



US Environmental Protection Agency Office of Pesticide Programs

Reregistration Eligibility Decision for Chlormequat Chloride

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Reregistration Eligibility Decision for Chlormequat Chloride

Reregistration Eligibility Decision (RED) Document for Chlormequat Chloride

List C

Case Number 3003

Approved by:

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Date:

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a
LD ₅₀	substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm. 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
LOD	Limit of Detection
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	Milligrams Per Liter
MOE	Margin of Exposure

MRID MUP	Master Record Identification (number) Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
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	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1^*	The Carcinogenic Potential of a Compound, Quantified by the EPA's
	Cancer Risk 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
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
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 (EPA or the Agency) decision regarding the reregistration eligibility of the registered uses of the active ingredient chlormequat chloride. The Agency has conducted human health and environmental fate and effects risk assessments and has determined that clormequat chloride-containing products are eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures.

Chlormequat chloride is a plant growth regulator (PGR) registered for use on ornamental plants grown in greenhouses, nurseries and shadehouses. As chlormequat chloride has no food/feed uses and no U.S. tolerances associated with its use, it is not subject to the Food Quality Protection Act of 1996.

The Agency concludes that there is no concern for potential acute or chronic dietary exposure from drinking water associated with the registered non-food uses of chlormequat chloride. All handler and postapplication occupational risks for chlormequat chloride are below the Agency's level of concern as well.

The Agency, using a screening level assessment, has identified potential ecological risks of concern associated with the current registered uses of chlormequat chloride for birds, amphibians, reptiles, mammals, and fish. To reduce these potential exposures and to address current risks of concern, the Agency has directed, and the registrant has agreed to prohibit the use of mechanical (tractor-drawn) multi-nozzle sprayer applications (groundboom), the application method of concern. The Agency is also requiring appropriate data to confirm the decision presented in this Reregistration Eligibility Decision (RED). Please see Appendix H for additional data required to support the outdoor uses of chlormequat chloride, including the groundboom application method.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all data submitted to the Environmental Protection Agency (hereafter referred to as EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of a pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. As chlormequat chloride has no food/feed uses and no U.S. tolerances associated with its use, it is not subject to the Food Quality Protection Act of 1996.

This document, consisting of five sections, presents the EPA decision regarding the reregistration eligibility of the registered uses of chlormequat chloride. Section I contains the regulatory framework for reregistration; Section II provides an overview of the chemical and a profile of its use and usage; Section III provides a reference to the human health and environmental fate and ecological risk assessments; and Section IV presents the Agency's decision on reregistration eligibility and risk management. Where labeling revisions are warranted, specific language is set forth in the summary table in Section V of this document. Finally, Section VI contains the appendices, which list related information, supporting documents, and studies evaluated for the reregistration decision. The risk assessments for chlormequat chloride and other supporting documents are available in the Office of Pesticide Program (OPP) public docket (http://www.regulations.gov) under docket number EPA-HQ-OPP-2007-0968

As a result of this review, the Agency has determined that all currently registered products containing the active ingredient chlormequat chloride are eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures.

II. Chemical Overview

Chlormequat chloride, [(2-chloroethyl) trimethylammonium chloride] is a plant growth regulator (PGR) that belongs to the quaternary ammonium class of chemicals. Chlormequat chloride works through inhibition of a plant hormone's biosynthesis, which is useful in regulating the growth characteristics of many plants. This early blockage prevents the synthesis of numerous plant hormones needed for normal plant growth and development. It is formulated as a soluble concentrate/liquid (SC/L). The product is applied to ornamental plants grown in greenhouses, nurseries and shadehouses. Outdoor use is restricted to containerized ornamentals. Table 1 includes a description of application methods and rates that are currently registered for chlormequat chloride.

Table 1. Chlormequat Chloride Use Patterns and Formulations				
Formulation	Use Site	Method of Application	Application Rate	Label Restrictions
CYCOCEL [®] Plant Growth Regulator - liquid (11.8% a.i.) For Commercial Use	Shadehouses and nurseries	foliar spray by low pressure handwand, backpack sprayer, or groundboom	 0.017 lb ai/gal (at 2,000 ppm) 3.7 lb ai/A (at 2,000 ppm and 1 gal/200 ft²) or 5.5 lb ai/A (at 2,000 ppm and 1.5 gal/200 ft² – only for larger plants with well defined canopies) 	Do not apply through any type of irrigation equipment. Apply only to containerized plants. Do not apply as a soil drench.
EPA Reg #241-74	Greenhouse	foliar spray by low pressure handwand, backpack sprayer	0.013 lb ai/gal (at 1,500 ppm)	Do not apply through any type of irrigation equipment.
	Greenhouse	drench by high pressure handwand	0.025 lb ai/gal (at 3,000 ppm)	Do not apply through any type of irrigation equipment.
Chlormequat E-Pro Plant Growth Regulator - liquid (11.8% a.i.)	Greenhouse	foliar spray by low pressure handwand, backpack sprayer	0.034 lb ai/gal (at 4,000 ppm)	
For Commercial Use EPA Reg # 81959-12	Greenhouse	drench by high pressure handwand	0.034 lb ai/gal (at 4,000 ppm)	

A. Regulatory History

The first chlormequat chloride registration was issued to BASF by the U.S. Department of Agriculture in 1962. This initial use was restricted to greenhouses. In 2006, the Agency assessed the human health and ecological effects of a proposed outdoor use and amended the registration of chlormequat chloride to include bedding plants and ornamentals in shadehouses and nurseries.

B. Chemical Identification of Chlormequat Chloride

Tables 2 and 3 provide an overview of chlormequat chloride's structure and properties.

Table 2. Test Compound Nomenclature		
Chemical Structure	CI N* CI- H ₃ C CH ₃	
Empirical Formula	$C_5H_{13}Cl_2 N$	
Common Name	Chlormequat chloride	
Company Experimental Name	N/A	
IUPAC Name	2-chloroethyl trimethyl ammonium chloride	
CAS Name	2-chloro- <i>N</i> , <i>N</i> , <i>N</i> -trimethylethanaminium chloride	
CAS Registry Number	999-81-5	
End-use Product/EP	CYCOCEL [®] Plant Growth Regulator	
Chemical Class	quaternary ammonium compound	
Use Type	plant growth regulator	
Known Impurities of Concern	N/A	

Table 3. The Physicochemical Properties of Chlormequat Chloride		
Parameter	Value	Reference
Molecular Weight	158.1	MSDS CYCOCEL [®] Plant Growth Regulator by BASF Canada, 08/15/2000
Melting Point	245°C	MSDS CYCOCEL [®] Plant Growth Regulator by BASF Canada, 08/15/2000
рН	5.14	MSDS CYCOCEL [®] Plant Growth Regulator by BASF Canada, 08/15/2000
Density	1.241 g/ml	Study: Surface Tension, Density and Vapour Pressure of Chlormequat-Chloride (PAI) by BASF Germany, 03/27/2001
Water Solubility (20° C)	74 g/100 ml	MSDS CYCOCEL [®] Plant Growth Regulator by BASF Canada, 08/15/2000
Surface Tension	70.3 mN/m	Study: Surface Tension, Density and Vapour Pressure of Chlormequat-Chloride (PAI) by BASF Germany, 03/27/2001
Vapor Pressure (20°C)	<1.0 x 10 ⁻⁸ mbar	Study: Surface Tension, Density and Vapour Pressure of Chlormequat-Chloride (PAI) by BASF Germany, 03/27/2001
Octanol/water partition coefficient, log K _{OW} (25°C)	Not Applicable	MSDS CYCOCEL [®] Plant Growth Regulator by BASF Canada, 08/15/2000

C. Use Profile	
Type of Pesticide:	Plant growth regulator
Summary of Use:	Chlormequat chloride is currently registered for use on a wide variety of ornamentals grown in greenhouses, shadehouses, and nurseries. Crops include herbaceous and woody annual and perennial plants such as begonias, vincas, azaleas, and poinsettias. Outdoor use is restricted to containerized ornamentals. Chlormequat chloride has no residential or food uses; therefore, there are no associated tolerances.
Formulation Type:	Soluble concentrate liquid
Application Methods:	Chlormequat chloride applications are applied using several types of application equipment including groundbooms, low-pressure handwands, backpack sprayers, and high-pressure handwands.
Common Trade Names:	Cycocel Plant Growth Regulant, ET-012, Chlormequat E-Pro Plant Growth Regulator
Basic Manufacturer(s):	BASF Corporation, Etigra LLC

III. Summary of Chlormequat Chloride Risk Assessment

Human health effects and environmental fate and effects assessments have been performed for chlormequat chloride. The Agency did not identify any human health risks of concern based on current use patterns and label restrictions. The environmental fate and effects assessment demonstrates potential environmental risks of concern resulting from the outdoor nursery use of chlormequat chloride. The full risk assessments and related supporting documents are not included in this document. For additional information, please refer to the revised human health and environmental fate and effects risk assessments for chlormequat, dated June 12, 2007, and April 11, 2007, respectively. These documents are also available in the public docket EPA-HQ-OPP-2007-0968 located on-line at http://www.regulations.gov.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support the reregistration of products containing chlormequat chloride as an active ingredient.

The Agency has completed its review of submitted data and its assessment of the dietary (drinking water only), occupational and ecological risks associated with the use of pesticide products containing the active ingredient chlormequat chloride. Dietary (food) risks were not assessed because there are no food/feed uses of chlormequat chloride. Based on a review of the chlormequat chloride data, the Agency has sufficient information on the human health and ecological effects of chlormequat chloride to make decisions as part of the reregistration process under FIFRA. The Agency has determined that currently registered uses of chlormequat chloride will not pose unreasonable risks or adverse effects to humans or the environment provided that the risk mitigation measures and label changes outlined in this RED are implemented; therefore, products containing chlormequat chloride are eligible for reregistration.

Products containing chlormequat chloride are eligible for reregistration provided that the risk mitigation measures outlined in the document are adopted, and label amendments are made to implement these measures. Additionally, outstanding data requirements, as identified as part of the November 2006 conditional registration for the outdoor use, must be submitted by June 2009. Label changes are described in Section V of this document. Appendix B identifies the generic data that the Agency reviewed as part of its determination of the reregistration eligibility of chlormequat chloride and lists the submitted studies that the Agency found acceptable.

Based on its evaluation of chlormequat chloride, the Agency has determined that chlormequat chloride 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 chlormequat chloride. If all changes outlined in this document are incorporated into the product labels, then current risks for chlormequat chloride will be adequately mitigated for the purposes of this determination under FIFRA. Once a comprehensive endangered species assessment is completed, further changes to these registrations may be necessary.

B. Public Comments and Responses

Because the risks associated with the use of chlormequat chloride were minimal, a public comment period on the chlormequat chloride risk assessments was not conducted. A 60-day public comment period will be conducted after the RED is issued, and will be announced in the Federal Register. Comments may be submitted under Docket Number EPA-HQ-OPP-2007-0968 at http://www.regulations.gov. The Agency will review and consider these comments and amend the RED if appropriate. In addition, the chlormequat chloride RED document may be accessed through the Agency's website at

http://www.epa.gov/pesticides/reregistration/status.htm.

C. Regulatory Position

1. Regulatory Rationale

The Agency has determined that chlormequat chloride is eligible for reregistration provided the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures.

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

a. Human Health Risk Management and Mitigation

No risks associated with the use of chlormequat chloride exceed the Agency's level of concern for human health effects. Therefore, no additional mitigation is required to address risks of human health.

For additional details on the chlormequat chloride human health risk assessment, please refer to the human health risk assessments for chlormequat chloride. This document is available in the public docket EPA-HQ-OPP-2007-0968, located on-line in the Federal Docket Management System (FDMS) at http://www.regulations.gov.

1. Drinking Water Risk Mitigation

There is no concern for potential acute and chronic dietary exposure from drinking water associated with the registered non-food uses of chlormequat chloride.

2. Occupational Risk Mitigation

All handler and postapplication occupational risks for chlormequat chloride are below the Agency's level of concern (LOC).

b. Ecological Risk Management and Mitigation

For additional details on the chlormequat chloride ecological fate and effects risk assessment, please refer to the ecological risk assessment for chlormequat chloride. This document is available in the public docket EPA-HQ-OPP-2007-0968, located on-line in the Federal Docket Management System (FDMS) at http://www.regulations.gov.

The Agency has conducted a screening-level ecological and environmental risk assessment for the registered outdoor use of chlormequat chloride. Based on the available data and using conservative assumptions, the outdoor use of chlormequat chloride may pose acute and subchronic risks of concern to birds, reptiles, terrestrial-phase amphibians, mammals, and both terrestrial and aquatic plants. Because chlormequat chloride is classified as practically nontoxic to freshwater fish and estuarine marine fish, the acute risk for freshwater fish and estuarine marine fish is presumed to be low. Chlormequat chloride is classified as practically nontoxic to honey bees (*Apis mellifera*) on both an acute contact and acute oral basis.

The available data indicate that chlormequat chloride is slightly toxic to birds, reptiles and terrestrial phase amphibians on an acute exposure basis. Due to an absence of data, avian terrestrial risk quotients (RQs) were considered representative of potential exposure for terrestrial-phase amphibians and reptiles. Dose-based RQs range from 6.9 for small birds (20g) foraging on short grass to 0.06 for large (1000g) birds foraging on fruit/pods/large insects. The acute avian LOC is exceeded for all size classes foraging on short grass, tall grass and broadleaf plants/small insects. A "no observed adverse effect concentration" (NOAEC) could not be determined in the avian reproduction study because effects were seen at the lowest dose tested; therefore, definitive chronic RQ values could not be calculated. However, calculating with the lowest dose tested provides an indication of the minimum extent to which LOCs are exceeded. RQ values calculated using the lowest dose tested exceed the chronic risk LOC (RQ \geq 1.0) for all forage groups The chronic LOC is exceeded by a factor of greater than 15X for birds foraging on short grass.

Chlormequat chloride is slightly toxic to mammals on an acute oral exposure basis. Mamalian RQs range from 0.01 for large (1000g) granivorous mammals to 2.2 for small (15g) mammals foraging on short grass, a 4-fold exceedance of the acute risk LOC (RQ \geq .5). There are exceedences of the acute risk LOC for all size classes foraging on short grass and broadleaf plant/small insects and for small- and medium-sized mammals foraging on tall grass. Dose-based RQs exceed the Agency's chronic risk LOC (1.0) for all size classes of mammals foraging on short grass, tall grass and broadleaf plants/small insects, by factors ranging from 3X to 12X.

For a single application of chlormequat chloride (3.7 lbs ai/A) the terrestrial plant LOC (1.0) is exceeded for dicotyledonous plants in wetlands adjacent to chlormequat use sites. There are no exceedances for adjacent upland species or as a result of drift alone.

While there are estimated exceedances of the LOC for some terrestrial and aquatic species, the ecological risks associated with the use of chlormequat chloride are expected to be extremely limited based on its use pattern and toxicity profile. Chlormequat chloride is not a widely used chemical. Due to the high cost of the treatment, the outdoor use is a niche use applied only on high value outdoor ornamentals with very limited acreage. The indoor uses, comprising approximately 97% of usage, such as use in greenhouses, interior landscapes and others, do not result in environmental exposure.

In addition to chlormequat chloride's low outdoor usage, the Agency's ecological and environmental risk assessment was conservative. This high-end, screening level assessment for the outdoor use assumed maximum application rates allowed by the label, and the minimum application intervals for chlormequat chloride. Furthermore, the models and scenarios used in this assessment were developed to simulate pesticide applications in open agricultural fields and not specifically for containerized ornamentals and bedding plants in nurseries and shadehouses, which generally are not present in large contiguous acreages.

Foliar application of chlormequat chloride to plants in containers is distinct from other outdoor use applications in that residues on treated foliage, in general, are not likely to be available to wildlife because of the high value and protected nature of the plants. The plants are held close together, and they are typically placed on bare ground, gravel or landscape barrier fabric where non-target plants cannot grow. Based on the typical density of the pots, 90% of the material applied will be intercepted by the foliage of the potted plant. When the ornamentals are initially placed outdoors they are free of insects and weeds. Each plant has a high value and will receive treatment for insects, if necessary, and weeds will not be allowed to grow in the containers.

Moreover, the use in nurseries is for containerized plants, which is expected to limit the amount of potential exposure from runoff and drift. Runoff is reduced in nurseries by wastewater containment programs currently in place, which further reduces risk to aquatic organisms. While there are currently no studies that can be used to quantify the effects of nursery wastewater containment practices, these practices are believed to be effective in reducing risk to nontarget species. The Agency is aware that most container nurseries use a variety of methods to control water runoff from nursery operations including grassed waterways, sediment control ponds, constructed wetlands, and irrigation runoff water recycling ponds. The practice of retaining water onsite is being driven by two factors: 1) the Clean Water Act and states' regulatory efforts regarding non-point pollution control and storm water management, and 2) water shortages that are appearing in various sections of the US, such as Florida, where nurseries need to insure a consistent supply of irrigation water. Furthermore, the Agency understands through discussions with the American Nursery Landscape Association that all new container nursery operations under development are being designed for zero or minimum offsite water discharge.

Despite chlormequat chloride's limited use, in order to ensure that the outdoor use of chlormequat chloride does not result in terrestrial and aquatic exposure, the Agency has directed, and the registrant has agreed, to modify the chlormequat chloride label to prohibit the use of mechanical (tractor-drawn) groundboom multi-nozzle sprayer applications. The technical registrant, BASF, submitted an amended label on September 11, 2007 with the groundboom application method removed. The Agency approved the amended label on September 19, 2007. This change will limit the outdoor application of chlormequat chloride to hand wand use only. It is recognized that hand wand application is more targeted, resulting in less of the pesticide being available for potential runoff, and less drift with associated potential for off-target exposures. Furthermore, applicators using hand wands do not treat large contiguous acreages in a short time frame as is typical for tractor mounted groundbooms. Specific language prohibiting this application method is set forth in the summary table in Section V of this document.

Additionally, the technical registrant has agreed to submit a freshwater fish life-cycle study and an avian reproduction study by June 1, 2009, as outlined in a November 2006 letter from the Agency to the technical registrant. These studies will fill current data gaps and confirm the Agency's belief that there is no unreasonable adverse effect to the environment from the use of chlormequat chloride. Please see Appendix H for additional data required to support the outdoor uses of chlormequat chloride, including the groundboom application method.

2. Endocrine Disruptor Effects

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

3. Endangered Species Considerations

a. The Endangered Species Program

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. 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. To analyze the potential of registered pesticide uses that may affect any particular species, the Agency 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 chlormequat chloride "may affect" listed species or their designated critical habitat, the Agency will employ the provisions in the Services' regulations (50 CFR Part 402). Until the 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

chlormequat chloride at levels of concern. The Agency is not requiring specific chlormequat chloride 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.

At this time, the Agency is not requiring label changes specific to the protection of listed species. While RQs exceeded the Agency's endangered species LOC for several taxa, including birds, mammals and both aquatic and terrestrial plants, these results are likely to be conservative due to the limited use of chlormequat chloride and the prohibition of ground boom application. These results were also based on a screening-level assessment, and do not constitute "may affect" findings under the Endangered Species Act. After a species-specific assessment is conducted, a determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service or National Marine Fisheries Service as appropriate.

4. Spray Drift Management

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

Because the outdoor use of chlormequat chloride is limited to direct, low-pressure, handwand application to containerized ornamentals, the Agency concludes that spray drift mitigation is not warranted as part of the reregistration eligibility determination.

5. Other Labeling Requirements

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

V. What Registrants Need to Do

The Agency has determined that chlormequat chloride is eligible for reregistration provided that the risk mitigation measures identified in this document are adopted and label amendments are made to reflect these measures; however, additional data are required to confirm this decision. The submission of this data was a condition for a previous label amendment granted by the Agency for the outdoor use of chlormequat chloride. The registrant has committed to completing and submitting these studies by June 2009. For product specific data, the registrant will have 8 months to submit data and amend labels.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of chlormequat chloride has been reviewed and determined to be adequate for this reregistration assessment. In order to reduce the uncertainty in the ecological risk assessment, BASF has already agreed to submit data conditional on their recent ammendment to the chlormequat chloride registration, which adds shadehouses and nurseries to the accepted use of chlormequat chloride labeled use sites.

2. Labeling for 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. In order to be eligible for reregistration, the technical registrants should amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The technical and MP labeling should also bear the labeling statements contained in Table 4, the Label Changes Summary Table.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

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.

3. Labeling Changes Summary Table

The following table describes how language on the labels should be amended.

Labeling Changes Summary Table

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

Table 4: Summary of Labeling Changes for Chlormequat Chloride		
Description	Amended Labeling Language	Placement on Label
	Manufacturing Use Products	
For all Manufacturing Use Products	"Only for formulation into a plant growth regulator for the following use(s) [fill blank only with those uses that are being supported by MP registrant]." "Not for formulation into end-use products that permit application with motorized groundboom equipment at outdoor sites."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user	 "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." 	Directions for Use
Environmental Hazards Statements Required by the RED and	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing	Precautionary Statements

Agency Label Policies	prior to discharge. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate"	
	End Use Products Intended for Occupational Use	
PPE Requirements Established by the RED ¹ For Liquid Formulations	 "Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (<i>registrant inserts correct chemical-resistant material</i>). "If you want more options, follow the instructions for category" [<i>registrant inserts</i> <i>A,B,C,D,E,F,G,or H</i>] "on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators and other handlers must wear: Long-sleeved shirts and long pants, Shoes plus socks." 	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	 "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them." 	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations	"User Safety RecommendationsUsers should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.Users should remove clothing/PPE immediately if pesticide gets inside.	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls

	Then wash thoroughly and put on clean clothing.
	Users should remove PPE immediately after handling this product. We the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."
Environmental Hazards	"This product is toxic to wildlife."
	"Do not apply directly to water, or to areas where surface water is pre or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate
	"Keep out of lakes, streams and ponds. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas spra
	For products packaged in containers equal to or greater than 5 gallons 50 lbs, add the following statement:
	"Do not discharge effluent containing this product into lakes, streams ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in wri prior to discharge. Do not discharge effluent containing this product sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."
Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for Agricultural Pesticides WPS)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."
Early Entry Personal	"PPE required for early entry to treated areas that is permitted under

roducts packaged in containers equal to or greater than 5 gallons or s, add the following statement:	
not discharge effluent containing this product into lakes, streams, s, estuaries, oceans, or other waters unless in accordance with the rements of a National Pollution Discharge Elimination System (ES) permit and the permitting authority has been notified in writing to discharge. Do not discharge effluent containing this product to r systems without previously notifying the local sewage treatment authority. For guidance contact your State Water Board or onal Office of the EPA."	
not enter or allow worker entry into treated areas during the cted entry interval (REI) of 12 hours."	Directions for Use, Under Agricultural Use Requirements Box
required for early entry to treated areas that is permitted under the	
15	

(Must be placed in a box.)

following the User Safety

Recommendations

Precautionary Statements immediately

Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: * coveralls, * shoes plus socks * chemical-resistant gloves made of any waterproof material."	Direction for Use Agricultural Use Requirements box
"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation."	Place in the Direction for Use directly above the Agricultural Use Box.
"Application with motorized groundboom equipment in outdoor sites is prohibited." Apply using handheld nozzles or hand-held equipment, such as low- pressure handwand equipment.	Directions for Use
	 has been treated, such as plants, soil, or water, is: * coveralls, * shoes plus socks * chemical-resistant gloves made of any waterproof material." "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation." "Application with motorized groundboom equipment in outdoor sites is prohibited."

VI. Appendices

A	Appendix A. Use	Patterns Eligible	for Reregistratio	n for chlormeq	uat chloride				
Z	Application Timing Application Equipment Application Type	Formulation	Maximum Single Application Rate	Maximum No. Of Applications per Year	Maximum Seasonal Rate	Pre- harvest Interval (days)	Minimum Retreatemen t interval (days)	Reentry Interval	Limitations
	Ornamental and/o	or Shade Trees	•			•	•		
	C ontainerized Drench. Drencher. F oliar Spray. Sprayer.	Soluble Concentrate/ liquid	0.0339 lb gal	NS	NS		NS	12 hr	Do not apply through any type of irrigation system Do not apply when drift is likely to occur. Do not contaminate food or feed by storage or disposal. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Keep out of lakes, streams, and ponds. This pesticide is toxic to wildlife.
	Ornamental and/o	or Shade Trees							
	F oliar Spray. Sprayer.	Soluble Concentrate/ liquid	3.7 lb ai/A	NS	NS		NS	12 hr	Do not apply through any type of irrigation equipment. Apply only to containerized plants. Do not apply as a soil drench
	Ornamental and/	or Shade Trees							
	Potted Drench /Spray. Drencher Sprayer.	Soluble Concentrate/ liquid	0.0625 lb pot	NS	NS		NS	12 hr	Do not apply through any type of irrigation system Do not apply when drift is likely to occur. Do not contaminate food or feed by storage or disposal. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Keep out of lakes, streams, and ponds. This pesticide is toxic to wildlife.
	Ornamental Herbaceous Plants								
	Foliar Spray.Sprayer Plant bed Drench /Spray. Drencher Sprayer.	Soluble Concentrate/ liquid	0.0339 lb gal	NS	NS		NS	12 hr	Do not apply through any type of irrigation system Do not apply when drift is likely to occur. Do not contaminate food or feed by storage or disposal. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Keep out of lakes, streams, and ponds.

							This pesticide is toxic to wildlife.
Ornamental Herb							-
Foliar Spray. Sprayer.	Soluble Concentrate/ liquid	3.7 lb ai/A	NS	NS	NS	12 hr	Do not apply through any type of irrigation equipment. Apply only to containerized plants. D not apply as a soil drench
Ornamental Herb	aceous Plants	-					
Potted Drench /Spray. Drencher /Sprayer.	Soluble Concentrate/ liquid	0.0625 lb pot	NS	NS	NS	12 hr	 Do not apply through any type of irrigation system Do not apply when drift is likely to occur. Do not contaminate food or feed by storage or disposal. Do not contaminate water by cleaning of equipme or disposal of equipment wash waters. Keep out of lakes, streams, and ponds. This pesticide is toxic to wildlife.
Ornamental Woo	dy Shrubs and Vi	ines					
Containerized Drench. Drencher. Cutting Drench /Spray. Drencher /Sprayer. Foliar	Soluble						Do not apply through any type of irrigation system Do not apply when drift is likely to occur. Do not contaminate food or feed by storage or disposal. Do not contaminate water by cleaning of equipmen or disposal of equipment wash waters.Keep out of lakes, streams, and ponds. This pesticide is toxic to wildlife.
Spray. Sprayer	Concentrate/ liquid	0.0339 lb gal	NS	NS	NS	12 hr	
Nurserystock Drench /Spray. Drencher /Sprayer							
Potted Drench /Spray.Drencher							
/Sprayer. Ornamental Woo							

Potted Drench /Spray.Drencher /Sprayer.	Soluble Concentrate/ liquid	0.0625 lb pot	NS	NS	NS	12 hr	Do not apply through any type of irrigation system Do not apply when drift is likely to occur. Do not contaminate food or feed by storage or disposal. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters.Keep out of lakes, streams, and ponds. This pesticide is toxic to wildlife.
Crnamental Wo	ody Shrubs and V	ines					
Foliar Spray. Sprayer.	Soluble Concentrate/ liquid	3.7 lb ai/A	NS	NS	NS	12 hr	Do not apply through any type of irrigation equipment. Apply only to containerized plants. Do not apply as a soil drench
Ornamental Wo	ody Shrubs and V	ines					
Early bloom Spray. Sprayer.	Soluble Concentrate/ liquid	0.0127 lb gal	NS	NS	NS	12 hr	Do not apply through any type of irrigation system Do not apply when drift is likely to occur. Do not contaminate food or feed by storage or disposal. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters.Keep out of lakes, streams, and ponds. This pesticide is toxic to wildlife.
NS = 1	Not Specified						

Data Supporting Guideline Requirements for the Reregistration of chlormequat chlorid Use Use							
	REQU	JIREMENT	Pattern	CITATION(S)			
		ECOLOGICAL EFF		1			
Non-	guideline	Avian Acute Oral Toxicity	С, Н, Ј	467152-11 (supplemental)			
850.2200	71-2A	Avian Dietary Toxicity - Quail	С, Н, Ј	467152-122 (supplemental)			
850.2300	71-4B	Avian Dietary Toxicity - Duck	С, Н, Ј	467152-13 (data gap)			
Non-guidel	ine	Avian Reproduction – Quail	С, Н, Ј	467152-14 (supplemental)			
850.1075	72-1A	Freshwater Fish Acute Toxicity - Bluegill	С, Н, Ј	001232-61			
850.1075	72-1B	Fish Acute Toxicity Fathead Minnow	С, Н, Ј	000374-33			
Non-guideline		Fish Acute Toxicity Rainbow Trout	С, Н, Ј	467152-17 (supplemental)			
850.1010	72-2A	Invertebrate Acute Daphnid Toxicity	С, Н, Ј	001387-19 (supplemental)			
850.1075	72-3A	Estuarine/Marine Fish Acute Toxicity	С, Н, Ј	ECOTOX			
850.1035	72-3C	Estuarine/Marine Acute Toxicity	С, Н, Ј	ECOTOX			
850.1300	72-4A	Daphnid Chronic Toxicity (life cycle)	С, Н, Ј	467152-16 (supplemental)			
850.1400	72-4C	Freshwater Fish Early Life Stage	С, Н, Ј	Data Gap			
Non-guideline		Terrestrial Plant Toxicity, Seedling Emergence	С, Н, Ј	467152-19 (supplemental)			
Non-guideline			С, Н, Ј	467152-20 (supplemental)			
850.4400	122-2	Vascular Aquatic Plant Toxicity - <i>lemna gibba</i> (Tier 1)	С, Н, Ј	467152-21			
850.4500	123-2	Aquatic Plant Growth - Algae	С, Н, Ј	467152-22			
850.4550	123-2	Aquatic Plant Growth – Cyanobacteria	С, Н, Ј	467152-23			
850.3020	141-1	Honey Bee Acute Contact	С, Н, Ј	467152-24			

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Appendix B Data Supporting Guideline Requirements for the Reregistration of chlormequat chloride						
	REQU	JIREMENT	Use Pattern	CITATION(S)		
870.3100 82-1		Oral subchronic Toxicity study – Rat	С, Н, Ј	00163408		
Non-guideli	ne	90-Day Oral Toxicity – Rodent	С, Н, Ј	00163408		
870.3200	82-2	21/28-Day Dermal Toxicity – Rabbit	С, Н, Ј	42246603		
870.3700	83-3	Prenatal Developmental Toxicity	С, Н, Ј	42246604		
Non-guideline		Prenatal Developmental Toxicity – Rabbit	С, Н, Ј	46715205		
870.3800	83-4	Reproduction and Fertility Effects – Rat	С, Н, Ј	46712006		
830.4100	83-1	Chronic Toxicity – Dog	С, Н, Ј	46715201		
870.4200a	83-2a	Carcinogenicity Study – rat	С, Н, Ј	46715203		
870.4200b	83-2b	Carcinogenicity Study – Mice	С, Н, Ј	46715204		
870.5100	84-2	Bacterial Reverse Mutation	С, Н, Ј	41721610		
ENVIRON	MENTAL F	FATE				
835.2120	161-1	Hydrolysis	С, Н, Ј	Data Gap		
835.2240	161-2	Photodegradation – Water	С, Н, Ј	Data Gap		
835.4200	162-2	Anaerobic Soil Metabolism	С, Н, Ј	Data Gap		
835.1230	163-1	Sediment and Soil Adsorption/Desorption	С, Н, Ј	46715228, 46715229		

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The docket contains the risk assessments and related documents as of September 30, 2007. The availability announcement will be published in the Federal Register. All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: www.epa.gov/pesticides/reregistration. The following list details all documents related to the Chlormequat chloride RED.

Health Effects Documents

- 1. chlormequat chloride. HED Human Health Risk Assessment for the Reregistration Eligibility Decision. D336712; D. Wilbur; June 12, 2007
- 2. chlormequat chloride: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document. D336714; C. Smith; June 12, 2007
- 4. chlormequat chloride. Screening-Level Acute and Chronic Dietary (Drinking Water Only) Exposure and Risk Assessment for the Reregistration Eligibility Decision. D336716; D. Wilbur; June 7, 2007
- 5. Review of chlormequat chloride Incident Reports. D342351; M. Hawkins; August 14, 2007
- 6. chlormequat chloride Carcinogenicity Studies in Rats and Mice (MRID # 46715203 and 46715204). D336713; J. Facey; June 11, 2007

Ecological Fate and Effects Documents

- 1. Environmental Fate and Ecological Risk Assessment for the Reregistration of chlormequat chloride. B. Kiernan and M. Echeverria; April 11, 2007
- 2. Tier I Drinking Water Assessment for chlormequat chloride in Support of Reregistration Eligibility Decision D336717; M. Echeverria; March 19, 2007

Appendix D. Citations Considered to be Part of the Database Supporting the Reregistration Decision (Bibliography)

GUIDE TO APPENDIX D

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

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

Bibliography

MRID	Citation Reference
9446	Welch, N.C. (1969) Report of Planned Work Accomplished: Growth Control Regulators in Brussels Sprouts: Proj. No. 75. (Unpublished study received Oct 3, 1972 under 2F1271; prepared by Univ. of California, Cooperative Extension Service, submitted by Uniroyal Chemical, Bethany, Conn.; CDL:091801-W)
9447	Rubatzky, V.E.; Sciaroni, R.H. (1970) Chemical Topping of Brussels Sprouts. (Papers for American Society for Horticultural ScienceWestern Region, Univ. of CaliforniaBerkeley, June 21-24, 1970; unpublished study received Oct 3, 1971 under 2F1271; prepared by Univ. of CaliforniaDavis, Agricultural Extension Ser- vice, Dept. of Vegetable Crops, submitted by Uniroyal Chemical, Bethany, Conn.; CDL:091801-Y)
9454	Kim, S.H.; Fieldhouse, D.J.; Morton, D.J. (1966) Effects of Bactericides and Growth Regulators on Bacterial Spot, Yield, and Fruit Weight of Pepper1966. (Unpublished study received Oct 3, 1972 under 2F1271; prepared by Univ. of Delaware, submitted by Uniroyal Chemical, Bethany, Conn.; CDL:091801-AG)
9486	Read, P.E.; Fieldhouse, D.J. (1970) Use of Growth Retardants for increasing tomato yields and adaptation for mechanical harvest. Journal of the American Society of Horticultural Science 95(1): 73-78. (Also in unpublished submission received Nov 4, 1975 under 400-79; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:094840-C)
9487	Bryan, H.H. (1970) Concentrating tomato maturity with growth regulators. Pages 123-126, In Preceedings of the Florida State Horticultural Society; Oct 27-29, 1970, Miami, Florida. N.P. (Also in unpublished submission received Nov 4, 1975 under 400-79; submitted by Uniroyal Chemical, Bethany, Conn.; CDL: 094848-H)
9534	Edgerton, L.J.; Powell, L.E. (1967) Effects of Some Growth Regulators on Bloom Date and Cold Hardiness of Apple and Cherry. (Unpublished study received Apr 10, 1967 under 7F0552; prepared by Cornell Univ., Dept. of Pomology, submitted by United States Rubber Co., Naugatuck, Conn.; CDL:094768-D)
9558	Bryan, H.H. (1967) Preliminary Non-Projected Studies: Tomato Yield Response to Growth Regulators. (Unpublished study received May 29, 1970 under 0F0923; prepared by Univ. of Florida, Sub-Tropical Experiment Station, submitted by Uniroyal Chemical, Bethany, Conn.; CDL:091577-I)
9569	Oyer, E. (1967) Effects of Growth Regulants on Flowering and Fruiting of Tomatoes. (Unpublished study received May 29, 1970 under 0F0923; prepared by Cornell Univ., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:091577-W)

MRID	Citation Reference
9580	Chilcote, D.O.; Phillips, J.C.; Frakes, R.V. (1974) Growth Regulators and Seed Yield in Alfalfa. (Unpublished study received Mar 4, 1976 under 6F1752; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:095528-C)
9581	Oregon State University, Crop Science Department (1972) Influence of Selected Growth Regulators on Alfalfa Seed Yield and Yield Components. (Unpublished study received Mar 4, 1976 under 6F1752; prepared in cooperation with Southern Oregon Experiment Station, submitted by Uniroyal Chemical, Bethany, Conn.; CDL: 095528-E)
9674	Shanks, J.B. (1963) Growth Retardants for Azaleas: Grower Divisions of the Allied Florists of Baltimore and the Allied Florists of Greater Washington. (Maryland florist, number 100; also In unpublished submission received Mar 4, 1964 under 400- 69; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:023348-C)
9728	Cathey, H.M; Heggestad, H.E. (1972) Reduction of ozone damage to Petunia hybrida Vilm. by use of growth regulating chemicals and tolerant cultivars. Journal of the American Society for Horticultural Science 97(6):695-700. (Also In unpublished submission received Feb 13, 1973 under 400-49; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:127889-A)
9750	Michigan State University, Sodus Horticultural Experiment Station (1966) Growth Regulators on Grapes. (Unpublished study received Aug 13, 1974 under 400-117; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:026600-K)
9775	Wu, C.H.; Santelmann, P.W. (1974) Plant Growth Regulators in Pea- nuts: No. GR 74-4. (Unpublished study received May 12, 1976 under 400-103; prepared by Oklahoma State Univ., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:230881-V)
24737	Hilton, H.W.; Nomura, N.S.; Kameda, S.S.; et al. (1976) Some patterns of herbicide and growth regulaor intake, persistence, and distribution in sugarcane. Archives of Environmental Contamination and Toxicology 4(4):385-394. (Also In unpublished submission received Jul 19, 1978 under 201-403; submitted by Shell Chemical Co., Washington, D.C.; CDL:234470-AP)
33740	Gill, D.L.; Stuart, N.W.; Munger, G.D.; et al. (1964) Summary: Effects of Cycocel on Shrub Growth. (Unpublished study received Jun 22, 1964 under 241-74; prepared in cooperation with U.S. Agricultural Research Service, Crops Research Div. and others, submitted by American Cyanamid Co., Princeton, N.J.; CDL: 001761-B)
33741	American Cyanamid Company (1962) The Name, Chemical Identity, and Composition of Cycocel. (Unpublished study received Mar 29, 1962 under 241-74; CDL:001758-A)

MRID	Citation Reference
33742	Paterson, W.W.; Besemer, S.T.; Oelschig, G.H.; et al. (1962) Introduction: CCC on Poinsettia Growth. (Unpublished study including published data, received Mar 29, 1962 under 241-74; prepared in cooperation with Rosemont Greenhouses, Inc. and others, submitted by American Cyanamid Co., Princeton, N.J.; CDL:001758-B)
35039	Wheldon, G.H.; Hunter, B. (1970) Long-Term Feeding Study of Cycocel Chlormequat in the Mouse (Interim Report 0-52 Weeks): Report No. 3458-70-271. (Unpublished study received Oct 23, 1970 under 241-214; prepared by Huntingdon Research Centre, submitted by American Cyanamid Co., Princeton, N.J.; CDL:002030-A)
35040	American Cyanamid Company (1965) Toxicity Data: Report No. 65-5. (Unpublished study received Oct 23, 1970 under 241-214; CDL: 002030-B)
35041	Huepen, W.C.; Conway, W.D. (1970) Chemical Carcinogenesis and Cancers: Charles C. Thomas. (pp. 343-344 only; also In unpublished submission received Oct 23, 1970 under 241-214; submitted by American Cyanamid Co., Princeton, N.J.; CDL:002030-C)
35042	Oettel, H.; Froberg, H.; Schilling, B. (1966) Final Report on the 2-Year Rat Feeding Experiment with Chlorcholine-chloride (CCC). (Translation; unpublished study received Jun 1, 1970 under 241- 214; prepared by BASF Institute for Industrial Hygiene & Pharmacology, submitted by American Cyanamid Co., Princeton, N.J.; CDL:002029-A)
35069	Levinskas, G.J.; Bushey, C.L.; Kunde, M.L.; et al. (1962) 2-Chloroethyl trimethylammonium chloride; CL 38, 555: Limited Release Toxicity Studies: Report No. 62-14. (Unpublished study received Feb 10, 1969 under 241-214; submitted by American Cyanamid Co., Princeton, N.J.; CDL:002027-A)
37483	Sleight, B.H., III (1972) The Acute Toxicity of Cycocel (R) and Experimental Insecticide AC 92,100 to Bluegill (Lepomis macrochirus) and Rainbow Trout (Salmo gairdneri). (Unpublished study received Apr 9, 1973 under 3G1340; prepared by Bionomics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:093584-U)
42261	Oettel, H.; Froberg, H. (1966) Final Report on the 2-Year Rat Feeding Experiment with Chlorcholine-chloride (CCC): Experiment No. XIV/145=xv/96. (Translation, unpublished study received Jun 1, 1970 under 241-37; prepared by BASF Institute for Industrial Hygiene & Pharmacology, West Germany, submitted by American Cyanamid Co., Princeton, N.J.; CDL:100635-A)
42262	Howard, D.J.; Woodard, G. (1969) Calnox 214-DN Acute Oral Toxicity to Rats. (Unpublished study received Oct 20, 1971 under 1757- 42; prepared by Woodard Research Corp., submitted by Drew Chemical Corp., Boonton, N.J.; CDL:100636-A)

MRID	Citation Reference
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Appendix E. Product Data Call-In (PDCI)

Appendix F. EPA's Batching of chlormequat chloride Products for Meeting Toxicity Data Requirements for Reregistration

EPA'S BATCHING OF CHLORMEQUAT CHLORIDE 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 CHLORMEQUAT CHLORIDE 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.

Four products were found which contain Chlormequat chloride as the active ingredient. These products have been placed into two batches in accordance with the active and inert ingredients and type of formulation.

Batching Instructions:

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 1	EPA Reg. No.	Percent Active Ingredient
	241-256	63.0
	81959-11	63.0

Batch 2	EPA Reg. No.	Percent Active Ingredient
	241-74	11.8
	81959-12	11.8

Appendix G. List of Available Related Documents and Electronically Available Documents

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

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

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

Instructions

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

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

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf

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

Pesticide Registration Kit

www.epa.gov/pesticides/registrationkit/

Dear Registrant:

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

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

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

- 3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).
 - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
 - b. EPA Form No. 8570-4, Confidential Statement of Formula
 - c. EPA Form No. 8570-27, Formulator's Exemption Statement

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

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

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

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

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

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

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

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

Documents Associated with this RED

The documents listed in Appendix C are part of the Administrative Record for this RED document and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents may also be obtained by contacting the person listed on the respective Chemical Status Sheet.

Appendix H. Data Required to Support the Outdoor Uses of Chlormequat Chloride

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1. In the first paragraph of the section "Conditions of Sale and Warranty", change "All such risks shall be assumed by the Buyer." to "To the extent consistent with applicable law, all such risks shall be assumed by the Buyer."

In addition, you must submit the following conditional data to support the shadehouse and nursery uses before the due date of June 1, 2009:

Rodenticide Act as amended, is acceptable provided the following change is made:

- 1. Freshwater Fish Early Life Stage Bluegill (72-4C, 850.1400)
- 2. Avian reproduction Duck (71-4B, 850.2300)
- 3. Hydrolysis (161-1)
- 4. Photolysis in water (161-2)
- 5. Soil Metabolism anaerobic (162-2)

In addition, the Agency may require that you submit the following conditional data:

- Bobwhite quail reproduction study (71-4A, 850.2300) may be required later depending on the duck reproduction results.
- Terrestrial field dissipation (164-1) may be required depending on results of the technical review of MRIDs 124060 and 137650 (DP333237).

One copy of the label stamped "Accepted with comments" is enclosed for your records. This label supersedes all labels previously accepted for this product. Please submit one copy of the final printed label that incorporates the required changes before the product is released for shipment.

EPA Reg. No. 241-74 CYCOCEL Plant Growth Regulator Page 2 of 2

If you have any questions, please contact Robert Westin by phone at (703) 305-5721 or via email at westin.robert@epa.gov.

Sincerely, Ciah om

Tony Kish Product Manager (22) Fungicide Branch Registration Division (7505P)

Enclosure