

US EPA ARCHIVE DOCUMENT



Reregistration Eligibility Decision
for
Chlorsulfuron
May 20, 2005

**Reregistration Eligibility Decision
for
Chlorsulfuron
Case No. 0631**

Reregistration Eligibility Decision (RED) for
Chlorsulfuron

List A

Case No. 0631

Approved by: _____

Debra Edwards, Ph.D., Director
Special Review and Reregistration Division

Date: May 20, 2005

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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
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
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 Observed 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
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	Pascal, unit measuring atmosphere pressure.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
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

RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Groundwater Computer Model
SF	
SLC	Single Layer Clothing
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 the public comments on the revised human health and environmental risk assessments for chlorsulfuron and is issuing its risk management decision. The decisions outlined in this document include the reregistration eligibility decision for chlorsulfuron, but not the final tolerance reassessment decisions. Chlorsulfuron dietary and residential aggregate risks were assessed in an Agency action published in the *Federal Register* on August 14, 2002 (volume 67, number 157). This action established new tolerances for residues for chlorsulfuron in or on grass, forage and grass hay. This action also reassessed all other existing tolerances of chlorsulfuron as required by the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA). Therefore, this Reregistration Eligibility Decision document and supporting risk assessments address only the environmental and occupational risks from the use of chlorsulfuron. For information on dietary and residential risks, please refer to the earlier notice published in the *Federal Register*.

The Agency estimates that chlorsulfuron usage averaged approximately 72,000 pounds of active ingredient per year to treat over 5.5 million acres. Its largest markets in terms of total pounds active ingredient are winter wheat (90%) and spring wheat (5%). Data are not yet available for the new use on pastures and rangelands approved by EPA in 2002; however, chlorsulfuron is reportedly used in these areas by the US Department of Interior (Bureau of Land Management) to control invasive weed species.

Risks summarized in this document are those that result only from the use of chlorsulfuron. The FQPA requires that 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.” The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect at would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for chlorsulfuron and any other substances and chlorsulfuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has assumed that chlorsulfuron does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

Overall Risk Summary

The Agency's human health risk assessment for chlorsulfuron 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 chlorsulfuron or are exposed to residues after chlorsulfuron is applied.

The ecological risk assessment for chlorsulfuron shows risk quotients (RQs) less than 0.01 for terrestrial and aquatic animals, which is significantly below the Agency's level of concern. For plants, refined RQs range from 12 to 103 for non-target plants and from 18 to 693 for endangered plants. These values are significantly above the Agency's level of concern of 1.0.

Dietary and Aggregate Risks

As mentioned earlier, chlorsulfuron dietary and residential aggregate risks were assessed in an Agency action published in the *Federal Register* on August 14, 2002 (volume 67, number 157). This assessment found that the risks from chlorsulfuron aggregate exposures (food + drinking water + residential) were not of concern. For all exposure scenarios, toddlers were the most highly exposed population subgroup. For both short-term and chronic exposure, aggregated risk from food, water and residential exposures account for a small portion of the risk cup. The expected concentration of chlorsulfuron in drinking water was 41.3 ppb for surface water and 3.5 ppb for groundwater. The Agency would have become concerned only if the expected concentrations in drinking water were greater than 1,461 ppb for short-term exposure and 161 for chronic exposure. Therefore, the risks from exposure to combined chlorsulfuron residues on food, in drinking water, and in a residential setting are not of concern. For more detailed information on dietary and residential risks, please refer to the earlier notice published in the *Federal Register*.

Occupational Risk

Occupational exposure to chlorsulfuron is not of concern to the Agency for handlers using baseline (i.e., long-sleeved shirt and long pants, shoes, socks, no respiratory protection and no chemical-resistant gloves) personal protective equipment. All route-specific and combined MOEs are greater than the target MOE of 100 and therefore risks are not of concern (MOEs range between 1,000 and 56,000). Not all registered labels contain these personal protective equipment requirements at this time.

Ecological Risk

Ecological risks for aquatic and terrestrial animals are below the Agency's level of concern, however, risks to aquatic and terrestrial plants are above the level of concern. Screening-level risk

quotients (RQs) for non-target and endangered/threatened aquatic plants range from 12 to 21 for non-target aquatic plants and from 18 to 31 for endangered aquatic plants. Likewise, RQs for terrestrial plants from the use on small grains range from 18 to 103 for non-target plants and from 122 to 1552 for endangered/threatened plants. Direct exposure scenarios were not calculated, but RQs for plants and endangered plants would be significantly higher than those estimated from exposure via spray drift and/or runoff.

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 reduce the risk to listed species of potential concern until such time as the Agency refines its analysis.

Regulatory Decision

The Agency has determined that chlorsulfuron is eligible for reregistration. These products will be reregistered provided that the required product specific data, confidential statements of formula and revised labeling outlined in this document are received and accepted by EPA. Products which contain ingredients in addition to chlorsulfuron will be reregistered when all of their other active ingredients also are reregistered. 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 chlorsulfuron and lists the submitted studies that the Agency found acceptable.

The Agency believes that specific drift language amendments proposed in this RED will substantially reduce, though may not completely eliminate, the risks to non-target plants. The Agency intends to conduct an additional assessment of chlorsulfuron, and may consider other similar herbicides, at a later date. Reviewing these pesticides as a possible group will allow the Agency to assess the risks from all of these pesticides simultaneously, rather than individually on a case-by-case basis. A cohesive, comprehensive decision to protect non-target plants (including endangered and threatened species) can then be implemented more consistently for all pesticides in the group. The Agency intends to initiate this review after August 3, 2006.

The Agency is issuing this RED document for chlorsulfuron as announced in a Notice of Availability published in the *Federal Register*. This RED includes guidance and time frames for making any necessary label changes for products containing chlorsulfuron.

Summary of Mitigation Measures

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

Dietary, Residential, and Aggregate Risks:

- No label changes are necessary
- Confirmatory data are required, including a two-generation reproduction study, as discussed in the 2002 notice published in the *Federal Register* and required by this RED

Occupational Risks

- Baseline PPE must be specified on the labels for all chlorsulfuron products. Additional PPE may be required on a product-specific basis.

Ecological Risks

- Label amendments to minimize the potential for spray drift.
- Confirmatory data are required to determine possible reproductive toxicity of chlorsulfuron to plants exposed to small droplets of chlorsulfuron through drift. These data are important to refine the risk to plant reproduction, which may be more sensitive than seedling emergence or vegetative vigor.

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 2, 1996, 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.”

Risks summarized in this document are those that result only from the use of chlorsulfuron. The FQPA requires that 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. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for chlorsulfuron and any other substances and chlorsulfuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has assumed that chlorsulfuron does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

This document presents the Agency’s decision regarding the reregistration eligibility of the registered uses of chlorsulfuron. The decisions outlined in this document include the reregistration eligibility decision, but not the tolerance reassessment decisions. Chlorsulfuron dietary and residential

aggregate risks were assessed in an Agency action published in the *Federal Register* on August 14, 2002 (volume 67, number 157). This action established new tolerances for residues for chlorsulfuron in or on grass, forage and grass hay. This action also reassessed all other existing tolerances of chlorsulfuron as required by the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the FQPA. Therefore, this Reregistration Eligibility Decision (RED) document and the supporting risk assessments address only the environmental and occupational risks from the use of chlorsulfuron. For information on dietary and residential risks and the tolerance reassessments, please refer to the earlier notice published in the *Federal Register*.

In an effort to simplify the RED document, the information presented herein is summarized from more detailed information, which can be found in the technical supporting documents for chlorsulfuron referenced in this RED document. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page at www.epa.gov/pesticides, and in the Public Docket at <http://www.epa.gov/edocket> under docket #OPP-2004-0219.

This document presents the Agency's revised occupational and ecological risk assessments and the reregistration eligibility decision for chlorsulfuron. 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 chlorsulfuron. 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 chlorsulfuron are available in the Public Docket at <http://www.epa.gov/edocket> under docket #OPP-2004-0219.

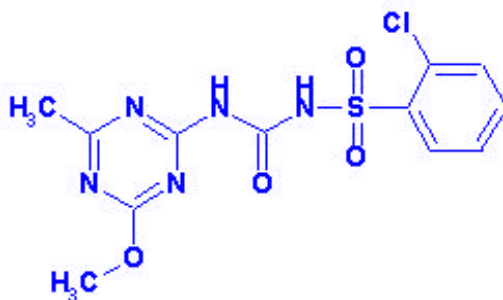
II. Chemical Overview

A. Regulatory History

Chlorsulfuron was first registered in the United States in 1982 by E.I. du Pont de Nemours and Company. It was formulated into products for use on food crops (wheat, barley, and forage grasses) and non-food crops (non-cropland grasses and tree plantings). Since 1988 additional products have been registered, mostly by DuPont. Nufarm Americas Inc. has one registered product containing chlorsulfuron (EPA Reg. # 228-375) and Lesco Inc has one registered product containing chlorsulfuron (EPA Reg. # 10404-59). In addition there are two products registered as Special Local Needs (SLN) registrations for use in Oklahoma and Texas to allow aerial application to wheat.

B. Chemical Identification

Chlorsulfuron:



Common Name:
Chlorsulfuron

Chemical Name:	2-chloro-N-[[4-methoxy-6-methyl-1,3,5-triazin-2-yl]amino]carbonyl]benzenesulfonamide
Chemical family:	Sulfonylurea
Case number:	0631
CAS registry numbers:	64902-72-3
OPP chemical code:	118601
Empirical formula:	C ₁₂ H ₁₂ ClN ₅ O ₄ S
Molecular weight:	357.7709
Trade and other names:	Glean®, Finesse®, Telar®
Basic manufacturer:	E.I. du Pont de Nemours and Company

Technical grade chlorsulfuron has a melting point of 174-178° C, octanol/water partition coefficient of 1.11, and vapor pressure of 4.6×10^{-6} mmHg at 25° C. Chlorsulfuron is soluble in water (125 ppm at 25° C).

C. Use Profile

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

Type of Pesticide: Herbicide

Mode of Herbicidal Action: Inhibits the activity of acetolactate synthase, which is an enzyme required for plant cell growth.

Summary of Use Sites:

Food and/or feed crops

- Cereal Grains
- Pasture and Rangelands

Non-food and outdoor residential

- Industrial sites
- Rights-of-way
- Turf grass

Public Health Uses: None

Target Pests: alta fescue (Kentucky 31), annual ryegrass, annual sowthistle, aster, bahiagrass, bedstraw, Bermudagrass, big bluestems, black mustard, blue grama, blue mustard, bluegrass, bluestem, bouncingbet, broadleaf plantain, broadleaf weeds, brome grass, buffalograss, bull thistle, bur beakchervil, burclover, buttercup, Canada thistle, chickweed, coast fiddleneck, common chickweed, common cinquefoil, common groundsel, common lambsquarters, common mallow, common mullein, common purslane, common ragweed, common speedwell, common sunflower, common tansy, common yarrow, conical catchfly, corn gromwell, corn spurry, cow cockle, crested wheatgrass, curly dock, cutleaf eveningprimrose, dandelion, downy brome, dyers woad, false chamomile, falseflax, fescue, fiddleneck, field pennycress, filaree, flixweed, foxtail, goldenrod, groundsel, hempnettle, henbit, hoary cress, horsetail, indiagrass, jim hill mustard, kochia, ladythumb, lambsquarters, london rocket, lovegrass, maretail, mayweed, minerslettuce, mouseear chickweed, musk thistle, needlegrass, orchardgrass, pennsylvania smartweed, perennial grasses, perennial pepperweed, perennial ryegrass, pineappleweed, poison hemlock, prickly lettuce, prostrate knotweed, prostrate pigweed, puncturevine, purslane, ragweed, red clover, redroot pigweed, redstem filaree, russian knapweed, russian thistle, ryegrass, sand bluestem, scotch thistle, scouringrush, setaria, shepherdspurse, sideoats grama, smooth brome, smooth pigweed, smutgrass, speedwell, sunflower, sweetclover,

switchgrass, tall fescue, tansymustard, tarweed, teasel, treacle mustard, tumble mustard, turkey mullein, velvetgrass, Virginia buttonweed, waterpod, western wheatgrass, wheatgrass, white clover, white cockle, whitetop, wild buckwheat, wild carrot, wild garlic, wild mustard, wild onion, wild parsnip, wild radish, wild turnip, wild violet, yellow rocket, yellow starthistle

Formulation Types Registered: Water-dispersible granules

Method and Rates of Application:

Equipment - Aircraft; boom sprayer; hand-held sprayer; handgun; low volume ground sprayer; sprayer

Method - Broadcast; low volume spray (concentrate); soil treatment; spot treatment; spray

Timing - Early postemergence; fallow; postemergence; postplant; preemergence; preplant; when needed

Use Classification: General use

A. Estimated Usage of Pesticide

This section summarizes the best estimates available for many of the pesticide uses of chlorsulfuron, based on available pesticide usage information. This information was used in the risk assessments for chlorsulfuron. 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.

The Agency estimates that chlorsulfuron usage averaged approximately 72,000 pounds of active ingredient per year to treat over 5.5 million acres. Its largest markets in terms of total pounds active ingredient are winter wheat (90%) and spring wheat (5%). The remaining usage is primarily on barley, oats, fallow fields and pasture/hay. Crops with a high percentage of the total U.S. planted acres treated include winter wheat (11%) and oats (2%), while registered sites with little or no usage include lawn and ornamental turf. Most chlorsulfuron usage is in California, Idaho, Kansas, Minnesota, North Dakota, Oklahoma, Oregon, South Dakota, Texas, and Washington. Data are not yet available for the new use on pastures and rangelands approved by EPA in 2002; however, chlorsulfuron is reportedly used in these areas by the US Department of Interior (Bureau of Land Management) to control invasive weed species.

Although chlorsulfuron is registered for residential use, this is very minor compared to the agricultural uses. Chlorsulfuron is used by homeowners as a spot treatment on lawns; however, usage data show little or no usage on lawns.

Table 1. Chlorsulfuron Estimated Usage

Crop	Average Pounds Active Ingredient Applied	Percent Crop Treated	
		Average	Maximum
Barley	1,000	1%	4%
Oats	1,000	2%	4%
Pasture and Hay, Other	1,000	0%	< 1%
Wheat, Spring	4,000	1%	3%
Wheat, Winter	65,000	11%	17%
Lawns and Ornamental Turf	< 1,000	-	-

III. Summary of Chlorsulfuron 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. Human health and ecological risk assessment documents and supporting information were used to formulate the safety finding and regulatory decision for the herbicide chlorsulfuron. These documents may be found in the Public Docket at <http://www.epa.gov/edocket> under docket #OPP-2004-0219.

Chlorsulfuron dietary and residential aggregate risks were assessed in an Agency action published in the *Federal Register* on August 14, 2002 (volume 67, number 157). This assessment found that the risks from chlorsulfuron aggregate exposures (food + drinking water + residential) were not of concern. For all exposure scenarios, toddlers were the most highly exposed population subgroup. For both short-term and chronic exposure, aggregated risk from food, drinking water and residential exposures account for a small portion of the risk cup. The expected concentration of chlorsulfuron in drinking water was 41.3 ppb for surface water and 3.5 ppb for groundwater. The Agency would have become concerned only if the expected concentration in drinking water were greater than 1,461 ppb for short-term exposure and 161 ppb for chronic exposure. Therefore, the risks from exposure to combined chlorsulfuron residues on food, in drinking water, and in a residential setting are not of concern.

This action established new tolerances for residues for chlorsulfuron in or on grass, forage and grass hay. This action also reassessed all other existing tolerances of chlorsulfuron as required by the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act

(FQPA). The August 14, 2002, *Federal Register* notice contains a detailed discussion of the dietary, residential and aggregate risks from chlorsulfuron. Therefore, this Reregistration Eligibility Decision document and the supporting risk assessments address only the environmental and occupational risks from the use of chlorsulfuron. For more detailed information on dietary and residential risks, please refer to the earlier notice published in the *Federal Register*.

As part of the public participation process for the RED, EPA released its preliminary environmental and occupational risk assessments for chlorsulfuron for public comment on September 24, 2004 (Phase 3 of the public participation process). In response to comments received and new studies submitted during Phase 3, the ecological risk assessment was updated and refined. The occupational risk assessment remained unchanged.

A. Human Health Risk Assessment

As outlined in the 2002 *Federal Register* notice for chlorsulfuron, EPA has reviewed all toxicity studies submitted to the Agency and has determined that the toxicity database is sufficient to support this reregistration eligibility decision for all currently registered uses. For specific details on the toxicological endpoints to assess dietary and residential exposure, FQPA Safety Factor, dietary, residential and aggregate risk assessments and tolerance reassessments, please see the notice published in the *Federal Register* on August 14, 2002 (volume 67, number 157).

1. Occupational Exposure and Risk

A summary of the Agency's occupational risk assessment is presented below. For detailed discussions of all aspects of the occupational risk assessment, see the technical support documents listed in Appendix C. Documents are available in the docket OPP-2004-0219 and on the internet at <http://www.epa.gov/edockets>.

Occupational workers can be exposed to a pesticide through mixing, loading, applying a pesticide, or re-entering treated sites. For chlorsulfuron, occupational handlers of chlorsulfuron 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 a margin of exposure (MOE), which is the ratio of the No Observed Adverse Effect Level (NOAEL) from an animal study with exposure. For chlorsulfuron, MOEs greater than 100 for occupational handlers are not of concern to the Agency. Based on the use pattern and site information for chlorsulfuron, exposure no longer than short-term exposure (1-28 days) is expected. Hence, intermediate-term (1 to 6 months) and long-term (greater than 6 months) occupational handler risks were not assessed. Because chlorsulfuron data show no evidence of carcinogenicity, no cancer risk assessment was conducted.

a. Toxicity

The toxicological endpoints used in assessing the risks from occupational exposures to chlorsulfuron are listed in Table 2. The assessment uses the NOAEL of 75 mg/kg/day from the rabbit developmental toxicity study as the endpoint for short-term dermal and inhalation exposure. Since no dermal or inhalation absorption data are available for chlorsulfuron, toxicity by the dermal and inhalation routes are considered to be equivalent to toxicity by the oral route of exposure (i.e., dermal absorption factor is assumed to be 100%).

Table 2. Summary of Toxicological Endpoint Used in the Human Occupational Risk Assessment for Chlorsulfuron

Assessment	Effect Level	Endpoint	Study	Absorption factor, % oral absorption
Short-term dermal	NOAEL = 75 mg/kg/day (LOAEL = 200 mg/kg/day)	Maternal toxicity, based on decreased body weight/ body-weight gain in females	Rabbit Developmental Toxicity Study (MRID 41983101)	100
Short-term inhalation				100

The acute toxicity profile for chlorsulfuron is summarized in Table 3. Chlorsulfuron is not acutely toxic via the oral and inhalation [Toxicity Category IV] routes of exposure and via the dermal [Toxicity Category III] route of exposure. Adequate data are not available for an assessment of eye or skin irritation potential or for dermal sensitization potential.

Table 3. Acute Toxicity Profile for Chlorsulfuron

Guideline	MRID	Study Type	Results	Toxicity Category
81-1	00031406	Acute Oral	LD ₅₀ = 5.5/6.3 g/kg (males and females)	IV
81-2	00083956	Acute Dermal	LD ₅₀ = 3400 mg/kg	III
81-3	00086825	Acute Inhalation	LC ₅₀ = 5.9 m/L	IV
81-4	00126597	Primary Eye Irritation ¹	Not an eye irritant	IV
81-4	45833702	Primary Eye Irritation ²	Not an eye irritant	IV
81-5	45833704	Primary Skin Irritation ²	Not a skin irritant	IV
81-6		Dermal Sensitization	No adequate study	N/A

1 MRID 00126597 is classified as unacceptable/nonguideline.

2 MRIDs 45833702 and 45833704 have not yet been formally reviewed. Results are preliminary and will be confirmed before end-use products are reregistered.

N/A Not available

b. Occupational Exposure

Agricultural Handler Exposure. EPA assessed occupational exposure to chlorsulfuron using the Pesticide Handlers Exposure Database (PHED). There were no chemical-specific data available to assess potential exposure to workers for chlorsulfuron. EPA also used standard assumptions about average body weight, work day, and daily areas treated. For adult handlers using chlorsulfuron, an average adult body weight of 70 kg was used for all exposure scenarios because all scenarios are occupational and the toxic effect was seen in both males and females. EPA derived information about use patterns, application methods, and the range of application rates used in the exposure assessment from the current chlorsulfuron labels. The application rates specified on the chlorsulfuron labels range from 0.0625 to 0.14 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 chlorsulfuron, EPA only conducted an assessment using baseline PPE.

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

- Scenario 1: Mixing and loading dry flowable for aerial application (wheat, high acreage)
- Scenario 2: Mixing and loading dry flowable for aerial application (cereal grains, low acreage)
- Scenario 3: Mixing and loading dry flowable for groundboom application (cereal grains)
- Scenario 4: Mixing and loading dry flowable for groundboom application (grass areas)
- Scenario 5: Mixing and loading dry flowable for high-pressure handwand (grass areas)
- Scenario 6: Applying sprays using aircraft (wheat)
- Scenario 7: Applying sprays using aircraft (cereal grains)
- Scenario 8: Applying sprays using groundboom (wheat)
- Scenario 9: Applying sprays using groundboom (cereal grain)
- Scenario 10: Applying sprays using high-pressure handwand (cereal grains)
- Scenario 11: Flagger for aerial application (cereal grains)

Chlorsulfuron 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. Some labels do not specify PPE, while other labels minimally require the PPE of long-sleeved shirt, long pants, shoes, socks, and gloves. This RED will address PPE needed solely based on the risk of the active ingredient chlorsulfuron.

c. Occupational Handler Risk Summary

As previously mentioned, EPA assessed exposure and risk for eleven scenarios. For chlorsulfuron, an MOE greater than 100 does not exceed the Agency's level of concern for effects from short-term exposure. Based on the use pattern and site information for chlorsulfuron, exposure no longer than short-term exposure (1-28 days) is expected. Hence, intermediate-term (1 to 6 months) and long-term (greater than 6 months) occupational handler risks were not assessed. EPA did not evaluate cancer risk to agricultural handlers because no chlorsulfuron data showed evidence of carcinogenicity.

At the baseline level of protection (i.e., long-sleeved shirt and long pants, shoes, socks, no respiratory protection and no chemical-resistant gloves) all route-specific and combined MOEs are greater than the target MOE of 100 and therefore risks are not of concern (MOEs range between 1,000 and 56,000). Therefore, risks are below EPA's level of concern and no additional levels of protection were considered in the risk assessment. Not all registered labels contain these personal protective equipment requirements at this time.

Risks for agricultural handlers are summarized in Table 4 when handlers are wearing baseline attire (long sleeve shirt, long pants, shoes, and socks).

Table 4. Summary of Chlorsulfuron Occupational Handler Risk: Baseline Clothing¹

Exposure Scenario	Application Rate (lbs a.i./Acre)	Area Treated ² (Acres/Day)	Combined (Dermal and Inhalation) Short-Term Margin of Exposure (MOE) ³
Mixer/Loader			
(1) Aerial - wheat	0.0625	1200	1000
(2) Aerial - grain		350	3600
(3) Broadcast - grain		200	6300
(4) Broadcast - grasses	0.14	80	7000
(5) High-pressure handwand (100 gallons)		10	56,000
Applicator			
(6) Aerial - wheat	0.0625	1200	14000
(7) Aerial - grain		350	47000
(8) Broadcast - wheat		200	28000
(9) Broadcast - grain	0.14	80	32000

Exposure Scenario	Application Rate (lbs a.i./Acre)	Area Treated ² (Acres/Day)	Combined (Dermal and Inhalation) Short-Term Margin of Exposure (MOE) ³
(10) High-pressure handwand (100 gallons)	0.14	10	2000
(11) Flagging aerial spray - grain applications	0.0625	350	21,000

¹ Baseline clothing includes long-sleeved shirt, long pants, socks and shoes.

² 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.

³ MOE (unitless) = NOAEL (mg/kg/day) ÷ Combined Absorbed Daily Dose (mg/kg/day), where a NOAEL of 75 mg/kg/day is used for short-term and dermal and inhalation exposures.

d. Post-Application Exposure and Risk

Because chlorsulfuron is used early in the season on crops/areas that have little worker activity, no post-application exposure is expected. Therefore, no post-application risks have been assessed.

Based on a preliminary evaluation of the eye and skin irritation studies, the Agency believes that a 12-hour Restricted Entry Interval (REI) would be sufficiently protective for chlorsulfuron. These data will be formally reviewed to confirm the toxicity category.

Chlorsulfuron also continues to be a candidate for a 4-hour REI. PR Notice 95-3 provides instructions and criteria for evaluating an end-use product to determine whether the 12-hour REI may be reduced to 4 hours. End-use products that currently contain a 4-hour REI may remain unchanged.

2. Incident Reports

Very few poisoning incidents related to the use of chlorsulfuron were reported in any of the data sources available to the Agency. Over nine years, only two incidents have been reported to the Poison Centers. Therefore, the Agency believes that the incident information for chlorsulfuron is insufficient to support any change in chlorsulfuron's use directions or Personal Protective Equipment.

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 are available in the docket OPP-2004-0219 and on the internet at <http://www.epa.gov/edockets>.

Based on public comment and new data, revisions have been made to the environmental risk assessment since the preliminary risk assessment was completed. The Agency has considered and

incorporated several of these comments, leading to a more refined risk assessment. Changes include recalculation of risk quotients for terrestrial plants based on the review of recent greenhouse studies that are more consistent with Agency guidelines than the previous studies, and the inclusion of terrestrial plant toxicity endpoints to better characterize the risk due to chlorsulfuron. However, the basic conclusions of the preliminary risk assessment of chlorsulfuron have not changed. Thus, adverse effects in nontarget aquatic and terrestrial plants are possible from the current labeled uses of chlorsulfuron modeled in this evaluation.

1. Environmental Fate and Transport

Chlorsulfuron is likely to be persistent and highly mobile in the environment. It may be transported to nontarget areas by runoff and/or spray drift. Degradation by hydrolysis appears to be the most significant mechanism for degradation of chlorsulfuron, but is only significant in acidic environments (23 day half-life at pH = 5); it is stable to hydrolysis at neutral to high pH. Degradation half-lives in soil environments range from 14 to 320 days. Additional information on the environmental fate of chlorsulfuron can be found 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 chlorsulfuron 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 (LD₅₀) or the median lethal concentration (LC₅₀). 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 5 below.

Table 5. EPA's Levels of Concern (LOCs) and Associated Risk Presumptions

RQ Value	Resulting Presumption
<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

RQ Value	Resulting Presumption
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 chlorsulfuron. Toxicity testing reported in this section does not represent all species of birds, mammals, or aquatic organisms. A few surrogate species are considered representative of all freshwater fish (2000+) and bird (680+) species in the United States. For mammals, acute studies are usually limited to Norway rat or the house mouse. Estuarine/marine testing is usually limited to a crustacean, a mollusk, and a fish. Also, neither reptiles nor amphibians are tested. The assessment of risk or hazard makes the assumption that avian and reptilian toxicities are similar. The same assumption is used for fish and amphibians. The results of these studies are summarized herein; for specific details, please see the documents referenced in Appendix C which also contain detailed discussion of toxicity studies for chlorsulfuron that have been published in public literature.

Toxicity to Aquatic Animals

Chlorsulfuron is practically nontoxic to both freshwater and estuarine/marine fish on an acute exposure basis and is slightly toxic to estuarine/marine invertebrates. Chronic exposure of rainbow trout (*Oncorhynchus mykiss*) to chlorsulfuron resulted in a No Observed Effect Concentration (NOEC) of 32 mg/L while a chronic study of waterfleas (*Daphnia magna*) resulted in a NOEC of 20 mg/L. Table 6 summarizes the most sensitive endpoints used in the risk assessment of aquatic animals.

Table 6. Summary of acute and chronic aquatic toxicity data for chlorsulfuron.

Species	Acute Toxicity			Chronic Toxicity	
	96-hr LC ₅₀ (mg/L)	48-hr EC ₅₀ (mg/L)	Acute Toxicity (MRID)	NOEC (mg/L)	Data Citation (MRID)
Rainbow trout <i>Oncorhynchus mykiss</i> (formulated product)	>250	NA	Practically Nontoxic (41976405)	32	41976405
Water flea <i>Daphnia magna</i>	NA	>370	Practically Nontoxic (00035262)	20	41976408

Species	Acute Toxicity			Chronic Toxicity	
	96-hr LC ₅₀ (mg/L)	48-hr EC ₅₀ (mg/L)	Acute Toxicity (MRID)	NOEC (mg/L)	Data Citation (MRID)
Sheepshead minnow <i>Cyprinodon variegatus</i>	>980	NA	Practically Nontoxic (41976401)	NA	NA
Mysid shrimp <i>Mysidopsis bahia</i>	89	NA	Slightly Toxic (41976402)	NA	NA

NA = Not Available

Toxicity to Aquatic Plants

Aquatic plant toxicity ranged from practically nontoxic to very highly toxic. Duckweed (*Lemna gibba*) was the most sensitive vascular aquatic plant, with an EC₅₀ of 3.5 x 10⁻⁴ mg ai/L and a NOEC of 2.4 x 10⁻⁴ mg/L. The most sensitive nonvascular aquatic plant is green algae with an EC₅₀ of 5.5x10⁻⁵ mg/L and an NOEC of 9.5x10⁻⁶ mg/L.

Table 8. Summary of Chlorsulfuron Aquatic Plant Growth Toxicity Tests

Species	Toxicity Value	Citation/MRID Author (Year)	Study Classification
<i>Pseudokirchneriella subcapitata</i>	EC ₅₀ = 0.000055 mg/L NOEC = 0.0000095 mg/L	42186801 Blasburg, J. <i>et al.</i> (1991)	Supplemental ¹
<i>Skeletonema costatum</i>	NOEC =126 mg/L EC ₅₀ >126 mg/L	45832902 R.L.Boeri <i>et al.</i> (2001)	Core
<i>Navicula pelliculosa</i>	NOEC =126 mg/L EC ₅₀ >126 mg/L	45832904 R.L.Boeri <i>et al.</i> (2001)	Core
<i>Anabaena flos-aquae</i>	NOEC = 0.236 mg/L EC ₅₀ = 0.609 mg/L	45832903 R.L.Boeri <i>et al.</i> (2001)	Core
<i>Lemna gibba</i>	NOEC = 0.00024 mg/L EC ₅₀ = 0.00035 mg/L	45832901 R.L.Boeri <i>et al.</i> (2001)	Supplemental ¹

¹ Studies conducted under static conditions. Concentrations should be renewed 3 - 4 times in 14-day test.

Because of guideline deviations, some studies are classified as supplemental and do not fulfill data requirements for plant toxicity testing. However, these studies were determined to be scientifically sound and are suitable for use in the screening-level risk assessment for non-target and endangered plants.

Toxicity to Terrestrial Animals

Chlorsulfuron is practically non-toxic to birds and mammals on an acute exposure basis and is also practically nontoxic to birds on a subacute dietary exposure basis. Following chronic exposure, bobwhite quail exhibited significant reductions in female body weight, 14-day old survivors/normal hatchlings, viable embryos/eggs set, and 14-day hatchling survival/eggs set. Chlorsulfuron is also practically nontoxic to honeybees on an acute contact basis. Table 9 provides a summary of the most sensitive ecological toxicity endpoints used in the hazard assessment of terrestrial animals for chlorsulfuron.

Table 9. Summary of Acute and Chronic Toxicity for Terrestrial Animals

Species	Acute Toxicity				Chronic Toxicity	
	LD ₅₀ ¹	Acute Oral Toxicity	5-day LC ₅₀ ¹ (ppm)	Subacute Dietary Toxicity	NOEC/LOEC (ppm)	Affected Endpoints
Northern bobwhite quail <i>Colinus virginianus</i>	NA	NA	NA	NA	174 / 961	reproduction
Mallard duck <i>Anas platyrhynchos</i>	NA	NA	>5,000	practically non-toxic	NA	NA
Honey bee <i>Apis mellifera</i>	25 µg/bee	NA	NA	NA	NA	NA
Laboratory rat <i>Rattus norvegicus</i>	5,500 ppm	practically non-toxic	NA	NA	NA	NA

¹ LD₅₀ is the dosage that causes lethality to 50% of the test animals

² LC₅₀ is the concentration that causes lethality to 50% of the test animals

NA Not available

Toxicity to Terrestrial Plants

Laboratory-derived toxicity values for terrestrial and aquatic plants are summarized Table 10. Chlorsulfuron is toxic to nontarget terrestrial plants with EC₂₅ values as low as 1.0 x 10⁻⁵ lbs a.i./A and an NOEC value of 5.4 x 10⁻⁶ lbs a.i. /A (vegetative vigor). Based on available data, the slope of the dose-response curve for chlorsulfuron varies between species, suggesting a range of expected sensitivities.

Chlorsulfuron exposure may cause visible symptoms in days or weeks and may effect plant reproduction (fruit or seed production) with limited visible symptoms. Plants that have absorbed sufficient chlorsulfuron on their foliage, in the short term, may show initial symptoms of spotting, and leaf

puckering or twisting (Felsot et al 1996). Exposed plants also may show chlorosis and discolored veins.

Chlorsulfuron symptoms may become more pronounced and lead to plant death or the plant may outgrow the symptoms in 1 to 2 months depending on the sensitivity of the plant and the magnitude of the exposure. Developmental/reproductive effects of chlorsulfuron exposure may not be apparent for three or more months after exposure. Reduced seed and fruit development resulting from chlorsulfuron exposure has been documented in canola, smartweed, soybean, and sunflower (Fletcher et al 1996). Because reproductive effects may occur in the absence of other more immediate symptoms of herbicide exposure, it is expected to be difficult to recognize chlorsulfuron toxicity in the field. The studies listed in Table 10, which serve as the basis for the risk assessment, measured lethality as the effect.

Table 10. Summary of Chlorsulfuron Toxicity Testing for Terrestrial Plants (based on most sensitive endpoints from MRIDs 46361801 and 46326801)

Plant Type	Crop	Seedling Emergence (Shoot dry weight)		Crop	Vegetative Vigor (Shoot dry weight)	
		NOEC (lbs ai/A)	EC ₂₅ (lbs ai/A)		NOEC (lbs ai/A)	EC ₂₅ (lbs ai/A)
Dicot	pea	1.8×10^{-4}	2.2×10^{-4}	sugar beet	5.4×10^{-6}	1.0×10^{-5}
Monocot	onion	4.6×10^{-5} (shoot length)	3.1×10^{-4}	onion	5.4×10^{-6}	2.2×10^{-5}

b. Environmental Exposure to Non-Target Organisms

Exposure to Aquatic Organisms

Surface water concentrations resulting from chlorsulfuron application to wheat and turf were based on a screening-level model assessment. Four scenarios were simulated: North Dakota wheat, Texas wheat, Pennsylvania turf and Florida turf. The assessment estimates application timing from the product labels and uses a range of application dates. Detailed descriptions and model inputs can be found in the supporting documents listed in Appendix C.

Because of its persistence, chlorsulfuron concentrations did not diminish over the simulation period, causing chronic and peak concentrations to be nearly the same for all scenarios tested. Table 11 presents the peak and average concentrations of chlorsulfuron that the model predicts for a simulated farm pond.

Table 11. Summary of Modeled Ecological Concentrations of Chlorsulfuron¹

Scenario	Formulation and Application	peak (ppb)	96 hr (ppb)	21-day (ppb)	60-day (ppb)	90-day (ppb)	yearly (ppb)
ND wheat	Glean® @ 0.023 lb/A	4.2	4.2	4.2	4.2	4.2	4.2
TX wheat	Glean® @ 0.023 lb/A	6.3	6.3	6.3	6.3	6.3	6.3
PA turf	Telar® @ 0.0625 lb/A	5.9	5.9	5.9	5.9	5.9	5.8
FL turf	Telar® @ 0.0625 lb/A	9.5	9.5	9.5	9.5	9.5	9.5

¹ Based on one application per season at maximum labeled rate applied aerially

Exposure to Terrestrial Organisms

Exposure to Animals

The Agency assessed exposure to terrestrial organisms by first predicting the amount of chlorsulfuron 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, Hoeger, Kenaga, et al.). EPA modeled the maximum and mean residues of chlorsulfuron in various food items based on a single application at 0.0625 lbs a.i./A. EPA's estimates of chlorsulfuron residues on various wild animal food items are summarized in Table 12. No monitoring data were available to use to estimate the terrestrial EECs.

Table 12. EECs of Chlorsulfuron on Wild Animal Food Items

Food Item	EEC (ppm)	
	Predicted Maximum Residue	Predicted Mean Residue
Short grass	15.00	5.31
Tall grass	6.88	2.25
Broadleaf/forage plants and small insects ¹	8.44	2.81
Seeds	0.94	0.44

¹ Surface to volume ratios of broadleaf plants and insects are similar; therefore, EPA assumes that they contain similar residue levels.

Exposure to Plants

A refined spray drift assessment was performed to better characterize the potential risk to non-target plants at varying distances from a chlorsulfuron-treated field. This assessment considered both ground and aerial application, maximum application rates for pasture and rangeland and typical application rates for wheat, and a variety of wind speeds and droplet size spectra.

c. Environmental Risk to Non-Target Organisms

As previously mentioned, EPA compares toxicity endpoints from ecological toxicity studies to EECs for chlorsulfuron and calculates risk quotients (RQs) to evaluate the potential risk to nontarget organisms. These RQs are then compared to the Agency's levels of concern (LOCs). The chlorsulfuron RQs show that acute LOCs are not exceeded for terrestrial or aquatic animals. Chronic LOCs are also not exceeded for terrestrial or aquatic animals. EPA does have risk concerns for both terrestrial and aquatic non-target plants.

Risk to Aquatic Organisms

Risk to Freshwater and Estuarine/Marine Fish. Acute and chronic risk quotients do not exceed the LOC for freshwater or marine/estuarine fish. With acute toxicity values (LC_{50} s) greater than 50 ppm and EECs less than 10 ppb, chlorsulfuron is not expected to pose an acute risk to aquatic animal species. Chronic toxicity tests result in NOECs that are greater than or equal to 20 ppm. Therefore, chlorsulfuron is expected to present low acute or chronic risks to freshwater and marine/estuarine fish. Both the acute and the chronic risk quotients for freshwater and estuarine/marine fish are less than 0.01, which is significantly below than the Agency's LOC.

Risk to Invertebrates. Acute and chronic risk quotients do not exceed the LOC for freshwater or marine/estuarine invertebrates. With acute toxicity values (LC_{50} s) greater than 50 ppm and EECs less than 10 ppb, chlorsulfuron is not expected to pose an acute risk to aquatic animal species. Chronic toxicity tests result in NOECs that are greater than or equal to 20 ppm. Therefore, chlorsulfuron is expected to present low acute or chronic risks to freshwater and marine/estuarine invertebrates. Both the acute and the chronic risk quotients for freshwater and estuarine/marine invertebrates are less than 0.01, which is significantly less than the Agency's LOC.

Risk to Non-target Aquatic Plants. Screening-level RQs for non-target and endangered/threatened aquatic plants are reported in Table 13. The Agency's LOC for non-target aquatic plants is exceeded in all modeled scenarios. The assessment uses the EC_{50} to assess risk to aquatic plants, since they generally have a shorter recovery period from potential population effects because their reproductive cycles are shorter than terrestrial plants. At current maximum application rates used on wheat, non-target aquatic plant RQs range from 12 to 16 and from 18 to 23 for endangered aquatic plant species. For use on turf (at the same rate as rangeland), RQs range from 17 to 21 for non-target aquatic plants and from 26 to 31 for endangered aquatic plants.

Table 13. Risk Quotients to Aquatic Plants from Runoff (LOC is 1.0)

Crop Scenario: application	Aquatic Plants ¹	
	Non-target	Endangered
Turf: ground	17 - 21	26 - 31

Crop Scenario: application	Aquatic Plants ¹	
	Non-target	Endangered
Grains: ground	12 - 16	18 - 23
Grains: aerial		
Past./Range: ground	Not Assessed	
Past./Range: aerial	Not Assessed	
Non-crop (industrial) ground	Not Assessed	

¹ PRZM/EXAMS was used to estimate peak Estimated Environmental Concentrations (EECs).

Risk to Terrestrial Organisms

Risk to Birds

With acute toxicity values (LC₅₀s) greater than 5,000 ppm and relatively low EECs, chlorsulfuron is not expected to pose an acute risk to avian species. The NOEC for avian reproduction (174 mg/kg/day) is more than an order of magnitude above the highest EEC. Both the acute and the chronic RQs for birds are less than 0.01, which is significantly less than the Agency's level of concern.

Risk to Mammals

Because of low acute toxicity to laboratory rats, RQs do not exceed the LOCs for mammals for acute risks. Both the acute RQs for mammalian species is less than 0.01, which is significantly below the Agency's level of concern. No data are currently available to assess the chronic risk to mammalian species, however, the registrant has recently submitted a two-generation reproduction study to the Agency for review. Preliminary results indicate that chronic risks are expected to be not of concern; therefore, these data are considered confirmatory.

Risk to Insects

RQ are not calculated for terrestrial insects; however, based on an acute contact study, chlorsulfuron is classified as practically nontoxic to honeybees. Therefore, the Agency expects direct risk to insects to be minimal.

Risk to Terrestrial Non-target Plants

The Agency's screening-level risk assessment for terrestrial non-target plants does not address direct application to plants, as this risk is assumed to be inevitable with the use of an herbicide. The Agency conducted a refined assessment of the risk to terrestrial plants from the use of chlorsulfuron. Whereas the initial assessment includes RQs calculated from the most sensitive EC₂₅ from guideline laboratory plant toxicity tests, the refined assessment looks at a range of effect levels (EC₁₀ to EC₉₀) for all the plants tested that might occur from exposure to spray drift only. The EC₂₅ is considered more appropriate for assessing effects to terrestrial plant populations, which typically have a longer

reproductive cycle than aquatic plants, and thus adverse effects on populations may require a greater recovery period. Additionally, because the actual distribution of plant responses cannot be assessed from the 10 species required in the guideline studies, conservative assumptions are used in the risk assessment. The risk to endangered species is estimated using the NOEC, a more sensitive endpoint than the EC_{25} used to estimate acute risk to non-listed plant species.

The results of this assessment indicate that while the extent of potential risk depends on the application rates and conditions chosen, almost all of the scenarios indicate the potential for adverse effects to plants hundreds of feet from chlorsulfuron-treated fields. The assessment focuses on risk due to exposures from off-target drift or runoff from four scenarios:

1. Off-target drift and runoff of chlorsulfuron from a one acre application site to an adjacent one acre terrestrial area using seedling emergence toxicity data to calculate risk quotients (Table 14), based on a single application of chlorsulfuron.
2. Off-target drift and no runoff of chlorsulfuron from a one acre application site to an adjacent one acre terrestrial area using vegetative vigor toxicity data to calculate risk quotients (Table 14), based on a single application of chlorsulfuron.
3. Off-target drift and runoff of chlorsulfuron from a ten acre application site to an adjacent one acre semi-aquatic area (wetland) using seedling emergence toxicity data to calculate risk quotients (Table 14), based on a single application of chlorsulfuron.
4. Use of contaminated irrigation water (groundwater or surface water inadvertently containing chlorsulfuron) using the vegetative vigor toxicity data to calculate risk quotients (Table 15), based on a single irrigation event.

RQs for ground application of chlorsulfuron to small grains (wheat, barley, and oats), pasture and rangeland range from 3 to 23 for non-target terrestrial plants and from 21 to 43 for endangered/threatened terrestrial plants. RQs for aerial application to small grains, pasture and rangeland range from 4 to 115 for non-target plants and from 28 to 213 for endangered/threatened plants. At the current maximum application rate of chlorsulfuron to small grains, rangeland and pasture, level of concerns are exceeded for non-target and endangered/threatened terrestrial plants. The application of chlorsulfuron to industrial areas results in the highest calculated RQs. Direct exposure scenarios were not calculated, but RQs for plants and endangered plants would be significantly higher than those estimated from exposure via spray drift and/or runoff.

Screening-level RQs for semi-aquatic areas (wetlands) resulting from off-target drift (concentrations estimated at the edge of the treated field) and runoff of chlorsulfuron from the application site (ten acres to one acre) are presented in Table 14. The RQs range from 122 to 1552 for endangered plants and from 18 to 230 for other non-target plants.

Table 14. Risk Quotients to Plants from Drift and/or Runoff (LOC is 1.0)

Crop Scenario: application	Terrestrial Plants ¹ RQs (drift and runoff)		Terrestrial Plants ² RQs (drift and no runoff)		Semi-aquatic Plants ³ RQs (drift and runoff)	
	Non-target	Endangered	Non-target	Endangered	Non-target ⁴	Endangered ⁵
Turf: ground	2 - 4	16 - 30	12 - 23	22 - 43	20 - 38	133 - 255
Grains: ground	3 - 4	21 - 30	16 - 23	30 - 43	26 - 38	177 - 255
Grains: aerial	4 - 6	28 - 40	80 - 115	148 - 213	18 - 26	122 - 175
Past./Range: ground	3 - 12	21 - 82	16 - 63	30 - 116	26 - 103	177 - 693
Past./Range: aerial	4 - 16	28 - 109	80 - 313	148 - 580	18 - 71	122 - 476
Non-crop (industrial) ground	4 - 27	40 - 83	12 - 140	22 - 259	38 - 230	255 - 1552

¹ Runoff modeled from one-acre application site to adjacent one-acre terrestrial area, using seedling emergence toxicity data based on single application

² Drift from one-acre application site to one-acre adjacent terrestrial area, using vegetative vigor toxicity data based on single application

³ Runoff modeled from ten-acre application site to one-acre adjacent wetland, using seedling emergence toxicity data based on a single application

⁴ EEC/EC₅₀

⁵ EEC/NOEC

These calculations suggest that non-target plants may be adversely affected through the use of irrigation water containing chlorsulfuron. Results of modeling suggest that using surface water for irrigation may increase the risk over groundwater irrigation because chlorsulfuron is more likely to contaminate surface water than it is groundwater.

Additionally, this screening-level assessment indicates that irrigation water may inadvertently contain high enough levels of chlorsulfuron to adversely impact sensitive agricultural crops (such as soybeans, sugarbeets, onions, etc.) if they are grown in fields that are irrigated with water containing chlorsulfuron. RQs for sensitive crops within irrigated fields range from 36 for irrigation using groundwater to 136 for using surface water to irrigate fields. In regions where chlorsulfuron has been used historically, agricultural crops grown in fields irrigated with groundwater or surface water containing chlorsulfuron could possibly be adversely affected. This assessment assumed that no endangered plants occur within irrigated fields.

Table 15. Risk Quotients for Non-target Plants Exposed to Irrigation Water¹

Location	EEC (lb ai/A) ²	Risk Quotients	
		Non-endangered Plants ³ (EEC/EC ₂₅)	Endangered Plants (EEC/NOEC)
Wetland and terrestrial areas adjacent to irrigated fields ⁴	Groundwater: 1.8×10^{-5} Surface water: 6.8×10^{-5}	Groundwater: 2 Surface water: 7	Groundwater: 3 Surface water: 13
Within the irrigated field ⁵	Groundwater: 3.6×10^{-4} Surface water: 1.4×10^{-3}	Groundwater: 36 Surface water: 136	N/A ⁶

¹ Irrigation water contains 1.6 ppb chlorsulfuron in groundwater or 6.0 ppb in surface water.

² Estimated Environmental Concentration assuming one inch of irrigation water is applied to the target field.

³ Non-target plants in areas adjacent to the irrigated field or sensitive agricultural crops within irrigated field.

⁴ Assumes 5% drift of irrigation water containing chlorsulfuron and no runoff of irrigation water.

⁵ Irrigation water applied directly to agricultural crops that may be sensitive to chlorsulfuron.

⁶ It is assumed that there are no endangered plants within agricultural fields that are irrigated.

d. Endangered/Threatened Species

Available data indicate that chlorsulfuron does not exceed the LOCs for endangered/threatened terrestrial or aquatic animals. However, the screening-level risk assessment for endangered species indicates that chlorsulfuron exceeds the acute LOC for endangered and threatened terrestrial and vascular aquatic plants. Thus, the Agency considers this to be indicative of a potential for adverse effects to those listed species that rely either on a specific plant species (plant species obligate) or multiple plant species (plant dependant) for some important aspect of their life cycle. Further analysis regarding the overlap of individual species with each use site is required prior to determining the likelihood of potential impact to listed species.

Chlorsulfuron was included in the small grains cluster consultation with the Fish and Wildlife Service (FWS) in 1983. As chlorsulfuron's risks were assigned a "no effect" determination with regard to aquatic and terrestrial animals, Reasonable and Prudent Alternatives and Reasonable and Prudent Measures were not provided for this pesticide. Risks to endangered plants were not considered in this Biological Opinion. The FWS completed the rangeland cluster Biological Opinion in December 1984. Although chlorsulfuron was included in this Opinion, it did not consider endangered plants nor the potential indirect effects of chlorsulfuron on listed animals.

Action Area

For listed species assessment purposes, the action area is considered to be the area affected directly or indirectly by the Federal action and not merely the immediate area involved in the action. At the initial screening-level, the risk assessment considers broadly described taxonomic groups and so conservatively assumes that listed species within those broad groups are co-located with the pesticide

treatment area. This means that terrestrial plants and wildlife are assumed to be located on or adjacent to the treated site and aquatic organisms are assumed to be located in a surface water body adjacent to the treated site. The assessment also assumes that the listed species are located within an assumed area, which has the relatively highest potential exposure to the pesticide, and that exposures are likely to decrease with distance from the treatment area.

If the assumptions associated with the screening-level action area result in RQs that are below the listed species LOCs, a "no effect" determination conclusion is made with respect to listed species in that taxa, and no further refinement of the action area is necessary. Furthermore, RQs below the listed species LOCs for a given taxonomic group indicate no concern for indirect effects upon listed species that depend upon the taxonomic group covered by the RQ as a resource. However, when the screening assumptions lead to RQs in excess of the listed species' LOCs for a given taxonomic group, a potential for a "may affect" conclusion exists and may be associated with direct effects on listed species belonging to that taxonomic group or may extend to indirect effects upon listed species that depend upon that taxonomic group as a resource. In such cases, additional information on the biology of listed species, the locations of these species, and the locations of use sites could be considered along with available information on the fate and transport properties of the pesticide to determine the extent to which screening assumptions regarding an action area apply to a particular listed organism. These subsequent refinement steps could consider how this information would impact the action area for a particular listed organism and may potentially include areas of exposure that are downwind and downstream of the pesticide use site.

Taxonomic Groups Potentially at Risk

The RQs calculated based on the ratio of estimated environmental concentrations (EECs) to toxicity endpoints, in this case the NOEC from plant toxicity studies, indicate potential to affect endangered plants should exposure to chlorsulfuron through spray drift or runoff occur.

Should estimated exposure levels occur in proximity to listed resources, the available screening-level information suggests a potential concern for direct effects on listed plant species associated with use of chlorsulfuron, particularly wheat and pasture/rangeland. This Level I screening assessment is based on the initial assumption that listed species within the taxonomic groups of concern are actually present in areas for which the estimated exposure levels used for RQ calculation can be expected to occur. A specific determination of "may affect" for any RQ in excess of listed species LOCs cannot be made until a determination of the co-occurrence of the listed species with the action area has been determined.

Indirect Effects Analysis

Because plant RQs are above non-endangered species LOCs, the Agency considers this to be indicative of a potential for effects to those listed species that rely either on a specific plant species

(plant species obligate) or multiple plant species (plant dependant) for some important aspect of their life cycle. The extent to which the use of chlorsulfuron on wheat and pasture/rangeland will indirectly affect listed animal species will require identification of listed species that co-occur in areas of chlorsulfuron use and an evaluation of critical habitat as described below. Because of the national extent of the labeled uses of chlorsulfuron, we cannot preclude the possibility of a “may affect” for all listed animals, given the current extent of analysis of exposure, effects, and co-occurrence of listed species and areas of use.

Critical Habitat

The screening-level risk assessment has identified potential concerns for indirect effects on listed species for those organisms dependant upon plants sensitive to chlorsulfuron. In light of the potential for indirect effects, the next step for the Agency and the Service(s) is to identify which listed species and critical habitat are potentially implicated. Analytically, the identification of such species and critical habitat can occur in either of two ways. First, the agencies could determine whether the action area overlaps critical habitat or the occupied range of any listed species. If so, the Agency would examine whether the pesticide's potential impacts on non-endangered species would affect the listed species indirectly, or directly affect a constituent element of the critical habitat. Alternatively, the agencies could determine which listed species depend on biological resources, or have constituent elements that fall into the taxa, that may be directly or indirectly impacted by the pesticide. Then the Agency would determine whether use of the pesticide overlaps the critical habitat or the occupied range of those listed species. At present, the information reviewed by the Agency does not permit use of either analytical approach to make a definitive identification of species that are potentially impacted indirectly or critical habitats that is potentially impacted directly by the use of the pesticide. The Agency and the Service(s) will work together to conduct the necessary analysis.

This screening-level risk assessment for critical habitat provides a listing of potential biological features that, if they are constituent elements of one or more critical habitats, would be of potential concern. These correspond to the taxa identified above as being of potential concern for indirect effects and include birds, mammals, terrestrial-phase amphibians, reptiles, fish, aquatic invertebrates and aquatic-phase amphibians. This list should serve as an initial step in problem formulation for further assessment of critical habitat impacts outlined above.

Co-occurrence Analysis

The goal of the analysis for co-location is to determine whether sites of pesticide use are geographically associated with known locations of listed species. At the screening-level, this analysis is accomplished using the Agency's LOCATES database. The database uses location information for listed species at the county level and compares it to agricultural census data for crop production at the same county level of resolution. The product is a listing of federally listed species that are located within states known to produce the crop upon which the pesticide will be used. Because the Level I screening

assessment considers both direct and indirect effects across generic taxonomic groupings, it is not possible to exclude any taxonomic group from a LOCATES database run for a screening risk assessment.

Although use data is available, the labeled wheat usage allows for nationwide application. Additionally, the LOCATES database does not have a pasture/rangeland co-occurrence search capacity at the present time. As noted previously, at the screening-level, it is not possible to evaluate all the potential indirect effects that could impact endangered animals, because the potential biological significance of the interdependency between directly affected plants and potentially adversely affected animals requires species-specific analysis. Therefore, we cannot preclude the possibility of a “may effect” designation all listed animals at the current extent of this analysis.

e. Ecological Incident Reports

Results from a number of field studies, greenhouse studies and laboratory studies suggest that chlorsulfuron applied at labeled rates may result in high risk to non-target plants grown in the vicinity of application sites. Several researchers have concluded that these studies indicate that small quantities of chlorsulfuron change plant reproduction without altering vegetative growth. If the effect of chlorsulfuron on cherry trees is characteristic of other plant species, spray drift may severely reduce both the crop yields and fruit development on plants, the keystone component of the habitat and food web for wildlife. Plant reproductive processes may be more sensitive to chlorsulfuron than growth effects. Low levels of chlorsulfuron appear to adversely influence plant reproduction, which is not characteristic of many common herbicides. For a complete discussion of the field and greenhouse studies, please see the document entitled, “Revised Environmental Fate and Ecological Risk Assessment of Chlorsulfuron,” listed in Appendix C.

There is uncertainty regarding the extent to which the incident data can be associated with chlorsulfuron alone. Additionally, while the risks to non-target plants from direct application of chlorsulfuron have not been estimated quantitatively in this risk assessment, RQs for direct application to plants are expected to be higher than those estimated for indirect exposure through runoff and/or drift.

There are five non-target plant incidents that may be linked to offsite drift of chlorsulfuron in the Agency’s Ecological Incident Information System (EIIS) database. The most recent of these incidents (incident #I013884-012) occurred in June 1998 in Benton County, WA, where an orchard bound on three sides by “dry land” wheat reported four years of reduced Bing cherry production. The Washington State Department of Agriculture investigated the allegation, but the cause remains unknown and the investigation was not continued. Chlorsulfuron was one of the herbicides used on the wheat fields.

While not in the Agency's EIS database, an alleged incident of chlorsulfuron drift was investigated by Fletcher (1991). An orchard suffered several years of reduce yield in the late 1980s in an area proximal to wheat farms at Horse Heaven Hills, where herbicides were regularly used. While the reduced yields and plant damage were not noted before the use of chlorsulfuron in the area, the investigation results were inconclusive.

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of Federal Insecticide, Fungicide and Rodenticide Act (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 chlorsulfuron 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 chlorsulfuron as well as a chlorsulfuron-specific dietary risk assessment. Based on a review of these data and public comments on the Agency's assessments for the active ingredient chlorsulfuron, EPA has sufficient information on the human health and ecological effects of chlorsulfuron to make decisions as part of the tolerance reassessment process under Federal Food, Drug and Cosmetic Act (FFDCA) and reregistration under FIFRA, as amended by the Food Quality Protection Act (FQPA). The Agency has determined that currently registered uses of chlorsulfuron will not pose unreasonable risks or adverse effects to humans or the environment if the risk mitigation measures and label changes outlined in the RED are implemented. The Agency has determined that chlorsulfuron is eligible for reregistration. These products will be reregistered provided that the required product specific data, confidential statements of formula and revised labeling outlined in this document are received and accepted by EPA. Products which contain ingredients in addition to chlorsulfuron will be reregistered when all of their other active ingredients also are reregistered. 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 chlorsulfuron and lists the submitted studies that the Agency found acceptable.

The Agency believes that specific drift language amendments proposed in this RED will substantially reduce, though may not completely eliminate, the risks to non-target plants. The Agency intends to conduct an additional assessment of chlorsulfuron, and may consider other similar herbicides, at a later date. Reviewing these pesticides as a possible group will allow the Agency to assess the risks from all of these pesticides simultaneously, rather than individually on a case-by-case basis. A cohesive, comprehensive decision to protect non-target plants (including endangered and threatened

species) can then be implemented more consistently for all pesticides in the group. The Agency intends to initiate this review after August 3, 2006.

B. Summary of Public Comments

When making its reregistration decision, the Agency took into account all comments received during Phase 3 of the public participation process for reregistration. These comments in their entirety are available in the public docket, under docket number OPP-2004-0219. DuPont, the technical registrant for chlorsulfuron, and several interested growers and grower groups submitted comments. The Agency has prepared responses to each of these comments, which are also available from Public Docket at <http://www.epa.gov/edocket> under docket #OPP-2004-0219. A summary of selected comments is provided below.

- Benefits information was provided by several users and user groups. Although the Agency not completed a comprehensive benefits assessment at this time, it has considered this information in formulating this RED.
- DuPont submitted risk assessments for several products which compete with chlorsulfuron in the cereal and fallow herbicide market. The purpose of the risk assessment for the chlorsulfuron RED is not to compare the environmental fate properties of chlorsulfuron to its alternatives, but rather to assess potential risks from the use of chlorsulfuron.
- DuPont also submitted extensive comments on some of the data and assumptions underlying the ecological risk assessment. The Agency considered this information, and incorporated it where applicable (such as using new plant toxicity data). A detailed response is available in the docket.

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 chlorsulfuron. 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. For purposes of tolerance reassessment and determination of reregistration eligibility of chlorsulfuron, EPA is assuming that chlorsulfuron does not share a common mechanism of toxicity with other compounds.

Chlorsulfuron dietary and residential aggregate risks were assessed in an Agency action published in the *Federal Register* on August 14, 2002 (volume 67, number 157). This action established new tolerances for residues for chlorsulfuron in or on grass, forage and grass hay. This action also reassessed all other existing tolerances of chlorsulfuron as required by the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA.

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, chlorsulfuron may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

c. Tolerance Summary

As mentioned earlier, chlorsulfuron dietary and residential aggregate risks were assessed in an Agency action published in the *Federal Register* on August 14, 2002 (volume 67, number 157). This action established new tolerances for residues for chlorsulfuron in or on grass, forage and grass hay. This action also reassessed all other existing tolerances of chlorsulfuron as required by the FFDCA, as amended by FQPA. This notice is available on the internet at:
<http://www.epa.gov/EPA-PEST/2002/August/Day-14/p20229.htm>.

1. Benefits Discussion

EPA believes that plant growth regulators and sulfonylureas are likely alternatives for chlorsulfuron. Although 2,4-D or metsulfuron are the most likely alternatives; there are several other plant growth regulators and sulfonylurea herbicides, both single and multiple active ingredient products, that may also be used. The treatment cost of alternatives does not appear to be significantly different from the treatment cost of chlorsulfuron or chlorsulfuron combined with metsulfuron. Therefore, pesticide choice by growers to control weeds would also depend on such factors as the product

efficacy, method of application, and other application costs; however, these factors were not quantified in this analysis.

Table 16 provides the percent of winter wheat acres treated by chlorsulfuron and four other alternative herbicides. The total number of acres harvested in the surveyed states were 22.2 million.

Table 16. Percent of Winter Wheat Treated with Herbicides in U.S., 2002

Herbicide	Percent US Acres Treated	Percent OK Acres Treated	Percent KS Acres Treated
2,4-D	13	8	6
Metsulfuron-methyl	13	19	16
Chlorsulfuron	10	18	18
Sulfosulfuron	6	13	3
Tribenuron-methyl	5	NA	NA

Source: NASS Agricultural Chemical Usage, Field Crop Summary 2002, May 2003

NA = Not Available

Chlorsulfuron (Glean®) is registered for control of broadleaf weeds and a few grass weeds. In Oklahoma and Kansas, chlorsulfuron commonly targets: wild mustard, wild buckwheat, redroot pigweed, kochia and henbit (EPA proprietary data). Of these weeds, chlorsulfuron claims partial control of kochia and wild buckwheat. The Crop Profile for Winter Wheat in Kansas mentions henbit, wild buckwheat, and kochia as common weeds in wheat fields (Crop Profile for Winter Wheat in Kansas, 1999).

Chlorsulfuron is often applied in combination with metsulfuron-methyl as the product, Finesse®. Mesosulfuron-methyl, registered in 2004 for use on wheat, has some limited overlap with chlorsulfuron. This herbicide is registered for control of grass weeds, but does not target some broadleaf weeds, such as wild mustard, henbit and redroot pigweed.

Based on comments received during the RED process, discussions with extension specialists, and its own analysis, the Agency believes that growth regulators and sulfonyleureas are likely alternatives for chlorsulfuron. Of the alternatives, EPA believes 2,4-D or metsulfuron-methyl are most commonly used. There are a number of other growth regulators and sulfonyleurea herbicides, as well as combination products, available that may also be used. The cost of alternatives does not appear to be significantly different from the cost of chlorsulfuron and chlorsulfuron combined with metsulfuron-methyl.

D. Regulatory Rationale

EPA has determined that certain mitigation measures and label amendments are necessary for the currently registered uses of chlorsulfuron to be eligible for reregistration. The following is a summary of the rationale for managing occupational and ecological risks associated with the current use of chlorsulfuron. 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, Homeowner and Aggregate Mitigation

Because these risks were addressed during the tolerance reassessment of chlorsulfuron, no further mitigation of dietary, homeowner, or aggregate risks is needed at this time.

b. Occupational Risk Mitigation

Agricultural Handler Risk

There are no risks of concern for agricultural handlers as summarized in Table 4. When handlers are wearing baseline attire (long sleeve shirt, long pants, shoes, and socks), MOEs are greater than 100 and are therefore not of concern. Chlorsulfuron labels will be amended to explicitly state that all handlers must wear baseline attire.

Post-Application Worker Risk

Because chlorsulfuron is used early in the season on crops/areas that have little worker activity, no post-application exposure is expected. Therefore, no post-application risks have been assessed.

Based on preliminary eye and skin irritation studies, the Agency believes that a 12-hour Restricted Entry Interval (REI) would be sufficiently protective for chlorsulfuron. These preliminary data will be formally reviewed to confirm the toxicity category before placing the 12-hour REI on current labels.

Chlorsulfuron also continues to be a candidate for a 4-hour REI. PR Notice 95-3 provides instructions and criteria for evaluating an end-use product to determine whether the 12-hour REI may be reduced to 4 hours. End-use products that currently contain a 4-hour REI may remain unchanged.

2. Environmental Risk Mitigation

Terrestrial and Aquatic Animal Risk

EPA has no concerns about the risk to terrestrial or aquatic animals potentially exposed to chlorsulfuron via runoff, so no mitigation is necessary.

Insect Risk

Risk quotients are not calculated for terrestrial insects; however, based on an acute contact study, chlorsulfuron is classified as practically nontoxic to honeybees. Therefore, direct risk to insects is expected to be minimal.

Non-target Plant Risk

As mentioned earlier, screening-level risk quotients (RQs) for non-target and endangered/threatened aquatic plants range from 12 to 21 for non-target aquatic plants and from 18 to 31 for endangered aquatic plants. Likewise, RQs for terrestrial plants from the use on small grains range from 2 to 313 for non-target plants and from 16 to 1552 for endangered or threatened plants. Direct exposure scenarios were not calculated, but RQs for plants and endangered plants would be significantly higher than those estimated from exposure via spray drift and/or runoff.

Because chlorsulfuron is an herbicide and may therefore harm non-target plants exposed via drift, the Agency requires that chlorsulfuron be applied in a manner that minimizes spray drift. Strict use restrictions to minimize spray drift will be placed on the labels for all chlorsulfuron products. This language will include:

- Application must be made using a Coarse or Very Coarse droplet spectrum (ASAE S572)
- Prohibit applications into temperature inversions
- Allow only one application per growing season, except for industrial use sites where total pounds applied per year may not exceed 0.125 lb ai/A (based on comments submitted by Pacific Gas and Electric Company)
- Restrictions on pressure settings
- Drift advisory language specifying further parameters that may be adjusted to reduce drift
- Restrict distance between outer-most operating nozzles on the boom and wingspan or rotor width
- Restrict application to industrial use sites to ground application only, except for rights-of-way where application by helicopter is permitted
- Limit application to fine turf and ornamentals to spot treatment only where the area being treated does not exceed 240 square yards per acre. This mitigation will ensure

that the application rate per acre to fine turf is no higher than the rate for unimproved industrial turf.

In addition, the technical registrant has agreed to conduct a special study to evaluate the risk to non-target plants exposed to small droplets of chlorsulfuron. The Agency is concerned with the potential for adverse reproductive effects of chlorsulfuron on off-site non-target plant species. Such effects can have consequences to plant populations and community dynamics, as well as to higher trophic-level organisms. Studies performed by Fletcher et al. (1993, 1995, 1996) and Bhatti et al. (1995) demonstrate that extremely low concentrations (e.g. 1/1000th of label rates) of chlorsulfuron cause significant (40-99%) reductions in seed production in a variety of plant species. The registrant has agreed to conduct a special study to determine whether these studies are indicative of effects from exposure reasonably expected due to spray drift. The Agency will work with the registrant to develop appropriate protocols with which this uncertainty can be minimized. The protocols should build on previous work (e.g. similar phenologic timing of application) and include ecologically relevant plant species. EPA will evaluate risks to non-target plants, and any additional mitigation, after these studies are repeated and acceptable data have been submitted and reviewed.

The Agency believes that specific drift language amendments proposed in this RED will substantially reduce, though may not completely eliminate, the risks to non-target plants. The Agency intends to conduct an additional assessment of chlorsulfuron, and may consider other similar herbicides, at a later date. Reviewing these pesticides as a possible group will allow the Agency to assess the risks from all of these pesticides simultaneously, rather than individually on a case-by-case basis. A cohesive, comprehensive decision to protect non-target plants (including endangered and threatened species) can then be implemented more consistently for all pesticides in the group. The Agency intends to initiate this review after August 3, 2006.

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 chlorsulfuron. For specific labeling statements, refer to Section V of this document

a. Endangered Species Statement

Available data indicate that chlorsulfuron does not exceed the LOCs for endangered/threatened terrestrial or aquatic animals. However, the screening-level risk assessment for endangered species indicates that chlorsulfuron exceeds the acute LOC for endangered and threatened terrestrial and vascular aquatic plants. Thus, the Agency considers this to be indicative of a potential for adverse effects to those listed species that rely either on a specific plant species (plant species obligate) or multiple plant species (plant dependant) for some important aspect of their life cycle. Further analysis

regarding the overlap of individual species with each use site is required prior to determining the likelihood of potential impact to listed species.

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 reduce the risk to listed species of potential concern until such time as the Agency refines its analysis.

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

V. What Registrants Need to Do

The Agency has determined that chlorsulfuron is eligible for reregistration provided that: (i) additional data are submitted to confirm this decision; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants will be required to amend their product labeling to incorporate the label statements set forth in the Label Summary Table in Section C below. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring label amendments, product specific data and additional generic (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product specific data, the registrant will have eight months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Below are tables of additional generic data and label amendments that the Agency intends to require for chlorsulfuron to be eligible for reregistration.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of chlorsulfuron for the above eligible uses has been reviewed and determined to be substantially complete. However, the data listed below are necessary to confirm the reregistration eligibility decision documented in this RED.

Table 16. Data Requirements for the Reregistration Eligibility Decision on Chlorsulfuron

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
UV/Visible Absorption	830.7050	None
21-Day Dermal Toxicity	870.3200	82-2
90-day Inhalation Toxicity	870.3465	82-4
Two-Generation Reproduction	870.3800	83-4
Plant Toxicity – Effects from small droplets	Special Study	

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 17.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant 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. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 17. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific 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.

C. Labeling Changes Summary Table

In order to be eligible for reregistration, all product labels must be amended to incorporate the risk mitigation measures outlined in Section IV. The following table (Table 17) describes how to amend the language on the labels.

Table 17. Summary of Labeling Changes for Chlorsulfuron

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
For all Manufacturing Use Products	"Only for formulation into an herbicide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	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)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"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."	Directions for Use
End Use Products Intended for Occupational Use		
PPE Requirements Established by RED ¹ for all end-use products intended for occupational use	"Personal Protective Equipment (PPE)" "Mixers, loaders, applicators, and other handlers must wear: Long-sleeved shirt and long pants Shoes plus socks."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
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 separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately after PPE Requirements.)

Description	Amended Labeling Language	Placement on Label
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 removing². As soon as possible, wash thoroughly and change into clean clothing.”	Precautionary Statements immediately following User Safety Requirements (Must be placed in a box.)
Environmental Hazards	“Do not apply directly to water, or 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 washwater or rinsate.”	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval	For products containing chlorsulfuron as the sole active ingredient: “Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours:” NOTE: This active ingredient continues to be a candidate for a 4-hour REI. The end-use product registrant may follow the instructions in PR Notice 95-3 to evaluate the end-use product using the criteria described within the PRN to determine if the default 12-hour REI may be reduced to 4 hours. If the end-use product currently contains a 4-hour REI, then that 4-hour REI may be retained. The correct statement for a 4-hour REI is: “Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours:”	Directions for Use, Agricultural Use Requirements Box
Early Re-entry Personal Protective Equipment established by the RED.	“PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: * coveralls, * shoes plus socks * chemical-resistant gloves made of any waterproof material”	

Description	Amended Labeling Language	Placement on Label
Spray Drift Language for all products applied outdoors (including ground boom and aerial application)	“Avoid drift at the application site. This product should be applied only when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops, native plant communities) is minimal (e.g. when wind is blowing away from the sensitive areas). Avoid application under conditions that may allow spray drift since very small quantities of spray may seriously injure susceptible crops during either active growth periods or dormancy. Follow the additional precautions below to minimize the potential for spray drift. The interaction of many equipment and weather-related factors determines the potential for spray drift. The user is responsible for considering all these factors when making application decisions. Where states have more stringent regulations, they must be observed. The applicator should be familiar and take into account the information covered in the following: Drift Control Adjuvants A drift control adjuvant may be used to further reduce the potential for drift. If a drift control adjuvant is used, follow the use directions and precautions on the manufacturer's label. Do not use an adjuvant which increases viscosity with Microfoil, Thru-Valve booms, or other systems that cannot accommodate viscous sprays. Controlling Droplet Size: - Nozzle Type Use a nozzle type according to manufacturer’s specifications that is designed for the intended application and produces a Coarse to Very Coarse droplet size spectrum (ASAE S572) under application conditions. Applicators must consider nozzle orientation, nozzle pressure, and flight speed in determining droplet size. Nozzles should always be oriented in the manner that minimizes the effects of air shear. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.”	Directions for Use

Description	Amended Labeling Language	Placement on Label
Spray Drift Language for all products applied outdoors (including ground boom and aerial application)	[Controlling Droplet Size (continued)]: “Pressure Do not exceed the nozzle manufacturer’s recommended pressures. When higher flow rates are needed, use a higher-capacity nozzle instead of increasing pressure.” “Swath Adjustment When applications are made with a crosswind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the application equipment upwind. Swath adjustment distance should increase with increasing drift potential. Wind Drift potential is lowest with a sustained wind between 2-10 mph. However, many factors, including droplet size and equipment type, determine drift potential at any given wind speed. Application should be avoided during gusty conditions, and when winds are below 2 mph due to variable wind direction and high potential for a temperature inversion. Note: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift. Temperature and Humidity When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry. Surface Temperature Inversions Applications must not occur during a local, surface temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds which are common during inversions. Temperature inversions are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of the smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.”	Directions for Use

Description	Amended Labeling Language	Placement on Label
Spray Drift Language for products applied by ground equipment	“Shielded Sprayers Shielding the boom or individual nozzles can reduce the effects of wind. However, it is the responsibility of the applicator to verify that the shields are preventing drift and not interfering with uniform deposition of the product. Boom Length/Height Setting the boom at the lowest referenced height (if specified) which provides uniform coverage reduces the exposure of droplets to evaporation and wind. The boom should remain level with the crop and have minimal bounce. Limit nozzle height to no greater than 4 feet above the top of the largest plants.”	Directions for Use
Spray Drift Language for products applied aerially	“Application Height Application more than 10 ft. above the canopy increases the potential for spray drift. Make applications no higher than 10 feet above the top of the target vegetation, unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind. Boom Length The boom length must not exceed 75% of the wing span for fixed wing aircraft or 90% for rotor blade helicopters. Using shorter booms decreases drift potential.”	Directions for Use
General Precautions and Restrictions	"Do not apply this product in a way that will contact workers or other people, either directly or through drift. Only protected handlers may be in the area during application."	Near the beginning of Directions for Use
Application Restrictions	<u>Cereal Grains:</u> “Maximum of one application per growing season.” <u>Industrial Use sites (including rights-of-ways):</u> “Application is restricted to ground application only, with the exception of rights-of-way, which may also be treated by helicopter.” “Do not apply more than three times per year. Do not apply more than 0.125 lbs ai/A per year.” <u>Fine turf and ornamentals:</u> “Broadcast application to lawns is prohibited. Application is limited to spot treatments of 240 square yards or less per acre.”	Place in the Directions for Use under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
End Use Products Intended Primarily for Use by Homeowners		
Application Restrictions	“Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application.”	Directions for Use under General Precautions and Restrictions
Entry Restriction	“Do not allow people or pets to enter the treated area until sprays have dried.”	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.

² Reference to gloves may be removed if the end-use product does not require gloves.

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

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

VI. Related Documents and How to Access Them

A list of technical support documents for the chlorsulfuron 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, 1801 S. Bell Street, Arlington, VA. The docket is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

Appendix A

Chlorsulfuron (Case 0631): Use Patterns Subject to Reregistration

Application Timing, Type and Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate	Maximum Applications Per Season	Maximum Seasonal Rate	Preharvest Interval, Days	Use Directions and Limitations
Turf						
Preemergence, early postemergence, postemergence Hand-held sprayer, backpack sprayer	Water-dispersible granule [228-375, 10404-59]	0.25 lb ai /A	2	0.5 lb ai/A	Not Applicable	Minimum retreatment interval is 60 days. Broadcast application to lawns is prohibited. Application is limited to spot treatments of 240 square yards or less per acre.
Non-Agricultural Rights-of-Way/Fencerows/Industrial Areas						
Preemergence, early postemergence Hand-held sprayer, boom sprayer, backpack sprayer, helicopter (rights-of-way only)	Water-dispersible granule [352-522, 352-404, 352-620, 352-621]	0.14 lb ai /A	1	0.14 lb ai/A	Not Applicable	Application is restricted to ground application only, with the exception of rights-of-way, which may also be treated by helicopter.
Cereal Grains (Wheat, Barlet, Oats)						
Fallow, preplant, Postplant, Postemergence, Low volume ground sprayer, aircraft	Water-dispersible granule [352-445, 352-522]	0.023 lb ai/A	1	0.023 lb ai/A	Not Applicable (due to timing)	

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Chlorsulfuron

<u>REQUIREMENT</u>				
New Guideline Number	Old Guideline Number	Title	USE PATTERN	CITATION(S)
<u>PRODUCT CHEMISTRY</u>				
830.1550	61-1	Product Identity and Composition	All	42454101
830.1600	61-2A	Start. Mat. & Mnfg. Process	All	42454101
830.1670	61-2B	Formation of Impurities	All	42454101
830.1700	62-1	Preliminary Analysis	All	42454101
830.1750	62-2	Certification of limits	All	42454101
830.1800	62-3	Analytical Method	All	42454102
830.6302	63-2	Color	All	42454102
830.6303	63-3	Physical State	All	42454102
830.6304	63-4	Odor	All	42454102
830.7050	None	UV/Visable Absorption	All	Data Gap
830.7200	63-5	Melting Point	All	42454102
830.7220	63-6	Boiling Point	All	Not Applicable (substance is solid at room temperature)
830.7300	63-7	Density	All	42454102
830.7840 830.7860	63-8	Solubility	All	42454102, 42454103, 42454104
830.7950	63-9	Vapor Pressure	All	42454102, 42454105

Data Supporting Guideline Requirements for the Reregistration of Chlorsulfuron

<u>REQUIREMENT</u>				
New Guideline Number	Old Guideline Number	Title	USE PATTERN	CITATION(S)
830.7370	63-10	Dissociation Constant	All	42454102, 42454106
830.7550	63-11	Octanol/Water Partition Coefficient	All	42454102, 42454107
830.7000	63-12	pH	All	42454102
830.6313	63-13	Stability	All	42454102, 42454108
<u>ECOLOGICAL EFFECTS</u>				
850.2100	71-1	Avian Acute Oral Toxicity		00035263 00035264
850.2200	71-2A	Avian Dietary Toxicity - Quail		00035265
850.2200	71-2B	Avian Dietary Toxicity - Duck		00035266
850.2300	71-4A	Avian Reproduction - Quail		42634001
850.2300	71-4B	Avian Reproduction - Duck		42634002
850.1075	72-1A	Fish Toxicity Bluegill		00035258
850.1075	72-1C	Fish Toxicity Rainbow Trout		41976405
850.1010	72-2A	Invertebrate Toxicity		00035262
None	72-3A	Estuarine/Marine Toxicity - Fish		41976401
None	72-3B	Estuarine/Marine Toxicity - Mollusk		41976403, 42328601
None	72-3C	Estuarine/Marine Toxicity - Shrimp		41976402, 41976408
None	72-4A	Fish- Early Life Stage		41976405

Data Supporting Guideline Requirements for the Reregistration of Chlorsulfuron

<u>REQUIREMENT</u>				
New Guideline Number	Old Guideline Number	Title	USE PATTERN	CITATION(S)
None	72-4B	Estuarine/Marine Invertebrate Life Cycle		41976408
850.4225	123-1(a)	Seedling Emergence, Tier II		46361801
850.4250	123-1(b)	Vegetative Vigor, Tier II		46326801
				42186801
				45832901
850.4400	123-2	Aquatic Plant Growth		45832902
				45832903
				45832904
<u>TOXICOLOGY</u>				
870.1100	81-1	Acute Oral Toxicity-Rat		00031406
870.1200	81-2	Acute Dermal Toxicity- Rabbit/Rat		00083956
870.1300	81-3	Acute Inhalation Toxicity-Rat		00086825
870.2400	81-4	Primary Eye Irritation-Rabbit		Data Gap
870.2500	81-5	Primary Skin Irritation		Data Gap
870.2600	81-6	Dermal Sensitization		Data Gap
870.6100	81-7	Acute Delayed Neurotoxicity - Hen		Not Required
870.6200	81-8	Acute Neurotoxicity Screen		Not Required
870.3100	82-1A	90-Day Feeding - Rodent		Satisfied by chronic study
870.3150	82-1B	90-Day Feeding - Non-rodent		00031420

Data Supporting Guideline Requirements for the Reregistration of Chlorsulfuron

<u>REQUIREMENT</u>				
New Guideline Number	Old Guideline Number	Title	USE PATTERN	CITATION(S)
870.3200	82-2	21-Day Dermal - Rabbit/Rat		Data Gap
870.3465	82-4	90-Day Inhalation-Rat		Data Gap
870.4100	83-1A	Chronic Feeding Toxicity - Rodent		00086003
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent		41862601
870.4200	83-2A	Oncogenicity - Rat		00086003
870.4200	83-2B	Oncogenicity - Mouse		00090030
870.3700	83-3A	Developmental Toxicity - Rat		41976406
870.3700	83-3B	Developmental Toxicity - Rabbit		41983101
870.3800	83-4	2-Generation Reproduction - Rat		Data Gap
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity		00086003
870.5100	84-2a	Gene Mutation (Bacterial)		Data Gap (MRID 00031425 may be upgraded)
870.5300	None	Gene Mutation (Mammalian)		Data Gap (MRID 00083943 may be upgraded)
870.5375	84-2B	Structural Chromosomal Aberration		00088755
870.5450	84-4	Other Genotoxic Effects		Data Gap (MRID 00090008 may be upgraded)
870.7485	85-1	General Metabolism		42540701
<u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u>				
875.2100	132-1A	Foliar Residue Dissipation		Waived due to low toxicity

Data Supporting Guideline Requirements for the Reregistration of Chlorsulfuron

<u>REQUIREMENT</u>				
New Guideline Number	Old Guideline Number	Title	USE PATTERN	CITATION(S)
875.2400	133-3	Dermal Passive Dosimetry Exposure		Waived due to low toxicity
875.2500	133-4	Inhalation Passive Dosimetry Exposure		Waived due to low vapor pressure
None	231	Estimation of Dermal Exposure at Outdoor Sites		Satisfied by DuPont's participation in the Spray Drift Taskforce
None	232	Estimation of Inhalation Exposure at Outdoor Sites		Satisfied by DuPont's participation in the Spray Drift Taskforce
<u>ENVIRONMENTAL FATE</u>				
835.2120	161-1	Hydrolysis		42156701
835.2240	161-2	Photodegradation - Water		42156702
835.2410	161-3	Photodegradation - Soil		42156703
835.4100	162-1	Aerobic Soil Metabolism		42214201, 01130013 01130024
835.4200	162-2	Anaerobic Soil Metabolism		42146704
835.1240	163-1	Leaching/Adsorption/Desorption		42156705
835.6100	164-1	Terrestrial Field Dissipation		42214202 41714401
None	165-4	Bioaccumulation in Fish		42214204

Data Supporting Guideline Requirements for the Reregistration of Chlorsulfuron

<u>REQUIREMENT</u>			USE PATTERN	CITATION(S)
New Guideline Number	Old Guideline Number	Title		
<u>RESIDUE CHEMISTRY</u>				
860.1300	171-4A	Nature of Residue - Plants		42248701, 43388402
860.1300	171-4B	Nature of Residue - Livestock		43600801, 43388401, 42248702, 43143501
860.1340	171-4C	Residue Analytical Method - Plants		44218601, 44183501, 4418601, 44183501, 43737701, 42900601, 42900602, 42948901, 43747301
860.1340	171-4D	Residue Analytical Method - Animals		42926601, 43107801, 43833001
860.1380	171-4E	Storage Stability		44705401, 41976407, 42292501
860.1500	171-4K	Crop Field Trials (Wheat)		44705401, 43767301
860.1520	171-4L	Processed Food/Feed (Wheat)		42900601
<u>OTHER</u>				
None	None	Plant toxicity from exposure to small droplets		Data Gap
850.3020	141-1	Honey Bee Acute Contact		42129902

Appendix C. TECHNICAL SUPPORT DOCUMENTS

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801, South Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The docket initially contained preliminary risk assessments and related documents as of September 26, 2004. Sixty days later the first public comment period closed. The EPA then considered comments and revised the risk assessment.

All documents and related addenda are available on the Agency's web page at www.epa.gov/pesticides and in the Public Docket at <http://www.epa.gov/edocket> under docket #OPP-2004-0219.

These documents include:

Documents supporting human health risk assessments:

1. Hanley, Susan. *Chlorsulfuron: Occupational and Residential Exposure and Risk Assessment/Characterization for Reregistration Eligibility Decision Document and the Proposed use on Pasture and Rangeland Grasses*. July 1, 2002.
2. Fort, Felicia. *Chlorsulfuron. Product Chemistry Chapter for the Reregistration Eligibility Decision*. December 16, 2002.
3. Taylor, Linda. *Toxicology Chapter for CHLORSULFURON*. July 17, 2002.
4. Taylor, Linda. *CHLORSULFURON - Report of the Hazard Identification Assessment Review Committee*. June 5, 2002.
5. Taylor, Linda. *CHLORSULFURON - Second Report of the Hazard Identification Assessment Review Committee*. June 17, 2002.

Documents supporting environmental fate and effects risk assessments:

1. Balluff, Young and Kiernan. *Environmental Fate and Ecological Risk Assessment for the Re-registration of Chlorsulfuron*. May 10, 2005.
2. Kiernan, Brian; Costello, Kevin. *Response to Comments on the Environmental Fate and Ecological Risk Assessment of Chlorsulfuron*. February 15, 2005.
3. Kiernan, Brian; Costello, Kevin. *Revised Environmental Fate and Ecological Risk Assessment of Chlorsulfuron*. January 31, 2005.
4. Birchfield, Norman; Costello, Kevin. *Review of DuPont's phase 1 "Error Correction" comments on the spray drift analysis for chlorsulfuron (MRID 46128400)*. July 26, 2004.

5. Birchfield, Norman. *Revised assessment of risk to non-target plants associated with chlorsulfuron spray drift*. July 27, 2004.

Documents supporting use analysis:

1. Scheltema, Christina. *Use Closure Memo for Chlorsulfuron*. February 13, 2003.
2. Zinn, Nicole; Kim, Jin. *BEAD Review of Chlorsulfuron Comments*. February 7, 2005.
3. Zinn, Nicole; Kim, Jin. *Addendum to Chlorsulfuron Benefits Discussion for Aerial Applications: Alternatives Analysis for Winter Wheat*. May 2, 2005.

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

GUIDE TO APPENDIX D

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

evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

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

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00031406	Trivits, R.L. (1979) Oral LD50 Test in Fasted Male and Female Rats: Report No. 399-79. (Unpublished study received Jun 16, 1980 under 352-EX-105; submitted by E.I. du Pont de Nemours & Co., Wil- mington, Del.; CDL:099460-A)
00031414	Brittelli, M.R. (1976) Eye Irritation Test in Rabbits: Report No. 744-76. (Unpublished study received Jun 16, 1980 under 352- EX-105; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:099460-I)
00031417	Goodman, N.C. (1976) Primary Skin Irritation and Sensitization Tests on GuineaReport No. 794-76. (Unpublished study received Jun 16, 1980 under 352-EX-105; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:099460-L)
00035262	Goodman, N.C. (1979) 48-Hour LC50 to~Daphnia magna~?: Haskell Lab- oratory Report No. 152-79. (Unpublished study received Jun 16, 1980 under 352-105; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:099462-H)
00035264	Hinkle, S.; Bristol, K.L. (1980) Final Report--Acute Oral LD50 Study in Mallard Ducks: Project No. 201-525. (Unpublished study received Jun 16, 1980 under 352-105; prepared by Hazelton Labo- ratories America, Inc., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:099462-J)
00035265	Hinkle, S. (1979) Final Report--Avian Dietary Toxicity (LC50) Study in Bobwhite Quail: Project No. 201-523. (Unpublished study re- ceived Jun 16, 1980 under 352-105; prepared by Hazleton Labora- tories America, Inc., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:099462-K)
00035266	Hinkle, S.; Wentz, K.L. (1979) Final Report--Avian Dietary Toxicity (LC50) in Mallard Ducks: Project No. 201-524. (Unpublished study received Jun 16, 1980 under 352-105; prepared by Hazleton Laboratories America, Inc., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:099462-L)
00083956	Edwards, D.F. (1979) Acute Skin Absorption Test on Rabbits--LD50: Haskell Laboratory Report No. 415-79. (Unpublished study received Sep 1, 1981 under 352-EX-109; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:245879-I)

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- 00086825 Ferenz, R.L. (1980) LC50--inhalation Test for Pesticide Registration – AlbinoHaskell Laboratory Report No. 129-80. (Unpublished study received Nov 13, 1981 under 352-404; sub- mitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:070471-H)
- 41714401 Dietrich, R.; Taylor, G. (1990) Field Soil Dissipation of {Phenyl (U)-(Carbonhlorsulfuron and {Triazine-2-(Carbon 14)} Chlosulfuron in Madera, California: Lab Project Number: AMR-1417-89: EF-89-03. Unpublished study prepared by E. I. du Pont de Nemours and Co. in Association with Pan-Agricultural Laboratories, Inc. 66 p.
- 41976401 Ward, T.; Boeri, R. (1991) Static Acute Toxicity of DPX-W4189-165 (Chlorsulfuron) to the Sheepshead Minnow, *Cyprindon variegatus*: Lab Project Number: MR-4581-866: 516-91: 9130-DU. Unpublished study prepared by EnviroSystems Division. 31 p.
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Appendix E. GENERIC DATA CALL-IN

A complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

Appendix F. PRODUCT SPECIFIC DATA CALL-IN

See attached table for a list of product-specific data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

United States Environmental Protection Agency
Washington, D.C. 20460OMB Approval 2070-0107
OMB Approval 2070-0057

DATA CALL-IN RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name 0631 Chlorsulfuron Chemical # and Name 118601 Chlorsulfuron		3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-118601-NNNN	
4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNN-NNNN		N.A.	N.A.		
8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative_____				9. Date	
10. Name of Company				11. Phone Number	

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name 0631 Chlorsulfuron EPA Reg. No. NNNNNN-NNNNN			3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-118601-NNNN				
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	<u>Product Chemistry Data Requirements (Conventional Chemical)</u>								
830.1550	Product Identity and composition (1)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.1600	Description of materials used to produce the product (2)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.1620	Description of production process (3)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	
830.1650	Description of formulation process (4)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.1670	Discussion of formation of impurities (5)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.1700	Preliminary analysis (6 ,7 ,8)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	
830.1750	Certified limits (9 ,10)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.1800	Enforcement analytical method (11)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.6302	Color (12)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law Signature and Title of Company's Authorized Representative _____							11. Date _____		
12. Name of Company _____							13. Phone Number _____		

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name 0631 Chlorsulfuron EPA Reg. No. NNNNNN-NNNNN			3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-118601-NNNN				
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.6303	Physical state (13)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.6304	Odor (14)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.6313	Stability to sunlight, normal and elevated temperatures, metals, and metal ions (15 ,16)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	
830.6314	Oxidizing or reducing action (17)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.6315	Flammability (18)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.6316	Explodability (19)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.6317	Storage stability of product (20)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.6319	Miscibility (21)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.6320	Corrosion characteristics (22)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.6321	Dielectric breakdown voltage (23)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
Initial to indicate certification as to information on this page (full text of certification is on page one).							Date		

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Washington, D.C. 20460

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REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name 0631 Chlorsulfuron EPA Reg. No. NNNNNN-NNNNN			3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-118601-NNNN				
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.7000	pH of water solutions or suspensions (24 ,25)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.7050	UV/Visible absorption					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	
830.7100	Viscosity (26)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	
830.7200	Melting point/melting range (27 ,28)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	
830.7220	Boiling point/boiling range (29 ,30)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	
830.7300	Density/relative density (31 ,32)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	
830.7370	Dissociation constant in water (33 ,34)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	
830.7550	Partition coefficient (n-octanol/water), shake flask method (35)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	
830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography (36)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	
830.7840	Water solubility: Column elution method, shake flask method (37)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	
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Washington, D.C. 20460

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REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name 0631 Chlorsulfuron EPA Reg. No. NNNNNN-NNNNN			3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-118601-NNNN				
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.7860	Water solubility, generator column method (38)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	
830.7950	Vapor pressure (39 ,40)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	
	<u>Toxicology Data Requirements (Conventional Chemical)</u>								
870.1100	Acute Oral Toxicity (41)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI,EP,dilute EP?	8	
870.1200	Acute dermal toxicity (42 ,43)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI,EP,dilute EP?	8	
870.1300	Acute inhalation toxicity (44)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI & EP	8	
870.2400	Acute eye irritation (45)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI & EP	8	
870.2500	Acute dermal irritation (46 ,47)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI & EP	8	
870.2600	Skin sensitization (48 ,49)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI & EP	8	
Initial to indicate certification as to information on this page (full text of certification is on page one).							Date		

United States Environmental Protection Agency
Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0631 Chlorsulfuron

DCI Number: PDCI-118601-NNNN

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI & EP = Technical Grade of the Active Ingredient and End-Use Product; TGAI or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI,EP,dilute EP? = Technical Grade of the Active Ingredient, End Use Product, and possibly diluted End Use Product; TGAI/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Use Categories Key:

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

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

- 1 Data must be provided in accordance with the "Product Composition" Section.(158.155)
- 2 Data must be provided in accordance with the "Description of Materials used to Produce the Product" Section.(158.160)
- 3 Data must be provided in accordance with the "Description of Production Process" Section.(158.162)
- 4 Data must be provided in accordance with the "Description of Formulation Process" Section.(158.165)
- 5 Data must be provided in accordance with the "Description of Formation of Impurities" Section(158.167)
- 6 Data must be provided in accordance with the "Preliminary Analysis" Section.(158.170)

United States Environmental Protection Agency
Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0631 Chlorsulfuron

DCI Number: PDCI-118601-NNNN

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI & EP = Technical Grade of the Active Ingredient and End-Use Product; TGAI or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI,EP,dilute EP? = Technical Grade of the Active Ingredient, End Use Product, and possibly diluted End Use Product; TGAI/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

7 Required for TGAIs and products produced by an integrated system.

8 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

9 Data must be provided in accordance with the "Certified Limits" Section(158.175)

10 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

11 Data must be provided in accordance with the "Enforcement Analytical Method" Section.(158.180)

12 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0631 Chlorsulfuron

DCI Number: PDCI-118601-NNNN

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGA I = Technical Grade Active Ingredient [TGA I]; TGA I & EP = Technical Grade of the Active Ingredient and End-Use Product; TGA I or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGA I,EP,dilute EP? = Technical Grade of the Active Ingredient, End Use Product, and possibly diluted End Use Product; TGA I/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGA I/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

- 13 If the TGA I cannot be isolated, data are required on the practical equivalent of the TGA I (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 14 If the TGA I cannot be isolated, data are required on the practical equivalent of the TGA I (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 15 If the TGA I cannot be isolated, data are required on the practical equivalent of the TGA I (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 16 Data on the stability to metals and metal ions is required only if the active ingredient is expected to come in contact with either material during storage.
- 17 Required if the product contains an oxidizing or reducing agent
- 18 Required when the product contains combustible liquids.

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Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0631 Chlorsulfuron

DCI Number: PDCI-118601-NNNN

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI & EP = Technical Grade of the Active Ingredient and End-Use Product; TGAI or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI,EP,dilute EP? = Technical Grade of the Active Ingredient, End Use Product, and possibly diluted End Use Product; TGAI/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

19 Required when the product is potentially explosive.

20 Please see attached "Additional Information and Requirements Pertaining to Storage Stability (OPPTS 830.6317) and Corrosion Characteristics (OPPTS 830.6320) Data Requirements of the Product Specific Data Call-Ins issued under the Reregistration Eligibility Decision (RED)/Interim Reregistration Eligibility Decision (IRED) Documents."

21 Required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.

22 Please see attached "Additional Information and Requirements Pertaining to Storage Stability (OPPTS 830.6317) and Corrosion Characteristics (OPPTS 830.6320) Data Requirements of the Product Specific Data Call-Ins issued under the Reregistration Eligibility Decision (RED)/Interim Reregistration Eligibility Decision (IRED) Documents."

23 Required if the end-use product is a liquid and is to be used around electrical equipment.

24 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

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Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0631 Chlorsulfuron

DCI Number: PDCI-118601-NNNN

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI & EP = Technical Grade of the Active Ingredient and End-Use Product; TGAI or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI,EP,dilute EP? = Technical Grade of the Active Ingredient, End Use Product, and possibly diluted End Use Product; TGAI/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

25 Required if the product is dispersible with water.

26 Required if the product is a liquid.

27 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

28 Required when the TGAI is solid at room temperature.

29 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

30 Required if the TGAI is liquid at room temperature.

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

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Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

- 31 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 32 True density or specific density are required for all test substances. Data on bulk density is required for MPs that are solid at room temperature.
- 33 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 34 Required when the test substance contains an acid or base functionality (organic or inorganic) or an alcoholic functionality (organic).
- 35 Required if the TGAI or PAI is organic and non-polar.
- 36 Required if the TGAI or PAI is organic and non-polar.

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

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Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

- 37 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 38 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 39 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 40 Not required for salts.
- 41 Not required if test material is a gas or a highly volatile liquid.
- 42 Not required if test material is a gas or a highly volatile liquid.

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

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Use Categories Key:

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

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

43 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

44 Required if the product consists of, or under conditions of use will result in, a respirable material (e.g., gas, vapor, aerosol, or particulate).

45 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

46 Not required if test material is a gas or a highly volatile liquid.

47 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

48 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

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Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

49 Required if repeated dermal exposure is likely to occur under conditions of use.

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Washington, D.C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0631,Chlorsulfuron

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
228	NUFARM AMERICAS INC.		1333 BURR RIDGE PARKWAY, SUITE 125A	BURR RIDGE	IL 605270866
352	E. I. DU PONT DE NEMOURS AND CO., INC.		PO Box 30 STINE-HASKELL RESEARCH CENTER/1090 ELKTON RD	NEWARK	DE 197140030
10404	LESCO INC		1301 EAST 9TH STREET, SUITE 1300	CLEVELAND	OH 441141849

Appendix G. EPA'S BATCHING OF CHLORSULFURON PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing chlorsulfuron as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (e.g., identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular), and labeling (e.g., signal word, use classification, precautionary labeling.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should 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. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within 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 the EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In notice (DCI) 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.

Eight products were found which contain chlorsulfuron as the active ingredient. These products have been placed into two batches and a "no batch" category in accordance with the active and inert ingredients and type of formulation. The batching for these products is contained in the following table.

Batch Number	EPA Reg. No.	% Active Ingredient
1	228-375	75.0
	352-522	75.0
2	352-404	75.0
	10404-59	75.0
No Batch	352-516	98.00
	352-445	Chlorsulfuron: 62.50 Metasulfuron: 12.50
	352-620	Chlorsulfuron: 18.75 Sulfometuron methyl: 56.25
	352-621	Chlorsulfuron: 25.00 Sulfometuron methyl: 50.00

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.