Overview of Oxyfluorfen Risk Assessment

January 11, 2002

Introduction

This document summarizes EPA's human health and ecological risk findings and conclusions for the herbicide oxyfluorfen, as presented fully in the documents, "Oxyfluorfen: Revised Human Health Risk Assessment" dated December 18, 2001, and "Revised Environmental Fate and Effects Division Preliminary Risk Assessment for the Oxyfluorfen Reregistration Eligibility Decision Document" dated December 11, 2001. The purpose of this summary is to assist the reader by presenting the key features and findings of these risk assessments, and to enhance understanding of the conclusions reached in the assessments. This overview was developed in response to comments and requests from the public which indicated that 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.

The risk assessments noted above as well as the supporting documents, are available on EPA's Internet site (www.epa.gov/pesticides/reregistration/oxyfluorfen) and in the Pesticide Docket for public viewing. Meetings with stakeholders (i.e., growers, extension personnel, commodity groups, and other government officials) are planned to discuss the identified risks and to solicit input on risk mitigation strategies. This feedback will be used to complete the Reregistration Eligibility Decision (RED) document, which will include the risk management decisions. The Agency plans to conduct a closure conference call with interested stakeholders to discuss the regulatory decisions presented in the RED.

The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Although it is possible that oxyfluorfen may express toxicity through a common mechanism with other compounds, at this time, the Agency does not have sufficient reliable information to make this determination. Consequently, the risks summarized in this document are only for oxyfluorfen. If EPA identifies other substances that share a common mechanism of toxicity with oxyfluorfen, aggregate exposure assessments will be performed on each chemical followed by a cumulative risk assessment.

Use Profile

- **Herbicide:** Oxyfluorfen is a broad spectrum pre- and postemergent herbicide registered for use on a wide variety of tree and vine crops, selected annual and perennial crops, as well as fallow bed and non-crop uses (e.g. roadsides), to control annual broadleaf and grassy weeds. Residential homeowners may use oxyfluorfen products for spot treatment of weeds.

- **Formulations**: Oxyfluorfen formulations include granular, emulsifiable and liquid concentrate, and ready-to-use (RTU) liquid ranging from 0.25% to 70% active ingredient. Common trade names: Goal® and Galigan®.

- **Methods of Application**: Liquid formulations are applied using groundboom, right of way and backpack sprayers. Aerial application is used mainly for fallow fields and chemigation is used primarily for bulb vegetables. With the exception of bulb vegetables and conifers, which have more tolerance to oxyfluorfen, over the top applications are not recommended. Residential formulations are packaged in RTU sprinkler jugs**,** RTU trigger sprayers, or as a liquid mixed in a sprinkler can or tank sprayer.

- **Use Rates**: Single application rates in agriculture range from 0.25 lbs ai/acre to 2 lbs ai/acre.

- **Annual Poundage:** Total annual domestic usage of oxyfluorfen is approximately 761,000 lbs a.i. for about 1,167,000 acres treated. Largest markets in terms of total pounds active ingredient are allocated to wine grapes, almonds, cotton, walnuts, and table grapes. Most of the usage occurs in CA, TX, MN, NM, and WA. Oxyfluorfen usage has increased significantly over the last several years.

- **Classification:** General use pesticide

- **Technical Registrant**: Dow AgroSciences

Hazard

Oxyfluorfen is of low acute toxicity: toxicity category IV for acute oral and inhalation toxicity and category III for acute dermal toxicity. Oxyfluorfen is a slight eye and dermal irritant and is not a dermal sensitizer. Both subchronic and chronic studies showed that toxicity at lower doses was generally not severe. Oxyfluorfen inhibits heme production by interfering with enzymes involved in heme biosynthesis. Heme is the part of the hemoglobin molecule that contains iron and binds oxygen. Deranged production of heme produces a variety of anemias; however, in toxicity studies, the observed anemia was generally mild. Mild liver and renal toxicity also occurred.

Developmental studies with the current 98% technical material found no developmental toxicity

in rats whereas an increase in late resorptions occurred in the rabbit study (principally in 1 litter). The current 98% technical material was tested in 12 genetic toxicology studies, all of which were negative, except for one Ames assay which was positive. A second Ames assay with 96% material was negative. Oxyfluorfen is classified as a category C (quantified), possible human carcinogen, based upon combined hepatocellular (liver) adenomas/carcinomas in the mouse carcinogenicity study.

Human Health Risk Assessment

Risks from dietary exposure (food and drinking water), residential exposure, aggregate exposures, and occupational exposures have been evaluated for oxyfluorfen. The following table summarizes the toxicological endpoints and doses that were used to complete the human health risk assessments for oxyfluorfen. No acute adverse effect (reflecting a single dose) was identified in toxicity studies. Although two does in the high-dose group of the rabbit developmental study aborted, these abortions are not considered an acute effect because they are secondary to the debilitating condition (generalized, systemic toxicity) of the mothers. Therefore, an acute endpoint was not selected and acute risk assessments were not performed.

Table 1. Summary of Doses and Toxicological Endpoints for Oxyfluorfen

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Chronic Dietary	NOAEL = 3.0 UF = 100	Liver toxicity occurring in dogs and mice at the LOAEL of 200 ppm in male (33.0 mg/kg/day) and female (42.0 mg/kg/day) mice.	Chronic dog and mouse carcinogenicity studies
		Chronic RfD = 0.03 mg/kg/day	
Cancer	Q_1* = 7.32 x 10^{-2} $(mg/kg/day)^{-1}$	Combined hepatocellular adenomas and carcinomas.	Mouse carcinogenicity study
Dermal, Short-Term[a]	NOAEL= 30 UF = 100	Abortions and clinical signs seen at the maternal LOAEL of 90 mg/kg/day	Developmental rabbit study (1998)
Dermal, Intermediate-Term[a]	LOAEL = 32 UF = 300	Liver toxicity and anemia seen at the LOAEL of 32 mg/kg/day.	90-day mouse
Inhalation, Short-Term[b]	NOAEL = 30 UF = 100	Abortions and clinical signs seen at the maternal LOAEL of 90 mg/kg/day.	Developmental rabbit study (1998)
Inhalation, Intermediate-Term[b]	LOAEL = 32 UF = 300	Liver toxicity and anemia seen at the LOAEL of 32 mg/kg/day.	90-day mouse

a. An oral endpoint was used for dermal exposure: a dermal absorption factor of 18% of oral exposure was selected from a dermal

absorption study in rats.
b. An oral endpoint was used for inhalation exposure: inhalation exposure is assumed equivalent to oral exposure.
NOAEL = no observed adverse effect level; LOAEL = lowest observed adverse effect level; UF=uncertainty factor; RfD = reference dose.

The Uncertainty Factor (UF) used in the risk assessments is 100 to account for both interspecies extrapolation (10X) and intraspecies variability (10X). An additional uncertainty factor of 3X was applied to intermediate-term exposures because the dose was derived from the LOAEL. The FQPA Safety Factor was reduced to 1X for the following reasons: (i) there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; (ii) a developmental neurotoxicity study with oxyfluorfen is not required; and (iii) the dietary (food and drinking water) and non-dietary (residential) exposure assessments will not underestimate the potential exposures for infants and children. The FQPA safety factor is applicable to the dietary and residential risk assessments for all population subgroups.

Dietary (Food) Risk Assessments for Oxyfluorfen

There are currently 53 food commodity tolerances for residues of oxyfluorfen in/on plant and livestock commodities [40 CFR §180.381], expressed in terms of oxyfluorfen *per se*.

For the chronic dietary (food) risk assessments, anticipated residues were primarily calculated using either USDA Pesticide Data Program (PDP) monitoring data or field trial data. Both data sets are consistent in that they show essentially all non-detectable residues. Non-detectable residues were assumed to be at a level of ½ LOQ (0.005 ppm). Estimates of percent crop treated (% CT) were used to refine the assessment. The chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model (DEEM™), which incorporates consumption data from USDA's Continuing Surveys of Food Intake by Individuals (CSFII), 1989-1992. Consumption data are averaged for the entire US population and within population subgroups for chronic exposure assessments.

Although a Tier 2/3 dietary risk assessment was conducted and is the most refined assessment to date for oxyfluorfen, there are some uncertainties associated with the exposure estimates as follows: (i) ½ LOQs (0.005 ppm) were used instead of ½ LODs (0.0015 ppm) for field trial residue values, which tends to over-estimate the residue values from the field trial studies. All of the field trial studies were non-detects; therefore, this assessment is an upper bound and the real residues are somewhere between this estimate and zero; (ii) no cooking studies were used; (iii) tolerance level residues were used for bananas and cacao beans as well as 100% crop treated for cacao beans; and (iv) DEEM default processing factors were used in the assessment.

Chronic Dietary (Food) Risk

Chronic dietary risk over a 70-year lifetime is calculated using average residues from field trials

in combination with data from nature of residue studies and weighted average percent crop treated data. A risk estimate that is less than 100% of the chronic Population Adjusted Dose (cPAD), the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected, does not exceed the Agency's risk concern. Risk estimates are significantly below EPA's level of concern (<1% cPAD) for all population subgroups assessed (Table 2).

Table 2. Chronic Dietary Exposure and Risk Summary for Oxyfluorfen

Population	Exposure (mg/kg body wt/day)	%cPAD
U.S. Population	0.000005	<1
All Infants	0.000011	<1
Children (1-6 yrs old)	0.000012	<1
Children (7-12 yrs old)	0.000009	<1
Females (13-50 yrs old)	0.000004	<1

Carcinogenic (Food) Risk

Oxyfluorfen is classified as a category C, possible human carcinogen based upon combined hepatocellular adenomas/carcinomas in the mouse carcinogenicity study. A cancer dietary risk assessment using a low-dose linear extrapolation was conducted. Using the Q_1* of 7.32 x 10^{-2} results in a maximum estimated lifetime cancer risk to the U.S. general population of 3.8 x 10^{-7} . EPA does not consider this lifetime cancer risk estimate to be of concern because it is less than 1.0 x 10^{-6}.

Drinking Water Dietary Risk

Drinking water exposure to pesticides can occur through ground water and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. To determine the maximum allowable contribution of treated water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food, then determines a "drinking water level of comparison" or DWLOC. The DWLOCs represent the maximum contribution to the human diet (in ppb) that may be attributed to residues of a pesticide in drinking water after dietary exposure is subtracted from the aPAD or cPAD. Risks from drinking water are assessed by comparing the DWLOCs to the estimated environmental concentrations (EECs) in surface water and ground water. The Agency generally has no risk concerns when the EECs are below the DWLOCs.

- **Water Exposure.** Oxyfluorfen in the environment is expected to be very persistent with low mobility. In general oxyfluorfen degrades very slowly in both soil and water and binds strongly to soil containing organic matter. Modeling results generally predict low concentrations in both

surface and groundwater. However, when oxyfluorfen reaches water it is likely to persist for long periods.

- **Monitoring data.** There are limited surface water monitoring data available for oxyfluorfen. It was not analyzed as a standard analyte under the National Water-Quality Assessment (NAWQA) Program of the U.S. Geological Survey (USGS). USGS did, however, measure oxyfluorfen concentrations in suspended sediment in the San Joaquin River in central California. The data showed frequent detections of oxyfluorfen associated with sediment during several years in the 1990's.

  Some samples have been collected and analyzed for oxyfluorfen in water and sediments in the Columbia River basin of Oregon and Washington as a result of an August, 2000 oxyfluorfen spill into creek yards which feed into the Columbia River. Of 35 background sediment measurements made in nearby rivers and streams ***which were unaffected by the spill***, 2 detections of oxyfluorfen in sediment were noted. The highest detection, 541 ppb, was downstream of orchards.

  The monitoring data are not adequate to perform a quantitative drinking water assessment because: 1) the majority of the data are limited to sediment levels; 2) oxyfluorfen use is widespread but the monitoring data are limited to a few locations; and 3) the monitoring data are temporally limited.

- **Surface Water Modeling.** PRZM 3.12/ EXAMS 2.7.97, a Tier II model, was performed with index reservoir (IR) scenarios and percent cropped area (PCA) adjustment factors. Three different crop scenarios; citrus in Florida (2 lbs ai/acre, 2X/season), apples in Oregon (2 lbs ai/acre, 1X/season), and cotton (0.5 lbs ai/acre, 1X/season) in Mississippi were chosen to estimate the concentration of oxyfluorfen in surface drinking water. These scenarios were selected to represent a geographically dispersed range of modeled surface water concentrations in areas representative of where oxyfluorfen is heavily used (west coast states and the Mississippi delta region) or has the potential for heavy use (Florida). Although the modeling results for citrus produced higher results, the apple scenario was selected for use in the human health risk assessment because oxyfluorfen use on citrus is limited to non-bearing[1] citrus which precludes large portions of watersheds from being treated simultaneously, as is simulated by the model.

- **Ground Water Modeling.** The SCI-GROW model, a Tier I model, was used to estimate the concentration of oxyfluorfen in drinking water from shallow ground water sources. Currently, there is no Tier II assessment tool for groundwater. Since SCI-GROW, unlike the

[1]"Non-bearing" refers to young trees which are not producing substantial amounts of fruit, and is distinct from dormant trees which are not in a fruiting season.

PRZM/EXAMS surface water model, does not require a specific crop scenario, EFED used the highest use rate of four applications at 2.0 lbs ai/acre as used for ornamentals to estimate the concentration of oxyfluorfen in drinking water from shallow groundwater sources.

Chronic and cancer DWLOCs for oxyfluorfen were calculated based on anticipated residues in food. Cancer DWLOCs calculated from food + residential exposure are presented in the aggregate risk section of this overview. Comparisons made between DWLOCs and the estimated concentrations of oxyfluorfen in surface water and ground water are presented in Table 3. If model estimates are less than the DWLOC, there is generally no dietary (food + water) concern.

Table 3. Chronic/Cancer DWLOCs and EEC Comparisons for Oxyfluorfen

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

[1] Based on the 1 in 10 yearly concentration

[2] Based on the 36 year annual mean concentration

Drinking Water - Chronic Dietary Risk. As shown in Table 3, the chronic DWLOCs for all populations are substantially higher than the estimated environmental concentrations (EECs) of oxyfluorfen in surface and groundwater based on conservative modeling. Consequently, there is no chronic concern for drinking water risk from surface or groundwater sources.

Drinking Water - Carcinogenic Risk. Upon comparison of the cancer DWLOC with the environmental concentrations of oxyfluorfen estimated using conservative modeling, the surface water concentration (5.7 ppb) is greater than the cancer DWLOC (0.315 ppb). Thus, there appears to be a potential for oxyfluorfen residues in drinking water to occur at levels of concern. Further refinement of the dietary risk estimate will not result in acceptable dietary (food + water) cancer risks, since EECs will exceed the cancer DWLOC even if the entire risk cup were reserved for water. Furthermore, surface water EEC's will exceed cancer DWLOCs for other use sites (e.g. cotton).

Non-dietary (Residential/Public) Risks

Oxyfluorfen is used in the residential environment by homeowners to kill weeds on patios,

driveways and similar surfaces. Oxyfluorfen products are intended solely for spot treatment; they are not used for broadcast treatment of lawns because they kill grass. The assessment evaluated spot treatment of weeds using four methods of application: 1) low pressure tank sprayer, 2) "mix your own" sprinkler can, 3) ready-to-use (RTU) invert sprayer, and 4) RTU trigger sprayer. The residential assessment for oxyfluorfen only addresses the applicator, because negligible postapplication exposure is anticipated from spot treatment of weeds.

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

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

- Clothing consisted of a short-sleeved shirt, short pants and no gloves.
- An area of 200 sq ft per application was treated with one gallon of the "ready to use" product or 2.67 quarts of the "mix your own" product in an invert jug or sprinkler can. An area of 300 sq ft per application was treated with one gallon of product in a low pressure hand carried tank sprayer.
- Two applications are made per year.
- Applicators have 50 years of potential exposure over a 70 year life span.

Residential Handler Risk Estimates. Residential handler *non-cancer* risk is measured as a Margin of Exposure (MOE), which determines how closely the exposure comes to a NOAEL. MOEs were calculated for short-term (1-30 day) exposure scenarios only based on the use pattern. Since the FQPA safety factor was reduced to 1X, the Agency's level of concern (i.e., target MOE) is 100. As with dietary risk, residential *cancer* risk estimates less than 1.0×10^{-6} do not exceed the Agency's level of concern. Dermal and inhalation exposures are combined in this assessment. As shown in Table 4, none of the residential applicator scenarios are of concern because the MOEs for non-cancer effects are greater than 100 and the cancer risks are less than 1.0×10^{-6}.

Table 4. Residential Risk Estimates for Non-cancer and Cancer Effects

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

Spot Treatment Scenarios	Combined Absorbed Daily Dose (mg/kg/day)	MOE	Lifetime Absorbed Daily Dose (mg/kg/day)	Cancer Risk
RTU Trigger Pump Sprayer	3.5×10^{-3}	8,500	1.2×10^{-5}	8.7×10^{-7}

Aggregate Risk

The aggregate risk assessment includes combined exposure from food, drinking water, and non-dietary (residential/public) uses.

Chronic (Non-cancer) Aggregate Risk. The chronic aggregate risk assessment addresses exposure to oxyfluorfen residues in food and water only, as there are no chronic residential scenarios identified. As shown previously in Table 3, comparison of the chronic DWLOCs with the environmental concentrations of oxyfluorfen shows that estimated surface and groundwater concentrations are substantially less than the DWLOCs for all populations. Consequently, the Agency concludes that residues of oxyfluorfen in food and drinking water do not result in a chronic aggregate risk of concern.

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

As shown in Table 5, surface and ground water concentrations estimated using conservative modeling are below the short-term DWLOCs for oxyfluorfen. Consequently, there is no short-term aggregate risk concerns from food, drinking water and residential exposures.

Table 5. Short-Term Aggregate Exposure and Risk Calculations

Population	Max Exposure[1] mg/kg/day	Average Food Exposure mg/kg/day	Residential Exposure[2] mg/kg/day	Aggregate MOE (food and residential)[3]	Max Water Exposure[4] mg/kg/day	Surface Water EEC[5] (ppb)	Ground Water EEC[5] (ppb)	Short-Term DWLOC[6] (ppb)
Adult Male	0.3	0.000005	0.0035	8600	0.296	7.1	0.08	10400

Adult Female	0.3	0.000004	0.0035	8600	0.296	7.1	0.08	8900

[1] Maximum Exposure (mg/kg/day) = NOAEL (30 mg/kg/day)/Target MOE of 100.

[2] Residential Exposure = [Dermal exposure + Inhalation Exposure]

[3] Aggregate MOE = [NOAEL ÷ (Avg Food Exposure + Residential Exposure)]

[4] Maximum Water Exposure (mg/kg/day) = Target Maximum Exposure - (Food Exposure + Residential Exposure)

[5] Application to apples was modeled.

[6] DWLOC(µg/L) = [maximum water exposure (mg/kg/day) x body weight (kg)] / [water consumption (L) x 10^{-3} mg/µg]

Cancer Aggregate Risk. The chronic food cancer risk estimate of 3.8×10^{-7}, combined with the residential cancer risk estimate of 8.7×10^{-7}, results in a food + residential cancer risk of 1.1×10^{-6}. Since the Agency's level of concern is 1.0×10^{-6}, the DWLOC is effectively zero and any additional water exposure will further contribute to potential risks of concern. As noted previously, the screening-level cancer EECs for surface water are also greater than the DWLOC when food exposure is considered alone.

Occupational Risk

Occupational handlers may be exposed to a pesticide through such tasks as mixing, loading, or applying a pesticide. Handler non-cancer risk is measured by a Margin of Exposure (MOE) which determines how close the occupational handler exposure comes to a No Observed Adverse Effect Level (NOAEL). For workers entering a treated site, restricted entry intervals (REIs) are calculated to determine the minimum length of time required before workers or others are allowed to enter. REIs are calculated in hours or days. The restricted entry interval for oxyfluorfen is currently set at 24 hours. See Table 1 for a summary of the toxicological endpoints and doses that were used to complete the occupational risk assessment.

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

- Maximum application rates and daily acreage were used to evaluate non-cancer occupational risk. Typical application rates and daily acreage were used to evaluate cancer occupational risk.
- A body weight of 60 kg was assumed for short-term exposures because the short-term endpoint relates to females 13-50 years of age. A body weight of 70 kg was assumed for intermediate-term exposures because the intermediate-term endpoint is not gender specific. A body weight of 70 kg was assumed for cancer scenarios.

Occupational Handler Exposure. Pesticide handlers are likely to be exposed during oxyfluorfen use, resulting in short (1 day to 1 month) and intermediate-term (1 to 6 months) exposures. Chronic exposures (longer than 6 months) are not expected because oxyfluorfen is generally only applied a few

times per year. Ten application methods were evaluated: 1) mixing/loading and spraying liquids with a large groundboom; 2) mixing/loading and spraying liquids with a small groundboom; 3) mixing/loading and spraying liquids with an ATV groundboom; 4) mixing/loading liquids for aerial application and applying liquids with a fixed-wing aircraft; 5) mixing/loading liquids for chemigation; 6) mixing/loading and spraying liquids with a right-of-way sprayer; 7) mixing/loading/applying liquids with a backpack sprayer; 8) loading and applying granules with an ATV drawn broadcast spreader; 9) loading/applying granules with a push type broadcast spreader; and 10) applying granules with a spoon.

Analyses for handler/applicator exposures were performed using the Pesticide Handlers Exposure Database (PHED) data. Baseline PPE includes long sleeve shirts, long pants and no gloves or respirator. Single Layer PPE includes baseline PPE with gloves and a dust mask (exposure was evaluated both with and without the dust mask). Double layer PPE includes coveralls over single layer PPE and a dust mask or cartridge respirator.

Short-/Intermediate-term Risk Estimates for Occupational Handlers. For oxyfluorfen, scenarios are of concern when the MOE is less than 100 for short-term exposures or the MOE is less than 300 for intermediate-term exposures. As seen in Table 7, calculations of occupational handler/applicator risk indicate that at the single layer PPE level (which in this case includes chemical resistant gloves, but does not include respiratory protection), none of the scenarios are of concern for short or intermediate term non-cancer risk (MOEs > 300). The PPE requirements currently listed on the labels range from baseline to double layer with most of the labels requiring chemical resistant gloves.

Table 7. Non-Cancer Combined MOEs for Occupational Exposure to Oxyfluorfen

Endpoint	Baseline MOEs (Long sleeved shirt, long pants)	Single Layer PPE MOEs (Baseline PPE + gloves)
Short-term	5.7 - 7500	490 - 9000
Intermediate-term	7.1 - 9400	520 - 9600

Cancer Risk Estimates for Occupational Handlers. There are two populations of workers exposed to oxyfluorfen in the agricultural environment. These include private growers who apply oxyfluorfen only to their own farms (assumed 10 days of exposure per year) and custom applicators who apply oxyfluorfen to multiple farms (assumed 30 days of exposure per year).

The overall results of cancer risk calculations for private growers and custom handlers/applicators are summarized in Table 8. EPA closely examines occupational cancer risks in the 1×10^{-4} to 1×10^{-6} range and seeks ways to reduce occupational cancer risks to the greatest extent feasible, preferably 10^{-6} or less. The cancer risks for custom applicator scenarios are less than 1.0×10^{-4} at the single layer PPE level. Higher levels of PPE reduce the risk to less than 1.0×10^{-5} for

most of the scenarios. At the highest level of mitigation (engineering controls), the risks for all custom applicator scenarios are reduced to less than 1.0×10^{-5} and some are reduced to less than 1.0×10^{-6}.

Table 8. Cancer Risks for Private Grower and Custom Handlers and Applicators

	Single Layer PPE (no respirator)	Double Layer	Double Layer (dust mask)	Double Layer (cartridge resp)	Engineering Controls
Private grower	1.4 e-06 to 1.7 e-05	1.1e-06 to 1.0e-05	5.3e-07 to 9.7e-05	4.3e-07 to 9.3e-06	3.7e-08 to 2.0e-06
Custom Applicator	3.6 e-06 to 8.0 e -05	3.4e-06 to 6.0e-05	1.6e-06 to 5.7e-05	1.3e-06 to 5.7e-05	1.1e-07 to 6.1e-06

Postapplication Worker Exposure. With the exception of bulb vegetables and conifers, which have more tolerance to oxyfluorfen, over the top applications are not recommended. Therefore, it was determined that significant postapplication exposure is only anticipated following applications of oxyfluorfen to conifer seedlings, conifer trees and bulb vegetables.

Short- and intermediate-term postapplication exposures to oxyfluorfen are expected to occur based on its use pattern. Only dermal exposures were evaluated in the postapplication worker assessment because inhalation exposures are not anticipated due to the low vapor pressure of oxyfluorfen (2.0e-07 torr at 20 C).

One chemical specific Dislodgeable Foliar Residue (DFR) study was submitted, which measured dislodgeable foliar residues following groundboom application of oxyfluorfen in conifer seedling beds (MRID 42098301). This study has serious deficiencies and an attempt was made to account for these deficiencies by applying correction factors. Even with these correction factors, the study data indicates faster dissipation rates than the default value. Exposure was assessed using both the default and study values. Because chemical specific DFR data were not provided for bulb vegetables, the default initial deposition and dissipation values were used.

Standard Agency values for transfer coefficients were used in the postapplication assessment for reentry workers. Currently there is no transfer coefficient for conifer seedling irrigation/scouting and a value was selected based on data collected for similar activities and preliminary Agricultural Reentry Task Force data that are currently in review.

Postapplication Non-Cancer Risk Estimates for Occupational Workers. Except for Christmas tree shearing, estimated postapplication risks based on default assumptions are not of concern as long as the current 24-hour REI is observed. As shown in Table 9, 10 days is required before risk is below the level of concern (MOE > 300) for Christmas tree shearing when using default assumptions; however, when the study data are used, the MOE rises above 300 after 24 hours.

Table 9. Oxyfluorfen Post Application Non-Cancer Risks

Crops	Application Rate	Input Values	Post Application Activities	DAT* when Short-term MOE >100	DAT* when Intermediate-term MOE >300
Bulb Vegetables	0.5	Default	Irrigation, scouting, weeding, thinning immature plants Irrigation and scouting mature plants	0 0	0 0
Conifer Seedlings	1.0	Default	Irrigation, scouting, hand weeding escaped weeds	0	0
Conifer Seedlings	1.0	Study Data	Irrigation, scouting, hand weeding escaped weeds	0	1
Conifer Trees	2.0	Default	Irrigation, scouting Shearing	0 1	0 10
Conifer Trees	2.0	Study Data	Irrigation, scouting Shearing	1 1	1 1

*DAT = Day after treatment

Postapplication Cancer Risk Estimates for Occupational Workers. Table 10 presents the cancer risks to commercial workers and private growers. A private grower is defined as a single grower or employee who only enters fields owned by that particular grower and is assumed to have ten days of post application exposure per year. A commercial worker may enter fields owned by multiple growers and is assumed to have thirty days of post application exposure per year.

The cancer risks to commercial workers performing re-entry activities with treated conifers exceeds 1.0×10^{-4} on day of treatment when using either default assumptions or study data. These risks decline to less than 1.0×10^{-4} in 4 to 14 days when using default assumptions or 1 to 2 days when using study data. The conifer scenario risks decline to less than 1.0×10^{-6} in 41 to 58 days when using default assumptions and 10 to 12 days when using study data. The cancer risk to commercial re-entry workers working with bulb vegetables is less than 1.0×10^{-4} on day zero and declines to less than 1.0×10^{-6} in 23 to 38 days. Estimated risks to private growers are generally less than those to commercial growers.

Table 10. Post Application Cancer Risks

Crops	Input Values	Application Rate (lbs ai/acre)	Activities	Commercial Workers		Private Growers	
				Days after treatment when cancer risk is less than:			
				1.0e-04	1.0e-06	1.0e-04	1.0e-06
Tree Seedlings, Conifer	Default	0.5	Irrigation, Scouting, Hand Weeding	0	41	0	30
Tree Seedlings, Conifer	Study Data	0.5	Irrigation, Scouting, Hand Weeding	1	11	0	6
Trees, Conifer	Default	1.0	Irrigation, Scouting Shearing	4 14	47 58	0 4	37 47
Trees, Conifer	Study Data	1.0	Irrigation, Scouting Shearing	1 2	10 12	1 1	7 12
Bulb Vegetables	Default	0.25	Irrigate and scout immature plants Irrigate and scout mature plants	0 0	23 38	0 0	12 28

Incidents. A total of 66 incidents were reported in the Office of Pesticide Programs (OPP) Incident Data System from 1994 to 2000 for oxyfluorfen alone (mixtures excluded). Most incidents involved irritant effects to the eyes, skin, and occasionally respiratory passages. 25 cases were reported in the California Pesticide Illness Surveillance Program from 1982-1999 for oxyfluorfen alone, and the majority of these cases involved minor symptoms of systemic illness such as headache, dizziness, and nausea.

Ecological Risk Assessment

EPA uses the quotient method to evaluate potential risk to nontarget organisms. Applying this method, risk quotients (RQs) are calculated by dividing the estimated concentrations of a pesticide in the environment by results from ecotoxicity studies in various organisms. A risk concern results when an RQ exceeds a Level of Concern (LOC). An LOC is a value calculated based on the category of nontarget organism and category of concern. EPA further characterizes ecological risk based on any reported aquatic or terrestrial incidents to nontarget organisms in the field (e.g., fish or bird kills).

In general, EPA believes oxyfluorfen presents the greatest risks to: (1) terrestrial plants through spray drift of liquid formulations and (2) aquatic organisms through spray drift of liquid formulations and runoff of dissolved and soil entrained oxyfluorfen. In addition, the potential of oxyfluorfen (as a light-dependent peroxidizing herbicide) to be more toxic in the presence of sunlight may lead to the occurrence of environmental effects that are not predicted by standard guideline toxicity tests.

There are only a few reported aquatic and terrestrial wildlife incidents, however, the major

concerns for risks to birds and mammals are chronic effects, which are much less apparent than acute effects (e.g. mortality). There are several reported incidents of damage to non-target plants, and these incidents are mainly attributed to drift.

Nontarget Terrestrial Animal Risk

Risks to Birds and Mammals

RQs were not calculated to evaluate the potential acute risks to birds and mammals because no adverse effects reflecting a single dose was identified at the highest dose tested. For the current labeled application rates, minimal acute risks to birds and mammals is anticipated. Sub-chronic and chronic risks to terrestrial birds and mammals do present a concern. Toxic effects may be manifested as reproductive, developmental, and hemolytic consequences.

- Assuming maximum residue values, the chronic LOC of 1.0 is estimated to be exceeded for birds when oxyfluorfen is applied to crops at application rates greater than or equal to 0.5 lbs ai/acre/acre (chronic RQs #14.9). Consumption of short grass leads to the highest chronic risk estimates for birds.

- For mammals, chronic risk quotients are estimated to exceed the Chronic LOC of 1.0 for the citrus scenario with the highest application rate (2 lbs ai/acre, 2 applications/season) and for all scenarios with a 2 lb ai/acre/year application rate (chronic RQs #1.7).

Nontarget Aquatic Animal Risk

Risks to Fish

In general, toxicity tests show oxyfluorfen is highly toxic to fish exposed for short or extended periods of time.

- For freshwater fish, the acute and chronic risk LOCs are not exceeded, but the endangered species acute LOC of .05 is exceeded for all modeled citrus scenarios as well as grapes at 2.0 lbs ai/acre (acute RQs #0.25)

- For estuarine fish, the acute risk LOC of 0.5 is not exceeded, but the endangered species acute LOC of 0.05 is exceeded for all modeled citrus and grape scenarios, and apples at the higher application rate of 2.0 lbs ai/acre (acute RQs #0.29)

Risks to Aquatic Invertebrates

Oxyfluorfen is classified as very highly toxic to moderately toxic for freshwater invertebrates and very highly toxic to estuarine invertebrates.

- For freshwater invertebrates, the acute risk LOC of 0.5 is exceeded for two citrus scenarios with higher application rates (RQs #0.62). The only modeled scenarios that do not have an exceedence of the endangered species LOC of .05 are walnut and cole crops.

- For estuarine invertebrates, the acute risk LOC of 0.5 is exceeded for all citrus scenarios (RQs #1.6). Of the modeled single-application scenarios, the only ones that do not have an exceedence of the endangered species LOC of 0.05 for estuarine invertebrates were the lower application rate on walnut and the ground application to cole crops.

Nontarget Plant Risk

- For nearly all modeled scenarios, the acute risk LOC of 1.0 for terrestrial plants adjacent to treated areas is exceeded. The RQs range from 1.14 to 93.02.

- The RQs for all modeled scenarios currently exceed the acute risk LOC of 1.0 for aquatic plants, and range from 4.59 to 171.59. Risks to aquatic vascular plants cannot be assessed at this time since data have only been submitted for one species, a non-vascular plant.