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Reregistration Eligibility Decision for Endothall

Reregistration Eligibility Decision (RED) Document for Endothall

List B

Case Number 2245

Approved by: _____ Date: _____

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formulation
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
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
GLN	Guideline Number
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of a substance per weight or volume of water, air, or feed, e.g., mg/l, mg/kg, or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligram Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification Number. EPA's system for recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides, and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million

PRZM/EXAMS	Tier II Surface Water Computer Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
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

Abstract

This document presents the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) decision regarding the reregistration eligibility of the registered uses of endothall. The Agency has determined that endothall is eligible for reregistration. Endothall is used as an aquatic herbicide, a desiccant, and a biocide. Endothall is applied as either the dipotassium salt or the N, N-dimethylalkylamine salt. There are currently seven tolerances established for endothall. The Agency has conducted human health and environmental fate and ecological effect risk assessments for endothall and reassessed all the existing tolerances. The risk conclusions of these assessments are summarized below.

In the human health risk assessment, chronic dietary risks (food and drinking water) do not exceed the Agency's level of concern, although drinking water risk for infants less than one year old is at the level of concern. However, the Agency believes that this risk estimate is the result of conservative assumptions and is discussed in detail in section III.5 of this document. Aggregate risks (food, drinking water, and residential exposure) also do not exceed the Agency's level of concern. To ensure that endothall exposures from drinking water do not result in risks of concern, the Agency is requiring that direct applications to water not be applied less than 600 feet from an active drinking water intake.

For terrestrial uses of endothall, all risks calculated for short-term and intermediate-term occupational exposures are below the Agency's level of concern with the exception of mixing and loading liquids for aerial applications. The Agency is requiring that workers mixing and loading liquids for aerial applications wear an 80% (PF5) respirator (NIOSH TC-21C). All risks for short-term and intermediate-term exposures from mixing, loading, and applying liquid formulations to aquatic use sites are below the Agency's level of concern when workers wear an 80% (PF5) respirator (NIOSH TC-21C). All risks for short-term exposures from loading and applying granular formulations for aquatic applications are below the Agency's level of concern when workers wear baseline protective equipment. For intermediate-term exposures from loading and applying granular formulations for aquatic applications, risks are of concern to the Agency. To protect workers in this scenario, workers are required to wear a 90% respirator (PF10 elastomeric half-face respirator with the appropriate cartridge, NIOSH TC-23C or NIOSH TC-14G). All occupational risks from use of endothall as a biocide in cooling towers are below the Agency's level of concern.

Technical endothall is classified as a severe dermal irritant. However, this regulatory decision does not include specific mitigation to address these dermal effects. Appropriate worker protections and label language will be established based on end-use product acute toxicity during product reregistration. Product reregistration follows active ingredient reregistration. A 48-hour re-entry interval is currently on labels for terrestrial uses and will be retained. In addition, a double notification statement to further protect workers will be added to endothall labels intended for terrestrial use.

Ecological risks were identified as a result of endothall use in terrestrial and aquatic settings. To potentially reduce risks to non-target plants and organisms, the Agency is requiring that endothall labels differentiate application rates for small and large applications of endothall dipotassium salt. Labels will specify that higher rates are only to be used for small, spot treatments, and lower rates are to be used for larger treatments. In addition, the use of N, N-dimethylalkylamine salt in lakes, streams, and ponds will be limited to algae, Hygrophila, Vallisneria, Hydrilla, Cabomba, bur-weed, *Elodea canadensis,* and Brazilian elodea.

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 Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data to the U.S. Environmental Protection Agency (EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of 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.

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

As mentioned above, FQPA requires EPA to consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposure to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://epa.gov/pesticides/cumulative/.

The Agency has found no information indicating endothall shares a common mechanism of toxicity with other substances. Endothall does not appear to

produce a toxic metabolite produced by other substances. Therefore, for the purposes of tolerance reassessment and a decision on reregistration eligibility, EPA has not assumed that endothall shares a common mechanism of toxicity with other compounds. In the future, if additional information suggests endothall shares a common mechanism of toxicity with other compounds, additional testing may be required and a cumulative assessment may be necessary.

This document presents EPA's revised human health and ecological risk assessments, its progress toward tolerance reassessment, and the reregistration eligibility decision for endothall. The document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and ecological risk assessments based on data, public comments, and other information received in response to the preliminary risk assessments. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list related information and supporting documents. The preliminary and revised risk assessments for endothall are available in the Public Docket, under docket number OPP-2004-0370 and on the Agency's web page, http://www/epa.gov/edockets.

II. Chemical Overview

Endothall is in the dicarboxylic acid class of chemicals. Endothall is applied as either a dipotassium salt or an N, N-dimethylalkylamine salt. Endothall acid is not directly applied to use sites; it is formed as a breakdown product resulting from application of the salt forms. The amine salt is the only form applied terrestrially, while both the dipotassium and amine salt are applied to aquatic use sites. The amine salt is also used to control algae and invasive mollusks in cooling towers. The majority of endothall is used in aquatic environments.

Endothall acid is a selective contact herbicide. Endothall acid works by interfering with plant respiration, by affecting protein and lipid biosynthesis, and by disrupting plant cell membranes.

A. Endothall and Salts Nomenclature

Endothall, acid	
Molecular Formula	$C_8H_{10}O_5$
CAS Name	7-oxabicyclo[2.2.1]heptane-2,3-dicarboxylic acid
CAS Number	145-73-3
PC Code	038901
Endothall, dipotassium salt	
Molecular Formula	$C_8H_8K_2O_5$
CAS Name	N/A
CAS Number	2164-07-0
PC Code	038904
Endothall, mono-N,N-dimethylalkylamine salt	
Molecular Formula	$C_{10}H_{17}NO_5$
CAS Name	N/A
CAS Number	66330-88-9
PC Code	038905

B. Use Sites

- Endothall is used as an aquatic herbicide to control submerged aquatic vegetation and algae in lakes, ponds, and irrigation canals.

- Endothall is also used as a desiccant on potatoes, hops, cotton, clover, and alfalfa. Tolerances are established for sugar beets and rice straw, although current labels do not allow applications to these crops.

- Endothall has one biocide use to control mollusks and algae in cooling towers/systems.

C. Formulations

- Formulated as either a granular or a soluble concentrate (liquid).

D. Methods of application

- For aquatic applications, endothall dipotassium salt and endothall N, N-dimethylalkylamine salt can be applied as a granular or a liquid. Granular applications are made using centrifugal or blower-type spreaders that are mounted to boats. Granular formulations can also be applied to aquatic sites by spreader equipment attached to helicopters. Liquid applications are made using low pressure hand wand sprayers, hand-gun sprayers, or

direct metering systems. Aerial application of liquids to aquatic sites is prohibited.

- For terrestrial applications, endothall is applied as a liquid. Terrestrial liquid applications can be made with either ground or aerial equipment. Only endothall N, N-dimethylalkylamine salt is used on terrestrial sites.

E. Use rates

- Maximum single application rates are 5 ppm for aquatic applications and 2 lbs acid equivalents/Acre for terrestrial applications. Application rates of both the salt forms of endothall are expressed as acid equivalents (ae) to equalize the application rates in terms of the acid.

F. Annual usage

- In terms of pounds used, endothall is most readily used as an aquatic herbicide. For terrestrial endothall uses, the majority of use is on potatoes (approximately 5% crop treated) and cotton (less than 2.5% crop treated). Of the two forms of endothall, the N, N-dimethylalkylamine salt accounts for the most use.

G. Tolerances in Use Profile

- There are currently five tolerances for endothall and its salts listed in CFR § 180.293(a)(1) on cotton seed (0.1 ppm), hops (0.1 ppm), potato (0.1 ppm), rice grain (0.05 ppm), and rice straw (0.05 ppm). One tolerance is listed in CFR § 180.319 for sugar beets (0.2 ppm).

- A tolerance is currently listed for potable water (0.2 ppm, CFR § 180.293(a)(2). The Agency is proposing that this tolerance be revoked. Currently, EPA's Office of Water has an MCL established for endothall.

- The Agency is proposing tolerances for cotton gin byproducts, animal commodities, processed commodities, and irrigated crops. When acceptable data are received these tolerances will be established.

- The registrant has proposed tolerances for fish and shellfish. This action is not incorporated into this document and will be addressed in a separate action. However, a fresh water finfish residue level of 0.1 ppm was included in the dietary exposure assessment. Current food consumption models cannot include residues in freshwater shellfish adequately; so freshwater shellfish were not incorporated into the current assessment, and were considered as a negligible source of residues.

H. Technical Registrant

- Cerexagri, Inc.

III. Summary of Risk Assessment

A. Human Health Risk Assessment

1. Hazard Profile

(For a complete discussion, see section 4 of Endothall: HED Chapter of the Reregistration Eligibility Decision Document, Corrected Following Public Comments, dated September 30, 2005.)

The toxicological database for endothall is considered complete. Endothall is Toxicity Category I by the oral, and ocular routes, and is a skin sensitizer. For dermal and inhalation toxicity, endothall is categorized as mildly toxic.

For dermal exposure, a toxicity endpoint was not identified, and a dermal risk assessment was not conducted since endothall is so toxic at the portals of entry and is therefore self-limiting. In the 21-day dermal toxicity study, in addition to weight loss, severe local effects were observed at the lowest dose tested, 30 mg/kg/day. Total body weight gain was also inhibited. The study indicated that systemic and local effects were co-occurant. Therefore, the Agency has determined that endothall will be classified as a severe dermal irritant. Label requirements addressing dermal effects through double notification will be placed on technical and end-use products. End-use products generally contain a lower percentage of active ingredient and it is appropriate to consider additional label requirements relating to endothall's dermal effects during product reregistration.

Endothall is not a neurotoxicant, nor does it induce developmental toxicity. Endothall is classified as "not likely to be carcinogenic to humans" and has no mutagenic potential. Endothall does not bioaccumulate.

Table 1. Acute Toxicity Data for Endothall

Guideline Number Study Type	MRID Number	Toxicity Category
870.1100 Acute Oral Toxicity	42289201	I
870.1200 Acute Dermal Toxicity	42289202	III
870.1300 Acute Inhalation Toxicity	42169501	II
870.2400 Acute Eye Irritation	42289203	I
870.2500 Acute Dermal Irritation	42289204 (unacceptable)	I_a
870.2600 Skin Sensitization	41871901	Yes

a. Endothall has been shown to be a skin irritant in a preliminary range finding study for the dermal absorption study (42169503) and the 21-day dermal toxicity study (43465201). This information is considered sufficient to classify endothall as a severe dermal irritant.

Although endpoints for all exposure scenarios were selected from the same study, it is important to note that for each scenario, different toxicity endpoints are appropriate. The two short-term exposure scenarios (1-30 days, incidental oral and short-term inhalation) use a separate endpoint (NOAEL of 9.4 mg/kg/day) based on decreases in body weight in offspring of endothall-treated parents. The remaining, longer-term scenarios use a more conservative value (LOAEL of 2 mg/kg; divided by 3 to extrapolate to an estimated NOAEL of 0.7 mg/kg) to accommodate the longer exposure scenarios. Because an inhalation study is not currently available (a 28-day inhalation study is being required), the inhalation exposure scenario uses an oral study assuming 100% absorption.

Table 2. Summary of Toxicological Doses and Endpoints for Endothall Used in the Human Health Risk Assessment

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (All Populations)	An appropriate endpoint attributable to a single dose was not available from any study, including the prenatal developmental toxicity study in rats. An acute RfD was not established.		
Chronic Dietary (All Populations)	LOAEL = 2[2] mg/kg/day UF = 300 (10X for intraspecies variations, 10X for interspecies differences, and 3X for extrapolation from LOAEL to NOAEL) Chronic RfD = 0.007 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD / FQPA SF = 0.007 mg/kg/day	2-generation reproduction study in rats LOAEL of 2 mg/kg/day based on proliferative lesions of the gastric epithelium in both sexes. (MRID 43152101)
Short-term Incidental Oral (1-30 days)	NOAEL=9.4[1] mg/kg/day UF = 100 (10X for intraspecies variations, 10X for interspecies differences)	Residential MOE = 100	2-generation reproduction study in rats LOAEL of 60 mg/kg/day based on decreased pup body weight in both sexes on Day 0 of second and third generations. (MRID 43152101)
Intermediate-term Incidental Oral (1-6 months)	LOAEL= 2 [2] mg/kg/day UF = 300 (10X for intraspecies variations, 10X for interspecies differences, and 3X for extrapolation from LOAEL to NOAEL)	Residential MOE = 300	2-generation reproduction study in rats LOAEL of 2 mg/kg/day based on proliferative lesions of the gastric epithelium in both sexes. (MRID 43152101)

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-term Inhalation (1-30 days)	NOAEL=9.4[1] mg/kg/day UF= 100 (10X for intraspecies variations, 10X for interspecies differences) (inhalation absorption rate is assumed to be 100% of oral dose; default assumption)	Residential MOE = 100 Occupational MOE = 100	2-generation reproduction study in rats LOAEL of 60 mg/kg/day based on decreased pup body weight (both sexes) on Day 0 in both F1 and F2 generations. (MRID 43152101)
Intermediate-Term Inhalation (1-6 months) and Long-Term Inhalation	LOAEL = 2 [2] mg/kg/day UF = 300 (10X for intraspecies variations, 10X for interspecies differences, and 3X for extrapolation from LOAEL to NOAEL)	Residential MOE = 300 Occupational MOE = 300	2-generation reproduction study in rats LOAEL of 2 mg/kg/day based on proliferative lesions of the gastric epithelium in both sexes. (MRID 43152101)
Cancer (oral, dermal, inhalation)	Classified as "not likely to be carcinogenic to humans" (MRID 41040301, 40685301, 43608301)		

UF= uncertainty factor, FQPA SF = Special FQPA safety factor, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (c = chronic), RfD = reference dose, MOE = margin of exposure
1. The NOAEL of 9.4 mg/kg/day is derived from the offspring LOAEL of 60 mg/kg/day for the endpoint referenced in the table.
2. The LOAEL of 2 mg/kg/day is derived from the parental LOAEL of 2 mg/kg/day for the endpoint referenced in the table.

2. Dietary Risk (Food)

(For a complete discussion, see Section 6.0 of Endothall: HED Chapter of the Reregistration Eligibility Decision Document, Corrected Following Public Comments, dated September 30, 2005.)

The dietary risk assessment incorporates both exposure to and toxicity of a given pesticide. The risk is expressed as a percentage of a maximum acceptable dose (i.e., the maximum dose which will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the Reference Dose (RfD) divided by the special FQPA Safety Factor. EPA is concerned when estimated dietary risk exceeds 100% of the PAD. The endothall dietary risk assessment was performed using the Dietary Exposure Evaluation Model (DEEM™). Table 2 above lists the endpoints used in the dietary risk assessment.

The Special FQPA Safety Factor was reduced to 1X because there are no residual exposure uncertainties, no sensitivity to infants and children, and the toxicity database is essentially complete. The uncertainty factor (UF) for chronic dietary exposure to endothall was determined to be 300. This takes into consideration a factor of 10X for interspecies variation, 10X for intraspecies variation, and 3X for the lack of a NOAEL in the study used for endpoint selection. When evaluating the toxicological database for endothall, the primary effects are seen at the point of entry (i.e., oral) and the weight of evidence suggests that endothall will be of no developmental concern. This evidence includes the results of a developmental toxicity study with rats, where endothall did not induce developmental toxicity at any of the doses tested. Effects that were observed in developmental toxicity studies (decreased pup weight gain) are not considered to be developmental toxicity effects. Therefore, no additional uncertainty factors were added for the lack of a rabbit developmental toxicity study. However, a rabbit developmental toxicity study is being required as confirmatory data.

Endothall metabolism results in either the formation of the monomethyl ester or complete decomposition into natural constituents of plant and animal tissues. The residues of concern in plants and animals are endothall and its monomethyl ester.

a. Acute Dietary Risk (Food)

No endpoint was identified for acute dietary exposures because the acute toxicity database is complete and does not suggest there is a potential acute risk concern. Normally, an acute hazard value is chosen from acute (non-lethal), subchronic, or developmental toxicity studies from which there is reasonable evidence that a single exposure can lead to a potential effect. Endothall is known to cause primarily local effects depending on the route of exposure. In the developmental rat study, there was evidence of a decrease in body weight gain in pregnant rats after a single exposure of endothall. However, this effect was coupled with a decrease in food consumption and the treated rats recovered by the end of gestation. At all time points, there was no difference in treated versus control body weights. Therefore, the available data suggests that a single exposure to endothall does not result in an effect of concern for risk assessment purposes. The Agency does not expect acute risks resulting from dietary exposure.

b. Chronic Dietary Risk (Food)

The chronic dietary risk endpoint for all populations was selected from the two-generation reproduction toxicity study using rats as the test subject. The endpoint of concern was proliferate lesions of the gastric epithelium, which was observed in both sexes. The Lowest Observed Adverse Effect Level (LOAEL) is 2 mg/kg/day in males and 2.3 mg/kg/day in females.

For the chronic dietary exposure assessment, an estimate of the residue level in each food or food-form on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food-form. The resulting residue consumption

estimate is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and risk is expressed as a percent of the chronic PAD (cPAD).

Food items may be exposed to residues of endothall in two ways: via direct application, or via irrigation water previously treated with endothall. To assess residues on food from the two uses, two assessments were performed. One assessment took into consideration only exposure to crops that are directly treated with endothall. The second assessment incorporated exposure to crops directly treated with endothall and crops that were irrigated with endothall-treated water. To assess exposures from both of these scenarios, a DEEM™ analysis was performed.

The results of the DEEM™ analysis using exposure from only directly treated crops was 1.2% of the cPAD for the general population. The most highly exposed population subgroup was children 3-5 years old with an exposure estimate of 3.0% of the cPAD. These results are based on tolerance level residues and 100% crop treated and are considered to be conservative estimates of chronic dietary risk.

When calculating residues on crops irrigated with endothall-treated water, an assumption that all crops are irrigated with water containing endothall was initially used directly in the DEEM™ program. This assumption led to an overestimate of exposure from irrigated crops. Using the amount of endothall produced per year, and information from the U.S. Geological Survey concerning irrigation practices, the Agency was able to refine exposure estimates. To conservatively address errors in this estimation and to assure that regional and crop differences in irrigation, and differences in consumption of crops are taken into consideration, a percent of the crops irrigated with treated irrigation water was conservatively estimated to be 1%. The actual increase in exposure to endothall through irrigation should be less than 1% of that originally estimated by DEEM™. Therefore, the results from the DEEM™ analysis for the portion of exposure due to irrigated crops were multiplied by a factor of 0.01. The results of the DEEM™ exposure analysis for exposure from directly treated crops and irrigated crops was 2.7% of the cPAD for the general population, and 7.8% cPAD for children 1-2 years old. Therefore, chronic dietary risks (food) are below the Agency's level of concern.

For a complete discussion of exposure to endothall from consumption of irrigated crops, please see "Endothall and its salts: Addendum to Chronic Dietary Exposure Assessment for the Reregistration Eligibility Decision", dated September 29, 2005.

Table 3. Summary of Chronic Dietary Exposure and Risk from Endothall (Directly Treated Crops and Crops Irrigated with 5 ppm Endothall)

Population Subgroup	Dietary Exposure mg/kg/day	% cPAD
General U.S. Population	0.000189	2.7
Children 1-2 years old	0.000544	7.8

3. Cancer Dietary Risk (Food)

The Agency has classified endothall as "not likely to be carcinogenic to humans" based on the lack of evidence of carcinogenicity in mice or rats.

4. Drinking Water Dietary Risk

(For a complete discussion, see Section 6.2 of the Endothall: HED Chapter of the Reregistration Eligibility Decision Document, Corrected Following Public Comments, dated September 30, 2005.)

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. For endothall, only non-cancer chronic dietary exposure from drinking water was assessed. As previously stated, an endpoint for acute dietary exposure was not identified and acute dietary risks are not of concern to the Agency. For endothall, drinking water exposure takes into consideration potential exposure from terrestrial, aquatic, and industrial (biocide) uses. Also, endothall is considered "not likely to be carcinogenic in humans".

a. Aquatic Uses

Direct applications to water were modeled assuming uniform application over an entire reservoir at the maximum labeled rate. Based on these assumptions, the peak (acute) concentration of endothall in surface water was estimated to be 5000 µg/L, and the annual mean (chronic) concentration was estimated to be 545 µg/L. EPA believes it is highly unlikely that concentrations of endothall would reach these levels in areas where surface water is directly used for drinking water for several reasons:

- The assumption that 100% of a water body is treated with endothall at the maximum label rate is conservative and highly unlikely. Typically, endothall is applied as a peripheral treatment around boat docks and piers, so that only a small percentage of a water body is treated.

- Endothall treatments are made to the upper 3 to 5 feet of the water body, whereas drinking water intakes are typically located at the deepest point in municipal reservoirs where endothall concentrations would be expected to be lower.

- Monitoring data for endothall suggest the average concentrations of endothall in drinking water are well below the modeled estimates. Monitoring data for finished water are available from the National Contaminant Occurrence Database (NCOD) for both surface and ground water. Detectable residues of endothall were found in only 7 of 27,494 or 0.025% of ground water samples and 8 of 5,112 or 0.15% of surface water samples.

  The maximum detected concentrations in ground and surface water were 4,550 ppb and 2,900 ppb, respectively; and the mean concentration for samples with detectable residues was 670 ppb in ground water and 865 ppb in surface water. Although these few values are well above the established Maximum Contaminant Level (MCL) for endothall of 100 ppb, greater than 99% of ground and surface water samples contained concentrations below the limit of detections (10 ppb). Endothall may be applied to water at concentrations up to 5000 ppb. These high values would not be representative of average concentrations in drinking water. This determination is further supported by additional monitoring data collected under the Safe Drinking Water Act (SDWA). Data collected under the Safe Drinking Water Information System (SDWIS) between 1993 and 2005 indicated only 2 occurrences of endothall residues that exceeded the established MCL of 100 ppb. Both of these occurred in 1994, with no violations occurring since that time. In addition, historical data analysis of compliance and occurrence data from treated water systems has shown detections of very low frequency to be outliers relative to whole datasets. Given the low frequency of detection and the more than an order of magnitude difference between the more than 27,000 samples below the detection limit and 8 detects above, the observed detects would appear to be statistical outliers.

For these reasons, EPA does not believe the modeled estimated concentrations are appropriate for use in estimating exposure to endothall in drinking water. As noted above, an MCL of 100 ppb has been established for endothall. The MCL is based on a chronic feeding study which established a NOEL of 2 mg/kg/day based on increased absolute relative weights of the stomach and small intestine. Although the MCL is likely to overestimate average (i.e., chronic) residues of endothall in drinking water, EPA believes it provides a reasonable high-end estimate of potential drinking water concentrations from the aquatic uses of endothall. Consequently, the MCL of 100 ppb was used in the dietary risk assessment.

b. Terrestrial Uses

Surface water concentrations from use on terrestrial crops were estimated using the Tier II model PRZM (version 3.12)/EXAMS (version 2.98.04) and ground water concentrations were estimated using the Tier I model of SCIGROW (version 2.2). A total of five scenarios were modeled for endothall use on terrestrial crops based on Agency standard scenarios. The scenarios modeled were cotton and alfalfa in California, Oregon hops, and potatoes in Maine and Idaho. These scenarios were chosen to estimate the concentration of endothall in surface drinking water over a geographically dispersed range of existing terrestrial crop production areas. These scenarios chosen for this assessment represent all relevant PRZM/EXAMS scenarios for the terrestrial use of endothall. Endothall may be applied by aerial or ground equipment as per the labels of this product. All terrestrial scenarios were modeled with aerial application equipment, which results in the highest amount of spray drift, except for hops, which is treated by ground equipment.

The estimated peak surface water concentration of endothall as a result of terrestrial use is 7.1 ppb. The estimated chronic (non-cancer) surface water concentration of endothall as a result of terrestrial use is 2.5 ppb. Modeled groundwater concentrations of endothall, both peak and chronic, are not expected to exceed 0.086 ppb.

5. Chronic Risk from Food Plus Drinking Water

To assess chronic risk from food plus drinking water, exposure estimates from both chronic dietary (both directly treated and irrigated crops) and chronic drinking water were combined in the DEEM™ modeling program. Estimated concentrations of endothall were modeled by the Agency as discussed above. Based on the rationale described above, the Agency assumed an endothall concentration of 100 ppb as the average concentration in drinking water. This concentration is the MCL for endothall. Because the Agency feels that modeled concentrations are not appropriate for use in estimating exposure to endothall in drinking water, the MCL of 100 ppb was used.

Chronic dietary risks (food and drinking water) do not exceed the Agency's level of concern, although drinking water risk for infants less than one year old is at the level of concern. As previously discussed, the Agency believes that this risk estimate is the result of conservative assumptions.

Table 4. Summary of Dietary Exposure and Risk from Directly Treated Crops, Irrigated Crops, and Drinking Water

Population Subgroup	Dietary Exposure mg/kg/day	% cPAD (Food + Water)
General U.S. Population	0.002297	33
All Infants (<1 year old)	0.007234	103
Children 1- 2 years old	0.003574	51

6. Residential Risk

Endothall products may be used in residential settings to control aquatic weeds and algae in ponds and garden pools. Therefore, homeowners may potentially be exposed to endothall by applying home-use formulations. In addition, there is also a potential for exposure to adults and children from incidental oral and dermal exposure during recreational activities in public waters treated with endothall. As a result, risk assessments were completed for both residential handlers and post-application scenarios. Residential risks are measured by a margin of exposure (MOE), which determines how close the exposure comes to a No Observed Adverse Effect Level (NOAEL) taken from animal studies. For residential risk from endothall, Margins of Exposure (MOEs) that are greater than or equal to 100 are below EPA's level of concern for short-term residential exposures.

Residential applications are only expected to occur over short-periods of time. Therefore, intermediate-term and long-term residential exposure assessments were not conducted. The anticipated use patterns that could potentially lead to residential handler exposure are: (1) loading/applying granular formulations with a belly grinder; and (2) applying granular formulations by hand.

The exposure pathway of concern for residential handlers is short-term inhalation. The short-term inhalation NOAEL is 9.4 mg/kg/day based on decreased pup body weight. This endpoint is taken from the two-generation rat reproduction study. Short-term inhalation MOEs for loading/applying granular formulations with a belly grinder range from 190 to 830. For handlers applying granular formulations by hand, the short-term inhalation MOE is 2700. Therefore, residential handler risks are below the Agency's level of concern.

For residential post-application exposures, exposures on the day of application after an application to a public water body are of the greatest concern. The Agency identified incidental oral exposure (from swallowing water while swimming) and the potential for dermal irritation while swimming as possible post-application exposure scenarios. The Agency conducted an assessment, using the SWIM modeling program, to assess incidental exposures. Risks were calculated using MOEs, where an MOE greater than or equal to 100 is below EPA's level of concern. The incidental oral endpoint for short-term exposure of 9.4 mg/kg/day was selected from a two-generation rat reproduction study (in which lesions in the gastric epithelium were observed). MOEs calculated for both children (ages 6-10) and adults are below the Agency's level of concern for incidental oral (280 and 900, respectively). The expected exposure to swimmers from the dermal route would be extremely low (the highest application rate results in a water concentration of 5 ppm) and would not likely result in any irritation to the skin. Currently, several Special Local Needs (SLN) labels have swimming restrictions that prohibit access to waters following commercial applications.

7. Aggregate Risk

(For a complete discussion, see Section 7.0 of the Endothall: HED Chapter of the Reregistration Eligibility Decision Document, Corrected Following Public Comments, dated September 30, 2005.)

Aggregate exposure to a pesticide combines exposure from food, drinking water, and, if applicable, residential exposure. For endothall, aggregate risk was measured as a margin of exposure. MOEs for short-term residential exposures above or equal to the target level (100) are not of concern to the Agency. In the case of endothall, residential exposures are only expected to be episodic, or short-term. Therefore, intermediate-term and long-term residential exposures were not assessed.

For adult short-term aggregate exposure, EPA aggregated inhalation exposure during residential applications, oral exposure during swimming, and dietary exposure from food and drinking water. For children (ages 6-10), EPA considered incidental oral exposure during swimming and dietary exposure (food and drinking water). Although infants are the most sensitive subgroup for chronic dietary concerns, the Agency did not find it appropriate to assume infants (less than one year old) participate in swimming activities in outdoor water bodies such as lakes and ponds. The MOEs calculated are above the target MOE, with values of 250 for children (ages 6-10) and 310 for adults (age 50 years and older). Therefore, short-term aggregate risks are below the Agency's level of concern.

Because EPA does not expect chronic residential exposure, chronic aggregate risks are equal to chronic dietary risks (food plus water). As described above in Section 5, these risks are at the Agency's level of concern.

8. Occupational Risk

(For a complete discussion, see the Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Endothall, dated August 12, 2005).

Workers can be exposed to a pesticide while mixing, loading, or applying a pesticide, and when entering a treated site. Handler and worker risks are measured by a margin of exposure (MOE), which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) taken from animal studies. The Agency initially calculates the handler risks using the least protective measures. This is called the baseline assessment, and assumes an individual's normal work clothing (e.g, long sleeve shirt and long pants), no gloves, and no respirator. If there is a concern at this level, the Agency considers the use of protective measures (e.g., personal protective equipment and engineering controls) to lower the risk. Personal protective equipment (PPE) can include an additional layer of clothing, chemical-resistant gloves, and a respirator. Common examples of engineering controls include: enclosed tractor cabs, closed loading systems, and water-soluble packaging.

a. Occupational Handler Summary

The Agency has determined that workers may be exposed to endothall while mixing, loading, applying, and flagging for aerial applications. In the absence of chemical-specific monitoring data for endothall, exposure analyses were performed using the Pesticide Handlers Exposure Database (PHED). The MOEs for occupational exposures were calculated for short-term and intermediate-term inhalation exposures for terrestrial, aquatic, and cooling tower applications. For the short-term inhalation exposure scenario the NOAEL is 9.4 mg/kg/day. This endpoint is based on decreased pup body weight. For the intermediate-term inhalation exposure scenario the LOAEL is 2 mg/kg/day based on proliferative lesions of the gastric epithelium. Both endpoints for the inhalation exposure scenarios are taken from the two-generation oral rat reproduction study. Toxicity from dermal exposures was not assessed because a dermal endpoint was not established for systemic effects. End-use product labels will address protection for workers regarding dermal exposure. For occupational risks, short-term MOEs that are greater than 100 and intermediate-term MOEs that are greater than 300 do not exceed the Agency's level of concern. The level of concern for short and intermediate-term exposures are based on 10X to account for interspecies extrapolation to humans from animal test species and 10X to account for intraspecies sensitivity. For intermediate-term exposures, an additional 3X is applied to account for the lack of a NOAEL.

i. Terrestrial Applications

All risks calculated for short-term inhalation exposure to mixers, loaders, and applicators are below the Agency's level of concern (MOEs range from 390 to 38,000) when wearing baseline attire. For intermediate-term inhalation exposure to mixers, loaders, and applicators, all risks are below the Agency's level of concern (MOEs range from 500 to 8,100 with baseline attire) with the exception of mixing and loading liquids for aerial applications (MOEs range from 83-290 with baseline attire).

ii. Aquatic Applications

In the absence of specific occupational exposure data for aquatic use scenarios, surrogate exposure scenarios were used to assess certain occupational scenarios. To assess exposure from mixing, loading, and applying liquid formulations for applications using boat-mounted spray equipment, the exposure scenario for mixing and loading liquids for ground boom equipment was used. To assess exposure from mixing and loading concentrate to direct metering/subsurface application equipment, the mixing and loading scenario for mixing and loading liquid formulations was used. To assess exposure from mixing, loading, and applying concentrate liquid formulations with a handgun sprayer, the lawn care operator (LCO) exposure information from the Outdoor Residential Exposure Task Force (ORETF) was used. Finally, to assess exposure from loading and applying granular formulations, the open loading granular application

scenario was used from the Pesticide Handler Exposure Database (PHED). For aquatic exposures, MOEs were calculated using an 80% (PF5) respirator. Current labels require workers to wear this type of protection.

All risks for short-term exposures from mixing, loading, and applying liquid formulations are below the Agency's level of concern when workers wear an 80% (PF5) respirator (NIOSH TC-21C) (MOEs range from 1150 to 130,000). All risks for intermediate-term exposures from mixing, loading, and applying liquid formulations are below the Agency's level of concern when workers wear an 80% (PF5) respirator (NIOSH TC-21C) (MOEs range from 400 to 275,000) with the exception of mixing and loading liquids for ground-spray type applications at high rates (MOE = 250). However, although the MOE for this scenario does not reach the target of 300, it is unlikely that typical applications will result in a risk to workers. For example, as part of this RED, the Agency is requiring aquatic labels to specify that applications at the highest rate are for spot treatments only. The exposure assessment for mixing and loading liquids assumed a treatment area of 30 acres. In addition, intermediate-term exposure assessments assume more than 30 days of exposure. It is unlikely that applications to large areas at high rates will be conducted for that length of time. As a result of these assumptions and the mitigation measures set forth in this RED, the Agency believes that the 80% respirator will adequately protect workers for the above scenarios.

All risks for short-term exposures from loading and applying granular formulations are below the Agency's level of concern (MOEs range from 208 to 860 with baseline attire). For intermediate-term exposure from loading and applying granular formulations, risks are of concern to the Agency (MOEs range from 220-240 with an 80% (PF5) respirator).

iii. Cooling Tower (Biocide) Applications

Occupational exposures were assessed for applications of endothall to cooling towers to control mollusks and algae. Labels indicate that endothall should be continuously fed into cooling tower waters for 6 to 144 hours. Although a continuous feed is a daily operation, handlers treating water systems are expected to apply endothall on a limited basis and are best represented by short-term exposure duration. All short-term inhalation risks for cooling tower uses are below the Agency's level of concern (MOEs range from 620 to 260,000).

b. Post-application Occupational Risk

The Agency did not assess occupational post-application risks to agricultural workers following treatments to agricultural crops, because no systemic dermal endpoint of concern was established. Based on acute toxicity of the active ingredient and potential to cause severe dermal irritation, endothall is classified as a severe dermal irritant. However, a re-entry interval of 48 hours is required for agricultural workers. Post-application occupational exposures following endothall applications to aquatic areas is

likely limited to persons who contact the treated water to perform tests, or persons such as agricultural workers who may contact treated water in irrigation canals.

9. Human Incident Summary

To assess occupational and non-occupation incidents, the Agency consults several incident reporting databases. These include: the Office of Pesticide Program Incident Data System, Poison Control Centers, California Department of Pesticide Regulation, National Pesticide Telecommunications Network, and the National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks.

Relatively few incidents of illness have been reported due to endothall. In general reports are of irritative effects to the eye and skin. No endothall related hospitalizations have been reported due to pesticide use. No recommendations are made based on the very limited incident data available for endothall.

B. Ecological Risk

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity studies using the risk quotient method. Risk quotients (RQs) are a screening level for potential risk and are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic, for various wildlife species. RQs are then compared to levels of concern (LOCs). Table 5 lists levels of concern used in the risk assessment. Generally, the higher the RQ, the greater the potential risk. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies. RQ values are provided in parentheses for indicated exceedances in the summary below.

Table 5. Levels of Concern for Ecological Risk

If RQ > LOC value given below…			**Then EPA presumes…**
Terrestrial Organisms	**Aquatic Organisms**	**Plants**	**Risk Presumption**
0.5	0.5	1	**Acute Risk**- there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification
0.2	0.1	N/A	**Acute Restricted Use**- there is potential for acute risk, but may be mitigated through restricted use classification
0.1	0.05	1	**Acute Endangered Species**- endangered species may be adversely affected; regulatory action may be warranted
1	1	N/A	**Chronic Risk**-there is potential for chronic risk; regulatory action may be warranted

1. Environmental Fate and Transport

(For a complete discussion, see the Environmental Fate and Ecological Risk Assessment of Endothall-Revised, dated April 22, 2005.)

The endothall environmental risk assessment includes an assessment of risks to aquatic organisms from both the aquatic and terrestrial uses. Endothall is applied as either endothall dipotassium salt or endothall N,N-dimethylalkylamine salt. After application of either the dipotassium salt or N,N-dimethylalkylamine salt, endothall acid is formed by degradation. The acid is the form of endothall that acts as an herbicide, desiccant, algaecide, and biocide. The three forms of endothall have dissimilar toxicity properties, with the endothall N,N-dimethylalkylamine salt being more toxic to aquatic animals than the dipotassium salt. However, the dipotassium salt and endothall acid have similar toxicity properties.

The dissociation constants of both of the endothall salts indicate that at most environmental pH levels, the endothall salt, endothall acid, and the corresponding cation (potassium or coco-alkylamine) will be present. After aquatic applications, endothall salts, acid, and cation components will be found mainly in the water column. The potassium ions that dissociate from the dipotassium salt are not of concern as a source for additional toxicity. The persistence of endothall acid in aqueous environments is expected to be less than ten days. In terrestrial environments, endothall acid degrades with a half-life of approximately ten days. The half-lives of the endothall N,N-dimethylalkylamine salt and the coco-amine have not been provided.

The environmental risk assessment is organized by risks posed by each form of endothall. Therefore, the following sections are also organized in that manner.

2. Terrestrial Organism Risk

(For a complete discussion, see the Environmental Fate and Ecological Risk Assessment of Endothall-Revised, dated April 22, 2005.)

a. Risks from Use of Endothall N, N-dimethylalkylamine Salt

The N,N-dimethylalkylamine salt form of endothall is the only form used terrestrially. In terrestrial scenarios, in addition to the presence of N,N-dimethylalkylamine salt, it is possible that the degradation products (endothall acid and coco-alkylamine cation) will be present. As a result of exposure to these compounds several groups of organisms are potentially at risk. Acute mammalian LOCs are exceeded from use on all terrestrial sites (RQs range from 0.12 to 9.74). Based on endothall acid chronic toxicity, birds feeding on grasses, broad leaf plants, and small insects are potentially at risk from the use of N, N-dimethylalkylamine salt on potatoes, hops, alfalfa, and clover (RQs range from 1.02 to 9.10). Chronic RQs for birds are based on early embryonic mortality. From use on alfalfa, clover, potatoes, and hops chronic LOCs for mammals are exceeded (RQs range from 1.04 to 3.03). Chronic RQs for mammals are based on decreased pup body weight and death of animal within one day.

Because endothall is a herbicide, non-target plants are potentially at risk from drift and runoff of endothall N,N-dimethylalkylamine salt away from target use sites. LOCs are exceeded for non-target plants caused by adjacent runoff and wetland area runoff from applications made to potatoes, hops, alfalfa, clover, and cotton (RQs range from 2.3 to 27.5). LOCs for acute algae toxicity are also exceeded for terrestrial use of N, N-dimethylalkylamine salt (RQs range from 1 to 7.65).

The Agency feels that potential risks to terrestrial organisms from the N, N-dimethylalkylamine salt may have been underestimated because terrestrial RQs were based on toxicity data using endothall acid and endothall dipotassium salt. Available ecotoxicity studies using the N, N-dimethyalkylamine salt indicate it is more toxic to organisms than dipotassium salt or endothall acid. Additional data pertaining to the fate and ecotoxicity of the N, N-dimethylalkylamine salt is being requested.

3. Aquatic Organism Risk

The RQs presented below are representative of RQs resulting from a range of application rates for aquatic use. The rates that were used in the assessment included 0.5, 1.0, 2.5, 3, 4, and 5 ppm. A range of application rates was used in order to compare RQs at low, average, and maximum application rates.

Although the assessment was performed using very high end label rates, typical rates used to control algae and plants are low, 0.05-0.3 ppm and 1-3 ppm, respectively. Therefore, RQs calculated at rates above 3 ppm are conservative expressions of risk and represent exposure scenarios that are infrequent.

a. Risks from Use of Endothall N, N-dimethylalkylamine Salt

The N,N-dimethylalkylamine salt form of endothall is more toxic than other forms of endothall (2 to 3 orders of magnitude) to aquatic organisms, both on an acute and chronic basis. On an acute basis, the N,N-dimethylalkylamine salt is considered to be highly toxic to very highly toxic to freshwater fish, moderately toxic to highly toxic to estuarine/marine fish, and moderately toxic to very highly toxic to estuarine/marine invertebrates. Acute LOCs are exceeded for freshwater and marine fish (RQs range from 0.6 to 119), invertebrates (RQs range from 3 to 417), vascular plants (RQs range from 2 to 7), and algae (RQs range from 217 to 2174) from all direct applications to water, including once-through cooling tower uses. Chronic LOCs are exceeded for freshwater fish (RQs range from 2.2 to 22.2) and invertebrates (RQs range from 133 to 1331.3) from all direct applications to water, including once-through cooling tower uses. For freshwater fish, chronic RQs are based on survival, and for freshwater invertebrates, chronic RQs are based on reproduction rate.

The Environmental Incident Information System (EIIS) database has records of two fish kills related to the use of endothall N, N-dimethylalkylamine salt. Accidental

misuse of the biocide formulation in a Minnesota power plant cooling chamber resulted in the deaths of thousands of green sunfish, catfish, and shiners due to the high water temperature (92° C) at application. The second incident occurred when a 5-gallon can of endothall N, N-dimethylalkylamine salt product spilled into a drain in California and resulted in the death of over one thousand carp.

Terrestrial use of N,N-dimethylalkylamine salt also poses risks to aquatic organisms from runoff and drift. Acute LOCs are exceeded for freshwater fish (RQs range from 0.5 to 0.92), freshwater invertebrates (RQs range from 0.5 to 3.23), and algae (RQs range from 1.04 to 7.65) from runoff.

b. Risks from Use of Endothall Dipotassium Salt

Endothall dipotassium salt is applied directly to the aquatic environment. The Agency used the acute toxicity values for endothall dipotassium salt to calculate risk to fish and aquatic invertebrates. On an acute basis, the dipotassium salt is considered to be slightly toxic to practically non-toxic to freshwater fish, slightly toxic to estuarine/marine fish, and moderately toxic to practically non-toxic to estuarine/marine invertebrates. Aquatic non-endangered vascular plant LOCs are exceeded for acute exposure from all direct applications to water (RQs range from 2.5 to 8). Acute LOCs are exceeded for freshwater fish at maximum application rates (RQ = 0.55). Chronic risk was calculated for aquatic animals using endothall acid and endothall dipotassium salt toxicity data due to the dissociation of the dipotassium salt to endothall acid. Chronic LOCs are minimally exceeded for freshwater fish from the highest application rate (RQ =1) and for freshwater invertebrates from the two highest application rates (RQs range from 1.1 to 1.4). Chronic RQs for freshwater fish are based on wet weight and length, and chronic RQs for freshwater invertebrates are based on length and number of offspring.

c. Risks from Endothall Acid

Although endothall acid is not directly applied to use sites, it is possible that plants and animals may be exposed to the acid. The dissociation constants of both of the salts indicate that at most environmental pH levels, the endothall salt, endothall acid, and the corresponding cation (potassium or coco-alkylamine) will all be present. Endothall acid is considered to be slightly toxic to freshwater fish, slightly toxic to practically non-toxic to aquatic freshwater invertebrates, practically non-toxic to estuarine/marine fish, and slightly toxic to estuarine/marine invertebrates on an acute basis. Chronic LOCs are minimally exceeded for freshwater fish from applications at the highest rate (RQ = 1), and for freshwater invertebrates from the two highest application rates (RQs range from 1.1 to 1.4). Chronic RQs for freshwater fish are based on wet weight and length, and chronic RQs for freshwater invertebrates are based on length and number of offspring.

4. Risk to Endangered Species

a. Risks from Use of Endothall N, N-dimethylalkylamine Salt

As discussed previously, endothall N,N-dimethylalkylamine salt is used in both aquatic and terrestrial environments. For this reason, aquatic organisms are susceptible to exposure from aquatic applications, and both terrestrial and aquatic organisms are susceptible to exposure from terrestrial applications. Acute threatened and endangered species LOCs are exceeded in the screening level risk assessment for freshwater fish (RQs range from 12 to 119), estuarine/marine fish (RQs range from .6 to 6.10), freshwater invertebrates (RQs range from 6 to 417), estuarine/marine invertebrates (RQs range from 3.10 to 31.10), freshwater endangered vascular plants (RQs range from 3 to 33), and freshwater algae (RQs range from 217 to 2174) from all direct applications to water, including once-through cooling tower uses. Chronic threatened and endangered LOCs are exceeded for freshwater fish (RQs range from 2.2 to 22.2) and invertebrates (RQs range from 133 to 1331.3) from all direct applications to water, including once-through cooling tower uses.

From applications of endothall N, N-dimethylalkylamine salt made to terrestrial environments, both aquatic and terrestrial organisms are potentially exposed. Acute threatened and endangered LOCs are exceeded in the screening level risk assessment for freshwater fish (RQs range from 0.06 to 0.92), estuarine/marine fish (RQs =0.05), freshwater invertebrates (RQs range from 0.05 to 3.23) and marine/estuarine invertebrates (RQs range from 0.05 to 0.24), and algae (RQs range from 1.04 to 7.65) from runoff. Acute threatened and endangered mammalian LOCs are also exceeded in the screening level risk assessment for all terrestrial uses (based on endothall acid toxicity values) (RQs range from 0.10 to 9.74). Chronic threatened and endangered species LOCs are exceeded in the screening level risk assessment for mammals (RQs range from 1.04 to 3.03) and birds (RQs range from 1.02 to 9.10) from use on potatoes, hops, alfalfa, and clover.

Threatened and endangered plants are potentially exposed to N, N-dimethylalkylamine salt from drift and runoff from targeted application sites. Threatened and endangered species LOCs for non-target vascular plants are exceeded in the screening level risk assessment from adjacent runoff, wetland area runoff, and spray drift associated with use on all crops (RQs range from 1.5 to 137.5).

Further, there may be potential for indirect effects to listed species in any taxa that are dependent upon a taxa that may experience effects from the use of this pesticide.

The Agency feels that potential risks to terrestrial organisms from the N, N-dimethylalkylamine salt may have been underestimated because RQs were based on toxicity data using endothall acid and endothall dipotassium salt. Available ecotoxicity studies using the N, N-dimethyalkylamine salt indicate it is more toxic to organisms than

dipotassium salt or endothall acid. Additional data pertaining to the fate and ecotoxicity of the N, N-dimethylalkylamine salt is being requested.

Risks to endangered species identified in the Environmental Fate and Ecological Risk Assessment for Endothall are based solely on EPA's screening level assessment and do not constitute "may effect" findings under the Endangered Species Act.

b. Risks from Use of Endothall Dipotassium Salt

Several threatened and endangered species level of concern exceedences in the screening level risk assessment occur from use of endothall dipotassium salt. Exceedences occur for acute effects to freshwater fish (RQs range from 0.05 to 0.55) and vascular plants (RQs range from 181 to 1087) from all direct applications to water. From applications at the highest rates (4 and 5 ppm), exceedences occur for marine/estuarine fish (RQs range from 0.05 to 0.06), freshwater invertebrates (RQs range from 0.06 to 0.08), and marine/estuarine invertebrates (RQs range from 0.06 to 0.07). Chronic RQs are minimally exceeded for freshwater fish (RQ = 1) and freshwater invertebrates (RQs range from 1.1 - 1.4) at maximum application rates. Data are unavailable with which to assess potential chronic risks to estuarine/marine species and therefore, potential risks can not be dismissed for these taxa. Further, there may be potential for indirect effects to listed species in any taxa that are dependent upon a taxa that may experience effects from the use of this pesticide. These findings are based solely on EPA’s screening level assessment and do not constitute “may affect” findings under the Endangered Species Act.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination or 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 endothall 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 supported products containing endothall.

The Agency has completed its assessment of the dietary, occupational, drinking water, and ecological risks associated with the use of pesticide products containing the active ingredient endothall. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient endothall, the Agency has sufficient information on the human health and ecological effects of endothall to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that endothall containing products are eligible for reregistration provided that (i) current data gaps and

confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are summarized in Section V. Appendix A summarizes the uses of endothall that are eligible for reregistration. Appendix B identifies generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of endothall, and lists the submitted studies the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data or data which are needed to confirm the decision presented here.

Based on its evaluation of endothall, the Agency has determined that endothall products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of endothall. If all changes outlined in this document are incorporated into the product labels, then all current risks for endothall will be adequately mitigated for the purposes of this determination under FIFRA. Additionally, once an endangered species assessment is completed, further changes to these registrations may be necessary as explained in section IV.D.5.a of this document.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for endothall. During the public comment period on the risk assessments, which closed on July 11, 2005, the Agency received comments from the registrant, the United States Army Corps of Engineers, endothall applicators, and concerned citizens. These comments in their entirety are available in the public docket, http://docket.epa.gov/edkpub/index.jsp, OPP-2005-0370. The Agency's responses to these comments are incorporated into the revised chapters and are available in the public docket.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with endothall. The Agency has concluded that tolerances for endothall meet the FQPA safety standards and that the aggregate (food, drinking water, and residential sources) exposure is within the "risk cup". The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children.

b. Determination of Safety to U.S. Population (Including Infants and Children)

The Agency has determined that the established tolerances for endothall, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b) (2) (D) and 408(b) (2) (c) of the FFDCA, and that there is a reasonable certainty that no harm will result to infants, children, or the general population or any subgroup from the use of endothall. The safety determination for infants and children considers factors including toxicity, use practices, and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of endothall residues in this population subgroup.

No special FQPA Safety Factor is necessary to protect the safety of infants and children. In determining whether or not infants and children are particularly susceptible to toxic effects from endothall residues, the Agency considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA safety factor has been removed (i.e., reduced to 1X) for endothall based on: (1) there was no quantitative or qualitative evidence of increased susceptibility following prenatal exposure to rats in the developmental toxicity study or pre/postnatal exposure to rats in the 2-generation rat toxicity study, (2) there are no concerns for residual uncertainty for prenatal toxicity in the available developmental study, or the 2-generation rat toxicity study, and (3) there are no residual uncertainties for exposure.

c. Endocrine Disruptor Effects

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

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, endothall may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

d. Cumulative Risks

Risks summarized in this document are those that result only from the use of endothall. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity". The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemicals substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for endothall.

For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative.

2. Tolerance Summary

A tolerance summary is presented below in Table 3. The Agency has determined that the residue of concern in plants, livestock, and fish is endothall and its monomethyl ester. The residue to be measured for tolerance enforcement is the combined residues of endothall and its monomethyl ester.

Tolerances for residues of endothall, from use of the mono-N,N-dimethyalkylamine salt, in/on plant commodities should be revised to be expressed in terms of endothall per se and its monomethyl ester [40 CFR § 180.293]. Tolerances that are currently established for residues in/ on undelinted cotton seed, hops, potato, and rice grain and straw will not change in value. An interim tolerance was established for residues of endothall in potable water; this tolerance will be proposed for revocation (an MCL is in effect for 100 µg/L). Under 40 CFR § 180.319 an interim tolerance exists for residues of endothall in/on sugar beets; this tolerance should be made permanent once additional data has been received and deemed acceptable. No tolerances have been established for livestock commodities. The available ruminant and poultry metabolism studies suggest that detectable residues of endothall are likely to be transferred to meat, milk, poultry and eggs as a result of registered uses on feedstuffs. The registrant has been required to conduct animal (ruminant and poultry) feeding studies in meat, milk, poultry, and eggs in order to set appropriate tolerances. Data have been submitted to support tolerances in finfish, catfish, and shellfish. This action is not incorporated into this document and will be addressed in a separate action.

A gas chromatography method with microcoulometric nitrogen detection is listed as Method I in the Pesticide Analytical Manual (PAM, Volume II) for the determination of endothall residues in/on crop commodities. An improved high performance liquid chromotography-mass selective detector (HPLC-MSD) method has been submitted as a confirmatory enforcement method for plants and fish. Data collection and regulatory analytical methods for animal commodities are currently not available and are required for reregistration.

The submitted magnitude of the residue studies for alfalfa seed, cottonseed, and potatoes have been reviewed and were deemed inadequate to satisfy reregistration requirements. The submitted data for hops supports the national Section 3 labels, but does not support the Section 24(c) Special Local Need uses because a different pre-harvest interval was used. The submitted residue data for irrigated cabbage, celery, grapefruit, pepper, and turnip have been deemed inadequate because the water treatment rate was less than the maximum label rate. The submitted confined rotational crop study was deemed inadequate because the test substance was applied at a rate less than the maximum registered seasonal rate for crops which can be rotated.

The submitted processing studies on cotton and potatoes are acceptable, and the results of these studies show that endothall does not concentrate in the processed fractions of cotton and potatoes. A sugar beet processing study was submitted and was deemed inadequate.

Although additional data are required to confirm the existing tolerance level in/on the following commodities, the Agency has no dietary, drinking water or residential risk concerns associated with these tolerances and considers them reassessed: cotton (undelinted seed), hop, potato, rice (grain), rice (straw), and sugar beet.

Endothall is registered for use on aquatic areas such as irrigation and drainage canals, and the treated water from these sites may be diverted to irrigate food or feed crops. The Agency requested the registrant to submit studies to address residues on irrigated crops. In response, the registrant submitted limited studies that investigated the magnitude of endothall residues on irrigated crops such as cabbage, celery, grapefruit, peppers, and turnips. These studies were not conducted using maximum labeled application rates or label-specified application intervals. Additional data on irrigated crops are required for reregistration. For the purpose of continuity, the Agency is requiring that the submitted studies be redone using current label instructions.

a. Tolerances Currently Listed and Tolerance Reassessment

Table 6. Tolerance Table

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments
Tolerances Listed Under 40 CFR § 180.293 (a)(1)			
Cotton, Undelinted Seed	0.1	To Be Determined (TBD)	Additional data are required. Data submitted by the registrant was performed in the wrong geographic area, used incorrect rates, the wrong pre-harvest interval, and the cotton was delinted prior to analysis.
Hop	0.1	TBD	Additional data are required. Submitted data does not support 24(c) registrations. Change commodity name to Hop, Dried Cones
Potato	0.1	TBD	Additional data are required. Data submitted by the registrant used incorrect application rate.
Rice, Grain	0.05 (N)	TBD	Although there are presently no registered uses on rice, the Agency recommends the retention of these tolerances until the registrant has submitted the requested irrigation crop data that should include data for rice commodities.
Rice, Straw	0.05 (N)	TBD	
Tolerance Listed Under 40 CFR § 180.293 (a)(2)			
Potable Water	0.2	Revoke Tolerance	EPA's Office of Pesticide Programs no longer establishes tolerances in drinking water. EPA's Office of Water has established an MCL for endothall at 0.1 ppm
Tolerance Listed Under 40 CFR § 180.319			
Beet, Sugar	0.2	TBD	Additional data are required. Although there are presently no registered uses on sugar beets, the Agency recommends the retention of the interim tolerance until the registrant has submitted the requested irrigation crop data. Residue data must include data for both sugar beet root and tops. Change commodity name to Beet, sugar, root.
Tolerances to be Proposed Under 40 CFR § 180.293			
Cotton Gin Byproducts	NA	TBD	A tolerance for cotton gin byproducts will need to be proposed when requesting cotton field trials and have been received and evaluated.
Animal Commodities	NA	TBD	Tolerances for animal commodities will need to be proposed when the requested cotton field trials have been received and evaluated.
Processed Commodities	NA	TBD	Tolerances for processed commodities may be needed if the levels of endothall residues expected in processed commodities are found to be significantly higher than the raw agricultural commodities.

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments
Fish and Shellfish	NA	TBD	Tolerances that have been proposed for fish and shellfish may become acceptable after the appropriate stability data and independently validated enforcement method have been submitted.

NOTE: The Agency has no dietary, drinking water, or residential risk concerns associated with these tolerances and consider them reassessed at the current tolerance level. The "TBD" designation is used, however, to convey that the Agency expects that the data required in the DCI that will be issued as a result of this RED will confirm that conclusion.

D. Regulatory Rationale

The Agency has determined that endothall is eligible for reregistration provided that additional required data are submitted to confirm this decision that the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures. This decision considers the risk assessments conducted by the Agency and the significance of the use of endothall.

The following is a summary of the rationale for managing risks associated with the use of endothall. Where labeling revisions are warranted, specific language is set forth in the summary tables in Section V of this document.

1. Human Health Risk Management

a. Dietary Risk Mitigation (food and drinking water)

As discussed in sections III.A.4 and 5, chronic dietary risks (food and drinking water) do not exceed the Agency's level of concern, although drinking water risk for infants less than one year old is at the level of concern. The Agency believes that this risk estimate is the result of conservative assumptions used in the risk assessment. However, to ensure that dietary (food and drinking water) risks are below the Agency's level of concern, drinking water intake setbacks will be added to endothall labels for aquatic uses. The following language will be added to aquatic use labels:

"Drinking Water (Potable Water)

- Consult with appropriate state or local water authorities before applying this product to public waters. State or local agencies may require permits. The drinking water (potable water) restrictions on this label are to ensure that consumption of water by the public is allowed only when the concentration of endothall is the water is less than the MCL (Maximum Contaminant Level) of 0.1 ppm. Applicators should consider the unique characteristics of the treated waters to assure that endothall concentrations in potable drinking water do not exceed 0.1 ppm at the time of consumption.

- For applications of endothall, the drinking water setback distance from functioning potable water intakes is greater than or equal to 600 feet.

- Note: Existing potable water intakes that are no longer in use, such as those replaced by a connection to a municipal water system or a potable water well, are not considered to be functioning potable water intakes.

- Drinking water setbacks distances do not apply to terrestrial applications of endothall adjacent to water bodies with potable water intakes."

b. Occupational Risk Mitigation

As discussed in Section III.A.8.a, most occupational exposure scenarios are below the Agency's level of concern. However, some mitigation is required to protect workers in scenarios the Agency has indicated might result in a risk to workers. To protect workers mixing and loading liquid formulations for aerial applications to terrestrial sites, workers are required to wear an 80% (PF5) respirator (NIOSH TC-21C). To protect workers mixing, loading, and applying liquid formulations for aquatic applications, workers must wear an 80% (PF5) respirator (NIOSH TC-21C). To protect workers loading and applying granular formulations for aquatic uses, workers are required to wear a 90% (PF10 eslastomeric half face respirator with appropriate cartridge) respirator (NIOSH TC-23C or NIOSH TC-14G). Specific label language will include:

- During granular applications, the respirator need not be worn, provided that the pesticide is applied in a manner (such as aerial application or subsurface release or from the rear of a vessel that is moving into the wind) that the applicator will have no contact with the pesticide.
- During liquid applications, the respirator need not be worn, provided that the pesticide is applied in a manner (such as direct metering or subsurface release from the rear of a vessel that is moving into the wind) that the applicator will have no contact with the pesticide.

The Agency has determined that endothall is a severe dermal irritant. Label requirements addressing dermal effects will be addressed when toxicity data is submitted for end-use products. The Agency will require personal protective equipment based on end-use product toxicity during product reregistration.

To protect workers from exposures during post-application activities, the re-entry interval of 48 hours will remain for agricultural workers (terrestrial applications). Because endothall is a severe skin irritant, the Agency is requiring that double notification statements be added to labels intended for terrestrial use.

c. Residential Risk Mitigation

Although the Agency did not identify any residential use scenarios that resulted in risk concerns, the following statement will be put on labels addressing residential uses:

"Consult local and state fish and game agency and water control authorities before applying this product. Permits may be required to treat such water."

2. Environmental Risk Management

To address risks to aquatic organisms, additional directions for use and use restrictions will be added to product labels to reduce potential risks. Specific language and restrictions are different for the dipotassium salt and the N, N-dimethylalkylamine salt, and are discussed below.

a. Dipotassium Salt

The Agency is requiring that labels for the dipotassium salt form of endothall specify different rates for different size applications. This language will specify that for large treatment areas, lower rates of endothall dipotassium salt must be used. For smaller, spot treatments, higher rates of endothall dipotassium salt can be used. For example, to treat infestations of Coontail, large areas can be treated with rates of 1-2 ppm and small areas can be treated using higher rates (2-3 ppm). Specific language will include:

"Only use higher rates (see above example) when making treatments to small areas with an increased potential for rapid dilution or when making long and narrow applications such as for boat lanes or shoreline treatments where dilution may reduce the exposure of plants and the herbicide."

"Use the lower rates (see above example) for large contiguous treatment blocks, or in protected areas such as coves where reduced water movement will not result in rapid dilution of the herbicide from the target treatment area or when treating entire lakes or ponds."

b. N, N-dimethylalkylamine Salt

The Agency is requiring that products used in lakes, ponds, streams, and other bodies of water are limited to applications to control algae, Hygrophila, Vallisneria, Hydrilla, Cabomba, bur weed, *Elodea canadensis* and Brazilian elodea. The following plants are to be removed from endothall N, N-dimethylalkylamine labels: Coontail, Milfoil, Naiad (*Najas* spp.), Pondweed (Potamogeton spp.), Water Stargrass, and Zannichellia.

3. Significance of Endothall Use

Endothall is an important part of aquatic weed and algae management. Currently there are not many aquatic herbicide alternatives available. Although endothall potentially poses risks to non-target plants and aquatic organisms, typical use patterns

and additional label requirements required in this RED will reduce exposure to non-target organisms while maintaining its most important uses.

The N, N-dimethylalkylamine salt is an important tool for controlling algae and aquatic weeds that cannot be controlled with endothall dipotassium salt. Typical rates used to control algae are low (0.05-0.3 ppm). In addition, RQs were calculated using a range of rates from 0.5 to 5 ppm. Therefore, RQs that were calculated using the lowest rate of 0.5 ppm potentially overestimates risk. When algae are dense, and a higher rate is needed, labels require that application areas are limited to no more than 10% of the water body. Further, when algae are dense, oxygen levels in the water are low. When conditions such as this exist, fish generally are not present and will not likely be exposed to high application rates. In addition, as required mitigation in this RED, the N, N-dimethylalkylamine salt will only be used on a select set of vascular plants (Hygrophila, Vallisneria, Hydrilla, Cabomba, bur weed, *Elodea Canadensis* and Brazilian elodea). Previous labels allowed use on Coontail, Milfoil, Naiad (*Najas* spp.), Pondweed (Potamogeton spp.), Water Stargrass, and Zannichellia. Current labels warn of toxicity to fish and aquatic organisms and do not recommend applications above 0.3ppm where fish are important resources. Another important aspect of N, N-dimethylalkylamine salt use is that commercial applicators are required to apply rates above 0.3 ppm and must get the appropriate state permitting to make an application.

Endothall dipotassium salt is an important part of aquatic weed management and controlling submerged aquatic vegetation. Although use of endothall dipotassium salt poses risks to non-target plants and aquatic organisms, typical use patterns will minimize exposure to non-target organisms. For example, higher rates of the dipotassium salt are used only for spot treatments in small areas where dense weeds are problematic. Large areas that require weed control with the dipotassium salt are treated with lower rates and entire bodies of water are not typically treated at one time. Similar to the N, N-dimethylalkylamine salt, proper permitting and approval is required.

In addition to the importance of aquatic uses of endothall, the terrestrial use of N, N-dimethylalkylamine salt is an important desiccant. The terrestrial use of N, N-dimethylalkylamine salt is minimal. Applications of endothall as a desiccant are reserved for sites where use of other desiccants poses risks to adjacent fields. Additionally, terrestrial application rates of endothall N, N-dimethylalkylamine salt are very low. Together, the minimal use and low application rates minimize risks to terrestrial organisms.

4. Other Labeling Requirements

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

5. Threatened and Endangered Species Considerations

a. The Endangered Species Program

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on threatened and endangered species, and to implement mitigation measures that address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and then 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, this species-specific analysis will also consider the risk mitigation measures that are being implemented as a result of this RED.

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

b. General Risk Mitigation

Endothall end-use products (EUPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing endothall specific to federally listed threatened and endangered species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all threatened and endangered species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting threatened and endangered species risk mitigation measures, the more stringent measure(s) must be adopted.

V. What Registrants Need to Do

The Agency has determined that endothall is eligible for reregistration provided that: (i) additional data that the Agency intends to require to confirm this decision; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table in Section B below (Table 6). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

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

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

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

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

Within the time limit specified in the generic DCI:

1. Cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Anne Overstreet at (703) 308-8068 with questions regarding generic registration.

By US Mail:
Document Processing Desk (DCI/SRRD)
Anne Overstreet
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Anne Overstreet
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1801 S. Bell Street
Arlington, VA 22202

For end-use products containing the active ingredient endothall, the registrant needs to submit the following items for each product:

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

1. Completed response forms to the PDCI (i.e., PDCI response form and requirement status and registrant's response form); and

2. Submit any time extensions and/or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. 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 labeling incorporating all the 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.

Please contact Venus Eagle at (703) 308-8045 with questions regarding product reregistration and/or the PDCI. All materials in response to the PDCI should be addressed as follows:

By US Mail:
Document Processing Desk
(PDCI/SRRD/PRB)
Venus Eagle
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk
(PDCI/SRRD/PRB)
Venus Eagle
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1801 S. Bell Street
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of endothall has been reviewed and determined to be substantially complete. However, the following additional data

requirements have been identified by the Agency as confirmatory and are included in the generic DCI for this RED.

Table 7. Confirmatory Data Requirements for Reregistration

Guideline Number	Study/Requirements
71-4 (850.2300)	Avian Chronic Reproduction study in quail or duck using N,N-dimethylalkylamine salt
72-4C (850.1400)	Estuarine/Marine Fish Early Life-Stage Study using N,N-dimethylalkylamine salt
72-4B (850.1350)	Estuarine/Marine Invertebrate Early Life-Stage study using N,N-dimethylalkylamine salt
72-5 (850.1500)	Fish Life-Cycle study using N,N-dimethylalkylamine salt
850.1735	Acute Freshwater Sediment study using N,N-dimethylalkylamine salt
850.1740	Acute Estuarine/Marine Sediment study using N,N-dimethylalkylamine salt
Special Study	Chronic Estuarine/Marine Sediment Testing using N,N-dimethylalkylamine salt
Special Study	65-day Test in Chironomus tentans using N,N-dimethylalkylamine salt
83-3B (870.3700B)	Developmental/Teratology in Non-rodent (rabbit) study
82-4 (870.3465)	28-day Inhalation study
171-4C & D (860.1340)	Residue Analytical Method-Plants and Animals. Radiovalidation data needed to determine whether the current enforcement methods for plants and the required enforcement method(s) for animals can adequately extract and convert aged residues of the monomethyl ester to endothall.
171-4D (860.1340)	Data collection and regulatory analytical methods are needed for the determination of endothall, per se, in animal commodities
171-4 (860.1340)	Submission of analytical reference standards for dipotassium and mono-N,N-dimethylalkylamine salts of endothall
171-4E (860.1380)	Storage stability data for processed plant commodities, animal commodities, and fish
171-4J (860.1480)	Livestock (ruminant and poultry) feeding studies
171-4H (860.1400)	Magnitude of residues in irrigated crops
171-4L (860.1520)	Magnitude of residue studies in potato, alfalfa seed, cotton seed, and cotton gin products. Magnitude of residue studies in raw agricultural commodities of sugar beet and rice if the registrant is supporting these uses
171-4L (860.1520)	Processing studies on apples, field corn, grapes, orange, rice, sorghum, soybeans, sugar beet, tomato, and wheat to cover irrigation uses
165-1 (860.1850)	A confined, rotational crop study after treatment at the proper maximum labeled rate for irrigation water

2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing use products (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The technical and MP labeling should bear the labeling contained in Tables 8 and 9, 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 the pesticides 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.

A product-specific data call-in, outlining specific data requirements, accompanies this RED.

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 the Label Changes Summary Table below.

Existing stocks time frames will be established case by case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy," Federal Register, Volume 56, No. 123, June 26, 1991.

a. Label 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 8. Summary of Required Labeling Changes for Products Registered for Aquatic Uses Only of Endothall

Description	Required Labeling Language	Placement on Label
	Manufacturing-Use Products	
Required on all Manufacturing Use Products	"Only for formulation into an herbicide for the following use(s) [fill blank only with those uses that are being supported by the MP registrants]."	Directions for Use
One of these statements may be added to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	AThis product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).@ AThis product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).@	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	AThis pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.@	Directions for Use
	End-Use Products Intended of Occupational Use	
	Note the following information when preparing labeling for all end-use products: For **sole-active -ingredient** end-use products that contain endothall, the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current label must be removed. For **multi-active -ingredient** end-use products that contain endothall, the handler PPE/engineering control requirements set forth in this section must be compared with the requirements on the current label, and the more protective language must be retained. For guidance on which requirements are considered to be more protective, see PR Notice 93-7. PPE that is established on the basis of Acute Toxicity testing with end-use products must be compared with the active ingredient PPE specified below in this document. The more protective PPE must be placed in the product labeling. For example, the Handler PPE in this RED does not require protective eyewear which may be required by the Acute Toxicity	

Description	Required Labeling Language	Placement on Label
	testing for the end-use product. For guidance on which PPE is considered more protective, see PE Notice 93-7.	
Handler PPE Requirements for Liquid Formulations for Aquatic Applications	"Mixers, loaders, applicators, and other handlers must wear: -long-sleeve shirt, -long pants, -shoes and socks, and -a NIOSH-approved respirator with a dust/mist filter with MSHNA/NIOSH approval number prefix TC-21C or any N, R, P, or He filter. Exception: during application, the respirator need not be worn, *provided* that the pesticide is applied in a manner (such as direct metering or subsurface release from the rear of a vessel that is moving into the wind) that the applicator will have no contact with the pesticide. See engineering controls for additional options."	Precautionary Statements: Hazards to Humans and Domestic Animals
Handler PPE Requirements for Granular Formulations for Aquatic Applications	"Mixers, loaders, applicators, and other handlers must wear: -long-sleeve shirt, -long pants, -shoes and socks, and -a NIOSH-approved half- or full-face respirator with a cartridge approved for dusts and mists or a canister approved for dusts and mists or a cartridge with any N*, R, P, or He filter. Note: the quarter-face cup-style respirator does not meet this requirement. Exception: during application, the respirator need not be worn, provided that the pesticide is applied in a manner (such as aerial application or subsurface release or from the rear of a vessel that is moving into the wind) that the applicator will have no contact with the pesticide. See optional engineering controls for additional instructions." *Instruction to registrant: Drop the "N" type pre-filter from the response statement if the pesticide product contains, or is used with, oil.	
Engineering Controls: Liquid Formulations Only	Engineering Control Statement for Optional Use (WPS only) "Engineering Controls:	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE

Description	Required Labeling Language	Placement on Label
	"When mixers and loaders use a closed system designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people AND the system is functioning properly and is used and maintained in accordance with the manufacturers written operating instructions, the handlers need not wear a respirator, provided the required respirator is immediately available for use in an emergency such as a spill or equipment breakdown."	and User Safety Requirements)
Engineering Controls: Enclosed Cockpit for Granular Aerial Applicators	"Engineering Controls: Pilots must used an enclosed cockpit that meets the requirements listed in the WPS for agricultural pesticides [40 CFR 170.240(d) (6)."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements)
User Safety Requirements	AFollow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.@ ADiscard clothing or other absorbent materials that have been drenched or heavily contaminated with this product=s concentrate. Do not reuse them.@	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements)
User Safety Recommendations	AUSER SAFETY RECOMMENDATIONS@ AUsers should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.@ AUsers should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.@ AUsers should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.@	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	"ENVIRONMENTAL HAZARDS" "This pesticide is toxic to fish. This pesticide is toxic to wildlife. " "Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal."	Precautionary Statements under Environmental Hazards

Description	Required Labeling Language	Placement on Label
Applications Restrictions for all products applied as a spray	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift."	Directions for Use directly above the Agricultural Use Box
Application Restrictions for Aquatic Applications-Liquids Formulations Only	"Aerial application is prohibited."	Directions for Use (near the beginning of the section)
Other Use/Application Restrictions	**Streams, Rivers, Channeled Water:** Do not contaminate water intended for irrigation or domestic purposes. Do not use water for spraying or irrigation within 7 days after treatment. **Swamps, Marshland, Wetlands, Stagnant Water:** Do not contaminate water intended for irrigation or domestic purposes. **Human Drinking Water Systems:** Do not contaminate water intended for irrigation or domestic purposes. **Commercial, Industrial Water Cooling Systems:** Do not discharge the effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW). Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restrictions).	Directions for Use under General Precautions and Restrictions and/or Application Instructions
Other Use/Application Restrictions	**Drinking Water (Potable Water)** ▪ Consult with appropriate state or local water authorities before applying this product to public waters. State or local agencies may require permits. The drinking water (potable water) restrictions on this label are to ensure that consumption of water by the public is allowed only when the concentration of endothall is the water is less than the MCL (Maximum Contaminant Level) of 0.1 ppm. Applicators should consider the unique characteristics of the treated waters to assure that endothall concentrations in potable drinking water do not exceed 0.1 ppm at the time of consumption. ▪ For applications of endothall, the drinking water setback distance from functioning potable water intakes is greater than or equal to 600 feet. ▪ Note: Existing potable water intakes that are no longer in use, such as those	Directions for Use under General Precautions and Restrictions and/or Application Instructions

Description	Required Labeling Language	Placement on Label
	replaced by a connection to a municipal water system or a potable water well, are not considered to be functioning potable water intakes. ▪ Drinking water setbacks distances do not apply to terrestrial applications of endothall adjacent to water bodies with potable water intakes."	
Additional Use/Application Restrictions for Endothall Dipotassium Salt	"Only use higher rates when making treatments to small areas with an increased potential for rapid dilution or when making long and narrow applications such as for boat lanes or shoreline treatments where dilution may reduce the exposure of plants and the herbicide." "Use lower rates for large contiguous treatment blocks or in protected areas such as coves where reduced water movement will not result in rapid dilution of the herbicide from the target treatment area or when treating entire lakes or ponds."	
Additional Use/Application Restrictions for Endothall N, N-Dimethylalkylamine Salt	**All Water bodies (except Irrigation Canals/Ditches):** Use of endothall N, N-dimethylalkylamine salt is limited to algae and the following plants: Hygrophila, Vallisneria, Hydrilla, Cabomba, bur weed, *Elodea canadensis*, and Brazilian elodea. **Lakes, Ponds, Reservoirs (with human or wildlife use):** Do not contaminate water intended for irrigation or domestic purposes. Do not use water for domestic purposes until 25 days after treatment of 5 ppm, 14 days for treatment of 3 ppm, and 7 days for treatment of 0.3 ppm. Do not use treated water for animal consumption within 25 days of treatment of 5 ppm, 14 days for treatment of 3 ppm, and 7 days for treatment of 0.3 ppm. Do not use treated water for spraying or irrigation within 25 days of treatment of 5 ppm, 14 days for treatment of 3 ppm, and 7 days for treatment of 0.3 ppm. Do not use where fish are important resources. Do not treat more than 10% of the area at one time with doses in excess of 1 ppm. **Agricultural Drainage Systems, Drainage Systems:** Do not use water for domestic purposes until 25 days after treatment of 5 ppm, 14 days for treatment of 3 ppm, and 7 days for treatment of 0.3 ppm. Do not use treated water for animal consumption within 25 days of treatment of 5 ppm, 14 days for treatment of 3 ppm, and 7 days for treatment of 0.3 ppm. Do not use treated water for spraying or irrigation within 25 days of treatment of 5 ppm, 14 days for treatment of 3 ppm, and 7 days for treatment of 0.3 ppm. Do not use where fish are important resources. Do not treat more than 10% of the area at one time with doses in excess of 1 ppm.	

Table 9. Summary of Required Labeling Changes for Products Registered for Terrestrial Uses Only of Endothall

Description	Required Labeling Language	Placement on Label
Manufacturing-Use Products		
Required on all Manufacturing Use Products	"Only for formulation into an herbicide for the following use(s) [fill blank only with those uses that are being supported by the MP registrants]."	Directions for Use
One of these statements may be added to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	AThis product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).@ AThis product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).@	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	AThis pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.@	Directions for Use
End-Use Products Intended of Occupational Use		
	Note the following information when preparing labeling for all end-use products: For **sole-active -ingredient** end-use products that contain endothall, the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current label must be removed. For **multi-active-ingredient** end-use products that contain endothall, the handler PPE/engineering control requirements set forth in this section must be compared with the requirements on the current label, and the more protective language must be retained. For guidance on which requirements are considered to be more protective, see PR Notice 93-7. PPE that is established on the basis of Acute Toxicity testing with end-use products must be compared with the active ingredient PPE specified below in this document. The more protective PPE must be placed in the product labeling. For example, the Handler PPE in this RED does not require protective eyewear which may be required by the Acute Toxicity	

Description	Required Labeling Language	Placement on Label
	testing for the end-use product. For guidance on which PPE is considered more protective, see PE Notice 93-7.	
Handler PPE Requirements	"Mixers, loaders, applicators, and other handlers must wear: -long-sleeve shirt, -long pants, -shoes and socks." "In addition, mixers and loaders supporting aerial applications must wear: -NIOSH-approved respirator with a dust/mist filter with MSHNA/NIOSH approval number prefix TC-21C or any N*, R, P, or He filter." *Instruction to registrant: drop the "N" type pre-filter from the respirator statement if the pesticide product contains, or is used with, oil. "See engineering controls for additional requirements."	Precautionary Statements: Hazards to Humans and Domestic Animals
Engineering Controls	"Engineering Controls: Pilots must use an enclosed cockpit that meets the requirements listed in the WPS for agricultural pesticides [40 CFR 170.240(d)(6). Human flagging is prohibited. Flagging to support aerial applications is limited to use of the Global Positioning System (GPS) or mechanical flaggers. When handlers use closed systems, enclosed cabs, or cockpits in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements)
User Safety Requirements	AFollow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.@ ADiscard clothing or other absorbent materials that have been drenched or heavily	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements)

Description	Required Labeling Language	Placement on Label
	contaminated with this product=s concentrate. Do not reuse them.@	
User Safety Recommendations	AUSER SAFETY RECOMMENDATIONS@ AUsers should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.@ AUsers should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.@ AUsers should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.@	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	"ENVIRONMENTAL HAZARDS" "Do not apply directly to water, or to areas where water is present to intertidal areas below the mean high water mark. This pesticide is toxic to fish. This pesticide is toxic to wildlife. Keep out of lakes, streams, and ponds."	Precautionary Statements under Environmental Hazards
Applications Restrictions for all products applied as a spray	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift."	Directions for Use directly above the Agricultural Use Box
Restricted-Entry Interval for WPS products as required by Supplement Three of PR Notice 93-7	"Do not ender or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours."	Directions for Use, Agricultural Use Requirements Box
Early Re-Entry Personal Protective Equipment for Products subject to WPS as required by Supplement Three of PR Notice 93-7	"PPE required for early entry to treated areas that is permitted under the WPS and that involves contact with anything that has been treated, such as soil or water, is: -coveralls over long sleeved shirt and long pants, -chemical-resistant gloves made of any waterproof material, -chemical-resistant footwear plus socks, -protective eyewear, and -headgear for overhead exposure.	Directions for Use, Agricultural Use Requirements Box
Double Notification Statement	"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated area"	Agricultural Use Requirements, following Early Entry PPE and REI statements
Other Use/Application Restrictions	"Treated crops must be harvested by mechanical means only. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water,	Directions for Use Associated with Each Crop

Description	Required Labeling Language	Placement on Label
	food, or feed by storage or disposal. Do not apply through any type of irrigation system. Do not apply where drift is likely to occur. **Alfalfa and Clover:** Do not feed treated fodder and/or forage to animals being finished for slaughter. Do not graze treated areas. Do not use seed for food, feed, or oil purposes. Grown for seed only. **Hops:** Do not feed treated fodder and/or forage to animals being finished for slaughter. 85-day Pre-Harvest Interval (PHI) **Potato:** Do not feed treated forage to animals being finished for slaughter. Do not graze treated areas. 14-day PHI. **Cotton:** 7-day PHI.	
Spray Drift Label Language for Products Applied as a Spray through Ground Equipment	RELEASE HEIGHT: "Apply using a nozzle height of no more than 4 feet above the ground or canopy cover."	Directions for Use under General Precautions and Restrictions
Spray Drift Label Language for Products Applied as a Spray through Airblast Equipment	"Sprays must be directed into the crop canopy." "Outward pointing nozzles should be turned off at row ends and when spraying outer rows." TEMPERATURE INVERSIONS: "If applying at wind speeds less that 3 miles per hour, the applicator must determine if a) conditions of temperature inversion exist, or b) stable atmospheric conditions exist at or below nozzle height. Do not make applications into areas of temperature inversions or stable atmospheric conditions."	Directions for Use under General Precautions and Restrictions
Spray Drift Label Language for Products Applied as a Spray through Aerial Equipment	RELEASE HEIGHT: "Do not release spray at a height greater than 14 feet above the ground or canopy." BOOM LENGTH: "The boom length must not exceed 70% of the wingspan or 85% of the rotor blade diameter." SWATH ADJUSTMENT: "When applications are made with a cross-wind, the swath will be displaced downwind.	Directions for Use under General Precautions and Restrictions

Description	Required Labeling Language	Placement on Label
	The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind. Leave at least one unsprayed at the downwind edge of the treated field."	

VI. Appendices

A. Table of Use Patterns for Endothall

Endothall Acid (PC 038901)

Site Application Timing	Formulation [EPA Reg. No.]	App. Type and Equipment	Max. Single App. Rate (ae)	Max. Number Apps. at Max. Rate	Max. Number Apps. per Year/Crop Cycle	Max. Seasonal Rate (ae)	PHI, PGI, Pre-feeding Interval	Use Directions and Limitations
Alfalfa Foliar	15.9% SC/L [4581-206]	Broadcast via Ground or Aircraft	0.7912 lb ae/A	NS	1-2			Grown for seed only. Do not apply through any type of irrigation system. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. This pesticide is toxic to wildlife. Do not feed treated forage to dairy animals or animals being finished for slaughter. Do not graze treated areas. Do not use seed for food, feed or oil purposes.
Clover Foliar	15.9% SC/L [4581-206]	Broadcast via Ground or Aircraft	0.7912 lb ae/A	NS	1-2			Same as "Alfalfa"
Cotton Pre-harvest	15.9% SC/L [4581-284]		0.0989 lb ae/A	NS	NS		PHI=7 days	Do not apply through any type of irrigation system. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean

Site Application Timing	Formulation [EPA Reg. No.]	App. Type and Equipment	Max. Single App. Rate (ae)	Max. Number Apps. at Max. Rate	Max. Number Apps. per Year/Crop Cycle	Max. Seasonal Rate (ae)	PHI, PGI, Pre-feeding Interval	Use Directions and Limitations
								high water mark. Do not contaminate water by cleaning of equipment or disposal of wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. This pesticide is toxic to wildlife.
Hops Foliar	15.9% SC/L [4581-206]	Ground - Basal Spray Treatment	0.9494 lb ae/A	NS	2		PHI=85 days	Do not apply through any type of irrigation system. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. This pesticide is toxic to wildlife. Do not feed treated forage to dairy animals being finished for slaughter. Do not graze treated areas.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type and Equipment	Max. Single App. Rate (ae)	Max. Number Apps. at Max. Rate	Max. Number Apps. per Year/Crop Cycle	Max. Seasonal Rate (ae)	PHI, PGI, Pre-feeding Interval	Use Directions and Limitations
	15.9% SC/L [OR03003600]		1 lb ae/A				PHI=28 days	Do not apply through any type of irrigation system. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. This pesticide is toxic to wildlife. Do not graze livestock in treated areas. Do not feed treated forage and/or fodder to animals being finished for slaughter.
Potato (White/Irish) Foliar	15.9% SC/L [4581-206]	Broadcast via Ground or Aircraft	1.0549 lb ae/A	NS	NS	NS	PHI=14 days	Do not apply through any type of irrigation system. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. This pesticide is toxic to wildlife. Do not feed treated forage to dairy animals being finished for slaughter. Do not graze treated areas.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type and Equipment	Max. Single App. Rate (ae)	Max. Number Apps. at Max. Rate	Max. Number Apps. per Year/Crop Cycle	Max. Seasonal Rate (ae)	PHI, PGI, Pre-feeding Interval	Use Directions and Limitations
Endothall Dipotassium Salt (PC 038904)								
Agricultural Drainage Systems When Needed	40.3% SC/L [4581-204]	Water treatment - Surface or Subsurface-Injection Equipment or Sprayer	22.5 lbs ae/mile	NS	NS	NS	NS	Do not use treated water for spraying or irrigation within 25 days after treatment. Do not apply when drift is likely to occur. Do not contaminate water, food, or feed by storage or disposal.
Drainage Systems When Needed	40.3% SC/L [FL87000500]	Surface Water Treatment	3 ppm (L)	NS	NS	NS	NS	NS
	40.3% SC/L [GA95000600] [TN94000200] [NY98000200] [WA96000600]	Water treatment- Surface - Aerosol can, Aircraft, Sprayer Subsurface-Injection Equipment	57.6 lb ae/A					Do not contaminate water, food, or fed by storage or disposal
	10.1% G [FL98000300]	Surface Water Treatment- Spreader	3.564 ppm (L)/A					Do not use treated water for spraying or irrigation within 7 days after treatment. Do not contaminate water, food, or feed by storage or disposal.
Human Drinking Water Systems When Needed	40.3%SC/L [FL96001500]	Water Treatment Surface- Aerosol can, Aircraft Subsurface-Injection Equipment	57.6 lb ae/A	NS	NS	NS	NS	Do not contaminate water, food, or feed by storage or disposal. Do not contaminate water intended for irrigation or domestic purposes.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type and Equipment	Max. Single App. Rate (ae)	Max. Number Apps. at Max. Rate	Max. Number Apps. per Year/Crop Cycle	Max. Seasonal Rate (ae)	PHI, PGI, Pre-feeding Interval	Use Directions and Limitations
Irrigation Systems When Needed	40.3% SC/L [AL85000800]	Water Treatment	1 L	NS	NS	NS	NS	
	40.3% SC/L [GA950006000] [TN94000200] [NY98000200]	Water Treatment Surface - Aerosol can, Aircraft, Sprayer Subsurface-Injection Equipment	57.6 lb ae/A					Do not contaminate water, food, or feed by storage or disposal. Do not contaminate water intended for irrigation or domestic purposes. Do not use treated water for spraying or irrigation within 25 days after treatment. Do not apply when drift is likely to occur.
	40.3% SC/L [4581-204]							
Lakes/Ponds/ Reservoirs (with Human or Wildlife Use) When Needed	40.3% SC/L [FL87000500]	Surface Water Treatment	3 ppm (L)	NS	NS	NS	NS	NS
	40.3% SC/L [GA95000600] [TN94000200] [SC93000100] [4581-204] [NY98000200] [TX99000200] [WA96000600]	Water Treatment Surface-Aerosol Can, Aerial, Sprayer Subsurface Treatment	57.6 lb ae/A					Do not contaminate water, food, or feed by storage or disposal. Do not contaminate water intended for irrigation or domestic purposes. Do not use treated water for spraying or irrigation within 25 days of treatment. Do not apply when drift is likely to occur.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type and Equipment	Max. Single App. Rate (ae)	Max. Number Apps. at Max. Rate	Max. Number Apps. per Year/Crop Cycle	Max. Seasonal Rate (ae)	PHI, PGI, Pre-feeding Interval	Use Directions and Limitations
	63% G [4581-388] [NY99000300] [NY99000300]	Surface Water Treatment-Broadcast, Granule Applicator	49.17 lb ae/A					Do not contaminate water, food, or feed by storage or disposal. Do not contaminate water intended for irrigation or domestic purposes. Do not use treated water for spraying or irrigation within 7 days of treatment. Do not apply when drift is likely to occur.
	10.1% G [4581-201] [FL98000300 (max 3.564 lb ae/A)]	Surface Water Treatment-Spreader, Granular Applicator	58.104 lb ae/A					Do not use treated water for spraying or irrigation within 7 days after treatment. Do not apply when drift is likely to occur. Do not contaminate water, food, or feed by storage or disposal.
Streams/ Rivers/ Channeled Water When Needed	40.3% SC/L [FL87000500]	Surface Water Treatment	3 ppm (L)	NS	NS	NS	NS	NS
	40.3% SC/L [WA96000600]	Water Treatment Surface-Sprayer Subsurface-	57.6 lb ae/A					Do not contaminate water, food, or feed by storage or disposal. Do not contaminate water intended for irrigation or domestic purposes.
	10.1% G [FL98000300]	Surface Water Treatment	3.564 ppm (ae) A					Do not use treated water for spraying or irrigation within 7 days after treatment. Do not contaminate water, food, or feed by storage or disposal.
Swamps/ Marshes/ Wetlands/	40.3 % SC/L [FL87000500]	Surface Water Treatment	3 ppm (L)	NS	NS	NS	NS	Do not contaminate water, food, or feed by storage or disposal. Do not contaminate water intended

Site Application Timing	Formulation [EPA Reg. No.]	App. Type and Equipment	Max. Single App. Rate (ae)	Max. Number Apps. at Max. Rate	Max. Number Apps. per Year/Crop Cycle	Max. Seasonal Rate (ae)	PHI, PGI, Pre-feeding Interval	Use Directions and Limitations
Stagnant Water When Needed	40.3% SC/L [WA96000600]	Water Treatment Surface-Sprayer Subsurface	57.6 lb (ae) A					for irrigation or domestic purposes.
Endothall N, N-dimethylalkylamine Salt (PC 038905)								
Agricultural Drainage Systems	53% RTU [AL81000900]	Water Treatment	15.12 lb ae/A-ft	NS	NS	NS	NS	Apply to not more than 10 percent of surface area of water.
	53 % SC/L [IN80000800]		0.2 ppm (L)					NS
Alfalfa Foliar	15.9% SC/L [CA87003100] [NV87000800]	Broadcast	1.0549 lb ae/A	NS	NS	NS	NS	Grown for seed only. Do not use treated seed for feed, food or oil purposes.
	15.9% SC/L [ID87001900] [WA87003600]	Broadcast-Ground, Aerial	0.6593 lb ae/A					

Site Application Timing	Formulation [EPA Reg. No.]	App. Type and Equipment	Max. Single App. Rate (ae)	Max. Number Apps. at Max. Rate	Max. Number Apps. per Year/Crop Cycle	Max. Seasonal Rate (ae)	PHI, PGI, Pre-feeding Interval	Use Directions and Limitations
	53% SC/L [4581-381] [AZ98000900]	Ground-Spray	1.5 qt/L (1.001 lb ae/A for AZ98000 9000					Do not apply through any type of irrigation system. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. This pesticide is toxic to wildlife. Do not use treated seed for feed, food or oil purposes. Do not graze treated areas. Do not feed forage to dairy animals or to animals being finished for slaughter. Grown for seed only. Keep out of lakes, streams, and ponds.
	53% SC/L [4581-381]	Aircraft- Low Volume Spray	0.7507 lb ae/A					
Alfalfa Pre-harvest	53% SC/L [WA98002900] [ID98001300] [NV98000200] [CA99000300]	Aerial-Spray Ground-Spray	1.001 lb ae/A					Grown for seed only. Do not apply through any type of irrigation system. Keep out of lakes, streams, and ponds. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. This pesticide is toxic to wildlife. Do

Site Application Timing	Formulation [EPA Reg. No.]	App. Type and Equipment	Max. Single App. Rate (ae)	Max. Number Apps. at Max. Rate	Max. Number Apps. per Year/Crop Cycle	Max. Seasonal Rate (ae)	PHI, PGI, Pre-feeding Interval	Use Directions and Limitations
								not use treated seed for feed, food or oil purposes. Do not graze treated areas. Do not feed forage to dairy animals or to animals being finished for slaughter.
Clover Foliar	53% SC/L [4581-381]	Aircraft-Low Volume Spray Ground-Spray	0.7507 lb ae/A	NS	NS	NS	NS	Do not apply through any type or irrigation system. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal or equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. This pesticide is toxic to wildlife. Do not use treated seed for feed, food or oil purposes. Do not graze treated areas. Do not feed forage to dairy animals or to animals being finished for slaughter.
Commercial/ Industrial Water Cooling Systems When Needed	53% SC/L [4581-380]	Water Treatment-Metering Pump	3.0-0.3 ppm endothall technical	NS	NS	NS	NS	Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW). Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water

Site Application Timing	Formulation [EPA Reg. No.]	App. Type and Equipment	Max. Single App. Rate (ae)	Max. Number Apps. at Max. Rate	Max. Number Apps. per Year/Crop Cycle	Max. Seasonal Rate (ae)	PHI, PGI, Pre-feeding Interval	Use Directions and Limitations
								(NPDES license restriction). This product is toxic to fish.
Cotton Pre-harvest	15.9% SC/L [TX81003200]	Aerial or ground Spray	0.1319 lb ae/A	NS	NS	NS	PHI= 3 Days	Do not apply through any type of irrigation system. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. This pesticide is toxic to wildlife.
Drainage Systems When Needed	53% RTU [AL81000900] [FL77000100]	Surface Treatment-Aerial, Boat Injection Equipment (max 11.2 lb ae/A-ft)	15.12 lb ae/A-ft	NS	NS	NS	NS	Apply to not more than 10 percent of surface area of water.
	53% SC/L [1448-352]	Surface Treatment-Injection Equipment, Ground (Sprayer)	3.1536 lb ae/A-ft					Do not use treated water for domestic purposes until 25 days after treatment. Do not use treated water for spraying or irrigation within 25 days after treatment. Do not use treated

Site Application Timing	Formulation [EPA Reg. No.]	App. Type and Equipment	Max. Single App. Rate (ae)	Max. Number Apps. at Max. Rate	Max. Number Apps. per Year/Crop Cycle	Max. Seasonal Rate (ae)	PHI, PGI, Pre-feeding Interval	Use Directions and Limitations
	53% SC/L [4581-174] [TX99000600]		13.51 lb ae/A-ft					water for animal consumption within 25 days after treatment. Do not apply when drift is likely to occur. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. Do not use where fish are important resources.
	11.2% G [4581-172]	Water Treatment-Aerial, Ground	13.5 lb ae/A-ft					Do not apply when drift is likely to occur. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. Do not contaminate water intended for irrigation or domestic purposes.
Hops Foliar	15.9% SC/L [ID87001500] [WA87001100] [OR87000400]	Basal Spray Treatment	0.3459 lb ae/A	NS	2	NS	PHI= 28 Days	
Industrial Processing Water When Needed	53% SC/L [4581-380]	Water Treatment-Metering Pump	3.0-0.3 ppm endothall technical	NS	NS	NS	NS	Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW). Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). This pesticide is toxic to fish. Do not contaminate water, food, or feed by storage or disposal.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type and Equipment	Max. Single App. Rate (ae)	Max. Number Apps. at Max. Rate	Max. Number Apps. per Year/Crop Cycle	Max. Seasonal Rate (ae)	PHI, PGI, Pre-feeding Interval	Use Directions and Limitations
Irrigation Systems When Needed	53% RTU [AL81000900] [FL77000100]	Surface Treatment-Aerial, Boat Injection Equipment (max. 11.2 lb ae/A-ft)	15.2 lb ae/A-ft	NS	NS	NS	NS	Apply to not more than 10 percent of surface area of water.
	53% SC/L [IN8000800] [AZ79001000]	Water Treatment	0.2 ppm (L)					NS
	53% SC/L [4581-174] [TX99000600] [1448-352] (max. 3.1536 lb ae/A-ft)	Injection Equipment, Sprayer	13.51 lb ae/A-ft					Do not use treated water for domestic purposes until 25 days after treatment. Do not use treated water for spraying or irrigation within 25 days after treatment. Do not use treated water for animal consumption within 25 days after treatment. Do not apply when drift is likely to occur. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. Do not use where fish are important resources.
	11.2% G [4581-172]	Water Treatment-Aerial, Ground	13.5 lb ae/A-ft					Do not apply when drift is likely to occur. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. Do not contaminate water intended for irrigation or domestic purposes.

Site Application Timing	Formulation [EPA Reg. No.]	App. Type and Equipment	Max. Single App. Rate (ae)	Max. Number Apps. at Max. Rate	Max. Number Apps. per Year/Crop Cycle	Max. Seasonal Rate (ae)	PHI, PGI, Pre-feeding Interval	Use Directions and Limitations
Lakes/Ponds/ Reservoirs (With Human or Wildlife Use) When Needed	53% RTU [FL77000100] [AL81000900]	Surface Water Treatment-Aerial, Boat Injection Equipment (max. 11.2 lb ae/A-ft)	15.12 lb ae/A-ft	NS	NS	NS	NS	Apply to not more than 10 percent of surface area of water.
	53% SC/L [4581-174]	Surface Water Treatment-Sprayer	8.008 lb ae/A-ft					Apply to not more than 10 percent of surface water. Do not use treated water for domestic purposes until 25 days after treatment. Do not use treated water for spraying or irrigation within 25 days after treatment. Do not use treated water for animal consumption within 25 days after treatment. Do not apply when drift is likely to occur. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. Do not use where fish are important resources.
	53% SC/L [1448-352]	Surface/Subsurface Treatment-Sprayer, Injection Equipment	1.588 lb ae/A-ft					
	53% SC/L [TX99000600]		6.807 lb ae/A-ft					
	11.2% G [TX99000500] [4581-172]	Water Treatment-by hand	162 lb/A-ft (L)					Buffer zone restriction (600 feet) on TX SLN. Do not contaminate water, food, or feed by storage or disposal. Do not apply when drift is likely to occur. This product is toxic to fish. Do not contaminate water intended for irrigation or domestic purposes.
Potato	53% SC/L	Aerial-Low	1.001 lb	NS	1	NS	PHI=14	Do not apply through any type or

Site Application Timing	Formulation [EPA Reg. No.]	App. Type and Equipment	Max. Single App. Rate (ae)	Max. Number Apps. at Max. Rate	Max. Number Apps. per Year/Crop Cycle	Max. Seasonal Rate (ae)	PHI, PGI, Pre-feeding Interval	Use Directions and Limitations
(White/Irish) Foliar	[4581-381]	Volume Spray Ground-Spray	ae/A				Days	irrigation system. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. This product is toxic to fish. Do not contaminate water, food, or feed by storage or disposal. This pesticide is toxic to wildlife. Do not graze treated areas. Do not feed forage to dairy animals or animals being finished for slaughter.
Swamps/Marshes/Wetlands/Stagnant Water When Needed	11.2% G [TX99000500]	Water Treatment-Hand Application	162 lb ae/A-ft (L)	NS	NS	NS	NS	Buffer zone restriction (600 feet). Do not contaminate water, food, or feed by storage or disposal.

B. Generic Data Requirements and Studies Used to Make the Reregistration Decision

Guide to Appendix B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case 2245 Endothall covered by this RED. It contains generic data requirements that apply to Endothall in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

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

2. Use Pattern (Column 4). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

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

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

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	A, B, E, F, G	41616401
830.1600	61-2 A	Description of Starting Material	A, B, E, F, G	41616401, 43873901, 43873902
830.1620	61-2 B	Description of Production Process	A, B, E, F, G	41616401, 43873901, 43783902
830.1670	61-2 B	Discussion of Formation of Impurities	A, B, E, F, G	41616401, 43873901, 43873902
830.1700	62-1	Preliminary Analysis	A, B, E, F, G	41616402, 42427901, Data Gap for 4581-204, 4581-174, 4581-380, 4581-381
830.1750	62-2	Certified Limits	A, B, E, F, G	41616402
830.1800	62-3	Enforcement of Analytical Method	A, B, E, F, G	41616402, 42427901
830.6302	63-2	Color	A, B, E, F, G	42629701, 42629901, 42629801
830.6303	63-3	Physical State	A, B, E, F, G	42629701, 42629901, 42629801
830.6304	63-4	Odor	A, B, E, F, G	42629701, 42629901, 42629801
830.6313	63-13	Stability	A, B, E, F, G	43265001, 43264901, 43265101, Data Gap for 4581-174, 4581-380, 4581-381, 4581-204
830.7000	63-12	pH	A, B, E, F, G	42629701, 42629901, 42629801
830.7200	63-5	Melting Point	A, B, E, F, G	42629701, 42629901, Data Gap for 4581-174, 4581-380, 4581-381
830.7220		Boiling Point	A, B, E, F, G	Data Gap for 4581-174, 4581-380, 4581-381
830.7300	63-7	Density	A, B, E, F, G	42629701, 42629901, 42629801
830.7550/ 7560/757 0	63-11	Partition Coefficient	A, B, E, F, G	43472803, 43441501
830.7370	63-10	Dissociation Constant	A, B, E, F, G	42668001, 42787702, 43081301
830.7840/ 7860	63-8	Water Solubility	A, B, E, F, G	41622801, 43339301, 43551701, 43472802
830.7950	63-9	Vapor Pressure	A, B, E, F, G	41622802, 43319601
830.7050	None	UV/Visible Absorption	A, B, E, F, G	Data Gap for 4581-257, 4581-204, 4581-174, 4581-380, 4581-381
ECOLOGICAL EFFECTS				

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
850.4100	122-1A	Seedling Emergence	A, B, E, F, G	
850.4150	122-1B	Vegetative Vigor	A, B, E, F, G	
850.4230	123-1	Early Seedling Growth Toxicity	A, B, E, F, G	
850.2100	71-2	Avian Acute Dietary Toxicity	A, B, E, F, G	43167701, 43167702, 43167801, 43167802, 43167901,43167902, 00035240, 00035241, 00116270, 00116271, 00035238, 00035239
850.2100	71-1	Avian Acute Oral Toxicity	A, B, E, F, G	0160000, 42359501, 00035237, 42359701*, 00074220*, 42359601*
850.2300	71-4	Avian Reproduction	A, B, E, F, G	42507301, 42507302*, Data Gap for N,N-dimethylalkylamine
850.1075	72-1	Freshwater Fish Acute Toxicity	A, B, E, F, G	442327701, 42327702, 40098001, 40094602, 00068507*, 114510*, 113971*, 43472801, 00084149, 00084148, 0084147, 00007113, 43196901, 00046269*, 00071148*00083025*, 42695401, 42695402, 00071134*
850.1010	72-2A	Freshwater Invertebrate Acute Toxicity Test	A, B, E, F, G	42359702, 42695403, 00035242, 00074221, 00074222, 00074227*, 00074228*, 43196902*, 05009242, 40098001, 00071137*, 00115863*, 00017800*, 00084150*, 00084151
850.1075	72-3 A	Estuarine/Marine Fish Acute Toxicity Test	A, B, E, F, G	42914102, 42695405, 43196903, 00074225, 44700401*, 00074226, 40098001
		Estuarine/Marine Invertebrate Acute Toxicity	A, B, E, F, G	00074223*, 0074224*, 42895201, 42914101, 43210001, 00035243, 00035244*, 43550201, 42695406, 42695404
850.1350		Estuarine/Marine Invertebrate Early Life Stage Study		Data Gap for N,N-dimethylalkylamine
850.1025	72-3B	Estuarine/Marine Toxicity - Mollusk	A, B, E, F, G	42895201, 42695404, 43550201
	72-3C	Estuarine/Marine Toxicity - Shrimp	A, B, E, F, G	42914101, 42695046, 43210001
850.1400	72-4A	Freshwater Fish Early Life-Stage Test	A, B, E, F, G	43295401, 00095812, 43276501, Data Gap for N,N-dimethylalkylamine
850.1500		Freshwater Fish Life Cycle Test		Data Gap for N,N-dimethylalkylamine
	72-4C	Freshwater Invertebrate Life-Cycle Test	A, B, E, F, G	43007801, 43437901
850.1735		Freshwater Acute Sediment Test		Data Gap for N,N-dimethylalkylamine
850.1400		Estuarine/Marine Acute Sediment Test		Data Gap for N,N-dimethylalkylamine

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
EPA/600/ R01/020		Chronic Estuarine/Marine Sediment Testing		Data Gap for N,N-dimethylalkylamine
EPA/600/ -99/064		65-day Test in Chironomous Tentans		Data Gap for N,N-dimethylalkylamine
Non-Guideline	Non-Guideline	Acute Toxicity to Amphibians		40098001
850.3020	141-1	Honey Bee Acute Contact Toxicity	A, B, E, F, G	44038201
850.4400	122-2	Aquatic Plant Growth	A, B, E, F, G	41613809, 44392802
850.4225	123-1A	Seedling Germination/ Seedling Emergence (Tier II)	A, B, E, F, G	42396405, 43870401, 44392803, 44127801
850.4250	123-1B	Vegetative Vigor (Tier II)	A, B, E, F, G	42396405, 43870401
		Aquatic Plant Toxicity (Tier I)	A, B, E, F, G	41613809, 42396401*,42396402*, 42396404, 42396403*, 44392801, 44392802
850.4400	123-2	Aquatic Plant Toxicity (Tier II)	A, B, E, F, G	42396406, 44949402, 44949203, 44127802*, 44127803*, 44127805*, 44127804*, 4427806*, 44976701, 44949202, 44949201, Acc. 244122*, 44408801
OCCUPATIONAL/RESIDUE EXPOSURE				
875.1600	236	Application Exposure Monitoring Data Reporting		44972201, 45250701
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity-Rat	A, B, E, F, G	42289201
N/A	N/A	Maximum Tolerated Oral Dose Toxicity - Dog	A, B, E, F, G	40745201
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	A, B, E, F, G	42289202
870.1300	81-3	Acute Inhalation Toxicity-Rat	A, B, E, F, G	42169501, 42408701
870.2400	81-4	Acute Eye Irritation - Rabbit	A, B, E, F, G	42289203
870.2500	81-5	Acute Dermal Irritation	A, B, E, F, G	42289204 (unacceptable)
870.2600	81-6	Dermal Sensitization	A, B, E, F, G	41871901

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
870.3100	82-1A	90-Day Feeding - Rodent	A, B, E, F, G	43480810
870.3150	82-1B	90-Day Feeding - Non-rodent	A, B, E, F, G	43480801, 43480802
870.3200	82-2	21-Day Dermal - Rabbit/Rat	A, B, E, F, G	42814101, 43465201
870.3465		28-day Inhalation		Data Gap
870.4100 B	83-1B	Chronic Feeding Toxicity - Non-Rodent	A, B, E, F, G	40745202
870.3700	83-3A	Prenatal Developmental Toxicity - Rat	A, B, E, F, G	42776301
870.4200	83-2B	Oncogenicity - Mouse	A, B, E, F, G	40685301, 43608301
870.3700	83-3B	Developmental Toxicity - Rabbit	A, B, E, F, G	Data Gap
870.3800	83-4	2-Generation Reproduction - Rat	A, B, E, F, G	43152101, 43629301
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity	A, B, E, F, G	41040301
870.5300	84-2	Gene Mutation (In vitro)	A, B, E, F, G	43437801
870.5100	84-2	Bacterial Gene Mutation Assay	A, B, E, F, G	43154801 (unacceptable)
870.5375	84-2B	*In vitro* Mammalian Cytogenetics	A, B, E, F, G	41700302
870.5395	84-2	*In vivo* Cytogenetics - Micronucleus Assay in Mice	A, B, E, F, G	43157401, 41700301
870.7485	85-1	Metabolism and pharmacokinetics	A, B, E, F, G	42169502, 44263501, 42200101
870.7600	85-3	Dermal Penetration	A, B, E, F, G	42169503
ENVIRONMENTAL FATE				
		Dissociation - Non-guideline	A, B, E, F, G	42668008, 43551501, 43081301
NONE	201-1	Droplet Size Spectrum	A, B, E, F, G	42427601
835.2120	161-1	Hydrolysis	A, B, E, F, G	44578401, 42289106
835.4100	162-1	Aerobic Soil Metabolism	A, B, E, F, G	44949401
835.4400	162-3	Anaerobic Aquatic Metabolism	A, B, E, F, G	42903901

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
835.4300	162-4	Aerobic Aquatic Metabolism	A, B, E, F, G	42618901
835.2240	161-2	Aqueous Photolysis	A, B, E, F, G	42289205, 42289205, 42289205, 42641201, Acc 259367
835.1230	163-1	Sediment and Soil Adsorption/ Desorption for Parent and Degradates	A, B, E, F, G	41616404
835.6100	164-1	Terrestrial Dissipation	A, B, E, F, G	42670101, 42670201
835.6200	164-2	Aquatic Field Dissipation	A, B, E, F, G	44093403, 44093402, 44820103, 44828802, 44828801, 44820101
NONE	165-4	Bioconcentration in Fish	A, B, E, F, G	42644001, 43315801
RESIDUE CHEMISTRY				
860.1300	171-4A	Nature of Residue - Plants	A, B, E, F, G	00040978, 00108102, 00113954, 00113965, 42619201, 42619202, 42619203, 43346601, 44077801
860.1300	171-4B	Nature of Residues - Animals	A, B, E, F, G	00035451, 00035452, 00113928, 00113963, 00133190, 42792701, 42816601
860.1340	171-4C	Residue Analytical Method -Plants	A, B, E, F, G	45156001, 44320401, 44320402, 44320403, 44322001, 44322002, Data Gap for conversion of monomethyl ester to endothall
860.1340	171-4D	Residue Analytical Method-Animal	A, B, E, F, G	45156001, Data Gap for conversion of monomethyl ester to endothall Data collection and regulatory analytical methods are needed for the determination of endothall, per se, in animal commodities
860.1340		Independent Laboratory Validation	A, B, E, F, G	Submission of analytic reference standards for dipotassium and mono-N,N-dimethylalkylamine salts of endothall are needed
860.1360	171-4M	Multi-residue Method	A, B, E, F, G	44608601
860.1850	165-1	Confined Rotational Crop		43300701, Data Gap
860.1340				Data Gap - Independent Laboratory Validation (ILV) of an enforcement method for the determination of endothall and its monomethyl ester in fish is needed to support proposed tolerances on fish.

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
860.1380	171-4E	Storage Stability	A, B A, B, E, F, G	43975901, 44077801, 44106301, 44263502, 44263503, 44263504, 44263505, 44274401, 45146302, Data Gap for additional studies on processed plant commodities, animal commodities, and fish.
860.1400	171-4H	Magnitude of Residue in Irrigated Crops	A, B, E, F, G	44343101, 44263506, 44334301, 44263508, 44263507, Data Gap
860.1480	171-4J	Magnitudes of residues in Meat, Milk, Poultry, Eggs Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses and Sheep Eggs and the Fat, Meat, and Meat Byproducts of Poultry	A, B, E, F, G	Data Gap
860.1400	171-4G	Magnitude of Residues in Fish	A, B, E, F, G	44820102, 43315801
860.1650	171-13	Analytical Reference Standards	A, B, E, F, G	Data Gap
860.1500	171-4K	Crop Field Trials	A, B	43953101, 45146301, 43975901, 44103701, 44037402, 45034701, 43953101
860.1520	171-4L	Processed Food/Feed	A, B,	44093401, 44012101, 45146302, 44037401, Data Gap (potato, alfalfa seed, cottonseed, and cotton gin products, apples, field corn, grapes, orange, rice, sorghum, soybeans, sugar beet, tomato, and wheat)

C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP Regulatory Docket, located in Room 119, Crystal Mall #2, 1801 South Bell Street, Arlington, VA 22202-4501. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4:00 pm.

The docket initially contained preliminary human health and ecological effects risk assessments and related documents that were published May 11, 2005. The public comment period closed sixty (60) days later on July 11, 2005. The EPA then considered comments and revised the risk assessments where appropriate. Final human health and ecological risk assessments, as well as additional support documents, will be published in the docket with this RED. These documents include:

Phase 3 Public Comment Documents:

1. Environmental Fate and Ecological Risk Assessment for Endothall-Revised, dated April 22, 2005

2. Environmental Fate and Effects Division Error-Only Corrections of the Endothall RED, dated April 22, 2005

3. Endothall: HED Chapter for the Reregistration Eligibility Decision Document (RED), dated April 18, 2005

4. Endothall- Report of the Hazard Identification Assessment Review Committee, dated June 14, 2004

5. Endothall-Report of the Health Effects Division (HED) Risk Assessment Review Committee (RARC), dated November 4, 2004

6. Drinking Water Assessment for Endothall for both Terrestrial and Aquatic Uses, dated May 5, 2004

7. Endothall and its salts: Chronic Dietary Exposure Assessment for the Reregistration Eligibility Decision. Revised per Registrant Corrections, dated April 11, 2005

8. Endothall and its salts: Residue Chemistry Considerations for Reregistration Eligibility Decision. Revised per Registrant Comment for Error Only, dated April 11, 2005

9. Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Endothall, dated April 1, 2005

10. Occupational and Residential Exposure Assessment-Response to Registrant's Error-Only Comments, dated March 18, 2005

11. Endothall and Salts: Occupational and Residential Exposure Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision, dated March 3, 2005

12. Ecological Risk from Antimicrobial Uses of Endothall to be Considered in the RED Document, dated January 12, 2005

13. Review of Endothall (and salts) Incident Reports, dated June 24, 2005

Final Risk Assessments and Additional Supporting Documents:

1. Endothall: HED Chapter of the Reregistration Eligibility Decision Document (RED). Corrected Following Public Comments, dated September 30, 2005

2. Endothall: HED Response to Public Comments, dated August 26, 2005

3. Environmental Fate and Effects Division Response to Public Comment for the Endothall RED, dated August 6, 2005

4. Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Endothall, dated August 12, 2005

5. Amended Response to a Submitted Dietary Exposure Assessment and a Comment on Fish Consumption in the US, dated July 25, 2005

6. Response to the Four Residue Chemistry Comments from Cerexagri in their "Response to the EPA's RED Comments for Endothall," dated August 30, 2005

7. Endothall and its Salts. Residue Chemistry Considerations for Reregistration Eligibility Decision. Revised per Registrant Comments, dated August 30, 2005

8. Endothall: Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision Document (RED), dated December 21, 2004

9. Endothall, Acute Mammalian Toxicity Batching Appendix for Endothall RED Document, dated September 21, 2005

10. Meeting with Army Corp of Engineers, Meeting Minutes, dated July 27, 2005

11. Revised Endothall and Salts: Occupational and Residential Exposure Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision Document, dated September 28, 2005

12. Addendum to Chronic Dietary Risk Assessment, dated September 29, 2005

13. Closure Call Meeting Minutes, dated September 26, 2005

14. Addendum to Drinking Water Assessment, dated September 29, 2005

D. Bibliography

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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69049	Pennwalt Corporation (1979) Phytotoxicity Summary. (Compilation; unpublished study received Jan 23, 1981 under 1F1105; CDL: 099882-A)	23-Jan-1981
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71136	Vilkas, A.G.; Seminara, J. (1979) The Acute Toxicity of Hyd- out(TM) Aquatic Weed Killer Code AHE 09H901, N.B. No. 84-112-1 to the Bluegill Sunfish, Lepomis macrochirus Rafinesque: UCES Project No. 11506-41-19. (Unpublished study, including letter dated Feb 7, 1980 from O. Keckemet to Agchem File, received Jan 23, 1981 under 4581-174; prepared by Union Carbide Corp., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:244131-H)	23-Jan-1981
71139	Vilkas, A.G.; Browne, A.M. (1979) The Acute Toxicity of Hydout (22.6% Active) (Sample Code 84-112-1; Lot AHE 09H9-01) to the Water Flea Daphnia magna Straus: UCES Project No. 11506-41-22. (Unpublished study, including letter dated Feb 7, 1980 from O. Keckemet to Agchem File, received Jan 23, 1981 under 4581- 174; prepared by Union Carbide Corp., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:244131-K)	23-Jan-1981
71140	Vilkas, A.G.; Seminara, J. (1980) The Acute Toxicity of Hydout, 22.6% Active Ingredient to the Grass Shrimp Palaemonetes pugio: USES Project No. 11506-41-23. (Unpublished study, including letter dated Feb 7, 1980 from O. Keckemet to Agchem File, received Jan 23, 1981 under 4581-174; prepared by Union Carbide Corp., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:244131-M)	23-Jan-1981
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71144	Vilkas, A.G.; Seminara, J. (1980) The Acute Toxicity of Hydout, 22.6% Active Ingredient to the Common Mummichog Fundulus heteroclitus (Linnaeus): UCES Project No. 11506-41-21. (Unpublished study, including letter dated Feb 7, 1980 from O. Keckemet to Agchem File, received Jan 23, 1981 under 4581-174; prepared by Union Carbide Corp., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:244131-Q)	23-Jan-1981
71146	Hestand, R.S., III (1974) Letter sent to Johnnie L. Frizzell dated Sep 27, 1974 Rough data on efficacy and toxicity of TD-1874 and Hydrothol 191. (Florida, Game and Fresh Water Fish Comission; unpublished study, including letter dated Sep 26, 1974 from R.S. Hestand, III to Johnnie L. Frizzell; CDL:244131-T)	23-Jan-1981
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72459	Vilkas, A.G.; Seminara, J. (1979) The Acute Toxicity of Hyd-out Aquatic Weed Killer Code AHE 09H901, N.B. No. 84-112-1 to the Bluegill Sunfish Lepomis macrochirus Rafinesque: UCES Project No. 11506-41-19. (Unpublished study, including letter dated Feb 7, 1980 from O. Keckemet to Agchem File, received Jan 23, 1981 under 1F1105; prepared by Union Carbide Corp., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:099883-H)	23-Jan-1981
72460	Vilkas, A.G.; Hughes, J.S. (1979) The Acute Toxicity of Endothall (Acid Monohydrate) to the Water Flea Daphnia magna Straus: UCES Project No. 11506-41-09. (Unpublished study received Jan 23, 1981 under 1F1105; prepared by Union Carbide Corp., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:099883-I)	23-Jan-1981
72461	Vilkas, A.G.; Browne, A.M. (1979) The Acute Toxicity of Hydout (22.6% Active) (Sample Code 84-112-1; Lot AHE 09H9-01) to the Water Flea Daphnia magna Straus: UCES Project No. 11506-41-22. (Unpublished study received Jan 23, 1981 under 1F1105; prepared by Union Carbide Corp., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:099883-K)	23-Jan-1981
72462	Vilkas, A.G.; Seminara, J. (1980) The Acute Toxicity of Hydout, 22.6% Active Ingredient to the Grass Shrimp Palaemonetes pugio: UCES Project No. 11506-41-23. (Unpublished study, including letter dated Feb 7, 1980 from O. Keckemet to Agchem File, received Jan 23, 1981 under 1F1105; prepared by Union Car- bide Corp., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL: 099883-M)	23-Jan-1981
72463	Vilkas, A.G.; Seminara, J. (1979) The Acute Toxicity of Hyd-out Aquatic Weed Killer Code AHE 09H901, N.B. No. 84-112-1 to the Fiddler Crab, Uca pugilator: UCES Project No. 11506-41- 24. (Unpublished study, including letters dated Feb 7, 1980 from O. Keckement to Agchem File and Jan 18, 1980 from A.G. Vilkas to B.D. McGaughey, received Jan 23, 1981 under 1F1105; prepared by Union Carbide Corp., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:099883-N)	23-Jan-1981
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72550	Pennwalt Corporation (1980) Efficacy Introduction: Hydout Aquatic Algicide and Herbicide. (Compilation; unpublished study received Jan 23, 1981 under 4581-EX-32; CDL:244117-A)	23-Jan-1981
73370	Moreno, M.T.; Moreno, O.M. (1979) Test for Guinea Pig Sensitiza - tion: Project No. MB 79-4140. (Unpublished study, including letter dated Dec 19, 1979 from O.M. Moreno to Obren Keckemet, received Jan 23, 1981 under 4581-174; prepared by MB Research Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:244123-C)	23-Jan-1981
74221	Vilkas, A.G.; Browne, A.M. (1979) The Acute Toxicity of Hydout (22.6% Active) (Sample Code 84-112-1; Lot AHE 09H9-01) to the Water Flea Daphnia magna Straus: UCES Project No. 11506-41-22. (Unpublished study, including letter dated Feb 7, 1980	23-Jan-1981

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74223	Vilkas, A.G.; Seminara, J. (1979) The Acute Toxicity of Hy-dout Aquatic Weed Killer, Code AHE 09H901, N.B. No. 84- 112-1, to the Fiddler Crab, Uca pugilator: UCES Project No. 11506-41-24. (Unpublished study, including letters dated Jan 18, 1980 from A.G. Vilkas to B.D. Mc Gaughey and Feb 7, 1980 from O. Keckemet to Agchem File, received Jan 23, 1981 under 4581-282; prepared by Union Carbide Corp., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:244122-N)	23-Jan-1981
74226	Vilkas, A.G.; Seminara, J. (1980) The Acute Toxicity of Hydout, 22.6% Active Ingredient, to the Common Mummichog Fundulus heteroclitus (Linnaeus): UCES Project No. 11506-41-21. (Unpublished study, including letter dated Feb 7, 1980 from O. Keckemet to Agchem File, received Jan 23, 1981 under 4581-282; prepared by Union Carbide Corp., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:244122-Q)	23-Jan-1981
74229	U.S. Department of the Interior, Bureau of Reclamation (1964) Results of Algaecidal Evaluation Tests of Selected Compounds: Report No. WC-21. (Unpublished study; CDL:244122-U)	23-Jan-1981
78180	Latven, A.R. (1975) Letter sent to Obren Keckemet dated Nov 18, 1975 Toxicology reports on seven products. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Pharmacology Research, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-B)	05-Jan-1978
78182	Latven, A.R. (1975) Toxicology Report for Pennwalt, Agchem Division: Accelerate (N.B. 58-196-3). (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Pharmacology Research, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL: 232580-D)	05-Jan-1978
78188	Latven, A.R. (1975) Toxicology Report for Pennwalt, Agchem Division: Ripenthol N.B. 58-188-3 (Isopropyl-butanol Formulation). (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Pharmacology Research, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-K)	05-Jan-1978
78189	Latven, A.R. (1975) Toxicology Report for Pennwalt, Agchem Division: Ripenthol N.B. 58-191-2 (Water Only Formulation). (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Pharmacology Research, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-L)	05-Jan-1978
78190	Latven, A.R. (1975) Toxicology Report for Pennwalt, Agchem Division: Ripenthol N.B. 58-191-2 (23.4%). (Unpublished study, including letter dated Aug 14, 1975 from A.R. Latven to Obren Kechemet, received Jan 5, 1978 under 4581-174; prepared by Pharmacology Research, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-M)	05-Jan-1978
78191	Latven, A.R. (1976) Letter sent to Obren Keckemet dated Jan 29, 1976 Toxicological study reports on endothall products. (Un- published study received Jan 5, 1978 under 4581-174; prepared by Pharmacology Research, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-N)	05-Jan-1978
78192	Latven, A.R. (1976) Toxicology Report for Pennwalt, Agchem Division: Endothall Products, Dermal Toxicity after Limited Expo- sure. (Unpublished study received Jan 5,	05-Jan-1978

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78194	Latven, A.R. (1976) Toxicology Report For Pennwalt, Agchem Division: Hydout N.B. 77-23-6 (10.3% Endothall). (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Pharmacology Research, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-Q)	05-Jan-1978
78196	Latven, A.R. (1976) Toxicology Report for Pennwalt, Agchem Division: Accelerate N.B. 77-23-5 (5.5% Endothall). (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Pharmacology Research, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-S)	05-Jan-1978
78199	Latven, A.R. (1971) Toxicology Report for Pennwalt Corporation: Ac- celerate. (Unpublished study received Jan 5, 1978 under 4581- 174; prepared by Pharmacology Research, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-W)	05-Jan-1978
78200	Becker, J.; Parke, G.S.E. (1977) Report: The Acute Dermal LD50 of Hydrothol 191 Liquid (N.B. 77-100-2) on New Zealand Albino Rabbits: Laboratory No. 7E-5662. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL: 232580-X)	05-Jan-1978
78201	Terrell, Y.; Parke, G.S.E. (1977) Report on Oral LD50 in Rats: Lab- oratory No. 7E-5661. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-AA)	05-Jan-1978
78202	Wise, M.T. (1977) Acute Inhalation Toxicity of Aquathol K (N.B. 77-100-4); Hydrothol 191 Liquid (N.B. 77-100-2); Hydrothol 47 Liquid (N.B. 77-100-3); Aquathol (N.B. 77-99-7); Des-i-cate Accelerate (N.B. 77-99-6); Knox- out 2 FM (N.B. 4414-94): Laboratory Nos. 7E-5660; 7E-5665; 7F-5670; 7E-5675; 7E-5680; 7E-5685. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL: 232580-AB)	05-Jan-1978
78217	St. Pierre, F.; Parke, G.S.E. (1977) Report: A Primary Dermal Irritation Study of Hydrothol 191 Granular (N.B. 77-99-2) on Abraded and Non-abraded Skin of New Zealand Albino Rabbits: Laboratory No. 7E-5694. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-AS)	05-Jan-1978
78218	Becker, J.; Parke, G.S.E. (1977) Report: The Effects of Hydrothol 191 Granular (N.B. 77-99-2) on the Eye Mucosa of New Zealand Albino Rabbits: Laboratory No. 7E-5693. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-AT)	05-Jan-1978
78219	Becker, J.; Parke, G.S.E. (1977) Report: The Acute Dermal LD50 of Hydrothol 191 Granular (N.B. 77-99-2) on New Zealand Albino Rabbits: Laboratory No. 7E-5692. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL: 232580-AU)	05-Jan-1978
78220	Terrell, Y.; Parke, G.S.E. (1977) Report on Oral LD50 in Rats: Lab- oratory No. 7E-5691. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-AV)	05-Jan-1978
78603	St. Pierre, F.; Parke, G.S.E. (1977) Report: The Effects of Hydout (N.B. 77-99-5) on the Eye Mucosa of New Zealand Albino Rabbits: Laboratory No. 7E-5703. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL: 232580-BA)	05-Jan-1978
78604	St. Pierre, F.; Parke, G.S.E. (1977) Report: A Primary Dermal Irritation Study of Hydout	05-Jan-

	(N.B. 77-99-5) on Abraded and Non-abraded Skin of New Zealand Albino Rabbits: Laboratory No. 7E- 5704. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-BB)	1978
78605	Becker, J.; Parke, G.S.E. (1977) Report: The Acute Dermal LD50 of Hydout (N.B. 77-99-5) on New Zealand Albino Rabbits: Laboratory No. 7E-5702. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-BC)	05-Jan-1978
78606	Terrell, Y.; Parke, G.S.E. (1977) Report on Oral LD50 in Rats: Lab- oratory No. 7E-5701. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-BD)	05-Jan-1978
78607	St. Pierre, F.; Parke, G.S.E. (1977) Report: The Effects of Des-i-cate /Accelerate (N.B. 77-99-6) on the Eye Mucosa of New Zealand Albino Rabbits: Laboratory No. 7E-5678. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-BE)	05-Jan-1978
78608	Becker, J.; Parke, G.S.E. (1977) Report: The Acute Dermal LD50 of Des-i-cate /Accelerate (N.B. 77-99-6) on New Zealand Albino Rabbits: Laboratory No. 7E-5677. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL: 232580-BF)	05-Jan-1978
78609	Terrell, Y; Parke, G.S.E. (1977) Report on Oral LD50 in Rats: Laboratory No. 7E-5676. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-BG)	05-Jan-1978
78610	Zeigler, R.L. (1977) Acute Inhalation Toxicity of 1. Aquathol Granular (N.B. 77-99-4); 2. Hydrothol 191 Granular (N.B. 77-99-2); 3. Hydrothol 47 Granular (N.B. 77-99-3); 4. Hydout (N.B. 77-99-5): Laboratory Nos. 7E-5690; 7E- 5695; 7E-5700; 7E-5705. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-BH)	05-Jan-1978
78614	St. Pierre, F.; Parke, G.S.E. (1977) Report: A Primary Dermal Irritation Study of Des-i-cate /Accelerate (N.B. 77-99-6) on Abraded and Non-abraded Skin of New Zealand Albino Rabbits: Laboratory No. 7E-5679. (Unpublished study received Jan 5, 1978 under 4581-174; prepared by Cannon Laboratories, Inc., submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:232580-BM)	05-Jan-1978
80436	Pennsalt Chemicals Corporation (1966) Summary of Justification: Disodium Endothall. Summary of studies 090585-B through 090585-F. (Unpublished study received on unknown date under 6G0503; CDL:090585-A)	
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92061999	Agchem Division-Pennwalt Corp. (1990) Reregistration Phase 3 Response: Mono(N,N-dimethyl alkyl amine) endothall (7-ocabicyclo(2. 2. Correspondence and Supporting Material.	25-May-1990

E. Generic Data Call-In

Note that the complete Data Call-In (DCI), with all pertinent instructions, will be sent to registrants under separate cover.

F. Product Specific Data Call-In

Note that the complete Data Call-In (DCI), with all pertinent instructions, will be sent to registrants under separate cover.

G. EPA's Batching of Endothall Products for Meeting Acute Toxicity Data Requirements for Reregistration

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

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

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

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

(Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Ten products were found which contain Endothall as the active ingredient. These products have been placed into two batches and a no batch group in accordance with the active and inert ingredients and type of formulation.

Batching Instructions:

No Batch: Each product in this Batch should generate their own data. EPA Reg. No. 4581-204 may rely on acute data used to support batch 2.

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

Batch #	EPA Reg. No.	Percent Active Ingredient
1	4581-172	11.2
	4581-201	10.1
2	1448-352	53.0
	4581-174	53.0
	4581-380	53.0
	4581-381	53.0
No Batch	4581-204	40.3
	4581-257	75
	4581-284	15.9
	4581-388	63.0

H. List of Registrants Sent Data Call-Ins

Technical Registrants Sent Generic Data Call-In:

1. Cerexagri, Inc.

End-Use Registrants Sent Product Data Call-In

1. Cerexagri, Inc.
2. Buckman Laboratory, Inc.

I. List of Available Related Documents and Electronically Available Forms

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

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

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

Instructions

1. Print our and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer than printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below or the Document Processing Desk.

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

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf

8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit: www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

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

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program—Storage and Disposal Statements

   b. 84-1 Clarification of Label Improvement Program

   c. 86-5 Standard Format for Data Submitted under FIFRA

   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)

   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement

   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement

   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

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

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

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

   b. EPA Form No. 8570-4, Confidential Statement of Formula

c. EPA Form No. 8570-27, Formulator's Exemption Statement

d. EPA Form No. 8570-34, Certification with Respect to Citations of Data

e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

a. Registration Division Personnel Contact List

b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

c. Antimicrobials Division Organizational Structure/Contact List

d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

1. The Office of Pesticide Programs' Web Site

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

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

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager Assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition. To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.