United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-96-019
March 1997

Reregistration Eligibility Decision (RED)

Mepiquat Chloride

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case Mepiquat Chloride (N,N-Dimethylpiperidinium chloride). The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the date of this letter. The second set of required responses is due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that the Food Quality Protection Act of 1996 ("FQPA") became effective on August 3, 1996, amending portions of both the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should also be noted that in continuing to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. Rather, these early determinations will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Emily Michell (703) 308-8583. Address any questions on required generic data to the Special Review and Reregistration Division representative Patrick Dobak (703) 308-8180.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

Mepiquat Chloride

LIST B

CASE 2375

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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MEPIQUAT CHLORIDE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Alan Halvorson	Economic Analysis Branch
Anita Hanson	Biological Analysis Branch
George Keitt	Biological Analysis Branch

Environmental Fate and Effects Risk Assessment

Karen Angulo	Science Analysis and Coordination Staff
Dan Balluff	Ecological Effects Branch
Gail Maske	Environmental Fate and Groundwater Branch

Health Effects Risk Assessment

Mary Clock	Risk Characterization and Analysis Branch
Tom Campbell	Occupational and Residential Exposure Branch
Felicia Fort	Reregistration Support Chemistry Branch
Krystyna Locke	Toxicology Branch I
Brian Steinwand	Dietary Risk Evaluation Section

Registration Support Risk Assessment

James Stone	Fungicide-Herbicide Branch
Tina Levine	Registration Support Branch

Risk Management

Patrick Dobak	Accelerated Reregistration Branch
Kathleen Depukat	Accelerated Reregistration Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration

GLOSSARY OF TERMS AND ABBREVIATIONS

NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 © of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
ug/L	Micrograms per liter
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision of the pesticide and active ingredient mepiquat chloride. This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products. Mepiquat chloride's only registered use is as a growth regulator on cotton. On August 3, 1996, the President signed the "Food Quality Protection Act of 1996" which amended the Federal Food Drug and Cosmetic Act and the Federal Insecticide, Fungicide and Rodenticide Act. These two Federal statutes provide the framework for pesticide regulation in the United States. FQPA became effective immediately upon signature and all reregistration eligibility decisions (REDs) signed subsequent to August 3rd are accordingly being evaluated under the new standards imposed by FQPA.

In establishing or reassessing tolerances, FQPA required the Agency to consider available information on aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information, as well as the potential for cumulative effects from a pesticide and other compounds with a common mechanism of toxicity. The Act further directs EPA to consider the potential for increased susceptibility of infants and children to the toxic effects of pesticide residue.

For mepiquat chloride the only type of exposure evaluated was dietary, since it has not been found in drinking water and no significant non-occupational exposure is expected. Structural similarities exist between mepiquat chloride and difenzoquat and there appears to be similar neurotoxic effects. The Agency concludes that cumulative effects would be virtually nil from dietary exposure to mepiquat chloride and difenzoquat for all population subgroups because of the small dietary contribution from each chemical. Therefore, the Agency has determined that the existing tolerances with amendments and changes as specified in this document meet the standards of FQPA. Under FIFRA, the Agency has concluded that this use, as described in this document, will not cause unreasonable risks to humans or the environment. The Agency has determined that the cotton use of mepiquat chloride is eligible for reregistration.

Based on the lack of significant human health or environmental risks, the Agency is not requiring any additional mitigation measures beyond those required by the Worker Protection Standard (WPS). Residue data supporting cotton gin byproducts have been required.

Before reregistering the products containing mepiquat chloride, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately. Among other things, FQPA amended the FFDCA by establishing a new safety standard for the establishment of tolerances. The FQPA does not, however, amend any of the existing reregistration deadlines set forth in §4 of FIFRA. Thus, EPA is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in-depth analysis of the new safety standard and how it should be applied to both food and non-food pesticide applications. However, in light of the unaffected statutory deadlines with respect to reregistration, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

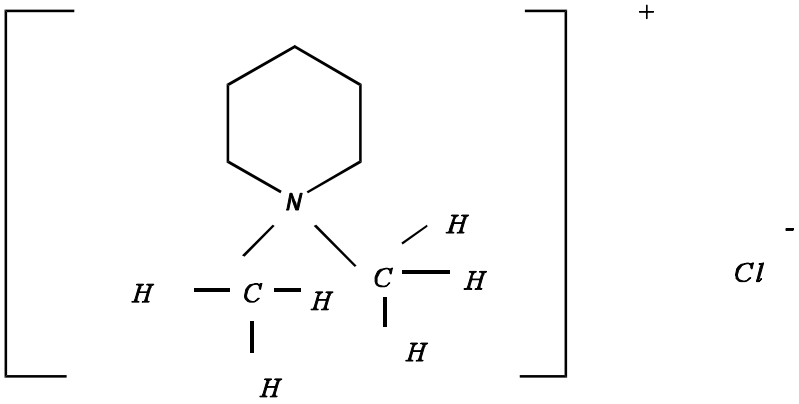
This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of mepiquat chloride including the risk to infants and children for any potential dietary, drinking water, dermal, inhalation or other oral exposures, and cumulative effects as stipulated under the FQPA. The document consists of six sections. Section I is the introduction. Section II describes mepiquat chloride, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for mepiquat chloride. Section V discusses the reregistration requirements for mepiquat chloride. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

- **Common Name:** Mepiquat Chloride
- **Chemical Name:** N,N-Dimethylpiperidinium chloride
- **Chemical Structure:**



- **CAS Registry Number:** 24307-26-4
- **OPP Chemical Code:** 109101
- **Empirical Formula:** $C_7H_{16}ClN$
- **Trade and Other Names:** Pix®
- **Basic Manufacturer:** BASF

B. Use Profile

The following is information on the currently registered use with an overview of use sites and application methods. A detailed table of this use of Mepiquat Chloride is in Appendix A.

For Mepiquat Chloride:

Type of Pesticide: Plant growth regulator

Use Sites: Cotton

Target Pests: N/A

Formulation Types Registered: Manufacturing Product (liquid, 99% AI) Soluble Concentrate, Formulation Intermediate, Emulsifiable Concentrate (liquid, 4.2 to 23.5%) Water Dispersible Granules (dry flowable, 35% AI) Pelleted/Tableted (99% AI)

Mechanism of Action: Inhibits gibberellic acid synthesis, reduces internode length, hastens maturity, retards abscission, increases yield potential.

Method and Rates of Application:

Equipment - Aerial application, ground boom

Method and Rate - *Soluble concentrate liquid*
At post-emergence, one or more spray or ultra low volume treatments by aircraft or ground equipment at 0.022 lb/A to 0.044 lb/A (not to exceed 0.132 lb/ai/A/season).

Timing - 4/year maximum

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide use of mepiquat chloride. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Table 1 summarizes mepiquat chloride's average annual cotton use for 1993-1995.

Table 1: Estimated Typical Annual Usage of Mepiquat Chloride

Acres (000) Planted	Acres Treated (000)		% of Crop Treated		Lb AI Applied (000)		Avg. Application Rate			States of Most Usage and % of Usage in these States
	Likely Average	Likely Max	Likely Average	Likely Max	Likely Average	Likely Max	lb ai/ year	appl / year	lb/ai/ A/app l	
13,595	4,510	6,215	33	46	135	200	0.030	1.4	0.021	MS CA AR TX LA NC: 77%

Sources:
- Gianessi and Anderson, Pesticide Use in U.S. Crop Production, National Summary Report, Feb. 1995.
- US EPA proprietary sources, 1987-1995.
- USDA/NASS, Agricultural Chemical Usage, 1991-1994 Field Crops Summaries.
- USDA/NASS, Crop Production, 1993-1994 Summaries.

D. Regulatory History

The active ingredient mepiquat chloride was first registered in the United States in 1980 for use as a growth regulator of cotton. The Phase 4 Data Call-In for this active ingredient was issued in April 1991 requiring additional residue and worker exposure data. Additional ecotoxicity data were required in January 1994. In October 1995, a DCI covering agricultural workers was issued for about 200 chemicals, including mepiquat chloride. There are currently nine products registered to three companies. The two subsequent registrants have entered the market since the original patent expired.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

TGAI: Mepiquat chloride

Color: Off-white

Physical State: Powder

Odor: Slightly sweet, musty smell

Melting Point: > 300°C (with discoloration at about 296°C)

Bulk density: 0.421 ± 0.07 g/mL

Solubility: Octanol - 0.95 g/100 mL
Water - 52.9 g/100 mL
Methanol - 5 g/100 mL

Vapor Pressure: < 2.3×10^{-6} Torr at 25.3°C

Octanol/Water Partition Coefficient: $K_{ow} < 10$

pH: 6.74 ± 0.01

Stability: Stable

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base for mepiquat chloride is substantially complete and will support reregistration eligibility. However, the Agency has required a rabbit developmental study as confirmatory data. Both the original and the replacement rabbit developmental studies reviewed rely on X-ray evaluation of the fetuses and are unacceptable. The purity information necessary to upgrade the subchronic dog study was requested of the registrant, but was not available. Since an acceptable chronic dog study is available, requiring a new subchronic dog study will not add significant knowledge to the human health database for this chemical.

a. Acute Toxicity

Table 2 below summarizes the acute toxicity studies on mepiquat chloride and the toxicity categories for the different routes of administration.

Table 2: Acute Toxicity Data for Technical Grade Mepiquat Chloride

Test	Results	Category
Acute Oral LD_{50} (Rat)	464 mg/kg	II
Acute Dermal LD_{50} (Rat)	> 2000 mg/kg; Limit dose	III
Acute Inhalation LC_{50} (Rat)	> 4.89 mg/L; HDT	IV
Eye Irritation (Rabbit)	Not an irritant; Score: 1.4/110	IV
Dermal Irritation (Rabbit)	Not an irritant; Score: 0/4	IV
Dermal Sensitization (Guinea pig)	Negative	-

An acute oral toxicity study in Wistar rats found the LD_{50} for mepiquat chloride to be 464 mg/kg for both sexes, placing mepiquat chloride in toxicity category II or moderately toxic to rats (MRID 41488101).

An acute dermal study in male and female Wistar rats found the LD_{50} to be greater than 2000 mg/kg, placing mepiquat chloride in toxicity category III for dermal toxicity, or slightly toxic to rats (MRID 41488102).

A rat acute inhalation study determined the LC_{50} to be greater than 4.89 mg/L, placing mepiquat chloride in inhalation toxicity category IV, practically non-toxic to rats for acute inhalation (MRID 41954101).

A primary eye irritation in young adult New Zealand white male and female rabbits concluded that mepiquat chloride is not an ocular irritant (MRIDs 00071942, 92091006).

A primary dermal irritation study in young adult New Zealand white male and female rabbits concluded that mepiquat chloride is not a dermal irritant (MRIDs 41488103, 92091007).

A dermal sensitization study in Pirbright White Guinea Pigs concluded that mepiquat chloride is not a skin sensitizer (MRID 41488104, 92091008).

b. Subchronic Toxicity

Rat

In a subchronic toxicity study, Wistar rats (10/sex/group) were fed mepiquat chloride (57.9% purity) in the diet for 3 months. Based on the results of a 4-week range-finding study, the dose levels selected for this study were 0, 250, 1000, 4000 or 8000 ppm. However, due to an error in the preparation of the diets which was discovered after the in-life portion of the study, (no adjustment for purity of mepiquat chloride was made) the actual dose levels of mepiquat chloride fed to the rats were 145, 579, 2316 or 4632 ppm. Mepiquat chloride, at all levels tested, had no effect on any parameters examined in the study. There were no unscheduled deaths. No systemic NOEL could be determined from this study. An additional study was conducted in which rats were fed diets containing 0 or 12000 ppm (about 889 mg/kg/day) of mepiquat chloride for 3 months. Toxic effects observed in the treated group were tremors in all rats; decreased body weight gain, food consumption and food efficiency; increase in thromboplastin time; decrease in serum calcium, creatinine glucose, total protein, albumin, globulin and the triglycerides; reduced grip strength of forelimbs and hindlimbs in both sexes; prolonged reaction time in the hot-plate test on day 93 in males; decreased absolute weight of liver, kidneys and adrenals in males, and liver and adrenals in females; decreased relative weight of liver in males; and increased relative weight of kidneys and testes in males and of kidneys in females. No effect on the macroscopic and microscopic pathology was observed.

These two studies together are acceptable and satisfy the requirements for guideline 82-1, for a subchronic feeding study in the rat and aid in the dose selection for the chronic feeding study. The NOEL for males and females is 4632 ppm (about 346 mg/kg/day) and the LOEL for males and females is 12000 pm (about 889 mg/kg/day) (MRIDs 42337102, 42337103).

Dog

In a subchronic toxicity study, technical mepiquat chloride (no purity given) was administered to 4 beagle dogs/sex/dose in the diet at dose levels of 0, 100, 300, 1000 or 3000 ppm (0, 3.3, 9.8, 32.4 or 95.3 mg/kg/day). The LOEL is 3000 ppm (95.3 mg/kg/day), based on clinical signs of toxicity (slight sedation); inhibition of body weights (up to 14% less); and hematological effects (up to 14% reduction in hemoglobin content and number of erythrocytes and reduced hematocrit). The NOEL is 1000 ppm (32.4 mg/kg/day).

This subchronic toxicity study is classified as upgradable, because of the lack of test material purity information. The Agency, however, has waived this requirement, based on the availability of an acceptable chronic dog study. Therefore, the additional information to upgrade the study is not being required (MRID 135720).

c. Chronic Toxicity

Rat

In a chronic feeding study mepiquat chloride (58%) was administered for 24 months in the diet to 20 Wistar rats/sex/dose at concentrations of 0, 290, 2316, or 5790 ppm (active ingredient), equivalent to doses of 0, 13, 106, 268 mg/kg/day for males and 0, 18, 146, or 371 mg/kg/day for females, respectively.

Total food consumption for rats in the high (5790 ppm) and medium (2316 ppm) dose groups was decreased for males and females relative to controls. The NOEL is 2316 ppm (106 mg/kg/day). The LOEL is 5790 ppm (268 mg/kg/day) based upon decreased body weights and body weight gains for males and females, increases in urinary crystals for males and pathological changes in the adrenal cortex in females. This study is classified as acceptable and satisfies the requirements for a chronic feeding study in rats (GDLN 83-1a) (MRID 43264402).

Dog - Study 1

In a chronic toxicity study, mepiquat chloride (99.5%) was administered to 6 beagle dogs/sex/dose in the diet at dose levels of 0, 200, 600 or 1800 ppm (0, 6.3, 19.9 or 58.4 mg/kg/day, respectively) for 12 months. The only treatment-related effect, observed at the 1800 ppm dose, was a very slightly increased (Grade 2 on the scale 1-5) storage of the iron pigment in the spleen of 3 male dogs and in the liver of 2 male dogs. All of the remaining male and female dogs in this group, and all of the males and the majority of the females in the remaining groups, including the controls, also had iron pigment in the spleen and liver, but of slightly lesser severity (Grade 1). There were no compound-related effects in mortality, clinical signs, body weight, food consumption, ophthalmoscopic findings, hematology, clinical chemistry, urinalysis, organ weights, gross pathology and, with the exception of the iron pigment noted above, histologic pathology (MRID 41488105).

Dog - Study 2

In a second chronic toxicity study, mepiquat chloride [56.05% a.i.(w/w) in water] was administered to 6 beagle dogs/sex/dose in the diet at dose levels of 0 or 6000 ppm (170 mg/kg/day) for 12 months in order to establish a NOEL.

Based on the results of the two chronic dog studies, the NOEL is 1800 ppm (58.4 mg/kg/day) and the LOEL is 6000 ppm (170 mg/kg/day) based on impaired neurological functions; epithelial vacuolization of the renal distal tubules; and increased hemosiderin (iron pigment; Grade 2) in the spleen (males only). Considered together, these studies are acceptable and satisfy the requirement for the chronic oral study (GDLN 83-1b) in dogs (MRIDs 41488105 and 43264403).

d. Carcinogenicity

Rat

In an oncogenicity study, mepiquat chloride was administered for 24 months in the diet to 50 Wistar rats/sex/dose at concentrations of 0, 290, 2316, or 5790 ppm (active ingredient), equivalent to doses of 0, 13, 105, 269 mg/kg/day for males and 0, 17, 141, or 370 mg/kg/day for females, respectively.

There were no treatment-related neoplastic findings for males or females treated with mepiquat chloride. Thus, mepiquat chloride did not exhibit carcinogenic potential in a 2-year feeding study involving male and female Wistar rats over this dose range. Based upon the decreased body weights and body weight gains, 5790 ppm is a maximum tolerated dose (MTD) for mepiquat chloride for 2-year feeding to male and female Wistar rats, and adequate for identifying carcinogenic potential. The LOEL for males and females is 5790 ppm (269 mg/kg/day), based upon decreased body weights, body weight gains, food consumption, food efficiency; and macroscopic and non-neoplastic microscopic pathological findings. The NOEL for males and females is 2316 ppm (105 mg/kg/ day) (MRID 43396001).

Mouse

In another oncogenicity study, mepiquat chloride was administered in the diet for 24 months to B6C3F1/CrlBr (50 mice/sex/dose) and for 12 months (10 mice/sex/dose) at concentrations of 0, 500, 2000, or 7500 ppm (active ingredient). These respective doses are equivalent to 0, 74, 297, or 1140 mg/kg/day for males and 0, 85, 328, or 1348 mg/kg/day for females, averaged over the 24-month feeding study.

There were no treatment-related effects of mepiquat chloride administration on group mean body weights or body weight gains over the 24-month treatment period. There were no treatment-related macroscopic, non-neoplastic microscopic pathological or neoplastic findings for males or females treated with mepiquat chloride. Thus, mepiquat chloride does not exhibit carcinogenic potential in a 2-year feeding study involving male and female B6C3F1 mice over this dose range. Based upon the lack of treatment-related findings, mepiquat chloride was not administered at the MTD. However, the high dose (7500 ppm or 1140 mg/kg/day) for the study was sufficient to assess carcinogenicity since the limit dose of 1000 mg/kg/day was exceeded. The NOEL for mepiquat chloride administered for 2 years in food is 7500 ppm (1140 mg/kg/day) for male and female B6C3F1 mice.

This study is acceptable and satisfies the guideline requirements for an oncogenicity study in mice (GDLN 83-2(b)) (MRID 43264404).

e. Developmental Toxicity

Rat

In a developmental toxicity study, pregnant Wistar strain rats, 25/group, were administered aqueous solutions of mepiquat chloride (57.9% purity) by gavage during gestation days (GD) 6 through 15. The doses used were 0, 50, 150 or 300 mg/kg/day and were based on the results of the range finding study in which 100, 300 or 600 mg of mepiquat chloride/kg/day were tested.

Treatment-related maternal effects were observed only in the high-dose (300 mg/kg) group and included clinical signs of toxicity and decreases in the food consumption and body weight gain. These effects were not observed when dosing with mepiquat chloride was discontinued. There were no unscheduled mortalities.

Most dams (22-24/25) in the high-dose group showed pronounced but reversible tremors, unsteady gait, indrawn flanks and hypersensitivity, whereas 4/25 dams also had ataxia. All of these findings were noted at approximately 1.5-2.0 hours after dosing, lasted for about 4 hours and, with the exception of ataxia, were less frequent during the second half of the treatment period. Ataxia was observed in 2 dams during GD 7 only, in one dam during GD 8 and in another dam during GD 9.

Compared with the control values, food consumption of the high-dose dams was reduced by 10-19% during the greater part of the dosing period (GD 6-13), but not thereafter. Mean body weight gains were also reduced during the same period by 16-65%, when compared with the control values. However, when mean body weights on GD 20 were corrected for uterine weights, the high-dose dams weighed 13% less than the controls.

Mepiquat chloride, at the three levels tested, had no effect on all of the developmental toxicity parameters examined. No embryotoxicity, fetotoxicity and no indications of any teratogenic effects were observed in this study. The Maternal Toxicity LOEL and NOEL are 300 and 150 mg/kg/day, respectively, based on clinical signs of toxicity, decreases in food consumption and body weight gain. The developmental NOEL > 300 mg/kg/day. The guideline 83-3 requirement for a developmental toxicity study in rats is satisfied (MRID 42337101).

Rabbit

In a developmental toxicity study, technical mepiquat chloride (99% a.i.) was fed to artificially inseminated Himalayan rabbits (21-22/group) in aqua bidest (twice distilled water) at dose levels of 0 (untreated control), 0 (vehicle control), 50, 100 and 150 mg/kg/day. The dosing was done by gavage (in a volume of 5 mL/kg of body weight) during GD 6-18 and the animals were sacrificed on GD 28. The animals received 130 g of dry food per day and water *ad libitum* during the study.

In the 50 mg/kg group, there was 1 abortion on day 26, weight loss and decreased food consumption during GD 6-12, and various amounts of amber-colored liquid in the abdomens of 5 rabbits. In the 100 mg/kg group, there was weight loss during GD 6-12 and decreased body weight gain during GD 12-28; decreased food consumption during GD 6-18; amber-colored liquid in the abdomens of 2 rabbits; diarrhea, trembling and apathy in one rabbit; and 6 abortions during days 18-28. In the 150 mg/kg group, there were 7 deaths during GD 6-18; 4 abortions during GD 18-21; weight loss during GD 6-18; decreased food consumption during GD 6-28; amber-colored liquid in the abdomens of 3 rabbits; and heart dilatation and hyperemia of organs in the nonsurvivors.

Based on the above findings, the maternal NOEL is 50 mg/kg/day (borderline value) and the LOEL is 100 mg/kg/day. Developmental effects were not observed in the 50 mg/kg group. Because of high abortion rate in the 100 mg/kg group (6/16 pregnant = 37.5%), only 8 litters and 26 fetuses were available for evaluation. Because of high death rate and abortion rate in the 150 mg/kg group (total 10/17 pregnant = 58.8%), only 7 litters and 36 fetuses were available for evaluation. The inadequate numbers of fetuses in the mid-dose and high-dose groups precluded the meaningful evaluation of developmental toxicity in this study (MRIDs 148090, 92091010).

The HED Reference Dose (RfD)/Peer Review Committee concluded on May 2, 1996 that a new developmental toxicity study with rabbits (83-3b) is required. The currently available studies are inadequate to meaningfully evaluate the developmental toxicity of mepiquat chloride in that species. In one study (1979; MRID 00148090), too few fetuses were available in the mid-dose and high-dose groups, and only X-rays (no staining techniques) were used for the evaluation of fetuses. The second study (1981; MRID 00148089), in which two doses of mepiquat chloride were tested, and in which X-rays were also used to evaluate the fetuses, was reported only as a brief summary and could not be evaluated. The replacement study (MRID 44102201) has been received by the Agency and reviewed, however since it also relies on X-ray evaluation of the fetuses it will also not be acceptable. The review of this study's findings have not impacted the Agency's developmental endpoint selection since they are consistent with existing information.

The toxicological data base for mepiquat chloride is essentially complete and will support reregistration eligibility. A new rabbit developmental study is required as confirmatory data.

f. Reproductive Toxicity

In a two generation reproductive toxicity study, Wistar rats (25/group/sex) were fed mepiquat chloride in their diets at concentrations of 0, 500, 1500, or 5000 ppm for 10 weeks (F_0) or 14 weeks (F_1) before mating, and during mating, gestation, and lactation. The F_0 parents were mated a second time 2 weeks after weaning the first litter. The doses corresponding to the dietary concentrations are 51.2 and 48.6, 153.1 and 146.6, and 499.3 and 574.5 mg/kg/day, respectively for F_0 and F_1 males and 54.0 and 53.3, 163.6 and 162.0, and 530.0 and 626.5 mg/kg/day, respectively for F_0 and F_1 females.

No treatment-related systemic effects occurred in male or female rats receiving 500 or 1500 ppm of the test material. In animals receiving 5000 ppm (high-dose), effects indicative of impaired neurological function included tremors and hypersensitivity upon handling in 70-85% of F_0 and F_1 dams. To a lesser extent, effects also included decreased forelimb and hindlimb grip strength in dams (before mating, during lactation or after weaning), decreased hindlimb grip strength in high-dose F_1 males, relative reductions in mean body weights of the high-dose F_0 males. Although mean body weights of high-dose F_1 males were reduced by about 50% relative to controls at the start of the premating period, by the end the animals had steadily gained weight such that the body weight gain was only slightly reduced. Effects also included reductions in relative food consumption in F_1 males, mean body weight and body weight gain during the premating period of high-dose F_0 females, gestation body weight and body weight gain of F_0 females, weight of high-dose F_0 and F_1 dams during lactation, weight gain of the F_1 and F_2 pups, and food consumption in the high-dose dams during lactation. Changes in hematologic, clinical chemistry, and urinalysis parameters in the adult high-dose rats were unrelated to dose, biologically insignificant, or were due to the reduced body weight. Plasma, erythrocyte, and brain cholinesterase activities were not affected by treatment with the test material. Decreased liver and kidney weights and decreased incidence of lipid storage in the liver in observed in high-dose males and females were consistent with the decreased terminal body weights and are unlikely to be due to toxicity of the test material. A significant number of high-dose F_1 and F_2 pups were slow in reaching developmental milestones, but these effects are attributed to retarded growth of the pups.

The LOEL for systemic toxicity is 5000 ppm (499 mg/kg/day) for male and female rats based on neurological impairment, decreased body weight and body weight gain in the adults, and retarded growth of F_1 and F_2 pups. The corresponding NOEL is 1500 ppm (147 mg/kg/day).

The OPP's Reference Dose (RfD)/Peer Review Committee concluded on May 2, 1996, that, because of the retarded growth of the pups in the 5000 ppm (499 mg/kg/day) group, the systemic NOEL of 1500 ppm (147 mg/kg/day) would also be regarded as the reproductive NOEL. This study is acceptable and satisfies the requirements for a multigeneration reproduction feeding study (GDLN 83-4) (MRID 43378601).

g. Mutagenicity

In a reverse gene mutation assay in bacteria, strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100 of *S. typhimurium* were exposed to mepiquat chloride (99.8% a.i.) in distilled water at concentrations of 0, 4, 20, 100, 500 or 2500 μg/plate in the presence and absence of mammalian metabolic activation (S-9 mix). Mepiquat chloride did not induce a significant increase in revertant colonies at any dose level up to 2500 μg/plate under the conditions of the assay, either with or without metabolic activation. Mepiquat chloride was neither tested up to cytotoxic concentrations nor the limit concentration, 5000 μg/plate. Solubility did not appear to be a problem and the positive controls induced the appropriate responses in the corresponding strains. Mepiquat chloride was neither tested up to cytotoxic concentrations nor the limit concentration, 5000 μg/plate.

This study is classified as acceptable for regulatory purposes and satisfies the requirement for GDLN 84-2 for *in vitro* mutagenicity (bacterial reverse gene mutation) data. Although mepiquat chloride was not tested at high enough doses for an adequate negative study (the limit dose is 5000 μg/plate), based on the results from the two other mutagenicity studies below, the two carcinogenicity studies, the rat reproduction study and the two developmental toxicity studies, each negative for the specific effect being measured, retesting mepiquat chloride in the *Salmonella* assay would not add any significant knowledge to the current database for this chemical. Therefore, a new study is not required (MRID 41488106).

In an acceptable mammalian cell cytogenetics assay (chromosome aberration in CHO cells), CHO cell cultures were exposed to mepiquat chloride (< 99% a.i.) at concentrations of 2.0, 3.0, 4.0, or 5.0 mg/ml, both with and without metabolic activation. Mepiquat chloride was tested up to the limit concentration, 5000 μg/mL. Positive controls induced the appropriate response. There was no evidence of induced increases in chromosomal aberrations over background (MRID 41488107).

In an acceptable unscheduled DNA synthesis assay, primary rat hepatocyte cultures were exposed to mepiquat chloride (99.86% a.i.) at concentrations ranging from 0.026 to 5000 μg/mL for 18-19 hours. Two trials were initiated, one ranging from 0.026 μg/mL to 1020 μg/mL and the other ranging from 0.25 μg/ml to 5000 μg/ml. Mepiquat chloride was tested up to cytotoxic concentrations. The positive controls induced an appropriate positive response. Under the conditions of the assay, there was no evidence that mepiquat chloride induces an increase in unscheduled DNA synthesis, as determined by radioactive tracer procedures (nuclear silver grain counts) when compared to the negative control group. In addition, there was no indication of a dose-response (MRID 41488108).

h. Metabolism

In a metabolism study, mepiquat chloride, labeled with ^{14}C in the 2,6-carbon atoms of the ring structure (radiochemical purity: 98%), was administered to young adult Sprague-Dawley rats (5/sex/group) either intravenously or orally. During the study, the rats received a standard diet (pellets) as follows: for body weight ≤ 150 g: 10% of body weight + 3 g; for body weight ≥ 150 g, 10% of body weight + 2 g. Water was provided *ad libitum*.

Mepiquat chloride was absorbed rapidly from the stomach, distributed evenly in the intra- and extracellular compartments of the blood, demonstrated high bioavailability via the oral route, was excreted mostly in urine, and did not accumulate in tissues. Other excretions of the administered radioactivity were as follows: feces, 2-15%; exhaled air, ($^{14}CO_2$), 0.20%; and bile, 0.23-0.31%.

The bioavailability of mepiquat chloride appears to depend on the presence of food in the gastrointestinal tract. In the two male rats used in the study of pulmonary elimination of mepiquat chloride as ^{14}C-volatiles, which had access to food immediately after dosing, the bioavailability

was much lower (58%) than that of a similar treatment group in which food was withheld until 4 hours after dosing (79%).

Mepiquat chloride did not accumulate in tissues. Urine, feces and bile samples from various treatments were used for studies of the metabolic fate of mepiquat chloride. In all cases, only the unchanged compound could be detected. Therefore, there was no biotransformation of mepiquat chloride *in vivo*. The potential metabolites, such as 1-methylpiperidine or piperidine, were not detected. This study is acceptable and satisfies the guideline requirement for a metabolism study (GDLN 85-1) in the rat (MRID 40299001).

i. Neurotoxicity

Because of the limited use of mepiquat chloride (on cotton only), very low application rates (0.022-0.044 lb/acre, not to exceed 0.132 lb a.i./acre/season) and the findings that mepiquat chloride was neurotoxic in rats at high levels only (300-889 mg/kg/day), neurotoxicity studies were not required.

2. Dose Response Assessment

a. Reference Dose

On May 2, 1996, the OPP's Reference Dose (RfD)/Peer Review Committee recommended that the RfD for mepiquat chloride be established at 0.6 mg/kg/day. This value was based on the systemic NOEL of 1800 ppm (58.4 mg/kg/day) from the one-year dog feeding study and the uncertainty factor (UF) of 100 (MRIDs 41488105 and 43264403).

b. Carcinogenicity Classification and Risk Quantification

The carcinogenic potential of mepiquat chloride was evaluated by the OPP's Reference Dose (RfD)/Peer Review Committee on May 2, 1996. The Committee classified mepiquat chloride into Group E (evidence of noncarcinogenicity for humans), based on a lack of carcinogenicity in acceptable studies with two animal species, rat and mouse (MRIDs 43264404 and 43396001).

c. Other Toxicological Endpoints for Risk Assessment

The OPP's Toxicology Endpoint Selection Committee (TESC) considered the available toxicology data for mepiquat chloride at a meeting held on May 7, 1996. Based upon a review of the database, toxicology endpoints and dose levels of concern have been identified for use in risk assessments.

(1) Dermal Absorption

Dermal absorption data are not available. The estimated dermal absorption was, therefore, extrapolated from an oral toxicity study in rats and an acute dermal toxicity study in rats (MRIDs 41488101, 41488102). No toxic signs were observed in the dermal study at the limit dose used (2000 mg/kg/day), but were observed at approximately 25% of that dose (464 mg/kg/day) in the oral study. Toxic signs observed in the acute oral study, in the nonsurvivors, were dyspnea, apathy, staggering, twitching and cyanosis. The amount absorbed was estimated to be 23.2%, based on the comparison of these two studies (acute oral LD_{50} divided by the acute dermal LD_{50}).

(2) Acute Dietary

The endpoint for acute dietary risk assessment was estimated based on the one-year dog feeding study with the 90-day dog feeding as a supporting study. Since there were no definite toxic effects detected in the one-year study in which the highest dose of mepiquat chloride tested was 1800 ppm (58.4 mg/kg/day), another one-year study with 6000 ppm (170 mg/kg/day) doses was conducted. The endpoint and dose for use in risk assessment is 1800 ppm (58.4 mg/kg/day) based on salivation (an indicator of impaired neurological functions) in all dogs at 2 hours after each feeding observed at the 6000 ppm dose level. Salivation was slight at first, moderate to severe during the next 4 hours and then gradually disappeared. In the subchronic feeding study, sedation (also a neurotoxic sign) was observed for 1-6 hours after each dosing with 3000 ppm (95.3 mg/kg/day; LOEL) of mepiquat chloride (MRIDs 41488105, 43264403, and 00135720).

(3) Short and Intermediate Term Occupational and Residential

The endpoint for short and intermediate term dermal exposure is 1800 ppm (58.4 mg/kg/day) based on the one-year dog feeding study and its supporting 90-day dog feeding study. The NOEL from the 90-day study was not used for the dermal short and intermediate term exposure since it was only classified as supplemental and an acceptable one-year feeding study was available. The endpoint for short-term inhalation exposure is 4.89 mg/L (NOEL) based on the acute inhalation study in rats. For intermediate term occupational inhalation exposure, is unlikely because of the limited use pattern (growth regulator for cotton only); the low application rates (0.022-0.044 lb/ai/A; not to exceed 0.132 lb/ai/A/season), and low volatility (MRIDs 41488105, 43264403, and 00135720).

3. Dietary Exposure and Risk Assessment/Characterization

a. Dietary Exposure

All residue chemistry data submissions in support of the reregistration of mepiquat chloride have been reviewed. As a result of changes to Table II of the Pesticide Assessment Guidelines (Subdivision O, Residue Chemistry, 9/95), field residue data have been required for cotton gin byproducts and a tolerance will be proposed for this commodity when adequate field residue data

have been submitted and reviewed. These data are due to the Agency by March 17, 1997. The outcome of this new data requirement does not affect the reregistration eligibility decision.

Additionally, tolerance revisions have been required. Tolerances for residues of mepiquat in/on cotton forage, cottonseed meal, eggs, milk, poultry fat, meat and meat byproducts will be proposed for revocation. The existing data constitutes a substantially complete database sufficient to assess dietary exposure and supports the reregistration of mepiquat chloride with respect to residue chemistry. (See Section IV.C for the complete list of tolerance revisions.)

(1) Directions for Use (GDLN 171-3): Agricultural Food Uses

The maximum single application rate is 0.044 lb ai/A/application. Up to four low-rate applications, with 7- to 14-day retreatment intervals, may be made provided the maximum seasonal rate of 0.132 lb ai/A is not exceeded. Application(s) may be made using ground or aerial equipment in a minimum of 2 gal of water per acre (GPA) except when application is made in CA. In CA, the minimum spray volume for ground and aerial equipment is 5 GPA. Ultra low volume (ULV) aerial applications, using oil as diluent (minimum spray volume of 2 pints oil/A), are permitted for the SC/L formulations in AL, AR, FL, GA, LA, MO, MS, NC, OK, SC, TN, and TX. The established pregrazing/feeding and preharvest interval is 30 days. A grazing/feeding restriction is in effect following ULV aerial applications in oil and for the DF formulation. Adequate field trial data are available to support the presently registered maximum use patterns. Adequate field trial data are also available to support the registrant's increased maximum seasonal rate from 0.066 lb ai/A (1x) to 0.088 lb ai/A (1.3x) or 0.132 lb ai/A (2x).

The reregistration requirements for this guideline topic (GDLN 171-3) are fulfilled, except for the need to establish a plantback interval which had not been previously established for rotational crops. Therefore, based on an acceptable confined rotational crop study, the registrant must amend all of its mepiquat chloride end-use products to establish a plantback interval of 2.5 months (42733601).

(2) Plant Metabolism (GDLN 171-4 (a))

The reregistration requirements for plant metabolism are fulfilled. An acceptable study, depicting the qualitative nature of the residue in cotton plants, has been submitted and evaluated. Based on this study, it has been determined that the residue of concern in/on plant commodities is mepiquat chloride *per se*. The current tolerance expression for plant commodities is appropriate (MRID 43024701).

(3) Animal Metabolism (GDLN 171-4 (b))

The reregistration requirements for animal metabolism are fulfilled. Acceptable studies, depicting the qualitative nature of the residue in ruminant and poultry, have been submitted and evaluated. The residue of concern in animal commodities is mepiquat chloride *per se*. The

current tolerance expression for animal commodities is appropriate (MRIDs 42394301/2/3, 43290401/2/3/4/5).

(4) Residue Analytical Method-Plants and Animals (GDLNs 171-4 (c) and (d))

The reregistration requirements for residue analytical methods are fulfilled. Acceptable methods are available for enforcement and data collection purposes for both plant and animal commodities.

Enforcement methods: The Pesticide Analytical Manual (PAM Volume II) lists Method I as available for the determination of residues of mepiquat chloride *per se* in/on plant and animal commodities. This GLC method, with nitrogen detection, has undergone successful Agency method tryout using plant (cottonseed, cotton forage, and cottonseed processed fractions) and animal (milk, eggs, and meat of chicken and beef) matrices. The stated limit of quantitation is 0.1 ppm for cotton and 0.05 ppm for animal products.

Multi residue methods: The FDA PESTDATA database dated 1/94 (PAM Volume I, Appendix I) does not have an entry for mepiquat chloride. The existing FDA multi-residue methods are not likely to recover mepiquat chloride residues because of its ionic nature (MRIDs 42426801, 42734601/2, 42394393/4, 42546201/2, 42734601/2, 42892201, 43379501, 43738603).

(5) Storage Stability (GDLN 171-4 (e))

The reregistration requirements for storage stability data are adequately fulfilled. Adequate information is available concerning the maximum storage intervals as well as the conditions of plant and processed commodities used in support of tolerance establishment or in support of data requested for reregistration. Acceptable storage stability studies have been submitted for cotton and its processed commodities. These studies have demonstrated that residues of mepiquat chloride *per se* are stable under frozen storage conditions at least 25 months in/on cottonseed and for at least 28.5 months in cottonseed hulls, meal, crude oil, refined oil, and soapstock.

The available plant and animal metabolism studies are validated by adequate storage stability data. In conjunction with the ruminant metabolism study, it was demonstrated that residues of mepiquat chloride *per se* are stable under frozen storage conditions for at least 45 months in milk and liver. An additional study depicting the freezer storage stability of residues of mepiquat chloride *per se* found residues to be stable for at least 26 months in ruminant and poultry tissue and eggs (MRIDs 42734601/2, 42892201, 43379501, 43738603).

(6) Magnitude of the Residue in Plants (GDLN 171-4 (k))

The reregistration requirements for magnitude of the residue in/on cottonseed are fulfilled. Adequate cottonseed field trial data, reflecting use of the registered SC/L and DF formulations

at the presently registered maximum use patterns, have been submitted. Adequate field trial data are also available to support the registrant's proposal to increase the maximum seasonal rate on cotton plants from 0.066 lb ai/A to 0.132 lb ai/A. It has been previously concluded that the established tolerance of 2 ppm for cottonseed is sufficient to cover additional residues of mepiquat chloride *per se* that may result from an increase in the maximum seasonal rate to 0.132 lb ai/A (42734601/2).

According to Table II of the Pesticide Assessment Guidelines (Subdivision O, Residue Chemistry, 9/95), cotton forage is no longer considered a significant livestock feed item and has been deleted from the table. Therefore, the previously requested data for cotton forage are no longer required and the established tolerance for this item should be revoked. Table II now recognizes cotton gin byproducts as a raw agricultural commodity of cotton. Therefore, field residue data must be submitted for cotton gin byproducts and a tolerance must be proposed for this commodity when adequate field residue data have been submitted. These data have been required and are due to the Agency by March 17, 1997.

(7) Magnitude of the Residue in Processed Food/Feed (GDLN 171-4 (l))

The reregistration requirements for magnitude of the residue in processed cottonseed commodities are fulfilled. An acceptable cottonseed processing study has been submitted. Any residue that may result in cottonseed meal as a result of processing will be covered by the RAC tolerance. Therefore, the established feed additive tolerance of 3.0 ppm for cottonseed meal should be revoked.

The temporary food and feed additive tolerances for grape processed commodities, originally established in accordance with an approved experimental use program, expired on June 30, 1991. Since there are presently no registered uses of mepiquat chloride on grapes, these expired food and feed additive tolerances should be revoked (MRID 42426803).

(8) Magnitude of the Residue in Meat, Milk, Poultry, and Eggs (GDLN 171-4(j))

The reregistration requirements for magnitude of the residue in livestock are fulfilled. There are no registered direct animal treatments for mepiquat chloride on cattle, goats, hogs, horses, sheep or poultry. The residue of concern in animals is mepiquat chloride *per se*, and acceptable animal feeding studies depicting mepiquat chloride have been submitted and evaluated.

The cattle feeding study indicated that the established tolerances of 0.1 ppm for mepiquat chloride residues in fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep are adequate. Pursuant to 40 CFR 180.6(a)(3), the milk tolerance will be proposed for revocation since data indicated that no residues are likely in this commodity.

The poultry feeding study indicated that no residues were found in poultry tissue samples at any dosage. This assessment includes the tolerances that will be proposed for revocation. Based on this result, there is no expectation of transfer of residues to poultry and eggs. Therefore, since data indicate that no residues are likely in these commodities, the poultry and egg tolerances established at 0.1 ppm for poultry fat, meat, and meat by-products and at 0.05 ppm for eggs will be proposed for revocation pursuant to 40 CFR 180.6(a)(3) (MRID 43738601).

b. Dietary Risk Assessment/Characterization

No dietary risks of concern were identified for mepiquat chloride for the general U.S. population nor any subgroup. Pursuant to the requirements under the Food Quality Protection Act of 1996, the Agency has determined that the use of mepiquat chloride will not pose dietary risks to infants and children due primarily to the chemical's low toxicity and its low usage rate.

(1) Chronic Dietary Risk Assessment

A Dietary Risk Evaluation System (DRES) chronic exposure analysis was performed using tolerance level residues (including those that will be proposed for revocation and the three grape and raisin tolerances recently revoked) and an assumption of 100 percent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. No Anticipated Residue (AR) information was used in this analysis. Existing tolerances result in a Theoretical Maximum Residue Contribution (TMRC) which represents less than 1% of the RfD for the U.S. general population and each of the 22 sub-groups, including non-nursing infants (< 1 year old).

The chronic analysis for mepiquat chloride is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with mepiquat chloride. Based on the risk estimates calculated in this analysis, it has been concluded that dietary exposure to mepiquat chloride does not pose a risk concern.

(2) Acute Dietary Risk Assessment

The DRES detailed acute analysis estimates the distribution of single-day exposures for the overall U.S. population and the subgroups of Infants less than 1 year old, Children 1-6 years old, and Females and Males 13+ years old. The analysis evaluates individual food consumption as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of mepiquat chloride in the commodity supply.

The Margin of Exposure (MOE) is a ratio of the NOEL to the exposure. Generally, the Agency concludes that there is no dietary concern when the acute dietary margins of exposure greater are than 100.

The results of the acute analysis indicate that mepiquat chloride in the diet represents no serious risk concern for acute exposure. All MOEs were well above the Agency's level of concern for acute dietary risk (ranging from a low of 3,893 for Infants to a High of 29,200 for Females 13+ years old).

4. Occupational and Residential Exposure and Risk Assessment/ Characterization

a. Residential Exposure and Risk Assessment

At this time products containing mepiquat chloride are only registered for occupational uses. Therefore, residential inhalation and dermal exposures to individuals, including infants and children, are not expected.

b. Occupational Mixer/Loader/Applicator Exposure Assessment

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. The short- and intermediate-term criteria for dermal exposure and short-term criteria for inhalation exposure have been triggered as determined above in Section III.B.2.

Mixer/loaders of mepiquat chloride are assumed to be using open methods of mixing/loading, and ground applicators are assumed to be spraying mepiquat chloride from open-cabbed tractors. Dermal absorption is estimated to be 23.2%. Aerial applicators are assumed to be spraying from aircraft with enclosed cockpits (engineering controls), as no data were available for open cockpit aircraft. No gloves or respirators are assumed to be worn for the baseline exposure estimates.

It has been determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with mepiquat chloride. Based on the use patterns, six major exposure scenarios were identified for mepiquat chloride: (1a) mixing/loading liquids for aerial application; (1b) mixing/loading liquids for groundboom application; (2a) mixing/loading dry flowables for aerial application; (2b) mixing/loading dry flowables for groundboom application; (3) aerial application of liquids (fixed-wing); (4) aerial application of liquids (helicopter); (5) groundboom application of liquids; and, (6) flagging liquid aerial applications.

c. Occupational Risk Assessment/Characterization

(1) Occupational Mixer/Loader/Applicator Risk Assessment

Short-term and intermediate-term dermal and inhalation exposures were estimated using the Pesticide Handlers Exposure Database (PHED), Version 1.1 (no chemical-specific exposure data were submitted).

Potential Daily Exposure is calculated using the following formula:

$$Daily\ Exposure\left(\frac{mg\ ai}{Day}\right) = Unit\ Exposure\left(\frac{mg\ ai}{lb\ ai}\right) x\ Max.\ Appl.\ Rate\left(\frac{lb\ AI}{Acre}\right) x\ Max.\ Area\ Treated\left(\frac{Acres}{Day}\right)$$

The Daily Dermal Dose is calculated using the following formula:

$$Daily\ Dermal\ Dose\left(\frac{mg\ ai}{Kg/Day}\right) = Daily\ Dermal\ Exposure\left(\frac{mg\ ai}{Day}\right) x\left(\frac{1}{Body\ Weight\ (Kg)}\right)$$

The Short-Term and Intermediate-Term Dermal MOEs were calculated using the following formula:

$$MOE = \frac{NOEL\left(\frac{mg}{kg/day}\right)}{Daily\ Dermal\ Dose\left(\frac{mg}{kg/day}\right)}$$

Potential daily exposure calculations are used to calculate an estimate of the daily dermal dose of mepiquat chloride to handlers. Risk resulting from dermal exposure is determined by applying the respective dermal NOEL to these exposure estimates. For short-term and intermediate-term dermal risk assessment, a NOEL of 58 mg/kg/day was used along with a 70 kg body weight.

The Daily Inhalation Dose is calculated using the following formula:

$$Daily\ Inhalation\ Dose\left(\frac{mg\ ai}{Kg/Day}\right) = Daily\ Inhalation\ Exposure\left(\frac{mg\ ai}{Day}\right) x\left(\frac{1}{Body\ Weight\ (Kg)}\right)$$

The Inhalation MOEs were calculated using the following formula:

$$MOE = \frac{NOEL\left(\frac{mg}{kg/day}\right)}{Daily\ Inhalation\ Dose\left(\frac{mg}{kg/day}\right)}$$

The daily inhalation dose calculations of mepiquat chloride received by handlers are used to estimate the inhalation risk to those handlers. Risk resulting from inhalation exposure is determined by applying the inhalation NOEL to these exposure estimates. To calculate the inhalation dose of mepiquat chloride to handlers, a NOEL of 370 mg/kg/day was used along with a 70 kg body weight.

Table 3: Short-Term and Intermediate-Term Risk from Mepiquat Chloride

Exposure Scenario (scenario #)	Baseline Absorbed Dermal Dose (mg/kg/day)[a]	Baseline Absorbed Dermal MOE[b]	Baseline Inhalation Dose (mg/kg/day)[c]	Baseline Inhalation MOE[d]
Mixer/Loader Risk				
Mixing/Loading Liquids for Aerial Application (la)	0.0033	17,576	0.0004	9.3×10^5
Mixing/Loading Liquids for Groundboom Application (lb)	0.00076	76,316	0.00009	4.1×10^6
Exposure Scenario (scenario #)	0.0053	10,943	0.00026	1.4×10^6
Mixing/Loading Dry Flowables for Groundboom Application (2b)	0.0012	48,333	0.00006	6.2×10^6
Applicator Risk				
Aerial Application of Liquids using Fixed-Wing Aircraft with Enclosed Cockpit (3)	0.00036[e]	1.6×10^5	0.00002[e]	1.9×10^7
Aerial Application of Liquids using Enclosed Cockpit Helicopter (4)	0.00013[e]	4.5×10^5	0.00043	8.6×10^5
Groundboom Application of Liquids (5)	0.00026	2.2×10^5	0.000053	7.0×10^6
Flagger Risk				
Flagging for Liquid Application (6)	0.00060	96,667	0.00009	4.1×10^6

[a] Baseline Absorbed Dermal Dose = (daily dermal exposure x dermal absorption factor 23.2 percent) / 70 kg.

[b] Dermal Absorbed MOE = NOEL (58 mg/kg/day) / daily dermal dose, assuming baseline PPE (long pants, shirt, shoes and socks).

[c] Baseline Inhalation Dose (mg/kg/day) = daily inhalation exposure (mg/kg/day) / 70 kg, assuming 8 hour exposure.

[d] Inhalation MOE = NOEL (2.59 mg/L) = $\{(2.59 \text{ mg/L}) \times 1 \text{ L}/(1 \times 10^{-3} \text{ m}^3)] = 2590 \text{ mg/m}^3$. Assuming a 10 m^3/day inhalation rate (2590 mg/m^3 x 10 m^3/day) / 70 kg = 370 mg/kg/day.

[e] Engineering controls were used: enclosed cockpit, single layer of clothing and no gloves.

(2) Occupational Risk Characterization

As can be seen from Table 3, the dermal and inhalation MOEs for all exposure scenarios greatly exceed 100. Although the risk to aerial applicators using open cabs or cockpits was not estimated, (the Pesticide Handlers Exposure Database does not contain sufficient data to estimate this exposure scenario), the Agency does not have concern for these handlers since the vast majority of aerial application is performed using aircraft with closed cabs and cockpits. In addition, the high margin of exposure for open cab tractors also suggest that open cockpit exposures are not a concern.

It has been determined that there is a potential for exposure to persons entering treated sites after application is complete and no post-application exposure data are available for mepiquat chloride. Based on the low maximum application rate of 0.044 pounds per acre and the high margins of exposure for mixers/loaders/handlers, the Agency expects post-application risks to be very low. In addition, post-application exposures are further limited because of the common practice of tank-mixing mepiquat chloride with pesticides with longer Re-Entry Intervals (REI). Therefore, the Agency believes that the risks from post-application exposures to mepiquat chloride will not pose unreasonable risks to persons entering treated areas.

Also, the Agency has reports of worker poisonings associated with mepiquat chloride. There were eight reported incidents involving mepiquat chloride in the California Pesticide Illness Surveillance Program data base from 1982 through 1992. However, the circumstances of these incidents are not fully known and may be attributable to exposure from other chemicals. For this reason, the Agency does not consider these incidents to be indicative of any significant risk.

5. Food Quality Protection Act (FQPA) Considerations

The Food Quality Protection Act of 1996 (FQPA) amended the FFDCA by setting a new safety standard for the establishment of tolerances. In determining whether a tolerance meets the new safety standard, section 408(b)(2)(C) directs EPA to consider available information concerning the susceptibility of infants and children to pesticide residues in food, and available information concerning aggregate exposure to infants and children of such residues, as well as the potential for cumulative effects from pesticide residues and other substances that have a common mechanism of toxicity.

The new section 408(b)(2)(C) says that, in the case of threshold effects, EPA must apply an additional 10-fold margin of safety for infants and children to take into accout potential pre- and post-natal toxicity unless EPA concludes, based on reliable data, that a different margin of safety will be safe for infants and children.

Section 408(b)(2)(D) establishes factors that the Agency must consider in determining whether the safety standard is met in deciding to issue or reassess tolerances. These factors include the consideration of available information on the aggregate exposures to the pesticide from dietary sources including drinking water as well as non-occupational exposures such as those derived from pesticides used in and around the home. The Agency must also consider the potential cumulative effects of the pesticide for which a tolerance is being sought as well as other substances that have a common mechanism of toxicity for the general population and major subgroups of the population.

Because mepiquat chloride is used on cotton, a crop used as animal feed which has tolerances, specific consideration of the risks to infants and children, as well as aggregate exposures and potential cumulative effects is warranted.

a. Potential Risks to Infants and Children

In determining whether an additional uncertainty factor is or is not appropriate for assessing risks to infants and children, EPA uses a weight of evidence approach taking into account the completeness and adequacy of the toxicity database, the nature of the effects observed in pre- and post-natal studies, and other information such as epidemiological data.

For the purpose of assessing the pre- and post-natal toxicity of mepiquat chloride, EPA has evaluated two developmental and one reproduction study. Based on current data requirements, these three studies when considered along with other required toxicity studies, constitute a complete database for evaluating pre- and post-natal effects for food use chemicals. However, the rabbit developmental study was considered supplemental and a new developmental study in rabbits is required as confirmatory

data. Additionally, as EPA fully implements the requirements of FQPA, additional data related to the special sensitivity of young organisms may be required.

Developmental and Reproductive Effects

The effects observed in the mepiquat chloride developmental and reproduction studies can be summarized as follows:

A developmental toxicity study with Wistar rats used doses of 0, 50, 150 or 300 mg/kg/day given by gavage on gestation days 6-15. The maternal toxicity NOEL was 150 mg/kg/day based on clinical signs of toxicity, decreases in food consumption and reduced body weight gain. The developmental toxicity NOEL is > 300 mg/kg/day because no effects on any of the developmental toxicity parameters were seen. In addition, no embryotoxicity, fetotoxicity and no indications of any teratogenic effects were observed in the study.

In a developmental toxicity study in Himalayan rabbits doses of 0, 50, 100 and 150 mg/kg/day was given by gavage on gestation days 6-18. The NOEL for maternal toxicity was 50 mg/kg/day mid- and high-dose groups included weight loss, decreased body weight gain, deceased food consumption, amber-color liquid in the abdomens of two rabbits, diarrhea, trembling, apathy and abortion. No developmental effects were seen at the 50 mg/kg/day-dose group. The developmental LOEL is 100 mg/kg/day, based on the observed abortions. The abortions observed at 100 mg/kg/day were considered evidence of developmental toxicity; however, due to the high abortion and death rates in the high dose groups, an inadequate number of fetuses and available which precluded the meaningful evaluation of fetal development in this study. Additionally, the fetal evaluation techniques used in the rabbit studies does not permit full evaluation of potential effects.

In a two-generation reproduction study Wistar rats were fed doses of 0, 500, 1500 (147 mg/kg/day) or 5000 ppm (499 mg/kg/day) of mepiquat chloride. Treatment-related system effects were seen only in the highest dose group and were indicative of impaired neurological function (including tremors and hypersensitivity upon handling); to a lesser extent, effects to the high-dose group also included decreased forelimb and hindlimb grip strength, reductions in relative food consumption, mean body weight, and body weight gain. The parental NOEL is 147 mg/kg/day. The parental LOEL for reproductive/systemic toxicity is 499 mg/kg/day based on neurological impairment, deceased body weight gain in the adults and retarded growth of F_1 and F_2 pups. The reproductive NOEL is also 147 mg/kg/day.

The developmental data for mepiquat chloride indicate developmental effects occurred at doses that were the same as or higher than doses which cause maternal toxicity. The Agency would generally be concerned when developmental/ reproductive effects are seen at doses lower than those which cause maternal effects. Considering the nature of the developmental effects and the dose level at which they occurred, the developmental studies in conjunction with the reproduction study do not indicate any additional sensitivity of young organisms to mepiquat chloride.

Uncertainty Factor

Based on the reliable data discussed above, and the absence of any incident or epidemiological data for mepiquat chloride, the Agency concludes that an additional uncertainty factor is not warranted for the mepiquat chloride chronic risk assessment, nor is the use of an additional uncertainty factor indicated for estimating risk from acute exposures detailed below.

b. Aggregate Exposure/Risk

In examining aggregate exposure, FQPA directs EPA to take into account available information concerning exposures from the pesticide residue in food and all other exposures for which there is reliable information. These other sources of exposure include drinking water, and non-occupational exposures, e.g., to pesticides used in and around the home. In addition to acute and chronic risks, the Agency, as appropriate, may also calculate risks for short-term and intermediate term exposures.

Mepiquat chloride has no residential or other non-occupational uses that might result in exposures to humans. Neither a Maximum Contaminant Level (MCL) nor a Hazard Advisory (HA) has been established for mepiquat chloride. According to the EPA's Pesticides in Ground Water Database, there have been no mepiquat chloride detections reported in monitoring wells. Based on its low application rate, relatively rapid degradation rate, and soil binding ability, the Agency does not expect mepiquat chloride to contaminate ground water or surface water. Consequently neither a chronic or acute drinking water assessment was performed.

Acute Risk

The acute toxicity of mepiquat chloride by the oral, dermal, and inhalation routes of exposure is very low. An acute dietary risk analysis was performed using tolerance-level residues and assumption of 100 percent crop treated. This analysis showed MOEs that were well above the Agency's level of concern. MOE values ranged from 3,893 for infants to 29,200 for females 13^{+} years.

Chronic Risk (Dietary Exposure)

A chronic dietary exposure analysis was performed, using tolerance level residues and assuming that 100 percent of the crops were treated, to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups.

Existing tolerances result in a TMRC which represents $<$ 1% of the RfD for the U.S. general population and each of the 22 subgroups.

The analysis for mepiquat chloride is a worst case estimate of dietary exposure with all residues assumed to be at tolerance levels and 100 percent of the commodities assumed to have been treated with mepiquat chloride.

Tolerances have been established in/on cottonseed at 2 ppm and animal commodities at 0.1 ppm. The available data for mepiquat chloride support the established tolerances listed in 40 CFR § 180.384. The tolerances for eggs, milk, poultry and byproducts will be proposed for revocation since data indicate that no residues are likely in these commodities. The tolerance for cotton forage will be proposed for revocation since it is no longer considered a significant livestock feed. The Section 409 tolerance for cottonseed meal is not needed because any residue that may result in cottonseed meal as a result of processing will be covered by the reassessed RAC tolerance. The field residue data for cotton gin byproducts have been required and a tolerance will be proposed for this commodity when adequate field residue data have been submitted and reviewed. These data are due to the Agency by March 17, 1997. The outcome of this new data requirement does not affect the reregistration eligibility decision. Additional tolerance revisions have been required. Tolerances for residues of mepiquat in/on cotton forage, cottonseed meal, eggs, milk, poultry fat, meat and meat byproducts will be proposed for revocation.

Conclusion Regarding Chronic Aggregate Exposure to Mepiquat Chloride

Based on mepiquat chloride's use pattern as a growth regulator on cotton, no chronic residential, other non-occupational or drinking water exposure is expected. Chronic aggregate exposure is limited to dietary exposure which is expected to be < 1% of the RfD for the general U.S. population and the 22 population subgroups. The Agency, therefore, concludes that aggregate risks to the general U.S. population, and to the population subgroups of infants and children, resulting from mepiquat chloride uses are not of concern.

c. Cumulative Effects

In assessing the potential risk from cumulative effects of mepiquat chloride and other pesticides and substances with a common mode/mechanism of toxicity, the Agency first considered structural similarities and common effects that exist between mepiquat chloride and other related compounds such as paraquat, diquat and difenzoquat. The Agency then considered other compounds which could potentially result in neurotoxic effects similar to mepiquat chloride.

With one substance, difenzoquat, there appears to be similar neurotoxic effects. The Agency has concluded that the cumulative effects from the combined dietary exposure to mepiquat and difenzoquat would be virtually nil because the chronic dietary exposure for all population subgroups is less than 1% of the RfD for both difenzoquat and mepiquat chloride. The acute dietary MOE range for difenzoquat is 50,000 to 16,000 while the acute dietary MOE range for mepiquat chloride is 3,900 to 29,000.

In evaluating other chemicals with neurotoxic effects similar to mepiquat chloride, the Agency determined that it is unlikely that these other chemicals share a common mode/mechanism of toxicity with mepiquat chloride, or that cumulative risk assessment would be required. Although the mode/mechanism of toxicity of mepiquat chloride has not been well defined, the effects noted on the nervous system appear to be secondary to general systemic toxicity that occurs at high dose levels. Based on available data and structure-activity relationship analyses, mepiquat chloride would be considered to have minimal neurotoxic activity.

C. Environmental Assessment

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

(1) Birds, Acute

An acute oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the toxicity of mepiquat chloride to birds. The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). Results of this test are presented in Table 4.

Table 4: Avian Acute Oral Toxicity

Species	% ai	LD_{50} (mg/kg a.i.)	Toxicity Category	MRID No., Author/year
Northern bobwhite quail *(Colinus virginianus)*	46	> 2,134	practically nontoxic	135130, Beavers et al. 1977[1]
Northern bobwhite quail *(Colinus virginianus)*	99	> 2,000[3]	practically nontoxic	43150701, Munk, R. 1993[2]

[1] Supplemental (study is scientifically sound, but does not satisfy guideline.) This study is supplemental because the birds were only 14 days old instead of 16 weeks and the study was conducted for 8 days instead of 14.
[2] Core (study satisfies guideline).
[3] Only one bird death was reported during the study (at 2,000 mg/kg).

The LD_{50} is > 2000 mg/kg. Therefore, mepiquat chloride is practically nontoxic to avian species on an acute oral basis. The guideline (71-1) is fulfilled (MRID 43150701).

Two subacute dietary studies using the TGAI are required to establish the toxicity of mepiquat chloride to birds. The preferred test species are mallard duck and bobwhite quail. Results of these tests are presented in Table 5.

Table 5: Avian Subacute Dietary Toxicity

Species	% ai	5-Day LC_{50} (ppm a.i.)	Toxicity Category	MRID No., Author/Year
Northern bobwhite quail *(Colinus virginianus)*	46	> 4,600[1]	practically nontoxic	135131, Beavers et al. 1977
Mallard duck *(Anas platyrhynchos)*	46	> 4,600[2]	practically nontoxic	135132, Beavers et al. 1977

[1] No deaths occurred at any dosage levels.
[2] Only one death occurred during the study (at 1,000 ppm).

The LC_{50} is > 4,600 ppm, therefore, mepiquat chloride is practically nontoxic to avian species on a subacute dietary basis. The guideline (71-2) is fulfilled (MRIDs 135131 and 135132).

(2) Birds, Chronic

Avian reproduction studies using the TGAI are required when birds may be subject to repeated or continuous exposure to the pesticide. Initial applications of mepiquat chloride may coincide with bird breeding; and when it may persist on avian food items in amounts that are potentially toxic on a chronic basis. The preferred test species are mallard duck and bobwhite quail.

No avian reproduction studies are available for mepiquat chloride. However, while mepiquat chloride meets the basic criteria for requiring avian reproduction studies, the relatively low application

rate, and the indication of low biological activity to nontarget laboratory vertebrate species suggest that the value-added of avian reproduction studies is low. The peak maximum estimated residue level on avian food items is 16 ppm for short grass. This level is many times lower than acute avian and mammalian effect concentrations and chronic mammalian effect concentrations. The rat LD_{50} value is 464 mg/kg and the bobwhite quail LD_{50} value is > 2,000 mg/kg. Furthermore, mepiquat chloride poses little acute, chronic, or reproductive risk to mammals. Therefore, these studies are not required and Guideline 71-4 is waived.

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, the rat or mouse toxicity values substitute for wild mammal testing. These toxicity values are reported in III.B.1. above.

Because the LD_{50} falls within the range of 51-500 mg/kg, mepiquat chloride is moderately toxic to small mammals on an acute oral basis. Chronic and subchronic studies indicate that mammals are affected at relatively high concentrations.

(4) Insects

A honey bee acute contact study using the TGAI is required for mepiquat chloride because its use on cotton may result in honey bee exposure. Results of this test are presented in Table 6.

Table 6: Nontarget Insect Acute Contact Toxicity

Species	% ai	LD_{50} (μg/bee)	Toxicity Category	MRID No., Author/Year
Honey bee *(Apis mellifera)*	46.3	> 100	practically nontoxic	41626703, Hoxter et al. 1990

The results indicate that mepiquat chloride is practically nontoxic to bees on an acute contact basis. The guideline (141-1) is fulfilled (MRID 41626703).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

(a) Acute

Two freshwater fish toxicity studies using the TGAI are required to establish the toxicity of mepiquat chloride to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). Results of these tests are presented in Table 7.

Table 7: Freshwater Fish Acute Toxicity

Species	% ai	96-hour LC_{50} (ppm a.i.) (measured/nominal)	Toxicity Category	MRID No., Author/Year
Rainbow trout *(Oncorhynchus mykiss)* (static)	99	> 92 (measured)	slightly toxic	41889006, Munk 1991[1]
Rainbow trout *(Oncorhynchus mykiss)*	46	730 (nominal)	practically nontoxic	096636, Kue et al. 1977[1]
Bluegill sunfish *(Lepomis macrochirus)* (static)	99	> 89 (measured)	slightly toxic	41889005, Munk 1991

Table 7: Freshwater Fish Acute Toxicity

Species	% ai	96-hour LC_{50} (ppm a.i.) (measured/nominal)	Toxicity Category	MRID No., Author/Year
Bluegill sunfish *(Lepomis macrochirus)*	46	2580 (nominal)	practically nontoxic	096636, Kue et al. 1977

[1] These studies are supplemental because the test concentration was less than 100 ppm but not high enough to produce mortality.

The LC_{50} has been demonstrated in some tests to be > 100 ppm, and therefore is considered to be practically nontoxic to freshwater fish on an acute basis. The guideline (72-1) is fulfilled (MRIDs 00135133, 41889005/6).

(b) Chronic

A freshwater fish early life-stage test using the TGAI is required for mepiquat chloride because the end-use product is expected to be transported to water from the intended use site. Based on available use information, its presence in water is likely to be continuous or recurrent. Although the estimated environmental concentration (0.82 ppb) resulting from its use is less than 0.01 of any acute LC_{50} or EC_{50} value, the aerobic soil metabolism half-life ranges from 3-21 days and it is stable to hydrolysis and photolysis. However, supplemental chronic toxicity studies with freshwater fish and invertebrates suggest low chronic toxicity. Furthermore, mepiquat chloride's low acute toxicity and application rate suggests that significant adverse chronic effects to aquatic organisms are unlikely. Therefore, a freshwater fish study (GDLN 72-4) is waived.

The sublethal toxicity study presented in Table 8 below did not address the standard endpoints for either the fish early-life stage or the fish full-life cycle studies.

Table 8: Freshwater Fish Sublethal Toxicity Under Flow-through Conditions (28 days)

Species/ Study Duration	% ai	NOEC (ppm)	Endpoints Affected	MRID No., Author/Year
Rainbow trout *(Oncorhynchus mykiss)*	99.0	> 100 (nominal)	none (growth, mortality, or toxic symptoms)	43155901, Munk, 1993

[1] This study is supplemental because juveniles and not embryos were used and the study duration was only 28 days instead of a minimum of 72 days.

(2) Freshwater Invertebrates

(a) Acute

A freshwater aquatic invertebrate toxicity test using the TGAI is required to establish the toxicity of mepiquat chloride to aquatic invertebrates. The preferred test species is *Daphnia magna*. Results of this test are presented in Table 9.

Table 9: Freshwater Invertebrate Acute Toxicity

Species	% ai	48-hour LC_{50}/EC_{50} (ppm a.i.)	Toxicity Category	Acc./MRID No., Author/Year
Waterflea *(Daphnia magna)*	46	50.8	slightly toxic	00135134, Vilkas et al. 1977
Waterflea *(Daphnia magna)* (static test)	54.6	106 (measured)	practically nontoxic	43471001 Drottart et al. 1994

The LC_{50}/EC_{50} falls in the range of > 10 to > 100 ppm, therefore, mepiquat chloride is slightly to practically nontoxic to aquatic invertebrates on an acute basis. Guideline 72-2 is fulfilled (MRID 00135134).

(b) Chronic

A freshwater aquatic invertebrate life-cycle test using the TGAI is required for mepiquat chloride because the end-use product is expected to be transported to water from the intended use site and it is intended for use such that its presence in water is likely to be continuous or recurrent. Although the estimated environmental concentration (0.82 ppb) resulting from its use is less than 0.01 of any acute LC_{50} or EC_{50} value, the aerobic soil metabolism half-life ranges from 3-21 days, and it is stable to hydrolysis and photolysis. The results using the preferred test species, *Daphnia magna*, are presented in Table 10.

Table 10: Freshwater Aquatic Invertebrate Life-Cycle Toxicity (Static Renewal)

Species	% ai	21-day NOEC/LOEC (ppm)	MATC[1] (ppm)	Endpoints Affected	MRID No., Author/Year
Waterflea *(Daphnia magna)*	99	12.5/25 (nominal)	18.8	mortality of adults	43155902, Elendt-Schneider, 1993[2]

[1] Defined as the geometric mean of the NOEC and LOEC.
[2] This study is supplemental because growth was not measured and extensive adult mortality occurred at 100 ppm.

Supplemental chronic toxicity studies with freshwater fish and invertebrates suggest low chronic toxicity. Furthermore, mepiquat chloride's low acute toxicity and application rate suggests that significant adverse chronic effects to aquatic organisms are unlikely. Therefore, the freshwater invertebrate study does not need to be repeated, and Guideline 72-4 is satisfied.

(3) Estuarine and Marine Animals

(a) Estuarine and Marine Fish, Acute

Acute toxicity testing with estuarine/marine fish using the TGAI is required for mepiquat chloride because the end-use product is expected to reach the marine/estuarine environment because of its use on cotton in coastal counties. The preferred test species is sheepshead minnow. Results of these tests are presented in Table 11 below.

Table 11: Estuarine/Marine Fish Acute Toxicity (Static Test)

Species	% ai	96-hour LC_{50} (ppm a.i.)	Toxicity Category	MRID No., Author/Year
Sheepshead minnow *(Cyprinodon variegatus)*	54.6	> 151 (measured)	practically nontoxic	43516701, Drottar et al. 1995

The LC_{50} is > 100 ppm, therefore, mepiquat chloride is practically nontoxic to estuarine/marine fish on an acute basis. The guideline (72-3(a)) is fulfilled (MRID 43516701).

(b) Estuarine and Marine Fish, Chronic

An estuarine/marine fish early life-stage test using the TGAI is required for mepiquat chloride because the end-use product is expected to be transported to water from its use on cotton in coastal

counties. Its presence in water is likely to be continuous or recurrent. Although the estimated environmental concentration resulting from use is less than 0.01 of any acute LC_{50} or EC_{50} value, the aerobic soil metabolism half-life ranges from 3-21 days and it is stable to hydrolysis and photolysis. The preferred test species is sheepshead minnow. No chronic toxicity studies for estuarine and marine fish are available for review. However, supplemental chronic toxicity studies with freshwater fish and invertebrates suggest low chronic toxicity. Furthermore, mepiquat chloride's low acute toxicity and application rate suggests that significant adverse chronic effects to aquatic organisms are unlikely. Therefore, the estuarine/marine fish study (GDLN 72-4) is waived.

(c) Estuarine and Marine Invertebrates, Acute

Acute toxicity testing with estuarine/marine invertebrates using the TGAI is required for mepiquat chloride because the end-use product is expected to reach the marine/estuarine environment because of its use on cotton in coastal counties. The preferred test species are mysid shrimp and eastern oyster. Results of these tests are presented in Table 12.

Table 12: Estuarine/Marine Invertebrate Acute Toxicity

Species/Static or Flow-through	% ai.	96-hour LC_{50}/EC_{50} (ppm a.i.)	Toxicity Category	MRID No. Author/Year
Eastern oyster (shell deposition or embryo-larvae) *(Crassostrea virginica)* (flowthrough)	54.6	12.6 (measured)	slightly toxic	435167-02 Drottar et al. 1995
Mysid *(Americamysis bahia)* (static)	54.6	> 136 (measured)	practically nontoxic	435167-03 Drottar et al. 1995

The LC_{50}/EC_{50} falls in the range of > 10 to > 100 ppm, therefore, mepiquat chloride is slightly to practically nontoxic to estuarine/marine invertebrates on an acute basis. The guidelines 72-3b and 72-3c are fulfilled (MRIDs 43516702 and 43516703).

(d) Estuarine and Marine Invertebrate, Chronic

An estuarine/marine invertebrate life-cycle toxicity test using the TGAI is required for mepiquat chloride because the end-use product is expected to be transported to the estuarine/marine environment from its use on cotton in coastal counties. Its presence in water is likely to be continuous or recurrent. Although the estimated environmental concentration resulting from use is less than 0.01 of any acute LC_{50} or EC_{50} value, the aerobic soil metabolism half-life ranges from 3-21 days, and it is stable to hydrolysis and photolysis. The preferred test species is mysid shrimp. No chronic toxicity studies for estuarine and marine invertebrates are available for review. However, supplemental chronic toxicity studies with freshwater fish and invertebrates suggest low chronic toxicity. Furthermore, mepiquat chloride's low acute toxicity and application rate suggests that significant adverse chronic effects to aquatic organisms are unlikely. Therefore, an estuarine/marine invertebrate study is waived.

c. Toxicity to Plants

(1) Terrestrial

Terrestrial plant testing (seedling emergence and vegetative vigor) may be required for a plant growth regulator that has terrestrial non-residential outdoor use patterns and may move off the application

site through volatilization (vapor pressure $\geq 1.0 \times 10^{-5}$mm Hg at 25°C) or drift (aerial), or that may have endangered or threatened plant species associated with the application site. Terrestrial plant testing is required because mepiquat chloride is used as a plant growth regulator and application is by air or ground to cotton.

For seedling emergence and vegetative vigor, the following plant species and groups should be tested: (1) six species of at least four dicotyledonous families, one species of which is soybean (*Glycine max*), and the second of which is a root crop, and (2) four species of at least two monocotyledonous families, one of which is corn (*Zea mays*).

Tier I tests measure the response of plants, relative to a control, at a test level that is equal to the highest use rate (expressed as lbs ai/A). Results of Tier 1 toxicity testing on the TGAI/TEP material are presented in Table 13.

Table 13: Nontarget Terrestrial Plant Seedling Emergence Toxicity (Tier I)[1] MRID 41488109: Hughes, 1989

Species	% Response	Endpoint affected[2]
Monocots:		
Corn *(Zea mays)*	-10	height
Ryegrass *(Lolium spp.)*	-13	height
Oat *(Avena sativa)*	-1	height
Onion *(Allium cepa)*	0	emergence
Dicots:		
Soybean *(Glycine max)*	-8	weight
Lettuce *(Lactuca sativa)*	0	weight
Cabbage *(Brassica oleracea)*	-16	emergence
Carrot *(Daucus carota)*	-5	height
Cucumber *(Cucumis sativus)*	2	emergence
Tomato *(Lycopersicon esculentum)*	-5	emergence

[1] 47% TGAI tested at 0.25 lbs ai/A.
[2] The endpoint with the greatest inhibition level was tabulated for each species.

For Tier I seedling emergence cabbage is the most sensitive dicot and ryegrass is the most sensitive monocot. The guideline (122-1) is fulfilled (MRID 41488109).

Table 14: Nontarget Terrestrial Vegetative Vigor Toxicity (Tier I)[1] MRID 41889008: deMonoch 1991

Species	% Response	Endpoint affected[2]
Monocots:		
Corn *(Zea mays)*	-	-
Ryegrass *(Lolium spp.)*	-	-
Oat *(Avena sativa)*	-	-
Onion *(Allium cepa)*	-	-
Dicots:		
Soybean *(Glycine max)*	-	-
Lettuce *(Lactuca sativa)*	-	-
Cabbage *(Brassica oleracea)*	-13	dry weight
Carrot *(Daucus carota)*	-11	height
Cucumber *(Cucumis sativus)*	-	-
Tomato *(Lycopersicon esulentum)*	-13	height

[1] 46.3% TGAI tested at 0.25 lbs ai/A
[2] Only significantly reduced endpoints were tabulated.

For Tier I vegetative vigor cabbage, tomato and carrots are the most sensitive dicots. No monocot endpoints were significantly reduced. The guideline (122-1) is fulfilled (MRID 41889008).

Terrestrial Tier II studies are not required because a negative response equal to or greater than 25% was not observed in Tier I tests.

(2) Aquatic

Aquatic plant testing may be required on a case by case basis for a plant growth regulator that has outdoor non-residential terrestrial uses that may move off-site by runoff (solubility > 10 ppm in water) or by drift. Results of Tier I toxicity testing on the technical material are presented in Table 15.

Table 15: Nontarget Aquatic Plant Toxicity (Tier I)[1] MRID 41488110: Hughes, 1989

Species	% Response	Endpoint affected
Vascular Plants		
Duckweed *(Lemna gibba)*	+21.3	growth
Nonvascular Plants		
Green algae *(Selenastrum capricornutum)*	+1.7	growth
Marine diatom *(Skeletonema costatum)*	+0.8	growth
Freshwater diatom *(Navicula pelliculosa)*	-4.5	growth
Blue-green algae *(Anabaena flos-aquae)*	-14.4	growth

[1] The test material was 47% a.i. (Technical) applied at 0.25 lbs ai/A.

The Tier I results indicate that blue-green algae is the most sensitive nonvascular aquatic plant tested. The guideline (122-2) is fulfilled (MRID 41488110). Aquatic Tier II testing is not required because the demonstrated effect levels were < 50%.

2. Environmental Fate

a. Environmental Fate Assessment

This environmental fate assessment is at present tentative. It is based on acceptable data (hydrolysis; photodegradation in water; aerobic and anaerobic metabolism, unaged leaching, adsorption/desorption, and terrestrial bare ground dissipation for vineyard use) and supplemental data (photodegradation on soil). Several studies are of uncertain value and, therefore, several environmental fate data requirements are not fulfilled. Nevertheless, these studies provide adequate information to assess the environmental fate of mepiquat chloride. Therefore, additional studies are not being required.

The available data indicate that the major route of dissipation is microbial mediated processes to CO_2 (aerobic soil metabolism half-lives ≈3 to 21 days). However, mepiquat chloride does appear to be stable to anaerobic metabolism (no half-life reported). Other laboratory data indicate the mepiquat chloride is stable to abiotic processes (hydrolysis and photolysis half-lives for pHs 3 to 9 = stable) and is relatively non-mobile in sandy loam, loam, and clay loam soils (Kds = 9.88, 12.0, and 25.0, respectively). However, mepiquat chloride does appear to be mobile in sand soil (Kd = 0.22). Field data of uncertain value for the lower cotton application rate supports the laboratory data (half-lives range from 3-21 days, with a longer half-life for the California site, and discernible only in surface 0-6 inch soil

depth). However, acceptable field bare-ground data for the vineyard application rate indicates that half-lives are longer for higher concentrations and/or are regional dependent (half-life for New York site = 6.5 days, half-lives for Washington and California sites = 71.9 and 87.2, respectively). Therefore, mepiquat chloride appears to have a limited potential for movement to groundwater. There is limited data on mepiquat chloride metabolites. They appear to be transitory, never reaching > 5% of applied, and are rapidly converted to CO_2. In addition, based on the octanol/water coefficient and information from one fish accumulation study, mepiquat chloride should not accumulate in fish.

b. Environmental Fate and Transport

These environmental fate and transport data are based on data submitted since 1989 for reregistration. Previously submitted data were not used by the registrant to support reregistration.

(1) Degradation

The guideline hydrolysis study was found to be acceptable to fulfill the data requirement (GDLN 161-1). These hydrolysis data indicated that mepiquat chloride is stable to hydrolysis. There was no significant degradation at pH 3 to pH 9 (< 10% at all pHs tested). Therefore, hydrolysis is not considered a route of dissipation (MRID 41488111).

The guideline photodegradation in water study was found to be acceptable to fulfill the data requirement (GDLN 161-2). These data indicate that mepiquat chloride is stable to photolysis and that aqueous photolysis is not a route of dissipation for mepiquat chloride. There were no discernible mepiquat chloride degradates (including CO_2) during the testing period. Recovery of applied parent mepiquat chloride was ≥95% (MRID 41488112).

The guideline photodegradation on soil study was found to be of uncertain value (supplemental) and not acceptable to fulfill the data requirement (GDLN 161-2). A discrepancy between the photolysis control data and the aerobic soil metabolism data was not addressed. Although this study does not fulfill the data requirement, repeating the photolysis study would not add any significant knowledge to the current environmental fate database for this chemical. Therefore, a new study is not required.

Even though there is still a concern with the photolysis study, the available data indicate that soil photolysis is not a route of degradation for mepiquat chloride. Mepiquat chloride is considered stable (no half-life calculated) to photolysis. At the termination of the study, mepiquat chloride recovery in the light exposed samples and the dark control samples was 85.5% and 88.6%, respectively (MRIDs 41889009, 00127749, 42412103, and 43455801).

(2) Metabolism

The guideline aerobic soil metabolism study was found to be acceptable. The data requirement (GDLN 162-1) is fulfilled. Under aerobic conditions, mepiquat chloride at a concentration of 1 ppm appears to degrade relatively rapidly (half-lives = 3 to 21 days) to CO_2. Potential metabolites like N-methylpiperidine and piperidine were not discernible during the testing period at concentrations > 5%

of applied. Therefore, they appear to be transitory and rapidly converted to CO_2 (MRIDs 43455801 and 42412103).

The guideline anaerobic soil metabolism study was found to be acceptable, and this data requirement (GDLN 162-2) is fulfilled. Under anaerobic conditions, mepiquat chloride was reported to be stable. There was no significant degradation of mepiquat chloride during the anaerobic testing period. Therefore, no anaerobic soil metabolism half-life was reported (MRIDs 41889010 and 43455801).

(3) Mobility

The guideline mobility study was found to be scientifically valid and acceptable to partially fulfill the data requirement (GDLN 163-1). The unaged study indicated that mepiquat chloride is relatively non-mobile. Kds reported for sandy loam, loam, and clay soils were 9.88, 12.0, and 25.0, respectively. However, mepiquat chloride does appear to be mobile in sand (Kd 0.22). Mobility data on aged mepiquat chloride were not provided. Although this study does not fulfill the data requirement, this data would not add significant knowledge to the current environmental fate database for this chemical. Therefore, a new study is not required (MRID 41488113).

(4) Accumulation

The one guideline study was considered supplemental. However, information from the study, when considered in combination with the K_{OW}, fulfills the guideline requirement. Mepiquat chloride is not expected to accumulate in fish (MRID 00136360).

(5) Field Dissipation

Two guideline studies were submitted to the Agency. One study is considered to be of uncertain value, and the second study is acceptable for the bare-ground portion of the vineyard use and partially fulfills the data requirement (GDLN 164-1).

The bare-ground data for the cotton use pattern are of uncertain value. However, these data indicate that mepiquat chloride degrades relatively rapid and is relatively non-mobile. Half-lives of 3, 21, and 17 days were reported for Mississippi, Texas, and California, respectively. In addition, mepiquat chloride was not detected below the 0-6 inch soil segment except for one 6-12 inch soil segment sample taken after the third application at the California test site.

The vineyard bare ground study indicates that mepiquat chloride is relatively non-persistent under the New York field conditions to moderately persistent under Washington and California field conditions. In addition, mepiquat chloride appears to be relatively non-mobile under all three field conditions. Half-lives for mepiquat chloride ranged from 6.5 to 87.2 days for the three sites, and mepiquat residues were not detected below the 0-6 inch soil depth except for two test samples during the test periods. Furthermore, these data indicate that higher mepiquat chloride application rates have longer half-lives and/or that mepiquat chloride's persistence is region-dependent (MRIDs 42353301 and 43415401).

c. Water Resources

(1) Ground Water

Even though binding strengths vary, mepiquat chloride appears to be relatively non-mobile in most soils. The Kds ranged from 9.88 for sandy loam, 12.0 for loam, to 25.0 for clay loam soils. Field data show mepiquat chloride to be relatively non-mobile (discernible only in the top 0-6 inches soil depth).

Because there are no mepiquat chloride metabolites that reach concentrations greater than 5% of applied, parent mepiquat chloride is the only residue of concern. The metabolites appear to be transitory and rapidly convert to CO_2 (half-life = 3 to 21 days).

In addition, there have been no mepiquat chloride detections reported in monitoring wells[1]. Therefore, based on its low application rate (0.022 to 0.44 lb ai/A or 0.132 lb a.i./A/season), relatively rapid degradation rate, and soil binding ability, mepiquat chloride is considered to have a limited potential for ground water contamination. However, if mepiquat chloride reaches anaerobic conditions and becomes stable, the chance for movement to lower soil profiles may increase.

(2) Surface Water

Even though there are no detections reported in surface water (Storet database), mepiquat chloride does have the potential to contaminate surface water. Mepiquat chloride adsorbs to sediment (Kds vary for soil textures, i.e., 9.88 for sandy loam, 12.0 for loam, and 25.0 for clay loam soils) and is very soluble in water. Therefore, mepiquat chloride contamination of surface water is possible from runoff of both dissolved and soil bound mepiquat chloride. The lack of detections may be explained by other environmental fate data (metabolism), which indicate that mepiquat chloride should degrade relatively rapidly (aerobic half-life = 3-21 days) in surface water.

Parent mepiquat chloride is the only residue of concern. Mepiquat chloride metabolites appear to be transitory and rapidly convert to CO_2. This rapid conversion apparently results in the metabolites never reaching concentrations greater than 5% of applied mepiquat chloride.

3. Ecological Exposure and Risk Characterization

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The means of integrating the results of exposure and ecotoxicity data is called the quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic.

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[1] EPA Pesticides in Ground Water Database - A compilation of Monitoring Studies: 1971-1991 National Summary put out by the EPA

RQ = EXPOSURE/TOXICITY

RQs are then compared to the Agency's levels of concern (LOCs). These LOCs are criteria used by the Agency to indicate potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories: 1) **acute high** - potential for acute risk is high, regulatory action may be warranted in addition to restricted use classification, 2) **acute restricted use** - the potential for acute risk is high, but this may be mitigated through restricted use classification, 3) **acute endangered species** - the potential for acute risk to endangered species is high, regulatory action may be warranted, and 4) **chronic risk** - the potential for chronic risk is high, regulatory action may be warranted. Currently, the Agency does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to mammalian or avian species.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from the results of required studies. Examples of ecotoxicity values derived from the results of short-term laboratory studies that assess acute effects are: 1) LC_{50} (fish and birds), 2) LD_{50} (birds and mammals, 3) EC_{50} (aquatic plants and aquatic invertebrates), and 4) EC_{25} (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: 1) LOEC (birds, fish, and aquatic invertebrates), 2) NOEC (birds, fish and aquatic invertebrates), and 3) MATC (fish and aquatic invertebrates). For birds and mammals, the NOEC value is used as the ecotoxicity test value in assessing chronic effects. Other values may be used when justified. Generally, the MATC (defined as the geometric mean of the NOEC and LOEC) is used as the ecotoxicity test value in assessing chronic effects to fish and aquatic invertebrates. However, the NOEC is used if the measurement endpoint is production of offspring or survival.

Risk presumptions, along with the corresponding RQs and LOCs are presented in Table 16.

Table 16: Risk Presumptions for Terrestrial Animals

Risk Presumption	RQ	LOC
Birds		
Acute High Risk	EEC[1]/LC_{50} or LD_{50}/sqft[2] or LD_{50}/day[3]	0.5
Acute Restricted Use	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day (or LD_{50} < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.1
Chronic Risk	EEC/NOEC	1
Wild Mammals		
Acute High Risk	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.5
Acute Restricted Use	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day (or LD_{50} < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.1
Chronic Risk	EEC/NOEC	1

[1] abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

[2] $\frac{mg/ft^2}{LD_{50} * \text{wt. of bird}}$ [3] $\frac{EEC}{LD_{50}/\text{proportion of bodyweight consumed}}$

Table 17: Risk Presumptions for Aquatic Animals

Risk Presumption	RQ	LOC
Acute High Risk	EEC[1]/LC_{50} or EC_{50}	0.5
Acute Restricted Use	EEC/LC_{50} or EC_{50}	0.1
Acute Endangered Species	EEC/LC_{50} or EC_{50}	0.05
Chronic Risk	EEC/MATC or NOEC	1

[1] EEC = (ppm or ppb) in water

Table 18: Risk Presumptions for Plants

Risk Presumption	RQ	LOC
Terrestrial and Semi-Aquatic Plants		
Acute High Risk	EEC[1]/EC_{25}	1
Acute Endangered Species	EEC/EC_{05} or NOEC	1
Aquatic Plants		
Acute High Risk	EEC[2]/EC_{50}	1
Acute Endangered Species	EEC/EC_{05} or NOEC	1

[1] EEC = lbs ai/A
[2] EEC = (ppb/ppm) in water

a. Exposure and Risk to Nontarget Terrestrial Animals

For pesticides applied as a nongranular product (e.g., liquid, dust), the estimated environmental concentrations (EECs) on food items following product application are compared to LC_{50} values to assess risk. The predicted 0-day maximum and mean residues of a pesticide that may be expected to occur on selected avian or mammalian food items immediately following a direct single application at 1 lb ai/A are presented in Table 19.

Table 19: Estimated Environmental Concentrations on Avian and Mammalian Food Items (ppm) Following a Single Application at 1 lb ai/A.

Food Items	EEC (ppm) Predicted Maximum Residue[1]	EEC (ppm) Predicted Mean Residue[1]
Short grass	240	85
Tall grass	110	36
Broadleaf/forage plants, and small insects	135	45
Fruits, pods, seeds, and large insects	15	7

[1] Predicted maximum and mean residues are for a 1 lb ai/A application rate and are based on Hoerger and Kenaga (1972) as modified by Fletcher *et al*. (1994).

Mepiquat chloride (N,N-dimethylpiperidinium chloride) is a plant growth regulator. It inhibits gibberellic acid synthesis, reduces internodal length, hastens maturity, retards abscission, and increases yield potential. It is registered for use on cotton. At post emergence, it may be applied one or more times (spray or ultra low volume) by aircraft or ground equipment at 0.022 lbs ai/A to 0.044 lbs ai/A (not to exceed 0.132 lbs ai/A/season).

Predicted residues (EECs) resulting from multiple applications are calculated in various ways. For mepiquat chloride, the EECs are based on the maximum application rate and assuming no degradation.

(1) Birds

The acute risk quotients for a single broadcast application of mepiquat chloride are presented in Table 20.

Table 20: Avian Acute Risk Quotients for a Single Application of Mepiquat Chloride Based on a Bobwhite Quail LC50 of 4,600 ppm.

Site/Application Method	Applic. Rate (lbs ai/A)	Food Items	Maximum EEC (ppm)	LC_{50} (ppm)	Acute RQ (EEC/LC_{50})
Cotton/broadcast aerial or ground	0.044	Short grass	11	> 4600	< 0.01
		Tall grass	5	> 4600	< 0.01
		Broadleaf plants/Insects	6	> 4600	< 0.01
		Seeds	1	> 4600	< 0.01

The results indicate that for a single broadcast application of mepiquat chloride, no avian acute levels of concern are exceeded at the registered maximum application rate of 0.044 lb ai/A.

The acute risk quotients for multiple broadcast applications of mepiquat chloride are presented in Table 21.

Table 21: Avian Acute Risk Quotients for Multiple Applications of Mepiquat Chloride Based on a Bobwhite Quail LC_{50} of 4600 ppm.

Site/Application Method	Application Rate (lbs ai/A/season)	Food Items	Maximum EEC[1] (ppm)	LC_{50} (ppm)	Acute RQ (EEC/LC_{50})
Cotton/broadcast aerial or ground	0.132	Short grass	32	4600	< 0.01
		Tall grass	14	4600	< 0.01
		Broadleaf plants/Insects	18	4600	< 0.01
		Seeds	2	4600	< 0.01

[1] EEC is based on Fletcher et al. (1994) without degradation.

The results indicate that for multiple broadcast applications of mepiquat chloride, no avian acute level of concern is exceeded at 0.132 lbs ai/A/season.

(2) Mammals

Estimating the potential for adverse effects to wild mammals is based upon the Agency's draft 1995 SOP of mammalian risk assessments and methods used by Hoerger and Kenaga (1972) as modified by Fletcher *et al*. (1994). The concentration of mepiquat chloride in the diet that is expected to be acutely lethal to 50% of the test population (LC_{50}) is determined by dividing the rat LD_{50} value by the proportion of body weight consumed. A risk quotient is then determined by dividing the EEC by this value. Risk quotients are calculated for three separate weight classes of mammals (15, 35, and 1000 g), each presumed to consume four different kinds of food (grass, forage, insects, and seeds). The acute risk quotients for broadcast applications of mepiquat chloride are presented in Table 22.

Table 22: Mammalian (Herbivore/Insectivore) Acute Risk Quotients for Broadcast Aerial or Ground Applications of Mepiquat Chloride Based on a the Rat LD_{50} of 464 mg/kg.

Site/Rate (lbs ai/A)	Body Weight (g)	% Body Weight Consumed	Rat LD_{50} (mg/kg)	EEC (ppm) Short Grass	EEC (ppm) Forage & Small Insects	EEC (ppm) Large Insects	Acute RQ[1] Short Grass	Acute RQ Forage & Small Insects	Acute RQ Large Insects
Cotton (single application)									
0.044	15	95	464	11	6	1	0.02	0.01	< 0.01
0.044	35	66	464	11	6	1	0.02	0.01	< 0.01
0.044	1000	15	464	11	6	1	0.01	< 0.01	< 0.01
Cotton (multiple applications)[2]									
0.132	15	95	464	32	18	2	0.07	0.04	< 0.01
0.132	35	66	464	32	18	2	0.04	0.02	< 0.01
0.132	1000	15	464	32	18	2	0.02	< 0.01	< 0.01

[1] RQ = $\frac{\text{EEC (ppm)}}{LD_{50}\text{ (mg/kg)/proportion of bodyweight consumed}}$

[2] EEC based on Fletcher et al. (1994) without degradation.

Table 23: Mammalian (Granivore) Acute Risk Quotients for Applications of Mepiquat Chloride Based on a Rat LD_{50} of 464 mg/kg.

Site/Application Rate (lbs ai/A/season)	Body Weight (g)	% Body Weight Consumed	Rat LD_{50} (mg/kg)	EEC (ppm) Seeds	Acute RQ[1] Seeds
Cotton/broadcast aerial or ground (multiple applications)[2]					
0.132	15	21	464	2	< 0.01
0.132	35	15	464	2	< 0.01
0.132	1000	3	464	2	< 0.01

[1] RQ = $\frac{\text{EEC (ppm)}}{LD_{50}\text{ (mg/kg)/proportion of body weight consumed}}$

[2] EEC based on Fletcher et al. (1994) without degradation.

The results indicate that for broadcast applications of mepiquat chloride, no mammalian acute levels of concern are exceeded at 0.132 lbs ai/A/season.

Table 24: Mammalian Chronic Risk Quotients for Multiple Applications of Mepiquat Chloride (Based on a Dog NOEL of 1000 ppm in a Subchronic Toxicity Study)

Site/Application method	Application Rate in lbs ai/A/season	Food Items	Maximum EEC[1] (ppm)	NOEC (ppm)[2]	Chronic RQ (EEC/NOEC)
Cotton/Broadcast aerial or ground	0.132	Short grass	32	1000	0.03
		Tall grass	14	1000	0.01
		Broadleaf plants/Insects	18	1000	0.02
		Seeds	2	1000	< 0.01

[1] Based on Fletcher without degradation.

[2] Based on clinical signs of toxicity at 3000 ppm, including: slight sedation, slight attacks of tonoclonic spasms, inhibition of body weight, hematological effects, number of erythrocytes, and reduced hematocrit.

The results indicate that for multiple broadcast applications of mepiquat chloride, the mammalian chronic level of concern is not exceeded at 0.132 lbs ai/A/season.

b. Exposure and Risk to Nontarget Aquatic Animals

The Agency calculates EECs using the GENeric Expected Environmental Concentration program (GENEEC). The EECs are used for assessing acute and chronic risks to aquatic organisms. Acute risk

assessments are performed using peak EEC values for single and multiple applications. Chronic risk assessments are performed using the 21-day EECs for invertebrates and 56-day EECs for fish.

The GENEEC program uses basic environmental fate data and pesticide label application information to estimate the EECs following treatment of 10 hectares. The model calculates the concentration (i.e. EEC) of a pesticide in a one hectare, two meter deep pond, taking into account the following: 1) adsorption to soil or sediment, 2) soil incorporation, 3) degradation in soil before wash-off to a water body, and 4) degradation within the water body. The model also accounts for direct deposition of spray drift into the water body (assumed to be 1% and 5% of the application rate for ground and aerial applications, respectively). (When multiple applications are permitted, the interval between applications is included in the calculations.) The environmental fate parameters used in the model for this pesticide are: soil K_{OC} is 1168; solubility is 500,000 ppm; aerobic soil metabolism half-life is 21 days; hydrolysis - stable; water photolysis - stable; and theoretical aquatic metabolism (based on the aerobic soil metabolism half-life of 21 days) is 42 days. EECs are presented in Table 25.

Table 25: Estimated Environmental Concentrations (EECs) For Aquatic Exposure Following Multiple Applications

Site	Application Method	Application Rate (lbs ai/A/season)	Initial (PEAK) EEC (ppb)	21-day average EEC (ppb)	56-day average EEC (ppb)
GENEEC					
Cotton	broadcast aerial	0.132	1.64	1.20	0.78
Cotton	broadcast ground	0.132	1.44	1.04	0.68

(1) Freshwater Fish

Acute risk quotients are presented in Table 26.

Table 26: Freshwater Fish Acute Risk Quotients for Multiple Applications of Mepiquat Chloride based on a Bluegill Sunfish LC_{50} of 730 ppm.

Site/Application Method/Rate (lbs ai/A/season)	LC_{50} (ppm a.i.)	EEC Initial/Peak (ppb)	Acute RQ (EEC/LC_{50})
Cotton/broadcast aerial (0.132)	730	1.64	< 0.01
Cotton/broadcast ground (0.132)	730	1.44	< 0.01

The results indicate that no acute levels of concern are exceeded for freshwater fish at the 0.132 lbs ai/A/season application rate.

(2) Freshwater Invertebrates

The acute and chronic risk quotients are presented in Table 27.

Table 27: Freshwater Invertebrate Acute and Chronic Risk Quotients for Multiple Applications of Mepiquat Chloride Based On a *Daphnia magna* LC_{50} of 50.8 ppm and NOEC of 12.5 ppm.

Site/Application method/Rate (lbs ai/A/season)	LC_{50} (ppm a.i.)	NOEL (ppm a.i.)	EEC Initial/ Peak (ppb)	21-Day Avg. EEC (ppm)	Acute RQ (EEC/LC_{50})	Chronic RQ (EEC/NOEC
Cotton/aerial (0.132)	50.8	12.5	1.64	1.20	< 0.01	< 0.1
Cotton/ground (0.132)	50.8	12.5	1.44	1.04	< 0.01	< 0.08

The results indicate that no acute or chronic levels of concern are exceeded for freshwater invertebrates at 0.132 lbs ai/A/season.

(3) Estuarine and Marine Animals

(a) Estuarine and Marine Fish

The acute risk quotients are presented in Table 28.

Table 28: Estuarine and Marine Fish Acute Risk Quotients for Multiple Applications of Mepiquat Chloride Based on a 151 ppm LC_{50} for Sheepshead Minnow.

Site/Application Method	Rate (lbs ai/A/season)	LC_{50} (ppm a.i.)	EEC Initial Peak (ppb)	Acute RQ (EEC/LC_{50})
Cotton/broadcast aerial	0.132	151	1.64	0.01
Cotton/broadcast ground	0.132	151	1.44	0.01

The results indicate that no acute levels of concern are exceeded for estuarine/marine fish at the 0.132 lb ai/season application rate.

(b) Estuarine and Marine Invertebrates

The acute risk quotients are presented in Table 29.

Table 29: Estuarine and Marine Invertebrate Acute Risk Quotients for Multiple Applications of Mepiquat Chloride Based on an Eastern Oyster LC50 of 12.6 ppm.

Site/Application Method	Rate in lbs ai/A/season	LC_{50} (ppm a.i.)	EEC Initial/Peak (ppb)	Acute RQ (EEC/LC50)
Cotton/broadcast aerial	0.132	12.6	1.64	0.13
Cotton/broadcast ground	0.132	12.6	1.44	0.11

The results indicate that endangered species acute levels of concern are exceeded for estuarine invertebrates at 0.132 lbs ai/A season. Although numerical values are exceeded, at the present time there are no federally listed endangered estuarine or marine invertebrates.

c. Exposure and Risk to Nontarget Terrestrial and Semi-Aquatic Plants

Terrestrial and semi-aquatic plants may be exposed to pesticides from runoff, spray drift or volatilization. Semi-aquatic plants are those that inhabit low-lying wet areas that may be dry at certain times of the year. However, no Tier I plant toxicity studies demonstrated an EC_{25} (tested at 0.25 lbs ai/A). These results indicate that acute levels of concern are not exceeded for nontarget plants at the 0.25 lbs ai/A application rate.

Product labels indicate that mepiquat chloride is applied to cotton during flowering stages. Off-target drift may affect the reproductive stages of nontarget plants (including adjacent crops). Therefore, additional studies evaluating adverse effects to reproductive stages may be required in the future pending the results of ongoing plant guideline harmonization efforts.

d. Endangered Species

Endangered species LOCs were exceeded for estuarine invertebrates for mepiquat chloride. However, at the present time, there are no federally listed estuarine invertebrates.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether 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 mepiquat chloride as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing mepiquat chloride. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of mepiquat chloride, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of mepiquat chloride and to determine that mepiquat chloride can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing mepiquat chloride as an active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target database required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of mepiquat chloride are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing mepiquat chloride, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

The Agency has determined that mepiquat chloride products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. In reassessing mepiquat chloride cotton tolerances under the Food Quality Protection Act of 1996, the Agency has determined that there is a reasonable certainty that no harm will result to infants, children or any general population subgroups from aggregate exposure to mepiquat chloride. There are no other uses of mepiquat chloride that present risks of dermal or inhalation exposure to infants, children or the general population. Additionally, mepiquat chloride has not been found in drinking water. Structural similarities exist between mepiquat chloride and difenzoquat and there appears to be similar neurotoxic effects. The Agency concludes that cumulative effects would be virtually nil from dietary exposure to mepiquat chloride and difenzoquat. The acute dietary MOEs for all populations including infants and children for both mepiquat chloride and difenzoquat are well above the Agency’s level of

concern and the chronic dietary exposures for all population subgroups are less than 1% of the RfD. Cumulative effects would also be virtually nil for workers exposed to mepiquat chloride and difenzoquat. Therefore, the Agency concludes that products containing mepiquat chloride for the current use on cotton are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that the currently registered use of mepiquat chloride on cotton is eligible for reregistration.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for mepiquat chloride. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for mepiquat chloride meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for the general population. In reaching this determination, EPA has considered the available information on the aggregate exposures (both acute and chronic) from the feed use on cotton, as well as the possibility of cumulative effects from mepiquat chloride and other chemicals with a similar mode/mechanism of toxicity.

Since there are no residential or lawn uses of mepiquat chloride, no dermal or inhalation exposure is expected in and around the home. No acute toxicity endpoints of concern have been identified for mepiquat chloride.

In assessing chronic dietary risk, EPA estimates that mepiquat chloride residues in food account for < 1% of the RfD and residues in drinking water are not expected. Thus, the aggregate exposures from all sources of mepiquat chloride (in this case, only dietary is relevant) account for < 1% of the RfD for the general population. Therefore, the Agency concludes that aggregate risks for the general population resulting from mepiquat chloride uses are not of concern.

In evaluating the potential for cumulative effects, EPA compared structural similarities and toxic effects seen in mepiquat chloride studies with other related compounds. With one substance, difenzoquat, there appears to be similar neurotoxic effects. However, the Agency has concluded that the cumulative effects from the combined dietary exposure to mepiquat chloride and difenzoquat would be virtually nil because the chronic dietary exposure for all population subgroups is less than 1% of the RfD for both difenzoquat and mepiquat chloride.

b. Determination of Safety for Infants and Children

EPA had determined that the established tolerances for mepiquat chloride meet the safety standard under the FQPA amendment to section 408(b)(2)(C) for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of mepiquat chloride residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from mepiquat chloride residues, EPA considered the completeness of the database for developmental and reproductive effects as well as other relevant toxicity studies, the nature of the effects observed, and other information.

Based on the current data requirements, mepiquat chloride has a substantially complete database for developmental and reproductive toxicity. However, the rabbit developmental study was considered supplemental. A new developmental study in rabbits is being required as confirmatory data. In the developmental studies effects were seen in the fetuses only at the same or higher dose levels than effects on the mothers. In the reproduction study, no effects on reproductive performance were seen. Also, because the NOELs from the developmental and reproduction studies were equal to or greater than the NOEL used for establishing the reference dose, EPA concludes that it is unlikely that there is additional risk concern for immature or developing organisms. Finally, the Agency has no epidemiological information suggesting special sensitivity of infants and children to mepiquat chloride. Therefore, EPA finds that the uncertainty factor (100X) routinely used in RfD calculations is adequately protective of infants and children, and an additional uncertainty factor is not warranted for mepiquat chloride.

EPA estimates that mepiquat chloride residues in the diet of infants and children account for less than 1% of the RfD and residues in drinking water are not expected. Thus, the chronic aggregate exposure from all sources of mepiquat chloride account for less than 1% for infants and children. The acute dietary MOE for infants and children exposed to mepiquat chloride is 3,893. Therefore, the Agency concludes that aggregate risks for infants and children resulting from mepiquat chloride uses are not of concern.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early, case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will consider itself free to pursue whatever action may be appropriate, including but not limited to, reconsideration of any portion of this RED.

2. Tolerance Reassessment

A summary of mepiquat chloride tolerance reassessments is presented in Table 30 below.

Table 30: Tolerance Reassessment Summary for Mepiquat Chloride

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.384:			
Cotton forage	3	Revoke	Not considered a significant livestock feed item (Table II, 9/95).
Cottonseed	2	2	*[Cotton, undelinted seed]*
Eggs	0.05	Revoke	40 CFR 180.6(a)(3) [Category 3] situation
Cattle, fat	0.1	0.1	
Cattle, mbyp	0.1	0.1	
Cattle, meat	0.1	0.1	
Goats, fat	0.1	0.1	
Goats, mbyp	0.1	0.1	
Goats, meat	0.1	0.1	
Hogs, fat	0.1	0.1	
Hogs, mbyp	0.1	0.1	
Hogs, meat	0.1	0.1	
Horses, fat	0.1	0.1	
Horses, mbyp	0.1	0.1	
Horses, meat	0.1	0.1	
Milk	0.05	Revoke	40 CFR 180.6(a)(3) [Category 3] situation
Poultry, fat	0.1	Revoke	40 CFR 180.6(a)(3) [Category 3] situation
Poultry, mbyp	0.1	Revoke	40 CFR 180.6(a)(3) [Category 3] situation
Poultry, meat	0.1	Revoke	40 CFR 180.6(a)(3) [Category 3] situation
Sheep, fat	0.1	0.1	
Sheep, mbyp	0.1	0.1	
Sheep, meat	0.1	0.1	
Tolerance That Needs To Be Proposed Under 40 CFR §180.384			
Cotton gin byproducts	N/A[1]	TBD[2]	A tolerance must be proposed for this commodity when adequate field residue data have been submitted and evaluated.
Tolerance Listed Under 40 CFR §186.2275(a):			
Cottonseed meal	3.0	Revoke	Any residue that may result in cottonseed meal as a result of processing will be covered by the reassessed RAC tolerance.

[1] N/A = not applicable

[2] TBD = to be determined.

3. Tolerance Revocations and Import Tolerances

As part of EPA's reregistration eligibility decision for mepiquat chloride, food additive tolerances are no longer needed. Under FQPA, residues on processed food/feed items will be regulated under FFDCA §408. Once a pesticide use is no longer registered in the United States, the related pesticide residue tolerance and/or food/feed additive regulation generally is no longer needed. It is EPA's policy to propose revocation of a tolerance, and/or food/feed additive regulation, following the deletion of a related food use from a registration, or following the cancellation of a related food-use registration. EPA has the responsibility under the Federal

Food, Drug, and Cosmetic Act (FFDCA) to revoke a tolerance/regulation on the grounds that the Agency cannot conclude that the tolerance/regulation is protective of the public health.

The Agency recognizes, however, that interested parties may want to retain a tolerance and/or food/feed additive regulation in the absence of a U.S. registration, to allow legal importation of food into the U.S. To assure that all food marketed in the U.S. is safe, under FFDCA, EPA requires the same technical chemistry and toxicology data for such import tolerances (tolerances without related U.S. registrations) as are required to support U.S. food use registrations and any resulting tolerances. See 40 CFR Part 158 for EPA's data requirements to support domestic use of a pesticide and establishment and maintenance of a tolerance and/or food/feed regulation. In addition, EPA requires residue chemistry data (crop field trials) that are representative of growing conditions in exporting countries in the same manner that EPA requires representative residue chemistry data from different U.S. regions to support domestic use of the pesticide and the tolerance and/or regulation. Additional guidance on the Agency's import tolerance policy will be published in an upcoming *Federal Register* Notice.

Parties interested in supporting an existing mepiquat chloride tolerance as an import tolerance should ensure that all of the data noted above are available to EPA during its further assessments of existing tolerances and regulations, so that the Agency may determine whether maintenance of the tolerance and/or regulation would be protective of the public health.

4. Specific Tolerance Reassessment Actions

The tolerances listed in 40 CFR §180.384, 40 CFR §185.2275 (a), (b), and (c), and 40 CFR §186.2275(a) and (b) are expressed in terms of mepiquat chloride [N,N-dimethylpiperidinium].

a. Cotton Forage (listed under 40 CFR §180.384)

Cotton forage is no longer considered a significant livestock feed item and has been deleted from Table II of the Pesticide Assessment Guidelines (Subdivision O, Residue Chemistry, issued 9/95). Therefore, the established tolerance for cotton forage will be proposed for revocation.

b. Meat, Milk, Poultry and Eggs (listed under 40 CFR §180.384)

The data indicate that tolerances for ruminant tissue are sufficient. The established tolerances of 0.1 ppm for mepiquat residues in fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep are adequate. Pursuant to 40 CFR 180.6(a)(3), milk, poultry and egg tolerances will be proposed for revocation since data indicate that no residues are likely in these commodities.

c. Cotton Gin Byproducts (needs to be proposed under 40 CFR §180.384)

Table II (issued 9/95) now recognizes cotton gin byproducts as a raw agricultural commodity of cotton. **Therefore, the Agency has already required that field residue data must be submitted by the registrants before March 18, 1997 for cotton gin byproducts and a tolerance must be proposed for this commodity when adequate field residue data have been submitted and evaluated.**

d. Cottonseed Meal (listed under 40 CFR §186.2275 (a)

A Section 409 tolerance is not needed for cottonseed meal. Any residue that may result in cottonseed meal as a result of processing will be covered by the reassessed RAC tolerance. Therefore, the established feed additive tolerance of 3.0 ppm for cottonseed meal will be proposed for revocation.

5. CODEX Harmonization

No maximum residue limits (MRLs) for mepiquat chloride have been established by Codex for any agricultural commodity. Therefore, no compatibility questions exist with respect to U.S. tolerances.

6. Tolerance Reassessment Conclusions with Respect to FQPA

Determination of Safety for Mepiquat Chloride

The Agency has reassessed the mepiquat chloride cotton related tolerances under the standards of FQPA and determined that, based on available information, there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to mepiquat residues. The only type of exposure evaluated was dietary, since mepiquat chloride has not been found in drinking water and no non-food use exposure is expected.

7. Labeling Rationale/Risk Mitigation: Occupational

All mepiquat chloride products are intended primarily for occupational use.

a. Personal Protective Equipment for Handlers (Mixers, Loaders, Applicators, etc.)

As a result of the reregistration evaluation of the acute and other adverse effects of mepiquat chloride, the Agency has determined that risks to handlers do not warrant the establishment of active-ingredient-based minimum personal protective equipment or engineering-control requirements that would apply to all mepiquat chloride end-use products. Handler PPE requirements for mepiquat chloride are to be based solely on the applicable acute toxicity

categories of individual end-use products. EPA notes that the exposure and risk assessment for aerial applications is based on the use of enclosed cockpits, since that is the only data available at this time. However, since application rates are extremely low and MOEs for aerial application are greater than 1 X 10^6, EPA has determined that imposing engineering control requirements (enclosed cockpits) for aerial application is not warranted. Therefore, open cockpits will be acceptable for use in applying mepiquat chloride.

b. Entry Restrictions

As a result of the reregistration evaluation of the acute and other adverse effects of mepiquat chloride, the Agency has determined that the risks from post-application exposures to mepiquat chloride by workers warrant the minimum WPS REI of 12 hours. Furthermore, since EPA has determined that the risks from adverse effects are minimal, EPA is establishing the minimum WPS early-entry PPE of coveralls, chemical-resistant gloves, shoes and socks. Registrants wishing to apply for a 4-hour REI need to first satisfy the associated epidemiological and end-use product toxicity data requirements.

c. Worker Notification

Mepiquat chloride is not classified as toxicity category I for acute dermal toxicity or skin irritation potential and is not classified as a severe skin sensitizer. Because EPA has no special concerns about mepiquat chloride for adverse effects where a single exposure can trigger the effect, EPA has not established an unusually long restricted-entry interval. Therefore, at this time, EPA is not requiring a WPS "double" notification statement on the labeling of mepiquat chloride end-use products.

d. Plant Back Interval

Based on the results of the rotational crop study, the registrant must amend all of its mepiquat chloride end-use products to establish a plant back interval of 2.5 months.

8. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Agency completes its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, the Agency may impose further refinements in spray drift management practices to further reduce off-target drift and risks associated with this drift.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

Table II of the Pesticide Assessment Guideline (Subdivision O), Residue Chemistry, issued 9/95) now recognizes cotton gin byproducts as a raw agricultural commodity of cotton. Therefore, field residue data must be submitted by the registrants by March 17, 1997 for cotton gin byproducts and a tolerance must be proposed for this commodity when adequate field residue data have been submitted and evaluated. The generic data base supporting the reregistration of mepiquat chloride for the above eligible uses has been reviewed and determined to be substantially complete. A rabbit developmental study has been required of the registrants as confirmatory data.

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

> "Only for formulation into an [fill blank with Insecticide, Herbicide or the applicable term which describes the type of pesticide use(s)] for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

(a) "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)."

(b) "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)."

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. Registrants 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 study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

When end-use product DCIs are developed (e.g., at issuance of the RED), the Agency will require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels.

a. PPE/Engineering Control Requirements for Pesticide Handlers

For sole-active-ingredient end-use products that contain mepiquat chloride, the handler personal protective equipment requirements set forth in this section must be incorporated on all mepiquat chloride product labels. Any conflicting PPE requirements on current labeling must be removed. There are currently no multiple-active-ingredient end-use products that contain mepiquat chloride.

Actual End-use Product PPE Requirements: PPE for handlers is to be established based on the acute toxicity of each end-use product, using the instructions in PR Notice 93-7. The personal protective equipment must be placed on the end-use product labeling in the location specified in PR Notice 93-7 and the format and language of the PPE requirements must be the same as is specified in that PR Notice.

b. Entry Restrictions

For sole-active-ingredient end-use products that contain mepiquat chloride, product labels must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on current labeling must be removed. There are currently no multiple-active-ingredient end-use products that contain mepiquat chloride.

The REI and early-entry PPE must be inserted into the standardized REI and early-entry PPE statements required by Supplement Three of PR Notice 93-7.

Restricted-entry interval: A 12-hour restricted entry interval (REI) is required for uses within the scope of the WPS (see tests in PR Notices 93-7 and 93-11) on all end-use products.

Early-entry personal protective equipment (PPE): The PPE required for early entry is:

-- coveralls,
-- chemical-resistant gloves, and
-- shoes plus socks.

c. Other Label Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing mepiquat chloride:

(1) Application Restrictions

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

"Do not plant another crop within 75 days after last treatment."

(2) User Safety Requirements

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

(3) User Safety Recommendations

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

d. Spray Drift Labeling

The following language must be placed on the label each product that can be applied aerially:

> "Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions."

The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.

2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they should be observed.

The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.

The following aerial drift reduction advisory information must be contained in the product labeling:

[This section is advisory in nature and does not supersede the mandatory label requirements.]

INFORMATION ON DROPLET SIZE

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE

- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

BOOM LENGTH

For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

APPLICATION HEIGHT

Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT

When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)

WIND

Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light

to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

C. Tolerance Revocation and Import Tolerances

GENERAL PROCESS AND INSTRUCTION INFORMATION

Several existing mepiquat chloride tolerances are being cancelled as part of EPA's reregistration eligibility decision regarding this pesticide. The specific need for each of these actions appears in the previous section. It is EPA's policy to propose revocation of a tolerance, and/or food/feed additive regulation, following the deletion of a related food use from a registration, or **following** the cancellation of a related food-use registration. As a result, any parties interested in supporting the tolerance/regulation for import purposes in the absence of a registered U.S. use should notify EPA as soon as possible.

In responding, EPA will provide detailed information on the outstanding data requirements for these tolerances and/or regulations. **The Agency** will consider commitments made to generate data to support such tolerances/regulations and the timeliness of data submissions in its assessment of whether the tolerances/regulations should be retained. Persons interested in establishing a new tolerance for import purposes only, or retaining a current tolerance for import purposes following cancellation of the related use, must submit a petition along with the appropriate fees and supporting data.

D. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, 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.

The Agency has determined that registrants may distribute and sell mepiquat chloride products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A REPORT &l3C

Case 2375[Mepiquat chloride] Chemical 109101[N,N-Dimethylpiperidinium chloride]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Dose	Max. Rate /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES												
COTTON (UNSPECIFIED)				Use Group: TERRESTRIAL FOOD+FEED CROP								
Low volume spray (concentrate), Foliar, Aircraft	DF	NA	.04375 lb A	*	1	NS	.066 lb	NS	14	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NM, NC, OK, SC, TN, TX, VA	C46, C92, CAL, CCC(2), G01(30), G83(30), G88, H01(30)
	FM/L	NA	.04397 lb A	*	1	NS	.066 lb	NS	14	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NM, NC, OK, SC, TN, TX, VA	C46, CAL, CAU, CCC(2), G01(30), G83(30), H01(30)
	FM/L	NA	.04375 lb A	*	1	NS	.066 lb	NS	21	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NM, NC, OK, SC, TN, TX, VA	C46, CAL, CAU, CCC(2), G01(30), G83(30), H01(30)
	P/T	NA	.04331 lb A	*	1	NS	.065 lb	NS	21	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NM, NC, OK, SC, TN, TX, VA	C46, CAG, CAL, CAU, CCC(2), G01(30), G83(30), H01(30)
Spray, Foliar, Aircraft	DF	NA	.02188 lb A	*	3	NS	.066 lb	NS	7	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NM, NC, OK, SC, TN, TX, VA	C46, C92, CAL, CCC(4), G01(30), G83(30), G88, H01(30)
	FM/L	NA	.02188 lb A	*	3	NS	.066 lb	NS	7	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NC, NM, OK, SC, TN, TX, VA	C46, CAL, CAU, CCC(4), G01(30), G83(30), H01(30)
	FM/L	NA	.02198 lb A	*	3	NS	.066 lb	NS	7	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NM, NC, OK, SC, TN, TX, VA	C46, CAL, CAU, CCC(4), G01(30), G83(30), H01(30)

APPENDIX A REPORT

Case 2375[Mepiquat chloride] Chemical 109101[N,N-Dimethylpiperidinium chloride]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps Max. Rate /crop /cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
COTTON (UNSPECIFIED) (con't)				**Use Group: TERRESTRIAL FOOD+FEED CROP (con't)**								
	P/T	NA	.02166 lb A	*	3	NS	.065 lb	NS	7	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NC, NM, OK, SC, TN, TX, VA	C46, CAG, CAL, CAU, CCC(4), G01(30), G83(30), H01(30)
Spray, Foliar, Ground	DF	NA	.02188 lb A	*	3	NS	.066 lb	NS	7	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NM, NC, OK, SC, TN, TX, VA	C46, C92, CAL, CCC(4), G01(30), G83(30), G88, H01(30)
	FM/L	NA	.02188 lb A	*	3	NS	.066 lb	NS	7	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NC, NM, OK, SC, TN, TX, VA	, C46, CAL, CAU, CCC(4), G01(30), G83(30), H01(30)
	FM/L	NA	.02188 lb A	*	3	NS	.066 lb	NS	7	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NC, NM, OK, SC, TN, TX, VA	C46, CAL, CAU, CCC(4), G01(30), G83(30), H01(30)
	FM/L	NA	.02198 lb A	*	3	NS	.066 lb	NS	7	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NM, NC, OK, SC, TN, TX, VA	C46, CAL, CAU, CCC(4), G01(30), G83(30), H01(30)
	P/T	NA	.02166 lb A	*	3	NS	.065 lb	NS	7	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NC, NM, OK, SC, TN, TX, VA	C46, CAG, CAL, CAU, CCC(4), G01(30), G83(30), H01(30)
Spray, Foliar, Sprayer	DF	NA	.04375 lb A	*	1	NS	.066 lb	NS	14	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NM, NC, OK, SC, TN, TX, VA	C46, C92, CAL, CCC(2), G01(30), G83(30), G88, H01(30)

APPENDIX A REPORT

Case 2375[Mepiquat chloride] Chemical 109101[N,N-Dimethylpiperidinium chloride]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. Rate /year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
COTTON (UNSPECIFIED) (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
	FM/L	NA	.04397 lb A	*	1	NS	.066 lb	NS	14	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NM, NC, OK, SC, TN, TX, VA		C46, CAL, CAU, CCC(2), G01(30), G83(30), H01(30)
	FM/L	NA	.04375 lb A	*	1	NS	.066 lb	NS	21	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NM, NC, OK, SC, TN, TX, VA		C46, CAL, CAU, CCC(2), G01(30), G83(30), H01(30)
	P/T	NA	.04331 lb A	*	2	NS	.065 lb	NS	21	0.5 d	AL, AR, AZ, CA, FL, GA, LA, MO, MS, NM, NC, OK, SC, TN, TX, VA		C46, CAG, CAL, CAU, G01(30), G83(30), H01(30)
Spray, Foliar, Ultra low volume	FM/L	NA	.02188 lb A	*	3	NS	.066 lb	NS	7	0.5 d	AL, AR, FL, GA, LA, MO, MS, NC, OK, SC, TN, TX		C46, CAL, CAU, CCC(4), G01(30), G83(30), G88, H01(30)
	FM/L	NA	.02198 lb A	*	3	NS	.066 lb	NS	7	0.5 d	AL, AR, FL, GA, LA, MO, MS, NC, OK, SC, TN, TX		C46, CAL, CAU, CCC(4), G88, H01(30)
	P/T	NA	.02166 lb A	*	3	NS	.065 lb	NS	7	0.5 d	AL, AR, FL, GA, LA, MO, MS, NC, OK, SC, TN, TX		C46, CAG, CAL, CAU, CCC(4), G01(30), G83(30), G88, H01(30)
Ultra low volume, Foliar, Aircraft	FM/L	NA	.04397 lb A	*	1	NS	.066 lb	NS	14	0.5 d	AL, AR, FL, GA, LA, MO, MS, NC, OK, SC, TN, TX		C46, CAL, CAU, CCC(2), G88, H01(30)
	FM/L	NA	.04375 lb A	*	1	NS	.066 lb	NS	21	0.5 d	AL, AR, FL, GA, LA, MO, MS, NC, OK, SC, TN, TX		C46, CAL, CAU, CCC(2), G01(30), G83(30), G88, H01(30)

APPENDIX A REPORT

Case 2375[Mepiquat chloride] Chemical 109101[N,N-Dimethylpiperidinium chloride]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes

USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

COTTON (UNSPECIFIED) (con't) — Use Group: TERRESTRIAL FOOD+FEED CROP (con't)

P/T	NA	.04331 lb A	*	1	NS	.065 lb	NS	21	0.5 d	AL, AR, FL, GA, LA, MO, MS, NC, OK, SC, TN, TX		C46, CAG, CAL, CAU, CCC(2), G01(30), G83(30), G88, H01(30)

APPENDIX A REPORT

Case 2375[Mepiquat chloride] Chemical 109101[N,N-Dimethylpiperidinium chloride]
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LEGEND
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Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Re-Entry Intv.	: Reentry Intervals
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

*	: Non-specific
C	: Coarse
M	: Medium
F	: Fine
O	: Others

FORMULATION CODES

DF	: WATER DISPERSIBLE GRANULES (DRY FLOWABLE)
FM/L	: FORM NOT IDENTIFIED/LIQUID
P/T	: PELLETED/TABLETED

ABBREVIATIONS

AN	: As Needed
NA	: Not Applicable
NS	: Not Specified (on label)
UC	: Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC	: Dosage Can Not be Calculated
No Calc	: No Calculation can be made
W	: PPM calculated by weight
V	: PPM Calculated by volume
U	: Unknown whether PPM is given by weight or by volume
cwt	: Hundred Weight
nnE-xx	: nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

APPENDIX A REPORT

Case 2375[Mepiquat chloride] Chemical 109101[N,N-Dimethylpiperidinium chloride]
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USE LIMITATIONS CODES
C46 : Do not apply through any type of irrigation system.
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
CAG : Do not apply where runoff is likely to occur.
CAL : Do not contaminate water, food or feed.
CAU : Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.
CCC : Do not make more than _____ applications per crop cycle.
G01 : __ day(s) pregrazing interval.
G83 : __ day(s) prefeeding interval.
G88 : Do not graze or feed forage.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
AL : Alabama
AR : Arkansas
AZ : Arizona
CA : California
FL : Florida
GA : Georgia
LA : Louisiana
MO : Missouri
MS : Mississippi
NC : North Carolina
NM : New Mexico
OK : Oklahoma
SC : South Carolina
TN : Tennessee
TX : Texas
VA : Virginia

REENTRY INTERVAL ABBREVIATIONS
d : day(s)

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case mepiquat chloride covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to mepiquat chloride in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

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 Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). 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 lists the identifying 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.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Mepiquat Chloride

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	ALL	41889001
61-2A	**Start. Mat. & Mnfg. Process**	ALL	41889001
61-2B	**Formation of Impurities**	ALL	41889001
62-1	**Preliminary Analysis**	ALL	41889002, 42690701
62-2	**Certification of limits**	ALL	41889003, 42690701
62-3	**Analytical Method**	ALL	41889002
63-2	**Color**	ALL	41626701
63-3	**Physical State**	ALL	41626701
63-4	**Odor**	ALL	41626701
63-5	**Melting Point**	ALL	41626701
63-7	**Density**	ALL	41626701
63-8	**Solubility**	ALL	41889004, 42690702
63-9	**Vapor Pressure**	ALL	41626701
63-11	**Octanol/Water Partition**	ALL	41910101
63-12	**pH**	ALL	41626701
63-13	**Stability**	ALL	41626701
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	ALL	43150701, 135130
71-2A	**Avian Dietary - Quail**	ALL	135131

Data Supporting Guideline Requirements for the Reregistration of Mepiquat Chloride

REQUIREMENT		USE PATTERN	CITATION(S)
71-2B	**Avian Dietary - Duck**	ALL	135132
71-4	**Avian Reproduction**	ALL	Waived
72-1A	**Fish Toxicity Bluegill**	ALL	41889005, 135133
72-1C	**Fish Toxicity Rainbow Trout**	ALL	41889006, 135133
72-2A	**Invertebrate Toxicity**	ALL	43471001, 135134
72-3A	**Estuarine/Marine Toxicity - Fish**	ALL	43516701
72-3B	**Estuarine/Marine Toxicity - Mollusk**	ALL	43516702
72-3C	**Estuarine/Marine Toxicity - Shrimp**	ALL	43516703
72-4A	**Early Life Stage - Fish**	ALL	43155901
72-4B	**Life Cycle - Invertebrate**	ALL	43155902
122-1A	**Seed Germination/Seedling Emergence**	ALL	41488109
122-1B	**Vegetative Vigor**	ALL	41889008
122-2	**Aquatic Plant Growth**	ALL	41488110
141-1	**Honey Bee Acute Contact**	ALL	41626703
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	ALL	41488101
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	ALL	41488102
81-3	**Acute Inhalation Toxicity - Rat**	ALL	41954101
81-4	**Primary Eye Irritation - Rabbit**	ALL	00071942, 92091006
81-5	**Primary Dermal Irritation - Rabbit**	ALL	41488103, 92091007
81-6	**Dermal Sensitization - Guinea Pig**	ALL	41488104, 92091008

Data Supporting Guideline Requirements for the Reregistration of Mepiquat Chloride

REQUIREMENT		USE PATTERN	CITATION(S)
81-7	**Acute Delayed Neurotoxicity - Hen**	ALL	42337104
82-1A	**90-Day Feeding - Rodent**	ALL	42337102, 42337103
82-1B	**90-Day Feeding - Non-rodent**	ALL	135720
83-1A	**Chronic Feeding Toxicity - Rodent**	ALL	43264402
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	ALL	41488105, 43264403
83-2A	**Oncogenicity - Rat**	ALL	43396001
83-2B	**Oncogenicity - Mouse**	ALL	43264404
83-3A	**Developmental Toxicity - Rat**	ALL	42337101
83-3B	**Developmental Toxicity - Rabbit**	ALL	148089, 148090, 92091010, 44102201
83-4	**2-Generation Reproduction - Rat**	ALL	43378601
84-2A	**Gene Mutation (Ames Test)**	ALL	41488106
84-2B	**Structural Chromosomal Aberration**	ALL	41488107
84-4	**Other Genotoxic Effects**	ALL	41488108
85-1	**General Metabolism**	ALL	40299001
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**	ALL	41889001
161-1	**Hydrolysis**	ALL	41488111
161-2	**Photodegradation - Water**	ALL	41488112
161-3	**Photodegradation - Soil**	ALL	127749, 41889009, 42412103, 43455801
162-1	**Aerobic Soil Metabolism**	ALL	43455801, 42412103

Data Supporting Guideline Requirements for the Reregistration of Mepiquat Chloride

REQUIREMENT		USE PATTERN	CITATION(S)
162-2	**Anaerobic Soil Metabolism**	ALL	41889010, 43455801
163-1	**Leaching/Adsorption/Desorption**	ALL	41488113
164-1	**Terrestrial Field Dissipation**	ALL	42353301, 43415401
165-1	**Confined Rotational Crop**	ALL	42733601
165-4	**Bioaccumulation in Fish**	ALL	136360
201-1	**Droplet Size Spectrum**	ALL	Spray Drift Task Force studies
202-1	**Drift Field Evaluation**	ALL	Spray Drift Task Force studies
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	ALL	43024701, 42330804
171-4B	**Nature of Residue - Livestock**	ALL	42394301/2/3, 43290401/2/3/4/5
171-4C	**Residue Analytical Method - Plants**	ALL	42426801, 42734601/2, 42734601/2, 42892201, 43378501, 43738603
171-4D	**Residue Analytical Method - Animal**	ALL	42394303, 42546201/2
171-4E	**Storage Stability**	ALL	42734601/2, 42892201, 43738603, 43379501
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	ALL	43738601/2
171-4K	**Crop Field Trials**	ALL	42734601/2
171-4L	**Processed Food**	ALL	42426803

GUIDE TO APPENDIX C

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 (19??), 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**

00071942 Leuschner, F. (1977) Tolerance of the Rabbit Ocular Mucosa to 1,1-Dimethylpiperidinium Chloride, Reg. No. 85559, Techn.-Called for Short DMP: Single Treatment. (Unpublished study received Nov 15, 1977 under 8G2022; prepared by Laboratorium fur Pharmakologie und Toxikologie, West Germany, by BASF Wyandotte Corp., Parsippany, N.J.; CDL:096634-L)

00127749 Otto, S. (1978) Investigations into the Aerobic Degradation of 14C-dimethylpiperidinium Chloride in Soil: Report No. 1505. (Unpublished study received Feb 22, 1978 under 7969-EX-9; prepared by BASF, AG, W. Ger., submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:097065-A)

00135131 Fink, R.; Beavers, J.; Brown, R. (1977) Eight-day Dietary LC50-Bobwhite Quail: BAS 083 00 W: Project No. 147-109: Final rept. (Unpublished study received Nov 15, 1977 under 8G2022; submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL: 096636-B)

00135132 Fink, R.; Beavers, J.; Brown, R. (1977) Eight-day Dietary LC50-Mallard Duck: BAS 083 00 W: Project No. 147-110: Final rept (Unpublished study received Nov 15, 1977 under 8G2022; submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL: 096636-C)

00135133 Kuc, W. (1977) Acute Toxicity of BAS 083 00W to the Bluegill Sunfish and Rainbow Trout: UCES Project #11506-17-04; BWC Project IV-1-G-124. (Unpub. study received Nov 15, 1977 under 8G2022; prepared by Union Carbide Corp., by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:096636-D)

00135134 Vilkas, A. (1977) The Acute Toxicity of BAS 08300 W to the Water Flea …: UCES Proj. #11506-17-04; BWC Project IV-3-G-124. (Unpublished study received Nov 15, 1977 under 8G2022; prepared by Union Carbide Corp., submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:096636-E)

00135720 Leuschner, F.; Leuschner, A.; Schwerdtfeger, W.; et al. (1977) Oral Toxicity of 1,1-Dimethylpiperidinium Chloride, Reg. No. 85559, Techn.--Called for Short DMP--in the Beagle Dog: Repeated Dosage over 3 Months. (Unpublished study received Nov 15, 1977 under 8G2022; prepared by Laboratorium fur Pharmakologie und Toxikologie, W. Ger., submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:096640-B)

00136360 Kuc, W. (1978) 14C-BAS 083 00 W: Bluegill Sunfish, Lepomis macrochirus Bioconcentration Study: UCES Proj. No. 11506-34; BWC Proj. No. IV-1-G-132. Final rept. (Unpublished study received Mar 30, 1979 under 7969-52; prepared by Union Carbide Corp., submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:098034-B)

00148089 Hildebrand, B.; Merkle, J. (1981) Study To Determine the Prenatal Toxicity of 1,1-Dimethyl-piperidinium Chloride in Rabbits. Unpublished study prepared by BASF Wyandotte Corp. 60 p.

00148090 Hofmann, T.; Merkle, J. (1979) Study of the Prenatal Toxicity of 1,1-Dimethyl-piperidinium-chloride on Rabbits. Unpublished study prepared by BASF Wyandotte Corp. 106 p.

BIBLIOGRAPHY

MRID	CITATION

40299001 Holloway, C. (1987) Study Report on the Biokinetics and Metabolic Fate of 1,1-Dimethylpiperidinium chloride in Young Adult Rats: Proj. No. NA 869748. Unpublished study prepared by NATEC Inst. fur Naturwissenschafflich-tenische Dienste GMbH. 329 p.

41488101 Kirsch, ?. (1989) Report on the Study of the Acute Oral Toxicity of Mepiquat Chloride in Rats: Lab Project Number: 89/0462. Unpublished study prepared by BASF Aktiengesellschaft. 15 p.

41488102 Kirsch, ?. (1989) Report on the Study of the Acute Dermal Toxicity of Mepiquat Chloride in Rats: Lab Project Number: 89/0461. Unpublished study prepared by BASF Aktiengesellschaft. 15 p.

41488103 Grundler, O. (1989) Report on the Study of the Sensitizing Effect of Mepiquat Chloride (…) in the Guinea Pig According to Proposed Rules" of EPA, Aug 22, 1078, Federal Register: Lab Project No: 85/0080. Unpublished study prepared by BASF Aktiengesellschaft. 18 p.

41488104 Leuschner, ?. (1976) Tolerance of the Rabbit Skin to 1,1-Dimethylpiperidinium Chloride (Patch Test): Lab Project Number: 76/0011. Unpublished study prepared by Laboratory for Pharmacology & Toxicology. 11 p.

41488105 Hellwig, ?. (1989) Report on the Study of the Toxicity of Reg. No. 85 559 in Beagle Dogs Administration via the Diet Over 12 Months : Lab Project Number: 89/0357. Unpublished study prepared by BASF Aktiengesellschaft, Dept. of Toxicology. 850 p.

41488106 Zeller, H. (1979) Report on the Testing of Reg. No. 85559 (Mepiquat Chloride) in the Ames Test: Lab Project Number: 79/0035. Unpublished study prepared by BASF Aktiengesellschaft. 18 p.

41488107 Taalman, R. (1987) Clastogenic Evaluation of Mepiquat Chloride in an in vitro Cytogenetic Assay Measuring Chromosomes Aberration Frequencies in Chinese Hampster Ovary (CHO) Cells: Lab Project No: 87-0450. Unpublished study prepared by Hazleton Biotechnologies. 28 p.

41488108 Cifone, M. (1987) Report on the Mutagenicity Test on Mepiquat Chloride in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay: Lab Project Number: 87/0393. Unpublished study prepared by Hazleton Laboratories America, Inc. 33 p.

41488109 Chetram, R. (1989) Tier 1 Seed Germination/Seedling Emergence Nontarget Phytotoxicity of BAS 083 W: Lab Project Number: 89/5092. Unpublished study prepared by Pan-Agricultural Laboratories, Inc. 147 p.

41488110 Hughes, J. (1989) The Toxicity of Mepiquat Chloride to the Growth and Reproduction of Aquatic Plants: Lab Project Number: 89/5159. Unpublished study prepared by Malcolm Pirnie, Inc. 103 p.

41488111 Funk, H. (1989) Hydrolysis of Mepiquat Chloride in pH 3, 5, 7, and 9 Aqueous Solutions at 25 Degrees C: Lab Project No. 89/0313. Unpublished study prepared by BASF Aktiengesellschaft, Metabolism Lab. 46 p.

BIBLIOGRAPHY

MRID	CITATION

41488112 Funk, H. (1990) Unsensitized and Sensitized Photolysis of Mepiquat Chloride in Water at pH 7: Lab Project Number: 90/0071. Unpublished study prepared by BASF Aktiengesellschaft. 57 p.

41488113 Ellenson, J. (1987) Soil Adsorption/Desorption of Mepiquat Chloride : Lab Project Number: 87/5076. Unpublished study prepared by BASF Corp. 30 p.

41585201 Kohl, W. (1989) The Metabolism of [Carbon 14]-Mepiquat Chloride in Laying Hens: BASF Registration Document No.: 89/0312. Unpublished prepared by BASF AG, Agricultural Research and Development. 112 p.

41585202 Giese, U. (1989) Dosing of Hens with [Carbon 14]-Mepiquat Chloride for Further Isolation and Identification of Metabolites: BASF Registration Document No.: 88/0604. Unpublished study prepared by NATEC Institute for Scientific and Technical Services. 27 p.

41585203 Cheng, T. (1988) Biokineticss and Metabolism Study of [Carbon 14]BAS 083 W in Laying Hens: BASF Registration Document No.: 89/5021. Unpublished study prepared by Hazleton Laboratories America. 73 p.

41585204 Kohl, W. (1989) The Metabolism of [Carbon 14]-Mepiquat Chloride in Lactating Goats: BASF Registration Document No.: 89/0424. Unpublished study prepared by BASF AG, Agricultural Research and Development. 95 p.

41585205 Giese, U. (1988) Dosing of Lactating Goat with [Carbon 14]-Mepiquat Chloride for Further Isolation and Identification of Metabolites: BASF Registration Document No.: 88/0616. Unpublished study prepared by NATEC Institute for Scientific and Technical Services. 31 p.

41585206 Cheng, T. (1988) Biokinetics and Metabolism Study of [Carbon 14]BAS 083 W in Lactating Goats: BASF Registration Document No.: 89/5022. Unpublished study prepared by Hazleton Laboratories America. 69 p.

41626701 Panek, E. (1990) Determination of the Color, Physical State, Odor, Melting Point, Bulk Density, and PH of Mepiquat Chloride TGAI: Lab Project Number: F9018. Unpublished study prepared by BASF Corp. 11 p.

41626703 Hoxter, K.; Smith, G. (1990) Mepiquat Chloride: An Acute Contact Toxicity Study with the Honey Bee: Lab Project Number: E9006. Unpublished study prepared by Wildlife International Ltd. 14 p.

41889001 Panek, E. (1991) Mepiquat Chloride: Product Identity and Composition: Lab Project Number: 91/5077. Unpublished study prepared by BASF. 87 p.

41889002 Panek, E. (1991) Mepiquat Chloride: 5-Batch Analysis and Method Validations: Lab Project Number: 91/5075. Unpublished study prepared by BASF. 87 p.

BIBLIOGRAPHY

MRID	CITATION

41889003 Panek, E. (1991) Mepiquat Chloride: Certification of Limits: Lab Project Number: 91/5076. Unpublished study prepared by BASF. 11 p.

41889004 Woodson, E. (1991) Determination of the Solubility of Mepiquat Choride in Selected Solvents: Lab Project Number: 91/5085. Unpublished study prepared by EPL Bio-Analytical Services, Inc. 41 p.

41889005 Munk, R. (1991) Report on the Study of the Acute Toxicity of Mepiquat Chloride on the Bluegill: Lab Project Number: 91-10227. Unpublished study prepared by BASF Aktiengesellschaft. 28 p.

41889006 Munk, R. (1991) Report on the Study of the Acute Toxicity of Mepiquat Chloride on the Rainbow Trout: Lab Project Number: 91-10228. Unpublished study prepared by BASF Aktiengesellschaft. 28 p.

41889008 DeMonch, P. (1991) Tier 1 Vegetative Vigor Nontarget Phytotoxicity Study Using Mepiquat Chloride: Lab Project Number: 91/5033. Unpublished study prepared by Pan-Agricultural Laboratories, Inc . 90 p.

41889009 Wood, N. (1991) Photolysis of Mepiquat Chloride on Soil: Lab Project Number: M9001: M9117: 91/5079. Unpublished study prepared by BASF Corp. 23 p.

41889010 Huber, R. (1991) Investigations into the Anaerobic Degradation of Mepiquat Chloride in Soil: Lab Project Number: 91-10108. Unpublished study prepared by Basf Aktiengesellschaft. 65 p.

41910101 Schweitzer, M. (1991) Determination of the n-Octanol/Water Partition Coefficient of Mepiquat Chloride: Lab Project Number: 91/ 5084. Unpublished study prepared by Battelle. 40 p.

41954101 Gamer, A. (1991) The Acute Inhalation Toxicity LC50 of Mepiquat Chloride as a Liquid Aerosol in Rats: 4 Hour Exposure: Lab Project Number: 91/10505. Unpublished study prepared by BASF Aktiengesellschaft. 29 p.

42330804 Goetz, A. (1992) Metabolism of [carbon 14]-BAS 083 W in Cotton (Gossypium hirsutum): Lab Project Number: M9016. Unpublished study prepared by BASF Corp. 90 p.

42337101 Hellwig, J. (1992) Study of the Prenatal Toxicity of Mepiquat Chloride in Rats after Oral Administration (Gavage): Lab Project Number: 92/10331. Unpublished study prepared by BASF Aktiengesellschaft. 358 p.

42337102 Schilling, K. (1992) Supplementary Study on the Oral Toxicity of Mepiquat Chloride in Wistar Rats Administration in the Diet over 3 Months: Lab Project Number: 92-10434. Unpub. study prepared by BASF Aktiengesellchaft. 286 p.

42337103 Schilling, K. (1992) Study on the Oral Toxicity of Mepiquat Chloride in Wistar Rats Administration in the Diet Over 3 Months: Lab Project Number: 92-10433. Unpublished study prepared by BASF Aktiengesellschaft. 378 p.

BIBLIOGRAPHY

MRID	CITATION
42337104	Franke, C. (1991) Report on the in vitro Test of the Action of Mepiquat Chloride at Nicontinic Acetylcholine Receptors of Adult Mouse Muscle: Supplemental: Lab Project Number: 91/11204. Unpublished study prepared by Instit. of Physiology of the Techn. Univ. Munchen. 23 p.
42353301	Eubanks, M. (1992) Pix Plant Regulator (BAS 083 05 W) Soil Dissipation in a Cotton Use Pattern Study: Lab Project Number: BASF 92/5083: ER92027. Unpublished study prepared by Pan-Ag Labs, Inc., Biospherics, Inc. and Harris Environmental Tech. 360 p.
42394301	Kohl, W. (1991) The Metabolism of [carbon 14]-Mepiquat Chloride in Lactating Goats--The Identification of a New Metabolite in Liver and Milk: Lab Project Number: 90/10385. Unpublished study prepared by BASF AG. 77 p.
42394302	Schepers, U. (1990) Method for Determination of Mepiquat Chloride Residues in Chicken and Cow Matrices Based on Ion Chromotography: Lab Project Number: 90/0147. Unpublished study prepared by BASF AG. 50 p.
42394303	Schepers, U. (1991) Mepiquat Chloride--Accountability of Method No. 286 in Goat Tissues and Milk: Lab Project Number: 91/11194. Unpublished study prepared by BASF AG. 74 p.
42394304	McAleese, D.; Schepers, U. (1990) Mepiquat Chloride--Accountability of Method No. 286 in Chicken Tissues and Eggs: Lab Project Number: 90/0138. Unpublished study prepared by BASF AG. 70 p.
42412103	Huber, R. (1991) Further Investigations into the Aerobic Degradation of Mepiquat Chloride in Soil: Lab Project Number: 91/10952: P87-M009: 2890. Unpublished study prepared by BASF AG. 92 p.
42426801	Burkey, J. (1992) Method for Determination of Mepiquat Chloride Residues in Cottonseed by Ion Chromatography: Lab Project Number: A9106: 92/5064. Unpublished study prepared by BASF Corp. 43 p.
42426803	Burkey, J. (1992) Magnitude of the Residues of Mepiquat Chloride in Processing Fractions of Cottonseed Following Treatment with Pix Plant Growth Regulator: Lab Project Number: A9139: 92/5110. Unpublished study prepared by BASF Corp. 150 p.
42546201	Burkey, J.; Malinsky, D. (1992) Method for Determination of Mepiquat Chloride Residues in Chicken and Cow Matrices Based on Ion Chromatography: Lab Project Number: A9104: 92/5130. Unpub. study prepared by BASF Corp. 59 p.
42546202	Gilles, C. (1992) Independent Laboratory Validation of Methodology to Determine Mepiquat Chloride in Animal Matrices: Lab Project Number: B9109-N1. Unpublished study prepared by Biospherics Incorporated. 67 p.
42690701	Panek, E. (1992) Mepiquat Chloride: Certification of Limits: Lab Project Number: FR9250: 92/5208: D12:FR9250.RPT. Unpublished study prepared by BASF. 7 p.

BIBLIOGRAPHY

MRID **CITATION**

42690702 Pawliczek, ?. (1987) Mepiquat Chloride Water Solubility: Method and Raw Data for MRID 41491001: Lab Project Number: 93/5020. Unpublished study prepared by BASF AG. 22 p.

42733601 Ellenson, J.; Seachrist, L. (1993) Mepiquat Chloride: (carbon 14)-BAS 083 W in Rotational Crops: Lab Project Number: M9015: M9212: 93/5035. Unpublished study prepared by BASF Corporation and Pan-Agricultural Labs, Inc. 187 p.

42734601 Nichols, K. (1993) The Magnitude of Mepiquat Chloride Residues in Cotton Seed Based on Ultra-low Volume Aerial Applications: Lab Project Number: R-92045: 93/5048: 9200537. Unpublished study prepared by Harris Labs and American Agricultural Services, Inc. 177 p.

42734602 Nichols, K. (1993) The Magnitude of Mepiquat Chloride Residues in Cotton Seed Based on Low-rate Multiple Applications: Lab Project Number: A9307: 9200535: R-92044. Unpublished study prepared by Harris Labs and American Agricultural Services, Inc. 200 p.

42892201 Burkey, J. (1993) Freezer Storage Stability of BAS 083 W in Cottonseed and its Processed Commodities: (Mepiquat Chloride): Interim Report: Lab Project Number: 93/5047: 91140: A9305. Unpublished study prepared by BASF Corp., Agricultural Research Center. 54 p.

43024701 Goetz, A. (1993) Metabolism of (carbon 14)-BAS 083 W in Cotton (Gossypium hirsutum): Amended Report: Lab Project Number: M9016: M9203: M9203A. Unpublished study prepared by BASF Corp. 87 p.

43150701 Munk, R. (1993) Avian Single Oral LD50 of Mepiquat Chloride to the Bobwhite Quail: Lab Project Number: 93/10694: 11W0697/90123. Unpublished study prepared by BASF Aktiengesellschaft. 41 p.

43155901 Munk, R. (1993) Sublethal Toxic Effects on the Rainbow Trout of Mepiquat Chloride in a Flow Through System (28 days): Lab Project Number: 93/10882: 42F0697/905167. Unpublished study prepared by BASF Aktiengesellschaft. 53 p.

43155902 Schneider, E. (1993) Determination of the Chronic Toxicity of Mepiquat Chloride to the Water Flea (Daphnia magna) Straus: Lab Project Number: 93/10316: 1/90/1892/51/3. Unpublished study prepared by BASF Aktiengesellschaft. 42 p.

43264401 Mellert, W. (1994) The Toxicity of Mepiquat Chloride in Beagle Dogs-Administration Via the Diet Over 4 Weeks: Lab Project Number: 94/10283: 30D0112/89109. Unpublished study prepared by BASF Aktiengesellschaft, Dept. of Toxicology. 220 p.

43264402 Mellert, W. (1994) Chronic Toxicity Study with Mepiquat Chloride in Wistar Rats-Administration in the Diet for 24 Months: Lab Project Number: 94/10285: 71S0112/89091. Unpublished study prepared by BASF Aktiengesellschaft, Dept. of Toxicology. 1532 p.

BIBLIOGRAPHY

MRID	CITATION

43264403 Mellert, W. (1994) Supplementary Study of the Toxicity of Mepiquat Chloride in Beagle Dogs-Administration Via the Diet Over 12 Months: Lab Project Number: 94/10282: 33D0001/92001. Unpublished study prepared by BASF Aktiengesellschaft, Dept. of Toxicology. 498 p.

43264404 Mellert, W. (1994) Carcinogenicity Study with Mepiquat Chloride in B6C3F1 Mice-Administration in the Diet for 24 Months: Lab Project Number: 94/10284: 80S0112/89107. Unpublished study prepared by BASF Aktiengesellschaft, Dept. of Toxicology. 1080 p.

43290401 Grosshans, F. (1994) The Metabolism of Mepiquat Chloride in Lactating Goats--Reinvestigation of Liver and Milk: Lab Project Number: 94/10029: P93-M002. Unpublished study prepared by BASF Aktiengesellschaft. 41 p.

43290402 Giese, U. (1989) Dosing of Lactating Goats with (carbon 14)-Mepiquat Chloride for the Determination of Accountability: Lab Project Number: 89/10508: NA 89 9230. Unpublished study prepared by NATEC. 23 p.

43290403 Panek, E. (1994) Dosing of Lactating Goat with (carbon 14) -Mepiquat Chloride for Determination of Accountability: Supplementary Report to Reg. Doc. #BASF 89/10508: Lab Project Number: 94/5078: M9420: 89/10508. Unpublished study prepared by BASF Corp. 8 p.

43290404 Panek, E. (1994) Dosing of Lactating Goat with (carbon 14) -Mepiquat Chloride for Further Isolation and Identification of Metabolites: Supplementary Report to MRID 41585202: Lab Project Number: 94/5079: M9419: 94/10045. Unpublished study prepared by BASF Corp. 11 p.

43290405 Giese, U. (1994) Dosing of Lactating Goat with (carbon 14) -Mepiquat Chloride for Further Isolation and Identification of Metabolites: Addendum to MRID 41585202: Lab Project Number: 94/10045: 88/0616: NA 88 9726. Unpublished study prepared by NATEC Institute. 7 p.

43378601 Hellwig, J. (1993) Reproduction Toxicity Study with Mepiquat Chloride in Rats: Continuous Dietary Administration over 2 Generation: Lab Project Number: 93/10983. Unpublished study prepared by BASF Aktiengesellschaft Dept. of Toxicology. 1702 p.

43379501 Burkey, J.; White, M. (1994) Freezer Storage Stability of BAS 083 W in Cottonseed and its Processed Commodities: Lab Project Number: 91140: A9425: 94/5120. Unpublished study prepared by BASF Corp. 74 p.

43396001 Mellert, W. (1994) Carcinogenicity Study with Mepiquat Chloride in Wistar Rats--Administration in the Diet for 24 Months: Lab Project Number: 94/10772: 71S0112/89092. Unpublished study by BASF Altiengesellschaft. 1680 p.

43415401 Evans, J.; Anderson, S. (1994) 1991 Ponnax Vineyard Soil Dissipation Study: Summary Report: Lab Project Number: 91007: ER93024: 94/5150. Unpublished study prepared by BASF Corp. 771 p.

BIBLIOGRAPHY

MRID	CITATION

43440301 Panek, E.; Kohl, W. (1994) Supplementary Information on Tissue Storage Conditions and Times For (carbon 14)-Mepiquat Chloride Goat Metabolism Studies (Mrid 42394301 and 42390405) and Accountability Studies (Mrid 42394303 and Reg. Doc. No. BASF 93/10672): Lab Project Number: M9428: 94/5153. Unpublished study by BASF Corp.; BASF Aktiengesellschaft. 18 p.

43455801 Goetz, A.; Butterfield, A. (1994) Further Identification Analysis of the (carbon 14) Residues Contained in the Soil Samples Obtained During the (carbon 14) BAS 083 W Rotational Crop Study (Study # M9015): Lab Project Number: 94099: M9429. Unpublished study by BASF Corp. Agricultural Products. 52 p.

43468701 Clark, J. (1994) BASF Rebuttal to the Review of Environmental Fate Studies in Support of the Reregistration for Mepiquat Chloride Case 2375: Lab Project Number: 94/5166. Unpublished study prepared by BASF Agricultural Research Center. 8 p.

43468702 Burkey, J.; White, M. (1994) Freezer Storage Stability of BAS 083 W in Soil (25-Month Interval): Interim Report: Lab Project Number: 94/6155: 91150: A9449. Unpublished study by BASF Agricultural Research Center. 25 p.

43471001 Drottar, K.; Swigert, J.; Holmes, C. (1994) Mepiquat Chloride: A 48-Hour Static Acute Toxicity Test with the Cladoceran (Daphnia magna): Lab Project Number: 147A/118: 94030: ER94032. Unpublished study prepared by Wildlife International Ltd. and BASF Agricultural Research Center. 70 p.

43516701 Drottar, K.; Swigert, J.; Holmes, C. (1995) Mepiquat Chloride: A 96-Hour Static Acute Toxicity Test With the Sheepshead Minnow (Cyprinodon variegatus): Lab Project Number: 147A-121: 94034: ER94034. Unpublished study prepared by Wildlife Int'l Ltd.; and BASF Corp. 66 p.

43516702 Drottar, K.; Swigert, J.; Holmes, C. (1995) Mepiquat Chloride: A 96-Hour Shell Deposition Test With the Eastern Oyster (Crassostrea virginica): Lab Project Number: 147A-120A: 94035: ER94053. Unpublished study prepared by Wildlife Int'l Ltd.; and BASF Corp. 71 p.

43516703 Drottar, K.; Swigert, J.; Holmes, C. (1995) Mepiquat Chloride: A 96-Hour Static Acute Toxicity Test With the Saltwater Mysid (Mysidopsis bahia): Lab Project Number: 174A-122: 94033: ER94035. Unpublished study prepared by Wildlife Int'l Ltd.; and BASF Corp. 71 p.

43738601 Riley, M.; Sears, L. (1995) Meat and Milk Magnitude of Residue Study with Mepiquat Chloride in Lactating Dairy Cows: Lab Project Number: 95/5094: A9529: A9062. Unpub. study prepared by BASF Corp. 256 p.

43738602 Riley, M.; Sears, L. (1995) Meat and Egg Magnitude of Residue Study with Mepiquat Chloride in White Leghorn Chickens: Lab Project Number: 95/5095: A9063: A9539. Unpublished study prepared by BASF Corp. 221 p.

43738603 Burkey, J.; Riley, M. (1995) Freezer Storage Stability of BAS 083 W in Animal Tissues, Eggs and Milk: Lab Project Number: 95/5096: A9538: 91149. Unpublished study prepared by BASF Corp. 77 p.

BIBLIOGRAPHY

MRID	CITATION
43785801	Burkey, J. (1995) Freezer Storage Stability of BAS 083 W in Soil: Terrestrial Field Dissipation Study: Lab Project Number: 95/5107: 91150: A9530. Unpublished study prepared by BASF Corp. 44 p.
44102201	Hildebrand, B.; Merkle, J. (1981) Study to Determine the Prenatal Toxicity of 1,1-Dimethyl-piperidinium Chloride in Rabbits: Lab Project Number: 81/9022. Unpublished study prepared by BASF Aktiengesellschaft. 295 p.
92091006	Kieczka, H. (1990) BASF Corporation Phase 3 Summary of MRID 00071942. Tolerance of the Rabbit Ocular Mucosa to 1, 1-Dimethyl/Piperidinium Chloride, Reg. No. 85559, Technical: BASF Reg. Doc. No. 77/0034; 90/6228. Prepared by LABORATORY FOR PHARMACY AND TOXICOLOGY. 6 p.
92091007	Kieczka, H. (1990) BASF Corporation Phase 3 Summary of MRID 41488104. Tolerance of the Rabbit Skin to 1,1-Dimethylpiperidinium Chloride, Reg. No. 85559 (Patch Test): BASF Reg. Doc. No. 76/0011; 90/6229. Prepared by Laboratory for Pharmacology and Toxicology. 6 p.
92091008	Kieczka, H. (1990) BASF Corporation Phase 3 Summary of MRID 41488103. Report on the Study of the Sensitizing Effect of Mepiquat Chloride (Reg. No. 85559) in the Guinea Pig According to "Proposed Rules" of EPA, Aug. 22, 1978, Federal Register, Vol. 43, No. 163, Page 37361.81-6: BASF Reg. Doc. No. 85/0080; 90/6230. Prepared by BASF Aktiengellschaft. 6 p.
92091010	O'Reilley, I. (1990) BASF Corporation Phase 3 Summary of MRID 00148089 and Related MRIDs 00148090. Study to Determine the Prenatal Toxicity of 1,1 Dimethylpiperidinium Chloride in Rabbits (Sept. 22, 1981), and … (February 14, 1979): 90/6235. Prepared by BASF AKTIENGESELLSCHAFT. 8 p.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-99).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In

Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time frame (Developing Data)

(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original

observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You

must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

    a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

    b. fulfill the commitment to develop and submit the data as required by this Notice; or

    c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms and the Confidential Statement of Formula Form

MEPIQUAT CHLORIDE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing mepiquat chloride.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of mepiquat chloride. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this mepiquat chloride Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for mepiquat chloride are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on mepiquat chloride are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible mepiquat chloride products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Emily Mitchell at (703) 308-8583.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Emily Mitchell
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **mepiquat chloride**

INSTRUCTIONS FOR COMPLETING THE **DATA CALL-IN RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**."

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data**

Compensation Requirements" form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "**Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a

product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

EPA'S BATCHING OF MEPIQUAT 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 the active ingredient Mepiquat 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. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

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

All these 9 products contain only one active ingredient, mepiquat, N,N-dimethylpiperidinium chloride.

The first table batches the two technicals. Data is available on the acute toxicity of a pure technical. No further testing of the technicals is required.

BATCH NO.	EPA REG. NO.	% of Mepiquat	Formulation Type
1	51036-187	99.0	Liquid
	51036-191	99.0	Liquid

BATCH NO.	EPA REG. NO.	% of Mepiquat	Formulation Type
2	7969-97	22.5	Liquid
	51036-189	23.5	Liquid

The compounds below have the same concentration of mepiquat (4.2%) and are batched together. It may be possible to bridge from the above batch.

BATCH NO.	EPA REG. NO.	% of Mepiquat	Formulation Type
3	7969-52	4.2	Liquid
	10136-186	4.2	Liquid
	51036-189	4.2	Liquid
	66996-1	4.2	Liquid

Only one product, 7969-107, remained unbatched. However, this product does have some acceptable studies in EPA's files.

Attachment 5. List of All Registrants Sent This Data Call-In (insert) Notice

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

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

Certification of Offer to Cost Share in the Development of Data

Form Approved OMB No. 2070-0106, 2070-0057 Approval Expires 3-31-99

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below:

Company Name	**Company Number**

Product Name	**EPA Reg. No.**

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firms on the following date(s):

Name of Firm(s)	**Date of Offer**

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	**Date**

Name and Title (Please Type or Print)

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires
3-31-99

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date

Name and Title (Please Type or Print)

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

The following is a list of available documents for mepiquat chloride that my further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Dee Henderson at (703)-308-8167.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for mepiquat chloride.

The following documents are part of the Administrative Record for mepiquat chloride and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1.Health and Environmental Effects Science Chapters.

2.Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria