms such as fish; however, as observed in studies using bluegill sunfish, the tendency toward bio-accumulation can be offset by a rapid rate of removal.

Nontarget Aquatic Organism Risk

Acute Assessments

- In studies using freshwater fish (Rainbow trout/Bluegill) and estuarine fish (Sheepshead minnows), oxadiazon was moderately toxic on an acute basis (LC_{50} = 0.88 ppm and 1.5 ppm, respectively).
- In studies with estuarine/marine invertebrates (Mysid), oxadiazon demonstrated a high acute toxicity (EC_{50} = 0.27 ppb), but the chemical appears to be moderately toxic on an acute basis to freshwater invertebrates (Daphnids LC_{50} = 2.18 ppm).
- Limited data show that oxadiazon is toxic to non-vascular aquatic plants (marine diatoms EC_{50} = 5.2 ppb) and vascular aquatic plants (duckweed EC_{50} = 41 ppb).
- The EPA's risk assessments suggest that acute exposures pose low risk to fish (RQ = 0.1-0.2) and invertebrates (RQ= 0.3 - 0.5), there is some uncertainty about the role of sunlight on oxadiazon toxicity in clear, shallow bodies of water.
- 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.

Chronic Assessments

- To assess the risk to freshwater fish from chronic exposure to oxadiazon, a No Observeable Adverse Effect Concentration (NOAEC) of 0.88 ppb and a Lowest Observeable Adverse Effect Concentration (LOAEC) of 1.7 ppb were used, based on effects on egg hatches in studies using Rainbow trout.
- To assess the risk to freshwater invertebrates from chronic exposure to oxadiazon, a NOAEC of 30.0 ppb and a LOAEC of 35.0 ppb were used, based on the incidence of reproductive effects in studies using Daphnids.
- Chronic exposure to oxadiazon may result in chronic 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.
- 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.

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 (acute and chronic) on this compound. 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.

Nontarget Terrestrial Organism Risk

Mammals

To estimate the potential adverse effect of a chemical on wild mammals, the concentration of the chemical in the diet that is expected to be acutely toxic to 50% of the test animals is determined by dividing the LD_{50} value by the per cent body weight consumed. An RQ is then determined by dividing the estimated environmental concentration by the acute toxicity value. RQ values are calculated for four different kinds of food (i.e. short grass, tall grass, forage/insects, and seeds). The per cent body weight consumed by herbivores and insectivores corresponding to three weight categories (15, 35, and 1000 g) is assumed to be 95%, 66%, and 15%, respectively.

- In studies with rats, oxadiazon was practically non-toxic on an acute basis (LD_{50} > 5,000 mg/kg). Reproductive effects were noted at > 200 ppm that resulted in inactive mammary tissue and fetal/neonatal death.
- According to the EPA's risk assessment, at proposed use rates (2.0 - 4.0 lbs ai/A), oxadiazon should not pose an acute risk to mammals (RQ < 0.2).
- 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 1.5 to 9.9.

Birds

- In studies with avian species (Northern Bobwhite quail and mallard duck), oxadiazon appears to be practically non-toxic on a subacute basis (LC_{50} > 5,000 ppm for both species) and an acute basis (LD_{50}>2,150 mg/kg and LD_{50} = 1,040 mg/kg, respectively).
- In chronic studies, no reproductive effects were observed at 500 ppm. At greater than 1,000 ppm, mortality was observed in adult females (Bobwhite quail).
- Chronic exposure to oxadiazon may result in low toxic risk to birds that feed on plants and grass (e.g. ducks, geese; RQs = 1.0 - 2.0). The split application scenario appears to lower the risk (RQ <1).
- Birds may be exposed to granular pesticides through ingestion when foraging for food or grit. Model estimates suggested no acute risk to birds from exposure to granular oxadiazon (RQ < 1.5 - 2.0).

Insects

- Oxadiazon was practically non-toxic to honey bees in acute exposure studies (LD_{50} > 25 µg/bee).

Endangered Species Risk

The endangered species LOCs for liquid and granular formulations of oxadiazon are exceeded for chronic risk to birds and mammals, and acute and chronic risk to freshwater and estuarine fish, invertebrates, and aquatic vascular plants. Although the data are outstanding, it is likely that endangered terrestrial plants are at risk since oxadiazon is an herbicide. Per the Endangered Species Act, the Agency is currently engaged in a Proactive Conservation Review with the Fish and Wildlife Service and the National Marine Fisheries Service. Subsequent to the completion of this process, the Agency will reassess the potential risk of oxadiazon to federally listed threatened and endangered species.

Summary of Pending Data

The following data requirements have been initially identified by the Agency:

Toxicology Data

- 28-Day Inhalation Study

Product and Residue Chemistry Data

- Current Confidential Statement of Formula containing nominal concentration and upper limits for all components, and the lower limits for the active ingredient.

Occupational Exposure Data

- Concurrent Transfer Coefficient measurements along with Transferable Turf Residue studies.

Ecological Effects

- Early-Life Stage Estuarine Fish
- Life Cycle Estuarine Invertebrate
- Seedling Emergence and Vegetative Vigor- using a liquid TEP to represent both granular and liquid formulations (note in the case that liquid formulations are not supported for reregistration, only seedling emergence testing would be required; vegetative vigor testing is not required for granular formulations)
- Aquatic plant testing (TierII) is required because oxadiazon has outdoor nonresidential terrestrial uses that may move off-site by runoff and/or aerial spray drift. The following species should be tested at Tier II: *Kirchneria subcapitata (Selenastrum capricornutum), Skeletonema costatum,* and *Anabaena flos-aquae.*
- Acute and Chronic Sediment Toxicity Testing - Oxadiazon shows a high K_{OC}, combined with a high persistence exhibited in the aerobic soil metabolism, and the anaerobic aquatic metabolism (>10 days). These fate properties indicate that there may be risk to benthic-

dwelling aquatic invertebrates, however the potential for risk cannot be assessed until data have been submitted. The Chronic Sediment Toxicity Testing data requirement is triggered, with *Chironomus tentans* and the Acute Chronic Sediment Toxicity Testing data requirement is triggered, with both *Hyalella azteca*, and *Chironomus tentans*.

- Phototoxicity studies on fathead minnow. A subchronic exposure duration would be adequate for proof of concept. Behavioral observations should be conducted in addition to mortality, growth, and morphology. All studies should be conducted under defined light conditions.