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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 28-JUL-2000

SUBJECT: ID#: 00NM0004. SECTION 18 EMERGENCY EXEMPTION FOR THE USE OF **OXYFLUORFEN** ON **CHILE PEPPERS** IN **NEW MEXICO.**

DP Barcode:	D265920	PRAT Case:	293096
Submission No.:	S579519	Caswell No.:	888B
Chemical No.:	111601	Class:	Herbicide
Trade Name:	GOAL 2XL	EPA Reg No.:	707-243
40 CFR:	§180.381		
MRID No.:	None		

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INTRODUCTION

The New Mexico Department of Agriculture is proposing specific a emergency exemption for the use of oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] on chile peppers for control of Wright groundcherry. This is the **first** year that this oxyfluorfen use has been requested. The proposed program will entail application of 1175 gallons of GOAL 2XL [2375 lbs ai] on 9400 acres throughout the state starting May 15, 2000 to July 31, 2000.

SUMMARY

HED concludes that occupational exposure and aggregate acute, short-term and chronic (non-cancer) risk estimates do not exceed HED's level of concern. However, the aggregate (food + residential) cancer risk is 1.3×10^{-6}, which exceeds the negligible risk (1×10^{-6}). If this Section 18 use is approved, then a time-limited tolerance for residues of oxyfluorfen in/on non-bell peppers should be established at **0.01 ppm**.

Adequate enforcement methods are available for determination of the regulated oxyfluorfen residues in plant and livestock commodities.

Acute Aggregate Risk (Food + Water)

Acute aggregate risk estimates do not exceed HED's level of concern. The acute dietary risk (food only) estimates are based upon 100% crop treated and tolerance level residues. HED has estimated that the acute dietary exposure to oxyfluorfen from food for females 13-50 years old will utilize **3%** of the acute Population Adjusted Dose (aPAD). The Environmental Fate and Effects Division (EFED) supplied surface and ground water modeling estimates which do not exceed HED's calculated Drinking Water Level Of Comparison (DWLOCs). Therefore, HED does not expect the acute aggregate exposure estimates to exceed the level of concern.

Chronic (Non-Cancer) Aggregate Risk

Chronic aggregate risk estimates do not exceed HED's level of concern. The chronic dietary risk estimates (food only) are based upon anticipated residues (ARs) and percent crop treated (%CT) data for several commodities. The most highly exposed population subgroup for chronic exposure (all infants, <1 year old) will utilize **1%** of the chronic Population Adjusted Dose (cPAD). EFED supplied surface and ground water modeling estimates which do not exceed HED's calculated DWLOCs for any subpopulation. The registered residential uses do not constitute a chronic scenario. Therefore, HED does not expect the chronic aggregate exposure estimates to exceed the level of concern.

Short- and Intermediate- Term Aggregate Risk

Short-term dermal and inhalation exposures are expected for adult population subgroups. HED concludes the short-term aggregate risk to the most highly exposed population subgroup (U.S. Population (48 states)) from home garden use of oxyfluorfen **does not** exceed HED's level of concern (margin of exposure (MOE) of ≤300). EFED supplied surface and ground water modeling estimates; these estimates do not exceed HED's calculated DWLOCs for any subpopulation. Based on the homeowner application scenarios, intermediate-term exposures are not expected.

Chronic (Cancer) Aggregate Risk

Aggregating the chronic dietary exposure (food only) and residential exposure (dermal and inhalation from garden uses) for the U.S. Population (48 states) results in a total cancer risk of

1.3×10^{-6}. A DWLOC for cancer could not be calculated as this value exceeded the negligible risk (1×10^{-6}). Further refinement in the chronic food exposure using additional %CT information would result in a lower estimate of chronic dietary exposure, potentially allowing a DWLOC for cancer to be calculated. However, as the estimated environmental concentration (EEC) for oxyfluorfen in surface waters (2.1 μg/L) greatly exceeds the DWLOC for cancer calculated when assuming 0 mg/kg/day average food + residential exposure, further refinements were not performed.

Occupational Exposure

Both short- and intermediate-term exposures are expected for the commercial handlers of oxyfluorfen. The estimated MOE is **6.5E+03** or greater for all mixer/loader and applicator activities. Therefore, since HED's level of concern for oxyfluorfen is for MOEs less than 100, potential risk to handlers is well below the level of concern. The cancer risk resulting from handler exposures was determined to be **8.4×10^{-7}** for the high-end scenario. Generally, HED's level of concern for occupational exposure is for cancer risk greater than 1×10^{-4}. Therefore, the cancer risk for workers handling oxyfluorfen does not exceed HED's level of concern.

DETAILED DISCUSSION

TOXICOLOGICAL PROFILE

The Hazard Identification Assessment Review Committee (HIARC) of HED met on June 6, 2000 to evaluate the available toxicological data base, review and select doses and endpoints for dietary and non-dietary exposure risk assessments, and address the potential enhanced sensitivity/susceptibility of infants and children from exposure to oxyfluorfen. The FQPA Safety Factor Committee (SFC) met on June 12, 2000 to evaluate the hazard and exposure data for oxyfluorfen in order to determine the FQPA Safety Factor (as required by Food Quality Protection Act of August 3, 1996). The nature of the toxic effects caused by oxyfluorfen are discussed in this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TOXICOLOGICAL ENDPOINTS

The dose at which no adverse effects are observed (NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer), HED uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD=NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The aPAD or cPAD is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer), the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (MOE = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q_1*) is the primary method currently used by HED to quantify carcinogenic risk. The Q_1* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q_1* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. Generally an MOE is calculated when the carcinogen is not mutagenic and a proposed mechanism of toxicity supporting nonlinearity has been accepted by EPA.

Table 1. Summary of Toxicological Dose and Endpoints for Oxyfluorfen for Use in Human Risk Assessment

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary females 13-50 years of age	NOAEL = **10** mg/kg/day UF = **100** **Acute RfD = 0.1** mg/kg/day	FQPA SF = **3** **aPAD** = acute RfD / FQPA SF = **0.03** mg/kg/day	**Pre-natal Developmental Study / Rabbit** LOAEL = **30** mg/kg/day based on **increased incidence of fused sternebrae**.
Acute Dietary general population including infants and children	**No appropriate endpoint was identified for the General Population.**		

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Chronic Dietary all populations	NOAEL= **0.3** mg/kg/day UF = **100** **Chronic RfD** = **0.003** mg/kg/day	FQPA SF = **1** **cPAD** = chronic RfD / FQPA SF = **0.003** mg/kg/day	**20-month Carcinogenicity Study / Mouse** LOAEL = **3** mg/kg/day based on **liver necrosis, hyperplastic nodules in liver, and increased liver weight**.
Short-/ Intermediate-Term Dermal (1 to 7 days)/7 days to several months (Residential)	oral study NOAEL= **10** mg/kg/day (dermal absorption rate = **8 %**)	**LOC for MOE** = **300** (Residential) for **Females 13-50.** **LOC for MOE** = **100** (Residential) for **General Pop.**	**Pre-natal Developmental Study / Rabbit** LOAEL = **30** mg/kg/day based on **anorexia, red exudate, and body weight loss**.
Short-/ Intermediate-Term Inhalation (1 to 7 days)/7 days to several months (Residential)	inhalation study NOAEL= **0.65** mg/L	**LOC for MOE** = **300** (Residential) for **Females 13-50.** **LOC for MOE** = **100** (Residential) for **General Pop.**	**30-Day Inhalation Toxicity Study / Rat** LOAEL > **0.65** mg/L based on **no effects noted at the highest dose tested**.
Cancer (oral, dermal, inhalation)	$Q_1^* = 7.32 \times 10^{-2}$ $(mg/kg/day)^{-1}$	N/A	Significant positive dose-related trends in liver adenomas, carcinomas and combined adenomas and/or carcinomas in male CD-1 mice. Supporting evidence included a strong association of oncogenicity with this class of chemical (diphenyl ether herbicides with nitro groups), some mutagenicity evidence, and the appearance of increased carcinomas (although not significant by pairwise comparison).

*** The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.**

RESIDUE CHEMISTRY

Proposed use

GOAL 2XL (EPA Reg No. 707-243) contains 2 lbs. of the a.i./gallon. Tolerances are established for residues of the herbicide oxyfluorfen, 2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene, in or on numerous plant and livestock commodities (40 CFR 180.381). Oxyfluorfen is a List B Chemical. The HED Residue Chemistry RED Chapter was issued 9/26/96 (D226225).

The Section 18 supplemental label proposes a maximum of 2 applications of GOAL 2XL with each application at 0.125 - 0.25 lbs a.i/A, for a total of 0.25 lbs a.i/A/year (preharvest interval (PHI) = 31 days). Rotational crop restrictions are specified on the national label as follows: for transplanted seedling crops, 30 days; for direct seed crops, 60 days; and for cereal grains, 10 months.

Provided the Section 18 supplemental label is revised to specify rotational crop restrictions as follows: for leafy vegetables, 120 days; for root and tuber vegetables, 90 days; and for cereal grains, 10 months (see below), HED concludes that the proposed use is adequate. The use pattern of the submitted crop field trials is the same as the Section 18 label use.

Nature of the Residue in Plants and Livestock

The nature of the residue in plants is adequately understood. The residue of concern is oxyfluorfen *per se* as specified in 40 CFR 180.381. There are no livestock feed items associated with non-bell peppers; consequently, a discussion of the nature of the residue in livestock commodities is not relevant to this petition.

Analytical Enforcement Methodology

Method I of PAM II is available for enforcement purposes. This is a common moiety method in which oxyfluorfen and its metabolites are hydrolyzed, derivatized and measured on GC. The limit of quantitation is 0.05 ppm. An improved version of this method, 31C-87-16 (MRID# 40223201), has been sent to FDA for inclusion in PAM II as Method III (Letter of 6/26/91, F. Griffith). The LOQ of this version is 0.01 ppm.

Magnitude of Residues

The petitioner submitted the preliminary results of 3 crop field trials on non-bell peppers. One foliar spray application of GOAL 2XL was made to non-bell peppers at a rate of 0.25-1.0 lb a.i./acre/application (1-4x). Samples were harvested at a 30-day PHI. Residues in all samples were **<0.01 ppm**. For the purposes of the proposed Section 18 use only, HED concludes that residues of oxyfluorfen will not exceed **0.01 ppm** on non-bell peppers; therefore, time-limited tolerance should be set at this level. These data will be submitted in conjunction with an IR-4 petition in 2000. Once a full review of this petition has been conducted, HED will determine the appropriate level for the permanent tolerance.

Processed Commodity

As there are no regulated processed food/feed items derived from non-bell peppers, processing studies and tolerances for residues in/on processed non-bell peppers commodities are not required.

Meat, Milk, Poultry, and Eggs

There are no livestock feed items associated with non-bell peppers; consequently, a discussion of potential transfer of secondary residues to livestock commodities is not relevant to this petition.

Rotational Crop Restriction

Rotational crop restrictions are specified on the national label as follows: for transplanted seedling crops, 30 days; for direct seed crops, 60 days; and for cereal grains, 10 months. However, HED has concluded that the registrant should change the minimum treatment to planting intervals as follows: for leafy vegetables, 120 days; for root and tuber vegetables, 90 days; and for cereal grains, 10 months (Residue Chemistry RED Chapter, 9/26/96; D226225). These restrictions apply to both transplanted seedling and seed crops.

International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits (MRL) for oxyfluorfen on non-bell peppers. Thus, harmonization is not an issue for this Section 18. A copy of the IRLS (International Residue Limit Status) sheet is attached to this memorandum.

EXPOSURES AND RISKS

Dietary Exposure (memo of 6/26/00, J Rowell, D266651)

HED conducts dietary risk assessments using the Dietary Exposure Evaluation Model (DEEM™), which incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. For acute dietary risk assessments, one-day consumption data are summed and a food consumption distribution is calculated for each population subgroup of interest. The consumption distribution can be multiplied by a residue point estimate for a deterministic exposure/risk assessment, or used with a residue distribution in a probabilistic (Monte Carlo) type risk assessment. Acute exposure estimates are expressed in mg/kg bw/day and as a percent of the aPAD. For chronic risk assessments, residue estimates for foods or food-forms of interest are multiplied by the averaged consumption estimate of each food/food-form of each population subgroup. Chronic exposure estimates are expressed in mg/kg bw/day and as a percent of the cPAD.

Acute Dietary Exposure Analysis

The acute analysis was performed for females 13-50 years old using published and proposed tolerance level residues for all commodities. For all commodities, 100% CT information was used. Therefore, the acute risk was analyzed at the 95th percentile. The aPAD for females 13-50 years old is 0.03 mg/kg/day. For acute dietary risk, HED's level of concern is >100% aPAD. Dietary exposure estimates and associated acute risk for females 13-50 years old is shown in Table 2. A full listing of acute dietary exposure estimates is attached (Attachment 2).

Table 2. Summary of Results of Acute DEEM ™ Analysis for Oxyfluorfen (Females 13-50 yrs.)

Subgroups	95th Percentile	
	Exposure (mg/kg/day)	% aPAD
Females (13-50 years old)	0.001023	3

Chronic (Non-Cancer) Dietary Exposure Analysis

For the chronic and cancer analyses, published tolerances level residues and ARs based on field trial data (Memo, G. Kramer, 11/9/98, D250388) were used. Some of the calculated ARs were < 1×10^{-6} ppm. The DEEM™ analysis system does not accept values less than 1×10^{-6} ppm. Therefore, the ARs for meat by-products (cattle, sheep, horse, goat, and hog) and hog meat were rounded up to 1×10^{-6} ppm. For several commodities, %CT information from the Biological and Economics Analysis Division (BEAD) were used.

The cPAD for the U.S. population and all subgroups is 0.003 mg/kg/day. For chronic dietary risk, HED's level of concern is >100% cPAD. Dietary exposure estimates for the U.S. population and other population subgroups (i.e., children, infants, females, and males) are presented in Table 3.

Table 3. Summary of Results from Chronic DEEM ™ Analysis of Oxyfluorfen.

Subgroups	Exposure (mg/kg/day)	% cPAD
U.S. Population (48 states)	0.000011	<1
All Infants (< 1 yr. old)	0.000028	1
Children 1-6 yrs. old	0.000024	1
Children 7-12 yrs. old	0.000013	<1
Females 13-50 yrs. old	0.000008	<1
Males 13-19 yrs. old	0.000008	<1
Males 20+ yrs. old	0.000008	<1
Seniors 55+ yrs. old	0.000010	<1

Cancer Dietary Exposure Analysis

The cancer analysis was performed using published tolerance level residues and ARs based on field trial data. For several commodities, %CT information was used. The upper bound lifetime

cancer risk for the general U.S. population was calculated to be $7.7x10^{-7}$ (based on a Q_1* value of 0.0732 $(mg/kg/day)^{-1}$). The cancer risk does not exceed HED's level of concern. The present estimate should be considered partially refined. Table 4 lists the results of the cancer analysis for oxyfluorfen.

Table 4. Summary of Results from Cancer DEEM ™ Analysis of Oxyfluorfen.

Subgroup	Exposure (mg/kg/day)	Lifetime Cancer Risk
U.S. Population (48 states)	0.000011	$7.7x10^{-7}$

Further refinement using additional %CT information would result in a lower estimate of chronic dietary exposure.

Drinking Water Exposure (memo of K. Costello, 6/5/00, D265921)

HED does not have monitoring data available to perform a quantitative drinking water risk assessment for oxyfluorfen at this time. EFED provided ground and surface water exposure estimates for use on apples based on the label rate of 2.0 lbs. a.i./acre.

Submitted acceptable and supplemental data indicate that oxyfluorfen is persistent in soil (hydrolysis, >97% parent remained after 30 days at pH 4, 7 and 10; aerobic soil metabolism half-lives of 291 and 294 days in a clay loam soil and 556 and 596 days in a sandy loam soil; and anaerobic soil metabolism half-lives between 554 and 603 days). On the other hand, the compound is readily degraded by sunlight when dissolved in water (half-lives = 2 and 7.5 days), and is moderately degraded by sunlight when on soil surfaces (half-life = 28 days, a minor route of dissipation). Soil binding and aqueous photodegradation are probably major routes of dissipation.

The leaching data indicate that the compound is slightly mobile in sandy soils and immobile in sandy loam, clay loam and silty clay loam soils (K_ds = 8.5. 62, 99, 228 mL/g).

The drinking water EECs for oxyfluorfen on apples were derived using a PRZM-EXAMS (surface water) simulation of runoff to an index reservoir using standard EFED files for apples.

PRZM-EXAMS modeling simulated oxyfluorfen concentrations in surface water of 7.5 ppb at the maximum annual application rate (acute) and 2.1 ppb for the 1-in-10 year annual concentration (chronic). These estimates replace those from an earlier assessment sent from Kevin Costello to Barbara Madden in March 1999 (DP Barcode 252219). Note that the previously determined value for groundwater (SCI-GROW), 0.049 ppb, is much less than the EECs for surface water (Memo, A. Al-Mudallal, 9/16/98).

Acute Risk. For purposes of risk assessment, the EEC for oxyfluorfen in surface and ground waters (7.5 ppb) should be used for comparison to the back-calculated human health DWLOCs for the acute endpoint. These DWLOCs for various population categories are summarized in Table 5.

Table 5. Drinking Water Levels of Comparison for **Acute** Exposure to Oxyfluorfen [1]						
Population Category	Acute RfD (mg/kg/day)	aPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure[2] (mg/kg/day)	DWLOC [3,4,5] (μg/L)	EEC[6] (μg/L)
Females (13-50 years old)	0.10	0.03	0.0010	0.032	970	7.5

[1] Values are expressed to 2 significant figures.
[2] Maximum Water Exposure (Chronic or Acute) (mg/kg/day) = aPAD or cPAD (mg/kg/day) - Food Exposure (mg/kg/day).
[3] DWLOC(μg/L) = Max. water exposure (mg/kg/day) x body wt (kg) ÷ [(10^{-3} mg/μg) x water consumed daily (L/day)].
[4] HED Default body weights are: General U.S. Population, 70 kg; Males (13+ years old), 70 kg; Females (13+ years old), 60 kg; Other Adult Populations, 70 kg; and, All Infants/Children, 10 kg.
[5] HED Default daily drinking rates are 2 L/day for adults and 1 L/day for children.
[6] EEC: Estimated Environmental Concentration, acute value.

Chronic (Non-Cancer) Risk. EECs of oxyfluorfen in surface and ground water for chronic exposure analysis are 2.1 and 0.049 μg/L (ppb), respectively. For purposes of chronic risk assessment, the EEC for oxyfluorfen in surface waters (2.1μg/L) should be used for comparison to the back-calculated human health DWLOCs for the chronic (non-cancer) endpoint. These DWLOCs for various population categories are summarized in Table 6.

Table 6. Drinking Water Levels of Comparison for **Chronic** Exposure to Oxyfluorfen [1]						
Population Category[2]	Chronic RfD (mg/kg/day)	cPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure[3] (mg/kg/day)	DWLOC [4,5,6] (μg/L)	EEC[7] (μg/L)
U.S. Population (48 states)	0.003	0.003	0.000011	0.0030	105	2.1
All Infants (< 1 yr. old)	0.003	0.003	0.000028	0.0030	30	2.1
Children 1-6 yrs. old	0.003	0.003	0.000024	0.0030	30	2.1
Children 7-12 yrs. old	0.003	0.003	0.000013	0.0030	30	2.1
Females 13-50 yrs. old	0.003	0.003	0.000008	0.0030	105	2.1
Males 13-19 yrs old.	0.003	0.003	0.000008	0.0030	105	2.1
Males 20+ yrs old.	0.003	0.003	0.000008	0.0030	105	2.1
Seniors 55+ yrs. old	0.003	0.003	0.000010	0.0030	105	2.1

[1] Values are expressed to 2 significant figures.
[2] Within each of these categories, the subgroup with the highest food exposure was selected.
[3] Maximum Water Exposure (Chronic or Acute) (mg/kg/day) = cPAD or aPAD (mg/kg/day) - Food Exposure (mg/kg/day).

[4] DWLOC(μg/L) = Max. water exposure (mg/kg/day) x body wt (kg) ÷ [(10^{-3} mg/μg) x water consumed daily (L/day)].
[5] HED Default body weights are: General U.S. Population, 70 kg; Males (13+ years old), 70 kg; Females (13+ years old), 60 kg; Other Adult Populations, 70 kg; and, All Infants/Children, 10 kg.
[6] HED Default daily drinking rates are 2 L/day for adults and 1 L/day for children.
[7] EEC: Estimated Environmental Concentration, chronic value.

Short- and Intermediate-Term Risk. For purposes of risk assessment, the maximum EEC for chronic exposure of oxyfluorfen from surface and ground waters (which is 2.1 μg/L, see below) should be used for comparison to the back-calculated human health DWLOCs for the short- and intermediate-term endpoint.

The DWLOC for short-term exposure to oxyfluorfen was calculated relative to the aPAD which was utilized for estimating risk for short-term oral exposure to oxyfluorfen. To calculate the DWLOC for short-term exposure relative to an acute toxicity endpoint, the sum of chronic dietary food exposure and the dermal exposure from oxyfluorfen home garden uses was subtracted from aPAD to obtain the acceptable short-term exposure to oxyfluorfen in drinking water (Chronic food data from Table 3; Dermal (expressed as the oral-equivalent) exposure from home garden uses = 0.0019 mg/kg bwt/day, data from **RESIDENTIAL EXPOSURE** below). DWLOCs were then calculated using default body weights and drinking water consumption figures, and then compared to EFED's chronic water number, as showed in Table 7.

Table 7. Drinking Water Levels of Comparison for **Short-Term** Exposure to Oxyfluorfen

Population Subgroup	aPAD (mg/kg/day)	Total Exposure[1] (mg/kg bwt/day)	Max. Exposure from Water[2] (mg/kg bwt/day)	DWLOC[3,4,5] (μg/L)	EEC[6] (μg/L)
U.S. Population (48 states)	0.1	0.001911	0.10	3500	2.1
Females 13-50 yrs. old	0.03	0.001908	0.031	940	2.1
Males 13-19 yrs. old	0.1	0.001908	0.10	3500	2.1
Males 20+ yrs. old	0.1	0.001908	0.10	3500	2.1
Seniors 55+ yrs. old	0.1	0.001910	0.10	3500	2.1

[1] Total Exposure = sum of exposures from chronic food plus home garden uses.
[2] Maximum Water Exposure (Short-term) (mg/kg/day) =aPAD (mg/kg/day) - Total Exposure (mg/kg/day).
[3] DWLOC(μg/L) = Max. water exposure (mg/kg/day) x body wt (kg) ÷ [(10^{-3} mg/μg) * water consumed daily (L/day)].
[4] HED Default body weight is: All Infants/Children, 10 kg.
[5] HED Default daily drinking rate is 1 L/day for children.
[6] EEC: Estimated Environmental Concentration, chronic value.

Based on the homeowner application scenarios, intermediate-term exposures are not expected.

Chronic (Cancer) Risk. EECs of oxyfluorfen in surface and ground water for chronic exposure analysis are 2.1 and 0.049 μg/L (ppb), respectively. For purposes of chronic risk assessment, the EEC for oxyfluorfen in surface waters (2.1 μg/L) should be used for comparison to the back-calculated human health DWLOCs for the cancer endpoint. A DWLOC for cancer could not be calculated as sum of chronic dietary food exposure and the dermal exposure from oxyfluorfen home garden uses exceeded the negligible risk ($1x10^{-6}$) (chronic food data from Table 3; dermal (expressed as the oral-equivalent) from home garden uses = 0.0000063 mg/kg bwt/day, data from RESIDENTIAL EXPOSURE below) (Table 8).

Table 8. Chronic Cancer Aggregate Risk Estimates for Oxyfluorfen

	Population Subgroup	US General Population
	Q_1*	7.32×10^{-2}
Food Only	Chronic Food Exposure (mg/kg/day)	0.000011
Residential Dermal	LADD Oral-Equivalent Exposure (mg/kg/day)	0.0000063
	Cancer Risk[1]	1.3×10^{-6}
Drinking water	Chronic Water Exposure[2]	n/a
	$DWLOC^3_{(cancer)}$ (ppb)	n/a
	Surface Water (ppb)	2.1

[1]Cancer risk = aggregate exposure (food + residential) (mg/kg/day) x Q_1*(mg/kg/day)$^{-1}$

[2]Chronic water exposure (mg/kg/day) = negligible risk($1x10^{-6}$)/Q_1* - [(average food + residential exposure (LADD) (mg/kg/day)]

[3]$DWLOC_{cancer}$= [chronic water exposure (mg/kg/day) x body weight (kg)]/[water consumption (L) x 10^{-3} (mg/μg)]

Further refinement in the chronic food exposure using additional %CT information would result in a lower estimate of chronic dietary exposure, potentially allowing a DWLOC for cancer to be calculated. However, as the EEC for oxyfluorfen in surface waters (2.1 μg/L) exceeds the DWLOC for cancer calculated when assuming 0 mg/kg/day average food + residential exposure (Table 9), further refinements were not performed.

Table 9. Chronic Cancer Aggregate Risk Estimates for Oxyfluorfen Assuming No Food Or Residential Exposures

	Population Subgroup	US General Population
	Q_1*	7.32×10^{-2}
Food Only	Chronic Food Exposure (mg/kg/day)	0
Residential Dermal	LADD Oral-Equivalent Exposure (mg/kg/day)	0
	Cancer Risk[1]	0
Drinking water	Chronic Water Exposure[2]	0.000014
	$DWLOC^{3}_{(cancer)}$ (ppb)	0.48
	Surface Water (ppb)	2.1

[1]Cancer risk = aggregate exposure (food + residential) (mg/kg/day) x Q_1*(mg/kg/day)$^{-1}$

[2]Chronic water exposure (mg/kg/day) = negligible risk($1x10^{-6}$)/Q_1* - [(average food + residential exposure (LADD) (mg/kg/day)]

[3]$DWLOC_{cancer}$= [chronic water exposure (mg/kg/day) x body weight (kg)]/[water consumption (L) x 10^{-3} (mg/ug)]

RESIDENTIAL EXPOSURE/RISK CHARACTERIZATION

GroundClear Triox is a homeowner-use product containing 0.7% oxyfluorfen. Other products, (such as ROUT and Regal-0-0, formulated as granules and applied at 2 lbs ai/Acre), prohibits homeowner applications but allows for commercial applications of residential landscapes.

Residential Handler Exposure Assessment

There is potential for homeowner spot applications to areas where vegetation is not desired, such as sidewalks, patios, gutters, driveways, along buildings or fences. Triox is a liquid concentrate formulation that is applied as a spot spray to eliminate and prevent weeds and grasses. According to the label, one container of Triox can treat up to 75 ft^2. Since the label states that the homeowner products are to be used every 6-8 months, residential exposure is expected to be of short-term duration. In order to present a high-end scenario of residential exposure, it was assumed that one person would complete all mixing, loading and application of oxyfluorfen by a sprinkler can for one entire container of product.

Since PHED does not contain this specific scenario, the surrogate table data for low pressure handwand was considered as the closest scenario. Exposure scenarios were assessed, at the maximum application rate, for mixing, loading, and application of one entire container of the Triox liquid concentrate product by low pressure handwand to represent the high-end scenario for the outdoor spot/crack and crevice use.

The residential handler exposure estimates are based on assumptions and generic data as specified by the December 18, 1997 Draft HED Standard Operating Procedures (SOPs) for

Residential Exposure Assessments. The Surrogate Table from PHED (v 1.1) was used as an estimate of unit exposure.

Since the label states that this product may be applied every 6-8 months, lifetime average daily dose (LADD) calculations were done assuming a homeowner would apply this product a maximum of twice per year. This exposure is expected for 50 years over a 70 year lifespan (HED ExpoSAC).

Table 10. Exposure & Risk Assessments for Homeowner Uses [1]								
Exposure Scenario (wearing no protective clothing)	Unit Exposure mg/lb ai		Area treated ft^2/day^2	AR[2] lb ai/ft^2	ADD[3] mg/kg/day	MOE[4]	LADD[5]	Cancer Risk[6]
Sprinkler can (low pressure Handwand)	dermal	100	75	0.00019	1.9E-03	5.4E+03	6.3E-06	4.6E-07
	inhalation	0.03			7.0E-06	2.4E+07		

1 Unit exposures and area treated estimates from Draft HED Standard Operating Procedures (SOPs) for Residential Exposure Assessments. December 18, 1997
2 Application Rate (AR) from Label, Ortho Ground Clear Triox, EPA reg #239-2622
3 Average Daily Dose (ADD) = Unit exposure X AR X Area/day X 1/60 kg bw X % Absorption (dermal = 8%, inhalation = 100%)
4 MOE = NOAEL/Exposure; short-term dermal NOAEL = 10 mg/kg/day; short-term inhalation NOAEL = 170 mg/kg/day; *level of concern for MOE is 300*
5 Lifetime Average Daily Dose (LADD) = ADD x (2 days/365 days a year) x (50 years/70 year lifetime)
6 Cancer Risk = LADD x Q_1*(0.0732 $mg/kg/day^{-1}$), using 70 kg BW

The calculated MOEs for the homeowner mixing, loading, and applying one entire container of the Triox product are 5.4E+03 and 2.4E+07 for dermal and inhalation, receptively. Both MOEs are below HED's level of concern for oxyfluorfen. The estimates for cancer risk is 4.6E-07. Generally, HED's level of concern for residential exposure is for cancer risk greater than 1 x 10^{-6}. Therefore, the cancer risk for homeowners applying oxyfluorfen is below HED's level of concern.

Residential Post-Application Exposure Assessment

Triox is used in small areas where vegetation is not desired such as sidewalks, patios, gutters, driveways, along buildings or fences. Due to the nature of the applications, minimal potential for post-application exposure is expected. Additionally, any potential exposure is not expected to exceed that the homeowner applying Triox. Since all homeowner handler MOEs are below HED's level of concern, a post-application assessment was not performed for this use.

Additionally, the labels for ROUT and Regal-0-0 prohibits homeowner applications but allows for commercial applications to ornamental landscapes. Both the Rout and the Regal-0-0 products are granular formulations for use as pre-emergent herbicides by commercial landscape personnel only. The labels state that both products are suited for container, field grown, landscape ornamentals, and foliage crops. Therefore, these products are expected to be used mostly in commercial nurseries which grow landscape ornamentals. In the event that these products are used in residential ornamental landscapes, both product labels require that the soil surface be left undisturbed after application and advise immediate irrigation (with approximately ½ inch of

water) to water in the herbicide. For these reasons, minimal potential for dermal contact is expected. A residential post-application assessment was not performed.

AGGREGATE RISK ASSESSMENT

Acute Aggregate Risk (Food + Water)

Using the conservative exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, HED has estimated that the acute exposure to oxyfluorfen from food for females 13-50 years old will utilize **3%** of the aPAD, as shown in Table 2.

Despite the potential for exposure to oxyfluorfen in drinking water, HED does not expect the aggregate exposure to exceed 100% of the aPAD for females 13-50 years old. As seen in Table 5, EFED's maximum EEC of oxyfluorfen in surface and ground water for acute exposure is minimal as compared to the calculated DWLOC. Under current HED guidelines, non-dietary uses of oxyfluorfen do not constitute an acute exposure scenario. HED concludes that there is a reasonable certainty that no harm will result to adults, infants or children from acute aggregate exposure to oxyfluorfen residues.

Chronic (Non-Cancer) Aggregate Risk (Food + Water + Residential)

Using the partially refined exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, HED has estimated that the chronic exposure to oxyfluorfen from food for the most highly exposed population subgroup (all infants, <1 year old) will utilize **1%** of the cPAD, as shown in Table 3. It was determined that an acceptable chronic dietary exposure (food plus water) of 100% or less of the cPAD is needed to protect the safety of all population subgroups.

Despite the potential for exposure to oxyfluorfen in drinking water, HED does not expect the aggregate exposure to exceed 100% of the cPAD. As indicated in Table 6, EFED's maximum EEC of oxyfluorfen in surface and ground water for chronic exposure is minimal as compared to the calculated DWLOC. Under current HED guidelines, the registered non-dietary uses of oxyfluorfen do not constitute a chronic exposure scenario. HED concludes that there is a reasonable certainty that no harm will result to adults, infants and children from chronic aggregate exposure to oxyfluorfen residues.

Short- and Intermediate-Term Aggregate Risk (Residential + Chronic Food + Chronic Water)

HED aggregated the chronic dietary exposure (food only) and residential exposure (dermal from garden uses) for the U.S. Population (48 states) and those population subgroups for which residential exposure is expected. As indicated in Table 11, the total MOE is 5200 (HED acceptable level for oxyfluorfen is ≥300).

Table 11. Short-Term Aggregate Exposure and Risk (Includes residential use of oxyfluorfen)				
Population Subgroup	Chronic Food Exposure (mg/kg bwt/day)	Residential Exposure[1] (mg/kg bwt/day)	Total Exposure[2] (mg/kg bwt/day)	MOE[3]
U.S. Population (48 states)	0.000011	0.0019	0.0019	5200
Females 13-50 yrs. old	0.000008	0.0019	0.0019	5200
Males 13-19 yrs. old	0.000008	0.0019	0.0019	5200
Males 20+ yrs. old	0.000008	0.0019	0.0019	5200
Seniors 55+ yrs. old	0.000010	0.0019	0.0019	5200

[1]Residential Exposure = total of oxyfluorfen exposure from dermal and inhalation exposures during homeowner applications.
[2]Total Exposure = Chronic Food Exposure plus Residential Exposure.
[3]MOE = $\frac{\text{LOAEL (10 mg/kg bwt/day)}}{\text{Total Exposure (mg/kg bwt/day)}}$

As noted in Table 7, potential short-term exposure from drinking water is at a level below HED's level of concern. HED concludes the short-term aggregate risk to the highest exposed population subgroup (U.S. Population (48 states)) as a result of all registered and proposed uses of oxyfluorfen **does not** exceed HED's level of concern. Based on the homeowner application scenarios, intermediate-term exposures are not expected.

Chronic (Cancer) Aggregate Risk (Food + Water + Residential)

Table 12 aggregates the chronic dietary exposure (food only) and residential exposure (dermal from garden uses) for U.S. Population (48 states). As indicated in Table 12, the total cancer risk is 1.3×10^{-6}.

Table 12. Cancer Aggregate Exposure and Risk (Includes residential use of oxyfluorfen)				
Population Subgroup	Chronic Food Exposure (mg/kg bwt/day)	Residential Exposure (LADD)[1] (mg/kg bwt/day)	Total Exposure[2] (mg/kg bwt/day)	Cancer Risk[3]
U.S. Population (48 states)	0.000011	0.0000063	0.000017	1.3×10^{-6}

[1] LADD = ADD x (2 days/365 days a year) x (50 years/70 year lifetime)
[2] Total Exposure = Chronic Food Exposure plus Residential Exposure.
[3] Cancer Risk = Total Exposure x Q_1^*(0.0732 mg/kg/day^{-1}),

A DWLOC for cancer could not be calculated as the sum of chronic dietary food exposure and the dermal exposure from oxyfluorfen home garden uses exceeded the negligible risk (1×10^{-6}).

Further refinement in the chronic food exposure using additional %CT information would result in a lower estimate of chronic dietary exposure, potentially allowing a DWLOC for cancer to be calculated. However, as the EEC for oxyfluorfen in surface waters (2.1 μg/L) exceeds the DWLOC for cancer calculated when assuming 0 mg/kg/day average food + residential exposure. further refinements were not performed.

OCCUPATIONAL EXPOSURE AND RISK ASSESSMENT/CHARACTERIZATION

Goal 2XL is a herbicide for control of annual grasses and broadleaf weeds. This product is formulated as an emulsifiable liquid concentrate and recommended as a postemergent post-direct spray. For this Section 18 petition, Goal 2XL will be applied by commercial applicators via ground equipment to control Wright groundcherry on chile peppers in New Mexico. Applications will be made at a maximum of 0.25 lbs ai/A/season. Table 13 summarizes the use pattern for this Section 18 petition for oxyfluorfen.

Table 13. Use Pattern Summary of Oxyfluorfen (in Goal 2XL) on Chile Peppers

Formulation	emulsifiable liquid concentrate
Crop to be treated	chile peppers
Pests	wright groundcherry
Application methods	groundboom sprayer
Maximum application rate	maximum of 0.25 lb a.i. per acre per season
Typical application rate	0.125 lbs ai/Acre
Maximum number of applications	single or multiple postemergent applications
Total Amount of Pesticide to be Used	2,350 lbs a.i ; 1,175 gallons of product
Use Period	15 May through July 31, 2000
Maximum Acres to be Treated	20,600 in New Mexico
Manufacturer	Rohm and Haas

An MOE of 100 is adequate to ensure protection for handler exposures to oxyfluorfen via the dermal and inhalation routes. Based on the use pattern, long-term exposures are not expected from the proposed use. Since the short- and intermediate-term endpoints are the same, the short-term scenario is expected to adequately represent occupational exposure for both the short- and intermediate-term durations. Based on evidence of carcinogenicity in mice and rats (at doses judged to be adequate to assess carcinogenic potential), oxyfluorfen is classified as a **"likely"** human carcinogen. The CPRC recommended that the Q_1^* approach be used to calculate cancer risk. A Q_1^* of 0.0732 mg/kg/day^{-1} was calculated based on male mouse combined liver tumor rates (adenomas and/or carcinomas) (Memo, L. Brunsman, 9/24/98).

Handler Exposure Assessment

Both short- and intermediate-term exposures are expected for the commercial handlers of oxyfluorfen. This exposure assessment was done using data from the Pesticide Handler Exposure Database (PHED) v1.1 Surrogate Table. Table 14 summarizes the HED estimates for

dermal and inhalation exposures for handlers including mixer/loaders, applicators, and mixer/loader/applicators.

The LADD calculation assumes that the individual would work 35 out of 70 years. LADD calculations were done using an average of 10 days worked per year. This information was supplied by the New Mexico Department of Agriculture (NMDA) specifically for commercial applicator exposures to Goal 2XL (Personal Communication from NMDA to D. Vogel, 6/20/00).

Table 14. Handler Exposure to Goal 2XL (23% Oxyfluorfen)

Job Function	Unit Exposure (mg/lb a.i.)[1]	AR[2]	Acres treated /Day[3]	Average Dermal Daily Dose (ADD)[4] (mg/kg/day)	Average Inhalation Daily Dose (ADD)[4] (mg/kg/day)	Short- and interm- Dermal MOE[5]	Short- and interm- Inhalation MOE[5]	LADD[6]	Cancer Risk[7]
Mixer/loaders	0.023 dermal 0.0012 inhalation	0.25	80	6.1E-04	4.0E-04	1.6E+04	4.3E+05	6.0E-06	4.4E-07
Groundboom-Applicators	0.014 dermal 0.00074 inhalation	0.25	80	3.7E-04	2.5E-04	2.7E+04	6.9E+05	3.6E-06	2.7E-07
Mixer/Loader/ Applicator	0.057 dermal 0.0013 inhalation	0.25	80	1.5E-03	4.3E-04	6.5E+03	3.9E+05	1.2E-05	8.4E-07

1 Source: Pesticide Handlers Exposure Database (PHED) V1.1, Surrogate Exposure Table. Mixer/loader unit exposure from PHED, (In support of Groundboom; open mixing of liquid, single layer with gloves). **HIGH CONFIDENCE DATA.** Applicator unit exposure from PHED: (Groundboom; liquid spray; open cab-single layer with gloves). **MEDIUM & HIGH CONFIDENCE DATA.** Mixer/Loader/Applicator - Liquid open pour, open cab. **MEDIUM & HIGH CONFIDENCE DATA.**

2 Source: Goal 2XL label.

3 Assumptions regarding acreage treated per day: Commercial applicators are expected to be able to treat a maximum of 2 farms per day ((Personal Communication from NMDA to D. Vogel, 6/20/00). Average farm size is approximately 40 acres (Personal Communication from Dr. J. Schraeder, New Mexico State University, to D. Vogel, 6/19/00)

4 ADD = Unit exposure(ug/lb a.i.) x AR x Acres/Day x 1/BW (60 kg) x % Absorption (8%, 100% - dermal and inhalation respectively).

5 MOE = NOAEL/ADD; (where NOAEL = 10 mg/kg/day, for short- and intermediate-term dermal, NOAEL = 170 mg/kg/day for short- and intermediate-term inhalation). *Level of concern is for MOEs below 100*

6 LADD = ADD x (10 days/365 days a year) x (35 years/70 year lifetime)

7 Cancer Risk = LADD x Q1*(0.0732 mg/kg/day-1), using typical AR = 0.125 (Personal Communication from Dr. J. Schraeder, New Mexico State University, to D. Vogel, 6/19/00) and 70 kg BW.

The estimated MOE is **6.5E+03** or greater for all mixer/loader and applicator activities. Therefore, since HED's level of concern for oxyfluorfen is for MOEs less than 100, potential risk to handlers is well below the level of concern. The cancer risk resulting from handler exposures was determined to be **8.4×10^{-7}** for the high-end scenario. Generally, HED's level of concern for occupational exposure is for cancer risk greater than 1×10^{-4}. Therefore, the cancer risk for workers handling oxyfluorfen does not exceed HED's level of concern

Worker Post-application Exposure Assessment

The majority of cultivation activities associated with chile peppers are related to plant thinning, irrigation, and hand-harvest (USDA Crop Profiles website, Chile peppers in New Mexico).

Irrigation Activities

According to the New Mexico Department of Agriculture (NMDA), irrigation tasks are not done in the treated crop area. Irrigation is set up in the area surrounding the treated field. Therefore, no exposure is expected for workers performing post-application tasks for irrigation of chile peppers.

Hand-thinning of chile pepper plants

Chile peppers plants are thinned by hand when they are 2-6 inches tall (USDA Crop profiles website for chile peppers in New Mexico). Since Goal 2XL will be applied, according to the label (when chile plants are a minimum of 8 inches tall) no post-application exposure is expected for workers performing hand thinning.

Hand-harvest of chile peppers

Most chile peppers grown in New Mexico are hand-harvested (Crop profiles website for chile peppers in New Mexico). Field trials were performed in New Mexico, South Carolina, and Puerto Rico to collect data on the residues of oxyfluorfen on non-bell peppers. Samples were collected on day 30 after treatment and no quantifiable residues of oxyfluorfen were found in the samples (Volume 2: Oxyfluorfen: Magnitude of the residue on peppers (non- bell)). Since the PHI is 31 days for this chemical, minimal dermal exposure is expected from the proposed use on chile peppers. Moreover, according to the Section 18 label, Goal 2XL is a post-direct shielded spray that is directed toward the soil. The use of spray shields is needed to avoid contact with the chile pepper plants. As stated on the label, "Spray should be directed toward the base of the chile pepper plant. Foliage receiving accidental spray or drift may be injured." For these reasons, it is expected that there will be minimal exposure to oxyfluorfen for workers performing hand-harvest activities of chile peppers.

Therefore, an occupational post-application assessment was not performed.

Re-entry Interval (REI)

The interim Worker Protection Standard (WPS) REI of 24 hours is adequate to protect workers performing re-entry activities for the proposed use of oxyfluorfen.

Incident Reports

Information on incidence data for oxyfluorfen is supplied in Attachment #3, (Electronic communication from J. Blondell to D. Vogel, 6/19/00)

ENDOCRINE DISRUPTER EFFECTS

The Food Quality Protection Act (FQPA; 1996) requires that EPA develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...." EPA has been working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists to develop a screening and testing program as well as a priority setting scheme to implement this program. The Agency's proposed Endocrine Disrupter Screening Program was published in the Federal Register of December 28, 1998 (63 FR71541). The Program uses a tiered approach and anticipates issuing a Priority List of chemicals and mixtures for Tier 1 screening in the year 2000. As the Agency proceeds with implementation of this program, further testing of oxyfluorfen and its end-use products for endocrine effects may be required.

CUMULATIVE EXPOSURE TO SUBSTANCES WITH A COMMON MECHANISM OF TOXICITY

Oxyfluorfen a member of the nitrophenyl ether class of herbicides. Other members include acifluorfen, aclonifen, bifenox, chlomethoxyfen, chlornitrofen, fluorodifen , fluoroglycofen, fluoronitrofen, fomesafen, furyloxyfen, halosafen, lactofen, nitrofen, and nitrofluorfen (Per Internet search, G. Kramer, 5/19/00, at http://www.hclrss.demon.co.uk/class_herbicides.html).

EPA does not have, at this time, available data to determine whether oxyfluorfen has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that oxyfluorfen has a common mechanism of toxicity with other substances.

CONCLUSIONS

Based on the above discussion, HED concludes that occupational exposure and aggregate acute, short-term and chronic (non-cancer) risk estimates do not exceed HED's level of concern. However, the aggregate (food + residential) cancer risk is 1.3×10^{-6}, which exceeds the negligible risk (1×10^{-6}). If this Section 18 use is approved, then a time-limited tolerance for residues of oxyfluorfen in/on non-bell peppers should be established at **0.01 ppm**.

Attachments : IRLS Sheet
Information on incidence data for oxyfluorfen
Acute and Chronic DEEM Analysis (6/26/00, J Rowell, D266651)

cc (without attachments): Kramer, Rowell, Nixon, Vogel
RDI: G.Herndon (7/19/00), RAB1 Chemists (7/15/00), RAB1 Team 1 (7/15/00), RAB1 (7/19/00)
G.F. Kramer:806T:CM#2:(703)305-5079:7509C:RAB1

Dana Vogel
07/13/2000 01:01 PM

To: George Kramer/DC/USEPA/US@EPA
cc:
Subject: Re: incident data on section18

Attachment for section 18 on incidents reports
---------- Forwarded by Dana Vogel/DC/USEPA/US on 07/13/2000 01:00 PM ----------

Jerry Blondell
06/16/2000 10:19 AM

To: Dana Vogel/DC/USEPA/US@EPA
cc: Karen Whitby/DC/USEPA/US@EPA, Elizabeth Doyle/DC/USEPA/US@EPA
Subject: Re: incident data on section18

Hi Dana,

Sorry it has taken me time to get back to you. If there is still time (2-3 weeks) I could do a more detailed analysis of the incident data. Otherwise I recommend you rely on the summary provided below. My colleague and I will be at a poisoning surveillance meeting nearly all of next week. Here is a brief overview of what we have:

1. The Incident Data System currently has 88 cases reported for this active ingredient. However, over 90% of these reports come from Solaris and are not described in any detail that would permit much in the way of conclusions.

2. California reports 12 cases from 1982 through 1996 and 5 of these affected the eyes and 4 the skin, suggesting the need for eye protection and skin protection. This is a relatively small number, especially given 430,000 applications reported in California in 1996, the ratio of poisoning per 1000 applications appears to be less than one-tenth the median for 28 insecticides (alternatives to parathion) and that's if even the dermal and eye effects were treated as serious systemic effects. It would be desirable to get a full report from California to see just how serious these cases were and what activities (application, mixing/loading, field reentry, drift) were associated with these cases. The remaining 3 cases were systemic, but 2 of these were classified as "possible" and only 1 as probable/definite.

3. Poison Control Center data for 1993-1996 reported 23 cases of exposure (again a relatively small number out of the 400,000+ for all pesticides). None of these cases experienced life-threatening effects and only 3 had moderate effects. Most (10) had unrelated or no effects and 9 cases had minor or no more than minor effects were expected. Of the 13 cases with symptoms potentially related to their exposures, most (5) were dermal with no other symptoms category showing more than 2 cases. The number of cases is too small for any kind of detailed analysis of hazard but my overall impression is that the incident data, even with more detailed analysis would not raise any red flags, other than the concern for protecting the eyes and skin mentioned above.
Jerry Blondell
Elizabeth Doyle

Elizabeth Doyle
06/12/2000 09:04 AM

To: Jerry Blondell

INTERNATIONAL RESIDUE LIMIT STATUS

Chemical Name:	Common Name:	☒ Proposed tolerance ☐ Reevaluated tolerance ☐ Other	Date:
2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene	oxyfluorfen		5/19/00

Codex Status (Maximum Residue Limits)	U. S. Tolerances
X No Codex proposal step 6 or above ☐ No Codex proposal step 6 or above for the crops requested	Petition Number: 00NM0004 DP Barcode: D265920 Other Identifier:
Residue definition:N/A	Reviewer/Branch: G.F. Kramer
	Residue definition: parent only

Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		NON-BELL PEPPERS	0.01

Limits for Canada	Limits for Mexico
X No Limits ☐ No Limits for the crops requested	☐ No Limits X No Limits for the crops requested
Residue definition:	Residue definition: oxyfluorfen

Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)

Notes/Special Instructions:.
S. Funk, 05/23/00