

US EPA ARCHIVE DOCUMENT

**Reregistration Eligibility Decision
for
Sodium Acifluorfen**

Case No. 2605

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
AGDCI	Agricultural Data Call-In
AR	Anticipated Residue
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CNS	Central Nervous System
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
GENEEC	Tier I Surface Water Computer Model
GLC	Gas Liquid Chromatography
GLN	Guideline Number
HDT	Highest Dose Tested
IR	Index Reservoir
LC ₅₀	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD ₅₀	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration

MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
OPP	EPA Office of Pesticide Programs
OPPT/SEPA	Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
PRZM/	
EXAMS	Tier II Runoff/Surface Water Computer Models
Q ₁ *	Unit Risk of Carcinogenic Potential of a Compound, Quantified by the EPA's Linear Low Dose Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Groundwater Computer Model
SF	Safety Factor
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)

TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	Unit of measure for atmospheric pressure
TRR	Total Radioactive Residue
UF	Uncertainty Factor
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Environmental Protection Agency (EPA or the Agency) has completed its review of public comments on the revised human health and environmental risk assessments for sodium acifluorfen and is issuing its risk management decision. The decisions outlined in this document include the final tolerance reassessment decision for sodium acifluorfen and the reregistration eligibility decision. Fifteen meat, milk, poultry and egg tolerances were proposed for revocation on July 16, 2003¹. Three of the remaining tolerances are unchanged and one tolerance will be increased based on residue data submitted to the Agency. The tolerance for strawberries will be reassessed once use directions have been submitted to the Agency.

Sodium acifluorfen is a member of the diphenyl ether group of herbicides, which includes lactofen, oxyfluorfen, nitrofen, and fomesafen. The Agency has evidence that compounds in the diphenyl ether group induce similar toxic effects but has not yet determined whether these compounds exhibit a common mechanism of toxicity. For the purposes of tolerance reassessment and a reregistration eligibility decision for sodium acifluorfen, EPA is assuming that sodium acifluorfen does not share a common mechanism of toxicity with other compounds. However, because lactofen will degrade to acifluorfen in the environment, the reregistration eligibility decision (RED) for sodium acifluorfen and the tolerance reassessment decision (TRED) for lactofen include assessments aggregating the potential exposure to acifluorfen from both pesticides.

Sodium acifluorfen was first registered in the United States in 1980 for post-emergent weed control on agricultural crops and was subsequently registered for residential spot treatment. The Agency did not issue a Registration Standard for sodium acifluorfen, but did issue three Data Call-Ins (DCIs) in June 1991, March 1995, and October 1995. Approximately 1.5 million pounds active ingredient (a.i.) of sodium acifluorfen are used annually in the United States, according to Agency and registrant estimates. The largest market for sodium acifluorfen, in terms of total pounds of a.i., is allocated to soybeans (94% of a.i. produced). Use of sodium acifluorfen has been declining in recent years with the availability of Roundup Ready[®] soybeans. Although sodium acifluorfen is registered for residential use, this use is very minor compared to the agricultural uses. Only one product, which is packaged as a spot treatment in a ready-to-use trigger sprayer, is registered for residential use. Broadcast use on lawns is not expected because the product packaging is not designed for broadcast application and sodium acifluorfen is a non-selective herbicide that will kill both weeds and grass.

EPA has conducted an aggregate drinking water assessment for lactofen and sodium acifluorfen because they share an environmental degradate, acifluorfen. Because lactofen was first registered after 1984, it is not subject to reregistration under FIFRA; however, the lactofen tolerances must be reassessed under The Federal Food, Drug and Cosmetic Act (FFDCA), as

¹ *Federal Register*, Vol. 68, No. 136

amended by the Food Quality Protection Act (FQPA). Therefore, this RED and the tolerance reassessment for sodium acifluorfen considers the aggregate exposures from both pesticides.

Overall Risk Summary

The Agency's human health risk assessment for sodium acifluorfen indicates minimal risks. Both acute and chronic risks from food are well below the Agency's level of concern. Dietary exposure from ground water or surface water sources of drinking water are also low and not of concern. There are no concerns about the risk to homeowners or occupational workers who handle sodium acifluorfen or are exposed to residues after sodium acifluorfen is applied to agricultural crops.

The screening-level ecological risk assessment for sodium acifluorfen shows risk quotients (RQs) ranging from less than 0.01 to 6.0 for terrestrial organisms. For aquatic organisms, all RQs are less than 0.01 and not of concern.

Dietary Risk

Acute and chronic dietary (food) risks are substantially less than 100% of the acute and chronic Population Adjusted Dose (aPAD and cPAD, respectively) for the general U.S. population and all population subgroups. Because the chronic dietary risk assessment for non-cancer effects is also protective of cancer effects, the chronic dietary risk assessment from cancer is not of concern. Because risk from dietary sources does not exceed the Agency's level of concern, no mitigation measures are necessary to reduce dietary risks from food.

For sodium acifluorfen, acute dietary exposure comprises less than 1% of the acute PAD for females age 13-50 years, the only population at potential risk from acute effects. The acute PAD for this population group includes a 10X FQPA safety factor. Acute dietary risk for the general population is not of concern because no endpoint has been established.

The chronic dietary risk from food alone is also well below the Agency's level of concern. Chronic dietary exposure comprises less than 1% of the chronic PAD for the U.S. population and all subpopulations.

The Agency determined that an MOE approach was appropriate for assessing the chronic dietary cancer risk from the use of sodium acifluorfen. Because this assessment would have used the same dose and uncertainty factors that were used to calculate the chronic risk, EPA believes that the chronic non-cancer dietary risk assessment is adequately protective of cancer effects.

Drinking Water Risk

Both sodium acifluorfen and a related pesticide, lactofen, will degrade to the degradate acifluorfen in the environment. Therefore, EPA has conducted an aggregate drinking water assessment that includes the degradate acifluorfen from both lactofen and sodium acifluorfen sources.

Estimated Drinking Water Concentrations (EDWCs) of total acifluorfen in surface water were modeled using PRZM-EXAMS with the Index Reservoir and Crop Area Factors. Based on currently registered uses, the maximum surface water EDWCs for total acifluorfen residues were 10.12 ppb for acute exposure, 2.43 ppb for chronic exposure, and 1.34 ppb for cancer exposure.

Monitoring studies show that acifluorfen may leach to groundwater under certain conditions. The prospective groundwater study for sodium acifluorfen showed leaching of the acifluorfen degradate in the central sands of Wisconsin, an extremely vulnerable soil. Therefore, the current groundwater label advisory is still necessary.

Ground water EECs for acifluorfen were derived from a Tier I screening-level model (SCI-GROW), which estimates the maximum ground water concentrations from the application of a pesticide to crops. The groundwater EEC for acifluorfen derived from lactofen was derived from a prospective groundwater monitoring study for lactofen, which monitored for both compounds. The maximum estimated ground water EDWC for total acifluorfen derived from both sodium acifluorfen and lactofen is 3.71 ppb.

Residential Risk

Homeowners or residential handlers can be exposed to sodium acifluorfen by applying it as a spot treatment, or by entering or performing other activities in treated areas. Residential handlers include homeowner applicators performing spot treatment of weeds along driveways, sidewalks, patios, and trees.

For the homeowner use of sodium acifluorfen, EPA is concerned about any MOE less than 1000, which incorporates the FQPA safety factor and is intended to be protective of females age 13-50 years. For the only potential exposure scenario, spot treatment with a ready-to-use trigger sprayer, EPA estimated an MOE of 18000, which is not of concern to the Agency. Furthermore, EPA has no concerns for post-application residential exposure because residential uses are limited to spot treatments, which do not include broadcast application to lawns, therefore, post-application exposure is expected to be negligible.

Aggregate Risk

An aggregate assessment was conducted for exposures through food, residential uses, and drinking water. Based on the results of this aggregate assessment, the Agency made a determination that the human health risks from these combined exposures to sodium acifluorfen, or the acifluorfen degradate, are not of concern.

The acute aggregate risk from food and drinking water are not of concern. The acute Drinking Water Level of Comparison (DWLOC) is for females 13 - 50 years old, the only population at potential risk from acute effects. The modeled acute surface water EDWC for the acifluorfen degradate is 10.12 ppb and the modeled acute groundwater EDWC is 3.71 ppb.

Short-term aggregate risk from food, drinking water, and residential exposure, are not of concern. The short-term DWLOC is 462 ppb for females 13 - 50 years old, the only population at potential risk from acute effects. The DWLOC is greater than the highest modeled EDWCs for total acifluorfen exposure of 2.43 ppb for surface water and 3.71 ppb for ground water.

The chronic aggregate risks from food and drinking water are also not of concern. The chronic drinking water EDWCs (for both surface and ground water sources) are less than the chronic DWLOCs, regardless of the source of drinking water. The chronic DWLOC for the general population is 120 ppb. The highest modeled chronic (average) drinking water EDWC is 2.43 ppb for surface water and 3.71 ppb for ground water. The cancer aggregate risk is also not of concern. The chronic drinking water EDWCs (for both surface and ground water sources) are less than the cancer DWLOCs.

Occupational Risk

EPA assessed occupational exposure to sodium acifluorfen using data from the Pesticide Handler Exposure Database (PHED) and proprietary data, including chemical-specific data submitted by the technical registrant for sodium acifluorfen. Occupational exposure to sodium acifluorfen is not of concern to the Agency for handlers using the PPE specified on the current labels or in this RED document.

Anticipated use patterns and current labeling for sodium acifluorfen indicate six major occupational exposure scenarios which can result in handlers receiving dermal and inhalation exposures to sodium acifluorfen. These exposure scenarios are based on the chemical formulations, equipment and techniques that handlers use to make sodium acifluorfen applications. At baseline PPE, handler risks for three of the six scenarios are not of concern. For the remaining three scenarios, the use of chemical-resistant gloves is sufficient to mitigate the risk.

The post-application occupational risk assessment considers exposures to agricultural workers re-entering treated areas for activities such as scouting, hand weeding, and irrigating.

All post-application exposure is considered to be short- or intermediate-term based on the frequency and duration of activities and the dissipation of acifluorfen.

The post-application worker risk calculations indicated that the MOEs were greater than 100 on Day 0, and therefore not of concern. Because sodium acifluorfen is in acute Toxicity Category I for eye irritation and Category II for skin irritation, the current restricted entry intervals of 48 hours are appropriate and will remain unchanged.

Ecological Risk

The Agency conducted a screening level ecological risk assessment to determine the potential impact of sodium acifluorfen use on non-target terrestrial and aquatic organisms. The Agency used modeling to evaluate ecological risks for sodium acifluorfen.

The Agency has minor concerns for chronic risk to birds that feed on short grasses with RQs slightly exceeding the Agency's level of concern. In a refined assessment, which uses mean residues, the only scenario that showed a potential risk concern was for birds that eat short grasses with RQs ranging from 0.15 to 1.6, which slightly exceed the level of concern of 1.0.

The Agency has no concerns for the impacts of sodium acifluorfen on mammalian species. In a worst case acute scenario, the acute RQ is less than 0.01 and not of concern. Chronic RQs for mammals range from less than 0.05 to less than 0.01. No chronic mammalian RQs exceed the Agency's level of concern for any registered use.

The Agency has no concerns for the impacts of sodium acifluorfen on aquatic organisms. The risk assessment shows that the RQs for all aquatic species are less than 0.1, which is well below any of EPA's levels of concern.

The Agency's review of sodium acifluorfen resulted in a determination that sodium acifluorfen will have "no effect" on threatened and endangered aquatic organisms, mammals, and birds. Although chronic RQs for birds which eat short grass exceed the level of concern, the only listed endangered species that consumes short grass is the Hawaiian goose, which resides on golf courses in Hawaii. Because sodium acifluorfen is not used in or around this bird's habitat, the Agency concludes that there is "no effect" to endangered birds.

Limited information is available about the toxicity of sodium acifluorfen to non-target plants. Because of the limited data, EPA is unable to conduct a risk assessment for non-target plants at this time. Because sodium acifluorfen is an herbicide, there may be some risk to non-target plants exposed via drift. Therefore, the Agency is requiring several label amendments to limit the potential for drift. In addition, the Agency is requiring confirmatory plant toxicity data.

Sodium acifluorfen belongs to a class of compounds known to have a phototropic mode of action in plants and animals. Since there is evidence that such chemicals have increased toxicity in the presence of light, a confirmatory phototoxicity study is required.

Regulatory Decision

The Agency has determined that sodium acifluorfen is eligible for reregistration provided that: (1) current data gaps and additional data needs are addressed and (2) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures. The Agency is issuing this RED document for sodium acifluorfen, as announced in a Notice of Availability published in the *Federal Register*. This RED includes guidance and requested time frames for making any necessary label changes for products containing sodium acifluorfen. The Agency is providing a final 30-day opportunity for stakeholders to respond to the sodium acifluorfen risk management decision. If substantive information is received during the comment period, which indicates that any of the Agency's assumptions need to be refined and that additional risk mitigation is warranted, appropriate modifications will be made at that time.

Summary of Mitigation Measures

EPA believes that sodium acifluorfen is eligible for reregistration provided the following actions are implemented, combined with the general mitigation measures previously described:

Dietary Risk

- An approved labeled use for strawberries and use directions are required to maintain the tolerance on strawberries (OPPTS 860.1200).
- A 100-day plant-back interval is necessary for all rotated crops except small grains, which require a 40-day plant-back interval.
- Groundwater label advisory must be maintained on all labels.
- Confirmatory data are required, including a developmental neurotoxicity study and determination of a lower LOQ for the analytical method.

Residential Risk

- No label changes are necessary.

Occupational Risk

- No label changes are needed.
- PPE can be reduced to baseline with chemical-resistant gloves for technical sodium acifluorfen. Additional PPE may be required on a product-specific basis.

Ecological Risk

- Label amendments to minimize the potential for spray drift.
- Confirmatory data are required, including Aquatic Phototoxicity (modified fish early life stage), Honey Bee Acute Contact, Vegetative Vigor, and Seedling Emergence studies.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency, henceforth referred to as EPA or "the Agency." Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require reassessment of all existing tolerances for pesticides in food and also requires that EPA review all tolerances in effect on August 3, 2006, the day before the enactment of the FQPA, by August 3, 2006. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. FQPA also 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." Sodium acifluorfen is a member of the diphenyl ether group of herbicides, which includes lactofen, oxyfluorfen, nitrofen, and fomesafen. The Agency has evidence that these compounds induce similar toxic effects but has not yet determined whether these compounds exhibit a common mechanism of toxicity. For the purposes of tolerance reassessment, and a determination of the reregistration eligibility for sodium acifluorfen, EPA is assuming that sodium acifluorfen does not share a common mechanism of toxicity with other compounds. However, sodium acifluorfen's primary degradate is the acifluorfen anion, which is also a degradate of another herbicide, lactofen. Because lactofen will degrade to acifluorfen in the environment, the reregistration eligibility decision (RED) for sodium acifluorfen and the tolerance reassessment decision (TRED) for lactofen include assessments aggregating the potential exposure to acifluorfen from the use of both pesticides.

The implementation of FQPA has required the Agency to revisit some of its existing policies relating to the determination and regulation of dietary risk, and has also raised a number of new issues for which policies need to be created. These issues were refined and developed through collaboration between the Agency and the Tolerance Reassessment Advisory Committee (TRAC), which was later superseded by the Committee to Assist with Reassessment and Transition (CARAT). Both federal advisory committees were composed of representatives from industry, environmental groups, and other interested parties. Although FQPA significantly affects the Agency's reregistration process, it does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

On September 29, 2000, the Agency issued a Pesticide Registration Notice (PR 2000-9) that presents EPA's approach for managing risks from organophosphate pesticides to occupational users. This Worker PR Notice describes the Agency's baseline approach to managing risks to handlers and workers who may be exposed to organophosphate pesticides. The Agency expects that other types of chemicals, such as sodium acifluorfen, will be handled similarly. Generally, basic protective measures such as closed mixing and loading systems, enclosed cab equipment, or protective clothing, as well as increased restricted entry intervals will be necessary for most uses where current risk assessments indicate a risk and such protective measures are feasible. The policy also states that the Agency will assess each pesticide individually, and based upon the risk assessment, determine the need for specific measures tailored to the potential risks of the chemical. The measures included in this RED are consistent with the Worker PR Notice.

This document presents the Agency's revised human health and ecological risk assessments; its progress toward tolerance reassessment; and the reregistration eligibility decision for sodium acifluorfen. This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's decision on reregistration eligibility and risk management for sodium acifluorfen. Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list references and contain other information, such as the Data Call-Ins (DCIs) to be issued with this RED. The preliminary and revised risk assessments for sodium acifluorfen dated through April 30, 2002 are available in the Public Docket, under docket numbers OPP-3424A and B, and on the Agency's web page, www.epa.gov/pesticides/reregistration/status.htm. Because the Agency implemented a new docketing system in July 2002, documents dated from May 1, 2002 to the present are in the docket OPP-2003-0293 and on the internet at a different site, <http://www.epa.gov/edockets>.

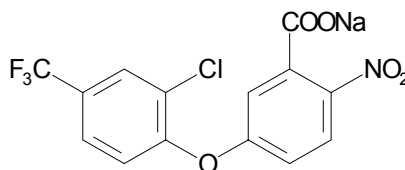
II. Chemical Overview

A. Regulatory History

Sodium acifluorfen was first registered in the United States in 1980 by the Rohm and Haas Company as the herbicide Blazer® for post-emergent weed control on agricultural crops. Sodium acifluorfen is also registered for residential spot treatment. There is no Registration Standard for sodium acifluorfen, but EPA issued three Data Call-Ins (DCIs) in June 1991, March 1995, and October 1995. BASF Corporation purchased the registration and supporting data in 1987. In 1984, another company, Rhone-Poulenc also registered a sodium acifluorfen product, Tackle®, but this product was sold to BASF, with supporting data, in 1992. BASF is currently the only technical registrant.

B. Chemical Identification

Sodium Acifluorfen:



Common Name:	Sodium salt of acifluorfen
Chemical Name:	Sodium 5[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate
Chemical family:	Diphenyl Ether
Case number:	2605
CAS registry numbers:	62476-59-9 (sodium acifluorfen) 50594-66-6 (acifluorfen)
OPP chemical code:	114402
Empirical formula:	C ₁₄ H ₇ ClF ₃ NO ₅
Molecular weight:	361.66
Trade and other names:	Blazer®, Status®
Basic manufacturer:	BASF Corporation

Technical grade sodium acifluorfen (78% pure) is a light yellow powder with a melting point of 274-279° C (with decomposition), octanol/water partition coefficient of 1.55 at pH 7, and vapor pressure of less than 1.33×10^{-5} Pascal at 25° C. Sodium acifluorfen is soluble in water (62.07 g/100 mL), and most organic solvents (64.15 g/100 mL in methanol, 5.37 g/100 mL in octanol), and is practically insoluble (less than 5.0×10^{-5} g/100 mL) in hexane at 25° C.

C. Use Profile

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

Type of Pesticide: Herbicide

Mode of Herbicidal Action: Primary target site appears to be protoporphyrinogen oxidase (protox), an enzyme involved with the biosynthesis of chlorophyll that is necessary for plants to carry out photosynthesis.

Summary of Use Sites:

Terrestrial or aquatic food and/or feed crop

- Soybeans
- Rice
- Peanuts

Terrestrial non-food and outdoor residential

- Mulch
- Ornamental and/or shade trees
- Ornamental herbaceous plants
- Ornamental lawns and turf
- Ornamental woody shrubs and vines
- Paths/patios
- Paved areas (private roads/sidewalks)

Public Health Uses: None

Target Pests: amaranth (Palmer and spiny); balloon vine; beggarweed (Florida); bindweed (field and hedge); buckwheat (wild); buffalo bur; bur gherkin; Canada thistle; carpetweed; cocklebur (common and heartleaf); copperleaf (hophornbeam and Virginia); crabgrass (large and smooth); crotalaria (showy); croton (tropic and woolly); cucumber (wild spring); Devil's claw; Eclipta; foxtail (giant, green, and yellow); galinsoga (hairy and small flower); gourd (Texas); ground cherry (cutleaf and lance leaf); jimsonweed; Johnson grass; indigo (hairy); lady's thumb; lambs quarters (common); mallow (Venice); melon (citron and smell); milkweed (climbing and common); morning glory (common, pitted, cypress vine, entire leaf, ivy leaf, palm leaf, purple moonflower, scarlet, small white, small flower, tall, and willow leaf); mustard (black and wild); nightshade (black); Panicum (fall); pigweed (prostrate, redroot, smooth, and spiny); poinsettia (wild); poorjoe; purslane (common), pusley (Florida); ragweed (common and giant); redvine; sandbur (field); senna (coffee); hemp sesbania; shatter cane; smartweed (Pennsylvania); spurge (prostrate, spotted); starbur (bristley); trumpet creeper, Velvetleaf; waterhemp (tall).

Formulation Types Registered: Liquid, ready-to-use (RTU) and soluble concentrate

Method and Rates of Application:

Equipment - Aircraft; Boom sprayer; Ground equipment; Hand held sprayer; Trigger spray bottle

Method - Band treatment; Broadcast; Low volume spray (concentrate); Spot treatment; Spray

Timing - At cracking; Early boot; Late tillering; Post-emergent; Post-plant; Pre-emergent; Tiller through boot

Use Classification: General use

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for many of the pesticide uses of sodium acifluorfen, based on available pesticide usage information for the years 1987 to 1997. This information was used in risk assessment for sodium acifluorfen. Additional details are available in the "Quantitative Use Assessment" document, which is available in the public docket and on the Internet. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Approximately 1.5 million pounds active ingredient (a.i.) of sodium acifluorfen are used annually, according to Agency and registrant estimates. The largest markets for sodium acifluorfen, in terms of total pounds of active ingredient, is allocated to soybeans (94% of a.i. produced). However, use of sodium acifluorfen has been declining in recent years with the availability of Roundup Ready® soybeans. The USDA's National Agricultural Statistics Service (NASS) reports that a total of only 325,000 lbs of sodium acifluorfen was applied to soybeans in 2002.

Although sodium acifluorfen is registered for residential use, this is very minor compared to the agricultural uses. Only one product is registered for residential use, however, the use of this product is limited to a spot treatment with a ready-to-use formulation packaged in a bottle with a trigger sprayer. Broadcast use on lawns is not expected because the product packaging is not designed for broadcast application, and sodium acifluorfen is a non-selective herbicide that will kill both weeds and grass.

Table 1. Sodium Acifluorfen Estimated Usage

Crop	Pounds Active Ingredient Applied		Percent Crop Treated	
	Weighted Average ¹	Estimated Maximum	Weighted Average	Likely Maximum
Peanuts	56,000	113,000	11	19
Rice	28,000	48,000	4	6

Soybeans	1,360,000	1,710,000	9	12
Total	1,444,000	1,871,000	N/A	N/A

¹ Weighted Average is based on data for 1987-1997; the most recent years and more reliable data are weighted more heavily.

N/A , Not applicable.

III. Summary of Sodium Acifluorfen Risk Assessment

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The following list of human health and ecological risk assessment documents and supporting information were used to formulate the safety finding and regulatory decision for the herbicide sodium acifluorfen. These documents may be found on the Agency's web page at www.epa.gov/pesticides/reregistration/status.htm (documents through April 2002) or at www.epa.gov.edockets under docket OPP-2003-0293 (documents from May 2002 to the present). Hard copies of these documents may be found in the OPP public docket numbers OPP-34241A and B, for documents dated through April 2002, and number OPP-2003-0293, for documents dated from May 2002 to the present. The OPP public docket is located in Room 119, Crystal Mall II, 1921 Jefferson Davis Highway, Arlington, VA. The public docket is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The term "sodium acifluorfen" refers to the technical active ingredient. Sodium acifluorfen is a salt which dissociates to sodium (Na⁺) and acifluorfen (acifluorfen-) ions in the environment. Therefore, the term "acifluorfen ion" or "acifluorfen degradate" is used to describe the chemical species that is seen in the environment under most conditions.

Lactofen, a pesticide related to sodium acifluorfen, can also degrade to the acifluorfen ion/degradate in the environment. Lactofen is an herbicide used on soybeans, snap beans, and cotton and in forestry. Plant and animal metabolism studies show that acifluorfen is not found in treated food, making drinking water the only potential source of exposure to the acifluorfen degradate derived from lactofen. Because approximately 58% of applied lactofen can degrade to acifluorfen in the environment, EPA estimated total acifluorfen residues from use of both sodium acifluorfen and lactofen to estimate the risk of exposure to the acifluorfen ion/degradate from drinking water.

A. Human Health Risk Assessment

EPA released its preliminary risk assessments for sodium acifluorfen for public comment on July 26, 2001 (Phase 3 of the public participation process). In response to comments received and new studies submitted during Phase 3, the risk assessments were updated and refined. EPA issued the revised risk assessments for sodium acifluorfen for a second public comment period on April 12, 2002 (Phase 5). The risk assessment was revised again on July 14, 2003 to incorporate comments and additional studies submitted by the registrant during and after Phase 5. Major revisions to the human health risk assessment include the following:

- Revising the cancer classification of sodium acifluorfen to include the mode of action of tumor formation from new studies and the Agency's revised cancer risk assessment guidelines;
- Using a margin of exposure (MOE) approach to evaluate cancer risks;
- Revising the drinking water assessment to include results from a new prospective groundwater monitoring study for lactofen;
- Considering personal protective equipment on current acifluorfen labels in the occupational exposure assessment; and
- Incorporating chemical-specific foliar dislodgeable residue data into the occupational exposure assessment.

1. Dietary Risk from Food

a. Toxicity

EPA has reviewed all toxicity studies submitted to the Agency and has determined that the toxicity database is substantially complete for all currently registered uses. Further details on the toxicity of sodium acifluorfen can be found in the technical support documents cited in Appendix C. The toxicology studies used for the dietary risk assessment are outlined in Table 2 in this document. For the purposes of this RED, sodium acifluorfen and the acifluorfen ion/degradate are assumed to be of equal toxicity.

b. FQPA Safety Factor

For acute dietary exposure, the 10X FQPA safety factor was retained based on (1) qualitative evidence of increased susceptibility to offspring following *in utero* exposure to sodium acifluorfen in a rat developmental toxicity study and (2) the lack of a developmental neurotoxicity study (OPPTS 870.6300) to further define neurotoxic potential. The rat developmental toxicity study showed treatment related anomalies in the development of the fetal nervous system in the presence of minimal maternal toxicity at the same dose. The developmental neurotoxicity study is designed to evaluate neurotoxic effects on the mother and fetus from fertilization of the egg through birth. This study is expected to provide additional information which could be used to further characterize the effects of sodium acifluorfen on the developing fetus, and will be included in the DCI for this RED as confirmatory data. The acute FQPA safety factor of 10X applies only to women of childbearing age (females age 13-50 years). Because the existing toxicology database for sodium acifluorfen shows no other acute effects relevant to the general population, the FQPA safety factor is not relevant to any other population subgroup. For the same reasons the 10X FQPA safety factor is applied to acute dietary exposure, a 10X FQPA safety factor is also applied to short-term residential exposure (to be discussed later in this document).

For chronic dietary exposure, the FQPA safety factor was reduced to 3X for women of childbearing age, infants, and children based on the data gap for the developmental neurotoxicity study. As previously mentioned, this study provides important information about the

susceptibility of infants, children, and women of childbearing age to potential neurotoxic effects following single or repeated exposure to a chemical *in utero*. For sodium acifluorfen, EPA has determined that the increased susceptibility seen in the rat developmental toxicity study, which supported use of a 10X FQPA safety factor for acute exposure, has no bearing on chronic exposure scenarios because the developmental effects could occur after a single dose.

c. Population Adjusted Dose (PAD)

The Population Adjusted Dose (PAD) is the dose at which an individual could be exposed where no adverse health effects would be expected. The PAD is derived from the acute or chronic Reference Dose (RfD), adjusted to account for the FQPA safety factor (i.e., the PAD is the acute or chronic RfD divided by the FQPA safety factor). In the case of sodium acifluorfen, the Agency has determined that different FQPA safety factors should be used to assess acute and chronic exposure. Specifically, the Agency has determined that a 10X FQPA safety factor should be used to assess risk from acute exposure and a 3X FQPA safety factor should be used to assess risk from chronic exposure. The acute PAD for females 13-50 years old is 0.02 mg/kg/day. No acute PAD has been established for the general population because the toxicity database did not indicate any potential acute effects other than developmental toxicity, which is relevant only to females of childbearing age. The chronic PAD for infants, children, and females 13-50 years old is 0.004 mg/kg/day and 0.013 mg/kg/day for all other population subgroups. Table 2 summarizes the data and the uncertainty factors used to derive each PAD used in the dietary risk assessment.

d. Carcinogenicity

Sodium acifluorfen was previously classified as a B2 chemical carcinogen (probable human carcinogen). Cancer risk from sodium acifluorfen was quantified using the Agency's default approach described in the Agency's 1986 Cancer Risk Assessment Guidelines. When much uncertainty exists regarding the mode of carcinogenic action, EPA assumes the tumor dose response from a cancer study is linear. In the absence of adequate information to the contrary, the linearized multistage procedure is applied to the tumor response data to calculate the cancer unit risk (Q_1^*), which is the upper confidence limit (95th percentile) of the dose response curve. This linear low dose approach used to estimate cancer risk is believed to be conservative.

In accordance with the Agency's draft 1999 Cancer Risk Assessment Guidelines, a Margin of Exposure (MOE) approach may be used for non-mutagenic carcinogens when a mode of action has been clearly demonstrated and the tumor dose-response data are not linear. This approach assumes that tumors occur only at doses above a certain threshold (at which effects are seen in rodent studies). Cancer risk is calculated as an MOE by dividing a NOAEL for cancer (or a precursor effect) by the exposure value. The uncertainty factor(s) that determine whether a cancer MOE is of concern will vary according to the specific chemical and the nature of the tumor and its precursor effects.

In February 2001, the registrant petitioned the Agency to reevaluate the cancer risk assessment for sodium acifluorfen using an MOE approach rather than the traditional linear low dose (Q_1^*) approach. As part of the petition to reevaluate the cancer risk assessment, the registrant developed additional data on a possible cancer mode of action involving peroxisome proliferation in the mouse liver, and submitted these data to the Agency. EPA evaluated these data using criteria developed at a 1995 International Life Sciences Institute (ILSI) workshop on peroxisome proliferation.² Based on this review, the Agency determined that these data are sufficient to support peroxisome proliferation as the mode of action of acifluorfen liver tumors in mice.

Based on the results of the mode of action studies with sodium acifluorfen and reviews of the carcinogen bioassays conducted with the pesticide, the Agency classified sodium acifluorfen as “likely to be carcinogenic to humans at high enough doses to cause the biochemical and histopathological changes in livers of rodents but unlikely to be carcinogenic at doses below those causing these changes.” The Agency also determined that the forestomach papillomas seen in male and female mice are of questionable relevance to human health risk assessment because humans do not have a forestomach and because the rodent forestomach has a structure and function not found in the human stomach. For sodium acifluorfen, EPA determined that an MOE approach is appropriate to estimate human cancer risk and that the NOAEL of 1.25 mg/kg/day from a rat 2-generation reproductive toxicity study is adequately protective. This NOAEL was used to derive the chronic RfD for sodium acifluorfen and is considered to be protective of all chronic effects, including the physiological changes that lead to cancer. Because of the threshold nature of the cancer effect, the cancer endpoint for sodium acifluorfen is relevant only to chronic or long-term exposure scenarios.

² The ILSI Criteria were published in *Regulatory Toxicology and Pharmacology* 27: 47-60, 1998.

Table 2. Summary of Toxicological Endpoints and Other Factors Used in the Human Dietary Risk Assessment of Sodium Acifluorfen

Population Group(s)	NOAEL (mg/kg/day)	Endpoint	Study	Uncertainty Factors	FQPA Safety Factor	PAD (mg/kg/day)
Acute Dietary						
Females 13-50 years	20 (LOAEL = 90)	decreased fetal weight & increased incidence of anatomical variations of brain	Rat Developmental Toxicity (MRID 00122743)	100	10	0.02
All Other Groups	None	No relevant acute endpoint	None	N/A	N/A	None
Chronic Dietary (Noncancer)						
Infants, Children, Females 13-50 yrs	1.25 (LOAEL = 25)	Kidney lesions (dilated renal tubules of outer medulla) in females of both generations	Rat 2-Gen. Repro. Toxicity Study (MRID 00155548)	100	3	0.004
All Populations	1.25 (LOAEL = 25)	Kidney lesions (dilated renal tubules of outer medulla) in females of both generations	Rat 2-Gen. Repro. Toxicity Study (MRID 00155548)	100	1	0.013
Chronic Dietary (Cancer)						
All Populations	1.25 (LOAEL = 25)	Kidney lesions (dilated renal tubules of outer medulla) in females of both generations	Rat 2-Gen. Repro. Toxicity Study (MRID 00155548)	100	1	0.013

NOAEL, no observed adverse effect level.

LOAEL, lowest observed adverse effect level.

UF, uncertainty factor used to derive RfD from the NOAEL. Typically, a UF of 10X is used to account for intraspecies variability and another 10X UF is used to account for interspecies extrapolation.

PAD, population adjusted dose, derived from the acute or chronic RfD adjusted for the FQPA safety factor.

e. Dietary Exposure from Food

Specific assumptions used in the acute, chronic, and cancer dietary assessments are summarized below. Dietary exposure to residues in food is from use of sodium acifluorfen herbicide only, and not from the use of lactofen because plant and animal metabolism studies show that lactofen does not metabolize to acifluorfen in food.

The dietary exposure analysis is based on the Dietary Exposure Evaluation Model (DEEM™). The DEEM™ analysis evaluated individual food consumption as reported by respondents in the USDA 1989-92 Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. Because no Food and Drug Administration (FDA) or US Department of Agriculture (USDA) residue monitoring data were available for sodium acifluorfen, the residue values used in the dietary risk assessment were

based on field trial data. The acute, chronic, and cancer dietary risk assessments were highly refined, Tier III probabilistic assessments, which incorporate percent crop treated information.

For the acute dietary exposure, high-end field trial residues incorporating the likely maximum percent crop treated information (from Table 1) were used as a point estimate for the blended commodities, rice, peanuts, and soybeans. Because no relevant effects following a single exposure of sodium acifluorfen were identified for the U.S. general population, an acute dietary risk assessment for the entire U.S. population was not conducted. The only acute effect identified was developmental toxicity, which is relevant only to women of childbearing age. Therefore, an acute dietary risk assessment was conducted for females 13-50 years of age only, because developmental effects could occur after a single dietary exposure.

For the chronic (non-cancer) dietary risk assessment, EPA used anticipated residue values based on field trial studies and concentration factors from processing studies. The Agency also used an average of consumption values for each sub-population combined with average residue values in/on commodities over a 70-year lifetime to determine average exposure.

Chronic (cancer) dietary risk is typically calculated by using the average consumption values for food and average residue values for those foods. For sodium acifluorfen, the chronic dietary cancer risk is based on the same NOAEL and uncertainty factors that were used to calculate the chronic PAD. Therefore, the chronic dietary risk assessment is considered to be protective of cancer effects.

f. Summary of Dietary Risk from Food

In general, a dietary risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's level of concern. The sodium acifluorfen acute and chronic dietary risk from food is well below the Agency's level of concern. The Tier III assessment showed that acute dietary exposure from food comprises less than 1% of the acute PAD for females age 13-50 years, the only population at potential risk from acute effects. Acute dietary risk for the general population is not of concern because no acute PAD has been established for this population group.

The chronic dietary risk from food alone is also well below the Agency's level of concern. Chronic dietary exposure from food comprises less than 1% of the chronic PAD for the U.S. population and all subpopulations. As mentioned previously, the chronic dietary (food) risk assessment for non-cancer effects is identical to protective of cancer effects. Therefore, the chronic dietary risk from cancer is also not of concern.

2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either screening-level modeling or actual monitoring data, if available, to estimate those risks. Modeling is a screening tool that provides a high-end estimate of risk. The PRZM-EXAMS models with the Index Reservoir and Crop Area Factor were used to estimate surface water concentrations. The SCI-GROW model was used in conjunction with the results of a sodium acifluorfen prospective groundwater monitoring study to estimate groundwater concentrations of the degradate acifluorfen. Although some surface water monitoring data were available for acifluorfen, these data were not considered appropriate to use as a basis for a national drinking water assessment.

In the environment, when the pH is greater than 3.5, sodium acifluorfen dissociates to sodium (Na^+) and the acifluorfen (acifluorfen⁻) ion/degradate. Lactofen, a related pesticide, can also degrade to the acifluorfen ion in the environment by a different pathway. Because approximately 58% of applied lactofen can degrade to acifluorfen, EPA estimated total acifluorfen residues, from both sodium acifluorfen and lactofen uses, to estimate the risk of exposure to the acifluorfen degradate. In other words, the Agency considered all sources of potential drinking water exposure to the acifluorfen degradate.

a. Environmental Parameters Impacting Water Assessment

The persistence and mobility of acifluorfen vary with soil conditions. Sodium acifluorfen exists as the negatively charged acifluorfen anion in most agricultural soils because it has an acid dissociation constant (pK_a) of 3.5. Soil pH usually exceeds the pK_a for sodium acifluorfen; therefore, under typical environmental conditions, the sodium acifluorfen salt dissociates to the sodium cation (Na^+) and the acifluorfen anion (acifluorfen⁻). When acifluorfen exists as the anion, it is not expected to sorb to negatively charged soil particles, such as clay, but it may be sorbed by other types of chemical reactions. The adsorption and desorption of acifluorfen to soil is dependent on soil pH, organic carbon content, and amount and type of clay, and content of other minerals. Sorption of the acifluorfen anion appears to be a non-equilibrium, time dependent process.

Sodium acifluorfen is extremely soluble in water and stable to hydrolysis in soil. An aerobic soil metabolism study for sodium acifluorfen shows that the acifluorfen degradate is relatively persistent in soil, with a half-life ranging from 108 to 200 days. The aerobic aquatic metabolism study also showed that the acifluorfen degradate is relatively stable in aquatic environments, with an approximate half-life of 117 days. However, sodium acifluorfen degrades more rapidly under anaerobic conditions, where the soil half-life is 30 days and the aquatic half-life is estimated to be 2.75 days.

The acifluorfen degradate may reach surface water via runoff events or from discharge of contaminated groundwater into surface water. In some vulnerable areas, acifluorfen may also migrate to groundwater, where it is expected to persist due to its stability to abiotic hydrolysis. Additional information about the environmental fate of sodium acifluorfen may be found in the environmental fate and ecological effects risk assessment and other technical support documents listed in Appendix C.

b. Water Monitoring

Because the environmental fate properties of the acifluorfen degradate and retrospective groundwater monitoring studies for sodium acifluorfen showed that acifluorfen has the potential to leach, EPA required a small-scale prospective groundwater (PGW) monitoring study for sodium acifluorfen. This study was conducted in the Central Sands of Wisconsin, on a soil type that is highly vulnerable to leaching. This study analyzed for acifluorfen and two other degradates, but only acifluorfen was detected, in concentrations ranging from 1 to 46 ppb in 56 of 283 groundwater samples. The mean concentration of all samples from this study was 8.36 ppb. The average concentration for the detects from the last day of sampling was 15.2 ppb. By comparison, modeled estimates of acifluorfen concentrations in groundwater range from 0.19 to 10.33 ppb. In the PGW study, acifluorfen was generally found in the shallowest monitoring wells, suggesting that it was moving with groundwater flow. Based on the multiple detections of acifluorfen residues and known use of sodium acifluorfen at the study site, EPA believes that acifluorfen may contaminate shallow groundwater in areas with highly vulnerable soils, such as the Central Sands of Wisconsin.

The acifluorfen degradate has also been detected in surface and groundwater monitoring conducted by the US Geological Survey (USGS) in the National Water Quality Assessment Program (NAWQA). For surface water, NAWQA reports a maximum detection of 2.2 ppb for acifluorfen. For groundwater, NAWQA reports acifluorfen detects ranging from 0.035 to 0.19 ppb. Other groundwater monitoring studies cited in the EPA's Pesticides in Groundwater Database showed detections ranging from 0.003 to 0.025 ppb in 4 of 1,185 wells sampled. However, none of this monitoring was specifically targeted to sodium acifluorfen use sites.

Lactofen, another herbicide which also degrades to acifluorfen, is not routinely included in water monitoring studies due to its short half-life and low mobility. The Agency is not aware of any reported detections of lactofen in surface water or groundwater. The lactofen registrant sponsored a small-scale, PGW study for lactofen, which was inconclusive because it did not confirm whether or not leaching actually occurred at the site. A second small-scale, lactofen PGW study conducted in Michigan was recently completed and submitted to the Agency (MRID 45691701). This study was also used to inform the decision for sodium acifluorfen. In this most recent study, neither lactofen nor acifluorfen were found in groundwater, although acifluorfen residues were detected in lysimeters at shallow and medium depths (3 and 6 feet). The limit of detection in the study was 0.05 ppb for lactofen and 0.035 ppb for acifluorfen. From this study, EPA concludes that lactofen is not expected to leach to groundwater, but that the acifluorfen degradate is likely to leach.

Much lower levels of the acifluorfen degradate were detected in the PGW study for lactofen than in the study for sodium acifluorfen. EPA believes that this is due to differences in the material tested (sodium acifluorfen vs. lactofen), different degradation pathways, and the sorption of the acifluorfen degradate. Specifically, in the lactofen study, less acifluorfen degradate was available because only a percentage of lactofen (58%) applied degrades to acifluorfen and because a lower application rate was used. Also, lactofen does not degrade instantaneously to acifluorfen in the soil. Lactofen may degrade via two pathways, either lactofen degrades directly to acifluorfen or lactofen degrades to desethyl lactofen and then to acifluorfen. The acifluorfen degradate derived from lactofen, therefore, will not move through the soil matrix as a single pulse. Literature suggests that sorption of acifluorfen to soil particles is time dependent; greater sorption occurs with longer contact time.

In conclusion, acifluorfen derived from sodium acifluorfen may have greater potential to leach to groundwater than acifluorfen derived from lactofen. The existing water monitoring data for acifluorfen and lactofen show that acifluorfen may leach to groundwater under certain conditions, but that these compounds do not leach to groundwater in all vulnerable soils. The PGW study for sodium acifluorfen showed leaching of the acifluorfen degradate in the Central Sands of Wisconsin, an extremely vulnerable soil. The acifluorfen degradate also leached to soil pore water in the PGW study for lactofen, but because of the factors discussed in the previous paragraph, the levels seen were much lower, and it was not found in groundwater.

A Tier II PRZM-EXAMS screening-level model was used to estimate the upper-bound concentrations of acifluorfen in drinking water derived from surface water sources. This model includes the Index Reservoir (IR) and Percent Crop Area (PCA) refinements. Two model scenarios were selected to represent sodium acifluorfen uses: peanuts in North Carolina and soybeans in Mississippi. Two modeling scenarios were also considered for lactofen: cotton and soybeans in Mississippi. The scenarios with lactofen reflect acifluorfen derived from lactofen. Soybeans and cotton uses were modeled because they are the crops with the highest application rates. EPA incorporated the PCA factor refinement into the model results, which are summarized in Table 3 below. The model results provided are Estimated Drinking Water Concentrations (EDWCs) of the degradate acifluorfen.

Table 3. Estimated Drinking Water Concentrations (EDWCs)¹ of Acifluorfen in Surface Water

Crop/Source of Acifluorfen	PCA	Surface Water EDWC (ppb)		
		1 in 10 Year Maximum (Acute)	1 in 10 Year Average (Chronic)	1 in 30 Year Average (Cancer)
Acifluorfen Derived from Sodium Acifluorfen				
Soybeans	0.41	7.47	1.91	1.10
Peanuts ²	0.87	11.40	4.22	2.51
	0.38	4.98	1.84	1.10
Acifluorfen Derived From Lactofen				
Cotton	0.20	2.99	0.53	0.21
Soybeans	0.41	2.65	0.52	0.24
Total Acifluorfen from all Sources				
Total from Soybeans	N/A	10.12	2.43	1.34

¹ Estimated values were calculated using the Tier II PRZM/EXAMS model, which was adjusted for the Percent Crop Area (PCA) factor.

² For peanuts, two PCA factors were modeled, a default PCA of 0.87 developed in 2000 and a regional PCA of 0.38 developed in 2003.

c. Groundwater Modeling

A Tier I screening-level model, SCI-GROW, was used to estimate the potential concentration of acifluorfen from sodium acifluorfen uses in groundwater sources for drinking water, such as wells or aquifers. The SCI-GROW screening model is used to estimate pesticide concentrations under vulnerable hydrological conditions. For the acifluorfen degradate, there is considerable uncertainty in several fate parameters used as model inputs, including the soil partition coefficient (K_{oc}), the aerobic soil metabolism half-life, and the sorption, which is influenced by site specific soil parameters such as pH and mineral content. Another major area of uncertainty is the sorption/desorption of acifluorfen to various soils. Therefore, EPA has considerable uncertainty in the estimated concentrations of acifluorfen in groundwater from sodium acifluorfen uses. To compensate for these uncertainties, EPA used conservative assumptions for the groundwater modeling, as discussed below.

d. Estimated Drinking Water Concentrations (EDWCs) for Groundwater

SCI-GROW estimates of acifluorfen concentrations in groundwater range from 0.61 to 3.67 ppb. These values may be uncertain in some vulnerable soils, because when the parameters from the Wisconsin PGW study were used as inputs to the SCI-GROW model, the model predicted the acifluorfen concentration to be 5.5 ppb, which is slightly less than the average monitoring value of 8.36 ppb. However, the 3.67 ppb value was used to assess risks of acifluorfen concentrations derived from sodium acifluorfen because it was modeled using the K_{oc} for sandy soil.

To assess the potential exposure to acifluorfen derived from lactofen, results of the lactofen PGW study were used, rather than model estimates. Because the study demonstrated that the acifluorfen degradate (from use of lactofen) did not meet or exceed the limit of detection (LOD, 0.035 ppb in groundwater), the LOD value was used to estimate the concentration of acifluorfen in groundwater, consistent with the available evidence. EDWCs for acifluorfen in groundwater are summarized in Table 4. For groundwater, only a single value is given to represent acute and chronic exposures because the concentration of a pesticide in groundwater is expected to be relatively constant over time, compared with concentrations in surface water, which are likely to peak at certain times of the year when pesticide use or runoff is high.

Table 4. Estimated Drinking Water Concentrations (EDWC) for Acifluorfen in Groundwater

Crop	EDWC, ppb (Acute and Chronic)
Acifluorfen Derived from Sodium Acifluorfen	
Peanut/Soybean	3.67
Acifluorfen Derived from Lactofen	
Cotton/Soybean	0.035*
Total Acifluorfen from All Sources	
Soybean	3.71

* LOD for acifluorfen in groundwater in lactofen PGW study.

3. Residential Exposure and Risk

Homeowners or residential handlers can be exposed to sodium acifluorfen by applying it as a spot treatment, or by entering or performing other activities in treated areas. Residential handlers include homeowner applicators performing spot treatment of weeds along driveways, sidewalks, patios, and trees.

Risk to residential handlers is estimated using an MOE, which is the ratio of the No Observed Adverse Effect Level (NOAEL) from an animal study with exposure. For sodium acifluorfen, residential MOEs greater than 1000 are not of concern to the Agency. As previously stated, the Agency retained the 10X FQPA safety factor for the short-term residential risk assessment. Because all residential handler exposure is expected to occur on an intermittent short-term basis, the Agency assessed only short-term (1 to 30 days) risks associated with the use of residential products. Hence, intermediate-term (1 to 6 months) and long-term (greater than 6 months) residential risks were not assessed. Moreover, long-term (chronic) exposure would be necessary to cause the physiological changes that can lead to tumor formation. Therefore, in the absence of long-term residential exposure, a residential cancer risk assessment is not necessary.

a. Toxicity

The toxicological endpoints, and other factors used in the occupational and residential risk assessments for sodium acifluorfen are listed in Table 5. The assessment uses the NOAEL

of 20 mg/kg/day from the rat developmental toxicity study as the endpoint for short-term dermal and inhalation exposure. The rat 21-day dermal toxicity study on sodium acifluorfen was not selected for dermal risk assessment because effects were seen at a lower dose in the rat oral developmental toxicity study. As previously mentioned, a chronic risk assessment (for cancer and noncancer) for residential exposure is not necessary or relevant.

To correct for differences in absorption between the oral and dermal routes of exposure, a 20% dermal absorption factor was used. This value is based on a dermal penetration study in rats, the toxicity observed in a 21-day dermal toxicity study, and the ratio of the Lowest Observed Adverse Effect Levels (LOAELs) from dermal and oral toxicity studies. Results of a dermal penetration study showed very little test compound in urine or feces, with about 40% of the test material remaining on the skin after washing and available for absorption, at the end of the study. The 21-day dermal toxicity study showed effects, including death at 570 mg/kg/day, which indicated that acifluorfen was absorbed through the skin. By taking all of these factors into consideration, the Agency believes that a dermal absorption factor of 20% is adequately protective and appropriate for use in the residential and occupational risk assessment for sodium acifluorfen. An absorption factor was not determined for inhalation exposure, therefore, the Agency assumed 100% absorption for this exposure route.

Table 5. Summary of Toxicological Endpoints and Other Factors Used in the Human Occupational and Residential Risk Assessments for Sodium Acifluorfen

Assessment	Effect Level	Endpoint	Study	Absorption factor, % of oral absorption
Short- and intermediate-term dermal	NOAEL = 20 mg/kg/day (LOAEL = 90)	Decreased fetal weight & increased incidence of dilated lateral ventricles of the brain	Rat Developmental Toxicity Study (MRID 00122743)	20
Short- and intermediate-term inhalation				100
Chronic inhalation & dermal exposure	N/A	No chronic exposure expected		N/A

Endpoints for short and intermediate-term exposure are included in this table for use in both the occupational (to be discussed later) and residential risk assessments. EPA assumes adult body weight of 60 kg for all scenarios.

b. Residential Exposure

The Agency has determined that residential handlers may be exposed to sodium acifluorfen while spot treating weeds in driveways, sidewalks, patios, and around trees. Although residential handlers may apply sodium acifluorfen to lawns as a spot treatment for weeds, broadcast use on lawns is not expected because the product packaging is not designed for broadcast application and sodium acifluorfen is a non-selective herbicide that will kill both weeds and grass. EPA assumes that residential handlers do not use any protective clothing and typically wear a short-sleeved shirt, short pants, and no gloves. Because homeowners often lack access to personal protective equipment (PPE) or knowledge of the proper use of PPE, the

Agency does not believe that a tiered mitigation approach like that used for assessing occupational handler risk is appropriate for residential uses. As previously stated, sodium acifluorfen products are only used for spot treatment in residential settings and homeowners are expected to be exposed for less than seven days, which is considered to be short-term exposure.

EPA used exposure monitoring data from a surrogate chemical to evaluate exposure to homeowner handlers. This residential exposure monitoring study included ready-to-use trigger sprayer applications of an insecticide to home vegetable plants and was considered to be the best available data to assess residential exposure from use of sodium acifluorfen.

c. Residential Risk Summary

For the homeowner use of sodium acifluorfen, EPA is concerned about any MOE less than 1000, which incorporates the FQPA safety factor and is intended to be protective of females age 13-50 years. For the only potential exposure scenario, spot treatment with a ready-to-use trigger sprayer, EPA estimated an MOE for combined dermal and inhalation exposures of 18000, which is not of concern to the Agency. Furthermore, EPA has no concerns for post-application residential exposure because residential uses are limited to spot treatments, which do not include broadcast application to lawns, therefore, post-application exposure is expected to be negligible.

4. Aggregate Risk

An aggregate risk assessment evaluates the combined risk from dietary exposure to residues in food and drinking water and, if applicable, residential exposure to homeowners who apply pesticide and toddlers who receive incidental oral exposure from mouthing grass or other items treated with pesticides. For sodium acifluorfen, EPA conducted acute, short-term and chronic (cancer and non-cancer) aggregate risk assessments. The aggregate risk assessment compares the Drinking Water Level of Comparison (DWLOC) for each scenario with the appropriate Estimated Drinking Water Concentrations (EDWCs) for the pesticide. The DWLOC is the maximum concentration in drinking water which, when considered together with food, and, if appropriate, residential exposure, does not exceed EPA's level of concern. Generally, EDWCs that are less than the corresponding DWLOC are not of concern to the Agency.

The aggregate assessment for sodium acifluorfen compares DWLOCs with the EDWCs for total residues of the acifluorfen degradate from the use of both sodium acifluorfen and lactofen, a related pesticide, which can degrade to acifluorfen in the environment. Total acifluorfen residues were calculated for the soybean scenario because both herbicides are registered for use on soybeans. Additional details of the Agency's drinking water analysis for sodium acifluorfen may be found in the drinking water section and in technical support documents listed in Appendix C.

a. Acute Aggregate Risk

The acute aggregate risk assessment for sodium acifluorfen includes only food and drinking water exposure. The acute DWLOC for acifluorfen is 600 ppb, and the acute EDWCs for acifluorfen from all sources is 10.12 ppb for surface water and 3.71 ppb for groundwater. Because the acute DWLOC is greater than the estimated acute concentrations of acifluorfen in both surface water and groundwater, the Agency does not have a concern for acute aggregate risk for females age 13-50, the only population at potential risk from acute effects. Although the sodium acifluorfen prospective groundwater study showed a value as high as 46 ppb acifluorfen, this value is still substantially below the acute DWLOC and not of concern. Moreover, as previously discussed, the Agency has some uncertainty of the modeled EDWC of acifluorfen in groundwater from sodium acifluorfen use. However, the value predicted by the model as well as the concentrations detected in the monitoring studies are all also substantially less than the calculated DWLOCs, and are therefore not of concern for acute exposure (and other exposure durations to be discussed below). The acute aggregate assessment is summarized in Table 6.

Table 6. DWLOCs for Acute Aggregate Risk

Population Subgroup	Estimated Drinking Water Concentration (EDWC) of Acifluorfen (ppb)		Acute DWLOC (ppb)
	Groundwater	Surface Water	
Derived from Sodium Acifluorfen			
Females 13-50 years	3.67	7.47	600
Derived from Lactofen			
Females 13-50 years	0.035	2.65	600
Total Acifluorfen from All Sources			
Females 13-50 years	3.71	10.12	600

b. Short-Term Aggregate Risk

The short-term aggregate risk assessment for sodium acifluorfen includes chronic dietary (food and drinking water) and short-term residential (dermal and inhalation) exposures. The short-term aggregate risk was estimated only for females age 13-50 years because this is the only population at potential risk from acute effects. The short-term DWLOC of 462 ppb is greater than the chronic EDWCs of 2.43 ppb for surface water and 3.71 ppb for groundwater; therefore, EPA has no concerns about risk from short-term aggregate exposure. The short-term aggregate assessment is summarized in Table 7.

Table 7. DWLOCS for Short-Term Aggregate Risk

Population Subgroup	Estimated Drinking Water Concentration (EDWC) of Acifluorfen (ppb)		Short-term DWLOC ⁷ (ppb)
	Groundwater	Surface Water	
Derived from Sodium Acifluorfen			
Females 13-50 years	3.67	1.91	462
Derived from Lactofen			
Females 13-50 years	0.035	0.52	462
Total Acifluorfen from All Sources			
Females 13-50 years	3.71	2.43	462

c. Chronic Aggregate Risk

The chronic aggregate risk assessment for sodium acifluorfen includes only food and drinking water. Residential exposure was not included in the chronic assessment because chronic exposures are not expected from residential use. For sodium acifluorfen, the chronic DWLOC is 40 ppb for infants and children age 1-6, the two most highly exposed subgroups of the US population. This DWLOC for infants and children is greater than the chronic EDWCs of 2.43 ppb for surface water and 3.71 ppb for groundwater; therefore, EPA has no concerns about risk from chronic aggregate exposure. The chronic aggregate assessment is summarized in Table 8.

Table 8. DWLOCs for Chronic Aggregate Risk

Population Subgroup	Estimated Drinking Water Concentration (EDWC) of Acifluorfen (ppb)		Chronic DWLOC (ppb)
	Groundwater	Surface Water	
Derived from Sodium Acifluorfen			
Children 1-6 yrs	3.67	1.9	40
Infants < 1 yr	3.67	1.9	40
Derived from Lactofen			
Children 1-6 yrs	0.035	0.53	40
Infants < 1 yr	0.035	0.53	40
Total Acifluorfen from all Sources			
Infants and Children	3.71	2.43	40

d. Aggregate Cancer Risk

Similar to the chronic assessment for sodium acifluorfen, the aggregate cancer risk assessment includes only food and drinking water. Residential exposures were not included

because lifetime exposure from residential use was not assessed. The cancer DWLOC for sodium acifluorfen is 455 ppb, which is greater than the EDWC of 2.43 for surface water and 3.71 for groundwater. Therefore, EPA has no concern for aggregate cancer risk from total acifluorfen residues in drinking water. The aggregate cancer assessment is summarized in Table 9 below.

Table 9. DWLOCs for Aggregate Cancer Risk.

Population Subgroup	Estimated Drinking Water Concentration (EDWC) of Acifluorfen (ppb)		Chronic DWLOC (ppb)
	Groundwater	Surface Water	
Acifluorfen Derived from Sodium Acifluorfen			
General Population	3.67	1.9	455
Acifluorfen Derived from Lactofen			
General Population	0.035	0.52	455
Total Acifluorfen from All Sources			
General Population	3.71	2.43	455

5. Occupational Exposure and Risk

Occupational workers can be exposed to a pesticide through mixing, loading, applying a pesticide, or re-entering treated sites. For sodium acifluorfen, occupational handlers of sodium acifluorfen include individual farmers or growers who mix, load, and/or apply pesticides, as well as professional or custom agricultural applicators.

Risk to occupational handlers is estimated using an MOE, which is the ratio of the NOAEL from an animal study with exposure. For sodium acifluorfen, MOEs greater than 100 for occupational handlers are not of concern to the Agency. Because sodium acifluorfen products are typically applied one or two times per year, the Agency assessed only short- (1 to 30 days) and intermediate-term (1 to 6 months) risks associated with the use of agricultural products. Hence, long-term (greater than 6 months) occupational handler risks were not assessed. Moreover, long-term (chronic) exposure would be necessary to cause the physiological changes that can lead to tumor formation. Therefore, in the absence of long-term exposure, an occupational cancer risk assessment was not conducted.

a. Toxicity

The toxicological endpoints, and other factors used in the occupational risk assessment for sodium acifluorfen were previously listed in Table 5. The assessment uses the NOAEL of 20 mg/kg/day from the rat developmental toxicity study as the endpoint for short- and intermediate-term dermal and inhalation exposure and a dermal absorption factor of 20%. The acute toxicity profile for sodium acifluorfen is summarized in Table 9. Sodium acifluorfen is a severe eye irritant and a moderate skin irritant, but it is not a dermal sensitizer. Sodium acifluorfen is

classified as Toxicity Category II for acute oral toxicity in the dog, based on an acute study performed with 50-70% active ingredient. Acute oral, dermal, and inhalation toxicity in other species are classified as Toxicity Category III, III, and IV, respectively.

Table 9. Acute Toxicity Profile for Sodium Acifluorfen

Guideline	MRID	% a.i.	Study Type	Results	Toxicity Category
81-1	00071887	21.4	Acute Oral (rats)	LD ₅₀ = 2025 mg/kg (males) LD ₅₀ = 1370 mg/kg (females)	III
81-1	00071889	40	Acute Oral (dog)	LD ₅₀ = 186 mg/kg	II
81-2	00122725	20.2	Acute Dermal (rabbits)	LD ₅₀ > 2000 mg/kg (males/females)	III
81-3	00122726	20.3	Acute Inhalation	LC ₅₀ > 6.9 mg/L	IV
81-4	00126597	21.4	Primary Eye Irritation	Severe eye irritant	I
81-5	00126597	21.4	Primary Skin Irritation	Moderate dermal irritant	II
81-6	00122728	20.2	Dermal Sensitization	Not a skin sensitizer	N/A

b. Occupational Exposure

Agricultural Handler Exposure. EPA assessed occupational exposure to sodium acifluorfen using the Pesticide Handlers Exposure Database (PHED) and proprietary data, including chemical-specific monitoring data submitted by BASF. In addition, EPA used standard assumptions about average body weight, work day, and daily areas treated. Because the short- and intermediate-term risk assessment endpoints for sodium acifluorfen are based on an endpoint from a developmental toxicity study, the standard adult female body weight of 60 kg was used. EPA derived information about use patterns, application methods, and the range of application rates used in the exposure assessment from the current sodium acifluorfen labels. The application rates specified on the sodium acifluorfen labels range from 0.158 to 0.375 lbs a.i./A in agricultural settings. The Agency typically uses acres treated per day values that are thought to represent eight hours of application work for specific types of application equipment.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach until the MOEs are no longer of concern, going from minimal to maximum levels of protection. The lowest suite of personal protective equipment (PPE) is baseline (long sleeve shirt, long pants, shoes and socks). If MOEs are of concern (less than 100) at baseline, increasing levels of PPE are applied. If MOEs are still less than 100, engineering controls are applied. For sodium acifluorfen, EPA also conducted an assessment using baseline PPE plus chemical-resistant gloves.

Based on currently registered uses, the Agency identified the following major occupational exposure scenarios for sodium acifluorfen:

- (1) Mixing/loading/applying liquids using groundboom equipment
- (2) Mixing/loading liquids for groundboom application
- (3) Applying liquids with a groundboom sprayer
- (4) Mixing/loading liquids for aerial application
- (5) Applying liquid spray with aircraft
- (6) Flagging aerial spray applications

Sodium acifluorfen labels contain a variety of PPE, depending on the toxicity of the end-use product and the risk to users from any additional active ingredients. All sodium acifluorfen labels minimally require the PPE of long-sleeved shirt, long pants, shoes, socks, and gloves. Protective eyewear is generally required on the basis of the toxicity of the end-use product. Labels for Blazer® (EPA Reg. No. 7969-79) and Conclude Ultra® (EPA Reg. No. 7969-168) require chemical-resistant headgear for overhead exposure. In addition, the label for Conclude Ultra® requires coveralls, chemical-resistant gloves, and chemical-resistant footwear. This RED will address PPE needed solely based on the risk of the active ingredient sodium acifluorfen.

Agricultural Handler Risk. To assess exposure to mixer/loader/applicators using groundboom equipment (Scenario 1), EPA used chemical-specific monitoring data for sodium acifluorfen. In a biomonitoring study on private grower/applicators who used sodium acifluorfen for weed control on sites in Wisconsin, New York, and Maryland and Delaware, sodium acifluorfen was applied to soybean fields at a rate of 0.5 lbs a.i./A using groundboom sprayers pulled by open cab tractors. The study monitored workers who mixed, loaded, and applied sodium acifluorfen. Because of study limitations, the Agency only used the dermal and inhalation exposure data from this study. EPA did not use the biomonitoring component of the study due to uncertainties in the pharmacokinetics of sodium acifluorfen and the limited number of test subjects.

EPA used PHED to estimate worker exposure for both private growers and custom applicators for the remaining five scenarios listed above because PHED unit exposure values are the best available estimates of exposure. The quality of the data used for each scenario assessed is discussed in depth in the occupational and residential exposure and risk assessment for sodium acifluorfen, listed in Appendix C.

c. Occupational Handler Risk Summary

As previously mentioned, EPA assessed exposure and risk for six scenarios. For sodium acifluorfen, an MOE greater than 100 does not exceed the Agency's level of concern for effects from short- or intermediate-term exposure. EPA did not evaluate cancer risk to agricultural handlers because no chronic or long-term exposure is expected from the use of sodium acifluorfen.

There are some risks of concern for agricultural handlers that are summarized in Table 10. When handlers are wearing baseline attire (long sleeve shirt, long pants, shoes, and socks), handler MOEs are of concern for two scenarios: (2) mixing and loading liquids for groundboom application and (4) mixing/loading liquids for aerial application. Also, scenario (1) mixing/loading/applying liquids for groundboom application was not assessed for baseline attire. However, the remaining scenarios, including (3) applying spray with a groundboom sprayer; (5) applying liquid spray with aircraft; and (6) flagging resulted in MOEs greater than 100 with baseline attire and are therefore not of concern.

When chemical-resistant gloves are added to handlers for scenarios 1, 2 and 4, the MOEs are greater than 100 and not of concern. Therefore, chemical-resistant gloves are needed to mitigate risk to agricultural handlers for these scenarios (mixers/loaders and mixer/loaders/applicators of liquid formulations).

Table 10. Summary of Acifluorfen Occupational Handler Risk

Exposure Scenario	Application Rate (lbs a.i./Acre)	Area Treated ^a (Acres/Day)	Combined (Dermal and Inhalation) Short-/Intermediate-Term Margin of Exposure (MOE) ^b	
			Baseline ^c	Baseline + Chemical-Resistant Gloves
(1) Mix/Load/Apply Liquids - Groundboom	0.158	80	Not Applicable	1000
	0.375	200	Not Applicable	420
(2) Mix/Load Liquids for Groundboom Application	0.158	80	160	1600
	0.375	200	28	2800
(3) Apply Spray with a Groundboom Sprayer	0.158	80	27000	27000
	0.375	200	4500	4500
(4) Mix/Load Liquids for Aerial Application	0.158	350	37	3700
	0.375	1200	4.6	460
(5) Applying Spray with Fixed- Wing Aircraft	0.158	350	20,000	Not Applicable
	0.375	1200	2500	Not Applicable
(6) Flagging Aerial Spray Applications	0.158	350	8500	Not Applicable
	0.375	1200	1000	Not Applicable

a Amounts of acreage treated per day are maximum values from the HED Science Advisory Council for Exposure Policy #009 "Standard Values for Daily Acres Treated in Agriculture," dated July 5, 2000.

b MOE (unitless) = NOAEL (mg/kg/day) ÷ Combined Absorbed Daily Dose (mg/kg/day), where a NOAEL of 20 mg/kg/day is used for short-term and intermediate-term dermal and inhalation exposures. The dermal exposure component was adjusted with a 20% dermal absorption factor.

c Baseline PPE includes long pants, long sleeved shirt, shoes, socks.

d. Post-Application Exposure and Risk

The post-application occupational risk assessment considers exposures to agricultural workers re-entering treated areas for activities such as scouting, hand weeding, and irrigating. High contact re-entry activities performed in the past, such as hand transplanting and hand harvesting were not assessed because these tasks are now largely automated and because the existing preharvest intervals preclude exposure to workers performing harvesting activities. All post-application exposure is considered to be short- or intermediate-term, based on the frequency and duration of activities and the dissipation of acifluorfen. Only dermal exposure was assessed, because inhalation exposures are not anticipated for re-entry workers.

Data from a foliar dislodgeable residue study for sodium acifluorfen on soybeans were used as surrogate data to assess dermal exposure to re-entry workers for sodium acifluorfen use on peanuts and rice. This study measured dislodgeable foliar residues (DFR) following groundboom application of sodium acifluorfen to control weeds in soybean fields in Indiana, Mississippi and Georgia. The DFR data for the Indiana and Mississippi sites were used for the calculations of post- application exposures and risks. The data from the Georgia site were not

used because DFR values on the day of treatment were substantially less than those for the Indiana and Mississippi sites. EPA used the more conservative (and more protective) values.

The post-application worker risk calculations indicated that the MOEs were greater than 100 on Day 0, and therefore not of concern. Because sodium acifluorfen is in acute Toxicity Category I for eye irritation, the current restricted entry intervals (REIs) of 48 hours are appropriate and will remain unchanged. The results of EPA's re-entry assessment for sodium acifluorfen are summarized in Table 11 below.

Table 11. Estimated Post-Application Occupational Exposure and Risk for Sodium Acifluorfen

Crop	Transfer Coefficient (cm ² /hr)	Re-Entry Activities	MOE on Day 0
Soybeans	1500	Irrigate and Scout -Medium Exposure	740 (IN data) 680 (MS data)

6. Incident Reports

No poisoning incidents related to the use of sodium acifluorfen were reported in any of the data sources available to the Agency. Little or no usage has been reported for this pesticide, either in surveys of home use or agricultural use in California. Sodium acifluorfen was not reported to be involved in any human incidents in calls to the National Pesticide Telecommunications Network (NPTN) received calls from 1984-1991.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the technical support documents listed in Appendix C. Documents dated through April 30, 2002 are available in the public docket (OPP-34241A and B) and on the internet at <http://www.epa.gov/oppsrrd1/reregistration/acifluorfen>. Because the Agency implemented a new docketing system in July 2002, documents dated from May 1, 2002 to the present are in the docket OPP-2003-0293 and on the internet at a different site, <http://www.epa.gov/edockets>.

Revisions have been made since the preliminary risk assessment was completed, and include: (1) a re-evaluation of the environmental fate database for acifluorfen and a change to the proposed data requirements, and (2) an evaluation of a prospective groundwater monitoring study for the herbicide lactofen, which degrades to acifluorfen in the environment.

1. Environmental Fate and Transport

The environmental fate of sodium acifluorfen varies based on the site-specific properties of the soil to which it is applied. Sodium acifluorfen is extremely soluble in water, and stable to hydrolysis and photolysis in soil. The acifluorfen ion/degradate is relatively persistent in soil, with a half-life ranging from 108 to 200 days and is relatively stable in aquatic environments,

with a half-life of approximately 117 days. However, acifluorfen degrades under anaerobic conditions. The anaerobic soil half-life is 30 days and the anaerobic aquatic half-life is estimated to be 2.75 days. Under anaerobic conditions, acifluorfen undergoes chemical reduction to amino acifluorfen, which can be persistent depending on soil conditions. The acifluorfen degradate is mobile in soils and available monitoring data indicate that it has the potential to enter surface water by runoff and enter groundwater by leaching. Additional information on the environmental fate of sodium acifluorfen can be found in the drinking water section of this document and in the supporting documents referenced in Appendix C.

2. Ecological Risk Assessment

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to nontarget organisms from the use of sodium acifluorfen products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the EEC to the toxicity endpoint values, such as the median lethal dose (LD_{50}) or the median lethal concentration (LC_{50}). These RQ values are then compared to the Agency's levels of concern (LOCs), which indicates whether a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. In general, the higher the RQ the greater the concern. When the RQ exceeds the LOC for a particular category, the Agency presumes a risk of concern to that category. The LOCs and the corresponding risk presumptions are presented in Table 12 below.

Table 12. EPA's Levels of Concern (LOCs) and Associated Risk Presumptions

IF...	THEN the Agency presumes...
<i>Mammals and Birds</i>	
Acute RQ > LOC of 0.5,	Acute risk
Acute RQ > LOC of 0.2,	Risk that may be mitigated through restricted use
Acute RQ > LOC of 0.1,	Acute effects may occur in endangered species
Chronic RQ > LOC of 1	Chronic risk to all species
<i>Fish and Aquatic Invertebrates</i>	
Acute RQ > LOC of 0.5	Acute risk
Acute RQ > LOC of 0.1	Risk that may be mitigated through restricted use
Acute RQ > LOC of 0.05	Acute effects may occur in Endangered species
Chronic RQ > LOC of 1	Chronic risks to all species
<i>Plants</i>	
The RQ > LOC of 1	Acute risk and endangered plants may be affected

a. Ecological Hazard Profile

Numerous ecological toxicity studies were conducted to support the reregistration of sodium acifluorfen. The results of these studies are summarized herein; for specific details, please see the documents referenced in Appendix C.

Toxicity to Aquatic Organisms

Fish. Sodium acifluorfen is slightly toxic to both freshwater and salt water fish with acute exposure. For Bluegill sunfish, the acute LC_{50} is 31 ppm. For Rainbow trout, the acute LC_{50} is 17 ppm. For Sheepshead minnow, the acute LC_{50} is 39 ppm. Chronic toxicity data are available for freshwater fish, but not for salt water fish. In a fish early life stage study on Fathead minnow (OPP Guideline 850.1400), reduced larval weight was reported at 1.5 ppm, the lowest dose level. Therefore, a No Observed Adverse Effect Concentration (NOAEC) could not be determined for this study, and the study must be repeated. In addition, fish exposed to light-dependent peroxidizing herbicides (LDPHs) and intense light, such as sunlight, can show increased toxicity relative to fish exposed to the same chemical in low intensity light. Because the available Fathead minnow test was conducted under low light levels, as well as not being conducted at low enough doses to determine a NOAEC, EPA requires that an additional fish early life stage study be conducted on sodium acifluorfen (OPPTS 850.1400, modified). The additional study should determine the NOAEC under both high and low intensity light.

Invertebrates. Sodium acifluorfen is slightly toxic to freshwater invertebrates. Acute toxicity testing on *Daphnia magna* showed LC_{50} values of 28.1 ppm for technical-grade material and 77 ppm for 25% a.i. material. Chronic toxicity testing for freshwater invertebrates was not required because EPA's EEC for acifluorfen in surface water is less than 1% of the lowest LC_{50} value. Therefore, the Agency can conclude with reasonable certainty that under the current use pattern, chronic risk to freshwater invertebrates is negligible.

For estuarine/marine invertebrates, sodium acifluorfen is classified as slightly toxic to practically nontoxic, based on the data submitted to support reregistration. For technical grade sodium acifluorfen, the acute LC_{50} for the Eastern oyster is 74 ppm and the LC_{50} for the Grass shrimp is 446 ppm. For 25% a.i. formulation, the LC_{50} for the Mysid is 3.8 ppm. Chronic toxicity testing for saltwater invertebrates is not being required for the same reasons discussed above.

Plants. In Tier I toxicity studies for aquatic plants, no growth reduction was seen 120 hours after exposure to the maximum label rate (355 ppb). In the Tier II toxicity studies, Duckweed was determined to be the most sensitive vascular plant to the effects of acifluorfen. The Duckweed EC_{50} was 378 ppb. The Tier II studies showed no effects on nonvascular aquatic plants at the maximum label rate.

Toxicity to Terrestrial Organisms

Birds. Sodium acifluorfen is moderately to practically nontoxic to birds on an acute oral basis. The LD₅₀ for the Mallard duck was 4,187 mg/kg. The LD₅₀ for Bobwhite quail was 325 mg/kg. Results of four subacute dietary studies showed that acifluorfen is practically nontoxic to the Bobwhite quail and to the Mallard duck. The LC₅₀ values range from 5620 to greater than 10,000 ppm, with no mortality.

In an avian reproduction study, the NOAEC for the Bobwhite quail was 20 ppm and the LOAEC was 100 ppm based on a reduced number of viable embryos. The NOAEC for the Mallard duck was greater than 100 ppm (the highest dose level tested); no LOAEC was determined.

Mammals. Wild mammal testing was not done for sodium acifluorfen, so the Agency relied on existing laboratory toxicity studies on rats to determine the potential acute toxicity to wild mammals. A rat acute oral study on sodium acifluorfen showed an LD₅₀ of 1540 mg/kg; therefore, sodium acifluorfen is classified as slightly toxic to rats. A rat reproductive study showed a NOAEC greater than 2,500 ppm with no reproductive effects. In a rat developmental study, the NOAEC for sodium acifluorfen was 20 mg/kg/day (400 ppm) based on decreased fetal body weight.

Insects. There is a data gap for the honey bee acute contact study (OPPTS Guideline 850.3020). This study is required because of the high potential of sodium acifluorfen to drift to off site vegetation in bloom.

Plants. Data from a nontarget terrestrial toxicity study were submitted to satisfy the data requirement for nontarget plants. This study satisfied the data requirement for seedling emergence, but not for vegetative vigor. EPA concluded that the study for vegetative vigor must be repeated (OPPTS Guideline 850.4150) because the submitted study used a very dilute solution of sodium acifluorfen, resulting in uncertainty in the dose used in the study.

b. Environmental Exposure to Non-Target Organisms

Exposure to Aquatic Organisms

The Agency used modeling to derive estimated environmental concentrations (EECs) for the acifluorfen degradate in surface water. Unlike the drinking water assessment described in the human health risk assessment section of this document, the ecological water resource assessment does not include the Index Reservoir (IR) and Percent-Crop Area (PCA) factor refinements. The IR and PCA factor represent a drinking water reservoir, not the variety of aquatic habitats, such as ponds adjacent to treated fields, relevant to a risk assessment for aquatic animals. Therefore, the EEC values used to assess exposure to aquatic animals are not the same as the values used to assess human dietary exposure from drinking water sources.

Table 13. Estimated Environmental Concentrations (EECs) of Acifluorfen in Surface Water

Crop/Chemical	Scenario	EECs of Acifluorfen in Surface Water (ppb)	
		1-in-10 year maximum (Acute Exposure)	21-day average (Chronic Exposure)
Soybean and Peanuts	MS Farm Pond	21.11	20.69
Rice*	Rice Paddy	26.6	15.96

* EECs for rice were derived from a modified version of GENEEC, GENEECx.

Exposure to Terrestrial Organisms

The Agency assessed exposure to terrestrial organisms by first predicting the amount of sodium acifluorfen residues found on animal food items and then by determining the amount of pesticide consumed by using information on typical food consumption by various species of birds and mammals. The amount of residues on animal feed items are based on the Fletcher nomogram (a model developed by Fletcher, Hoerger, Kenaga, et al.)³ and the current maximum application rate for sodium acifluorfen. Current labels allow a maximum single application of 0.25 to 0.375 lbs a.i./Acre and up to two 0.25 lb a.i./A applications per season for a total seasonal maximum rate of 0.5 lb a.i./A. Therefore, EPA modeled the maximum and mean residues of sodium acifluorfen in various food items immediately after the second of two 0.25 lbs a.i./A applications. The Agency assumed no dilution due to the growth of the plants or degradation of sodium acifluorfen. EPA's estimates of sodium acifluorfen residues on various wild animal food items are summarized in Table 14. No monitoring data were used in the development of terrestrial EECs.

Table 14. EECs of Sodium Acifluorfen on Wild Animal Food Items

Food Item	EEC (ppm) ¹	
	Predicted Maximum Residue	Predicted Mean Residue
Short grass	120	43
Tall grass	55	18
Broadleaf plants/Insects ²	68	23
Seeds	8	4

¹ Residual EEC immediately after the second of two applications of 0.25 lb a.i./A, assuming no degradation of sodium acifluorfen.

² Surface to volume ratios of broadleaf plants and insects are similar; therefore, EPA assumes that they contain similar residue levels.

³ This model was originally developed by Hoerger and Kenaga and later modified by Fletcher, Nellessen, and Pflieger.

c. Environmental Risk to Non-Target Organisms

As previously mentioned, EPA compares toxicity endpoints from ecological toxicity studies to EECs for sodium acifluorfen and calculates RQs to evaluate the potential risk to nontarget organisms. These RQ values are then compared to the Agency's levels of concern (LOCs). The sodium acifluorfen RQs show that acute LOCs are not exceeded for terrestrial animals, freshwater and estuarine animals, or aquatic plants. Chronic LOCs are exceeded for insectivorous and herbivorous birds but not for mammals. Chronic LOCs are not exceeded for freshwater invertebrates and estuarine animals. EPA has a potential risk concern for phototoxicity to aquatic organisms (i.e., toxicity enhanced by the presence of sunlight) which will be evaluated at a later date, when adequate data are available. The Agency was unable to conduct a chronic risk assessment for freshwater fish due to lack of adequate data. Likewise, EPA was unable to conduct a risk assessment for terrestrial plants or insects because there were no adequate data. Because sodium acifluorfen is an herbicide, EPA assumes that there will be some risk to nontarget plants and therefore, it should be applied in such a way to minimize drift.

Risk to Aquatic Organisms

Risk to Freshwater Fish. The acute RQ for Rainbow trout is less than 0.01 for sodium acifluorfen use on soybeans and peanuts and less than 0.01 for use on rice. No acute LOCs were exceeded for freshwater fish.

As mentioned above, EPA was unable to conduct a chronic risk assessment on freshwater fish because a NOAEC was not established in the Fathead minnow early life stage study. This study must be repeated (OPP 850.1400). Because acifluorfen is a light-dependent peroxidizing herbicide, aquatic organisms inhabiting small shallow water bodies exposed to high levels of sunlight would be expected to be at greatest risk for potential phototoxic effects. Therefore, the Agency is requiring a phototoxicity study using a small fish species to assess the potential of light to increase toxicity of sodium acifluorfen. The fish early life stage study may be modified to fulfill both data requirements.

Risk to Estuarine/Marine Fish. The acute RQ for Sheepshead minnow is less than 0.01 for sodium acifluorfen use on soybeans and peanuts and less than 0.01 for use on rice. No acute LOCs were exceeded for estuarine fish. Chronic toxicity testing is not required for estuarine and marine fish because the acute RQ is less than 0.01, and therefore chronic toxicity is expected to be low. The Agency does not have any acute or chronic concerns about risk to estuarine and marine fish.

Risk to Freshwater Invertebrates. The acute RQ for *Daphnia magna* is less than 0.01 for sodium acifluorfen use on soybeans, peanuts, and rice. No acute LOCs were exceeded for freshwater invertebrates. Chronic toxicity testing is not required for freshwater invertebrates because the acute RQ is less than 0.01, and therefore, chronic toxicity is expected to be low. The Agency does not have any acute or chronic risk concerns for freshwater invertebrates.

Risk to Estuarine/Marine Invertebrates. The acute RQ for Mysid shrimp is less than 0.01 for soybeans, peanuts, and rice. No acute LOCs were exceeded for saltwater invertebrates. Chronic toxicity testing is not required for saltwater invertebrates because the acute RQ is less than 0.01, and therefore, chronic toxicity is expected to be low. The Agency does not have an acute or chronic risk concerns for saltwater invertebrates.

Risk to Nontarget Aquatic Plants. The RQs for both vascular and nonvascular aquatic plants are less than 1.0, based on the results of the existing Tier II aquatic plant toxicity test data. No acute LOCs were exceeded for aquatic plants.

Risk to Terrestrial Organisms

Risk to Birds. Acute RQs from a single application of sodium acifluorfen range from less than 0.01 to 0.02. Acute RQs from two applications of sodium acifluorfen (for a seasonal maximum of 0.5 lb a.i./A) range from less than 0.01 to 0.04. No acute LOCs are exceeded for any registered use. Chronic RQs for birds range from 0.3 to 6.0, based on maximum residues and a reproductive endpoint (a reduced number of viable embryos in Bobwhite quail). In a more refined assessment, which uses mean residues, the only birds that continued to have risks of concern were those that eat short grass, with RQs ranging from 0.15 to 1.8. These RQs slightly exceeded EPA's level of concern (1.0) for chronic risk.

Risk to Mammals. Risks to mammals were estimated for a variety of food types, body weights, and percentage of body weight consumed as food. In a worst case acute scenario, when sodium acifluorfen is applied at the maximum seasonal rate of 0.5 lb a.i./A, the acute RQ is less than 0.01, and not of concern. No acute LOCs were exceeded for any registered use. In a worst case chronic scenario, the chronic RQ was less than 0.05 and not of concern. No chronic mammalian LOCs were exceeded for any registered use.

Risk to Insects. The Agency was unable to conduct a risk assessment for insects due to a data gap for the honey bee acute contact study (OPPTS Guideline 850.3020). This study is required.

Risk to Nontarget Plants. As previously mentioned, limited information is available about the toxicity of sodium acifluorfen to nontarget plants because the study submitted to fulfill the FIFRA guideline requirement used an extremely dilute test substance. Because of the limited data, EPA is unable to conduct a risk assessment for nontarget plants at this time. However, because sodium acifluorfen is an herbicide, there may be some risk to nontarget plants exposed via drift.

Risk to Endangered Species

The Agency's review of sodium acifluorfen resulted in a determination that sodium acifluorfen will have "no effect" on threatened and endangered aquatic species, mammals, and "no effect" from acute exposures to avian species. Using the data available, acifluorfen does not

exceed a level of concern for chronic effects to avian species based upon mean residues in the field except for the birds that eat short grass. The only listed species that consumes short grass is the Hawaiian goose which routinely is on golf courses in Hawaii. Because sodium acifluorfen is not used on golf courses, the Agency does not believe that its continued use would effect the Hawaiian goose or any other listed species.

As an herbicide, sodium acifluorfen has the potential to affect federally listed threatened and endangered vascular plants. Until additional data are submitted and a determination made whether a species specific assessment needs to be conducted for listed plants, the mitigation strategy articulated in this document will serve as interim protection to reduce the likelihood that listed species will be exposed to sodium acifluorfen.

d. Ecological Incident Reports

There are no reports of ecological incidents attributed to sodium acifluorfen.

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submissions of relevant data concerning an active ingredient, whether pesticides containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., an active ingredient specific) data required to support reregistration of products containing sodium acifluorfen as the active ingredient.

The Agency has completed its assessment of the residential, occupational, and ecological risks associated with the use of pesticides containing the active ingredient sodium acifluorfen, as well as an acifluorfen-specific dietary risk assessment. Based on a review of these data and public comments on the Agency's assessments for the active ingredient sodium acifluorfen, EPA has sufficient information on the human health and ecological effects of sodium acifluorfen to make decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that sodium acifluorfen is eligible for reregistration provided that: (1) current data gaps and additional data needs are addressed and (2) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures. Label changes are described in Section V. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of sodium acifluorfen and lists the submitted studies that the Agency found acceptable.

B. Summary of Phase 5 Comments

When making its reregistration decision, the Agency took into account all comments received during Phase 5 of the public participation process for reregistration. These comments in their entirety are available in the public docket, under docket number OPP-3424B. BASF, the technical registrant for sodium acifluorfen, was the only entity that submitted comments. The Agency has prepared responses to each of these comments, which are also available in the public docket and on the internet.

BASF requested that the Agency revise the cancer classification of sodium acifluorfen, considering both the new cancer risk assessment guidelines and the proposed peroxisome proliferation mode of action. BASF submitted additional data to support the proposed mode of action. BASF also commented on the 10X FQPA safety factor for sodium acifluorfen and questioned the need for a developmental neurotoxicity study. They also submitted comments on product and residue chemistry, occupational exposure, environmental fate, and the drinking water and ecological risk assessments. These comments, and any new information, have been considered in this regulatory decision, where appropriate.

C. Regulatory Position

1. FQPA Assessment

a. “Risk Cup” Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with the use of sodium acifluorfen. The assessment is for this individual pesticide only. FQPA requires the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity. Sodium acifluorfen is a member of the diphenyl ether group of herbicides, which includes lactofen, oxyfluorfen, nitrofen, and fomesafen. The Agency has evidence that these compounds induce similar toxic effects but has not yet determined whether these compounds exhibit a common mechanism of toxicity. For purposes of tolerance reassessment and determination of reregistration eligibility of sodium acifluorfen, EPA is assuming that sodium acifluorfen does not share a common mechanism of toxicity with other compounds.

EPA has determined that risk from exposure to sodium acifluorfen is within its own “risk cup.” In other words, EPA is able to conclude today that the tolerances for sodium acifluorfen meet the FQPA safety standards for the US population and sensitive subgroups, including infants and children. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food, residential uses, and drinking water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks

from all exposures to sodium acifluorfen, including acifluorfen derived from lactofen, “fit” within the individual risk cup.

b. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, sodium acifluorfen may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

c. Tolerance Summary

In the individual assessment, tolerances for residues of sodium acifluorfen in/on plant commodities [40 CFR §180.383] are presently expressed in terms of combined residues of parent sodium-5[2-chloro-4-(trifluoromethyl) phenoxy]-2-nitrobenzoic acid and its metabolites (the corresponding acid, methyl ester, and amino analogues). The current tolerance expression is appropriate and will remain unchanged.

Raw Agricultural Commodities, 40 CFR §180.383(a)

The nature of the residue in plants and animals is adequately understood. The current tolerances for most plant commodities are appropriate and will remain unchanged. However, the tolerance value for rice straw should be increased from 0.1 ppm to 0.2 ppm, based on available residue data. Tolerances for livestock commodities are no longer needed because the residue data show that residues do not transfer from treated feed items to livestock tissues. These 15 livestock tolerances were proposed for revocation in the *Federal Register* under 40 CFR 180.6(a)(3) on July 16, 2003 (Federal Register, Vol. 68, No 136). These tolerances will be revoked pending publication of a final rule in the *Federal Register*. However, the grazing restrictions for soybeans and peanuts must be retained. The tolerance reassessment for sodium acifluorfen is summarized in Table 15.

Table 15. Tolerance Summary for Sodium Acifluorfen

Commodity	Current Tolerance, ppm	Reassessed Tolerance, ppm	Comment [Correct Commodity Definition]
Tolerances for Raw Agricultural Commodities Established Under 40 CFR §180.383(a)			
Cattle, kidney	0.02	Revoke	Revocation pending publication of final rule
Cattle, liver	0.02	Revoke	Revocation pending publication of final rule
Egg	0.02	Revoke	Revocation pending publication of final rule
Goat, kidney	0.02	Revoke	Revocation pending publication of final rule
Goat, liver	0.02	Revoke	Revocation pending publication of final rule
Hog, kidney	0.02	Revoke	Revocation pending publication of final rule
Hog, liver	0.02	Revoke	Revocation pending publication of final rule
Horse, kidney	0.02	Revoke	Revocation pending publication of final rule
Horse, liver	0.02	Revoke	Revocation pending publication of final rule
Milk	0.02	Revoke	Revocation pending publication of final rule
Peanut	0.1	0.1	
Poultry, fat	0.02	Revoke	Revocation pending publication of final rule
Poultry, meat byproducts	0.02	Revoke	Revocation pending publication of final rule
Poultry, meat	0.02	Revoke	Revocation pending publication of final rule
Rice, grain	0.1	0.1	Data show that residues do not concentrate in processed commodities; therefore, a tolerance is needed only for rice grain.
Rice, straw	0.1	0.2	Available data indicate maximum combined residues of sodium acifluorfen and metabolites were <0.124 ppm in/on rice straw
Sheep, kidney	0.02	Revoke	Revocation pending publication of final rule
Sheep, liver	0.02	Revoke	Revocation pending publication of final rule
Soybean	0.1	0.1	[Soybean, seed]
Strawberry	0.05	To Be Determined*	Currently there are no registered uses of sodium acifluorfen on strawberries, but IR4 is committed to supporting tolerance.

Note: Existing data show that residues of acifluorfen are not transferred from treated feed items to livestock tissues. Therefore, tolerances were proposed for revocation on July 16, 2003 (*Federal Register*, Vol. 68, No 136)(FRL-7301-5).

* Strawberry tolerance to be determined pending submission of directions for use (OPPTS 860.1200) and approval of a label for use on strawberries.

Codex

There are no Codex Maximum Residue Limits (MRLs) for sodium acifluorfen and therefore no issues regarding compatibility of US Tolerances with Codex MRLs.

Residue Analytical Methods

Adequate methods are available for enforcement of the tolerances for sodium acifluorfen in plant and animal commodities as currently expressed. For determination of sodium acifluorfen residues in/on plant commodities, the *Pesticide Analytical Manual Volume II* (PAM II) lists a gas chromatography/electron capture detector (GC/ECD) method, designated as Method I, for the enforcement of tolerances in plant commodities. Method I determines residues of sodium acifluorfen, acifluorfen, acifluorfen amine, and any other compounds that can be converted to acifluorfen methyl ester or the heptafluorobutyramide derivative. Identifications are confirmed by Gas Liquid Chromatography Mass Spectrometry (GLC/MS) according to Method A in PAM II. The detection limit for Method I is 0.01-0.02 ppm. The requirement for radiovalidation data is waived based on the low residues found in metabolism and field trial studies.

D. Regulatory Rationale

EPA has determined that certain mitigation measures and label amendments are necessary for the currently registered uses of sodium acifluorfen to be eligible for reregistration. The following is a summary of the rationale for managing risks associated with the current use of sodium acifluorfen. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Mitigation

a. Dietary Mitigation

Food. Risk from dietary exposure to sodium acifluorfen residues in food is not of concern. Acute dietary exposure from food comprises less than 1% of the acute PAD for females age 13-50 years, the only population at potential risk from acute effects. Chronic dietary exposure from food comprises less than 1% of the chronic PAD for the US general population and all subgroups, which indicates that neither chronic nor cancer dietary risk is of concern. Because there are no dietary risks of concern from food, no risk mitigation is necessary.

Drinking Water. Risk from dietary exposure to acifluorfen residues in drinking water is not of concern. The Agency has estimated levels of acifluorfen residues from both sodium acifluorfen and lactofen uses. Although acifluorfen residues may leach to groundwater in certain vulnerable soils, screening-level model results, which are designed to provide high-end estimates, indicate that acifluorfen levels in surface water and groundwater are not of concern for any exposure duration. Therefore, no risk mitigation is necessary for drinking water.

However, because ground water monitoring studies show that acifluorfen residues may leach to groundwater when sodium acifluorfen is used in regions with soils vulnerable to leaching, the current groundwater advisory shall remain on the labels. Additional adsorption/desorption studies on sandy soils would allow the Agency to better characterize the local soil conditions under which groundwater leaching may occur and may allow EPA to change the groundwater label advisory. Because there is no longer a human health risk concern, these data are not required at this time.

b. Homeowner Risk Mitigation

For the homeowner use of sodium acifluorfen as a spot treatment with a ready-to-use trigger sprayer, the combined dermal and inhalation MOE is 18000, which is not of concern to the Agency. EPA has no additional concerns for post-application residential exposure because residential uses are limited to spot treatments, where any post-application exposure is expected to be negligible. Therefore, no mitigation is necessary for this specific use pattern.

b. Aggregate Risk Mitigation

As previously mentioned, the aggregate risk assessment for sodium acifluorfen includes dietary exposure from food, drinking water, and residential exposure where appropriate. The aggregate risk assessment also includes total residues in drinking water of the acifluorfen degrade from the use of both sodium acifluorfen and lactofen, a related pesticide, which can degrade to acifluorfen. Total acifluorfen residues in drinking water were calculated for the soybean scenario, because both herbicides are registered for use on soybeans.

Acute Aggregate Risk

The acute aggregate risk assessment for sodium acifluorfen includes only food and drinking water. For acute aggregate risk, the potential drinking water exposure derived from either groundwater or surface water is not of concern for females age 13-50, the only population at potential risk from acute effects. As indicated in Table 6, the estimated acute (peak) groundwater (3.71 ppb) and surface water (10.12 ppb) concentrations of acifluorfen are well below the acute DWLOC of 600 ppb. Therefore, no mitigation measures are necessary to address acute aggregate risk.

Short-Term Aggregate Risk

The short-term aggregate risk assessment for sodium acifluorfen includes chronic dietary (food and drinking water) and short-term residential exposure (dermal and inhalation). For short-term aggregate risk, the potential exposure to drinking water derived from surface water or groundwater is not of concern for the relevant population, females age 13-50. As indicated in Table 7, the short-term DWLOC is 462, which is greater than the chronic (average) groundwater (3.71 ppb) and surface water (2.43 ppb) concentrations of acifluorfen from all sources. Therefore, no mitigation measures are necessary to address short-term aggregate risk.

Chronic Aggregate Risk

The chronic aggregate risk assessment for sodium acifluorfen includes only food and drinking water. Residential exposure was not included in the chronic aggregate risk assessment because long-term (chronic) exposures are not expected from use of residential products. For chronic aggregate risk, the potential drinking water exposure derived from either groundwater or surface water is not of concern for infants (less than 1 year old) and children (age 1-6), the most highly exposed population subgroups. As indicated in Table 8, the chronic DWLOC of 40 ppb is greater than the chronic concentration of acifluorfen in surface water (2.43 ppb) or groundwater (3.71 ppb). Therefore, no mitigation measures are necessary to address chronic aggregate risk.

Aggregate Cancer Risk

Similarly, the cancer aggregate risk assessment for sodium acifluorfen includes only food and drinking water. Residential exposure was not included in the cancer aggregate risk assessment because long-term (chronic) exposures are not expected from use of residential products. For cancer aggregate risk, the potential drinking water exposure derived from either ground or surface water is not of concern for the US general population, the only population for which cancer risk is assessed. As indicated in Table 9, the cancer DWLOC for sodium acifluorfen is 455, which is greater than the concentration of acifluorfen in surface water (2.43 ppb) or groundwater (3.71 ppb). Therefore, no mitigation measures are necessary to address cancer aggregate risk.

c. Occupational Risk Mitigation

Agricultural Handler Risk

There are some risks of concern for agricultural handlers which are summarized in Table 10. When handlers are wearing baseline attire (long sleeve shirt, long pants, shoes, and socks), handler MOEs are of concern for two scenarios: (2) mixing and loading liquids for groundboom application and (4) mixing/loading liquids for aerial application. Also, scenario (1) mixing/loading/applying liquids for groundboom application was not assessed for baseline attire. However, the remaining scenarios, including (3) applying spray with a groundboom sprayer; (5) applying spray with a fixed-wing aircraft; and (6) flagging resulted in MOEs greater than 100 with baseline attire and are therefore not of concern.

When chemical-resistant gloves are added to handlers for scenarios 1, 2 and 4, the MOEs are greater than 100 and not of concern. Therefore, chemical-resistant gloves are adequate to mitigate risk to agricultural handlers for these scenarios (mixers/loaders and mixer/loaders/applicators of liquid formulations).

Post-Application Worker Risk

Post-application risks to agricultural workers re-entering areas treated with sodium acifluorfen are summarized in Table 11. MOEs on the day of application are above 100, the Agency's level of concern for re-entry workers; therefore, no mitigation is necessary. Restricted Entry Intervals (REIs) are driven both by post-application worker risk and by the acute toxicity of a pesticide. Sodium acifluorfen is a severe eye irritant (Toxicity Category I); therefore, the current label REI of 48 hours is appropriate.

2. Environmental Risk Mitigation

EPA has no concerns about the risk to aquatic organisms potentially exposed to acifluorfen via runoff, so no mitigation is necessary. The Agency has no concerns about the risks to mammals. EPA's screening-level assessment shows a slight chronic risk concern for birds that eat short grass containing sodium acifluorfen residues; however, these risks are expected to be mitigated through additional label language intended to minimize drift. The Agency does not have concerns about endangered species, as discussed in Section III.

EPA was unable to evaluate risks to honeybees because there are no available data. The confirmatory DCI for this RED will include the Honeybee Acute Contact Study (OPPTS Guideline 850.3020). EPA will evaluate risk to honeybees, and any additional mitigation, after these data are submitted and reviewed.

Likewise, the Agency was unable to conduct a risk assessment for nontarget plants because of limited data. Because sodium acifluorfen is an herbicide and may therefore harm nontarget plants exposed via drift, the Agency requires that sodium acifluorfen be applied in a manner that minimizes spray drift. In addition, the seedling emergence and vegetative vigor studies must be repeated to comply with a previous DCI. The registrant has submitted a schedule for completion of this study and submission of data by June 30, 2004. EPA will evaluate risks to nontarget plants, and any additional mitigation, after these studies are repeated and the data are submitted and reviewed.

3. Other Labeling

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

a. Endangered Species Statement

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that address these impacts. EPA is not requiring specific label

language at the present time relative to threatened and endangered species. The general risk mitigation required through this RED will serve to protect listed species of potential concern until such time as the agency refines its risk assessment for plants. If in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at www.epa.gov/espp. A final Endangered Species Protection Program, which may be altered from the interim program, was proposed for public comment in the Federal Register December 2, 2002.

b. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, we will continue to work with all interested parties on this important issue.

From its assessment of sodium-acifluorfen, as summarized in this document, the Agency concludes that certain measures are needed to address the potential for off-target drift from sodium-acifluorfen products. Label statements implementing these measures are listed in the "spray drift management" section of the label table (Table 16) in Chapter V of this RED document. In the future, sodium-acifluorfen product labels may need to be revised to include additional or different drift label statements.

V. What Registrants Need to Do

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

A. Technical Registrants

For sodium acifluorfen technical grade active ingredient products, registrants need to submit the following items.

Within 90 days from receipt of the generic data call-in (DCI):

- Completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and

- Any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

- Citations for any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Christina Scheltema at (703)308-2201 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be sent to the following address:

By US mail:

Document Processing Desk (DCI/SRRD)
Christina Scheltema
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:

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

B. Registrants of End-Use Products

For end-use products containing the active ingredient sodium acifluorfen, registrants need to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

- Completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and
- Any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

- Two copies of the confidential statement of formula (EPA Form 8570-4);
- A completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration;"
- Five copies of the draft label incorporating all label amendments outlined in Table 16 of this document;
- A completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

- If applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and
- The product-specific data responding to the PDCI.

Please contact Veronica Dutch at (703)308-8585 with questions regarding product reregistration and/or the PDCI. Address all materials submitted in response to the PDCI to:

By US mail:

Document Processing Desk (PDCI/PRB)
Veronica Dutch
US EPA Office of Pesticide Programs
Mail Code 7508C
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service only:

Document Processing Desk (PDCI/PRB)
Veronica Dutch
US EPA Office of Pesticide Programs
(7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

C. Additional Generic Data Requirements

1. Outstanding Data Requirements

The generic data base supporting the reregistration of sodium acifluorfen has been reviewed and determined to be substantially complete. However, there are a few data gaps remaining. Because all of these data requirements were included in previous DCIs, they are not included in the generic DCI for this RED, but these data must be submitted or the Agency may take regulatory action on registrations of products containing sodium acifluorfen.

- Analytical Methods - Plants (OPPTS Guideline 885.2300) for rice straw, to include a lower LOQ.
- Seed Germination/Seedling Emergence (OPPTS 850.4100)
- Vegetative Vigor (OPPTS 850.4150)

Registrant has committed to conduct and submit plant studies by June 30, 2004.

2. Confirmatory Data Requirements

The Agency has determined that additional studies are necessary to confirm the regulatory conclusions presented in this RED. The following confirmatory data requirements are included in the generic DCI for sodium acifluorfen:

- UV/visible Absorption (OPPTS 830.7050)
- Fish Early Life Stage Toxicity Study (OPPTS 850.1400), modified for Aquatic Phototoxicity
- Honey Bee Acute Contact (OPPTS 850.3020)

- Directions for Use (on strawberries) (OPPTS 860.1200)
- Developmental Neurotoxicity Study in Rats (OPPTS 870.6300)

D. Labeling for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing-use product (MUP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MUP labeling must bear the labeling contained in Table 16 at the end of this section.

E. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

A product-specific data call-in (PDCI), outlining data requirements for all sodium acifluorfen products, accompanies this RED. Appendix G batches or groups sodium acifluorfen products for the purpose of conducting the acute toxicity testing required as part of the PDCI.

2. Labeling for End-Use Products

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 16.

F. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this RED document. Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to “*Existing Stocks of Pesticide Products; Statement of Policy*,” *Federal Register*, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell sodium acifluorfen products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than the registrant remain obligated to meet pre-existing label requirements and existing stocks requirements applicable to products they sell or distribute.

G. Labeling Changes Summary Table

To be eligible for reregistration, all product labels are to be amended to incorporate the risk mitigation measures outlined in Section IV. Table 16, which follows, describes how language on the labels should be amended.

Table 16: Summary of Labeling Changes for Sodium Acifluorfen

Description	Amended Labeling Language for Sodium Acifluorfen	Placement on Label
Manufacturing Use Products		
For all Manufacturing Use Products	“Only for formulation into an herbicide for the following use(s): peanuts, rice, and soybeans and residential spot treatment ”	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”	Directions for Use
	“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such uses(s).”	Directions for Use
Environmental Hazards Statements including Groundwater Statements	“Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.”	Precautionary Statements

Description	Amended Labeling Language for Sodium Acifluorfen	Placement on Label
End Use Products Intended for Occupational Use (WPS)		
PPE Requirements Established by the RED ¹ for all products	“Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>). If you want more options, follow the instructions for category (<i>registrant inserts A,B,C,D,E,F,G,or H</i>) on an EPA chemical-resistance category selection chart. Mixers, loaders, and applicators must wear: long sleeve shirt, long pants, and shoes and socks. In addition to the PPE above, mixers and loaders must also wear chemical-resistant gloves.”	Immediately following the Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	“User Safety Requirements Follow manufacturer’s instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separate from other laundry.”	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls	“Engineering Controls When handlers use closed systems, enclosed cabs, or cockpits in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS.”	Precautionary Statements: Immediately following User Safety Requirements
User Safety Recommendations	“User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

Description	Amended Labeling Language for Sodium Acifluorfen	Placement on Label
Environmental Hazards	<u>For products that do not contain Directions for Use on rice:</u> “Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters. Do not apply when weather conditions favor drift from target area. <u>For products that contain Directions for Use on rice:</u> “Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark, except as specified on this label for application to rice. Do not contaminate water when disposing of equipment wash waters. Do not apply when weather conditions favor drift from target area.” <u>For all products:</u> <u>Ground Water Advisory</u> “Sodium acifluorfen is known to leach through soil to groundwater under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable (sandy or sandy/loamy soils) and water tables are shallow could result in contamination of groundwater. Use of irrigated water in such areas will increase the likelihood of groundwater contamination.”	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval	“Do not enter or allow workers to enter into treated areas during the restricted entry interval (REI) of 48 hours.”	Directions for Use, Agricultural Use Requirements Box
Early Entry PPE	“The following PPE is required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water: Coveralls over long sleeved shirt and long pants, Chemical-resistant gloves made of any waterproof material Chemical-resistant footwear plus socks, Chemical resistant headgear if overhead exposure, and Protective eye wear.”	Direction for Use, Agricultural Use Requirements Box
Double Notification	“Notify workers of pesticide application by warning them orally and by posting warning signs at entrances to treated areas.”	

Description	Amended Labeling Language for Sodium Acifluorfen	Placement on Label																	
General Application Restrictions	“Do not apply this product in a way that will contact workers or other people, either directly or through drift. Only handlers wearing PPE may be in the treatment area during application.” “This pesticide is toxic to vascular plants and should be used strictly in accordance with the drift and run-off precautions on this label to minimize off-site exposures.” “A 40-day plant back interval is necessary for small grains and a 100-day plant back interval is necessary for all other rotated crops.” “Do not allow livestock to graze on treated forage for soybeans or peanuts. Do not feed treated vines ”	Place in the Direction for Use directly above the Agricultural Use Box.																	
Spray Drift Label Language for Products Applied Outdoors as a Liquid	“SPRAY DRIFT MANAGEMENT” “Use best practices to avoid drift to all other crops and non-target areas. Do not apply when conditions favor drift from target areas. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. Avoiding spray drift at the application site is the responsibility of the applicator. The applicator must follow the most restrictive use precautions to avoid drift, including those found in this labeling as well as applicable state and local regulations and ordinances. A drift control agent may reduce drift, however, it may also decrease weed control.” “<u>Requirements for ground applications:</u>” “For ground applications, adjust nozzle height and droplet size with wind speed according to the following table:” <table data-bbox="470 987 1478 1263"> <thead> <tr> <th>Wind speed</th><th>Nozzle height</th><th>Droplet size for standard nozzles (ASAE standard 572)</th></tr> </thead> <tbody> <tr> <td rowspan="3">Less than 10 mph</td><td>Up to 2 feet</td><td>medium or coarser</td></tr> <tr> <td>2-4 feet</td><td>coarse or coarser</td></tr> <tr> <td>4-6 feet</td><td>very coarse or coarser</td></tr> <tr> <td rowspan="3">10 to 15 mph</td><td>0-2 feet</td><td>coarse or coarser</td></tr> <tr> <td>2-4 feet</td><td>very coarse or coarser</td></tr> <tr> <td>4-6 feet</td><td>extremely coarse</td></tr> </tbody> </table> Do not apply when the wind speed exceeds 15 miles per hour. Do not apply with a nozzle height of greater than 6 feet above the ground or crop canopy. Apply as a medium or coarser spray (ASAE standard 572).	Wind speed	Nozzle height	Droplet size for standard nozzles (ASAE standard 572)	Less than 10 mph	Up to 2 feet	medium or coarser	2-4 feet	coarse or coarser	4-6 feet	very coarse or coarser	10 to 15 mph	0-2 feet	coarse or coarser	2-4 feet	very coarse or coarser	4-6 feet	extremely coarse	Directions for Use under General Precautions and Restrictions
Wind speed	Nozzle height	Droplet size for standard nozzles (ASAE standard 572)																	
Less than 10 mph	Up to 2 feet	medium or coarser																	
	2-4 feet	coarse or coarser																	
	4-6 feet	very coarse or coarser																	
10 to 15 mph	0-2 feet	coarse or coarser																	
	2-4 feet	very coarse or coarser																	
	4-6 feet	extremely coarse																	

Description	Amended Labeling Language for Sodium Acifluorfen	Placement on Label
Spray Drift Label Language for Products Applied Outdoors as a Liquid	“<u>Requirements for aerial applications:</u>” “For aerial applications, apply only when the wind speed is less than or equal to 15 miles per hour using a release height of no more than 10 feet above the ground or crop canopy. If the wind speed is less than 10 mph, apply as a medium or coarser spray (ASAE standard 572). If the wind speed is between 10 mph and 15 mph, apply as a coarse or coarser spray (ASAE standard 572).” “The boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter.” “Do not make aerial applications into temperature inversions.” “When aerial applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind.”	Directions for Use under
End Use Products Intended Primarily for Use by Homeowners		
Spray Drift Label Language for Home- Use Products Applied as a Liquid	“Do not apply this product in a way that will contact people or pets, either directly or through drift.”	Directions for Use under General Precautions and Restrictions
Application/Entry Restriction	“Use this product for spot treatment only. This product is not intended for wide area or broadcast use.” “Keep all people, children, and pets out of the treated area until sprays have dried.”	Directions for Use under General Precautions and Restrictions
Eligibility Restrictions	For residential use, only ready-to-use products packaged in a spray trigger bottle are eligible for reregistration.	Directions for Use under General Precautions and Restrictions

¹ PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

VI. Related Documents and How to Access Them

A list of technical support documents for the sodium acifluorfen RED is provided in Appendix C. All technical support documents for this RED may be viewed on paper in the OPP Public Docket or electronically via the Internet. These documents may be found on the Agency's web page at www.epa.gov/pesticides/reregistration/status.htm (documents through April 2002) or at www.epa.gov.edockets under docket OPP-2003-0293 (Documents from May 2002 to the present). Hard copies of these documents may be found in the OPP public docket, under docket numbers OPP-34241A or B, for documents dated through April 2002, or under docket number OPP-2003-0293, for documents dated from May 2002 to the present. The OPP public docket is located in Room 119, Crystal Mall II, 1921 Jefferson Davis Highway, Arlington, VA. The docket is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

VII. APPENDICES

- A. Use Patterns Eligible for Reregistration**
- B. Data Supporting FIFRA Guideline Requirements for the Reregistration of Sodium Acifluorfen**
- C. List of EPA's Technical Support Documents for Sodium Acifluorfen**
- D. Bibliography of MRID Citations Supporting the RED**
- E. Generic Data Call In (DCI)**
- F. Product-Specific DCI**
- G. Batching of Products for Meeting Acute Toxicity Data Requirements**
- H. List of Registrants sent the DCI**
- I. List of Electronically Available Forms**

Appendix A

Sodium Acifluorfen (Case 2605): Use Patterns Eligible for Reregistration

Site Application Timing Application Type Application Equipment ¹	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval, Days	Use Directions and Limitations ^{2,3,4}
Peanuts						
Preemergence, at cracking, or postemergence Broadcast Ground/Aerial	1.33 lb/gal SC [7969-76]	0.25 lb/A	2	0.5 lb/A	75	Minimum retreatment interval is 15 days. Do not feed or graze livestock on treated hay, forage, or fodder.
Preemergence, at cracking, or postemergence Broadcast Ground/Aerial	0.67 lb/gal SC [7969-77]	0.25 lb/A	2	0.42 lb/A	75	Do not feed or graze livestock on treated hay, forage, or fodder.
Preemergence, at cracking, or postemergence Broadcast or banded foliar Ground/Aerial	2 lb/gal SC [7969-79] [7969-80]	0.375 lb/A	2	0.5 lb/A	75	Minimum retreatment interval is 15 days. For banded applications, minimum band width is 15 inches and minimum application volume is 15 gal/A. Do not feed or graze livestock on treated hay, forage, or fodder.

Site Application Timing Application Type Application Equipment ¹	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval, Days	Use Directions and Limitations ^{2,3,4}
Rice						
Late tillering to early boot Broadcast Ground/Aerial	1.33 lb/gal SC [7969-76]	0.25 lb/A	1	0.25 lb/A	50	May be used on first and second (ratoon) crops. Rice must be past the 3-leaf stage. The following are prohibited: use of ground equipment when fields are flooded; application where commercial cultivation of catfish or crayfish is practiced; use of water containing residues from rice cultivation to irrigate crops other than soybean or peanuts.
Late tillering to early boot Broadcast or banded foliar Ground/Aerial	2 lb/gal SC [7969-79] [7969-80]	0.25 lb/A	2 (at 0.125 lb ai/A)	0.25 lb/A	50	Rice must be past the 3-leaf stage. For banded applications, minimum band width is 15 inches and minimum of application volume is 15 gal/A. The following are prohibited: application after rice reaches the boot stage, harvesting catfish or crayfish for food from treated areas; use of water containing residues from rice cultivation to irrigate crops other than those labeled for use with this product.
Soybeans						
Postemergence Broadcast foliar Ground/Aerial	1.33 lb/gal SC [7969-76] 0.67 lb/gal SC [7969-77]	0.25 lb/A	2	0.5 lb/A	50	Minimum retreatment interval is 15 days [EPA Reg. No. 7969-76 only]. Do not feed or graze livestock on treated hay, forage, or fodder.
Postemergence Broadcast or banded foliar Ground/Aerial	2 lb/gal SC [7969-79] [7969-80]	0.375 lb/A	2 (at 0.25 lb ai/A)	0.5 lb/A	50	Minimum retreatment interval is 15 days. For banded applications, minimum band width is 15 inches and minimum application volume is 15 gal/A. Do not feed or graze livestock on treated hay, forage, or fodder.

Site Application Timing Application Type Application Equipment ¹	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval, Days	Use Directions and Limitations ^{2,3,4}
Postemergence Broadcast foliar Ground/Aerial	0.84 lb/gal SC [7969-168]	0.25	1	0.5 lb/A ⁷	75	Soybeans must be at the second to third trifoliate leaf stage. Minimum retreatment interval is 5-days. Do not feed or graze livestock on treated hay, forage, or fodder.
Residential Use as a Spot Treatment						
Postemergence Ready-to-Use Spot Treatment	0.12% a.i. [71995-3]	Not Specified (Spot Treatment)			Not Applicable	

¹ Applications may be made in 10-50 gal/A by ground equipment or 5-10 gal/A by aerial equipment.

² Cultivation within 5 days before or 7 days after application for peanuts, rice, and soybeans. A restricted entry interval (REI) of 48 hours and an 18-month plantback interval for root crops are currently in effect.

³ One of the following additives is needed depending on crop and tank mix used: ammonium sulfate, crop oil concentrate, nonionic surfactant, or urea ammonium nitrate.

⁴ Except as noted, the following components are approved for tank mixing. For peanuts: 2,4-DB, alachlor, bentazon, dimethenamid, imazamethapyr, metolachlor, paraquat, and sethoxydim. For rice: bentazon, propanil, and quinclorac. For soybeans: 2,4-D LVE (preplant burndown only), 2,4-DB, bentazon, chloransulam-methyl, chlorimuron-ethyl, clethodim, dimethenamid, fenoxaprop-p-ethyl, fluazifop-p-butyl, flumiclorac-pentyl ester, glyphosate, imazamox, imazaquin, imazethapyr, quizalofop-p-ethyl, sethoxydim, and thifensulfuron-methyl.

APPENDIX B: Data Supporting FIFRA Guideline Requirements for Sodium Acifluorfen

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 0005 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 0005 in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

**Data Supporting FIFRA Guideline Requirements
for Sodium Acifluorfen**

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
<u>PRODUCT CHEMISTRY</u>				
830.1550	61-1	Chemical Identity & Composition	All	41891203
830.1600	61-2A	Starting Material & Manufacturing Process	All	41891201
830.1670	61-2B	Formation of Impurities	All	41891201
830.1700	62-1	Preliminary Analysis	All	41891202
830.1750	62-2	Certification of limits	All	41891203
830.1800	62-3	Analytical Method	All	41891202
830.6302	63-2	Color	All	41891204
830.6303	63-3	Physical State	All	41891204
830.6304	63-4	Odor	All	41891204
830.7050	None	UV/Visable Absorption	All	New Data Requirement
830.7200	63-5	Melting Point	All	41891204
830.7220	63-6	Boiling Point	All	N/A
830.7300	63-7	Density	All	41891204
830.7840 830.7860	63-8	Solubility	All	41650302

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
830.7950	63-9	Vapor Pressure	All	41784601
830.7370	63-10	Dissociation Constant	All	41731901, 41891205
830.7550	63-11	Octanol/Water Partition Coefficient	All	41891206
830.7000	63-12	pH	All	41891204
830.6313	63-13	Stability	All	41891209
	<u>ECOLOGICAL EFFECTS</u>			
850.2100	71-1	Avian Acute Oral Toxicity	ABCDK	00083058, 00122748
850.2200	71-2A	Avian Dietary Toxicity - Quail	ABCDK	00083059, 00122750
850.2200	71-2B	Avian Dietary Toxicity - Duck	ABCDK	00083060, 00122749
850.2400	71-3	Wild Mammal Toxicity	ABCDK	00071887, 00122743
850.2300	71-4A	Avian Reproduction - Quail	ABCDK	00107491
850.2300	71-4B	Avian Reproduction - Duck	ABCDK	00107492
850.1075	72-1A	Fish Toxicity Bluegill	ABCDK	00107493, 00122751, 00071901
850.1075	72-1B	Fish Toxicity Sheepshead Minnow	ABCDK	00124223
850.1075	72-1C	Fish Toxicity Rainbow Trout	ABCDK	00071901, 00122752
850.1010	72-2A	Invertebrate Toxicity	ABCDK	00071901, 00122754
None	72-3A	Estuarine/Marine Toxicity - Fish	ABCDK	00122753, 00124223
None	72-3B	Estuarine/Marine Toxicity - Mollusk	ABCDK	00111964

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
None	72-3C	Estuarine/Marine Toxicity - Shrimp	ABCDK	00111962, 00122755
850.1400	72-4A	Fish Early Life Stage/ Aquatic Phototoxicity	ABCDK	Data Gap/New Data Requirement
850.4100	123-1(a)	Seedling Germination/Seedling Emergence	BD	Data Gap
850.4150	123-1(b)	Vegetative Vigor	BD	Data Gap
850.4400	122-2	Aquatic Plant Growth, Tier I	BD	41680702
	123-2	Aquatic Plant Growth, Tier II	BD	41680702
850.3020	141-1	Honey Bee, acute contact	ABCDK	New Data Requirement
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity-Rat	All	00122724
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	All	00061626
870.1300	81-3	Acute Inhalation Toxicity-Rat	All	00061627
870.2400	81-4	Primary Eye Irritation-Rabbit	All	00061628
870.2500	81-5	Primary Skin Irritation	All	00061629
870.2600	81-6	Dermal Sensitization	All	40814601
870.3100	82-1A	90-Day Feeding - Rodent	All	Waived
870.3150	82-1B	90-Day Feeding - Non-rodent	All	Waived
870.3200	82-2	21-Day Dermal - Rabbit/Rat	All	00122731

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
870.4100	83-1A	Chronic Feeding Toxicity - Rodent	All	00128353
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent	All	00122732, 00122734
870.4200	83-2A	Oncogenicity - Rat	All	00128353
870.4200	83-2B	Oncogenicity - Mouse	All	00122732, 00122734
870.3700	83-3A	Developmental Toxicity - Rat	All	00122743
870.3700	83-3B	Developmental Toxicity - Rabbit	All	00122744
870.3800	83-4	2-Generation Reproduction - Rat	All	00155548
870.5140	84-2A	Gene Mutation (Ames Test)	All	45393901, 41480101, 41480103
870.5375	84-2B	Structural Chromosomal Aberration	All	00122741
None	84-4	Other Genotoxic Effects	All	00122738, 00122739, 00122742
870.7485	85-1	General Metabolism	All	00122746, 00156020
870.6300		Developmental Neurotoxicity in Rats	All	New Data Requirement
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2100	132-1A	Foliar Residue Dissipation	ABCD	44091101
875.2200	132-1B	Soil Residue Dissipation	ABCD	42019301
875.2400	133-3	Dermal Passive Dosimetry Exposure	ABCD	42361501, 44459801

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
875.2500	133-4	Inhalation Passive Dosimetry Exposure	ABCD	42361501, 44459801
None	231	Estimation of Dermal Exposure at Outdoor Sites	ABCD	42361501
None	232	Estimation of Inhalation Exposure at Outdoor Sites	ABCD	42361501
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	All	00107479
835.2240	161-2	Photodegradation - Water	ABCD	41891208, 42793502, 44195001, 44195002
835.2410	161-3	Photodegradation - Soil	ABCD	41688501, 44412901
835.4100	162-1	Aerobic Soil Metabolism	ABCD	00143572
835.4200	162-2	Anaerobic Soil Metabolism	ABCD	Satisfied by Anaerobic aquatic metabolism study
835.4400	162-3	Anaerobic Aquatic Metabolism	CD	43155201
835.4300	162-4	Aerobic Aquatic Metabolism	CD	42330601
835.1240	163-1	Leaching/Adsorption/Desorption	All	42793501, 44412902
835.6100	164-1	Terrestrial Field Dissipation	AB	Addressed in MRID 41833202 (Groundwater Monitoring Study)
	164-2	Aquatic Field Dissipation	CD	43270801
835.1850	165-1	Confined Rotational Crop	AD	42785601, 43372501, 43666601
None	165-4	Bioaccumulation in Fish	All	Waived

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
	166-1	Groundwater monitoring, small scale retrospective	All	41833202, 42152201, 41448501, 41651101
<u>RESIDUE CHEMISTRY</u>				
860.1200		Directions for Use (Strawberries)	All	New Data Requirement
860.1300	171-4A	Nature of Residue - Plants	ABD	41688504, 42330604, 42368301, 42368302, 42865801, 42865802, 43182001, 43181901, 43295501, 43881001, 43584501
860.1300	171-4B	Nature of Residue - Livestock	ABD	42815601, 42828201
860.1340	171-4C	Residue Analytical Method - Plants	ABD	00028858, 42815702, 43451001, 44137901, 44153801, 92168036, 92168048
860.1340	171-4D	Residue Analytical Method - Animals	ABD	00028858, 92168036, 92168048
860.1360		Analytical Method for rice straw	ABD	Data gap for rice straw
860.1380	171-4E	Storage Stability	ABD	00107488, 43290101,43601401, 43666602,44137901, 92168037, 92168049, 42815601, 42828201
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	ABD	00107488, 92168050, 42828201, 42815601
860.1500	171-4K	Crop Field Trials (Soybeans)	ABD	00107488, 42815701, 92168045, 92168053

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
860.1500	171-4K	Crop Field Trials (Rice)	ABD	42330604, 42825701
860.1500	171-4K	Crop Field Trials (Peanut)	ABD	00028857, 00028858, 92168042, 92168052
860.1500	171-4K	Crop Field Trials (Strawberry)	ABD	41285901
860.1520	171-4L	Processed Food/Feed	ABD	43254901, 42330605, 43584501, 43254902
860.1500	171-4K	Confined Rotational Crops	ABD	42785601, 43372501, 43666601
860.1500	171-4K	Field Rotational Crops	ABD	Conditional requirement to support shorter plant back intervals

APPENDIX C: LIST OF EPA's TECHNICAL SUPPORT DOCUMENTS FOR SODIUM ACIFLUORFEN

Additional documentation in support of this IRED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The docket is open Monday through Friday, excluding Federal holidays, from 8:30 am to 4:00 pm.

The preliminary and revised risk assessments for sodium acifluorfen are available in the Public Docket, under docket numbers OPP-3424A and B, and on the Agency's web page, www.epa.gov/pesticides/reregistration/status.htm. Because the Agency implemented a new docketing system in July 2002, documents dated from May 1, 2002 to the present are in the docket OPP-2003-0293 and on the internet at a different site, <http://www.epa.gov/edockets>.

EPA released the preliminary risk assessments for sodium acifluorfen on July 26, 2001 and the revised risk assessments on April 12, 2002 under docket numbers OPP-3424A and B. During and after the second public comment period, the registrant submitted additional voluntary data for sodium acifluorfen. EPA reviewed there data and incorporated them into the final revised risk assessments for sodium acifluorfen. These final revised risk assessments form the basis of the regulatory decision described in the RED.

All final revised risk assessment and technical support documents may be viewed in the OPP docket room , in hard copy form, or downloaded or viewed electronically via the Internet at the following site: www.epa.gov/edockets. These documents include the following:

Human Health Risk Assessment Documents

- Michael Metzger (OPP/HED/RRB1). *Sodium Acifluorfen. Revision to HED Chapter for Reregistration Eligibility Decision Document*. July 14, 2003.
- Jessica Kidwell (OPP/HED/SIMB). *Acifluorfen: Report of the Cancer Assessment Review Committee*. July 9, 2003.
- Paul Chin (OPP/HED/RRB1). *Mechanism of Toxicity SARC Second Report: Acifluorfen*. July 9, 2003.
- Paul Chin (OPP/HED/RRB1) and Irving Mauer (OPP/HED/RRB1). *Acifluorfen (Tackle/Blazer): Review of 3 mechanism studies*. May 13, 2003.
- Kit Farwell (OPP/HED/RRB1). *SODIUM ACIFLUORFEN. HED Chapter for the Reregistration Eligibility Decision Document*. January 15, 2002.
- Felicia A. Fort (OPP/HED/RRB1). *Sodium Acifluorfen. Revised Product and Residue Chemistry Chapters of the Reregistration Eligibility Decision*. December 18, 2001.
- Timothy Dole (OPP/HED/RRB1). *Sodium Acifluorfen: Second Revised Occupational and Residential Exposure and Risk Assessment for the RED*. November 13, 2001.
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- James Wolf (OPP/EFED/ERBIII). *Drinking Water Exposure Assessment for Lactofen, updated for Prospective Ground Water (PGW) Monitoring Study.* January 21, 2003.
- James Goodyear (OPP/EFED/ERBIII). *Addendum to EFED RED Chapter for Sodium Acifluorfen.* September 15, 2003.
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- James J. Goodyear and James K. Wolf. (OPP/EFED/ERBIII). *Reregistration of sodium acifluorfen.* June 8, 2000.

Use and Usage

- Christina Scheltema (OPP/SRRD/RB3). *Use Closure Memo for Sodium Acifluorfen,* dated November 1, 1999.
- Frank Hernandez (OPP/BEAD/EIB). *Quantitative Use Assessment for Sodium Acifluorfen,* dated July 9, 1999.

Appendix D

BIBLIOGRAPHY OF MRID CITATIONS SUPPORTING THE RED

GUIDE TO APPENDIX D

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

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

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00061626	Whittaker Corporation (19??) Acute Dermal LD 50--Rabbits: Study No. 410-0250. (Unpublished study received Jan 5, 1981 under 2224-EX-18; submitted by Mobil Chemical Co., Industrial Chemicals Div., Richmond, Va.; CDL:244147-E)
00061627	Cavender, F.L.; Horath, L.L. (1980) Acute Inhalation LC 50--Rats: Study No. 420-0251. (Unpublished study received Jan 5, 1981 under 2224-EX-18; prepared by Whittaker Corp., submitted by Mobil Chemical Co., Industrial Chemicals Div., Richmond, Va.; CDL:244147-F)
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00071887	Parsons, R.D. (1976) Toxicity Data: (Experimental) Herbicide RH 6201, Aqueous Technical, 39.6% Active Ingredient; Sodium 5-(2-Chloro-4-trifluoro-methyl-phenoxy)2-nitrobenzoate, Aqueous Technical 39.6% (PL-76/8017): Report No. 76-171. (Unpublished study received Jan 17, 1977 under 707-EX-87; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:095736-I)
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00083059	Fink, R. (1976) Final Report: Eight-day Dietary LC50--Bobwhite Quail: Project No. 129-108. (Unpublished study received Jan 17, 1977 under 707-EX-87; prepared by Wildlife International, Ltd., submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:095736-AC)
00083060	Fink, R. (1976) Final Report: Eight-day Dietary LC50-Mallard Duck: Project No. 129-109. (Unpublished study received Jan 17, 1977 under 707-EX-87; prepared by Wildlife International, Ltd., submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:095736-AD)
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00122730	Barnett, J. (1982) Evaluation of Ninety Day Subchronic Toxicity of Tackle in Fischer 344 Rats: GSRI Project No. 413-971-40; Rhone-Poulenc Agrochemie No. 372-80. (Unpublished study received Dec 20, 1982 under 359-708; prepared by Gulf South Research Institute, submitted by Rhone-Poulenc, Inc., Monmouth Junction, NJ; CDL:071308-A)
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00122734	Sigler, F. (1982) Evaluation of Oncogenic Potential of Tackle in B6C3F1 Mice: Project No. WIL-81159. Final rept. (Unpublished study received Dec 20, 1982 under 359-708; prepared by WIL Research Laboratories, Inc., submitted by Rhone-Poulenc, Inc., Monmouth Junction, NJ; CDL:071313-A; 071314)
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00122737	Bowman, J.; Mackerer, C.; Bowman, S.; et al. (1981) <i>Drosophila</i> Mutagenicity Assays of Mobil Chemical Company Compound MC 10109: (MRI # 533): Study No. 009-275-533-9. (Unpublished study received Dec 20, 1982 under 359-708; prepared by EG & G Mason Research Institute and others, submitted by Rhone-Poulenc, Inc., Monmouth Junction, NJ; CDL:071318-A)
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00122741	Schreiner, C.; Skinner, M.; Mehlman, M.; et al. (1981) Metaphase Analysis of Rat Bone Marrow Cells Treated in vivo with Tackle 2S: Study No. 1041-80. (Unpublished study received Dec 20, 1982 under 359-708; prepared by Mobil Environmental Health Sciences Laboratory, submitted by Rhone-Poulenc, Inc., Monmouth Junction, NJ; CDL:071318-E)
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00122746	Low, L.; Meeks, J.; Mackerer, C.; et al. (1982) Pharmacokinetics and Metabolism of MC 10978 (Sodium 5-2-Chloro-4-(trifluoro-methyl) phenoxy -2-nitrobenzoate): Study No. 63281 (983-80F). Final rept. (Unpublished study received Dec 20, 1982 under 359-708; prepared by Mobil Environmental and Health Science Laboratory, submitted by Rhone-Poulenc, Inc., Monmouth Junction, NJ; CDL:071321-A)
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00122748	Fink, R.; Beavers, J.; Brown, R.; et al. (1981) Acute Oral LD50--Bobwhite Quail: 10318001: MEHSL Study No. 2021-80. Final rept.(Unpublished study received Dec 20, 1982 under 359-708; prepared by Wildlife International Ltd. and Washington College, submitted by Rhone-Poulenc, Inc., Monmouth Junction, NJ; CDL:071322-B)
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Appendix E. GENERIC DATA CALL-IN

This is a placeholder for the Generic Data Call-In (DCI) for the active ingredient, sodium acifluorfen. A complete DCI, with all pertinent instructions, will be sent to registrants under separate cover after the DCI is approved by the Office of Management and Budget. The generic data requirements are also listed in the body of the RED.

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Appendix F. PRODUCT SPECIFIC DATA CALL-IN

This is a placeholder for the product specific Data Call-In (DCI) for all sodium acifluorfen products. See attached table for a list of product-specific data requirements. A complete product-specific DCI, with all pertinent instructions, will be sent to registrants under separate cover after the DCI is approved by the Office of Management and Budget.

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Appendix G

BATCHING OF PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS

To reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing sodium acifluorfen as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity testing. Factors considered in the sorting process include the active and inert ingredients for each product (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). The Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns. Regardless of the batching, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit, or cite a single battery of six acute toxicological studies to represent all the products within that batch. The registrant may choose to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

When deciding how to meet the product-specific data requirements, registrants must follow the directions given in the Data Call-In (DCI) Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3)

or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

EPA identified ten registered products containing the active ingredient sodium acifluorfen. Of these, the following sodium acifluorfen products can be grouped together for purposes of acute toxicity testing.

EPA Reg. No.	% Active Ingredient
4-433	Sodium Acifluorfen: 0.12 Glyphosate: 0.50
71995-3	Sodium Acifluorfen: 0.12 Glyphosate: 0.50

The remaining registered products containing sodium acifluorfen cannot be grouped together for acute toxicity testing. These products are listed in the following table.

EPA Reg. No.	% Active Ingredient
7969-87	44.0
241-321	Sodium Acifluorfen: 20.93 Imazaquin: 5.61
7969-76	Sodium Acifluorfen: 13.4 Sodium Bentazon: 29.2
7969-77	Sodium Acifluorfen: 6.8 Sodium Bentazon: 33.4
7969-79	20.1
7969-80	21.4
7969-168	Sodium Acifluorfen: 9.1 Sodium Bentazon: 20.0 Sethoxydim: 14.0
7969-179	Sodium Acifluorfen: 7.47 Sodium Bentazon: 16.28 Sethoxydim: 11.15

Appendix H. LIST OF REGISTRANTS SENT THIS DATA CALL-IN

Placeholder for List of Registrants, to Be Inserted at Time of DCI Mailing

Appendix I. LIST OF ELECTRONICALLY AVAILABLE FORMS

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

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

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

Instructions

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

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

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf

8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit

www.epa.gov/pesticides/registrationkit/

Dear Registrant:

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

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
 - a. 83-3 Label Improvement Program--Storage and Disposal Statements
 - b. 84-1 Clarification of Label Improvement Program
 - c. 86-5 Standard Format for Data Submitted under FIFRA
 - d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
 - e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
 - f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
 - g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
 - h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

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

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

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

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

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

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

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

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.
4. The National Pesticide Information Center (NPIC) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPIC by telephone at (800) 858-7378 or through their website: <http://npic.orst.edu..>

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or

petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

1. Date of receipt;
2. EPA identifying number; and
3. Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.