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September 2008

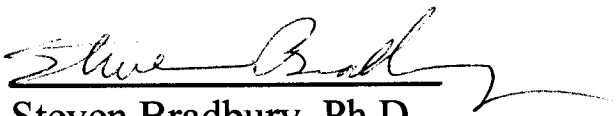
Reregistration Eligibility Decision

Acrolein

Reregistration Eligibility Decision (RED) Document for Acrolein

List B

Case No. 2005

Approved by: 

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Glossary of Terms and Abbreviations

ai	Active Ingredient
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
G	Granular Formulation
GLN	Guideline Number
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

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, and amended again by the Food Quality Protection Act of 1996 (FQPA). FIFRA calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all data submitted to the U.S. Environmental Protection 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 risks arising from the currently registered uses of a 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.

This document summarizes EPA's human health and ecological risk assessments and reregistration eligibility decision (RED) for acrolein. The document consists of six sections. Section I contains the regulatory framework for reregistration; Section II provides an overview of the chemical and a profile of its use and usage; 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 (Section VI) list related information, supporting documents, and studies evaluated for the reregistration decision. The risk assessments for acrolein and all other supporting documents are available in the Office of Pesticides Program (OPP) public docket at www.regulations.gov under docket number EPA-HQ-OPP-2007-0588.

II. Chemical Overview

There are 8 active acrolein registrations: two registered under section 3 of FIFRA, and six Special Local Need (SLN or 24c) registrations registered under section 24(c) of FIFRA. Acrolein has two use patterns: as an herbicide and biocide. The herbicidal use (EPA Reg# 10707-9) is for direct applications to water irrigation canal systems in the western U.S. Water from the irrigation system may be used on cropland immediately after application of the herbicide, but a specific "holding time" is required before irrigation water can be discharged to natural water systems. All six SLNs are associated with the herbicide registration. Three of these SLNs (WA0400017, ID900005, and NE030003) reduce the holding time specified on the Section 3 label for treated water. The other three SLNs (UT030001, OR910018 and CA780039) are for reservoir use. The reservoirs are irrigation water use only and are not used to store drinking water. The Section 3 registration (EPA Reg# 10707-10) is for application as a biocide for oil well drilling equipment. All registrations for use of acrolein in rodent burrows and burrow entrances have been cancelled. See Table 1 for a current product listing.

Table 1. Summary Report of Supported Registered Products

Reg #	Name	Company Name	%Active Ingredient
10707-9	MAGNACIDE H HERBICIDE	Baker Petrolite Corporation	95
10707-10	MAGNACIDE B MICROBIOCIDE		95
CA780039	MAGNACIDE H HERBICIDE		95

Table 1. Summary Report of Supported Registered Products			
Reg #	**Name**	**Company Name**	**%Active Ingredient**
ID900005	MAGNACIDE H HERBICIDE		95
NE030003	MAGNACIDE H HERBICIDE		95
OR910018	MAGNACIDE H HERBICIDE		95
UT030001	MAGNACIDE H HERBICIDE		95
WA040017	MAGNACIDE H HERBICIDE		95

A. Regulatory History

The acrolein reregistration case (2005) contains only one active ingredient, acrolein, which was first registered as an herbicide by Baker Petrolite Corporation (BPC) in November 1975. Baker Petrolite Corporation is the sole technical registrant for both Magnicide H Herbicide and Magnicide B Microbicide. Prior to its registered use as an herbicide, acrolein was registered in 1959 as a biocide. Several Data Call-In (DCI) notices were previously issued in the late 1980s and early 1990s identifying outstanding data needs for acrolein. The DCIs included requests for plant and animal metabolism studies in order to determine the need for crop tolerances.

B. Chemical Identification

Acrolein is registered as a restricted use pesticide for control of submerged and floating aquatic weeds and algae in irrigation canals as well as irrigation reservoirs in some states. In addition, acrolein is used as a biocide to kill bacteria that accumulate within the pipes of petroleum producing systems. Acrolein forms several degradates (acrylic acid, allyl alcohol, propanol, propionic acid, oxalic acid, and ultimately carbon dioxide) in the environment. In addition, glycidol, a metabolite of acrolein, is considered a probable human carcinogen by the International Agency for Research on Cancer (part of the World Health Organization). The National Toxicology Program Annual Report concludes that glycidol is reasonably anticipated to be a human carcinogen based on sufficient evidence of carcinogenicity in experimental animals. The chemical structures and properties of acrolein and its metabolite (glycidol) are presented in Tables 2-4.

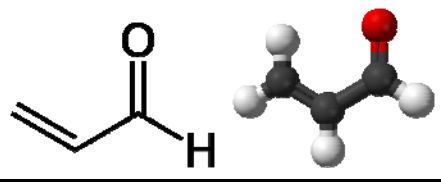
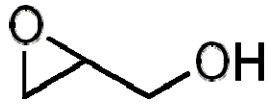
Table 2: Acrolein Nomenclature	
Chemical Structure	
Common Name	Acrolein
Synonyms	2-propenal, acrylaldehyde, acrylic aldehyde, allyl aldehyde, propenal, trans acrolein, acquinite, aqualin, biocide, crolean, ethylene aldehyde, Magnicide, Magnicide H, NSC 8819, prop-2-en-1-al, 2-propene-1-one, slimicide, prop-2-enal
Molecular Formula	C_3H_4O
PC Code	000701

Table 2: Acrolein Nomenclature	
IUPAC Name	2-propenal; Acrylaldehyde
CAS Registry Number	107-02-8

Table 3: Physiochemical Properties of Acrolein	
Melting Point/Range	-88 °C (-126 °F)
Boiling Point	53 °C (127 °F)
Molecular Weight	56.1 g/mol
Specific Gravity	0.0839
Vapor Density	1.94 (air = 1)
Solubility	208 g/L at 20 °C soluble in water, alcohol, ether, and acetone
Vapor Pressure	220 torr at 20 °C
Flashpoint	-15 °F (-26.1 °C)
Octanol Water Partition Coefficient (Log k)	0.98-1.10
Description	Clear, colorless to yellow liquid

Table 4: Nomenclature and Physiochemical Properties of Glycidol	
Chemical Structure	
Molecular Formula	$C_3H_6O_2$
IUPAC Name	Oxiranylmethanol
CAS Registry Number	556-52-5
Melting Point/Range	-54 °C
Boiling Point	167 °C (decomposes)
Molecular Weight	74.1 g/mol
Specific Gravity	0.0839
Vapor Density	2.15 (air = 1)
Solubility	Miscible
Vapor Pressure	120 Pa at 20 °C
Flashpoint	72 °C
Octanol Water Partition Coefficient (Log p)	- 0.95
Description	Clear, colorless liquid

C. Acrolein Use Profile

Type of Pesticide: Acrolein is an aquatic herbicide and biocide.

Summary of Use: Acrolein has two use patterns: as an herbicide for the control of vegetation in irrigation canals and as a biocide in water pumped into injection wells associated with petroleum production.

Mode of Action: Acrolein binds to organic material and degrades cellular structure by cross-linking proteins.

Formulation Type: Both section 3 acrolein products: Magnicide H (aquatic herbicide, EPA Registration #:10707-9) and Magnicide B (biocide, EPA Registration #: 10707-10) are packaged as liquids and stored under an inert gas blanket. Each contains 95% acrolein as the active ingredient.

Application Methods: As an herbicide, acrolein is injected directly below the surface of moving water and moves with the flow of water killing weeds on contact in irrigation canals and holding ponds. Acrolein is also used as a biocide in water pumped into injection wells associated with petroleum production. Acrolein is not directly applied to any crops. Both the herbicide and biocide products are applied through a closed system.

Application Rates: For herbicidal use in irrigation canals, the maximum single application concentration of acrolein is 15 ppm. The typical application rate is 8 ppm. For the biocide use, the maximum single application rate is 15 ppm. No maximum number of applications or minimum re-application intervals are specified on the labels.

Application Timing: Magnacide H and Magnacide B applications can occur multiple times during a year. Magnacide H may be applied up to 26 times per year in some irrigation systems with an application interval as short as every 7 days, but 6 applications per year is the most common, with a two to three week interval between applications. In some irrigation systems applications are more frequent but at lower concentrations to control the lower weed density. Detailed application information for Magnacide B is not currently available.

Registrant: Baker Petrolite Corporation

D. Estimated Usage

Based on available data, approximately one million pounds of acrolein is sold annually. Acrolein is a restricted use pesticide subject to strict use limitations. It can only be sold to and applied by trained and certified applicators or persons under their direct supervision, and can only be used for a use covered by the applicator's certification. There are no products available for residential application.

III. Summary of Acrolein Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of the human health and environmental risk assessments, and to help the reader better understand the conclusions reached in the assessments. The assessments and supporting documents referenced in Appendix C were used to formulate the safety finding and regulatory decision for the pesticidal use of acrolein.

While the risk assessments and related addenda are not included in this document, they are available in the OPP Public Docket at www.regulations.gov, docket number EPA-HQ-OPP-2007-0588. In addition, the documents may be accessed through the Agency's website at http://www.epa.gov/pesticides.

- *Acrolein HED Risk Assessment for Reregistration Eligibility Decision (RED) Document (PC Code No. 000701)* (B. Daiss.; 3/25/08, D348777).
- *Environmental Fate and Ecological Risk Assessment Chapter in Support of Phase V of the Reregistration Eligibility Decision of Acrolein* (Jones, R.D., Ph.D., Garber, K. and Steeger, T., Ph.D.; 7/23/08, D354775).

A. Human Health Risk Assessment

Acrolein is a pesticide with two registered uses in the U.S. In agriculture, acrolein is registered for application in irrigation systems only in the western U.S. In petroleum production industries, acrolein is applied to injection wells to control slime-producing organisms in drilling muds. The human health risk assessment addresses potential exposure risks from all registered sources; however, exposures to acrolein from the biocide use in petroleum production (Magnicide B) are not expected since the current use pattern consists of application through closed systems and with no release of the fluids to the above ground environment. Therefore, only potential occupational and residential bystander exposures resulting from the use of the herbicide (Magnicide H) were assessed.

Acrolein exposure to handlers can occur in occupational environments. There are no registered food/feed uses for acrolein and thus no food-related dietary risk assessments were conducted based on the use pattern and available data on plant metabolism. Risks from drinking water exposures were not assessed because applications are made to irrigation canals and holding ponds. The Agency does not anticipate that the water released from these canal systems would contain acrolein residues that would reach drinking water sources.

Since there are no residential uses of acrolein, an assessment of residential handler and post-application exposure scenarios was not required. However, residential bystanders may be exposed due to the volatilization of acrolein from irrigation canals. For this reason, potential inhalation exposure for bystanders was assessed using available air monitoring data collected during and after the application of acrolein to canals.

In addition to the parent compound, acrolein, compounds of potential concern include glycidol, a metabolite of acrolein that has been found in fish, and 3-hydroxypropanal, a metabolite of acrolein that has been found in acrolein-treated water. While acrolein forms 3-hydroxypropanal spontaneously in solution, it is an equilibrium process and acrolein will be reformed from 3-hydroxypropanal as acrolein is dissipated by other processes. Therefore, 3-hydroxypropanal is not considered a metabolite of concern for risk assessment purposes.

An assessment of the dietary exposure of subsistence fishermen to glycidol was conducted because glycidol is a potential human carcinogen. Based on available data on acrolein concentrations in fishable waters, and EPA data on the location and fishing habits of

tribes living in areas proximate to treated canals, the Agency believes exposures to subsistence fishermen are possible. Therefore, the Agency conducted a cancer dietary risk assessment for glycidol and this assessment of dietary exposure of subsistence fishermen to glycidol indicates cancer risks do not exceed the Agency's level of concern. For the complete human health risk assessment, refer to the *Acrolein HED Risk Assessment for Reregistration Eligibility Decision (RED) Document,* dated March 25, 2008, which is available in the public docket.

1. Toxicity of Acrolein

The human health risk assessment utilized animal toxicity studies to estimate risk to humans exposed to acrolein. The toxicological database for acrolein is considered adequate for evaluating and characterizing acrolein toxicity and selecting endpoints for the purpose of a risk assessment.

Acrolein is acutely toxic by inhalation, oral, and dermal exposures (Toxicity Category I for all routes). It is a potent irritant to the mucous membranes. Direct contact with liquid acrolein causes rapid and severe eye and skin irritation or burns. Dermal exposure to acrolein liquids or vapors may cause stinging of the eyes, lacrimation, and reddening, ulceration, or necrosis of the skin. Table 5 describes the acute toxicity profile of acrolein.

Table 5: Acrolein Acute Toxicity Profile

Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral [rat]	41257001	LD_{50} = 11 mg/kg	I
870.1200	Acute dermal [rabbit]	00141028	LD_{50} = 231 mg/kg	I
870.1300	Acute inhalation [rat]	40945404	LC_{50} = 0.019mg/L	I
870.2400	Primary eye irritation [rabbit]	00141025	Severely irritating	I
870.2500	Acute dermal irritation [rabbit]	00141026	Severely irritating	I
870.2600	Skin sensitization	Sustin and Breienstein, 1990	Suggestive/limited data	N/A

Chronic Toxicity

Apart from rare cases of sensitization, no adverse effects in humans chronically exposed to low concentrations of acrolein have been reported. Animal studies indicate that the respiratory system is the major target organ for acrolein inhalation toxicity. Oral acrolein exposure may result in gastrointestinal discomfort, vomiting, and stomach ulceration and/or hemorrhage. Also, changes in body and organ weights, hematology, and serum biochemistry have been observed in animals exposed orally to acrolein, although some of these effects are believed to be secondary effects of gastrointestinal and/or respiratory tract irritation. In addition, the central nervous system does not appear to be a target of acrolein toxicity based on an Agency for Toxic Substances Disease Registry (ATSDR) 2005 review.

Developmental Toxicity

In a rat developmental toxicity study, the LOAEL was 10 mg/kg/day based on decreased fetal weights and litter weights and on incomplete ossification of the skeleton and general retarded development of the fetuses. The developmental NOAEL was 6 mg/kg/day. In a rabbit developmental toxicity study, the LOAEL was > 2 mg/kg/day and the developmental NOAEL was 2 mg/kg/day (the highest dose tested).

In a two-generation reproduction toxicity study for rats, the LOAEL for parental toxicity was 6 mg/kg/day, based on decreased body weights, body weight gains, and food consumption in both sexes and both generations during pre-mating and on gross and microscopic findings in the stomach. The NOAEL for this same study was 3 mg/kg/day.

Therefore, based on these developmental studies in rats and rabbits and reproductive toxicity study in rats, fetal or neonatal toxicity from the administration of acrolein does not occur at doses lower than doses causing effects in parental animals.

Carcinogenicity and Mutagenicity Toxicity

The evidence for the carcinogenicity of acrolein is equivocal, with a significant tumor incidence found in a single animal drinking water study. While the potential carcinogenicity of acrolein cannot be determined definitively due to insufficient data, the Agency does not believe cancer studies are required based on use patterns, anticipated exposure patterns, severe acute toxicity, and available data on mutagenicity and carcinogenicity. Oral exposures to acrolein via dietary and drinking exposure are not expected or assessed based on use patterns and physical/chemical property data. Continuous chronic exposures via inhalation and dermal pathways are not expected based on established use patterns. In vitro studies have shown acrolein to be weakly mutagenic.

Glycidol is a metabolite of acrolein reported in a fish metabolism study. Glycidol is reasonably anticipated to be a human carcinogen based on sufficient evidence of carcinogenicity in experimental animals (NTP 1990, IARC 2000). Two-year studies were conducted with mice and rats that were administered glycidol by gavage. Rats showed increased incidences of various effects such as tumors. To quantify the carcinogenic response of glycidol, a multistage model BMD analysis was performed to derive a slope factor of 0.16 $(mg/kg/day)^{-1}$. This method is explained further in the following section (Endpoint Selection) as well as in the *Acrolein HED Risk Assessment for Reregistration Eligibility Decision (RED) Document*.

Neurotoxicity Studies

The central nervous system does not appear to be a target of acrolein toxicity based on an Agency for Toxic Substances Disease Registry (ATSDR) 2005 review. Symptoms of central nervous system depression were observed in rodents after oral exposure to acrolein, but only after lethal concentrations (Sprince et al. 1979). No such effects were observed in animals after inhalation. In addition, no behavioral changes were observed in animals exposed to acrolein by any route. There were no studies addressing the neurotoxicity of acrolein

following dermal exposure. As such, the available data do not indicate that the central nervous system is the major target of acrolein toxicity.

2. Endpoint Selection

Acrolein

The inhalation endpoint was selected from a 1977 study in human volunteers (Weber-Tschopp et al. 1977; MRID 47060601). Acrolein is a component of cigarette smoke and the human study was conducted to determine the effects of different components of cigarette smoke on human volunteers. This study was subject to review by the Human Studies Review Board (HSRB). The HSRB reviewed the study at its June 2007 meeting and determined it to be ethically acceptable and sufficiently sound from a scientific perspective, to be used to estimate a safe level of acute inhalation exposure to acrolein. Because a human study is being used for the short-term intermittent inhalation exposure scenario for acrolein, an interspecies uncertainty factor is not necessary. To account for the individual variability, an intraspecies uncertainty factor of 10X applies. The endpoint selected was based on LOAELs for both (1) eye irritation and (2) nasal and throat irritation and decreased respiratory rate.

For eye irritation effects, the LOAEL was determined to be 0.09 ppm. Because a minimal (relatively non-severe) LOAEL threshold effect is used, a 3X uncertainty factor is sufficient along with the intraspecies factor. Therefore, a total of 30X uncertainty factor is applied to the endpoint.

For nasal and throat irritation and decreased respiratory rate, the LOAEL was determined to be 0.3 ppm. This LOAEL was divided by a factor of 100 (10X for using a LOAEL and 10X for human variability).

Therefore, based on both the LOAEL of 0.09 ppm for eye irritation and the LOAEL of 0.3 ppm for nasal and throat irritation, the concentration of concern for humans is determined to be 0.003 ppm when appropriate uncertainty factors are considered. Thus, the study provides the most comprehensive description available of acute/short-term effects in humans and provides the best information available for establishing a Point of Departure (PoD) for short-term intermittent inhalation worker and residential bystander exposure scenarios.

Glycidol

The Agency's Benchmark Dose (BMD) software (version 1.3.2) was used to fit a multistage model to the human lifetime average daily dose (LADDs). The benchmark response was randomly selected to be 10% (note that when calculating slope factors, the selection of benchmark response does not greatly affect the calculated slope factor). The BMD_{10} was calculated to be 0.79 mg/kg/day and the lower 95% confidence limit on the BMD_{10}, the Benchmark Dose Level $(BMDL)_{10,}$ was calculated to be 0.63 mg/kg/day. Thus, the slope factor is obtained by dividing the benchmark response level (0.1 or 10%) by the $BMDL_{10}$ of 0.63 mg/kg/day which equates to 0.16 $(mg/kg/day)^{-1}$.

Table 6 summarizes the toxicological doses and endpoints used in the human health risk assessment of acrolein.

Table 6: Summary of Toxicological Doses and Endpoints for Acrolein for Use in Human Health Risk Assessment			
Exposure Scenario	**Dose Used in Risk Assessment**	**Uncertainty/Safety Factor**	**Study and Toxicological Effects**
Acute and Chronic Dietary – (All populations)	Acute and chronic oral (dietary and drinking water) exposures to acrolein are not expected based on use patterns, physical-chemical properties, and plant metabolism data. Therefore, RfDs are not required and were not selected for this assessment.		
Incidental Oral (all durations)	There are no residential uses for acrolein. Therefore, incidental oral exposure endpoints are not required and not selected for this assessment.		
Dermal (all durations)	Worker dermal exposures are not expected based on use patterns and personal protective equipment requirements. There are no residential uses for acrolein and dermal exposures to residential bystanders are not expected based on use patterns and physical-chemical properties. Therefore dermal exposure endpoints are not required and have not been selected for this assessment.		
Short –Term Inhalation (1-30 days)	LOAELs 0.09 ppm for eye irritation 0.3 ppm for nasal and throat irritation	Occupational LOC=30 Residential LOC=30 Eye irritation UF_H = 10x 3x lack of a NOAEL Nasal and throat irritation UF_H = 10x 10x lack of a NOAEL	Human volunteers (healthy male and female college students) exposed by inhalation for 60 minutes (Weber-Tschopp et al. 1977) based on a minimal effect LOAEL of 0.09 ppm for eye irritation. The LOAEL of 0.3 ppm for nasal and throat irritation and decreased respiratory rate is also considered for endpoint selection. (MRID 47060601)
Cancer (oral, dermal and inhalation)	"The potential carcinogenicity of acrolein is inconclusive; however, exposure to parent acrolein is not expected. Glycidol is a metabolite of acrolein in fish. Glycidol is anticipated to be a human carcinogen by NTP and IARC. To quantify the carcinogenic response of glycidol, a multistage model BMD analysis was performed to derive a cancer slope factor of 0.16 $mg^{-1}kg^{-1}day^{-1}$ at a 0.95 confidence level.		

UF_H = uncertainty factor for potential variation in sensitivity among members of the human population (intraspecies), NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, MOE = margin of exposure, LOC = level of concern, RfD = Reference Dose

3. Dietary Exposure and Risk (All Populations)

Acrolein

Dietary exposures (acute and chronic) to acrolein are not expected based on the use pattern (no direct applications of acrolein to crops except through irrigation) and available data on plant metabolism. A lettuce metabolism study indicates that acrolein is readily decomposed/incorporated into natural products showing that the only residue of concern is acrolein on the day of application by irrigation. Since it is unlikely that plants would be harvested immediately after irrigation, there is little likelihood that there would be dietary exposure from irrigation water applied to the crop.

Additionally, risks from drinking water exposures were not assessed. There is currently no Maximum Contaminant Level (MCL) set for the protection of drinking water for acrolein under the Safe Drinking Water Act. Also, the Agency did not calculate quantitative estimated environmental concentrations (EECs) for use in the risk assessment since acrolein is applied to irrigation water and there is a holding period before irrigation water is discharged to natural waters, which could serve as drinking water sources. While uncertainties remain regarding the potential for drinking water exposure, such exposures are considered unlikely due to the fact that most, if not all, of any acrolein that could reach a drinking water source from an irrigation ditch would volatilize before and during the aeration stages of drinking water treatment.

Glycidol

An assessment of potential dietary exposure of subsistence fishermen to glycidol, a metabolite of acrolein in fish, was also conducted. Based on Agency data on acrolein concentrations in fishable waters and on the location and fishing habits of tribes living in areas proximate to treated canals, the Agency believes that a subsistence fisherman scenario is possible.

No glycidol was noted in plant metabolism studies and would not be expected from animal studies since acrolein exposure is not expected for terrestrial animals.

In the residue study in fish and shellfish, glycidol accounted for as much as 10 ppb of the total radioactive residue in catfish in a study conducted at 20 ppb water concentration of acrolein. Normalizing the water concentration to account for a mean fish LC_{50} of 34 ppb would result in a estimated glycidol residue concentration of 17 ppb or 0.17 ug/g. Based on data provided in EPA's Exposure Factors Handbook Volume II dated August 1997, the mean Native American subsistence fish harvest is 70 g/day. Multiplying 0.17 ug/g by the recommended mean intake of 70 grams/day would give 11.9 ug/day or 0.0119 mg/day of glycidol. This value must be divided by the weight of an adult in kilograms (70 kg) which gives 0.00017 mg/kg/day. The maximum number of applications reported in the states of Washington, Oregon, and Idaho was 17 applications during a year for a ratio of 17/365 or 0.0466. Multiplying 0.00017 mg/kg/day by 0.0466 would give 7.9×10^{-6} mg/kg/day. This value is then multiplied by the glycidol Q_1* of 0.16 to give a conservative estimated cancer risk of 1.2×10^{-6}. Therefore, based on this conservative assessment, dietary exposure of subsistence fishermen to glycidol does not present cancer risks of concern.

The Agency recognizes that 70 grams of fish/day is a mean value and is not the maximum reported. However, the projected concentration of glycidol in fish is expected to be very conservative since it is based on the assumption that all fish consumed are exposed to 34 ppb acrolein for 17 applications per year.

4. Residential (Non-Occupational) Exposure and Risk

Acrolein products are restricted-use pesticides. The sale and use of these products is limited to certified applicators or persons under their direct supervision. The products may only be applied for uses covered by the certified applicators certification. However, inhalation

exposure to acrolein may occur from the volatilization of MAGNACIDE H from irrigation canals during treatment.

In 2005, California Air Resources Board (CARB) collected acrolein air monitoring data during the application of acrolein into an irrigation canal as part of a pilot study conducted in 2005 to determine the applicability of the proposed field test methods before proceeding to the full scale study. Six samples were collected with acrolein levels ranging from 15.9 to 59.8 ppb. In 2006, CARB collected acrolein air monitoring information during the application of acrolein (MAGNACIDE H) into an irrigation canal as part of a full scale study conducted in 2006. These data summarized in Table 7 can be found at *http://www.cdpr.ca.gov/docs/empm/pubs/tac/studies/acrolein.htm*. Air monitoring was conducted during a 4 hour application period and for 4 hours post-application. The treatment rate was 4.0 ppm with a canal flow rate of 357 cubic feet per second. Acrolein levels ranged from 8.4 to 24 ppb during application and from 1.2 to 5.3 ppb in the post-application period. These data are considered to be very high quality, but only represent one set of conditions at one location. For additional information regarding the results of the CARB monitoring, please refer to the *Acrolein HED Risk Assessment for Reregistration Eligibility Decision (RED) Document,* dated March 25, 2008, which is available in the public docket.

Table 7. Results of 2006 CARB Monitoring of Acrolein During Application

Test Location Application Rate Canal Flow	**Sampling Site (AP = Application Point) 4 Hour Application Period**	**Air Concentration (ppb)**
Kern County California 4.0 ppm 357 cfs	1. West bank AP	11
	2. West bank AP collocated sample	10
	3. East bank AP	11
	4. East bank AP collocated sample	15
	5. West bank 25 m south, 9.6 m west of AP	10
	6. East bank 19.5 m south, 10 m east of AP	9.5
	7. West bank 50 m south of AP at Canal's Edge	8.4
	8. East bank 42 m south of AP at Canal's Edge	14
	9. West bank 100 m south of AP at Canal's Edge	17
	10.East bank 88 m south of AP at Canal's Edge	20
	11. West bank 150 m south of AP at Canal's Edge	16
	12. East bank 137 m south of AP at Canal's Edge	13
	13. West bank 200 m south of AP at Canal's Edge	13
	14. East bank 187 m south of AP at Canal's Edge	18
	15. West bank 250 m south of AP at Canal's Edge	24
	16. East bank 237 m south of AP at Canal's Edge	11
Results of 2006 CARB Monitoring of Acrolein Four Hours after Application		
Kern County California 4.0 ppm 357 cfs	1. West bank AP	5.3
	2. East bank AP	3.2
	3. West bank 25 m south, 9.6 m west of AP	1.4
	4. East bank 19.5 m south, 10 m east of AP	2.2
	5. West bank 50 m south of AP at Canal's Edge	2.7
	6. East bank 42 m south of AP at Canal's Edge	2.7
	7. West bank 100 m south of AP at Canal's Edge	1.9
	8.East bank 88 m south of AP at Canal's Edge	2.2

Table 7. Results of 2006 CARB Monitoring of Acrolein During Application		
Test Location Application Rate Canal Flow	**Sampling Site (AP = Application Point) 4 Hour Application Period**	**Air Concentration (ppb)**
	9. West bank 150 m south of AP at Canal's Edge	2.6
	10. East bank 137 m south of AP at Canal's Edge	3.2
	11. West bank 200 m south of AP at Canal's Edge	1.2
	12. East bank 187 m south of AP at Canal's Edge	1.4
	13. West bank 250 m south of AP at Canal's Edge	2.4
	14. East bank 237 m south of AP at Canal's Edge	1.7

In reference to the air monitoring studies listed above, Table 8 provides a summary of the results from the MAGNACIDE H Field Air Monitoring samples that were collected in 2002. The highest result of 63 ppb occurred at the California #1 Test Location where a leak reportedly occurred. The results at the other two test locations ranged from not detectable to 30 ppb. The limit of detection was not specified but was estimated to be approximately 1 ppb based on the lowest reported result, which was 1.5 ppb.

Table 8. Results of MAGNACIDE H Field Air Monitoring (MRID 469769-12)		
Test Location, Application Rate, Canal Flow	**Sampling Site**	**Air Concentration (ppb)**
Washington, 1.98 ppm, 840 cubic feet per second (cfs)	Application point	25
	Downstream, right-of-way	4
	Downstream, right-of-way	None Detected
	Downstream, 150 feet into field	2
	Downstream, 150 feet into field	None Detected
Central California #1 8 ppm for 2 hours 200 cfs	Application point	63*
	Downstream, right-of-way	38
	Downstream, right-of-way	13
	Downstream, 150 feet into field	None Detected
	Downstream, 150 feet into field	7.8
Central California #2 7.2 ppm for 2 hours 48 cfs start 38 cfs finish	Application point	13
	Downstream, right-of-way	20
	Downstream, right-of-way	30
	Downstream, 150 feet into field	1.5
	Downstream, 150 feet into field	7.9

* Equipment leak experienced and operating vehicle entered the test site

c.) Residential Exposure

There are no residential handler (applicator) uses for acrolein. However, residential bystander exposure through the inhalation pathway can occur as a result of the application of MAGNACIDE H to irrigation canals, which may be located near residential areas. There are no requirements for the establishment of area restrictions in the proximity of the application site or the treated canal.

The acrolein exposure level at which inhalation risks are not of concern is 3 ppb. Measured air concentrations based on monitoring data associated with sites near irrigation ditches ranged from 1.5 to 63 ppb (see Table 8). The target LOC or MOE for short-term inhalation exposure to acrolein is 30. Short-term MOEs for residential exposure calculated using concentrations from the air monitoring data ranged from 1.5 to 60 (see Table 9). Therefore, depending on the scope to which residential areas are located within the vicinity of treated canals and/or non-workers are conducting activities near treated canals (during or near the time of treatment), inhalation MOEs for residential bystander exposure exceed the Agency's level of concern.

Monitoring data indicates that air concentrations of acrolein generally decrease with distance from the source (*e.g.*, the treated canal). Therefore, the highest potential risks are to persons standing adjacent to the canal and the exposures decrease away from the treated water body. It should be noted that available monitoring data provide insufficient information to determine the appropriate dimensions of a restricted area relative to the application point or area source (*e.g.*, the canal).

Although, the current acrolein label does not prohibit swimming during applications, irrigation district personnel discourage swimming in canals because of public safety concerns, particularly the risks of drowning in the canal. While a separate swimmer assessment was not conducted due to lack of appropriate endpoints for dermal and oral exposure, the Agency notes that acrolein is irritating at low concentrations and would presumably present some risks to swimmers.

5. Aggregate Exposure and Risk

The Agency has not conducted a quantitative or qualitative aggregate assessment for acrolein. An aggregate exposure assessment considers the different pathways (food, water, occupational, and residential) through which exposure to acrolein may occur when there are potential residential exposures to the pesticide. Since there are no anticipated dietary/drinking water exposures to residues of acrolein, an assessment of aggregate exposure from food and non-food sources is not required. Further, the metabolite of acrolein, glycidol, only forms in fish and depurates quickly. Although a dietary cancer assessment was conducted for glycidol, exposures to glycidol via drinking water, inhalation, and dermal pathways are not expected. Therefore, an aggregate assessment is not required.

6. Occupational Exposure and Risk

a) Occupational Handler/Application Assessment

Based on current use patterns, acrolein exposure to occupational handlers can occur. MAGNACIDE H and MAGNACIDE B are applied through a closed system transfer from steel cylinders designed to prevent applicator exposure. Both products are supplied in pressurized containers where nitrogen is used to force the liquid chemical out of the container through a metering device. It is then injected directly below the surface of moving water in the canal where it is carried along by the flow (MAGNACIDE H) or is injected into closed injection well

piping (MAGNACIDE B) through sealed hoses. It is important to note that applicators must use only specified application equipment built specifically for use of these particular products as directed by the technical registrant Baker Petrolite.

Magnacide H

During the set up and/or break down of equipment, exposure to acrolein from the application of MAGNACIDE H is not expected because applicators must comply with stringent label requirements for personal protective equipment (PPE) (i.e., full face air purifying respirator, butyl rubber gloves, etc.) throughout these activities. Use of a closed application system combined with stringent training, certification and PPE requirements is expected to effectively prevent dermal exposures of concern to workers during handling and application activities.

However, since the application of MAGNACIDE H can vary in time (30 minutes to 8 hours) and respiratory protection is not required after initial set up and prior to break down of equipment, inhalation exposures to workers during application is possible. The exposure level at which inhalation risks are not of concern is 3 ppb (90 ppb LOAEL ÷ UF 30). The target MOE for short-term inhalation exposure to acrolein is 30 and all MOE's >30 are potentially of concern.

Table 9: Estimated Inhalation Exposure and Risk to Workers and Bystanders

Range of Measured Concentrations (ppb) (see Tables 7 and 8)	LOAEL (ppb)	Target MOE	Calculated MOE
1.5 - 63 (0.0015-0.063 ppm)	90 (0.09 ppm)	30	1.5 - 60

Calculated MOE = Acute Inhalation NOAEL (90 ppb) ÷ estimated inhalation concentration (1.5 – 63 ppb).

Some of the calculated MOEs exceed the Agency's level of concern for worker exposure during the application period between set up and breakdown of equipment as well as after disassembling of the equipment has been completed.

The Baker Petrolite Corporation also submitted summary results from a MAGNACIDE H HERBICIDE Industrial Hygiene Monitoring Study. The Industrial Hygiene Monitoring Results reported by Baker Petrolite from an air sampler near the worker's breathing zone indicated that acrolein applicator exposures were all below the limit of detection (LOD), which ranged from 2.2 to 70 ppb.

Magnacide B (biocide)

Occupational exposures to acrolein from the use of MAGNACIDE B are not expected because it is applied via a closed system. MAGNACIDE B Microbiocide is applied in injection systems associated with petroleum production. The MAGNACIDE B product is applied by pumping acrolein from pressurized containers into closed injection well piping systems. The closed application system combined with stringent training and PPE requirements is intended to effectively prevent exposures of concern from any MAGNACIDE B biocide product.

b) Occupational Post-application Exposures

Post-application exposures of MAGNACIDE H to workers may also occur depending on the length of time the worker remains in the area after application has been completed and the equipment disassembled. Therefore, depending on the extent to which workers remain in the vicinity of the treated canal after acrolein has been applied and the requirement for use of a respirator is no longer applicable, inhalation MOEs for worker post-application exposure may exceed the Agency's level of concern.

7. Endocrine Disruption

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

8. Incident Reports

The following data bases were consulted for poisoning incident data on the active ingredient acrolein; OPP Incident Data System (IDS), Poison Control Centers, California Department of Pesticide Regulation, National Pesticide Telecommunications Network (NPTN), and National Institute of Occupational Safety and Health's (NIOSH) Sentinel Event Notification System for Occupational Risks (SENSOR).

Three incident reports in the OPP Incident Data System (IDS) were related to acrolein. One incident occurred in 1999, when a valve on a cylinder that contained Magnacide H, was struck by an overhead obstacle while entering a service station. A man at the site reported eye irritation, difficulty breathing, and chemical burns. Two of the incidents resulted in death, which was directly attributable to an applicator not wearing the required personal protective equipment. The incident in 1999 occurred when the applicator accidentally ran over and damaged parts of the delivery system, spilling a few gallons of the product. The applicator proceeded, without personal protective equipment, to close off the cylinder valve of the delivery system. He then washed himself off in the canal and traveled to the hospital where he was treated and then released. He was later found unconscious in his home and died the next day. The latest incident in 2007 occurred when the applicator was sprayed directly in his face with acrolein that was under pressure, after he attempted to tighten a connection in the delivery system. An initial evaluation showed signs of respiratory distress so he was transported to a medical center where he received immediate treatment. Despite the treatment, the individual died within several days.

Based on exposures reported to Poison Control Centers from 1993 through 2003, 47 cases were reported. A wide range of symptoms were reported including eye irritation/lacrimation (4 cases reported), headache (3 cases), nausea (2 cases), cough/choke (2 cases), superficial burns (2 cases), and one single event of throat irritation, vomiting, erythema skin irritation, and pruritus.

Fifteen cases submitted to the California Pesticide Illness Surveillance Program (1982-2003) were reviewed. In 14 of these cases, acrolein was used alone or was judged to be responsible for the health effects. Applicator and coincidental activities were associated with 8 of the 14 reported exposure related illnesses. These illnesses included symptoms of coughing, headache, nausea, and burns on the arm.

The National Pesticide Information Center (NPIC) received calls from 1984-1991 and acrolein was not reported to be involved in human incidents. There have been no reported incidents involving bystanders or persons exposed in residential settings. From 1998 to 2003 there was one case reported in the NIOSH SENSOR database involving acrolein. The exposed individual reported blurred vision and a feeling of warmth. Poison Control Center Data generally support the finding that acrolein's main effect is due to its irritant properties. Incidents involving more severe effects resulted from accidental exposures or misuse of the acrolein product Magnacide H.

In conclusion, if acrolein products are applied according to their labels and user manuals, the Agency does not anticipate human health incidents from registered acrolein uses.

B. Environmental Fate and Ecological Risk Assessment

The Agency conducted an environmental fate and ecological risk assessment for acrolein for the purpose of making a reregistration decision. The environmental fate and effects risk assessment is largely based on field studies and monitoring data. Since these monitoring studies only report the parent active ingredient, data are only available to consider the risks due to the parent acrolein at this time. In addition, based on available information regarding volatilization, persistence, and direct and indirect toxicity, acrolein has the potential to compromise survival and cause sub-lethal effects in non-target aquatic animals and plants, terrestrial mammals, birds and plants. As such, the assessment endpoints for acrolein include survival, reproduction and growth of birds, mammals, freshwater fish and invertebrates, estuarine/marine fish and invertebrates, terrestrial plants, insects, and aquatic plants and algae. A summary of the environmental risk assessment findings and conclusions is provided below. For more detail on the acrolein environmental exposure and risk assessment, refer to the *Environmental Fate and Ecological Risk Assessment Chapter in Support of Phase V of the Reregistration Eligibility Decision on Acrolein*, dated July 23, 2008, which is available in the public docket.

1. Environmental Fate and Transport

Acrolein is considered a contact herbicide that is phytotoxic to most submersed aquatic vegetation. Submersed aquatic plants treated with Magnicide H are intended to gradually

disintegrate into small fragments and then float downstream. Contact herbicides act quickly by destroying plant cells; however, they do not kill plant roots and re-application may be required. Due to the reactivity with organic matter, acrolein is not likely to persist in the environment. However, despite the lack of persistence, it can move considerable distances in fast moving water such as within irrigation canals.

Degradation and volatilization are believed to be the major pathways for dissipation of acrolein in water. Acrolein may also bind to plant material and this may serve as an additional route of dissipation from the water column. The Agency has no acceptable data to assess microbial degradation or photolysis. Therefore, it is unknown whether these pathways are significant routes of degradation in the environment.

No acceptable data are available for estimating desorption coefficient (K_d) values for acrolein. In the aerobic (MRID 43227101) and anaerobic (MRID 42949201) aquatic metabolism studies, acrolein was not identified in the sediment of the test vessels which suggests that acrolein does not partition into sediment to any major degree. In addition, the very high solubility (237 g/L at 25^{o}C) would indicate a very low tendency to absorb to sediment.

Acrolein does not undergo hydrolytic degradation in aqueous solution. Rather, it goes into equilibrium with a hydration product, 3-hydroxypropanal, where water has added to the double bond. The equilibrium constant is assumed to be independent of pH.

Data of the dissipation rate of acrolein from foliage is not of sufficient quality to allow for the estimation of a degradation rate. However, even though the data was limited in its quality; the Agency was able to utilize a 1-day foliar dissipation half-life. Usually, in the absence of this information, the Agency relies on a default foliar dissipation half-life of 35 days to estimate potential residues on terrestrial animal forage items. However, given the volatility and reactivity of acrolein, the default value of 35 days is not justifiable. Thus, given the uncertainties of the submitted data, a 1-day foliar dissipation half-life was used. It is noteworthy that monitoring studies, included in the ecological risk assessment, show the toxicity of acrolein is such that even with a dissipation half-life of less than 1 day, acrolein is persistent enough to move long distances with concentrations that remain a concern for wildlife.

2. Ecological Exposure and Risk

In ecological risk assessments, the ecological effects characterization describes the types of effects a pesticide can potentially produce in an animal or plant. This characterization is generally based on registrant-submitted studies that describe acute and chronic effects information for various aquatic and terrestrial animals and plants; however, these data may also be supplemented by data reported in ECOTOX (http://www.epa.gov/med/Prods_Pubs/ecotox.htm) or open/public literature sources that have met Agency criteria for acceptability.

To estimate potential ecological risk, the EPA integrates the results of exposure and ecotoxicity studies using the risk quotient method. The risk quotient (RQ) approach is used in

this assessment to reach conclusions regarding the potential for adverse effects associated with the proposed use of acrolein. The basis of the RQ approach is a comparison of the ratio of exposure concentrations to effects endpoints with predetermined levels of concern (LOCs). Risk quotients are calculated by dividing estimated environmental concentrations (EECs), based on environmental fate characteristics, by ecotoxicity values (acute and chronic) for various wildlife and plant species. RQs are then compared to LOCs, and when the RQs exceed the level of concern for a particular category, the Agency presumes a potential risk of concern to that category.

Although risk is often defined as the likelihood and magnitude of adverse ecological effects, the risk quotient-based approach does not provide a quantitative estimate of likelihood and/or magnitude of an adverse effect. These LOCs are indicators of whether a pesticide, used as directed on the label, has the potential to cause adverse effects on non-target organisms. See Table 10 for the Agency's 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. To the extent feasible, the Agency seeks to reduce environmental concentrations in an effort to reduce the potential for adverse effects to non-target organisms.

Table 10. EPA's Levels of Concern and Associated Risk Presumptions

Risk Presumption	RQ	LOC
Terrestrial animals (birds and wild mammals)		
Acute High (Non-listed) Risk	EEC[1]/LC_{50} or LD_{50}/ft^2 or LD_{50}/day[3]	0.5
Acute Endangered (Listed) Species	EEC/LC_{50} or LD_{50}/ft^2 or LD_{50}/day	0.1
Chronic Risk	EEC/NOAEC	1
Aquatic animals		
Acute High (Non-listed) Risk	EEC[4]/LC_{50} or EC_{50}	0.5
Acute Endangered (Listed) Species	EEC/LC_{50} or EC_{50}	0.05
Chronic Risk	EEC/NOAEC	1
Terrestrial and Semi-Aquatic Plants		
Acute High (Non-listed) Risk	EEC[5]/EC_{25}	1
Acute Endangered (Listed) Species	EEC/EC_{05} or NOAEC	1
Aquatic Plants		
Acute (Non-listed) Risk	EEC[6]/EC_{50}	1
Acute Endangered (Listed) Species	EEC/EC_{05} or NOAEC	1

[1] abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items
[2] $\frac{mg/ft^2}{LD_{50} * wt. of bird}$ [3] $\frac{mg\ of\ toxicant\ consumed/day}{LD_{50} * wt. of bird}$ [4] EEC = (ppm or ppb) in water [5] EEC = lbs ai/A [6] EEC = (µg/L or mg/L) in water

a. Terrestrial Organisms Exposure and Risk

1) Bird and Mammal Toxicity

Avian

Acrolein is very highly toxic (LD_{50} <10 mg/kg) to birds on an acute oral exposure basis. The acute oral toxicity of acrolein to the mallard duck (*Anas platyrhynchos*) and northern bobwhite quail (*Colinus virginiana*) was assessed in separate single-dose studies. Male mallard ducks were dosed with 92% acrolein, which resulted in a LD_{50} of 9.1 mg/kg a.i. with sub-lethal effects including weakness, withdrawal, muscular debility, and imbalance. Sub-lethal effects were also observed at 3.3 mg/kg treatment intervals (MRID 00117668). Another acceptable mallard duck study via oral dosing with 95.09% acrolein resulted in a LD_{50} of 28 (18-38) mg a.i./kg-bw. Sub-lethal effects were noted such as lethargy, labored breathing, tremors, anorexia among others. Body weight and food consumption reductions were also noted (MRID 42183301). In addition, data in a supplemental study for the oral toxicity of 92% acrolein to bobwhite quail resulted in a LD_{50} of 19 mg/kg (MRID 92001003). Therefore, the most sensitive endpoint used to assess the acute oral toxicity of acrolein is 9.1 mg a.i./kg-bw. Refer to Table 11 below for a complete listing of the acute toxicity values for birds used in the risk assessment.

Table 11. Summary of acute toxicity data for terrestrial organisms (birds) exposed to acrolein.

Species (common name)	Measure of effect	End-point	Mean Concentration (C.I.)	Test Substance (% a.i.)	Study Classification	Reference (MRID)
Mallard duck *Anas platyrhynchos*	Mortality	LD_{50}	9.11 mg a.i./kg (6.32-13.1)	92	Acceptable	00117668

No data are available to evaluate the subacute dietary toxicity (LD_{50}) of acrolein to birds either through registrant-submitted data or through a search of the open literature contained in ECOTOX.

In addition, no data are available to evaluate the chronic toxicity of acrolein to birds either through registrant-submitted data or through a search of the open literature contained in ECOTOX. Therefore, due to a lack of chronic toxicity data for birds, only acute, dose-based exposures to birds were considered in the assessment.

In order to assess the risk to birds from inhalation, it is necessary to estimate the inhalation LD_{50} for acrolein from rat inhalation toxicity data since there are no direct measurements of acrolein inhalation toxicity available for birds. The oral LD_{50} for gulls and songbirds were estimated using the weight of the bird relative to the weight and LD_{50} of the mallard. The method for calculating the expressed values listed below in Table 12 are outlined in the *Environmental Fate and Ecological Risk Assessment Chapter in Support of Phase V of*

the Reregistration Eligibility Decision on Acrolein, dated July 23, 2008, which is referenced in Appendix D of this document.

Table 12. LD_{50} for representative birds estimated from the acute oral LD_{50} for mallard duck and the adjusted rat inhalation LD_{50}.

Species	Body weight (g)	Oral LD_{50} ($mg \cdot kg^{-1}$)	Inhalation LD_{50} ($mg \cdot kg^{-1}$)
Mallard	1580	9.1	0.574[3]
Ring-bill gull	350	7.25[1]	0.458[2]
Songbird	20	4.72[1]	0.298[3]

[1] oral $LD_{50(oral, A)} = LD_{50(oral, mallard)}(BW_A/BW_{mallard})^{(1.15-1)}$

[2] inhalation $LD_{50(inh, gull)} = LD_{50 (or, gull)} /(LD_{50(or, rat)} * Fre / LD_{50(inh,rat)})$, Fre calculation is in text)

[3] adjusted $LD_{50(inh)}$ for mallard and songbird: $LD_{50(inh,A)} = LD_{50(inh, gull)}(BW_A/BW_{gull})^{(1.15-1)}$

Mammal

Acrolein is highly toxic (LD_{50} 10-50 mg/kg) to mammals on an acute oral exposure basis. In an acute study on rats (*Rattus norvegicus*; MRID 41257001), acrolein was administered by gavage to male and female rats. The acute oral LD_{50} for male and female rats was 10.3 and 11.8 mg/kg, respectively. The rats were observed for 4 hours, with sublethal signs of toxicity that included lethargy, hypothermia, changes in respiration and weight loss. Acrolein is also considered to be a skin/mucous membrane and eye (lacrimator) irritant. In addition, due to the volatility of acrolein, wildlife may also be exposed through the inhalation route. The inhalation LC_{50} for acrolein is 17 mg/m^3/4 hours in rats. However, for assessment purposes, this value was converted to a dose-based toxicity value to determine risks from inhalation of acrolein. For further detail on the process of this conversion, please refer to the Environmental Fate and Ecological Risk Assessment referenced above in this section. Table 13 provides a summary of the results for acute oral toxicity.

Table 13. Summary of acute toxicity data for terrestrial organisms (mammals) exposed to acrolein.

Species (common name)	Measure of effect	End-point	Mean Concentration (C.I.)	Test Substance (% a.i.)	Study Classification	Reference (MRID)
Laboratory rat *Rattus norvegicus*	Mortality	LD_{50}	Males: 10.3 (6.4-16.7) mg/kg Females: 11.8 (7.9-17.6) mg/kg	96.58	Acceptable	412570-01

In a 2-generation (rat) reproduction study (MRID 41869101), a LOAEL of 6 mg/kg/day was determined for parental toxicity. This value was based on decreases in body weight and in food consumption as well as other adverse effects. The NOAEL was determined to be 3 mg/kg/day for parental toxicity. Likewise, the LOAEL and NOAEL for offspring toxicity are 6 mg/kg/day based on body weight decrease in the F_1 generation, and 3 mg/kg/day, respectively.

2) Bird and Mammal Exposure

The EEC values for residues on food and feed items used for terrestrial exposure are derived from the Kenaga nomograph, as modified by Fletcher *et al.* (1994). Risk quotients are based on the most sensitive LD_{50} for birds (mallard) and LD_{50} and NOAEL values from rat studies.

In order to estimate risks to terrestrial mammals and birds inhabiting and eating in fields irrigated with acrolein-treated water, it was necessary to calculate the application rate of acrolein to a field in units of lbs a.i./A. This calculation requires conversion from the concentration of acrolein in irrigation water (mg/L) to the amount of acrolein that could potentially remain on the foliage after an irrigation event. Note: this method is relevant when sprinkler irrigation is used in order that the irrigation water is applied to the foliage. Thus, dietary exposure (other than drinking water) should not be a concern for flood or furrow irrigation as there is little contact of the irrigation water with the above ground foliage. To achieve this estimate, a measure of the amount of irrigation water that sticks to the crop was required. Therefore, in order to provide conservative estimates of risk, the CINTCP value (a parameter used in the Pesticide Root Zone Model (PRZM) that defines the maximum interception storage of a crop) for orchards was utilized to estimate exposures to terrestrial mammals and birds consuming food in fields receiving irrigation water containing various concentrations of acrolein.

Although acrolein is applied directly to irrigation water and terrestrial plants are not initially treated with acrolein, the label requires that treated water is to be applied to fields and thus, terrestrial organisms may potentially be exposed to acrolein-treated water. Typically, screening-level ecological risk assessments do not take drinking water exposure into account; however, terrestrial animals could potentially drink water from treated irrigation canals. Therefore, in order to assess potential risks, dose-based exposures were estimated for several representative mammalian and avian species, including mink, river otter, spotted sandpiper, belted kingfisher, herring gull, osprey, mallard duck, great blue heron and bald eagle.

The EEC values used to assess exposure to birds and mammals can be found in the *Environmental Fate and Ecological Risk Assessment Chapter in Support of Phase V of the Reregistration Eligibility Decision on Acrolein*, dated July 23, 2008, which is available in the public docket.

3) Bird and Mammal Risk

Birds

For the drinking water only exposure, no acute risk LOC is exceeded for non-listed birds, the acute risk LOC for Federally listed endangered and threatened (listed) species (RQ>0.1) is exceeded for the spotted sandpiper and belted kingfisher. Therefore, the Agency's screening-level assessment indicates a potential for acute risk to listed birds (especially smaller birds) consuming drinking water treated with acrolein at the maximum label rate. Thus, an analysis will be conducted to determine if any listed or candidate species may co-occur in the area of acrolein application or areas downstream that could be contaminated from drift or

runoff. If it is determined that listed or candidate species may be present in the proposed application areas (irrigation canals and reservoirs), further biological assessment will be undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act. Refer to Table 14 for additional information.

Table 14. Acute dose-based RQ values for birds exposed to Acrolein through drinking water.

Avian Species	BW (kg-bw)	DW (L/kg-bw/d)	EEC (mg/kg-bw/d)	Adjusted Toxicity Values (mg/kg-bw)	Acute RQs
Spotted Sandpiper	0.043	0.167	2.500	5.31	**0.471**[1]
Belted kingfisher	0.148	0.111	1.662	6.39	**0.260**[1]
Herring gull	1.1	0.057	0.858	8.63	0.099
Osprey	1.5	0.052	0.774	9.04	0.086
Mallard duck	1.58	0.051	0.761	9.11	0.084
Great blue heron	2.39	0.044	0.664	9.69	0.068
Bald eagle	4.65	0.036	0.533	10.71	0.050

[1] Exceeds the acute LOC (0.1) for listed species.

The acute risk LOC (RQ>0.5) is exceeded for all-sized birds feeding on all forage categories except large birds (1000 g) feeding on fruits/pods/large insects at application rates of 0.54 lbs a.i./A representing water treatment rate of 15 mg a.i./L. At an application rate of 0.05 lbs a.i./A (representing water treatment rate of 1.5 mg a.i./L), the acute risk LOC is exceeded for small (20 g) and medium (100 g) birds feeding on short grasses, tall grasses and broadleaf plants/small insects (RQ range 0.78 – 3.09). The acute listed species LOC is exceeded across all-sized birds feeding in all forage categories except fruits/pods/large insects at application rates equivalent to 0.05 lbs a.i./A or greater. At the lowest application rate evaluated (0.005 lbs a.i./A) (representing water treatment rate of 0.15 mg a.i./L), the acute risk to listed species LOC is exceeded for small birds feeding on all forage categories except fruits/pods/large insects and for medium sized birds feeding on short grasses (Table 15).

Table 15. Acute dose-based RQs for birds of different size and feeding classes exposed to acrolein on foodstuffs treated with irrigation water.

Food Type	Small (20 g)	Medium (100 g)	Large (1000 g)
Application Rate: 0.535 (15 mg/L in water)			
Short Grass	**30.92**[1, 2]	**13.85**[1, 2]	**4.39**[1, 2]
Tall Grass	**14.17**[1, 2]	**6.35**[1, 2]	**2.01**[1, 2]
Broadleaf plants/sm insects	**17.39**[1, 2]	**7.79**[1, 2]	**2.47**[1, 2]
Fruits/pods/lg insects	**1.93**[1, 2]	**0.87**[1, 2]	**0.27**[2]
Application Rate: 0.0535 (1.5 mg/L in water)			
Short Grass	**3.09**[1, 2]	**1.38**[1, 2]	**0.44**[1, 2]
Tall Grass	**1.42**[1, 2]	**0.63**[1, 2]	**0.20**[1, 2]
Broadleaf plants/sm insects	**1.74**[1, 2]	**0.78**[1, 2]	**0.25**[1, 2]
Fruits/pods/lg insects	**0.19**[2]	**0.09**	**0.03**

Table 15. Acute dose-based RQs for birds of different size and feeding classes exposed to acrolein on foodstuffs treated with irrigation water.			
Food Type	**Small (20 g)**	**Medium (100 g)**	**Large (1000 g)**
Application Rate: 0.00535 (0.15 mg/L in water)			
Short Grass	**0.31**[1, 2]	**0.14**[2]	**0.04**
Tall Grass	**0.14**[2]	**0.06**	**0.02**
Broadleaf plants/sm insects	**0.17**[2]	**0.08**	**0.02**
Fruits/pods/lg insects	**0.02**	**0.01**	**0.00**

[1] Exceeds LOC (RQ≥0.5) for acute exposures to non-listed terrestrial birds.
[2] Exceeds LOC (RQ≥0.1) for acute exposures to listed terrestrial birds.
Foliar dissipation half life: 1 day
Number of applications: 1
Avian LD50: 9.11 (mallard duck)

Lower bound RQs are calculated from CARB monitoring data and do not exceed the Agency's LOC except for listed, small birds. Upper-bound risk quotients for acute mortality to birds based on inhalation exceed the acute risk LOC for all birds. Upper-bound concentrations used to calculate these RQs assume that the air along the sides of the canal is in equilibrium with the canal water. However, because volatilization from the water's surface is a time-dependent process, the water is moving, and the air in and around the canal is unbounded; it is unlikely that equilibrium would ever be approached (Table 16).

Table 16. Acute risk RQs for birds via the inhalation route.					
Species	**Inhalation LD_{50}** $mg \cdot kg^{-1}$	**Lower Bound VID** $mg \cdot kg^{-1}$	**Upper Bound VID** $mg \cdot kg^{-1}$	**Lower Bound RQ** $mg \cdot kg^{-1}$	**Upper Bound RQ** $mg \cdot kg^{-1}$
Mallard	0.574	2.21×10^{-2}	2.17×10^{1}	0.04	**38**[2]
Gull	0.458	3.12×10^{-2}	$3.0.7 \times 10^{1}$	0.07	**67**[2]
Songbird	0.298	6.03×10^{-2}	5.93×10^{1}	**0.20**[1]	**199**[2]

[1]Exceeds LOC (RQ > 0.1) for listed birds and for restricted use for birds
[2] Exceed LOC (RQ > 0.5) for high risk to birds

Mammals

Although no acute risk LOC is exceeded for non-listed mammals, for the drinking water only exposure scenario the acute risk LOC for endangered species (RQ>0.1) is exceeded for mammals. Therefore, there is a potential for acute risk to listed mammals consuming drinking water treated with acrolein at the maximum label rate. No chronic risk LOC is exceeded for mammals (Table 17).

Table 17. Acute and chronic dose-based RQ values for mammals exposed to Acrolein through drinking water.							
Mammalian Species	**BW (kg-bw)**	**DW (L/kg-bw/d)**	**EEC (mg/kg-bw/d)**	**Adjusted Toxicity Values (mg/kg-bw)**		**Risk Quotients**	
				Acute	**Chronic**	**Acute**	**Chronic**
Mink	1.0	0.099	1.485	7.92	2.31	**0.187**[1]	0.644
River otter	8.0	0.080	1.206	4.71	1.37	**0.256**[1]	0.879

[1] Exceeds the acute LOC (0.1) for listed species.

The acute risk LOC (RQ>0.5) is exceeded for all sized mammals feeding on all forage categories except large mammals (1000 g) feeding on grass, broadleaf plants and small insects at application rates of 0.54 lbs. a.i./A (representing water treatment rate of 15 mg a.i./L). At the highest application rate of acrolein, RQs exceed the LOC for listed species of all sizes and feeding categories of mammals, with the exception of granivores. At an application rate of 0.0535 lbs a.i./A (representing water treatment rate of 1.5 mg a.i./L), the acute risk LOC is exceeded only for small-sized (15 g) mammals feeding on short grasses (RQ=0.54). The acute listed species LOC for mammals is exceeded for all sized mammals feeding on short grass, broadleaf plants and small insects (Table 18).

Table 18. Acute dose-based RQs for mammals of different size and feeding classes exposed to acrolein.

Food Type	Small (15 g)	Medium (35 g)	Large (1000 g)
Application Rate: 0.534 lbs a.i.A (15 mg/L in water)			
Short Grass	**5.41**[1, 2]	**4.62**[1, 2]	**2.48**[1, 2]
Tall Grass	**2.48**[1, 2]	**2.12**[1, 2]	**1.13**[1, 2]
Broadleaf plants/sm insects	**3.04**[1, 2]	**2.60**[1, 2]	**1.39**[1, 2]
Fruits/pods/lg insects	**0.34**[2]	**0.29**[2]	**0.15**[2]
Seeds (granivore)	**0.08**	**0.06**	**0.03**
Application Rate: 0.0534 lbs a.i./A (1.5 mg/L in water)			
Short Grass	**0.54**[1, 2]	**0.46**[2]	**0.25**[2]
Tall Grass	**0.25**[2]	**0.21**[2]	**0.11**[2]
Broadleaf plants/sm insects	**0.30**[2]	**0.26**[2]	**0.14**[2]
Fruits/pods/lg insects	**0.03**	**0.03**	**0.02**
Seeds (granivore)	**0.01**	**0.01**	**<0.01**

[1] Exceeds LOC (RQ≥0.5) for acute exposures to non-listed terrestrial mammals.
[2] Exceeds LOC (RQ≥0.1) for acute exposures to listed terrestrial mammals.
Foliar dissipation half life: 1 day
Number of applications: 1
Mammalian LD_{50}: 10.30

The inhalation LC_{50} for rats exposed to acrolein is 18 mg/m^3/4 hours with an LD_{50} of 2.0 mg·kg^{-1}. For mammals, the lower bound inhalation RQ based on monitoring is >0.1 and the calculated upper bound inhalation RQ is 20 which exceeds the LOC (RQ >0.5) for acute risks to mammals.

4) Non-target Terrestrial Plants

There are no terrestrial plant toxicity data with which to evaluate potential risks to terrestrial plants; however, there is an incident report of adverse effects to agricultural crops to which acrolein-treated water is routinely applied to dissipate the chemical. It has been hypothesized that the waxy cuticle of terrestrial plants that protects them from dehydration may also serve to protect them from the toxic effects of acrolein. However, no data have been submitted with which to evaluate this hypothesis. Residue data collected from terrestrial plants indicates dicysteine residues in terrestrial plants treated with acrolein; these data suggest that in terrestrial plants acrolein can cross-link sulfhydryl residues in proteins.

5) Non-target Insects

There are no data available in order to evaluate the acute toxicity of acrolein to beneficial insects. However, risk is presumed for insects in the absence of data and based on the chemical's mode of action.

b. Aquatic Organism Exposure and Risk

On an acute exposure basis acrolein is very highly toxic to freshwater fish and invertebrates, estuarine/marine invertebrates and it is highly toxic to estuarine/marine fish. Chronic exposure to acrolein resulted in reduced growth and survival in fish and reduced survival in aquatic invertebrates. Available toxicity data indicate that aquatic animals are just as sensitive, if not more so, to acrolein than aquatic plants.

1) Fish, Invertebrate, and Aquatic Plant Toxicity

Freshwater Fish/Amphibians

There are several 96-h LC_{50} values available to describe the acute toxicity of acrolein to freshwater fish and amphibians. The most conservative value identified to describe the toxicity of acrolein to freshwater vertebrates is a 96-h LC_{50} of 7 µg a.i./L for larval African clawed frog (*Xenopus laevis)* (Holcombe *et al.* 1987). Supplemental data submitted to the Agency using guideline test species indicate that the 96-hr LC_{50} of acrolein (96.4% a.i.) to bluegill sunfish (*Lepomis macrochirus)*, and rainbow trout (*Oncorhynchus mykiss)*, under flow-through exposures is 22.4 and <31 µg a.i./L, respectively (MRIDs 415132-01 and 415132-03). Thus, acrolein is classified as very highly toxic to freshwater fish on an acute exposure basis. The most sensitive endpoint used to assess the acute toxicity of acrolein to freshwater fish is the 96-hr LC_{50} for fathead minnow (*Pimephales promelas)* of 14 µg a.i./L (Geiger *et al*. 1990; Holcombe *et al*. 1987); for aquatic-phase amphibians, the most sensitive endpoint is the African clawed frog 96-h LC_{50} of 7 µg a.i./L.

The chronic toxicity of acrolein to fathead minnow (*Pimephales promelas)* and flag fish *(Jordanella floridae)* were assessed. The NOEC from an EPA fish lifecycle study on fathead minnow study was 11.4 µg a.i./L (MRID 05008271). Other toxicity data for fathead minnow indicate that the NOEC for growth and survival are 14 and 35 µg a.i./L, respectively. Additional data from chronic exposures of flag fish to acrolein indicate a NOEC for growth of 32 µg a.i./L. Thus, the most sensitive endpoints used to assess the chronic toxicity of acrolein to freshwater vertebrates (fish) was a NOEC value of 11.4. Refer to Table 19.

Table 19. Summary of acute and chronic toxicity data for freshwater fish exposed to acrolein.					
Species (common name)	**Measure of Effect**	**End-point**	**Duration (days)**	**Mean concentration (µg a.i./L)**	**Ref. (MRID)**
African Clawed Frog *Xenopus laevis*	Mortality	LC_{50}	4	7.0	Holcombe 1987*
Bluegill Sunfish *Lepomis macrochirus*	Mortality	LC_{50}	4	22.4	41513201
Fathead minnow *Pimephales promelas*	Mortality	LC_{50}	4	14	Geiger, 1990*
Fathead minnow	Growth and reproduction	NOEC	32	9.1	Sabourin 1986*
Fathead Minnow	Survival of newly hatched fry	NOEC	60	11.4	05008271
Fathead Minnow	Survival	NOEC	32	14	Spehar 1989*
Flagfish *Jordanella floridae*	Survival and Growth	NOEC	32	16	Spehar 1989*

*Data value identified in ECOTOX literature search.

Freshwater Invertebrates

An acute 48-hour toxicity study was conducted to determine the effects of acrolein on freshwater invertebrates. Data available for the waterflea (*Daphnia magna)* shows that the 48 hour EC_{50} values for immobilization are <31 and 57 µg a.i./L, based on two submitted studies. Additional values describing the acute toxicity of acrolein to freshwater invertebrates (e.g. midge) were identified in the ECOTOX literature search; however, these values were greater (*i.e.*, less sensitive) than those submitted to the Agency. Thus, the most sensitive endpoint used to assess the acute toxicity of acrolein to freshwater invertebrates was <31 µg a.i./L. Acrolein is classified as very highly toxic to freshwater invertebrates on an acute exposure basis.

In an EPA study (MRID 05008271), three generations of water flea were exposed to flow-through concentrations of acrolein for three weeks. A NOEC for survival of 7.1 µg a.i./L was determined after two generations with a NOEC of 16.9 µg a.i./L after the third generation. The draft aquatic life criteria from the Office of Water cited this study and used the higher NOEC determined after the third generation. For calculating RQs, the lower value was chosen consistent with more conservative assumptions used in a screening level risk assessment. Refer to Table 20 for a summary of this study.

Table 20. Summary of chronic toxicity data for freshwater invertebrates exposed to acrolein.					
Species (common name)	**Measure of Effect**	**End-point**	**Duration (days)**	**Mean concentration (µg a.i./L)**	**Ref. (MRID)**
Water Flea *Daphnia magna*	Survival	NOEC	3 Gener-ations	7.1	05008271

Estuarine/Marine Fish

Results of an EPA study on acrolein for longnose killifish (*Fundulus similis)*, and sheepshead minnow (*Cyprinodon variegates)* indicated that the 48-h LC_{50} value for longnose killifish was 240 µg a.i./L and the 96-h LC_{50} for sheepshead minnow was 428 µg a.i./L. The most sensitive endpoint used to assess the acute toxicity of acrolein to estuarine/marine fish is the 48-hr LC_{50} value for longnose killifish. Acrolein is classified as highly toxic to estuarine/marine fish on an acute exposure basis. Refer to Table 21 for referenced values.

Table 21. Summary of acute toxicity data for estuarine/marine fish exposed to acrolein.					
Species (common name)	**Measure of Effect**	**End-point**	**Duration (days)**	**Mean concentration (µg a.i./L)**	**Ref. (MRID)**
Longnose killifish *Fundulus similis*	Mortality	LC_{50}	48	240	40228401
Sheepshead minnow *Cyprinodon variegatus*	Mortality	LC_{50}	96	428	43225202

No data are available to estimate the chronic toxicity of acrolein to estuarine/marine fish. Thus, in the absence of data, risk is presumed for estuarine/marine fish.

Estuarine/Marine Invertebrates

A 96-hour acute toxicity study was conducted to determine the effect of acrolein on Eastern oyster (*Crassostrea virginica)*, brown shrimp (*Penaeus aztecus)*, and mysid shrimp (*Americamysis bahia)*. The reported 96-h EC_{50} values for Eastern oyster are 55 and 106 µg a.i./L. Data available for brown and mysid shrimp are 48-h EC_{50} of 100 µg a.i./L, and a 96-h LC_{50} of 500 µg a.i./L, respectively. The most sensitive endpoint used to assess the acute toxicity of acrolein to estuarine/marine invertebrates is 55 µg a.i./L. Acrolein is classified as very highly toxic to the estuarine/marine invertebrates on an acute exposure basis. Refer to Table 22 for referenced values.

Table 22. Summary of acute toxicity data for estuarine/marine invertebrates exposed to acrolein.					
Species (common name)	**Measure of Effect**	**End-point**	**Duration (days)**	**Mean concentration (µg a.i./L)**	**Ref. (MRID)**
Eastern oyster *Crassostrea virginica*	Shell Growth	EC_{50}	96	55	40228401
Brown Shrimp *Penaeus aztecus*	Immobility	EC_{50}	48	100	40228401
Eastern oyster *Crassostrea virginica*	Shell Deposition	EC_{50}	96	106 (73-183)	43164302
Mysid shrimp *Americamysis bahia*	Mortality	LC_{50}	96	500 (390-650)	43164301

No data are available to estimate the chronic toxicity of acrolein to estuarine/marine invertebrates. Thus, in the absence of data, risk is presumed for estuarine/marine invertebrates.

Aquatic Plants

In separate Tier 2 (non-vascular) acute toxicity tests, green algae (*Pseudokirchneriella subcapitatum*), blue-green algae (*Anabaena flos-aquae*), freshwater diatom (*Navicula pelliculosa*) and marine diatom (*Skeletonema costatum*) were exposed to acrolein for 5 days (MRIDs 426209-01, 426209-02, 426209-03 and 426209-05). The most sensitive species tested is the marine diatom, which has an EC_{50} for reduction of cell density of 28 µg a.i./L

Also, in a freshwater vascular plant toxicity test for duckweed the NOAEC is 25 µg a.i./L and the EC_{50} is 72 µg a.i./L (MRID 42620904). Median effect concentrations for vascular and non-vascular aquatic plants are 36 and 72 ug/L, respectively.

2) Fish, Invertebrate, and Aquatic Plant Exposure

Estimated Environmental Concentrations (EECs) for characterizing aquatic exposure were represented by the maximum application rate of acrolein (15 mg/L) as well as by available data from monitoring conducted in Washington State for the purpose of the National Pollution Discharge Elimination System (NPDES).

3) Fish, Invertebrate, and Aquatic Plant Risk

At currently registered maximum treatment rates (15 mg/L for up to 8 hours), non-target aquatic animals and plants in treated water ways will be exposed to acrolein and thus exposure will likely result in acute mortality of aquatic animals and plants following a single treatment. Monitoring data collected for NPDES permitting indicate that while many

application events result in non-detections, several detections in the receiving water bodies at the compliance points result in exceedances an order of magnitude above the Agency's LOC. One data point showed acrolein concentrations up to 67 ppb have been measured up to 61 miles from the point of application and up to 54 hours after application. These data were measured in Washington State which has a SLN allowing discharge to receiving waters 48 hours after treatment.

RQs in Table 23 were calculated based on the maximum application rate in the canal and the highest measured concentrations from the discharge point of an irrigation canal in Washington State following release after a two day holding period. For additional information and an extensive review of the monitoring data, please refer to the *Environmental Fate and Ecological Risk Assessment Chapter in Support of Phase V of the Reregistration Eligibility Decision on Acrolein*, dated July 23, 2008, which is available in the public docket.

Table 23. Acute RQs for aquatic animals and plants.

Species	Toxicity Endpoint (µg/L)	EEC (µg/L) Max app rate	RQ* From max app rate	EEC (µg/L) Monitored Concentration	RQ*[a] (from monitoring)
Fathead Minnow *Pimephales promelas*	14	15,000	1,071	67	5
African clawed frog *Xenopus laevis*	7	15,000	2,143	67	10
Water Flea *Daphnia magna*	<31	15,000	>484	67	>2
Sheepshead Minnow *Cyprinodon variegatus*	428	15,000	35	67	0.15
Eastern Oyster *Crassostrea virginica*	55	15,000	273	67	1.2
Blue-green Algae *Anabaena flos-aquae*	36	15,000	417	67	1.8
Duckweed *Lemna gibba*	72	15,000	208	67	0.9

* Risk Quotient = EEC/Toxicity
a Monitoring value from a Washington State NPDES permit Measurement at compliance point with release of canal water after 2-day holding consistent with the Washington State Special Local Needs label.

Freshwater Fish/Amphibians

At the maximum treatment rate of 15 mg/L, acrolein concentrations in the canals exceed acute risk LOCs (RQ≥0.5) with RQs of up to 1071 for freshwater fish and up to 2143 for aquatic-phase amphibians. Monitoring data collected for NPDES permitting indicate that while many application events result in non-detections, several detections in the receiving water bodies at the compliance points result in exceedances an order of magnitude above the Agency's LOC. Calculated RQs for fish and amphibians are up to 10 based on the highest concentration observed in the monitoring studies after the required holding times. Most of the NPDES monitoring values result in no risks of concern at the compliance points.

Freshwater Invertebrates

Although aquatic invertebrates are less sensitive than fish and aquatic-phase amphibians to acrolein, the acute risk level of concern (RQ≥0.5) for freshwater invertebrates in the canal is >484. As discussed above for the freshwater fish, the highest observed concentration in the monitoring data would also result in an RQ of 2 which is above the Agency's LOC. Most of the NPDES monitoring values result in no risks of concern at the compliance points.

Estuarine/Marine Fish

Using the sheepshead minnow as a surrogate, the acute risk RQ for estuarine fish in the canal is 35 which is above the LOC (RQ≥0.5) for estuarine/marine fish; however, the acute risk at the compliance point for the highest observed concentration in the monitoring data gives an RQ of 0.15 which does not exceed the LOC.

Estuarine/Marine Invertebrates

Based on the toxicity of acrolein to the Eastern oyster, in the canal, the acute RQ is 273 which exceeds the LOC (RQ≥0.5) for estuarine/marine invertebrates. The highest observed concentration in the monitoring data resulted in an RQ of 1.2 at the compliance point. Most of the NPDES monitoring values result in no risks of concern at the compliance points.

Aquatic Plants

Aquatic plants are particularly sensitive to acrolein. In the canal, the acute risk LOC for vascular and non-vascular aquatic plants (RQ≥1.0) is exceeded with RQs of 208 and 417, respectively. In addition, RQ values exceed the acute risk to endangered species LOC (RQ≥1.0) for vascular and nonvascular plants with RQs of 600 and 1,250, respectively. For the highest observed monitoring value, the RQs are 0.9 for vascular plants and 1.8 for non vascular plants and the corresponding endangered plant RQs are 2.7 and 5.4. Most of the NPDES monitoring values result in no risks of concern for listed or non-listed plants at the compliance points.

c.) Listed Species Risk

Table 24 provides a summary of potential direct and indirect effects to listed species in the irrigation canals. It is unlikely that listed species would be found in or around treated irrigation canals since the canals are designed to deliver water to agricultural fields. While as noted above, fish and invertebrate listed species are potentially at risk from the highest observed concentration in the monitoring data, calculations using most of the compliance monitoring data would not indicate risks of concern for listed species. Any inadvertent release of treated canal water may have an effect on listed species in the immediate area, but these risks are not assessed here.

Table 24. Potential listed species risks associated with direct or indirect effects due to treatment of irrigation canals with acrolein.			
Listed Taxon	**RQ**	**Direct Effects from Acute Exposures**	**Indirect Effects**
Aquatic			
Aquatic vascular plants	1,250	Yes	Yes[6]
Freshwater invertebrates	>484	Yes	Yes[4,5]
Marine/estuarine invertebrates	273	Yes	Yes[4,5]
Freshwater fish	1,071	Yes	Yes[4,5]
Marine/estuarine fish	35	Yes	Yes[4,5]
Aquatic phase amphibians	2,143	Yes	Yes[4,5]
Terrestrial			
Semi-aquatic plants	presumed[1]	presumed[1]	presumed[2]
Terrestrial plants	presumed[1]	presumed[1]	presumed[2]
Insects	presumed[1]	presumed[1]	presumed[2]
Birds	0.47	Yes	Yes[3,4]
Terrestrial phase amphibians	0.47	Yes	Yes[3]
Reptiles	0.47	Yes	Yes[3,4]
Mammals	0.26	Yes	Yes[3,4]

[1] No toxicity data are available to define RQ values for this exposure.
[2] Since the risks of direct effects to semi-aquatic and terrestrial plants are unknown, risks of indirect effects to organisms relying upon these plants are unknown.
[3]Direct effects to small mammals, amphibians, reptiles and birds could result in indirect effects to animals that rely upon them as food.
[4]Direct effects to aquatic animals could result in indirect effects to animals that rely upon them as food.
[5]Direct effects to aquatic plants (including unicellular and vascular) could result in indirect effects to animals that rely upon them as food.
[6]Direct effects to aquatic plants (including unicellular and vascular) could result in alterations in the plant community structure through changes in species interactions.

3. Risk Characterization

The Agency has considered the ecological risks associated with the use of acrolein. Based on the EPA's assessment and taking into account its use pattern, the use of acrolein according to label directions may potentially result in direct acute or chronic effects to fish, aquatic invertebrates and/or aquatic plants. Risk is expected for all aquatic organisms in the canals at all recommended application rates. Risks in the natural fish bearing waters which

receive canal outflow range from 0 up to an RQ of 10 for aquatic phase amphibians when label required holding times are observed. The NPDES permit monitoring data are not extensive, but most detected concentrations are low and do not violate the permit level of 21 ug/L And as indicated by reported incidents, inadvertent releases can result in mortality for large numbers of fish.

Risk is presumed for terrestrial plants and insects in the absence of data and the chemical's mode of action. Based on the most sensitive endpoint for each of the taxa evaluated, the RQ values for acute effects to listed and non-listed species exceed the LOC for acrolein. The potential for chronic risk of acrolein is uncertain and highly dependent on location and treatment regimen. Additionally, the acute toxicity of acrolein suggests that few biological receptors would survive the initial contact with the chemical; reducing the likelihood of chronic exposure to acrolein.

Although there is no acute risk LOC exceeded for non-listed birds, there is a potential for acute risk to listed birds consuming drinking water treated with acrolein at the maximum label rate. There is also a potential for acute risk to listed mammals consuming drinking water treated with acrolein at the maximum label rate. Based on upper-bound estimated environmental concentrations for acrolein in the air surrounding treated canals, there is a risk of acute mortality for both birds and mammals through inhaling acrolein fumes. Terrestrial mammals and birds foraging on vegetation, seeds and insects in agricultural fields where acrolein is applied as irrigation may also experience acute mortality depending on the size of the animal and the nature of the forage material.

Although the potential for chronic risk cannot be precluded for acrolein, there are no avian chronic toxicity data available with which to evaluate potential risk; this data gap contributes to uncertainty. While there are chronic toxicity data for mammals, the potential for chronic risk to mammals and/or birds is considered low since acrolein residues in treated water are expected to deter most animals from consuming the water. Additionally, field monitoring studies indicate that acrolein residues in treated fields dissipate with half-lives of less than 1 day; therefore, potential chronic exposure does not appear to be likely. While multiple applications may represent a potential source of repeated exposure, frequent repeat applications are conducted at much lower treatment concentrations than the maximum rate modeled in this assessment and as discussed previously would be more appropriately characterized as pulsed acute exposures. Therefore, the potential for chronic exposure is considered low and as such, potential chronic risk from the use of acrolein is considered low.

a) Endangered Species

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 and considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and

behavioral aspects of the particular species. When conducted, these analyses take into consideration any regulatory changes recommended in this RED being implemented at that time.

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by the pesticide. Rather, this assessment serves as a screen to determine the need for any species-specific assessment that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. The species-specific assessment refines the screening-level assessment to take into account information such as the geographic area of pesticide use in relation to the listed species and the habits and habitat requirements of the listed species. If the Agency's specific assessments for acrolein result in the need to modify use of the pesticide, any geographically specific changes to the pesticide's registration will be implemented through the process described in the Agency's *Federal Register* Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

4. Ecological Incidents

A review of the Ecological Incident Information System (EIIS) database identified a total of 14 incidents that have been reported to the Agency, which may have involved exposures of acrolein between 1971 and 2007. Of the 14 reported incidents, 1 involved terrestrial plants; 12 involved effects to fish, amphibians and/or aquatic invertebrates and 1 involved effects to aquatic birds. About half of all reported incidents occurred in California. It should be noted that many more incidents may have occurred due to acrolein exposures, but may not have been reported due to various factors, such as a lack of reporting, or a lack of witnessing effects. Therefore, the lack of an incident report may not accurately indicate an overall absence of incidents.

In nearly all reported incidents involving acrolein, hundreds to tens of thousands of fish were reportedly killed. Some of the incidents were classified as accidental misuse, while the majority was considered "probable" to "highly probable".

One incident occurred in 2004 to a private fish pond resulting in a fish kill involving Koi (*Cyprinus carpio*), listed by the South San Joaquin Irrigation District in their monitoring report. It was reported that the owner was not properly informed that the irrigation water for his pond was being treated with acrolein.

The most recent incident (2007) associated with the use of acrolein involved the loss of approximately 2400 game fish and 2800 non-game fish on a 1.5 mile stretch of the Cub River in Idaho. Various species of fish were killed as a result of the application of Magnacide® H to the Cub River Canal adjacent to the Cub River. A leaky gate was observed 2 miles above the fish kill; however, no dead fish were noted in the river above the beaver ponds which impounded the water. No residues were collected, nor were any other pollutants reported; investigators determined the incident was "unlikely" to be directly attributed to acrolein.

In 2008, one of the irrigation districts in Idaho noted that aquatic herbicides applied in a particular irrigation district had traveled from the irrigation canals through a shallow 'karst-

like' aquifer and resulted in fish kills at aquaculture facilities. For clarification purposes, it is noted that at least some of these Idaho incidents are believed to be due to xylene. This district no longer uses acrolein.

These reported incidents, as were previously mentioned, may not accurately reflect the actual number that may be associated with the use of acrolein as an herbicide. Current data indicate that roughly one third of the reported incidents resulted from the registered use of acrolein; however, the incidents involving the highest level of mortality resulted from misuses. To date, the largest loss of aquatic animals, *i.e.*, 338,600 animals killed in 1977, resulted from an inadequate holding time. However, given the toxicity of acrolein at maximum application rates, direct contact of any aquatic animal would likely prove lethal within a relatively short period of time. For a more detailed account of each reported incident, please refer to the *Environmental Fate and Ecological Risk Assessment Chapter in Support of Phase V of the Reregistration Eligibility Decision on Acrolein*, dated July 23, 2008, which is available in the public docket.

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after 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 acrolein 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 acrolein. The Agency has determined that acrolein is eligible for reregistration provided that the risk mitigation measures and label amendments specified in this RED are implemented.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for acrolein. EPA released its revised risk assessments on acrolein for public comment on April 2, 2008, for a 60-day public comment period (Phase 5 of the public participation process). During the public comment period on the risk assessments, which closed on June 2, 2008, the Agency received comments from the Washington Department of Ecology, Boise Project Board of Control, U.S. Department of the Interior (Bureau of Reclamation), commercial applicators, a registrant (SePRO Corporation), several irrigation districts and canal companies in the western U.S., as well as the technical registrant Baker Petrolite. These comments in their entirety, responses to the comments, as well as the preliminary and revised risk assessments, are available in the public docket for acrolein (EPA-HQ-OPP-2007-0588) in the EPA's electronic docket at http://www.regulations.gov.

Benefits Analysis

The following is a summary of the Agency's review of submissions containing use (application timing, pest spectrum, etc.) and economic information in response to comments received during the latest comment period referenced above. The use of acrolein as a herbicide in irrigation conveyance systems is considered by irrigation districts to be "vital" to their mission to efficiently provide irrigation water at a low cost and with a minimal loss of water (e.g. overflow). Based on the data provided in the comments, the cost of using acrolein is substantially less than other possible alternatives; such is the case with mechanical methods and biological controls. Although mechanical control does seem to be feasible in some situations, the expenses of using these methods are substantially more than acrolein, and are often debated whether or not they tend to expose workers to additional risks.

The alternatives to acrolein have other drawbacks, in addition to higher cost, that make their use less than ideal. Labor intensive, cumbersome equipment, lack of accessibility, damage to concrete lined and earthen canals, as well as problems with suspended plant debris and sediment in the water are some of the many drawbacks. While there are many aquatic herbicides on the market, a common restriction of these herbicides is that most are not labeled for use in irrigation water. Those that are labeled for irrigation water have required holding periods following application and prior to irrigation. Those herbicides that do not have a holding or containment time in the canal will need to provide a rapid kill through either a high use rate to maximize contact time with weeds, or will need to be able to work with a minimum of contact time.

It is the flow of the irrigation water that presents challenges for weed control. The primary need by water managers is an herbicide to control submerged aquatic vegetation as well as an algaecide. Although the Agency believes that irrigation districts and canal companies in the West would still be able to deliver irrigation water if alternative methods were imposed, it is clear that costs to users would be substantially higher, and it is possible that increased weed growth would adversely impact the delivery of needed irrigation water.

C. Risk Mitigation and Regulatory Position

The following is a summary of the rationale for managing risks associated with the use of acrolein. For the use in the petroleum industry, no changes to the label or use pattern are required for MAGNICIDE B based on the assumptions of completely closed delivery and use systems. For acrolein use as an herbicide, labeling revisions are required and specific language is set forth in the summary tables of Chapter V of this document.

1. Human Health Risk Management

There were several potential human health risks of concern identified for acrolein. Based on the current use pattern, acrolein exposure to occupational handlers can occur. This is due to the fact that the application of MAGNICIDE H can vary in time (depending on site) and respiratory protection is not required after initial set up and prior to break down of equipment. However, this period of time after initial setup and prior to break down of equipment can also potentially be a concern for post-application risk to workers remaining in the vicinity of the

treated canal that are not using respirators. However, if proper safety precautions are followed as outlined in the *Magnacide H Herbicide Application and Safety Manual*, for acrolein applicators, potential exposure can be limited.

In order to address risks to occupational handlers/workers, the following mitigation is required:

- Instead of requiring the registrant-provided applicator training a minimum of every three years, the training requirement will be annual.
- Upon request, the registrant must provide State Lead Agencies the names of all applicators who have received registrant-specific training.
- During application, two trained applicators must be on site at all times.
- All applications must be made during daylight hours.

In order to reduce exposures to bystanders, the following mitigation is required:

- Applicators must post "Do Not Enter" "DANGER" "Pesticide Application in Progress" signs at the site of application and around the application equipment.
- Certified applicators may only apply at sites where the irrigation district managers or owners have "No Swimming" signs posted.

Additionally, the following changes to the March 2005 version of the *Magnacide H Herbicide Application and Safety Manual* are required because these statements could be interpreted to mean that acrolein is less toxic than it is:

- On Page 5, paragraph 2 the following language must be **removed** from the Note to Physician: "Because of the extreme lacrymatory effect, the concentration tolerable by man is far below the minimum lethal concentration."
- On Page 24, in Appendix A, **remove** the table indicating "probable human response" to acrolein at various concentrations and times of exposure.
- On Page 24, in Appendix A, the paragraphs describing drinking water studies must be **removed**.
- The following language should be **added** to Appendix A:
    - Adverse health effects have been shown to occur in humans at concentrations as low as 0.09 ppm;
    - serious irreversible health effects may occur at concentrations as low as 0.4 ppm for 10 minutes;
    - OSHA does not allow workers to be exposed to concentrations over 0.3 ppm for longer than 15 minutes;
    - the 8-hour workplace standard is 0.1 ppm; and
    - the IDLH is 2.0 ppm

2. Ecological Risk Management

There were several ecological risks of concern identified for acrolein. Based on the current use pattern, acrolein exposure to wildlife can occur. It is required that application of acrolein directly to water be made only through close adherence to established standard operation procedures (SOPs) provided in the acrolein manual. This will limit the extent to which acrolein can move beyond targeted treated areas. In order to limit non-target effects, rigorous SOPs should be adhered to for the application of acrolein to agricultural fields.

- The registrant is required to include a module on reducing wildlife exposures in the annual training program and in the *Magnacide H Herbicide Application and Safety Manual*. This module should focus on risks to fish and aquatic organisms and should include information on the importance of limiting the contamination of natural fish bearing waters by release of acrolein treated canal water. The current label statement *"Water treated with Magnacide H herbicide must be used for the irrigation of fields, either crop-bearing, fallow or pasture, where the treated water remains on the field OR must be held for 6 days before being released into fish bearing waters or where it will drain into them."* should remain on the label and be included in the training and manual along with instructions and examples of how to contain the irrigation water while the acrolein is degrading.

Additionally, the following application restrictions are required to be added to all acrolein product labels:

- Maximum of eight (8) applications- annually.
- Minimum two (2) week re-treatment interval per application.

V. What Registrants Need to Do

The Agency has determined that products containing acrolein (PC Code: 000701) are eligible for reregistration provided that the risk mitigation measures identified in this document are adopted and label amendments are made to reflect these measures. Additional data are required to fill data gaps identified and to confirm this decision. The Agency intends to issue Data Call-In Notices (DCIs) requiring product-specific data and generic (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product specific data, the registrant will have 8 months to submit data and amend labels. For generic data, due dates can vary depending on the specific studies being required.

For acrolein technical grade active ingredient products, the registrant needs to submit the following items:

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

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

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

Within the time limit specified in the generic DCI:

1. Citations of any existing generic data that address data requirements or submit new generic data responding to the DCI.

Please contact Laura Parsons at (703) 305-5776 with questions regarding generic reregistration.

By U.S. Mail:
Document Processing Desk (DCI/SRRD)
Laura Parsons
U.S. EPA (7508P)
1200 Pennsylvania Ave., NW
Washington, DC 200460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Laura Parsons
Office of Pesticide Programs (7504P)
Room S-4900
One Potomac Yard
Arlington, VA 22202

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

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

(1) completed response forms to the generic DCI (i.e. DCI response form and requirements status and registrant's response form); and
(2) any time extension and/or waiver requests with a full written justification.

Within eight months from receipt of the PDCI:

(1) submit two copies of the confidential statement of formula, EPA form 8570-4;
(2) a completed original application for reregistration (EPA form 8570-1). Indicate on the form that it is an "application for reregistration";
(3) five copies of the draft label incorporating all label amendments outlined in Table 7 of this document;
(4) a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);
(5) if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and
(6) the product-specific data responding to the PDCI.

Within the time limit specified in the PDCI:

(1)Citations of any existing generic data that address data requirements or submit new generic data responding to the DCI.

Please contact Karen Jones at 703-308-8047 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

By U.S. Mail:
Document Processing Desk (DCI/SRRD)
Karen Jones
Office of Pesticide Programs (7508P)
1200 Pennsylvania Ave., NW
Washington, DC 200460

By Express or Courier Service:
Document Processing Desk (DCI/SRRD)
Karen Jones
Office of Pesticide Programs (7508P)
Room S-4900
One Potomac Yard
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of acrolein has been reviewed. The risk assessments identified the potential need for certain ecological, environmental fate, and residue chemistry data. The studies are as follows:

Ecological and Environmental Fate

- Photodegradation (Water); {GDLN 835.2240)
- Photodegradation (Soil); {GDLN 835.2410}
- Photodegradation (Air); {GDLN 835.2370}
- Aerobic Aquatic Metabolism; {GDLN 835.4300}
- Aerobic Soil Metabolism; {GDLN 835.4100}
- Anaerobic Aquatic Metabolism; {GDLN 835.4400}
- Anaerobic Soil Metabolism; {GDLN 835.4200}
- Leaching (Adsorption/Desorption); {GDLN 835.1240/ 835.1230}
- Seedling Emergence/Vegetative Vigor; {GDLN 850.4100/ 850.4150}

Residue Chemistry

- Registrants need to submit the data required for the acrolein TGAIs/MPs, and must either certify that the suppliers of beginning materials and the manufacturing processes for these TGAIs/MPs have not changed since the last comprehensive product chemistry review or submit complete updated product chemistry data packages.
- An enforcement analytical method must be developed and validated, including validation by an independent laboratory, for the determination of glycidol in fish and shellfish, if the registrant continues to support the SLN use in reservoirs and labels for these uses are not revised to provide effective fishing prohibitions (e.g., posting, restricted entry, etc.).
- If the registrant continues to support the SLN use in reservoirs and labels for these uses are not revised to provide effective fishing prohibitions (e.g., posting, restricted entry, etc.), magnitude of the residue of acrolein and glycidol in fish and shellfish are required. The submission of a protocol is preferable prior to beginning any study.
- A confirmatory nature of the residue study in root and tuber (preferably radish) is required.

2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. In order to be eligible for reregistration, the technical registrants also must amend all product labels to incorporate the risk mitigation measures outlined in Section IV.

The technical and MP labeling should also bear the labeling statements contained in Table 26, the Label Changes Summary Table.

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 a pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure 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 Registrations Response Form provided for each product.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 25, the Label Changes Summary Table.

C. Labeling Changes Summary Table

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

Table 25: Summary of Labeling Changes for Acrolein

Description	Amended Labeling Language	Placement on Label
End Use Products Intended for Occupational Use		
Restricted Use Requirement	"Restricted Use Pesticide due to a high acute toxicity. For retail sale to and use by certified applicators and only for those uses covered by the certified applicator's certification."	Top of the front panel
Manual	"THIS PRODUCT MUST BE ACCOMPANIED BY AN EPA-APPROVED PRODUCT LABEL AND THE EPA-APPROVED '*Magnacide H Herbicide Application and Safety Manual*.' THE *Magnacide H Herbicide Application and Safety Manual* IS LABELING. READ AND UNDERSTAND THE ENTIRE LABELING AND MANUAL PRIOR TO USE. ALL PARTS OF THE LABELING AND MANUAL ARE EQUALLY IMPORTANT FOR SAFE AND EFFECTIVE USE OF THIS PRODUCT."	Immediately below the RUP statement on the label and on the cover page of the Acrolein Manual.
PPE Requirements Established by the RED	"All certified applicators participating in the application during the setting up and breaking down of application equipment and during visual inspection must wear: • Long-sleeved shirt and long pants, • Shoes and socks, • Chemical-resistant gloves made of butyl rubber, and • a NIOSH-approved full-face respirator with either o organic-vapor-removing cartridges with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or o a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Table 25: Summary of Labeling Changes for Acrolein		
Description	**Amended Labeling Language**	**Placement on Label**
PPE Requirements Established by the RED For all Formulations	Respirator fit testing, medical qualification, and training: Employers must ensure that all acrolein handlers are: • Fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134) • Trained using a program that confirms to OSHA's requirements (see 29CFR Part 1910.134) Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined by a qualified medical practitioner if their health status or respirator style or use-conditions change.	PPE Requirements Established by the RED For all Formulations
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls
User Safety Requirements	"User Safety Requirements If acrolein is spilled or leaked on clothing, gloves, or shoes, immediately remove them and wash thoroughly with soap and water. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Table 25: Summary of Labeling Changes for Acrolein		
Description	**Amended Labeling Language**	**Placement on Label**
	instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing, gloves, shoes, and other absorbent materials that have come into contact with acrolein. Do not reuse them."	
Engineering Controls	"Engineering Controls "Handlers must use a closed system that is designed by the manufacturer to prevent dermal and inhalation exposures by removing the product from the container and applying the product below the water's surface. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that will limit drippage to no more than 2 ml per disconnect. The closed system must function properly and be used and maintained in accordance with the manufacturer's written operating instructions. Handlers must wear the personal protective equipment required on this labeling."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
Environmental Hazards	"The pesticide is extremely toxic to fish and wildlife.	Precautionary Statements immediately following the User Safety Recommendations
Application Restrictions: Certified Applicator Requirements	"At least two certified applicators must be at the application site and able to maintain visual contact with all certified applicators participating in the application." "No handlers are allowed to participate in the application unless they are state certified applicators and have completed the registrant's training program with in the last 12 months."	Directions for Use
Application Restrictions	Maximum number of applications: 8 application per year	Directions for Use

Table 25: Summary of Labeling Changes for Acrolein		
Description	**Amended Labeling Language**	**Placement on Label**
	Minimum retreatment interval: 2 weeks	
Application Restrictions: Posting of Application Equipment Area	"Posting of Application Equipment Area" "The Certified Applicator in charge of the application must post signs around the perimeter of the application equipment area (truck, hoses, and skids). Signs must be no more than 15 feet apart and contain the following information:" * Skull and crossbones symbol * "DANGER/PELIGRO" * "DO NOT ENTER/NO ENTRE: Pesticide Application/Aplicacíon de Pesticidas" * The name of the product applied * The start date and time of application * The end date and time of application. * The name, address, and telephone number of the Certified Applicator in charge of the application "Signs must remain legible during the entire posting period and must be removed once the application is completed and no later than 3 days after treatment."	Directions for Use under the heading "Posting of Application Equipment Area"
Other Application Restrictions	"Applications with [Magnacide H] may only be made in canals with posted no swimming signs. Contact the local irrigation district if the signs are not posted."	Directions for Use

ACROLEIN APPENDICES

Appendix A. Non-Food and Non-Feed Use Patterns Subject to the Reregistration of Acrolein

Product Type	Product Use Site	Max % A.I.	Max AR
Occupational Uses			
PRL	Non-food Crops-Irrigation Canals	95	15 ppm (15mg/L)
PRL	Non-food Crops-Deep Well Injection	95	0.25 lb a.i./1000 sq. ft

FORMULATION CODES
PRL: Pressurized Liquid

Appendix B. Data Supporting Guideline Requirements for Acrolein

Data Supporting Guideline Requirements for the Reregistration of Acrolein		
Guideline Number	**Study Description**	**Citation(s)**
PRODUCT CHEMISTRY		
830.1550	Product Identity and Composition	CSF (1-23-04)
830.1600	Description of Materials Used	CSF (1-23-04)
830.1700	Preliminary Analysis	41896901, 46181201
830.1750	Certified Limits	41896901, CSF (1-23-04)
830.1800	Enforcement Analytical Method	41896901, 46181201
830.6302	Color	40840601
830.6303	Physical State	40840601
830.6304	Odor	40840601
830.6313	Stability	40840601
830.7000	pH	40840601
830.7200	Melting Point	N/A
830.7220	Boiling Point	40840601
830.7300	Density	40840601
830.7370	Dissociation Constant	N/A
830.7550 830.7570	Octanol / Water Partition Coefficient	40840604
830.7840 830.7860	Solubility	40840601
830.7950	Vapor Pressure	40840603
ECOLOGICAL EFFECTS		
850.1010	Aquatic Invertebrate Acute	40228401, 41513202, 05008271
850.1025	Oyster Acute Toxicity Test	40228401
850.1035	Mysid Acute Toxicity Test	43164301
850.1045	Penaeid Acute Toxicity Test	40228401
850.1075	Fish Acute Toxicity – freshwater	41513201, 41513203, 45205107
	Fish Acute tox estuarine/marine	40228401, 43225202
850.2100	Avian Acute Oral Toxicity (Duck)	42183301,
850.2400	Mammal Toxicity (Rat)	41257001, 41869101
850.4100	Seedling Emergence and Growth	Data gap
850.4150	Vegetative Vigor	Data gap
850.4400	Aquatic Plant Growth	42620904
850.4500	Algal Plant Toxicity	42620901, 42620905, 4260902
TOXICOLOGY		
870.1100	Acute Oral Toxicity	41257001
870.1200	Acute Dermal Toxicity	00141028
870.1300	Acute Inhalation Toxicity	40945404
870.2400	Acute Eye Irritation	00141025
870.2500	Acute Dermal Irritation	00141026
870.3200	21/28 -Day Dermal Toxicity-Rabbit	00141030
870.3700	Prenatal Developmental Toxicity—Rabbit	40392401

	Prenatal Developmental Toxicity--Rat	00156438
870.3800	Reproduction and Fertility Effects, 2-Generation Reproduction	41869101
870.4100	Chronic Oral Toxicity--Dogs	41071701
	Chronic/Carcinogenicity Feeding--Rats	41306401, 46568001, 46568002
870.4200	Carcinogenicity	41334901
870.5300	In vitro Mammalian Cell Gene Mutation Assay	41579501
870.5375	In vitro mammalian chromosomal aberration assay- CHO	00141033
870.5900	In vitro sister chromatid exchange	00141032
870.7485	Metabolism and Pharmacokinetics	42031001, 43177101, 43275901
RESIDUE CHEMISTRY		
860.1300	Nature of residue in plants (lettuce)	43607101, 42295101
860.1300	Nature of residue in plants (root	Data gap
860.1300	Nature of residue in animals	43942101, 43938701
860.1300	Nature of residue in fish	43225201
860.1400	Potable water monitoring	41855401
ENVIRONMENTAL FATE		
835.1230	Leaching and Adsorption / Desorption	Data gap
835.2120	Hydrolysis	40945401
835.2240	Photodegradation in Water	Data gap
835.2410	Photodegradation in Soil	Data gap
835.2370	Photodegradation in Air	Data gap
835.4100	Aerobic Soil Metabolism	Data gap
835.4200	Anaerobic Soil Metabolism	Data gap
835.4300	Aerobic Aquatic Metabolism	Data gap
835.4400	Anaerobic Aquatic Metabolism	Data gap

Appendix C. Technical Support Documents

Additional documentation in support of the acrolein RED is maintained in the OPP Regulatory Public Docket, located in Room S-4400 One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 a.m. to 4:00 p.m. All documents may be viewed in the OPP Docket room or viewed and/or downloaded via the Internet at http://www.regulations.gov. The Agency's documents in support of this RED include the following:

1.) Daiss, B. Acrolein HED Risk Assessment for Reregistration Eligibility Decision (RED) Document. March 25, 2008.

2.) Garber, K., Jones, R.D., and Steeger, T. Environmental Fate and Ecological Risk Assessment for the Reregistration of Acrolein, 2nd Revision. July 18, 2008

3) Morton, T., Revised Dietary Risk and Exposure Estimate For Acrolein Through Subsistence Diets for Indigenous People of United States. March 25, 2008

4) Phillips, W., Berwald, D., Acrolein Alternatives Assessment Summary and Uncertainties. March 26, 3008

5) Daiss, B., Acrolein: Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision. March 25, 2008

6) Morton, T., Acrolein: Revised Product and Residue Chemistry Considerations. September 27, 2007

7) Jones., R.D., Assessment of Drinking Water Exposure and Acrolein Concentrations to which Fish May be Exposed, 2nd Revision. May 23, 2007

Appendix D. Bibliography

In addition to the studies listed in Appendix B, this bibliography contains additional citations considered to be part of the database supporting the reregistration decision for acrolein.

In addition to the MRID study references listed in Appendix B, this bibliography contains the expanded study citations as well as additional literature considered to be part of the database supporting the reregistration decision for acrolein.

MRID	Citation
Human Health References	
00141025	Dunn, G.R. and J. Goodband (1981) Summary report: Primary eye irritation study for Acrolein in rabbits. Bioassay Systems Corporation, Woburn, MA. BSC Project No.: 10258, July 20, 1981. . Unpublished. 7 pages
00141026	Dunn, G.R. and J. Goodband (1981) Summary report: Primary dermal irritation study for Acrolein in rabbits. Bioassay Systems Corporation, Woburn, MA. BSC Project No.: 10258, March 21, 1981. Unpublished. 5 pages.
00141028	Muni, I.A.(1981) Acute dermal toxicity (LD_{50}) of Acrolein (Lot No. SFSL-5993) in rabbits. Bioassay Systems Corporation, Woburn, MA. BSC Project No.: 10258, September 17, 1981. Unpublished.
00141030	Muni, I.A. (1982) 21-Day dermal test of Acrolein in rabbits. Bioassay Systems Corporation, Woburn, MA. Project No.: 10258, July 28, 1982. Unpublished. 109 pages.
00141032	Loveday, K.S. (1982) Effects of Acrolein on the *in vitro* induction of sister chromatid exchanges in Chinese hamster ovary cells. Bioassay Systems Corporation, Woburn, MA. BSC Project No.: 10258, May 11, 1982. Unpublished
00141033	Gorodecki, J. and G.M. Seixas (1982) Effects of Acrolein on the *in vitro* induction of chromosomal aberrations in Chinese hamster ovary cells. Bioassay Systems Corporation, Woburn, MA. BSC Project No.: 10258, July 23, 1982. Unpublished.
00156438	King, M. (1982) Teratology study of acrolein in rats. Bioassay Systems Corporation, Woburn, MA. Laboratory Project No.: 10258, November 12, 1982. Unpublished. 82 pages.
40392401 .	Hoberman, A.M. (1987) Developmental toxicity (embryo/fetal toxicity and teratogenic potential) study of acrolein administered orally (stomach tube) to New Zealand White rabbits. Argus Research Laboratories, Inc., Horsham, PA. Laboratory Project Id.: 603-001, May 20, 1987. Unpublished
40840601	Caravello, H. (1988) Physical Properties of Acrolein: A Summary: Study No. RD 0070.188. Unpublished study prepared by Baker Performance Chemicals, Inc. 41 p.
40840603	Robillard, K. (1988) Vapor Pressure of Acrolein: Laboratory Project ID: HAEL No.: 88-0300: Study No. EN-030-UKA001-1. Unpublished compilation prepared by Health and Environment Laboratories. 31 p.
40840604	Matherly, R.; Hackerott, J.; Nguyen, N. (1987) Octanol/Water Parti- tion Coefficient of Acrolein: Study No. RD0008.287. Unpublished study prepared by Baker

	Performance Chemicals. 24 p.
40945404	Nachreiner, D.J. and D.E. Dodd. (1987) Acute inhalation toxicity of Acrolein vapor by one and four hour exposures. Union Carbide Corp., Bushy Run Research Center, Export, PA. Laboratory Report No.: 49-170, February 2, 1987. MRID 40945404. Unpublished. 45 pages.
41071701	Long, J.E. (1987) Acrolein - chronic (12 month) oral toxicity study in the dog. Tegeris Laboratories, Inc., Laurel, MD. Laboratory Project ID.: TL 85016, October 23, 1987. Unpublished. 1047 pages.
41068801	Long, J.E. (1986) Acrolein - range finding oral toxicity study in the dog. Tegeris Laboratories, Inc., Laurel, MD. Laboratory Project ID.: TL 86003, August 7, 1986. Unpublished. 54 pages.
41257001	David, R.M. (1989) Acute oral toxicity study of Acrolein, inhibited in rats. Microbiological Associates Inc., Bethesda, MD. Laboratory Study No.: G-7230.220, September 19, 1989. Unpublished. 87 pages.
41306401	Long, J.E. and J.A. Johnson (1989) 24-month chronic toxicity and oncogenicity study in the rat with acrolein. Tegeris Laboratories, Inc., Temple Hills, MD. Laboratory Project Id.: TL 85047, September 6, 1989. Unpublished. 3701 pages.
41334901	Long, J.; Johnson, J. (1989) 18-Month Oncogenicity Study in the Mouse with Acrolein: Lab Project Number: TL/86057. Unpublished study prepared by Tegeris Laboratories, Inc. 2267 p.
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