United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7509P)

EPA 738-R-06-014
July 2006

Reregistration Eligibility Decision (RED) for Inorganic Chlorates

REREGISTRATION ELIGIBILITY

DECISION

for

Inorganic Chlorates

Case No. 4049

Approved by:

_____
Debra Edwards, Ph.D.
Director, Special Review and
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Glossary of Terms and Abbreviations

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
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
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD_{50}	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.

MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NTP	National Toxicology Program
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RAC	Raw Agricultural Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TSH	Thyroid Stimulating Hormone
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for the Inorganic Chlorates and is issuing its risk management decision and tolerance reassessment. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products and additional information received through the public docket. After considering the risks identified in the revised risk assessments, comments received, and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of inorganic chlorates that pose risks of concern. As a result of this review, EPA has determined that inorganic chlorate-containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document.

Sodium chlorate is an inorganic salt herbicide that was first registered in 1966. It is a defoliant and a desiccant that is primarily used on cotton, but it also has other agricultural and non-agricultural uses. As a non-selective herbicide it is used to kill grasses and weeds in industrial and non-agricultural sites such as driveways, tennis courts, and recreational areas. The initial risk assessment indicated some ecological and occupational risks of concern. Risk assessments were revised based on refinements to the assessments as well as mitigation measures. Occupational and ecological risks resulting from non-agricultural uses have been mitigated by reducing application rates, as well as limiting applications of sodium chlorate to spot treatments only. Use on rights-of-way and ditch banks will be cancelled. The Agency may require changes to the language of the sodium chlorate label in the future if deemed necessary under the Endangered Species Protection Program.

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 (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 or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act (FQPA) was signed into law. This Act amends FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food. FQPA also requires EPA to review all tolerances in effect on August 2, 1996, by August 3, 2006. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility of infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern and the Agency concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

Of the inorganic chlorates listed as active ingredients (*i.e.*, sodium chlorate (073301), calcium chlorate (073302), potassium chlorate (073303), and magnesium chlorate (530200)), only sodium chlorate is present as an active ingredient in currently registered products. As such, sodium chlorate is the primary focus of the reregistration eligibility decision. Sodium chlorate is a strong oxidizer and may be reduced to a variety of chemical species depending on the environmental conditions. As a consequence of its reaction as an oxidant, sodium chlorate generates reduced chloro species (i.e., chlorine in lower oxidation states than chlorate), such as chlorite and hypochlorite. Since chlorite is also an active ingredient and is being considered in the chlorite/chlorine dioxide reregistration eligibility decision (case number 4043). The Agency will not consider the tolerances for chlorate reassessed until the assessment of chlorite is complete. As mentioned above, FQPA requires EPA to consider available information concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposures to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals.

EPA has not made a common mechanism of toxicity finding as to parent sodium chlorate and any other substances, and sodium chlorate does not appear to produce a toxic metabolite that is in common with those produced by other substances. For the purposes of this reregistration eligibility decision (RED), therefore, EPA has not assumed that the inorganic chlorates 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 EPA's revised human health and ecological risk assessments, its progress toward tolerance reassessment, and the reregistration eligibility decision for inorganic chlorates. The 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 human health and environmental effects risk assessments; Section IV presents the Agency's decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The revised risk assessments for inorganic chlorates are available in the Office of Pesticide Programs (OPP) public docket under docket number OPP-2005-0507 available on the Agency's web page at http://www.epa.gov/oppsrrd1/reregistration/inorganicchlorates/.

II. Chemical Overview

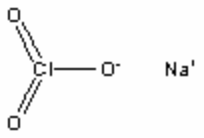
Of the inorganic chlorates listed as active ingredients (*i.e.*, sodium chlorate (073301), calcium chlorate (073302), potassium chlorate (073303), and magnesium chlorate (530200)), only sodium chlorate is present as an active ingredient in currently registered products. Sodium chlorate, calcium chlorate, and potassium chlorate are present as inert ingredients in currently registered products and exposures as a result of those uses are addressed herein. Sodium chlorate is a defoliant/desiccant, and is used as an herbicide.

A. Regulatory History

Sodium chlorate was first registered in February 23, 1966 by Value Gardens Supply, LLC, for use on both annual and perennial grasses and weeds for the following non-agricultural use sites: garage areas, tennis courts, curbs, driveways, walks, and patios. On October 30, 1968, Helena Chemical Company registered it for use as a desiccant on agricultural sites (sorghum and cotton). Currently, there are 56 active product registrations containing sodium chlorate as an active ingredient, including 11 technical (manufacturing use) registrations, and 45 end-use products ranging from 2.3% to 99.7% active ingredient. Sodium chlorate is currently manufactured by seven companies. The compound may be used in combination with other herbicides, such as atrazine, 2,4-D, bromacil, diuron, and sodium metaborate.

B. Chemical Identification – Sodium Chlorate

Chemical Structure:



Common Names:	Sodium chlorate, soda chlorate, chloric acid, sodium salt
Chemical Name:	Sodium chlorate
Trade Names:	Ferti-Lome, Barespot, Tri-Kil, Bareground, Prometon, Pramitol, Killsall, TriChlor
Chemical Family:	Inorganic salt
Case Number:	4049
CAS Number:	7775-09-9
PC Code:	073301
Molecular Weight:	106.5
Empirical Formula:	$NaClO_3$
Technical Registrants:	EKA Chemicals, ERCO Chemicals, Kerr-McGee Chemical, Nexen Chemical USA, Moore Agricultural Products Company, Inc.

C. Use Profile

The following is information on the currently registered uses of sodium chlorate, including an overview of use sites and application methods. A detailed table of the uses of sodium chlorate eligible for reregistration is available in Appendix A.

Type of Pesticide:	Herbicide (desiccant/defoliant)
Target Pest:	Broadleaf weeds
Mode of Action:	Non-selective, contact herbicide that penetrates the cuticle causing cell death by altering the metabolic processes.
Use Sites	
Agricultural uses:	Agriculturally, it is primarily used on cotton; however, it is also applied to a wide variety of other crops including, but not limited to, rice, corn, soybeans, dry beans, potatoes, sunflowers, flax, safflower, chili peppers (for processing only), grain sorghum, and wheat.
Non-agricultural Uses:	Sodium chlorate is used on nonagricultural (residential and industrial) areas such as rights-of-ways, building perimeters, ditch banks, bleachers, airport runways, vacant lots, fire hydrants, or as a pre-paving treatment. It is also used by a small percentage of water treatment facilities for the generation of chlorine dioxide.
Use Classification:	General Use
Formulation Types:	Agricultural products are all formulated as soluble concentrates/liquids; non-crop products are formulated as soluble concentrates/liquids and granules or pellets/tablets.
Application Methods:	Sodium chlorate as a defoliant/desiccant in agricultural settings is applied using aerial and groundboom equipment. As an herbicide in nonagricultural settings, it is applied using handheld equipment such as a low-pressure handwands or sprinkling cans; it is also applied via groundboom or handgun sprayer application methods for larger commercial scenarios. Granular formulations can be applied using belly grinders, push-type spreaders, tractor-drawn spreaders, or by hand.
Application Rates:	In agriculture, rates range from 6 pounds active ingredient per acre (6 lb ai/A) to 12.5 lbs ai/A. Industrial and other noncrop site rates range from 132 to 1032 lbs ai/A, based on current labels. Sodium chlorate can be applied multiple times per year.
Application Timing:	Sodium chlorate is applied post-emergence.

D. Estimated Usage of Sodium Chlorate

The primary non-pesticidal use for sodium chlorate is as a precursor in chlorine dioxide generation through a closed system to bleach wood pulp/paper. The pesticidal uses of sodium chlorate, including the agricultural uses as a defoliant/desiccant, are a small percentage (approximately 2%) of the total sodium chlorate used in the United States. According to Agency

data, approximately 2.8 million pounds of sodium chlorate are applied annually to agricultural, residential, and commercial use sites. A screening-level usage analysis (SLUA) of sodium chlorate from 1998 to 2005 indicates that approximately 2.1 million pounds of sodium chlorate are used annually on agricultural use sites in the United States. In terms of pounds applied, the greatest use is on cotton (1.9 million lbs ai per year); annually this represents approximately 5 percent of cotton acreage treated.

Exposure to the chlorate may also occur as a result of the drinking water disinfection process. This use and resulting exposure are explained in detail in this document.

III. Summary of Inorganic Chlorates Risk Assessments

The following is a summary of EPA's revised human health and ecological risk assessments for inorganic chlorates, as presented fully in the documents, revised *Inorganic Chlorates. HED Chapter of the Reregistration Eligibility Decision Document (RED),* dated January 26, 2006, and the revised *Sodium Chlorate Ecological Risk Assessment,* dated June 1, 2006. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments.

The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to reach the safety finding and regulatory decision for sodium chlorate. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket, located at http://www.regulations.gov, under docket number EPA-HQ-OPP-2005-0507.

EPA's use of human studies in the sodium chlorate risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

A. Human Health Risk Assessment

The human health risk assessment incorporates potential exposure, hazard, and risks from all sources, which include food, drinking water, residential (if applicable), and occupational scenarios. Aggregate assessments combine food, drinking water, and any residential or other non-occupational (if applicable) exposures to determine potential exposures to the U.S. population. The Agency's human health assessment considers all U.S. populations, including infants and young children. For more information on the inorganic chlorates human health risk assessment, see *Revised Inorganic Chlorates. HED Chapter of the Reregistration Eligibility Decision Document (RED)* dated June 26, 2006.

1. Toxicity of Sodium Chlorate

Toxicity assessments are designed to predict whether a pesticide could cause adverse health effects in humans (including short-term or acute effects such as skin or eye damage, and lifetime or chronic effects such as cancer, developmental effects, or reproductive effects), and the level or dose at which such effects might occur. The Agency has reviewed all toxicity studies submitted for sodium chlorate and has determined that the toxicological database is complete, reliable, and sufficient for reregistration. For more details on the toxicity and carcinogenicity of the inorganic chlorates, see *Revised Inorganic Chlorates. HED Chapter of the Reregistration Eligibility Decision Document (RED)* dated January 26, 2006, which is available under docket number EPA-HQ-OPP-2005-0507.

a. Acute Toxicity Profile

In acute toxicity tests, sodium chlorate is slightly toxic by the oral (Toxicity Category IV), dermal (Toxicity Category III), and inhalation routes (Toxicity Category IV). Sodium chlorate crystals were mildly irritating to the rabbit eye (Toxicity Category III), and were a

minimal to mild dermal irritant (Toxicity Category III). Incident reports show that ingestion of toxic doses of sodium chlorate by humans produces gastritis, hemolysis, methemoglobinemia, hemoglobinurea, late toxic nephritis, and acute renal failure. Doses in excess of 100 mg/kg are generally fatal to humans. The acute toxicity profile for sodium chlorate is summarized in Table 1 below.

Table 1. Acute Toxicity Profile - Sodium Chlorate

Guideline Number	Study Type	MRID No.	Results	Toxicity Category[a]
870.1100	Acute oral -Rats	41819901	$LD_{50} \geq 5000$ mg/kg (rat)	IV
870.1200	Acute dermal - Rabbits	42497601	$LD_{50} = > 2000$ mg/kg	III
870.1300	Acute inhalation - Rats	41819903	$LC_{50} = 5.59$ mg/L	IV
870.2400	Acute eye irritation - Rabbit	00085090 00102998 41819904	mildly irritating	III
870.2500	Acute dermal irritation - Rabbit	42497602	minimally irritating	III
870.2600	Skin sensitization - guinea pigs	41819906	not a dermal sensitizer	NA

a. 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.

b. FQPA Safety Factor Considerations

The Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), directs the Agency to use an additional ten fold (10x) safety factor (SF) to account for potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FQPA authorizes the Agency to modify the 10x FQPA SF only if reliable data demonstrate that the resulting level of exposure would be safe for infants and children.

For sodium chlorate, based on the hazard data and the exposure data, the FQPA SF was reduced to 1x. There was no pre- or postnatal sensitivity or susceptibility observed in the submitted developmental studies in rats and rabbits or the 2-generation reproduction study in rats. However, there is a concern for developing offspring because of the effects of inorganic chlorate on thyroid function in rats. The thyroid hormone system plays a critical role in development, and it is therefore important to understand whether the thyroid hormone system in the developing young differs in response to thyroid toxicants compared to adults. There exists, therefore, an uncertainty regarding information on comparative thyroid response in young versus (vs.) adult rats; however, a SF reflecting the uncertainty in comparative response is not necessary and the 10x FQPA SF can be removed (reduced to 1x).

The rationale for removal of the FQPA SF lies in the comparative thyroid physiology of rats vs. humans. As a consequence of these dynamic differences, rats are much more sensitive to thyroid toxicants, such as chlorate, than humans and non-human primates. As discussed in the section below, the chronic reference dose (RfD) for inorganic chlorates is 0.03 mg/kg/day based on thyroid hypertrophy in adult rats. There is a study of the effects of chlorate on adult monkeys, in which the no observed adverse effects level (NOAEL) for effects on blood thyroxine levels

was 58 mg/kg/day. If the NOAEL from the monkey study were used to derive a chronic RfD with uncertainty factors of 10x for interspecies extrapolation and 10X for intraspecies variability, and an FQPA SF of 10x reflecting uncertainties in effects to the young, the chronic RfD would be 0.06 mg/kg/day. The chronic RfD selected by the risk assessment team of 0.03 mg/kg/day derived from a chronic rat study, conducted by the National Toxicology Program (NTP), is therefore protective of thyroid effects in primates (including a 10X factor for uncertainty with respect to developing young) without the necessity of an additional uncertainty factor applied to the rat data.

In addition, the moderately refined dietary food assessment uses field trial data and percent crop treated estimates for all commodities, and the residential exposure assessment is based on reliable data; as such, exposure will not be underestimated. The dietary drinking water assessment uses residues in finished drinking water collected from water treatment facilities, which use chlorine dioxide or hypochlorite to treat drinking water. See *Revised Inorganic Chlorates. HED Chapter of the Reregistration Eligibility Decision Document (RED)* dated January 26, 2006, for additional details.

c. Toxicological Endpoints

The toxicological endpoints used in the human health risk assessment for sodium chlorate are listed in Table 2 below. Although several studies were considered, an acute reference dose (aRfD) was not identified. None of the available studies provided an endpoint of toxicity attributable to a single exposure.

Sodium chlorate is unlikely to be absorbed by the skin based on its high water solubility and ionic nature; therefore, a risk assessment for dermal exposure is not needed and a dermal endpoint was not selected. For inhalation absorption, a default factor of 100% was used since, per Agency policy, the inhalation dose was derived from an oral endpoint.

The usual interspecies uncertainty factor is 10x, but there are several important quantitative dynamic differences between rats and humans with respect to thyroid function that permit an interspecies factor of less than 10x for a thyroid toxicant like sodium chlorate. The half-life of thyroid hormone T4 in rats is approximately 12 hours, whereas in humans, the half-life is 5-9 days. The shorter half-life in rats is likely related to a high-affinity binding globulin for thyroxin that is present in humans, but absent in rodents. In the absence of a functional thyroid gland, a rat requires approximately 10-times more T4 than an adult human for full reconstitution. Constitutive thyroid stimulating hormone (TSH) levels are nearly 25-times higher in rats than in humans, reflecting the increased activity of the thyroid-pituitary axis in rats. Therefore, the 10x interspecies factor can be reduced to 3x based on dynamic considerations. The uncertainty factors (UF) and safety factors used to account for interspecies extrapolation, intraspecies variability, and susceptibility of infants and children (FQPA SF) are also described in Table 2.

Table 2. Summary of Toxicological Doses and Endpoints for Chlorate *per se* for Use in Human Risk Assessments for Inorganic Chlorates			
Exposure Scenario	**Dose, Uncertainty Factors**	**FQPA Safety Factor and Level of Concern**	**Study and Endpoint for Risk Assessment**
Acute Dietary	Acute RfD= not applicable	Although several studies were considered, an acute reference dose (aRfD) was not identified. None of the available studies provided an endpoint of toxicity attributable to a single exposure.	
Chronic Dietary (all populations)	BMDL[1] = 0.9 mg/kg/day UF = 30 (3x interspecies and 10x intraspecies) Chronic RfD = 0.03 mg/kg/day	FQPA SF = 1X cPAD = $\frac{\text{Chronic RfD}}{\text{FQPA SF}}$ cPAD= 0.03 mg/kg/day	Chronic Study in rats (NTP, 2004). The LOAEL= 5 mg/kg/day based on increased thyroid gland follicular cell hypertrophy and follicular cell mineralization.
Short- and Intermediate-Term Incidental Oral	Oral NOAEL =30 mg/kg/day UF = 100	FQPA SF = 1X Residential LOC for MOE =100	Subchronic study in rats McCauley *et al*, 1995. Pituitary effects (vacuolization) and thyroid gland effects (colloid depletion), body weight decrease and organ weight changes and reduction in erythrocyte counts and hemoglobin content at the LOAEL of 100 and 150 mg/kg/day in males and females, respectively
Short-, Intermediate-, and Long-Term Dermal	Not applicable	Dermal absorption is unlikely due to the ionic nature and water solubility of sodium chlorate	
Short-, Intermediate-, and Long-Term Inhalation	NOAEL =30 mg/kg/day[2] UF = 100	FQPA SF = 1X Residential LOC for MOE =100 Occupational LOC for MOE =100	McCauley *et al*, 1995
Cancer (Oral, dermal, inhalation)	Classification: Not likely to be carcinogenic to humans at doses that do not alter thyroid hormone homeostasis.		

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic), RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

1. A NOAEL was not identified in this study. Therefore a bench mark dose (BMD) analysis was performed and a BMDL of 28 mg sodium chlorate/L (22 mg chlorate/L) was calculated. This corresponds to 0.9 mg chlorate/kg/day oral dose.
2. A 100% inhalation absorption factor is used for extrapolating from an oral endpoint of toxicity.

2. Carcinogenicity of Sodium Chlorate

Sodium chlorate is a thyroid toxicant producing thyroid gland follicular cell hypertrophy in rats and mice following chronic exposures. The Agency classified sodium chlorate as not likely to be carcinogenic to humans at doses that do not alter thyroid hormone homeostasis in accordance with the EPA policy, *Assessment of Thyroid Follicular Cell Tumors,* dated March

1998. This policy states that nonmutagenic pesticides that induce elevated levels of TSH and thyroid follicular cell tumors in the rat are classified as not likely to be carcinogenic to humans at doses that do not alter thyroid hormone homeostasis.

The preliminary results of a draft 2-year National Toxicology Program (NTP) bioassay study on sodium chlorate to determine the potential of this chemical to induce tumors in laboratory animals (rats and mice) (NTP, 2004) showed evidence of thyroid gland follicular cell hyperplasia and follicular cell tumors in male rats. The effects may be attributed to changes in levels of thyroid hormones seen after administration of high doses of sodium chlorate. A final study report is expected later this year. In female mice there was equivocal and marginal evidence of increased pancreatic islet carcinoma. Sodium chlorate was negative in most bacterial gene mutation assays and in several cytogenetics tests, including a hypoxanthine-guanine phosphoribosyl-transferase (HGPRT) assay in Chinese hamster ovaries and a micronucleus assay.

The Agency selected a chronic endpoint based on the thyroid effects from the NTP bioassay study using a benchmark dose analysis approximation of the NOAEL. This endpoint is protective for all populations, including children because children are not expected to be more susceptible to chlorate-induced thyroid effects than adults. Therefore, the current chronic risk assessments presented in this document are protective of any cancer-related effects for all populations. For more information, see the document *Revised Inorganic Chlorates. HED Chapter of the Reregistration Eligibility Decision Document (RED)* dated January 26, 2006.

3. Sodium Chlorate Endocrine Effects

The EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including pesticides active and other ingredients) "may have an effect in humans similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system.

The available toxicity studies on sodium chlorate demonstrate the thyroid gland to be its target of toxicity. The endpoints selected to assess chronic dietary risk and short- and intermediate-term oral and inhalation risks in this document are protective of the observed thyroid effects seen in the available toxicity studies. When additional appropriate screening and/or testing protocols being considered under the Agency's Endocrine Screening Disruption Program have been developed, sodium chlorate may be subject to further screening and/or testing to better characterize effects related to endocrine disruption.

4. Metabolites and Degradates

The Agency reviewed the metabolism of the inorganic chlorates, and concluded that there are several residues of concern in food. In plants, the terminal residues of sodium chlorate in/on plants are likely chlorate (ClO_3^-), chlorite (ClO_2^-), and chloride (Cl^-). Based on published rat metabolism data,

terminal residues of sodium chlorate in animal tissues are also expected to be chlorate (ClO_3^-), chlorite (ClO_2^-), and chloride (Cl^-).

In the environment, because chlorate is a strong oxidizing agent (oxidation state V), it gets reduced to chlorine species in lower oxidation states, such as the oxyanions chlorite (ClO_2^-, oxidation state III) and hypochlorite (ClO^-, oxidation state I), chlorine dioxide (oxidation state IV), and chloride (oxidation state -I). Thus, at least some, and possibly a substantial, reduction of the chlorate resulting from the application of sodium chlorate is likely to occur in the field prior to any runoff to surface water. Under environmental (terrestrial field) redox conditions, and based on chemical equilibria alone, the thermodynamically favored, end reduction product of chlorate in soil and in water is the chloride anion. Any intermediate chlorine dioxide that may form under environmental conditions will undergo photochemical reactions when exposed to sunlight. The chlorine oxyanions, chlorite and hypochlorite (other possible more reduced intermediates in the ultimate reduction of chlorate to chloride), are strong oxidizers in themselves; thus, they are also reduced and/or undergo disproportionation reactions. Although reduction reactions of chlorate, chlorite, and hypochlorite are said to occur very fast, how fast they occur is not known (*i.e.*, the actual rate constants in the environment are not known). Therefore, at any given time the distribution of reduced species (type and concentration) cannot be estimated. However, it is unlikely that a single reduced species would be present. Chlorite is being considered in the chlorite/chlorine dioxide reregistration eligibility decision (case number 4043). (See *Revised Inorganic Chlorates. HED Chapter of the Reregistration Eligibility Decision Document (RED)* dated January 26, 2006, for additional details.)

5. Dietary Exposure and Risk (Food)

Dietary exposure (food only) to inorganic chlorates as the chlorate ion (ClO_3^-) may be expected from the following dietary exposure routes: 1) from sodium chlorate as an active ingredient in conventional (agricultural) pesticides used on food crops; 2) from sodium chlorate and potassium chlorate as inert ingredients in conventional pesticides used on food crops or in poultry premises; 3) from secondary residues in meat/milk/poultry/eggs due to residues in animal feedstuffs; 4) from sodium chlorate and calcium chlorate as inert ingredients in antimicrobial agents used as fruit, vegetable, and egg sanitizing washes, as treatments to mushrooms to control bacterial blotch, as treatments to seed used for sprouting, for conditioning live oysters, in poultry drinking water, in fish filleting, and in pecan cracking/dyeing; and 5) as a potential redox of chlorine dioxide and sodium chlorite in conventional and antimicrobial pesticides; (6) from degradation of hypochlorites in antimicrobial agents used as fruit and vegetable washes; and, (7) from translocation of very small amounts of chlorate ion (ClO_3^-) by plants (translocation of significant amounts would be phytotoxic to plants) from the environment which may be present as a result of inorganic chlorate pesticide uses.

No acute dietary endpoint was selected because effects attributable to a single dose were not seen in the available data. Chronic and cancer dietary analyses were conducted for the general U.S. population and various population subgroups.

a. Exposure Assumptions

A chronic dietary risk assessment was conducted using the Dietary Exposure Evaluation

Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. No food monitoring data are available for this risk assessment; therefore, exposure estimates in food were based on field trial data or, in the case of fruit/vegetable/other washes, were derived from a film thickness model. No chemical-specific livestock metabolism or feeding data are available; exposure estimates in meat, milk, poultry, and eggs were derived from rat metabolism data, field trial data, and livestock reference information concerning feed consumption, tissue weights, and milk production. Default concentration factors (no chemical-specific processing data are available) and the effects of washing after foliar treatments were also incorporated into the risk assessment. Percent crop treated data were used in this analysis. Exposures were single point estimates; no residue decline was utilized.

b. Population Adjusted Dose

A population adjusted dose, or PAD, is the reference dose (RfD) adjusted for the FQPA SF. A risk estimate that is less than 100% of the acute PAD (aPAD), the dose at which an individual could be exposed over the course of a single day and no adverse health effects would be expected, does not exceed EPA's level of concern. Likewise, a risk estimate that is less than 100% of the chronic PAD (cPAD), the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected, does not exceed EPA's level of concern.

c. Acute Dietary Risk (Food)

No acute dietary endpoint was selected because effects attributable to a single dose were not seen in the available data; therefore, an acute dietary risk assessment was not conducted.

d. Chronic Dietary Risk (Food)

A chronic (non-cancer) dietary risk assessment was conducted for all potential chlorate dietary exposure routes using food consumption data from 1994-1996 and 1998. The chronic dietary exposure and risk estimates resulting from food intake were determined for the general U.S. population and various population subgroups.

The chronic (non-cancer) dietary (food only) risk is below the Agency's level of concern for the general US population and all population subgroups. The most likely highest exposed population subgroup, children 1-2 years of age, was at 28% of the cPAD. See Table 3 below for details.

Table 3. Results of Chronic Dietary (Food only) Exposure Analysis

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	% cPAD
All populations	0.03	0.002730	9
All infants (< 1 year old)		0.004511	15

Table 3. Results of Chronic Dietary (Food only) Exposure Analysis			
Children 1-2 years old		0.008376	28
Children 3-5 years old		0.006906	23

A cancer dietary risk assessment was conducted for all potential chlorate dietary exposure routes, using the same dietary (food only) exposure estimates used in the chronic (non-cancer) dietary risk assessment for the US population. As discussed above, sodium chlorate is a thyroid toxicant producing thyroid gland follicular cell hypertrophy in rats and mice following chronic exposures, and may be producing follicular cell tumors in rats. The lack of mutagenicity indicates that the thyroid tumors are induced by a non-mutagenic mechanism. Children are not expected to be more susceptible to chlorate-induced thyroid effects than adults, and the endpoint selected for the thyroid effects is protective for all populations, including children. Therefore, as shown in Table 3 above, the chronic (food only) dietary risk assessment is protective for cancer for the general US population, since the estimated risk does not exceed 100% of the cPAD.

6. Dietary Exposure and Risks (Drinking Water)

Drinking water exposure to pesticides can occur through surface and groundwater contamination. Chronic dietary (water only) risk assessments were conducted using DEEM-FCID™ Version 2.03 and drinking water consumption data from the USDA's CSFII from 1994-1996 and 1998. Exposures were single point estimates; no residue decline was utilized.

Drinking water exposure can result from several different uses for sodium chlorate. Agriculturally, sodium chlorate is used as a defoliant and dessicant, primarily on cotton; however, it is also applied to a wide variety of other crops including, but not limited to, rice, corn, soybeans, dry beans, potatoes, sunflowers, flax, safflower, chili peppers (for processing only), grain sorghum, and wheat. As a non-selective herbicide, it is applied to industrial/non-crop areas such as rights-of-ways, building perimeters, ditch banks, bleachers, airport runways, vacant lots, fire hydrants, or as a pre-paving treatment. Sodium chlorate is also used to generate chlorine dioxide, which is then used to bleach wood pulp/paper and, in some cases, treat drinking water. All of these uses could result in chlorate reaching water systems. However, the majority of chlorate in drinking water is a result of drinking water disinfection treatment practices.

In the US, there are two primary methods of drinking water treatment. The first method is the generation of chlorine dioxide. In the second method, either gaseous chlorine or hypochlorite is used to produce free chlorine. Each of these methods, except the use of gaseous chlorine, produce chlorate as a disinfection byproduct (DBP). The American Water Works Association (AWWA) Disinfection Systems Committee tracks disinfection practices in US community water systems. AWWA's most recent comprehensive survey (completed in 1998) estimated that, of all community water systems (CWS), approximately 20% of CWSs serving populations greater than 10,000 use sodium hypochlorite (2% generated it on-site), 8% use chlorine dioxide, and <1% use calcium hypochlorite. For CWSs using groundwater and serving populations less than 10,000, the survey estimated that approximately 34% use sodium hypochlorite, none use chlorine dioxide, and at least 4.5% use calcium hypochlorite. For CWSs

using surface water and serving less than 10,000, the survey estimated that 17% use sodium hypochlorite, 6% use chlorine dioxide, and 9% use calcium hypochlorite.

For chlorine dioxide generation, both sodium chlorate and sodium chlorite are used as precursor materials, and both typically result in chlorate byproduct in finished drinking water. Sodium chlorite is more commonly used than sodium chlorate. The free chlorine disinfection process involves the use of either gaseous chlorine, or sodium or calcium hypochlorite, as precursor materials. Historically, gaseous chlorine has far more widely been used than hypochlorite to produce free chlorine. In recent years, primarily as a result of various homeland security measures, many drinking water systems are switching from gaseous chlorine to hypochlorite. While the use of gaseous chlorine does not result in chlorate byproduct in finished drinking water, the use of either sodium or calcium hypochlorite can produce chlorate byproduct, and this will be discussed in greater detail later in this section.

Chlorine Dioxide

The use of chlorine dioxide can introduce chlorate into the finished water by several routes. Drinking water plants generally use sodium chlorite as a starting material (*i.e.,* feedstock) in the production of chlorine dioxide. Chlorate ion may be present as a contaminant in the sodium chlorite feedstock (usually less than four percent of the active chlorite is chlorate). A typical range of chlorate carryover to the finished water from chlorite feedstock contamination is about 50 µg/L for a 1 mg/L dose of chlorine dioxide. Technology to generate chlorine dioxide using sodium chlorate is now available to the drinking water industry, which introduces the possibility of chlorate carryover to the finished water from the chlorate feedstock. However, since this method is more technically complicated than the method used with sodium chlorite, sodium chlorite is far more commonly used in the generation of chlorine dioxide than sodium chlorate.

Chlorate ion (ClO_3^-) may also be produced due to inefficient generation of chlorine dioxide. Excess chlorine will favor the production of chlorate over chlorine dioxide, as will keeping the generator mixtures at highly alkaline (pH > 11) or acidic (pH < 3) conditions. If the concentrations of feedstock reactants are too low, or too much dilution water is added during the reaction, chlorate formation is also favored.

Chlorite ion (ClO_2^-) is a major degradation product resulting from the reaction of chlorine dioxide with inorganic and organic constituents in the water. When free chlorine is used after the application of chlorine dioxide in the treatment process, chlorite is oxidized to chlorate. This conversion will continue over time as the water travels through the distribution system. Chlorate ion is also formed by photodecomposition of chlorine dioxide when treated water is exposed to bright sunlight in open basins.

There are ways that water systems can control the levels of chlorate in drinking water, and these will be discussed in Section 4 of this document.

Hypochlorite

Chlorine-based disinfectants, such as free chlorine, are also used by drinking water treatment systems to treat drinking water. Some of these water systems use sodium hypochlorite or calcium hypochlorite as their source of free chlorine. Chlorate ion can be formed in these products during the manufacturing process, but the decomposition of hypochlorite solutions during storage is the more significant source of chlorate ion in systems using hypochlorite.

Chlorate ion concentrations increase between the time of manufacture and delivery to the water plant. The rate at which hypochlorite ion disproportionates to chlorate is influenced by concentration of hypochlorite, pH, and temperature. As with the chlorine dioxide methods, there are several ways that water systems using hypochlorite can control the levels of chlorate; these will be discussed in Section 4 of this document.

a. Drinking Water Exposure

Data on the occurrence of chlorate ion in drinking water were available from two primary sources: 1) the Information Collection Rule (ICR) Auxiliary 1 Database, Version 5.0, and 2) the American Water Works Association Research Foundation (AwwaRF) study on the control of chlorate ion in hypochlorite solutions. The ICR data is the more extensive data set, and the water systems represented in the ICR database serve 60% of the total US population. The EPA Office of Water (OW) issued the ICR in order to collect data to support future regulation of microbial contaminants, disinfectants, and disinfection byproducts. Monitoring for chlorate was included in the ICR, since chlorate is a disinfection byproduct. Source water and drinking water were monitored for chlorate ion between July 1997 and December 1998. Water systems serving a population of at least 100,000 were required to monitor for chlorate ion at treatment plants using chlorine dioxide or hypochlorite solutions in the treatment process. Plants using chlorine dioxide collected monthly samples of the source water entering the plant, the finished water leaving the plant, and at three sample points in the distribution system (near the first customer, an average residence time, and a maximum residence time). Plants using hypochlorite solutions were required to collect quarterly samples of the water entering and leaving the plant. If chlorine dioxide or hypochlorite solutions were used intermittently at a plant, chlorate ion samples were only required in sample periods in which they were in use.

The ICR Database was considered the more appropriate data source for estimating average chlorate concentrations in drinking water from individual water treatment plants. The AwwaRF study is a less robust data set, consisting of only one sample per utility, whereas the ICR database included multiple samples over an 18 month period. Both the AwwaRF study and the ICR data reveal high concentrations of chlorate ion to be a local problem affecting a relatively small number of systems.

Based on the ICR monitoring data, the Agency was able to assess exposure to chlorate in drinking water. The ICR data confirm the presence of chlorate in untreated source water which may be the result of agricultural and other uses of sodium chlorate. However, the chlorate concentrations in ambient water are generally very low and are minor compared to those observed in drinking water treated with chlorine dioxide or hypochlorite. Table 4 below

summarizes the annual chlorate concentrations calculated for each plant. The data listed for hypochlorite plants is the average chlorate concentrations, taken from samples collected at the entry point to a distribution system. The figures for chlorine dioxide in the next two columns (chlorine dioxide plans and combined hypochlorite and chlorine dioxide plants) represent the distribution system average chlorate concentrations. As previously explained, for chlorine dioxide plants, samples were collected from three points in the distribution systems; the data from these three collection points were used to calculate a distribution system average. Monitoring in the distribution system was required by the ICR, since chlorate concentrations are expected to change as the water travels through the distribution system. The concentration changes, because many of the chlorine dioxide systems use chlorine to maintain a disinfectant residual in the distribution system, and chlorine reacts with the chlorite ion to form chlorate ion.

Table 4. Distribution of Average Annual Chlorate Concentrations - ICR Data

	Hypochlorite Plants[a]	Chlorine Dioxide Plants[b]	Combined Hypochlorite and Chlorine Dioxide Plants
Number of Public Water Systems	44	22	66
Number of Water Treatment Plants	61	29	90
Chlorate Concentration (µg/L)			
10th Percentile	23	52	24
20th Percentile	37	79	53
50th Percentile (Median)	99	129	108
80th Percentile	155	217	179
90th Percentile	239	264	242
Maximum	502	691	691

a. Concentrations for hypochlorite plants are an average of samples collected from distribution system entry points.

b. For chlorine dioxide pants, the distribution system average concentration was calculated for each WTP using the three distribution system sample points.

b. Acute Dietary Risk (Drinking Water)

No acute dietary endpoint was selected because effects attributable to a single dose were not seen in the available data; therefore, an acute dietary (drinking water only) risk assessment was not conducted.

c. Chronic Dietary Risk (Drinking Water)

The chronic dietary (water only) risk assessment for chlorate in drinking water, using the highest annual average concentration estimated at 0.69 mg/L, is below 100% of the cPAD, and therefore, is below the Agency's level of concern for the general US population and all population subgroups except infants (<1 year of age). The highest exposed subgroup, infants, was 159% of the cPAD, based on the highest annual average concentration of chlorate in Table 4 (0.69 mg/L). Using the 90th percentile annual average concentration estimated at 0.24 mg/L, the chronic (non-cancer) dietary (water only) risk for infants was 55% of the cPAD. Also for infants, using the median annual average concentration estimated at 0.11mg/L, the risk was 25%

of the cPAD. See Table 5 below for details.

Table 5. Sum Table 5. Summary of Estimated Chronic Dietary (water only) Exposure and Risk for Sodium Chlorate by Average Annual Concentration in Large Drinking Water Systems				
Population Subgroup	**cPAD mg/kg/day**	**% cPAD**		
		Water Estimated at the Highest Annual Average (0.69 mg/L)	**Water Estimated at the 90th Percentile Annual Average (0.24 mg/L)**	**Water Estimated at the Median Annual Average (0.11 mg/L)**
General U.S. Population	0.03	49	17	8
All Infants (< 1 yr)		159	55	25
Children 1-2 yrs		72	25	12
Children 3-5 yrs		67	23	11
Children 6-12 yrs		47	16	7
Youth 13-19 yrs		35	12	6
Adults 20-49 yrs		45	16	7
Adults 50+ yrs		48	17	8
Females 13-49 yrs		45	16	7

7. Residential Exposure and Risk

Residential exposure assessments consider all potential non-occupational pesticide exposure, other than exposure due to residues in foods or in drinking water. For sodium chlorate, the Agency has evaluated potential exposure and risk to sodium chlorate for homeowners who handle (mix, load, and apply) products containing sodium chlorate. The Agency also evaluated potential post-application exposure and risk to adults and children entering sodium chlorate-treated areas, such as lawns, or patio areas. Since the episodic nature of residential exposure for sodium chlorate is inconsistent with the mechanism of chlorate carcinogenicity, a residential cancer risk assessment was not conducted.

To estimate residential non-cancer (dermal and inhalation) risks, the Agency calculates a margin of exposure (MOE), which is the ratio of the NOAEL selected for risk assessment to the exposure. This MOE is compared to a level of concern which is the same value as the uncertainty factor (UF) applied to a particular toxicity study. The standard UF is 100x (10x to account for interspecies extrapolation and 10x for intraspecies variation), plus any additional FQPA SF retained due to concerns unique to the protection of infants and children. The FQPA SF for sodium chlorate is reduced to1x for reasons explained above; thus, the Agency's LOC is 100.

a. Residential Handler Risks

The Agency determined that there is the potential for residential handlers to be exposed to sodium chlorate in outdoor residential settings during the application of conventional pesticide

products containing sodium chlorate as the active ingredient. Sodium chlorate can be used as a non-selective herbicide in outdoor residential environments as a spot treatment or edging treatment around patios, along fence lines, lawn edges, around foundations, underneath or around wood decks, and in cracks and crevices of driveways. Although there is the potential for dermal exposure by residential handlers, sodium chlorate is an inorganic salt; therefore, significant absorption of sodium chlorate through intact skin is not expected. Hence, only a short-term risk assessment for residential handlers exposed to sodium chlorate *via* the inhalation exposure route was conducted.

The risk assessment considered seven residential exposure scenarios based on the types of equipment and techniques that can potentially be used to make sodium chlorate applications, such as handheld equipment (hand wand sprayers) and ready-to-use (RTU) methods (sprinkler cans). The use patterns assessed are representative of the range of sodium chlorate residential uses.

The Agency considered residential handler exposure scenarios to be short-term (1-30 days) only due to infrequency of use associated with homeowner products. The residential risk assessment is also based on estimates of what and how much homeowners would typically treat, such as the size of the lawn or garden, based on the Agency's standard operating procedures for residential exposures. For more information on the daily volume handled and the area treated used in each residential handler scenarios, refer to *Inorganic Chlorates: Residential and Occupational Exposure Assessment for the Reregistration Eligibility Decision Document*, dated January 26, 2006.

Risk to homeowners handling sodium chlorate products are below the Agency's LOC. The inhalation MOEs for all scenarios assessed are greater than 100 (ranging from 370 to 710,000). See Table 6 for further detail.

Table 6. Sodium Chlorate Residential Risk Estimates[1]

Exposure Scenario (Scenario #)	Daily Area Treated	Crop/Target	Application Rate	Inhalation MOE[2]
Mixing/loading/applying liquids with a low pressure hand wand sprayer	1000 ft^2/day	Spot/edging treatment	23.7 lb ai/1000 ft^2	3000
Loading/applying RTU liquid with a trigger pump sprayer	1 gallon/day	Spot/edging treatment	0.196 lb ai/gallon	87000
Mixing/loading/applying liquids with a sprinkler can	1000 ft^2/day	Spot/edging treatment	23.7 lb ai/1000 ft^2	5200
Applying liquid with a RTU sprinkler can	1 gallon /day	Spot/edging treatment	0.27 lb ai/gallon	710000
Applying granules by hand	1000 ft^2/day	Spot/edging treatment	12 lb ai/1000 ft^2	370
Loading and applying granules with a	1000 ft^2/day	Spot/edging treatment	12	2800

Table 6. Sodium Chlorate Residential Risk Estimates[1]				
Exposure Scenario (Scenario #)	**Daily Area Treated**	**Crop/Target**	**Application Rate**	**Inhalation MOE[2]**
belly grinder			lb ai/1000 ft^2	
Loading and applying granules with a push-type spreader	1000 ft^2/day	Spot/edging treatment	12 lb ai/1000 ft^2	200000

1. Residential exposures assessments do not include personal protective equipment (PPE).
2. Inhalation MOE = Oral NOAEL (30 mg/kg/day) / Daily Inhalation Dose. The LOC for MOE is 100.

b. Residential Post-Application Risks

The Agency uses the term "post-application" to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Unlike residential handler exposure, where the EPA assumed only adults will be handling and applying sodium chlorate products, individuals of varying ages can potentially be exposed when reentering or performing activities in areas that have been previously treated. For products containing sodium chlorate as the active ingredient, a post-application exposure assessment was not conducted for the following reasons:

- Although potential for post-application dermal exposure in residential and occupational settings exists, sodium chlorate is an inorganic salt; therefore, significant absorption of sodium chlorate through the skin is not expected.
- Post-application inhalation exposure is not expected due to a negligible vapor pressure.
- Post-application exposure assessments for residential settings (dermal and incidental oral) are not typically performed for spot treatments/edging treatments.

However, for products containing sodium chlorate as an inert ingredient, there is the potential for post-application exposure in outdoor residential settings from entering areas previously treated. Therefore, a residential post-application risk assessment was conducted based on this use. As an inert ingredient in herbicide formulations professionally broadcast on residential sites, there is potential for children to have incidental oral exposures *(i.e.,* hand-to-mouth, object-to-mouth, and soil ingestion). As stated above, residential post-application exposures *via* dermal and inhalation routes are not of concern. Although there is the potential for post-application dermal exposure in residential settings, sodium chlorate is an inorganic salt; therefore, significant dermal absorption of sodium chlorate through intact skin is not expected. Post-application inhalation exposure for sodium chlorate is not expected due to negligible vapor pressure.

A series of conservative assumptions and exposure factors served as the basis for completing the residential post-application risk assessment, and those assumptions and factors are listed in detail in the previously referenced *Inorganic Chlorates: Residential and Occupational Exposure Assessment for the Reregistration Eligibility Decision Document,* dated January 26, 2006. The risk estimates for incidental oral exposures to sodium chlorate as an inert ingredient in other pesticide formulations and the highest exposed population subgroup are

shown in Table 7. The combined oral MOE of 23,000 is greater than 100; therefore, the risk is below the Agency's level of concern.

Table 7. Residential Post-application Risk Estimates for Sodium Chlorate as an Inert Ingredient in Herbicide Products Applied Professionally to Residential Sites

Population Subgroup	Scenario	Route	MOE	Combined MOE
Child	Hand-to-Mouth	Oral	29000	23000
	Object-to-Mouth	Oral	110000	
	Soil Ingestion	Oral	8600000	

8. Aggregate Risk

The FQPA amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there is reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure.

In accordance with FQPA, the Agency must consider and aggregate pesticide exposures and risks from three major sources: food, drinking water, and if applicable, residential or other non-occupational exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, the Agency considers both the route and duration of exposure. Aggregate exposure and risk assessments for sodium chlorate include the following scenarios: short-term (food + water + residential handler) and chronic dietary (food + drinking water). Results of the aggregate risk assessment are summarized here, and are discussed more extensively in the document: *Revised Inorganic Chlorates. HED Chapter of the Reregistration Eligibility Decision Document (RED)* dated January 26, 2006, which is available in the public docket and on the internet.

a. Short-Term Aggregate Risk (food + drinking water)

Short-term aggregate risk was assessed for adults only, using the highest exposure scenario (inhalation exposure while applying granules by hand). Short-term aggregate risk for children would be less than the short-term aggregate risk for adults (MOE of 324), because the short-term MOE for residential risk to children from the use of sodium chlorate as an inert is significantly greater *(i.e.*, lower risk) than the residential handler short-term MOE for adults. Thus, all short-term aggregate risks are below the Agency's level of concern (*i.e.*, MOEs are greater than 100), as presented in Table 8.

Table 8. Short-Term Aggregate Risk Calculations				
Population	**Target Aggregate MOE**	**MOE Food + water**	**MOE inhalation**	**Aggregate MOE (food + water + residential)**
Adult	100	1715	400	324

b. Chronic Aggregate Risk (food + drinking water)

Since no chronic residential (non-dietary) exposure scenarios have been identified, the chronic aggregate risk assessment considers exposure only through food and drinking water. To assess aggregate risks from chronic food and drinking water exposure, the Agency used conservative Tier 1 chronic food estimates and incorporated drinking water monitoring data collected under the Information Collection Rule (ICR). For chronic aggregate dietary risks, using the estimated highest annual average of drinking water concentrations, food and drinking water chronic exposure estimates were above the Agency's level of concern for all infants (<1 year old), the most highly exposed population, at 174% cPAD. Chronic aggregate dietary risks were at the Agency's level of concern (100 % cPAD) for children 1-2 years of age. All other population subgroups were <100 % cPAD, and therefore, below the Agency's level of concern. At the 90th percentile and median annual average water concentration, all population subgroups are below the Agency's LOC. The results of this assessment for sodium chlorate are presented below in Table 9.

Table 9. Summary of Chronic Dietary Aggregate (food + drinking water) Risk for Sodium Chlorate				
Population Subgroup[a]	**cPAD (mg/kg/day)**	**% cPAD (food + drinking water)**		
		Highest Annual Average (0.69 mg/L)	**90th Percentile Annual Average (0.24 mg/L)**	**Median Annual Average (0.11 mg/L)**
General US Population	0.03	58	26	17
All Infants (< 1 yr)		174	70	40
Children 1-2 yrs		100	53	39
Children 3-5 yrs		90	47	34

9. Occupational Exposure and Risk

The occupational risk assessment addresses risks to workers who may be exposed to sodium chlorate when mixing, loading, or applying a pesticide (i.e., handlers), and when entering treated sites for routine tasks (post-application). Please see Table 2 for the toxicological endpoints used in the sodium chlorate occupational assessment. Based on the registered use patterns of sodium-chlorate, short-term (1-30 days) and intermediate-term (1-6 months) occupational exposures were assessed; long-term (> 6 months) exposure is not expected.

Exposure for workers generally occurs via the dermal or inhalation route; however, since sodium chlorate is an inorganic salt, and significant absorption of sodium chlorate through the skin is not expected, a dermal toxicological endpoint was not selected. As such, a risk assessment for dermal exposure was not performed. Similarly, post-application exposure was not assessed due to the physical and chemical characteristics of sodium chlorate as an inorganic salt; no significant amount of sodium chlorate is expected to be absorbed through the skin, and the vapor pressure is negligible. Further, for the antimicrobial use of sodium chlorate in chlorine dioxide generation for drinking water treatment, exposure to chlorate is expected to be negligible because of its conversion to chlorine dioxide inside the closed generators. Post-application exposure to chlorine dioxide will be addressed in the chlorine dioxide risk assessment and RED.

The occupational assessment estimates non-cancer risks using the MOE approach. MOEs greater than 100 are below the Agency's level of concern for short- and intermediate-term occupational exposure.

Occupational exposure to sodium chlorate was assessed using data from the Pesticide Handler Exposure Database (PHED) and Outdoor Residential Exposure Task Force (ORETF). In addition, standard default assumptions pertaining to average body weight, work day, and area treated daily were used to calculate risk estimates. Application rates used in this assessment are derived directly from current sodium chlorate labels. Worker exposure and risk estimates are based on the best data currently available to the Agency.

The occupational risk assessment is summarized here. For further detail, see the following documents: (1) *Revised Inorganic Chlorates. HED Chapter of the Reregistration Eligibility Decision Document (RED)* dated January 26, 2006; (2) *Inorganic Chlorates: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision (RED) Document (Case 4049),* dated June 13, 2005; and (3) Sodium Chlorate: Occupational and Residential Exposure Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision Document dated January 24, 2005.

a. Handler Risks

Occupational handler exposure assessments are conducted by the Agency using different levels of protection. The Agency typically evaluates all exposures with minimal protection and then adds protective measures in a tiered approach to determine the level of protection necessary to obtain appropriate MOEs. The lowest level (baseline) includes long sleeve shirts, long pants, shoes, and socks. A single layer of PPE includes the addition of chemical-resistant gloves to the baseline attire of long sleeves, long pants, shoes, and socks. A respirator may also be added if there is a concern for inhalation exposure. If MOEs at that level of PPE are less than 100, increasing levels of PPE are applied (*i.e.,* coveralls are added to provide a double layer of protective clothing or respirators). If MOEs are still less than 100 with maximum PPE, then engineering controls are applied (*i.e.,* enclosed cabs or cockpits and closed mixing/loading systems). Note that the lower levels of PPE protect against dermal exposure, and dermal exposure is not anticipated for sodium chlorate. The types of protection, including PPE and engineering controls, which were used to calculate inhalation occupational exposure from sodium chlorate are as follows:

- Baseline: No respirator
- PPE: Dust/mist respirator with an 80% reduction factor
- Engineering Controls: Enclosed cockpits or enclosed cabs

Anticipated use patterns and current labeling for sodium chlorate indicate several major occupational exposure scenarios that can result in handlers receiving inhalation exposures to sodium chlorate, including the antimicrobial use of sodium chlorate to generate chlorine dioxide for drinking water treatment. These exposure scenarios are based on the chemical formulations, equipment, and techniques that handlers can use to make sodium chlorate applications. Exposures are also considered based on their duration. The Agency assessed short- (1 to 30 days) and intermediate-term (30 days to several months) exposures to sodium chlorate, though the results were essentially the same because the toxicological endpoints for short- and intermediate-term exposures are the same in the case of sodium chlorate. For short and intermediate-term exposures, MOEs greater than 100 are not of concern to the Agency.

Risks to handlers treating water systems are below the Agency's level of concern, with inhalation MOEs of 800 to 95,000 depending on the size of the generator. All sodium chlorate applications to chlorine dioxide generators occur in closed delivery systems. In addition, risk for most occupational handler scenarios do not exceed the Agency's level of concern of 100 (i.e, most scenarios had MOEs > 100) at the baseline level of protection. However, risks for the following occupational scenarios did exceed the Agency's level of concern at baseline level of protection:

- Mixing/Loading liquids for groundboom application to industrial/non-crop sites at 1032 lb ai per acre (MOE = 42) and 523 lb ai per acre (MOE = 84);
- Loading granules for tractor-drawn spreader applications to industrial/non-crop sites at 523 lb ai per acre (MOE = 59);
- Applying sprays to industrial/non-crop sites using groundboom equipment (open cab) at 1032 lb ai per acre (MOE = 69); at 523 lb ai per acre (MOE = 140);
- Mixing/Loading/Applying liquids for low pressure handwand applications to industrial/non-crop sites at 1032 lb ai per acre (MOE = 34) and 523 lb ai per acre (MOE = 67); and
- Loading/Applying granules to industrial/non-crop sites using a belly grinder at 523 lb ai per acre (MOE = 65);

Inhalation handler risk for these scenarios did not exceed the Agency's level of concern with the addition of a dust/mist respirator (with an 80% reduction factor). Additionally, risks for certain scenarios were below the Agency's level of concern, without the application of PPE or engineering controls, once lower application rates were used. All risks of concern were at the high end of application rates ($\geq$523 lb ai per acre), whereas at lower rates the risks were not of concern. Table 10 summarizes the risk results for short-term and intermediate-term occupational handlers.

Table 10. Sodium Chlorate: Short- and Intermediate-Term Occupational Inhalation Exposure						
Exposure Scenario	**Daily Area Treated[1]**	**Crop/Target**	**Application Rate (lb ai/A)**	**Baseline Inhalation MOE[2]**	**PPE[3]**	**Engineering Controls**
Mixer/Loaders						
Mixing/Loading liquids for aerial application	1200	Cotton, Corn, Rice, Dry Beans, Grain Sorghum, Flax, Safflower, Sunflower, Soybeans	7.5	190	-------	--------
		Fallow Land, Wheat	6	240	-------	--------
	350	Chili Peppers (for processing only), Potatoes	12.5	400	-------	--------
		Ornamental Gourds, Cucurbits (grown for seed)	6	830	-------	--------
		Guar Beans, Southern Peas	7.5	670	-------	--------
Mixing/Loading liquids for groundboom application	200	Cotton, Corn, Rice, Dry Beans, Grain Sorghum, Flax, Safflower, Sunflower, Soybeans	7.5	1200	-------	--------
		Fallow Land, Wheat	6	1500	-------	--------
	80	Chili Peppers (for processing only), Potatoes	12.5	1800	-------	--------
		Ornamental Gourds, Cucurbits (grown for seed)	6	3600	-------	--------
		Guar Beans, Southern Peas	7.5	2900	-------	--------
	40	Industrial/Non-Crop Sites	1032	42	210	--------
			523	84	420	--------
			132	330	-------	--------
Mixing/Loading liquids for rights-of-way sprayer application	5	Rights-of-Way & Industrial/Non-Crop Sites	1032	340	-------	--------
			523	670	-------	--------
			132	2700	-------	--------
Loading granules for tractor-drawn spreader application	40	Industrial/Non-Crop Sites	523	59	300	--------
			240	130	-------	--------
			161	190	-------	--------
Applicators						
Aerial spray applications (enclosed cockpit)	1200	Cotton, Corn, Rice, Dry Beans, Grain Sorghum, Flax, Safflower, Sunflower, Soybeans	7.50	--------	-------	3400

Table 10. Sodium Chlorate: Short- and Intermediate-Term Occupational Inhalation Exposure						
Exposure Scenario	**Daily Area Treated[1]**	**Crop/Target**	**Application Rate (lb ai/A)**	**Baseline Inhalation MOE[2]**	**PPE[3]**	**Engineering Controls**
Groundboom spray applications		Fallow Land, Wheat	6	--------	-------	4300
	350	Guar Beans, Southern Peas	7.5	--------	-------	12000
		Chili Peppers (for processing only), Potatoes	12.5	--------	-------	7100
		Ornamental Gourds, Cucurbits (grown for seed)	6	--------	-------	15000
	1200	Cotton, Corn, Rice, Dry Beans, Grain Sorghum, Flax, Safflower, Sunflower, Soybeans	7.5	1900	-------	--------
		Fallow Land, Wheat	6	2400	-------	--------
	350	Guar Beans, Southern Peas	7.5	4700	-------	--------
		Chili Peppers (for processing only), Potatoes	12.5	2800	-------	--------
		Ornamental Gourds, Cucurbits (grown for seed)	6	5900	-------	--------
	40	Industrial/Non-Crop Sites	1032	69	340	1200 (closed cab)
			523	140	-------	2300 (closed cab)
			132	540	-------	9200 (closed cab)
Rights-of-way sprayer applications	5	Rights-of-Way & Industrial/Non-Crop Sites	1032	110	-------	--------
			523	210	-------	--------
			132	820	-------	--------
Tractor-drawn spreader applications	40	Industrial/Non-Crop Sites	523	84	420	460 (closed cab)
			240	180	-------	990 (closed cab)
			161	270	-------	1500 (closed cab)
Flaggers						
Flagging for aerial spray applications	350	Various Agricultural Crops	12.5	1400	-------	--------
Mixer/Loader/Applicators & Loader/Applicators						
M/L/A liquids with a low pressure handwand sprayer	2	Industrial/Non-Crop Sites	1032	34	170	--------
			523	67	330	--------
			132	270	-------	--------

Table 10. Sodium Chlorate: Short- and Intermediate-Term Occupational Inhalation Exposure						
Exposure Scenario	**Daily Area Treated[1]**	**Crop/Target**	**Application Rate (lb ai/A)**	**Baseline Inhalation MOE[2]**	**PPE[3]**	**Engineering Controls**
M/L/A liquids with a handgun sprayer	5	Industrial/Non-Crop Sites	1032	230	-------	--------
			523	450	-------	--------
			132	1800	-------	--------
L/A granules with a belly grinder	1	Industrial/Non-Crop Sites	523	65	320	--------
			240	140	-------	--------
			161	210	-------	--------
L/A granules with a push-type spreader	5	Industrial/Non-Crop Sites	523	110	-------	--------
			240	240	-------	--------
			161	360	-------	--------

1. Amount treated is presented in acres/day.
2. Inhalation MOE = Oral NOAEL (30 mg/kg/day) / Daily Inhalation Dose. LOC for MOE is 100.
3. PPE dust/mist respirator with an 80% reduction factor.

a. Incident Reports

Available sources of incident data in humans were reviewed for the active ingredients sodium chlorate and calcium chlorate (not currently registered). No data were found in any of the available databases on calcium chlorate, so this review exclusively addresses sodium chlorate. Data were available from the following sources: OPP Incident Data System (IDS) consisting of reports submitted to EPA by registrants, other federal and state health and environmental agencies, and the public, since 1992; Poison Control Centers (1993-2001); California Department of Pesticide Regulation for pesticide poisoning since 1982; National Pesticide Telecommunications Network (NPTN) for ranking of the top 200 active ingredients for which phone calls were received during calendar years 1984-1991; and National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (NIOSH SENSOR) from 1998-2002.

A total of 21 cases were recorded by the Poison Control Center from 1993 through 2001. Seven reported minor symptoms, and two reported moderate medical outcomes, primarily due to dermal effects such as swelling and rash. It is difficult to draw any conclusions from these reports because of the small number of cases.

Detailed descriptions of 36 cases submitted to the California Pesticide Illness Surveillance Program (1982-2002) were reviewed. However, sodium chlorate was determined to be the primary cause of illness in just four of these cases, and all four occurred in an agricultural setting (three in cotton fields and one unknown). Two of these cases were classified as systemic and one each involved skin or eye effects. The two systemic cases involved applicators; one with nausea and the other with nausea, headache, and itching skin after spraying for one week.

Both of these cases were classified as "possibly" due to sodium chlorate. The skin case involved a worker exposed to drift from an adjacent field and the eye case occurred when a worker bumped into a spray nozzle while getting off the tractor and was splashed in the face. The skin case was classified as "probably," and the eye case as "definitely," due to sodium chlorate.

A number of suicidal ingestions of sodium chlorate have been reported in the literature, and many of these have led to death. The chance of ingesting a fatal dose accidentally is small unless the compound is mistaken for a drug and taken purposely. However, a near-fatal poisoning occurred when a 13-year-old boy "tasted" crystals of this weed killer which he found in his father's shed. In spite of intensive treatment, recovery did not begin until about the 15th day and required a little over 40 days.

Dermal absorption associated with agricultural use of sodium chlorate is not sufficient to cause systemic poisoning. Even by mouth, a large dose is required to produce illness. A 6.35% solution of potassium chlorate was long used as a gargle, or a 300-mg tablet was allowed to dissolve slowly in the mouth to treat pharyngitis before modern antibiotics became available. The toxicities of the sodium and potassium salts are similar. It was considered that a dose of 10,000 mg was fatal. The smallest recorded fatal dose was 7500 mg. However, vigorous treatment saved one person who had ingested about 40,000 mg.

B. Environmental Fate and Effects Risk Assessment

A summary of the Agency's environmental fate and effects risk assessment is presented below. For detailed discussion of all aspects of the environmental risk assessment, please see the *Revised Environmental Fate and Ecological Risk Assessment of Sodium Chlorate,* dated June 1, 2006; it is available on the internet and in the public docket. This risk assessment was refined and updated to incorporate public comments and data received during the phase 3 public comment period.

1. Environmental Fate and Transport

Sodium chlorate, an inorganic salt, is not a naturally occurring chemical. It is made by electrolysis of brine under controlled temperature and pH conditions to optimize the efficiency of the process and yield. Since targeted, guideline studies designed to understand the environmental fate of chlorate are not available, open, peer-reviewed chemical literature and descriptive chemistry of the chlorine system were used as the basis for understanding the redox behavior of chlorate (at least on a qualitative basis) and for generating a screening-level environmental fate assessment.

Physical and chemical properties of a chemical can be used to identify potential routes of exposure. For example, the vapor pressure and Henry's Law Constant provide an indication of the potential to volatilize from soil and water (partitioning into air), and the n-octanol/water partition coefficient provides an indication of the potential to bioaccumulate in fish or other aquatic organisms. Based on the very low vapor pressure and very high solubility of sodium chlorate in water, sodium chlorate is not expected to volatilize from soil or water. In addition, the low log n-octanol/water partition coefficient indicates that sodium chlorate has low potential

to bioaccumulate.

As stated above, sodium chlorate is highly soluble. In addition, sodium chlorate is completely ionized in water, thus producing sodium (Na^+) and the chlorate (ClO_3^-) anion. Anions do not bind readily to soil or sediment particulates[1] and, therefore, are expected to be very mobile. Assuming that chlorate does not undergo any redox reactions, it is expected to be very mobile and to partition predominantly into the water. However, extensive redox reactions are expected to occur in the environment that will reduce the concentration of chlorate in the water column.

The redox chemistry[2] of chlorate affects its behavior in soils and natural water. Therefore, identification of the conditions under which chlorate and other oxyanions of chlorine may predominate is an important consideration in the environmental fate and risk assessment of chlorate. The oxidation-reduction reactions of chlorate with organic matter and other inorganic chemical species are very complex and depend on the redox conditions of the media, nature and concentration of reductants, chlorate concentration, temperature, pH, and degree of moisture (soils). For example, chlorate is generally more stable under alkaline than acidic conditions; however, when a chemical element (chlorine) can exist in two or more oxidation states (i.e., chlorite and chlorate), the redox potential of the media also effects the predominance of the reduction products. Nitrate concentrations in soil and water (as well as other physical and chemical properties of soil and water) play an important role in the redox chemistry of chlorate in the environment.

2. Ecological Exposure and Risk

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity studies using the risk quotient method. Risk quotients (RQs) are calculated by dividing acute and chronic estimated environmental concentrations (EECs) by ecotoxicity values for various wildlife and plant species. RQs are then compared to levels of concern (LOCs), and when the RQ exceeds the level of concern for a particular category, the Agency presumes a risk of concern to that category. See Table 11 below for the Agency's ecological LOCs. Risk characterization provides further information on potential adverse effects and the possible impact of those effects by considering the fate of the chemical and its degradates in the environment, organisms potentially at risk, and the nature of the effects observed.

[1] Unless they chemisorb to soil or sediment particulates. Chemisorption of chlorate is unlikely.

[2] The term "redox chemistry" is used as an overall term for oxidation and reduction reactions. Other terms that are frequently used for oxidizers are "oxidants," "oxidizing agents." Reductants are frequently referred to as "reducing agents." All redox reactions require an oxidant and a reductant. Reductants are electron donors, while oxidants are electron acceptors.

Table 11. EPA's Ecological Levels of Concern (LOCs) and Risk Presumptions			
If a calculated RQ is greater than the LOC presented, then the Agency presumes that…	**LOC terrestrial animals**	**LOC aquatic animals**	**LOC plants**
Acute Risk …there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification	0.5	0.5	1.0
Acute Endangered Species …endangered species may be adversely affected	0.1	0.05	1.0
Chronic Risk …there is potential for chronic risk	1	1	NA

a. Terrestrial Organisms

1. Birds and Mammals

a. Exposure

Sodium chlorate may be applied as a spray (agricultural and nonagricultural uses) or as granules (nonagricultural uses only). The Agency's methods for assessing exposure to terrestrial organisms are different for each of these application methods and are discussed below.

For spray applications, the Agency's terrestrial exposure model (ELL-FATE) was used to estimate exposures and risks to avian and mammalian species. Input values on avian and mammalian toxicity, as well as chemical application and foliar dissipation half-life data, are required to run the model. The model provides estimates of both exposure concentrations and RQs. Specifically, the model provides estimates of concentrations (maximum and average) of chemical residues on the surface of different types of foliage that may be sources of exposure to avian, mammalian, reptilian, or terrestrial phase amphibian receptors. The surface residue concentration (ppm) is estimated by multiplying the application rate (pounds active ingredient per acre) by a value specific to each food item. In all screening-level assessments, the organisms are assumed to consume 100% of their diet as one food type. These exposure estimates are only applicable to the applied pesticide, sodium chlorate. It is uncertain to what extent exposure to reduced species of chlorate, such as chlorite, may occur.

ELL-FATE was run for sodium chlorate for use on agricultural crops using the inputs provided in Table 12 below. In the absence of foliar dissipation half-life data for sodium chlorate, the Agency's default half-life value of 35 days was used for all scenarios.

Table 12. Input Parameters for Sodium Chlorate Used in ELL-FATE			
Crop	**Maximum labeled application rate**	**No. of applications**	**Application interval**
Chili peppers; white/Irish potatoes	12.5 lbs ai/A	1	N/A
Cotton	7.5 lbs ai/A	2	30 days
Corn; flax, guar; southern peas; rice; safflower; sorghum; soybeans; sunflower	7.5 lbs ai/A	1	N/A

Table 12. Input Parameters for Sodium Chlorate Used in ELL-FATE			
Crop	**Maximum labeled application rate**	**No. of applications**	**Application interval**
Agricultural fallow land; dried beans; corn; cucurbits, flax, gourds; guar; southern peas; white/Irish potatoes; rice; safflower; sorghum; soybeans; sunflower	6 lbs ai/A	1	N/A

The predicted upper 90th percentile and mean chlorate EECs (agricultural and non-agricultural uses) on various wild animal food items are presented in Table 13 below.

Table 13. EECs (mg ai/kg-food item) for Terrestrial Animal Risk Assessment for Sodium Chlorate								
Crops	**Predicted 90th Percentile Residue Levels**				**Predicted Mean Residue Levels**			
	short grass	**tall grass**	**broadleaf forage, small insects**	**fruit, pods, seeds, small insects**	**short grass**	**tall grass**	**broadleaf forage, small insects**	**fruit, pods, seeds, small insects**
Agricultural Uses (Spray Applications)								
Chili peppers; white/Irish potatoes	3000	1400	1700	190	1100	450	560	88
Cotton	2800	1300	1600	170	990	420	520	81
Corn; flax, guar; southern peas; rice; safflower; sorghum; soybeans; sunflower	1800	830	1000	110	640	270	340	53
Agricultural fallow land; dried beans; corn; cucurbits, flax, gourds; guar; southern peas; white/Irish potatoes; rice; safflower; sorghum; soybeans; sunflower	1400	660	810	90	510	220	270	42
Non-Agricultural Uses (Spray Applications)								
Industrial sites such as driveways, paths, brick walks, cobble gutters, tennis courts	12500	5700	7000	780	4400	1900	2300	360

Table 13. EECs (mg ai/kg-food item) for Terrestrial Animal Risk Assessment for Sodium Chlorate								
Crops	**Predicted 90th Percentile Residue Levels**				**Predicted Mean Residue Levels**			
	short grass	**tall grass**	**broadleaf forage, small insects**	**fruit, pods, seeds, small insects**	**short grass**	**tall grass**	**broadleaf forage, small insects**	**fruit, pods, seeds, small insects**
Parking lots, fence lines, building perimeters, ditch banks, picnic areas, vacant lots, wood decks, bleachers, cemeteries, fuel tanks, runways, helo pads, etc.	125,000	57,000	70,000	7800	44,000	19,000	23,000	3600

For granular applications, estimation of chlorate loading per unit area (mg/ft^2) is calculated. This approach, which is intended to represent exposure via multiple routes (e.g., incidental ingestion of contaminated soil, dermal contact with treated seed surfaces and soil during activities in the treated areas, preening activities, and ingestion of drinking water contaminated with pesticide) and not just direct ingestion, considers observed effects in toxicity studies and relates them to the amount of pesticide applied to surface area. The maximum labeled application rate for the active ingredient is the basis for the exposure estimate. The terrestrial EECs for sodium chlorate's non-agricultural use granular applications are presented in Table 14 below.

Table 14. Range of Terrestrial EECs (Granular Applications) for Sodium Chlorate Non-Agricultural Uses		
Use	**Application Rate (lbs ai/A)**	**EEC (mg/ft^2)[a]**
Parking lots, under asphalt paving, fence lines, building perimeters, ditch banks, picnic areas, vacant lots, wood decks, bleachers, cemeteries, fuel tanks, runways, helo pads, etc.	520	5400
Around buildings, storage areas, fences, pumps, machinery, fuel tanks, recreational areas, roadways, guard rails, airports, rights of ways.	160	1700

a. EEC = Application rate (lbs/Acre) x 453,000 mg/lb ÷ 43,600 sq ft/Acre

b. Toxicity

Effects characterization describes the potential effects a pesticide can produce in a terrestrial organism, and is based on registrant-submitted studies that describe acute and chronic toxicity effects for various terrestrial animals. Table 15 summarizes the toxicity effects and reference values used to assess risks for sodium chlorate to mammals and birds.

Table 15. Toxicity Reference Values for Mammals and Birds for Sodium Chlorate.			
Exposure Scenario	**Species**	**Toxicity Value Used in Risk Assessment**	**Effect**
Mammals			
Acute	Rat	LD_{50} = > 5000 mg/kg-bw	At 5000 mg/kg-bw, 1/10 animals died.
Chronic	Rat	NOAEC = 500 mg/kg-bw, highest dose tested (approx. 10,000 ppm)	No reproductive effects
Birds			
Acute	Mallard duck	LD_{50} > 2510 mg/kg-bw	No mortality and no clinical signs of toxicity were observed.
Chronic	Bobwhite quail	NOAEC = 271 ppm	The LOAEC was 964 ppm based on effects on egg production and thickness, embryonic survival, and hatchling body weight.

c. Avian Risk Estimates

Acute RQs for birds were not calculated, because no mortality or signs of toxicity were observed in the submitted subacute or acute toxicity studies at concentrations that are above the limit for these types of studies.

Avian chronic RQs for agricultural crops, at the estimated upper 90th percentile residue levels, are presented in Table 16 below. RQ values for all crops and all avian food items assessed, except the fruits, pods, seeds, and small insects category, marginally exceeded the Agency's chronic LOC of 1.0. The highest chronic avian RQ was 11 (chili pepper/potato and short grass scenario). Chronic RQs based on mean EECs, although not presented here, would be approximately three times lower for most food items than those based on the 90th percentile residue levels shown below.

Table 16. Avian Chronic Risk Quotients for Sodium Chlorate Agricultural Uses				
Crops	**Short grass**	**Tall grass**	**Broadleaf forage, small insects**	**Fruit, pods, seeds, small insects**
Chili peppers; white/Irish potatoes	11.0	5.2	6.3	0.7
Cotton	10.0	4.8	5.9	0.63
Corn; flax, guar; southern peas; rice; safflower; sorghum; soybeans; sunflower	6.6	3.1	3.7	0.41
Agricultural fallow land; dried beans; corn; cucurbits, flax, gourds; guar; southern peas; white/Irish potatoes; rice; safflower; sorghum; soybeans; sunflower	5.2	2.4	3.0	0.33

Chronic RQs for birds are not presented for chlorate's non-agricultural uses (granular or

spray). However, RQs would be considerably higher for birds foraging where chlorate is applied at the rates assessed for the non-agricultural uses. EECs ranged from 12,500 to 125,000 (short grass food item), which would result in chronic avian RQs of 46 to 460. The size of the treated areas for these uses is uncertain, and this will be discussed further in Section IV of this document; therefore, the likelihood that a bird would consume 100% of its diet from a non-agricultural area treated with sodium chlorate is uncertain.

d. Mammalian Risk Estimates

Acute RQs were not calculated for mammals. The LD_{50} from a core acute oral toxicity study in rats was >5000 mg/kg-bw. In this study, 10% (1/10) of the rats administered 5000 mg/kg died. Mortality was not observed at any other dose. Therefore, the data were not sufficient to allow for characterization of the dose-response relationship and the proximity of the LD_{50} to 5000 mg/kg-bw is uncertain. For this reason, acute RQs were not calculated. However, Tables 17 and 18 below present a comparison of the body weight adjusted LD_{50}s to the agricultural and non-agricultural EECs, respectively, based on current use rates and the spray application method. These ratios can be used to estimate high-end acute risk to exposed mammals. Actual RQs would be lower than the values in Tables 17 and 18.

Table 17. Proximity of the lowest observed acute toxic dose in mammals to the upper 90th percentile EEC (mg/kg-bw) for the range of maximum application rates for all agricultural uses

Food item	Size of mammal (grams)	Adjusted lowest observed toxic dose (mg/kg-bw)	Range of EECs (mg/kg-bw)[a]	Ratio of lowest observed toxic dose to the upper 90th percentile EEC (unitless)
Short grass	15	10,989	1400 - 2900	0.13 - 0.26
	35	8891	950 - 2000	0.11 - 0.22
	1000	3846	200 - 450	0.052 - 0.12
Tall grass	15	10,989	630 - 1300	0.057 - 0.12
	35	8891	440 - 910	0.049 - 0.10
	1000	3846	99 - 210	0.026 - 0.055
Broadleaf plants/small insects	15	10,989	770 - 1600	0.070 - 0.15
	35	8891	540 - 1100	0.061 - 0.12
	1000	3846	120 - 250	0.031 - 0.065
Fruits, pods, large insects	15	10989	86 - 180	<0.01 - 0.016
	35	8891	59 - 120	<0.01 - 0.013
	1000	3846	14 - 28	<0.01 - <0.01

a. EECs were calculated by assuming that small, medium, and large mammals consume 95%, 66%, and 15% of their body weight daily. Only the highest and lowest EECs from chlorate's agricultural uses are used in this assessment.

For sodium chlorate's agricultural uses, all of the acute ratios are below the Agency's acute and endangered species LOC of 1.0 and 0.1, respectively, with the exception of small

mammals eating short grass. The highest exceedence is for 15 gram mammals eating short grass (ratio = 0.26).

Based on current non-agricultural use application rates, the only group that does not exceed the Agency's acute mammalian LOC of 1.0 is animals eating fruits, pods, or large insects (ratios range from 0.3 to 0.7). The Agency's acute mammalian endangered species LOC of 0.1 is potentially exceeded for all size animals and food items. While the ratios presented in Table 18 suggest that there could be risk to mammals of all sizes that forage in the area where chlorate is used for the non-agricultural spray applications, the risk was likely over-estimated, since an LD_{50} has not been established. The highest dose tested in the available toxicity studies (5000 mg/kg-bw) induced 10% mortality. The proximity of the LD_{50} to 5000 mg/kg-bw is uncertain. Furthermore, many of the non-agricultural uses will likely result in small contiguously treated areas; therefore, the likelihood that an animal will consume 100% of its diet from the areas treated with sodium chlorate is low for some of these uses. Nonetheless, the EECs were predicted to be up to 11 times higher than 5000 mg/kg-bw for the non-agricultural uses. Therefore, there may be some acute risk to mammals at levels of concern to the Agency for non-agricultural uses.

Table 18. Proximity of the lowest observed acute toxic dose in mammals to the predicted EEC (mg/kg-bw) for the range of maximum application rates for all non-agricultural uses (spray applications)

Food item	Size of mammal (grams)	Adjusted lowest observed toxic dose (mg/kg-bw)	Range of EECs (mg/kg-bw)[a]	Ratio of lowest observed toxic dose to the upper 90th percentile EEC (unitless)
Short grass	15	10989	11,900 - 119,000	1.1 - 11
	35	8891	8200 - 82,000	0.93 - 9.3
	1000	3846	1900 - 19,000	0.49 - 4.9
Tall grass	15	10989	5400 - 54,000	0.49 - 4.9
	35	8891	3800 - 38,000	0.43 - 4.3
	1000	3846	860 - 8600	0.22 - 2.2
Broadleaf plants/small insects	15	10989	6700 - 67,000	0.61 - 6.1
	35	8891	4600 - 46,000	0.52 - 5.2
	1000	3846	1100 - 11,000	0.27 - 2.7
Fruits, pods, large insects	15	10989	740 - 7400	0.07 - 0.7
	35	8891	520 - 5200	0.06 - 0.6
	1000	3846	120 - 1200	0.03 - 0.3

a. EECs were calculated by assuming that small, medium, and large mammals consume 95%, 66%, and 15%, respectively, of their body weight daily, and were calculated using the lowest and highest labeled application rates (52 lbs ai/A and 520 lbs ai/A) that are most likely to result in exposure

RQs were not calculated for acute risk for non-agricultural granular applications for reasons previously discussed. However, Table 19 below presents a comparison of the body weight adjusted lowest observed toxic dose in rats (5000 mg/kg-day) to the granular application

EECs (mg/ft^2). These ratios indicate a potential acute risk to mammals of all size classes, as the lowest ratio (0.43 for large mammals and the building and storage area perimeter scenario) exceeds the acute endangered species LOC of 0.1.

Table 19. Range of ratios of chlorate's body weight adjusted LD_{50} to granular EECs (mg/ft^2) for sodium chlorate's non-agricultural uses (granular formulations)

Use	Body Weight (g)	Rat LD_{50} mg/kg-bw	EEC (mg/ft^2)[a]	Ratio of LD_{50} to EEC
Parking lots, under asphalt paving, fence lines, building perimeters, ditch banks, picnic areas, vacant lots, wood decks, bleachers, cemeteries, fuel tanks, runways, helo pads, etc.	15	10,989	5400	33
	35	8891	5400	17
	1000	3846	5400	1.4
Around buildings, storage areas, fences, pumps, machinery, fuel tanks, recreational areas, roadways, guard rails, airports, rights of ways.	15	10,989	1700	10
	35	8891	1700	5.4
	1000	3846	1700	0.43

a. EEC = Application rate (lbs/Acre) x 453,000 mg/lb ÷ 43,600 sq ft/Acre

For mammals, the Agency typically evaluates the mammalian reproductive effects for exposures greater than 30 days. Interpretation of the RQs resulting from the NOAEL of 500 mg/kg-day observed in a 2-generation rat study is difficult in this respect. Although the study did indicate some chronic effects, reproduction effects were not observed at any dose level tested. Because 500 mg/kg was the highest dose tested, it is uncertain whether there is a NOAEL for reproductive effects. In addition, if there is an actual NOAEL for reproductive effects, it could be much greater than 500 mg/kg.

However, the Agency calculated RQs based on the 500 mg/kg-day NOAEL as a conservative estimate of risk, as presented in Table 20. Based on this conservative estimate, chronic mammalian LOC of 1.0 was only slightly exceeded for the smallest weight classes of mammals for most food items and the largest weight class of mammals feeding on short grass. Based on the lack of observed reproductive effects in the chronic study and the slight RQs exceedances for agricultural uses, the Agency does not anticipate a chronic risk of concern to mammals from agricultural uses of sodium chlorate.

Table 20. Mammalian Chronic Risk Quotients for Sodium Chlorate's Agricultural Uses (Spay Application)

Use	Food Item	15-gram mammal	35-gram mammal	1000-gram mammal
Single application of 12.5 lbs ai/A				
Chili peppers; white/Irish potatoes	Short Grass	2.6	2.2	1.2

Table 20. Mammalian Chronic Risk Quotients for Sodium Chlorate's Agricultural Uses (Spay Application)				
Use	**Food Item**	**15-gram mammal**	**35-gram mammal**	**1000-gram mammal**
Single application of 12.5 lbs ai/A				
Chili peppers; white/Irish potatoes	Tall Grass	1.2	1.0	0.55
	Broadleaf plants/small insects	1.5	1.3	0.67
	Fruits/pods/large insects	0.16	0.14	0.07
Multiple applications (7.5 lbs ai/A, 2 applications, 30-day interval)				
Cotton	Short Grass	2.4	2.1	1.1
	Tall Grass	1.1	0.95	0.51
	Broadleaf plants/small insects	1.4	1.2	0.62
	Fruits/pods/large insects	0.15	0.13	0.07
Single application (7.5 lbs ai/A)[a]				
Corn; flax, guar; southern peas; rice; safflower; sorghum; soybeans; sunflower **Agricultural fallow land;** dried beans; corn; cucurbitsa, flax, gourds; guar; southern peas; white/Irish potatoes; rice; safflower; sorghum; soybeans; sunflower	Short Grass	1.6	1.3	0.72
	Tall Grass	0.72	0.61	0.33
	Broadleaf plants/small insects	0.88	0.75	0.40
	Fruits/pods/large insects	0.10	0.08	0.04

a. EECs and RQs are similar for the 7.5lbs a.i/A (corn, et al.) and 6.0 lbs a.i./A (agricultural fallow land, et al.) and single applications, and LOC exceedances are equivalent; therefore, only results from the single application of 7.5 lbs ai/A are presented.

Reproduction RQs were not calculated for chlorate's non-agricultural uses (spray or granular applications). However, based on the high application rates and resulting high potential EECs, risks from chlorate's non-agricultural uses could be considerably higher than risks presented for agricultural uses.

2. Non-Target Insects

EPA currently does not estimate RQs for terrestrial non-target insects. Furthermore, the Agency has no insect toxicity data for sodium chlorate.

3. Non-Target Terrestrial Plants

Based on chlorate's non-selective mode of action and lack of adequate toxicity data, the Agency presumes risk to non-target terrestrial plants at levels above the Agency's level of concern for all uses. The risks to plants cannot be quantified at this time due to lack of data; however, the Agency will require data to address this uncertainty.

b. Aquatic Organisms

At the present time, there is no methodology to estimate exposure concentrations in water for non-metal inorganic chemical species that can be found in different oxidation states (e.g., for inorganic chemical species that can exhibit extensive pH-pE dependent redox chemistry, such as the chlorine system). As an approximation on the impact of chlorate on surface water quality, the Tier I GENEEC-2 simulation model was used to estimate exposure concentrations in aquatic systems. Extreme assumptions in the environmental persistence of chlorate were made that resulted in high-end exposure concentrations in the standard ecological pond scenario. The predicted chlorate concentrations are believed to be high because the chemical speciation of chlorate was not considered in the assessment. As previously discussed, under thermodynamic equilibrium conditions, chloride is likely the predominant species in natural environments. This analysis, however, indicates that chlorate can be reduced to chloride, but not how fast the reduction will occur. Since there are no input parameters for the model that take into account the redox behavior of chlorate, it was assumed that unchanged chlorate runs off into surface water, where it remains as chlorate.

Unlike the drinking water assessment described in the human health risk assessment section of this document, the exposure values used in the ecological risk assessment do not include the Index Reservoir (IR) and Percent Cropped Area (PCA) factor refinements. These factors represent a drinking water reservoir, not the variety of aquatic habitats relevant to a risk assessment for aquatic animals, such as ponds adjacent to treated fields. Therefore, the EEC values used to assess exposure and risk to aquatic animals are not the same as those used to assess exposure and risk to humans from pesticides in drinking water.

1. Fish

Acute toxicity studies for both freshwater and marine/estuarine fish were consistent with a "practically non-toxic" designation for fish. No effects were observed in sheepshead minnows (estuarine/marine) or bluegill (freshwater) fish at up to 1000 mg/L. For inorganic chlorates, RQs were not calculated for freshwater or estuarine/marine fish, since the proximity of the LC_{50} to the highest concentration tested (1000 mg/L) could not be estimated. Although 1000 mg/L is not an LC_{50}, which is the toxicity value usually used to derive RQs, this value was used only to estimate high-end risk to exposed fish. EECs for both agricultural and nonagricultural uses of sodium chlorate were more than 20-fold lower than the toxic concentration observed in fish of 1000 mg/L (all RQs would be less than 0.05, and below the Agency's acute LOC of 0.5 and the acute endangered species LOC of 0.05). Therefore, acute risk to freshwater and estuarine/marine fish is not of concern to the Agency.

No chronic toxicity studies in fish have been submitted to the Agency, nor were any

identified in the ECOTOX database. However, the Agency will require data to address this area of uncertainty.

2. Aquatic Invertebrates

For freshwater invertebrates, acute RQs are based on the EC_{50} of 920 mg/L (*daphnids*) and EECs calculated by GENEEC-2; these are presented in Table 21 below. All RQs are below the acute LOC of 0.5 and the endangered species acute LOC of 0.05; therefore, acute risk to freshwater invertebrates is not of concern to the Agency.

Table 21. Acute Freshwater Aquatic Invertebrate Risk Quotients

Use	Application Rate Range	Maximum EEC	EC50	RQ
Agricultural uses	4.5–7.5 lb ai/A	0.91 mg/L	920 mg/L	<0.01
Non-agricultural uses	132–520 lb ai/A	39 mg/L	920 mg/L	<0.042

For saltwater invertebrates, acute RQs were not calculated, because the proximity of the LC_{50} from a supplemental 96-hr study (*mysid* shrimp) to the highest concentration tested (1000 mg/L), could not be estimated. However, the ratios of chlorate's EECs (agricultural and nonagricultural uses) to the concentration of 1000 mg/L were calculated, and the highest resulting value was 0.04. As this is well below the acute LOC of 0.5, in addition to the endangered species acute LOC of 0.05, acute risk to saltwater invertebrates is not of concern to the Agency.

Chronic risk to invertebrates was not assessed, since treatment-related effects were not observed at any concentration in available studies.

3. Aquatic Plants

Toxicity (EC_{50}) and exposure (EEC) values, as well as RQs, for non-endangered aquatic plants are shown in Tables 22. For non-endangered aquatic plants, the Agency calculates RQs by dividing EECs by EC_{50} values.. For sodium chlorate, the LOC (1.0) was not exceeded for either the agricultural or nonagricultural uses of chlorate; therefore, risk to non-endangered aquatic plants is not of concern to the Agency.

Table 22. Risk Quotients for Non-endangered Aquatic Plants

Use	Maximum Peak EEC	Algal EC_{50}	Duckweed EC_{50}	Algal RQ	Duckweed RQ
Agricultural	Up to 0.9 mg/L	133 mg/L	43 mg/L	<0.01	0.02
Non-agricultural	Up to 39 mg/L	133 mg/L	43 mg/L	Up to 0.29	0.91

The RQs for endangered aquatic plants are presented in Table 23. The Agency calculates

RQs for endangered aquatic plants by dividing EECs by NOAECs. For endangered aquatic plants, the Agency's LOC (1.0) was exceeded for sodium chlorate's non-agricultural uses (RQ = 12.6). However, the EECs for the non-agricultural use sites are likely conservative; therefore, additional information on use patterns would allow for characterization of potential risks to aquatic plants. Also, testing on three additional required plant species is required for herbicides. Overall, additional data are needed to allow for a full characterization of potential risk to aquatic plants.

Table 23. Endangered Species Algal Risk Quotients Agricultural and Non-Agricultural Uses

Use	Maximum Peak EEC	Algal EC_{50}	Duckweed EC_{50}	Algal RQ	Duckweed RQ
Agricultural	Up to 0.9 mg/L	62.5 mg/L	3.1 mg/L	Up to 0.014	Up to 0.29
Non-Agricultural	Up to 39 mg/L	62.5 mg/L	3.1 mg/L	Up to 0.62	Up to 12.6

c. Endangered Species

The Agency's screening level assessment results in the determination that sodium chlorate will have no acute risks to birds, no acute risks to fish (freshwater and estuarine/marine), and no acute or chronic risks to aquatic invertebrates (freshwater and estuarine/marine).

However, the preliminary risk assessment for endangered species indicates that RQs exceed endangered species LOCs for chronic risks to birds (RQs up to 11 for agricultural uses and greater for non-agricultural uses); acute risks to mammals (RQs up to 33); chronic risks to mammals (RQs up to 1.2 for agricultural uses and greater for non-agricultural uses); and risks to aquatic plants (RQs up to 13). Risks could not be calculated for terrestrial plants and for chronic risks to fish; however, the Agency will be requiring data.

Further, potential indirect effects to any species dependent upon a species that experiences effects from use of sodium chlorate can not be precluded based on the screening level ecological risk assessment. These findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

d. Ecological Incidents

A review of the Ecological Incident Information System (EIIS) database for ecological incidents involving chlorate was completed on October 25, 2004. There were no chlorate incidents in the database

IV. Risk Management, Reregistration, and Tolerance Reassessment

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing sodium chlorate as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing sodium chlorate.

The Agency has completed its assessment of the dietary, occupational, residential, and ecological risk associated with the use of pesticide products containing the active ingredient sodium chlorate. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient sodium chlorate, the Agency has sufficient information on the human health and ecological effects to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that sodium chlorate-containing products are eligible for reregistration provided that: (i) the risk mitigation measures outlined in this document are adopted, (ii) label amendments are made to reflect these measures, and (iii) a safety finding can be made for sodium chlorite. Label changes are described in Section V. Appendix A summarizes the uses of sodium chlorate that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of sodium chlorate, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of sodium chlorate, the Agency has determined that sodium chlorate products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of sodium chlorate. If all changes outlined in this document are incorporated into the product labels, then all current risks for sodium chlorate will be adequately mitigated for the purposes of this determination under FIFRA. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in Section III.B.2.c. of this document.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for sodium chlorate. EPA released its sodium chlorate preliminary risk assessments for public comment on February 1, 2006, for a 60-day public comment period (Phase 3 of the public participation process). During the public comment period on the risk assessments, which closed on April 3, 2006, the Agency received comments from the sodium chlorate task force, technical registrants, and private citizens. These comments in their entirety,

responses to the comments, as well as the preliminary and revised risk assessments, are available in the public docket (OPP-2005-0507) at http:www.regulations.gov.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. The Agency has determined that, if the mitigation described in this document is adopted and labels are amended, and a safety finding can be made for sodium chlorite, human health risks as a result of exposures to sodium chlorate are within acceptable levels. In other words, EPA has concluded that the exemptions from tolerances for sodium chlorate meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as exposures to sodium chlorate from all possible sources.

b. Determination of Safety to U.S. Population

The Agency has determined that provided a safety finding can be made for sodium chlorite, the Agency has determined that the established tolerance exemptions for sodium chlorate, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of sodium chlorate. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of sodium chlorate. As discussed in Section III, the acute, chronic, and cancer dietary (food and drinking water) risks from sodium chlorate are below the Agency's acute and chronic LOC, provided that mitigation measures outlined in this document are adopted and labels are amended.

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerance exemptions for sodium chlorate, with amendments and changes as specified in this document, and provided that a safety finding can be made for sodium chlorite, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors on the toxicity, use practices and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of sodium chlorate residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of sodium chlorate, the Agency considered the completeness of

the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. On the basis of this information, the FQPA SF has been reduced to 1X for sodium chlorate. The rationale for the decisions on the FQPA SF can be found in Section III and the following document: *HED Chapter of the Reregistration Eligibility Decision Document (RED),* dated January 26, 2006.

2. 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 endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis 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 EPA include evaluations of potential effects in wildlife. For pesticides, 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 for additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The available toxicity studies on sodium chlorate demonstrate the thyroid gland to be its target of toxicity. The endpoints selected to assess chronic dietary risk and short- and intermediate-term oral and inhalation risks in this document are protective of the observed thyroid effects seen in the available toxicity studies. When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, sodium chlorate may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

3. Cumulative Risks

The FFDCA, as amended by 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 as would a higher level of exposure to any of the substances individually. The EPA has not made a common mechanism of toxicity finding as to sodium chlorate and any other substances. For the purposes of this reregistration eligibility decision (RED), therefore, EPA has not assumed that the inorganic chlorates 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/.

4. Endangered Species

The Agency's screening-level assessment results in the determination that sodium chlorate will have no acute risks to birds, no acute risks to fish (freshwater and estuarine/marine), and no acute or chronic risks to aquatic invertebrates (freshwater and estuarine/marine).

However, the preliminary risk assessment for endangered species indicates that RQs exceed endangered species LOCs for chronic risks to birds (RQs up to 11 for agricultural uses and greater for non-agricultural uses); acute risks to mammals (RQs up to 33); chronic risks to mammals (RQs up to 1.2 for agricultural uses and greater for non-agricultural uses); and risks to aquatic plants (RQs up to 13). Risks could not be calculated for terrestrial plants and for chronic risks to fish; however, the Agency will be requiring data.

Further, potential indirect effects to any species dependent upon a species that experiences effects from use of sodium chlorate cannot be precluded based on the screening-level ecological risk assessment. These findings are based solely on EPA's screening-level assessment and do not constitute "may affect" findings under the Endangered Species Act.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers it in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species, as part of a refined species-specific analysis. When conducted, this species-specific analysis will take into consideration any regulatory changes in this RED that are being implemented at that time.

Following this future species-specific analysis, a determination that there is a likelihood of potential impact to a listed species or its critical habitat may result in: limitations on the use of sodium chlorate, other measures to mitigate any potential impact; or consultations with the Fish and Wildlife Service or the National Marine Fisheries Service as necessary. If the Agency determines use of sodium chlorate "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species-specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to sodium chlorate at levels of concern. EPA is not requiring specific sodium chlorate label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

D. Tolerance Reassessment Summary

Table 24 summarizes the reassessment of the sodium chlorate tolerance exemptions pending a safety finding can be made for sodium chlorite. 40 CFR must be updated to reflect the tolerance exemptions in the table below. The tolerance exemptions listed in 40 CFR must be reorganized in order to: (i) incorporate the recommendations made by the Agency concerning the sodium chlorate residues of concern that need to be regulated for plant and animal commodities; (ii) include tolerance exemptions that are needed to cover sodium chlorate residues of concern in/on the raw agricultural commodities and processed commodities of rotational crops; and (iii) conform with the requirements of FQPA.

Table 24. Tolerance Reassessment Summary for Sodium Chlorate			
Listed under 40 CFR 180.1020(a)			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**[*Correct Definition*] Comments**
Beans, dry, edible	Exempt	Exempt	[*Bean, dry, seed*]
Corn, fodder	Exempt	Exempt	[*Corn, field, stover; Corn, field, forage; Corn, field, grain; Corn, sweet, stover; Corn, pop, stover; Corn, pop, grain; Corn, sweet, forage*]
Corn, forage	Exempt		
Corn, grain	Exempt		
Cottonseed	Exempt	Exempt	[*Cotton, undelinted seed*]
Flaxseed	Exempt	Exempt	[*Flax, seed*]
Flax, straw	Exempt	Revoke	Flax straw is not listed in Table 1 of OPPTS 860.1000
Guar beans	Exempt	Exempt	[*Guar, seed*]
Peas, southern	Exempt	Exempt	[*Pea, southern, seed*]
Potatoes	Exempt	Exempt	[*Potato*]
Peppers, chili	Exempt	Exempt	[*Pepper, nonbell*]
Rice	Exempt	Exempt	[*Rice, grain; Rice, straw*]
Rice, straw	Exempt		
Safflower, grain	Exempt	Exempt	[*Safflower, seed*]
Sorghum, grain	Exempt	Exempt	[*Sorghum grain, grain; Sorghum, grain, stover; Sorghum, grain, forage*]
Sorghum, fodder	Exempt		
Sorghum, forage	Exempt		
Soybeans	Exempt	Exempt	[*Soybean, seed*]

Table 24. Tolerance Reassessment Summary for Sodium Chlorate			
Listed under 40 CFR 180.1020(a)			
Sunflower seed	Exempt	Exempt	*[Sunflower, seed]*
Wheat	None	Exempt	[*Wheat, grain*]
Listed under 40 CFR 180.1020(b)			
Wheat	Exempt	Revoke	[*Wheat, grain*] Time-limited exemption currently expires on 12/31//2006

Existing Exemptions

Sodium chlorate is currently registered for preharvest and foliar applications as a defoliant or desiccant to the following food/feed crops: beans, corn, cotton, flax, guar, chili peppers, potatoes, rice, safflower, sorghum (grain), southern peas (*i.e.*, cowpeas), soybeans, and sunflowers.

Sodium chlorate exemptions under 40 CFR 180.1020(a) from the requirement of a tolerance should be amended as follows to: (1) specify defoliant and desiccant use only, (2) specify use on crops rather than raw agricultural commodities, and (3) include an exemption for wheat (grain).

40 CFR 180.1020(a) Sodium chlorate is exempt from the requirement of a tolerance for residues when used as a defoliant or desiccant in accordance with good agricultural practice on the following crops: Bean (dry, seed), Corn (field, stover), Corn (field, forage), Corn (field, grain), Corn (sweet, stover), Corn (pop, stover), Corn (pop, grain); Corn (sweet, forage), Cotton (undilented seed), Flax (seed), Guar (seed), Peas (southern, seed), Peppers (nonbell), Potatoes, Rice (grain), Rice (straw), Safflower (seed), Sorghum (grain, grain), Sorghum (grain, stover), Sorghum (grain, forage), Soybean (seed), and Sunflower (seed).

Under 40 CFR 180.1020(b), a time-limited exemption from the requirement of a tolerance is established for residues of the defoliant/desiccant in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. This exemption was granted for wheat and expires 12/31/06. The use of sodium chlorate on wheat is also addressed herein with the intention to convert the time-limited exemption status to a permanent exemption from the requirement of a tolerance under 40 CFR.1020 (a). The proposed use rate is for a single application of sodium chlorate to wheat at 6 lbs ai/A with a 3-day PHI.

Needed Exemptions

Sodium chlorate (873301) as an inert ingredient in herbicide formulation products can be applied professionally to agricultural (corn, guava, macadamia nuts, sorghum grain, sugarcane, wheat), commercial (non-agricultural), and residential sites. These conventional pesticide products contain < 1 % sodium chlorate and can be applied at rates no greater than 0.07 lb (as sodium chlorate) per acre.

Potassium chlorate (900583) as an inert ingredient in fungicide products can be applied in poultry premises. These conventional pesticide products contain < 20% potassium chlorate and can be applied at rates not greater than 0.01 lb (as potassium chlorate) per 500 ft^3. See Table 25 below for the tolerance exemptions needed for sodium chlorate.

Table 25. Tolerance Exemptions Needed for sodium chlorate

Tolerance Exemption Expression	PC Code	CAS Reg No.	40 CFR §	Use (Pesticidal)	List Classification
Sodium chlorate	873301	7775-09-9	180.920 [1]	Stabilizer	3
Potassium chlorate	900583	3811-04-9	180.930 [2]	Oxidizer	3

1. Residues listed in 40 CFR §180.920 [formerly 40 CFR§ 180.100(d)] are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only.
2. Residues listed in 40 CFR §180.930 [formerly 40 CFR§ 180.100(e)] are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals.

Codex/International Harmonization

There are no Codex maximum residue limits (MRLs) for sodium chlorate.

E. Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the use of sodium chlorate for sodium chlorate products to be eligible for reregistration. Where labelling revisions are warranted, specific language is set forth in Table 28 of Section V.

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

Acute Dietary (Food) Risk

No acute dietary endpoint was selected for sodium chlorate, because effects attributable to a single dose were not seen in the available data. Therefore, dietary acute risk is not of concern to the Agency, and no mitigation measures are required to address acute risk.

Chronic Dietary (Food) Risk

The chronic dietary risk assessment for food only is below the Agency's level of concern (LOC) for the general US population and all population subgroups. The most highly exposed population subgroup, children 1-2 years of age, was at 28% of the chronic Population Adjusted Dose (cPAD). Since this is less than 100% of the cPAD, no mitigation is needed.

b. Residential Risk Mitigation

All residential (non-occupational) handler and post-application risk estimates for inorganic chlorates, as active or inert ingredients in conventional pesticide products used in residential environments, are below the Agency's LOC (*i.e.*, MOEs are greater than the LOC of 100). The handler inhalation MOEs ranged from 370 to 710,000. The post-application combined MOE (for inert ingredients) was 23,000 for all potential routes of exposure to children; therefore, no residential mitigation is necessary.

c. Aggregate Risk Mitigation

As discussed in Section III of this RED, aggregate risk refers to the combined risk from food, drinking water, and residential exposures. Aggregate risk can result from one-time (acute), short-term and/or chronic exposures.

Acute Aggregate Risk

For sodium chlorate, acute aggregate risk was not assessed, because effects attributable to a single dose were not seen in the available data. Therefore, acute aggregate risk is not of concern to the Agency.

Short-Term Aggregate Risk

Short-term aggregate risk was quantitatively assessed for adults only, using the highest exposure scenario (inhalation exposure while applying granules by hand) resulting in an MOE of 324. Short-term aggregate risk for children was qualitatively assessed and not of concern to the Agency because the short-term residential risk to children from the use of sodium chlorate as an inert is minimal (MOE of 23,000). All short-term aggregate risks are below the Agency's LOC (*i.e.*, MOEs are greater than 100); therefore, no mitigation is necessary.

Chronic Aggregate Risk

Since no chronic residential (non-dietary) exposure scenarios have been identified for sodium chlorate, the chronic aggregate risk assessment considers exposure only through food and drinking water. The Agency believes there is no chronic risk of concern, for the US general population or any subpopulation group, for the reasons described below.

The chronic dietary (water only) risk assessment for chlorate in drinking water, using the highest annual average concentration from ICR data of 0.69 mg/L, is below the Agency's level of concern for the general US population and all subgroups except all infants <1 year of age. The highest exposed population subgroup, all infants <1 year of age, was 159% of the cPAD. Using the 90th percentile annual average concentration of 0.24 mg/L, the chronic dietary (water only) risk for all infants <1 year of age was <55% of the cPAD; using the median annual average concentration estimated at 0.11 mg/L, estimated chronic risk from drinking water was 25% of the cPAD. The contribution of exposure from food sources increases total dietary risk (food + drinking water) to 174% of the cPAD for infants <1 year of age at the highest annual average,

but remains below EPA's level of concern at the 90th percentile (70% of the cPAD).

Data on the occurrence of chlorate ion in drinking water were available from two primary sources: the Information Collection Rule (ICR) Auxiliary 1 Database, Version 5.0, and the AwwaRF research study on the control of chlorate ion in hypochlorite solutions. The most extensive data are from the ICR where source water and drinking water were monitored for chlorate ion between July 1997 and December 1998. Water systems serving a population of at least 100,000 were required to monitor for chlorate ion at treatment plants using chlorine dioxide or hypochlorite solutions in the treatment process. Although the ICR water systems represent roughly one percent of the total number of drinking water systems in the United States, these systems serve almost 60% of the population. Under the ICR, plants using chlorine dioxide collected monthly samples of the source water entering the plant, the finished water leaving the plant, and at three sample points in the distribution system (near the first customer, an average residence time, and a maximum residence time). Samples were taken throughout the distribution systems for plants using chlorine dioxide, since the concentration of chlorate is expected to change within the system due to the conversion of chlorine dioxide to chlorate that occurs in the presence of chlorine. Plants using hypochlorite solutions were required to collect quarterly samples of the water entering and leaving the plant.

The AwwaRF data consists of samples collected in 1993 by 111 water treatment plants using hypochlorite. The majority of the systems in the AwwaRF project serve populations less than 100,000, and a large subset of those serve populations less than 10,000. Samples of source water, hypochlorite solution, and finished drinking water from 111 of water systems were analyzed for chlorate. Only one set of samples was collected for each system, and samples were not collected at plants using chlorine dioxide. Furthermore, the background information on the 111 water systems that participated in the project was not linked to the samples they provided; therefore, the chlorate concentrations can not be directly related to the size of the water system or type of hypochlorite solution in use.

The AwwaRF samples were typically found to have higher concentrations of chlorate than the samples collected from the larger ICR systems. The difference in chlorate concentrations could be the result of a number of factors, such as: 1) The AwwaRF data represents a single point in time, while the ICR data reflects an average over 18 months; 2) most of the AwwaRF samples were collected from utilities that served populations of less that 100,000, while all of the ICR samples were from utilities serving at least 100,000; and 3) hypochlorite treatment plant practices may have changed between when the AwwaRF samples were collected (1993) and the ICR samples were collected (1997-1998). When the AwwaRF study was conducted, utilities were just becoming aware of the formation of chlorate ion in hypochlorite solutions. The AwwaRF project was funded in order to provide water treatment facilities with information on how to minimize the formation of chlorate byproduct; it is possible that facilities consequently revised their treatment practices.

The ICR Database was considered the more appropriate source for estimating exposure averages from individual water treatment plants, primarily because the AwwaRF study is a less robust data set consisting of only one sample per utility, whereas the ICR database collected multiple samples over an 18 month period, from plants using both hypochlorite and chlorine

dioxide. Both the AwwaRF study and the ICR data reveal high concentrations of chlorate ion to be a local situation affecting a relatively small number of systems. Of the ICR data set, only four water treatment plants had average chlorate ion concentrations that exceeded the Agency's level of concern (i.e., 370 ppb or 0.37 mg/L, for the infant subpopulation) including one treatment plant serving 218,000 people that had the highest annual average (0.69 mg/L). Of the four plants that exceeded, two treatment plants used chlorine dioxide, and two used hypochlorite. The total number of people served by the four water treatment plants exceeding 0.37 mg/L represents 0.5% of the ICR population, or 621,000 people. All three exposure ranges (highest average, 90th percentile, and median) are presented in Section III. Only the "highest average" exposures resulted in potential chronic risk estimates that were above the Agency's LOC, and only for infants. Over 99% of the ICR population receives finished water below the Agency's LOC of 0.37 mg/L.

The chlorate ion (ClO_3^-) is a disinfection byproduct (DBP) of water treatment which can be formed during the on-site generation of chlorine dioxide (ClO_2^-), the decomposition of chlorine dioxide in the water treatment system, the decomposition of hypochlorite (OCl^-) during storage, and the interaction of chlorite ion and free chlorine. Treatment of public water supplies is necessary to kill pathogens that may exist in the drinking water, such as cholera, typhoid, and dysentery. Outbreaks of these diseases decreased significantly when disinfection of the water systems was introduced in the early 1900s. While there are many important public functions of water treatment, the Agency is taking steps to limit the exposure of chlorate ion as a DBP to the public.

In order to help reduce potential exposure to chlorate, the Agency's Office of Pesticide Programs (OPP), in conjunction with the Office of Water (OW), is working with the American Water Works Association (AWWA), the Chlorine Institute, and individual water communities to provide community water systems with information on Best Management Practices (BMPs) for use in drinking water treatment. BMPs may include measures such as production modifications, operational changes, materials substitution, materials and water conservation, and other such measures. For example, water systems that use hypochlorite solutions can minimize the levels of chlorate ion by purchasing high quality hypochlorite solutions and through careful storage during use. While decomposition of hypochlorite solutions cannot be avoided, the rate of decomposition can be managed. Among the major factors affecting stability are the following: concentration of the hypochlorite solution, temperature of the solution, pH of the solution, and exposure to light sources. The pH of the solution should be in the 12 to 13 range to minimize decomposition. Hypochlorite solutions should be protected from high temperatures and sunlight, and storage time should be minimized, both from the time of manufacture to delivery, and from the time of delivery to use. The solutions can also be diluted to control decomposition as long as the proper pH is maintained and high quality dilution water is used. The primary ways in which water systems using chlorine dioxide can control the levels of chlorate in the finished water is through high efficiency operation of their chlorine dioxide generators and by reducing chlorite ion concentrations prior to the addition of free chlorine. The BMPs could also include additional training of the water systems employees on the proper handling of these chemicals.

The Agency believes that sodium chlorate does not constitute a risk of concern to the general population or any population subgroups, since the LOC exceedances are associated with

a small number of water treatment facilities and inappropriate treatment practices. Furthermore, the Agency anticipates that the community water system outreach strategy previously discussed will greatly reduce potential drinking water byproduct exposure.

d. Occupational Risk Mitigation

With the consideration of mitigation measures proposed by registrants and the use of engineering controls (enclosed cockpits or cabs), all occupational handler risks for the use of inorganic chlorates as an active or inert ingredient in conventional pesticides are below the Agency's LOC (*i.e.*, MOEs are greater than the LOC of 100). For sodium chlorate, occupational exposure durations are short- (1-30 days) and intermediate term (1-6 months) only. Long-term (> 6 months) exposure is not expected based on the use pattern for sodium chlorate. Post-application dermal and inhalation exposures are negligible due to the chemical's physical and chemical characteristics as an inorganic salt. No significant amount of sodium chlorate is expected to be absorbed through the skin and the vapor pressure is negligible; therefore, a post-application exposure assessment was not conducted.

Antimicrobial Uses of Sodium Chlorate

Risks to handlers treating water systems are below the Agency's LOC; therefore, no mitigation measures are necessary.

Agricultural Uses of Sodium Chlorate

With the exception of aerial applications, for which enclosed cockpits are required, the handler and flagger MOEs for sodium chlorate's agricultural uses are below the Agency LOC at baseline level of protection (long sleeve shirt, long pants, shoes, and socks). MOEs range from 190 (mixing/loading liquids for aerial application on cotton, corn, et al.) to 3600 (mixing/loading liquids for groundboom application on ornamental gourds and cucurbits). Further, the maximum application rate for use on cotton will be reduced from 7.5 lbs ai/A to 6 lbs ai/A, with a limitation of one application (except for California, where two applications will be allowed). No additional mitigation is required for occupational risk resulting from the agricultural uses of sodium chlorate.

Non-agricultural Uses of Sodium Chlorate

The Agency's review of sodium chlorate labels, in addition to discussions with registrants, indicates that the current non-agricultural use labels are not reflective of actual use practices. The non-agricultural use labels currently allow for larger application rates than are necessary for efficacy, as well as allow for unlimited treatment areas, although sodium chlorate's non-agricultural formulations are typically used as spot treatments.

Mitigation measures for sodium chlorate's non-agricultural uses to be included on product labels will reduce risk from the occupational and ecological exposures to sodium chlorate. The registrants have agreed to the following non-agricultural use mitigation measures for sodium chlorate:

- All non-agricultural uses will be limited to spot treatments only (with the exception of the granular formulation for use under asphalt, although this use will be limited to an 8000 ft^2 treatment area). The uses limited to spot treatments include, but are not limited to: building perimeters (including farm buildings), driveways, parking lots, fence rows, military installations, pipelines, railroads, lumberyards, industrial sites (transformers, generators, utility poles, etc.), tennis court perimeters, picnic areas, bleachers, cemeteries, fuel tanks, airport runways, helo pads, wood decks, guard rails, highway medians, sidewalks/walkways, vacant lots, fire hydrants, recreational areas, and other similar areas.

- Use on rights-of-way and ditch banks will be cancelled.

- The label will specify a maximum application rate of 0.9 lb ai/100 ft^2

The Agency generally converts application rates to a per acre basis for assessment purposes; therefore, the rate of 0.9 lb ai/100 ft^2 is referred to as 392 lb ai/A in this document. However, because all non-agricultural uses will be limited to spot treatment applications only, all 392 pounds of a.i. will not be applied on any one given acre. Assuming only one acre is considered for treatment, sodium chlorate can only be applied to up to 8000 ft^2, which equates to up to approximately 78 lbs ai being applied to any given acre. It is assumed that more than one acre will be treated.

Risk calculations have been developed to better represent the current, actual use pattern for sodium chlorate, and occupational risk was reassessed based on the revised use pattern discussed above (i.e., application rates, target sites, and amount treated). Following is a summary of the *Inorganic Chlorates: Addendum to the Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision (RED) Document*, dated May 18, 2006.

All data, factors, and assumptions used in the addendum are the same as those used in the previous occupational risk assessment. These include, but are not limited to:

- body weight (70 kg representing adult handlers);
- toxicological endpoints (short-/intermediate-term oral NOAEL of 30 mg/kg/day) and uncertainty factors (Level of Concern (LOC) for the MOE is 100);
- application rates (in lb ai/A – presented as a range to encompass the various registered products); and,
- unit exposures (from PHED and/or ORETF database, both of which have undergone appropriate review by the Human Studies Review Board).

However, factors regarding application equipment used and daily area treated were revised based on updated use pattern information and proposed product label revisions. The previous assessment, summarized in Section III, was based on applications with larger, industrial equipment such as tractor spreaders or groundboom sprayers. As a result of mitigation measures agreed to by the technical registrants, sodium chlorate applications to non-agricultural areas (*i.e.*, building perimeters, ditch banks, bleachers, airport runways, vacant lots, fire hydrants, or as a pre-paving treatment) will be limited to "handheld" equipment such as rotary spreaders and

pump or power sprayers. In addition, the standard Agency assumptions for the amount applied per work day is based on the application equipment used to determine exposure and risk. Since submitted information indicates that no more than 8,000 ft^2 of an acre (approximately 20%) will be treated with sodium chlorate, the Agency has adjusted the standard assumptions for acres treated per day to reflect this spot treatment-type scenario.

Based on the revised assumptions for the daily area treated and on application methods suitable for spot treatments (low-pressure handwand sprayers, belly grinders, push-type spreaders), the risks for all non-agricultural uses, even at the currently labeled application rate (523 lbs ai/A instead of 392 lb ai/A), are below the Agency LOC. The higher application rate of 523 lb ai/A was used, because at the time the *Inorganic Chlorates: Addendum to the Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision (RED) Document*, dated May 18, 2006, was prepared, the 392 lb ai/A maximum application rate mitigation measure was not yet finalized. The mitigation measures outlined above reduce the occupational risk from all of sodium chlorate's non-agricultural uses to below the Agency's level of concern at baseline level of protection (long sleeve shirt, long pants, shoes, and socks). The risks based on the revised non-agricultural use patterns for sodium chlorate are summarized in Table 26 below.

Table 26: Sodium Chlorate: Short- and Intermediate-Term Occupational Inhalation Exposure

Exposure Scenario	Daily Area Treated (Acres/day)	Crop/Target	Application Rate (lbs ai/Acre)[a]	Inhalation MOE (at baseline)
Mixer/Loader/Applicators & Loader/Applicators				
Mixing/Loading/Applying liquids with a low-pressure handwand sprayer	0.4	Industrial/Non-Crop Sites	523	330
			132	1300
M/L/A liquids with a handgun sprayer	1	Industrial/Non-Crop Sites	523	2200
			132	8800
L/A granules with a belly grinder	0.2	Industrial/Non-Crop Sites	523	320
			240	710
			161	1100
L/A granules with a push-type spreader	1	Industrial/Non-Crop Sites	523	550
			240	1200
			161	1800

a. Application rate will be reduced to 0.9 lb ai/100 ft^2 (392 lb ai/A).

2. Non-Target Organism (Ecological) Risk Management

Chlorate is a strong oxidizer and may be reduced to other chemically related species under some environmental conditions. The extent and rate to which this occurs will depend on the redox chemical species (including organic matter) in the water or soil. Extensive spatial and

temporal variability is expected for the reactions of chlorate in the environment. However, the currently available simulation models do not allow for a quantitative evaluation of the potential exposure levels of each the reduced products of chlorate (i.e., speciation and predominance) and how fast these chemical species may form. Therefore, there is a high degree of uncertainty in the ecological exposure and risk assessment. This is important because a reduction product of chlorate (chlorite) is expected to be more toxic to most aquatic and terrestrial species, particularly aquatic invertebrates.

a. Terrestrial Organisms

1. Birds and Mammals

EPA's screening-level risk assessment, based on currently labelled maximum application rates, for both agricultural and non-agricultural uses for sodium chlorate, suggests potential acute and chronic risk for birds

Avian Acute Risk

Avian acute risk was not calculated, since no mortality or signs of toxicity were observed in the submitted subacute or acute toxicity studies at concentrations that are above the limit for these types of studies; therefore, acute risk to birds is not expected. However, the Agency cannot preclude acute or subacute risk from the non-agricultural uses. Some labels have maximum application rates up to 1032 lbs ai/A, and the ecological assessment for risk from non-agricultural uses was based on rates ranging from 52 to 523 lbs ai/A, with corresponding EECs from 12,500 and 125,000 ppm, respectively. These EECs are approximately 2.5 to 25-fold higher than the highest concentration tested in the subacute bird toxicity studies. The non-agricultural use mitigation outlined above, including the reduction of the maximum application rate to 392 lbs ai/A, and a limitation to spot treatments only (except for use under asphalt, although this use is limited to no more than an 8000 ft^2 area). Reducing the maximum application rate from 520 lbs ai/A to 392 lbs ai/A will reduce the estimated environmental concentrations of chlorate by approximately 25%. Further, to the extent that there is any potential acute risk to birds from the non-agricultural uses, the fact that these uses will result in small contiguously treated areas could limit avian exposure.

Avian Chronic Risk

Maximum chronic RQs, based on EECs derived with 90th percentile residue estimates from the Kenaga nomogram, exceed the Agency's avian LOC of 1.0 for all agricultural uses assessed for birds eating short grass, tall grass, broadleaf forage, and small insects. Chronic RQs based on EECs derived with mean residue estimates from the Kenaga nomogram, although not presented in Section III, would be approximately three times lower for any single application of sodium chlorate. The highest agricultural use chronic RQ was 11 (chili peppers/white, Irish potatoes and the short grass food category). The second highest RQs were for cotton (ranging from 10.0 for the short grass food category, to 0.63 for fruits, pods, seeds, and small insects). Cotton is also by far the most common agricultural use of sodium chlorate, with approximately 1,900,000 lbs ai applied annually.

To address the chronic risk to birds from use on cotton, the maximum application rate will be reduced from 7.5 lbs ai/A to 6 lbs ai/A, and applications will be limited to a single applications in all states except California, where a second application will be allowed. This mitigation measure will reduce chronic risk to birds from use on cotton by approximately one-half, with RQs ranging from 5.31 (on the short grass food category), to 0.33 (on fruits, pods, seeds, and small insects) for all states except California. In California, the chronic avian RQs based on the reduced maximum application rate of 6 lbs ai/A, and two applications, will be reduced to a range of 8.25 (on the short grass food category) to 0.52 (on fruits, pods, seeds, and small insects).

Chronic avian RQs for sodium chlorate were based on a NOAEC of 271 ppm from the bobwhite quail chronic reproductive toxicity test. However, maximum EECs for a majority of the uses and classes of food items were also higher than the LOAEC in bobwhite quail of 964 ppm. At the LOAEC, reproductive effects occurred, including a 67% reduction in eggs laid and 64% reduction in number of hatchlings per egg laid. Therefore, if actual exposure is equivalent to the maximum values calculated with the T-REX model, there is a greater certainty that frank reproductive effects in birds might occur.

However, the duration of exposure needed to produce reproductive effects in birds is an uncertainty. This uncertainty is significant in the case of sodium chlorate, because as a broad-spectrum herbicide, its toxic effects on plants are visible within several days. Since the vegetation in the treated area will die, it is uncertain whether or not this vegetation will be attractive to birds as a feed item long enough for the chronic effects to occur.

Chronic RQs were not calculated for sodium chlorate's non-agricultural uses. However, based on the high application rates and resulting high potential EECs, risks from sodium chlorate's non-agricultural uses could be considerably higher than those described in Section III for the agricultural uses. The non-agricultural use mitigation outlined above, including a reduction in the maximum labeled application rate to 0.9 lbs ai/100 ft^2 (392 lbs ai/A), would reduce the EECs of chlorate by approximately 25% in the areas treated. Furthermore, the limitation of most non-agricultural uses to spot treatments only is expected to reduce the likelihood that a terrestrial organism will come into contact and consume all of its diet from a treated area. However, RQs still exceed the chronic LOC for birds (1.0). See the *Analysis of proposed changes to sodium chlorate's application rates and maximum treated area on potential ecological risks presented in EFED's reregistration eligibility decision (RED) document*, dated June 13, 2006 for further detail.

Mammalian Acute Risk

Acute RQs were not calculated for mammals. The LD_{50} from a core acute oral toxicity study in rats was >5000 mg/kg-bw. In this study, 10% (1/10) of the rats administered 5000 mg/kg died. Mortality was not observed at any other dose. Therefore, the data were not sufficient to allow for characterization of the dose-response relationship and the proximity of the LD_{50} to 5000 mg/kg-bw is uncertain. Although RQs were not calculated for mammals, Tables 17, 18 and 19 in Section III present a comparison of the body weight adjusted LD_{50}s to EECs for

agricultural spray, and the non-agricultural spray and granular, formulations, respectively. These ratios can be used to estimate high-end risk to exposed mammals. Risk quotients would be lower than the values in Section III.

For sodium chlorate's agricultural uses, all of the mammalian acute risk estimates are below the Agency's acute and endangered species LOC of 1.0 and 0.1, respectively, with the exception of small mammals eating short grass. The highest exceedence is for 15 gram mammals eating short grass (risk ratio = 0.26); therefore, no mitigation is necessary.

For sodium chlorate's non-agricultural uses, the ratios indicate a potential acute concern to mammals for both spray and granular formulations, with the highest ratios calculated for small mammals (ratios =11 and 33 for spray and granular formulations, respectively). While the ratios presented in Section III suggest that there could be acute risk to mammals of all sizes that forage in the area where sodium chlorate is applied to non-agricultural use sites, the risk was likely over-estimated, since an LD_{50} has not been established. Furthermore, as previously explained, a reduction in the maximum application rate for the non-agricultural uses to 392 lbs ai/A would reduce the EEC's of chlorate in treated areas by approximately 25%. Limitation of the treatments to spot treatments only would be expected to further reduce the likelihood that a terrestrial organism will come into contact and consume all of its diet from that area.

Mammalian Chronic Risk

For mammals, the Agency typically evaluates the mammalian reproductive effects for exposures greater than 30 days. The interpretation of the effects seen in the 2-generation rat reproduction toxicity study, used to derive the mammalian reproduction toxicity endpoint for sodium chlorate, is difficult in this respect. While effects were observed at 70 mg/kg-bw and above, the effects are not clearly associated with reduced reproductive success or survival. The mammalian reproductive NOAEC is based on the highest dose tested in this study (500 mg/kg-bw), although no toxic or reproductive effects were observed at this level. Therefore, the NOAEC could be higher than 500 mg/kg-bw, which would result in lower mammalian reproduction risk estimates. However, the Agency calculated risk ratios based on the 500 mg/kg-day NOAEL as a conservative estimate of risk, as presented in Section III. For the agricultural uses of sodium chlorate, the chronic mammalian LOC of 1.0 was only slightly exceeded for the smallest weight classes of mammals for most food items and the largest weight class of mammals feeding on short grass (RQs range from 2.6 to 0.07). The mitigation measures previously outlined for sodium chlorate use on cotton (maximum application rate reduced from 7.5 lbs ai/A to 6 lbs ai/A, with the limitation of a single application, except in California, where a second application will be allowed), will further reduced chronic mammalian risk. Furthermore, based on the lack of observed reproductive effects in the chronic study and the slight LOC exceedances for agricultural uses, the Agency does not anticipate a chronic risk of concern to mammals from these uses.

As with the agricultural uses, mammalian reproduction RQs were not calculated for sodium chlorate's non-agricultural uses. However, the higher application rates for the non-agricultural uses, and the resulting higher EECs, suggest that the risk for these uses would be higher than the risk estimates presented for the agricultural uses. Note that the mammalian

reproduction RQs for the agricultural uses of sodium chlorate, presented in Section III, are a conservative estimate of risk. Furthermore, as previously explained, to reduce risk from sodium chlorate's non-agricultural uses, the maximum application rate will be reduced to 0.9 lb ai/100 ft^2. This mitigation measure will reduce the EECs by approximately 25%. In addition, the limitation to spot treatments will reduce the likelihood that mammals will come into contact and consume all of its diet from a treated area. See the *Analysis of proposed changes to sodium chlorate's application rates and maximum treated area on potential ecological risks presented in EFED's reregistration eligibility decision (RED) document*, dated June 13, 2006, for further detail.

2. Non-Target Insects

EPA currently does not estimate RQs for terrestrial non-target insects. In addition, the Agency has no toxicity data for sodium chlorate. Therefore, EPA will require data to address this uncertainty.

3. Non-Target Terrestrial Plants

Based on chlorate's non-selective mode of action and lack of adequate toxicity data, the Agency presumes risk to non-target terrestrial plants at levels above the Agency's level of concern for all uses. The risks to plants cannot be quantified at this time due to lack of data; however, the Agency will require data to address this uncertainty.

b. Aquatic Organisms

1. Fish

There is no acute risk of concern, from either the agricultural or non-agricultural uses of sodium chlorate, to freshwater or estuarine/marine fish. All risk ratios are less than 0.05, which is below the Agency's acute LOC of 0.5 and below the acute endangered species LOC of 0.05. However, some data suggest that brown trout (freshwater fish) could be substantially more sensitive than other fish species tested to chlorate's toxicity. It is uncertain if these data are reliable; therefore, the Agency will require additional testing in brown trout to address this area of uncertainty.

No chronic fish toxicity studies are available to allow for chronic risk to fish to be quantified. Therefore, the Agency will require data to address this uncertainty.

2. Aquatic Invertebrates

For freshwater invertebrates, acute RQs are below the acute LOC of 0.5 and the endangered species acute LOC of 0.05, for both agricultural and non-agricultural uses of sodium chlorate. Therefore, acute risk to freshwater invertebrates is not of concern to the Agency, and no mitigation is required.

For saltwater invertebrates, the acute risk ratios for sodium chlorate's agricultural and nonagricultural uses were below the Agency's acute LOC of 0.5, in addition to the endangered species acute LOC of 0.05 (highest ratio = 0.04 for non-agricultural uses). Therefore, acute risk

to saltwater invertebrates is not of concern to the Agency.

Chronic risk to invertebrates (freshwater and saltwater) was not assessed, since treatment-related effects were not observed at any concentration in available studies.

3. Aquatic Plants

For non-endangered aquatic plants, the Agency's LOC of 1.0 was not exceeded for either the agricultural or nonagricultural uses of sodium chlorate (highest RQ = 0.91 for non-agricultural uses). Therefore, risk to non-endangered aquatic plants is not of concern to the Agency.

For endangered aquatic plants, the Agency's LOC of 1.0 was not exceeded for sodium chlorate's agricultural uses (highest RQ = 0.29), but the LOC was exceeded for sodium chlorate's non-agricultural uses (highest RQ = 12.6). However, the mitigation measures listed above for the non-agricultural uses of sodium chlorate, including a reduction in the application rate and treated area, result in a reduction of the endangered vascular plant RQ from 12.6 to 1.5. While this is a significant improvement, it is still above the Agency's endangered plant LOC of 1.0. Furthermore, because of a lack of submitted data, there is uncertainty remaining on sodium chlorate's toxicity to aquatic plants. The Agency will require data to address this area of uncertainty.

3. Summary of Mitigation Measures

The following mitigation measures are necessary for sodium chlorate to be eligible for reregistration. These include use restrictions, voluntary cancellations and/or use deletions, and personal protective equipment.

Agricultural use mitigation:

- Engineering controls (enclosed cockpits) for aerial applications on agricultural crops.
- For cotton, the maximum application rate will be reduced from 7.5 lbs ai/A to 6 lbs ai/A, and applications will be limited to a single applications in all states except California, where a second application will be allowed.

Non-agricultural use mitigation:

- All non-agricultural uses will be limited to spot treatments only (with the exception of the granular formulation for use under asphalt, although this use will be limited to an 8000 ft^2 treatment area). The uses limited to spot treatments include, but are not limited to: building perimeters (including farm buildings), driveways, parking lots, fence rows, military installations, pipelines, railroads, lumberyards, industrial sites (transformers, generators, utility poles, etc.), tennis court perimeters, picnic areas, bleachers, cemeteries, fuel tanks, airport runways, helo pads, wood decks, guard rails, highway medians, sidewalks/walkways, vacant lots, fire hydrants, recreational areas, and other similar areas.

- Use on rights-of-way and ditch banks will be cancelled.

- The label will specify a maximum application rate of 0.9 lb ai/100 ft^2.

F. Other Labeling Requirements

To be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing sodium chlorate. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

1. Endangered Species Considerations

The Agency's screening level assessment results in the determination that sodium chlorate will have no acute risks to birds, no acute risks to fish (freshwater and estuarine/marine), and no acute or chronic risks to aquatic invertebrates (freshwater and estuarine/marine).

However, the preliminary risk assessment for endangered species indicates that RQs exceed endangered species LOCs for chronic risks to birds (RQs up to 11 for agricultural uses and greater for non-agricultural uses); acute risks to mammals (RQs up to 33); chronic risks to mammals (RQs up to 1.2 for agricultural uses and greater for non-agricultural uses); and risks to aquatic plants (RQs up to 13). Risks could not be calculated for terrestrial plants and for chronic risks to fish; however, the Agency will be requiring data.

Further, potential indirect effects to any species dependent upon a species that experiences effects from use of sodium chlorate can not be precluded based on the screening level ecological risk assessment. These findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers it in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species, as part of a refined species-specific analysis. When conducted, this species-specific analysis will take into consideration any regulatory changes recommended in this RED that are being implemented at that time.

Following this future species-specific analysis, a determination that there is a likelihood of potential impact to a listed species or its critical habitat may result in: limitations on the use of sodium chlorate, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service or the National Marine Fisheries Service as necessary. If the Agency determines use of sodium chlorate "may affect" listed species or their designated critical habitat,

EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species-specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to sodium chlorate at levels of concern. EPA is not requiring specific sodium chlorate label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

2. 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, EPA will continue to work with all interested parties on this important issue.

From its assessment of sodium chlorate, as summarized in this document, the Agency concludes that certain drift mitigation measures are needed to address the risks from off-target drift for sodium chlorate, including a requirement for medium to coarse droplet size. Label statements implementing these measures are listed in the "spray drift management" section of the label table (Table 28 in Section V of this RED document. In the future, sodium chlorate product labels may need to be revised to include additional or different drift label statements.

V. What Registrants Need to Do

A. Manufacturing-Use Products

1. Generic Data Requirements

The generic data base supporting the reregistration of sodium chlorate has been reviewed and determined to be substantially complete. However, there are a few data gaps remaining, and these data, presented in Table 27, must be submitted or the Agency may take regulatory action on registrations of pesticide products containing sodium chlorate.

Table 27. Guideline Requirements for Sodium Chlorate

Data Requirement	Old Guideline Number	New OPPTS Guideline No.
Magnitude of the Residue- Meat/Milk/Poultry/Eggs	171-4j	860.1480
Submittal of Analytical Reference Standards	171-13	860.1650
28-Day Inhalation Toxicity	82-4	870.3465
Terrestrial Field Dissipation or Retrospective Monitoring Study	164-1	835.6100
Freshwater Fish Early Life Stage	72-4 (a)	850.1400
Avian Reproduction (1-Generation, Duck)	71-4b	850.2300
Seedling Emergence (Tier II only)	123-1 (a)	850.4225
Vegetative Vigor (Tier II only)	123-1 (b)	850.4250
Aquatic Plant Toxicity, using *Lemna* spp. (Tier II)	123-2	850.4400
Honey Bee Acute Contact Toxicity	141-1	850.3020

While the terrestrial field dissipation (835.6100) guideline study may not be appropriate for sodium chlorate, the Agency is still concerned about the prolonged use of sodium chlorate on cotton (about 50 years). Terrestrial field dissipation data are not available for sodium chlorate, and the guideline requirement for this study was never waived. There are some reports that sodium chlorate can be persistent in the field (ranging from 6 months to 5 years, depending on application rate, soil type, fertility, organic matter, moisture, and weather conditions). Also, several labels report that sodium chlorate is effective for the control of weeds for up to a year, which indicates that chlorate may persist for up to a year. Therefore, the range of persistence of sodium chlorate in the field remains a major uncertainty in the environmental fate behavior of this chemical. Use of sodium chlorate in the field requires that it be applied in conjunction with a fire retardant to minimize fire incidents. It is unclear how the fire retardant could influence the persistence in the field. Even though the persistence of chlorate in the field is uncertain, a terrestrial field dissipation data from a study conducted as per guideline 835.6100 may not provide adequate data because of the complexity of the chlorine oxyanion system and analytical chemistry methodology. Given that chloride is the end chemical species of chlorate, it poses the

question of increased chloride from year-after-year usage (*i.e*., salinization), and leaching of chloride to ground water, particularly in areas where chloride is not a significant, natural component in soil and/or ground water. Therefore, the Agency recommends a retrospective monitoring study (soil; ground water) aimed to address the effect of prolong use of sodium chlorate on cotton. The study must be conducted upon agreement of a protocol, but monitoring sites in coastal areas should not be included.

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 28.

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 provided in Table 28. 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

For sodium chlorate to be eligible for reregistration, all sodium chlorate labels must be amended to incorporate the risk mitigation measures outlined in Section IV. Table 28 describes how language on the labels should be amended.

D. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 18 months after the date of approval of revised labels implementing the changes described in this RED. Registrants and all other persons remain obligated to meet pre-existing label requirements

and existing stocks requirements applicable to stocks they sell or distribute.

Table 28. Summary of Labeling Changes for Sodium Chlorate		
Description	**Amended Labeling Language**	**Placement on Label**
Manufacturing Use Products		
For all Manufacturing Use Products	"Only for formulation as a defoliant/dessicant applied to agricultural crops [Registrant insert crops supported], as an herbicide applied in nonagricultural settings (residential, commercial, and industrial) or as an antimicrobial for the following uses: - [Registrant, please insert]."	Directions for use
Environmental Hazards Statements	"ENVIRONMENTAL HAZARDS" "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 Pollutant Discharge Eliminations 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 Environmental Protection Agency."	Precautionary Statements: Environmental Hazards

Table 28. Summary of Labeling Changes for Sodium Chlorate		
Description	**Amended Labeling Language**	**Placement on Label**
End-Use Products Intended for Occupational Use (WPS and Non-WPS)		
PPE Requirements for All Formulations	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]." For more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on the chemical-resistance category selection chart. "All mixers, loaders, applicators, and other handlers must wear: - long-sleeved shirt and long pants, and - shoes and socks" "See engineering controls for additional requirements." Note: this statement should be placed on labels containing agricultural crop scenarios. It should not be placed on labels where the sole uses are in nonagricultural settings, including commercial, industrial, or residential.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Engineering Controls for products within the scope of the Worker Protection Standard (WPS)	Enclosed Cockpits/Cabs "Applicators must use an enclosed cockpit or enclosed cab that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Table 28. Summary of Labeling Changes for Sodium Chlorate		
Description	**Amended Labeling Language**	**Placement on Label**
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." "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/ PPE immediately if pesticide gets inside, then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals (Must be placed in a box.)
Environmental Hazards Statements	"ENVIRONMENTAL HAZARDS" "Do not apply directly to water, or to areas where surface water is present, or to inter-tidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwater or rinsate."	Precautionary Statements: Hazards to Humans and Domestic Animals
Restricted-Entry Interval *For products within the scope of the Worker Protection Standard (WPS)*	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."	Directions for Use, in Agricultural Use Requirements box

Table 28. Summary of Labeling Changes for Sodium Chlorate		
Description	**Amended Labeling Language**	**Placement on Label**
Early Reentry Personal Protective Equipment *For Products Subject to WPS as required by Supplement 3 of PR Notice 93-7*	"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 soil or water, is - coveralls, - shoes and socks, and - chemical-resistant gloves made of any waterproof material."	Directions for Use, in Agricultural Use Requirements Box
Entry Restrictions for Non WPS Uses	Product applied as a spray: "Do not enter of allow others to enter until treated areas have dried" Products applied dry: "Do not enter or allow other to enter until dusts have settled."	If no WPS uses on the product label, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions. If the product also contains WPS uses, then create a Non-Agricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Directions for Use directly above the Agricultural Use Box
Application Restrictions-Agricultural Uses	For cotton, the maximum application rate is 6 lbs ai/A per application. A maximum of one application per year is permitted, except in California, where a maximum of two applications per year is permitted.	Place in the Directions for Use for applications to cotton.
Application Restrictions-Non-agricultural Uses	Application rates for products labeled for non-agricultural use must be amended to reflect the maximum application rate: 0.9 lb ai/100 ft^2. Liquid formulations: "Non-agricultural uses are limited to spot treatments only. Broadcast applications are prohibited."	Place in the Directions Under Application Resrictions.

Table 28. Summary of Labeling Changes for Sodium Chlorate		
Description	**Amended Labeling Language**	**Placement on Label**
	Use on rights-of-way and ditch banks is prohibited. Granular formulations: "Non-agricultural uses are limited to spot treatments with the exception of applications under asphalt. Applications under asphalt may only be applied with handheld equipment such as a rotery spreader and are limited to 8,000 square feet per site". Use on rights-of-way and ditch banks is prohibited.	

Table 28. Summary of Labeling Changes for Sodium Chlorate		
Description	**Amended Labeling Language**	**Placement on Label**
Spray Drift Label Language for Products Applied as a Spray to Agricultural Sites	"Spray Drift Management**"** "A variety of factors including weather conditions (e.g., wind direction, wind speed, temperature, relative humidity) and method of application can influence pesticide drift. The applicator must evaluate all factors and make appropriate adjustments when applying this product." <u>Wind Speed</u> "Do not apply at wind speeds greater than 15 mph." <u>Droplet Size</u> "Apply as a medium or coarser spray (ASAE Standard 572)" <u>Temperature Inversions</u> "If applying at wind speeds less than 3 mph, the applicator must determine if a) conditions of temperature inversion exist, or b) stable atmospheric conditions exist at or below nozzle height. Do not make applications into areas of temperature inversions or stable atmospheric conditions." <u>Other State and Local Requirements</u> "Applicators must follow all state and local pesticide drift requirements regarding application of sodium chlorate. Where states have more stringent regulations, they must be observed." <u>Equipment</u> "All application equipment must be properly maintained and calibrated using appropriate carriers or surrogates." *Additional requirements for aerial applications:* 1. "The boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter." 2. "Release spray at the lowest height consistent with efficacy and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety." 3. "When applications are made with a crosswind, the swath must be displaced downwind. The applicator must compensate for this displacement at the up and downwind edge of the application area by adjusting the path of the aircraft upwind."	Directions for Use under General Precautions or Restrictions and/or Application Instructions

Table 28. Summary of Labeling Changes for Sodium Chlorate		
Description	**Amended Labeling Language**	**Placement on Label**
	Additional requirement for groundboom application: "Do not apply with a nozzle height greater than 4 feet above the crop canopy."	
End Use Products Primarily Used by Consumers/Homeowners		
Environmental Hazards Statement	"ENVIRONMENTAL HAZARDS" "This product is toxic to fish and shrimp. Do not apply directly to water. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate." "Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas."	Precautionary Statements under Environmental Hazards
Entry Restrictions	Products applied as a spray: "Do not allow adults, children, or pets to enter the treated area until sprays have dried." Products applied dry: "Do not allow adults, children, or pets to enter the treated area until dusts have settled."	Directions for use under General Precautions and Restrictions
General Application Restrictions	"Do not apply this product in a way that will contact adults, children, or pets, either directly or through drift."	Place in the Direction for Use

Table 28. Summary of Labeling Changes for Sodium Chlorate		
Description	**Amended Labeling Language**	**Placement on Label**
Application Restrictions	Liquid Formulations "Use is limited to spot treatments only. Broadcast applications are prohibited Use on ditch banks is prohibited." Granular Formulations "Use is limited to spot treatments only, with the exception of applications under asphalt. Applications under asphalt are limited to 8,000 square feet per site. Use on ditch banks is prohibited. " Application rates for products labeled for non-agricultural use must be amended to reflect the maximum application rate: 0.9 lb ai/100 ft^2.	Place in the Directions under Application Restrictions