



Reregistration Eligibility Decision (RED) Diquat Dibromide



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 diquat dibromide which includes the active ingredient 6, 7-dihydrodipyrido(1,2-a:2',1,-c)pyrazinediium dibromide. 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 ingredients 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 are due 90 days from the date of this letter. The second set of required responses are 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.

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 Franklin Rubis at (703) 308-8184. Address any questions on required generic data to the Special Review and Reregistration Division representative Kylie Rothwell at (703) 308-8055.

Sincerely yours,

Lois 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 data waivers must be submitted as part of the 90-day response. Requests for time extensions for product specific data should be submitted in 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 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

Diquat Dibromide

LIST A

CASE 0288

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

TABLE OF CONTENTS

DIQUAT DIBROMIDE REREGISTRATION ELIGIBILITY DECISION TEAM	i
EXECUTIVE SUMMARY	v
I. INTRODUCTION	1
II. CASE OVERVIEW	2
A. Chemical Overview	2
B. Use Profile	2
C. Estimated Usage of Pesticide	5
D. Data Requirements	6
E. Regulatory History	6
III. SCIENCE ASSESSMENT	6
A. Physical Chemistry Assessment	6
B. Human Health Assessment	7
1. Toxicology Assessment	7
a. Acute Toxicity	8
b. Subchronic Toxicity	8
c. Chronic Toxicity	10
d. Carcinogenicity	11
e. Developmental Toxicity	12
f. Reproductive Toxicity	15
g. Mutagenicity	16
h. Metabolism	17
i. Neurotoxicity	18
j. Other Toxicological Considerations	19
2. Exposure Assessment	20
a. Dietary Exposure	20
b. Occupational and Residential	27
3. Risk Assessment	31
a. Dietary Chronic Risk Analysis	31
b. Occupational and Residential	32
C. Environmental Assessment	36
1. Ecological Toxicity Data	36
a. Toxicity to Terrestrial Animals	36
b. Toxicity to Aquatic Animals	38
c. Toxicity to Plants	41
2. Environmental Fate	43
a. Environmental Fate Assessment	43
b. Surface Water Assessment	44
c. Environmental Fate and Transport	44
3. Exposure and Risk Characterization	47

	a.	Ecological Exposure and Risk Characterization	47
	b.	Freshwater Invertebrates	57
	c.	Estuarine and Marine Animals	57
	4.	Exposure and Risk to Nontarget Plants	57
IV.		RISK MANAGEMENT AND REREGISTRATION DECISION	60
	A.	Determination of Eligibility	60
	1.	Eligibility Decision	61
	B.	Regulatory Position	61
	1.	Tolerance Reassessment	61
	2.	Risk Mitigation Measures	69
	3.	Endangered Species Statement	69
	4.	Labeling Rationale	70
V.		ACTIONS REQUIRED BY REGISTRANTS	74
	A.	Manufacturing-Use Products	74
	1.	Additional Generic Data Requirements	74
	2.	Labelling Requirements for Manufacturing-Use Products	74
	B.	End-Use Products	75
	1.	Additional Product-Specific Data Requirements	75
	2.	Labeling Requirements for End-Use Products	75
	C.	Spray Drift Label Advisory	80
	D.	Labeling for Endangered Species	83
	E.	Existing Stocks	83
VI.		APPENDICES	85
		APPENDIX A. Table of Use Patterns Subject to Reregistration	87
		APPENDIX B. Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision	143
		APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Diquat Dibromide	155
		APPENDIX D. List of Available Related Documents	173
		APPENDIX E.	177
		PR Notice 86-5	179
		PR Notice 91-2	201
		APPENDIX F. Combined Generic and Product Specific Data Call-In	207
		Attachment 1. Chemical Status Sheets	227
		Attachment 2. Combined Generic and Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions	231
		Attachment 3. Generic and Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions	237
		Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration	245
		Attachment 5. EPA Acceptance Criteria	251

Attachment 6. List of All Registrants Sent This Data Call-In (insert) Notice	
.....	265
Attachment 7. Cost Share, Data Compensation Forms, Confidential	
Statement of Formula Form and Instructions	267
APPENDIX G. FACT SHEET	277

DIQUAT DIBROMIDE REREGISTRATION ELIGIBILITY DECISION TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
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
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
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 ₁₀	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
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MOE	Margin of Exposure
NOEC	No effect concentration
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OP	Organophosphate

GLOSSARY OF TERMS AND ABBREVIATIONS

OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PPE	Personal Protective Equipment
ppb	Parts Per Billion
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
SLN	Special Local Need (Registrations Under Section 24 (c) 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.
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

Reregistration Decision

This Reregistration Eligibility Decision document (RED) addresses the reregistration eligibility of the pesticide diquat dibromide.

Diquat dibromide is a non-selective contact herbicide, desiccant and plant growth regulator for use as a general herbicide for control of broadleaf and grassy weeds in terrestrial non-crop and aquatic areas; as a desiccant in seed crops and potatoes; and for tassel control and spot weed control in sugarcane. When used as a desiccant, diquat can be applied by aircraft or ground equipment. In aquatic sites, diquat may be injected below the water surface for submerged weeds, or sprayed for weed control along the edges of aquatic sites. Applications in crop areas are made 5 days to two weeks before harvest. Diquat is used for aquatic, indoor, greenhouse, and terrestrial food crops; aquatic non-food industrial, outdoor, greenhouse and residential; terrestrial feed crops, and outdoor residential uses. Additional use pattern information is described in the Profile section.

Based on the reviews of environmental fate, residue chemistry, toxicology, and ecological effects data of the active ingredient diquat dibromide, the Agency has determined that the uses of diquat dibromide as currently registered will not cause unreasonable risk to humans or the environment. All currently registered uses are eligible for reregistration. The Agency however is requiring additional terrestrial plant studies and an independent laboratory validation of enforcement methods for plant and animal commodities.

Health Effects

Diquat dibromide is classified as Toxicity Category II for acute dermal toxicity and primary eye irritation; Category III for acute oral and acute inhalation toxicity; and Category IV for dermal irritation. Diquat dibromide is not a skin sensitizer.

Diquat dibromide is classified as a Group E carcinogen (evidence of non-carcinogenicity for humans) based on a lack of evidence in acceptable animal studies. The Reference Dose (Rfd) was determined to be 0.005 mg/kg/day, expressed as diquat cation, based on the chronic toxicity study in dogs with a NOEL of 0.5 mg/kg/day, with an uncertainty factor (UF)/safety factor(SF) of 100.

The registrant has proposed revised tolerances for soybeans, soybean hulls, alfalfa and clover seed, sorghum grain, fish and shellfish, leafy and fruity vegetables, avocados, cottonseed, hops and sugarcane, meat, milk and eggs. Furthermore, the registrant will submit a label amendment request for the establishment of a preharvest interval (PHI) of 3 days for alfalfa and clover seed.

Occupational Safety

The Agency is concerned with the potential for postapplication/reentry exposure to workers outside the scope of the Worker Protection Standard (WPS) occupational uses to employees. In order to reduce the postapplication/exposure risks, the Agency is establishing a 4-day entry restriction to non-crop areas (other than aquatic sites) for non-WPS uses. For occupational uses(WPS uses), the Agency requires a 7-day interim restricted entry interval (REI). In addition, product use is limited to registered spot treatment for residential use. The Agency is also concerned about post-application exposure to homeowners and is requiring a product label requesting people and pets not to touch treated plants until the sprays have dried.

The registrant has proposed new enforcement methods for plant and animal commodities. Both methods have been validated by the registrant, however, an independent laboratory validation must be conducted followed by Agency validation.

There is an exposure potential for mixers, loaders, applicators or other handlers during ordinary use, therefore the Agency requires closed mixing/loading of diquat liquid formulations for aerial applications.

Environmental Fate and Ecological Effects

Diquat dibromide is immobile (binds irreversibly to the soil), is persistent, and will accumulate in soil. Diquat dibromide exceeds the levels of concern (LOCs) for acute and chronic effects to aquatic and estuarine organisms: however these effects are likely to be minimal in actual practice because diquat dibromide tends to bind rapidly to suspended matter in the water column and becomes biologically unavailable. Diquat dibromide exceeds the levels of concern for chronic effects to birds and terrestrial mammals. The registrant has not presented risk mitigation measures to reduce the chronic risk to birds.

The Agency is requiring additional ecological effects data, which include terrestrial and aquatic plant studies needed to complete the risk assessment for diquat dibromide. The registrant has submitted an aquatic plant study which is currently in review.

Before reregistering the products containing diquat dibromide, 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.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of diquat dibromide. The document consists of six sections. Section I is the introduction. Section II describes diquat dibromide, 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 diquat dibromide. Section V discusses the reregistration requirements for diquat dibromide. 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:** diquat dibromide
- **Chemical Name:** 6,7-dihydrodipyrido(1,2-a:2',1'-c)pyrazinedium dibromide
- **Chemical Family:** Bipyridylum, dipyridylum
- **CAS Registry Number:** 85-00-7
- **OPP Chemical Code:** 032201
- **Empirical Formula:** $C_{12}H_{12}Br_2N_2$
- **Trade and Other Names:** Reglone, Weedkiller Conc. D, Aquacide, Dextrone, FB 2, Reglox, Weedtrine D, Reward
- **Basic Manufacturer:** Zeneca Ag Products

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these uses of diquat dibromide is in Appendix A.

For Diquat Dibromide:

Type of Pesticide: algicide, defoliant, desiccant, herbicide

Use Groups and Sites:

AQUATIC FOOD CROP

Agricultural drainage systems, irrigation systems, lakes/ponds/reservoirs (with human or wildlife use)

AQUATIC NON-FOOD INDUSTRIAL

Drainage systems, lakes/ponds/reservoirs (without human or wildlife use)

AQUATIC NON-FOOD OUTDOOR

Aquatic areas/water, intermittently flooded areas/water, streams/rivers/channeled water

AQUATIC NON-FOOD RESIDENTIAL

Ornamental ponds/aquaria

GREENHOUSE FOOD CROP

Greenhouse-in use

INDOOR FOOD

Storage areas-empty and full

INDOOR NON-FOOD

Greenhouse-empty

OUTDOOR RESIDENTIAL

Residential lawns, household/domestic dwellings outdoor premises

TERRESTRIAL FEED CROP

Alfalfa, bermudagrass, clover

TERRESTRIAL FOOD CROP

Carrot (including tops), cucumber, melons (cantaloupe), melons (water), pepper, radish, squash (all or unspecified), turnip

TERRESTRIAL FOOD+ FEED CROP

Potato (white/irish), sorghum, soybeans (unspecified), tomato

TERRESTRIAL NON-FOOD CROP

Agricultural fallow/idleland, agricultural/farm structures/buildings and equipment, agricultural rights-of-way/fencerows/hedgerows, agricultural uncultivated areas, airports/landing fields, commercial/industrial lawns, commercial/institutional/industrial premises/equipment (outdoor), golf course turf, industrial areas (outdoor), nonagricultural outdoor buildings/structures, nonagricultural rights-of-way/fencerows/hedgerows, nonagricultural

uncultivated areas/soils, nonagricultural uncultivated soil sterilization, ornamental and/or shade trees, ornamental woody shrubs and vines, recreation area lawns, recreation areas

TERRESTRIAL NON-FOOD+ OUTDOOR RESIDENTIAL

commercial/institutional/industrial premises/equipment (outdoor), fencerows/hedgerows, ornamental and/or shade trees, nonagricultural outdoor buildings/structures, nonagricultural rights-of-way/fencerows/hedgerows, nonagricultural uncultivated soil sterilization, ornamental herbaceous plants, ornamental lawns and turf, ornamental flowering plants, ornamental woody shrubs and vines, paths/patios, paved areas (private roads/sidewalks)

Target Pests: algae: pithophora, spirogyra; weeds: bladderwort, crabgrass, elodea, jimsonweed, leafy spurge, naiad, poison ivy, salvinia, shepherdspurse, waterlettuce; desiccant/defoliant of seed crops: alfalfa, carrot (including tops), clover, potato (white/irish), radish, sorghum, turnip

Formulation Types Registered:

Single active ingredient

Liquid-Ready to Use--0.0940 to 0.2300% diquat
Soluble Concentrate/Liquid--0.1900 to 37.45% diquat
Manufacturing Use--35.3 to 37.45% diquat

Multiple active ingredient

Liquid-Ready to Use--0.1540% diquat + 1 other AI

Method and Rates of Application:

Soluble Concentrate/Liquid

For desiccation of seed crop, apply by ground or aircraft at 0.5 lb diquat cation (CI) per acre, or apply to tomatoes at post-final harvest as a spray at .375 lb (CI) in FL, GA and PR; or for golf course treatment, apply as needed with sprayer at 0.008 to 1.0 lb (CI), or for pre-renovation apply as a desiccation ground application at 1 lb (CI); or apply when needed as water subsurface treatment by injection or by boat at 4 lb (CI) per acre, or up to 4.2 lb (CI) per acre foot.

Liquid-Ready to Use

Apply to household/domestic dwellings, outdoor premises or nonagricultural outdoor buildings/structures as edging or spot treatment - or apply to woody shrubs and vines, paths/patios, and paved areas (private roads/sidewalks as directed spray, edging or spot treatment) - when needed with sprayer at .05 lb (CI)/1000 square feet: or apply to ornamental woody shrubs and vines with hand held or mechanical sprayer as a spray when needed at .02 lb (CI)/1000 square feet.

Use Practice Limitations:

(Please refer to Appendix A for a list of use limitations.)

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of diquat dibromide. 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.

The table below summarizes the pesticide use by site.

Percent of Various U.S. Crops Treated Annually with Diquat Dibromide, 1990 - 1992

Site/1	Acres Grown/2 (000)	Acre Treatments/3 (000)	Percent Crop Treated	Pounds a.i./ac
		low - high	low - high	low -high
Alfalfa	25,048	25 - 105	< 1 - < 1	15 - 60
Cantaloupe	131	1 - < 5	1 - < 5	1 - < 5
Clover	146	2 - < 5	1 - < 5	2 - < 5
Cucumber	132	1 - < 5	1 - < 5	1 - 1
Ornamentals	597	50 - 75	8 - 13	45 - 55
Pepper	93	10 - 15	11 - 16	1 - < 5
Potato	1,378	300 - 500	22 - 36	175 - 275
Sorghum	11,625	5 - 10	< 1 - < 1	1 - 5
Tomato	475	5 - 23	1 - 5	4 - 15
Watermelon	251	1 - 5	< 1 - 2	1 - < 5
Other/4	N/A	N/A - N/A	N/A	150 - 250
TOTAL		400 - 748		396 - 681

/1 - Site identification based on REFS.

/2 - Based on USDA/NASS publications from 1990 - 1993.

/3 - Acre treatments represent the number of acres treated times the number of applications.

/4 - Includes home and garden, non-crop, and aquatic uses; acre treatments are difficult to quantify because of spot treatments.

There are no known site specific usage data available for turnip.

There is no known usage on carrots, radishes, soybeans, squash, and sugarcane.

Data based on proprietary sources, USDA, Zeneca Ag, Inc., and state statistics.

D. Data Requirements

Data requested in the June 1986 Registration Standard for diquat dibromide include studies on product chemistry, ecological effects, health effects, environmental fate, toxicology, and residue chemistry. These data were required to support the uses listed in the Registration Standard. In 1991, the Data Call-In (DCI) notice required toxicology, ecological effects, environmental fate and residue chemistry studies. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Diquat dibromide is the accepted common name for 6,7-dihydrodipyrido(1,2-a:2',1'-c) pyrazinediium dibromide. It is manufactured by Zeneca, Inc. and is marketed under the trade name Diquat. Currently, there are forty-three active products containing diquat dibromide which are registered under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act.

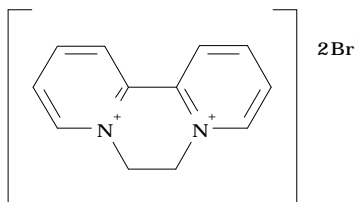
In June, 1986, EPA issued a Registration Standard for products containing diquat dibromide as an active ingredient (NTIS# PB87-105490). A Pesticide Fact Sheet for diquat dibromide was issued in June, 1987 (NTIS# PB92-126986). These documents provide a summary and the rationale of the regulatory position for diquat dibromide.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

1. Identification of the Active Ingredient

Diquat dibromide [6,7-dihydrodipyrido(1,2-a:2',1'-c)pyrazinediium dibromide] is a non-selective contact herbicide, desiccant, and plant growth regulator. Pure diquat dibromide is an odorless yellow solid with a melting point of ca. 300°C. Diquat dibromide is very soluble in water (700 g/L at 20°C), slightly soluble in alcohol and hydroxylic solvents, and practically insoluble in non-polar organic solvents. Diquat dibromide decomposes under basic conditions and is susceptible to ultraviolet decomposition. The molecular structure of diquat dibromide is:



Empirical Formula:	C ₁₂ H ₁₂ Br ₂ N ₂
Molecular Weight:	344.0
CAS Registry No.:	85-00-7
Shaughnessy No.:	032201

There are four EPA manufacturing use product (MPs) registrations for diquat dibromide (Reg. No(s): 10182-378 (37.45% ai); 10182-354 (37.45% ai); 10182-355 (35.3% ai) and 10182-376 (35.3% ai). None of the physical/chemical data requirements are satisfied for EPA Reg. No. 10182-355 or EPA Reg. No. 10182-354. The outstanding physical/chemical data requirements are specified in the data tables (Appendix B). In addition, the registrant must either certify that the suppliers of starting materials and the manufacturing processes for diquat dibromide MPs have not changed since the last comprehensive product chemistry review or submit a complete updated product chemistry data package.

2. Other Product Chemistry Issues

The manufacture of diquat dibromide may result in the occurrence of ethylene dibromide (EDB) as a process impurity in final formulations because EDB is a starting material in the manufacture of diquat dibromide. EDB is considered a carcinogen, and all pesticide uses of EDB were canceled. Since EDB may remain in diquat dibromide formulations, potential exposure risks were assessed (Guidance Document, 6/86). The Agency concluded that the presence of EDB, which may result from the use of diquat dibromide in aquatic and terrestrial sites, does not pose a significant dietary risk, based on worst case assessments. In addition, the registrant certified an upper certified limit of 10 ppb for EDB in diquat dibromide, and demonstrated that EDB does not persist as an impurity in diquat dibromide and will slowly dissipate over time.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on diquat dibromide is adequate and will support reregistration eligibility.

a. Acute Toxicity

Acute Toxicity

Test	Results	Category
Acute Oral LD ₅₀ (rat) ¹	0.81 g/kg ♂	III
	0.60 g/kg ♀	III
Acute Dermal LD ₅₀ (rabbit) ²	262.0 mg/kg ♂	II
	315.0 mg/kg ♀	II
	288.5 mg/kg ♂+ ♀	II
Acute Inhalation LC ₅₀ (rat) ³	0.80 mg/L ♂	III
	1.09 mg/L ♀	III
	0.97 mg/L ♂+ ♀	III
Eye Irritation (rabbit) ⁴ *	Slight to severe irritation	II
Dermal Irritation (rabbit) ⁵ *	Slight irritation	IV
Skin Sensitization (guinea pig) ⁶ *	Negative	N/A ⁷

¹ MRID No. 00081506

³ MRID No. 00107903

² MRID No. 00100614

⁶ MRID No. 00155475

³ Acc. No. 26385

⁷ Not Applicable

⁴ MRID No. 00081507

* Note: Data pertaining to acute eye irritation, dermal irritation and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented for informational purposes.

The above LD₅₀ and LC₅₀ values are expressed in terms of the test material and not, as is commonly done with diquat, in terms of the diquat cation.

With the exception of the dermal sensitization study which was conducted with the technical diquat (Diquat Herbicide Concentrate), the above studies were conducted with the end-use products, Diquat Water Weed Killer (studies 1, 2, 3 and 5) and Diquat 2 Spray (study 4). Because the only difference between the technical diquat and the end-use products is 2.15% of water, studies with the end-use products have been accepted to satisfy the generic data requirements for acute studies.

b. Subchronic Toxicity

In a repeated dose dermal toxicity study, male and female rabbits (strain not specified), 3/sex/group, were exposed (intact skin) to technical diquat dibromide for 20 consecutive days. The dose levels used, expressed as diquat cation, were 0, 20, 40, 80 or 160 mg/kg/day. The effects at the site of application included erythema and scabbing. Systemic effects were reported only at dose levels above 20 mg/kg/day. These effects included loss of weight, unsteadiness, muscular weakness and inability to stand. Pathological changes associated with the test material included distal convoluted renal tubules with cell necrosis (thought to be associated with an electrolyte imbalance). Based on these findings, the NOEL and LOEL for systemic toxicity, for both sexes, are 20 mg diquat cation/kg/day and 40 mg diquat cation/kg/day, respectively. Because hematology, clinical chemistry and urinalysis were not determined, this study was classified as supplementary data. However, this study provided

useful information "to indicate that diquat dibromide is toxic via repeated dermal exposure."
(MRID 00140576)

In a repeated dose dermal toxicity study, male and female Sprague-Dawley rats, 6/sex/group, were exposed (intact skin) to technical diquat dibromide for 3 weeks (6 hours/day, 7 days/ week). The dose levels used, expressed as diquat cation, were 0, 5, 20, 40 or 80 mg/kg of body weight/day and were based on the results of two preliminary studies. Treatment-related effects included high mortality in the 40 mg/kg female group (67%) and in the 80 mg/kg male (83%) and female (100%) groups; decreased weight gain for the 80 mg/kg males and females; decreased food consumption, for the 80 mg/kg males (11-36%) and females (3-41%); hypothermia, hypoactivity, dyspnea, cyanosis, pale extremities, general poor condition and an emaciated appearance, all in the nonsurvivors; dermal irritation (erythema, edema, atonia and desquamation) and tissue destruction (necrosis and eschar formation) at the application site, at all dose levels, sores, severe erythema, fissures, acute necrotizing purulent dermatitis, and degeneration of hair follicles and sebaceous glands, all at the application site in the 20, 40 and 80 mg/kg male and female groups; and congestion in the lungs, liver and kidneys, mostly in the nonsurvivors from the 40 and 80 mg/kg male and female groups. Based on the above findings, the NOEL and LOEL for systemic toxicity, for both sexes, are 5 mg diquat cation/kg/day and 20 mg diquat cation/kg/day, respectively. The NOEL for dermal toxicity, for both sexes, is < 5 mg diquat cation /kg/day (LDT). (MRID 40308101)

In a repeated dose inhalation toxicity study, groups of 10 male and 10 female Fischer 344 rats were exposed (whole body) to respirable aerosols of Diquat Concentrate (technical diquat) for 3 weeks (6 hours/day, 5 days/week). The exposure concentrations (analytical) were 0, 0.49, 1.1 or 3.8 ug/L, expressed as diquat cation, and were based on the results of a preliminary inhalation study. A satellite group of the control and high-dose males and females was treated similarly and then observed for 3 weeks for reversibility of toxic effects. The average mass median aerodynamic diameter of the aerosols was 1.9, 1.7 and 1.7 um in the low- mid- and high-concentrations groups, respectively. Because whole animals were exposed to diquat, the animals, including controls, were rinsed with tap water for about 5 seconds and blotted dry after each exposure before they were returned to their cages in the housing area. The purpose of the rinse was to remove diquat which had deposited on the animals' fur and to minimize any oral exposure to diquat which could occur from grooming. Treatment-related effects, observed at the lowest concentration of diquat cation tested (0.49 ug/L), included significant ($p < 0.01$) increases in the mean lung weight (18%), and the lung/body weight (18%) and the lung/brain weight (19%) ratios for the male rats; mottling and reddening of the lungs in the females; and the lung lesions (multi-focal chronic interstitial pneumonia and alveolar macrophages) in the males and females. All toxic effects, except mottling and reddening of the lungs, were reversible during the 21-day recovery period (satellite group). Considering the above findings, the NOEL for subchronic (21 days) inhalation toxicity is < 0.49 ug/L, expressed as diquat cation (LDT). (MRID 40301701)

In a second repeated dose inhalation toxicity study, groups of 10 male and 10 female Fischer 344 rats were exposed (whole body) to respirable aerosols of Diquat Concentrate (technical diquat) for 3 weeks (6 hours/day, 5 days/week). The exposure concentrations used were 0 and 0.1 ug/L, expressed as diquat cation, and the average mass median aerodynamic diameter of the aerosols was 1.5 um. This study was conducted in the same manner as an earlier study (MRID 40301701) in which three concentrations of diquat cation were used (0.49, 1.1 or 3.8 ug/L), but in which the NOEL was not determined. Therefore, in order to establish the NOEL and LOEL for the 21-day inhalation exposure, both studies should be considered together. In the current study, the only concentration of diquat cation tested (0.1 ug/L) had no effect on any of the parameters examined. In the earlier study (MRID 40301701), toxic effects were observed at the lowest concentration of diquat cation tested (0.49 ug/L). Therefore, for the repeated 21 days inhalation exposure, the NOEL and LOEL for both sexes are 0.1 ug/L and 0.49 ug/L, respectively, expressed as diquat cation. (MRID 40640801)

c. Chronic Toxicity

A chronic feeding/carcinogenicity study was conducted using Sprague-Dawley rats which were fed diets containing 0, 5, 15, 75 or 375 ppm of diquat cation for 104 weeks. These dose levels were equivalent to 0, 0.19, 0.58, 2.91 or 14.88 mg/kg/day (males) and 0, 0.24, 0.72, 3.64 or 19.44 mg/kg/day (females) of diquat cation (analytical values), and were based on a 4-week preliminary study. There were 60 rats/sex in each group. The interim sacrifice (10 rats/sex/group) took place at 52 weeks. With the exception of minimal lens opacity (cataracts), in 7/52 (13%) male rats and 3/41 (7%) female rats which died or were sacrificed moribund in the 5 ppm and 15 ppm groups during weeks 79-104, nothing remarkable was observed in these groups. Treatment-related effects in the 75 ppm group were: lens opacity in 4/9 (44%) males and 6/10 (60%) females which were sacrificed at week 52 (interim sacrifice); lens opacity in 19/21 (90%) males and 15/20 (75%) females, and marked or severe cataracts in 5/21 (14%) males and 7/20 (10%) females which were sacrificed at the termination of the study; lens opacity in 12/28 (43%) males and 16/30 (53%) females, and marked or severe cataracts in 4/28 (14%) males which died or were sacrificed during weeks 53-104; and extralenticular lesions (vitreous adhesions, retinal detachment and synechia) in 4-6/59 (7-10%) males and 1-3/60 (2-5%) females during the entire study. The systemic NOEL for both sexes is 15 ppm (0.58 mg/kg/day for males and 0.72 mg/kg/day for females, expressed as diquat cation); and the systemic LOEL is 75 ppm (2.91 mg/kg/day for males and 3.64 mg/kg/day for females, expressed as diquat cation). (MRID 00145855), (MRID 00155474 - amended pages to replace pages 145 and 146 of the original report, MRID 00145855) and (MRID 40185601 - 4-week preliminary study).

Groups of 4 male and 4 female beagle dogs were administered technical grade diquat dibromide in the diet for 52 weeks. Male dogs received daily 400 g and females 350 g of the diquat-containing pellets. The dose levels used were 0, 0.5, 2.5 or 12.5 mg/kg/day, expressed as diquat cation, and were based on the results of previous toxicity studies with diquat dibromide (details were not provided). Nothing remarkable was observed in the 0.5 mg/kg

male and female groups. Treatment-related effects in the 2.5 mg/kg group included unilateral cataracts in two females; decreased mean adjusted weight of the adrenals in the males (13.8%; $p < 0.05$) and decreased mean absolute weight (16.2%; $p < 0.05$) and adjusted weight (16.1%; $p < 0.05$) of the epididymides in the males. Diquat was not detected in the plasma of dogs from the 0.5 mg/kg group. In the 2.5 mg/kg group, diquat was detected in the plasma of most dogs only after feeding (concentrations of diquat cation detected: 21-43 ng/mL in the males and 20-54 ng/mL in the females). In the 12.5 mg/kg group, diquat was detected in the plasma of most dogs before and after feeding. The concentrations of diquat cation detected before feeding were: 21-59 ng/mL in the males and 23-186 ng/mL in the females. The concentrations of diquat cation detected after feeding were: 24-153 ng/mL in the males and 44-255 ng/mL in the females. Based on the above findings, systemic NOEL for both sexes is 0.5 mg/kg/day and systemic LOEL is 2.5 mg/kg/day. (MRID 41730301)

d. Carcinogenicity

A chronic feeding/carcinogenicity study was conducted using Sprague-Dawley rats which were fed diets containing 0, 5, 15, 75 or 375 ppm of diquat cation for 104 weeks. These dose levels were equivalent to 0, 0.19, 0.58, 2.91 or 44.88 mg/kg/day (males) and 0, 0.24, 0.72, 3.64 or 19.44 mg/kg/day (females) of diquat cation (analytical values). There were 60 rats/sex in each group.

The interim sacrifice (10 rats/sex/group) took place at week 52. During the initial review of this study, there were some concerns about the carcinogenic potential of diquat for the following reasons: there were statistically significant increases in several tumor types at single dose level, although dose-related trends were lacking and there were increased incidences of some rare tumors, but the statistical significance was lacking. The tumor types in question, all in the male rats, were hepatocellular adenomas/carcinomas; benign/malignant pheochromocytomas and mixed medullary tumors of the adrenal gland; follicular and parafollicular cell adenomas/carcinomas of the thyroid; squamous carcinomas of the Zymbal gland; and osteosarcomas of the bone. However, following an evaluation of the submitted historical control data, the Agency concluded that diquat was not carcinogenic with respect to all neoplasms but osteosarcomas. The incidence of osteosarcomas in the 0 (control), 5, 15, 75 and 375 ppm male groups was 0/50, 1/50 (2%), 0/50, 0/50 and 3/49 (6%)*, respectively, whereas the historical control incidence was 0-2%. Because the historical control incidence was lower than the observed incidence in this study and because osteosarcomas of the bone were rare tumors, the decision concerning the carcinogenic potential of diquat was determined by the Health Effects Division RfD/Peer Review Committee. [* During repeated examination of the individual histopathology data, only 2/49 (4%) osteosarcomas and not 3/49 (6%) as reported in the summary tables of the submitted report were found. One rat died during week 96 and another during week 100]. (MRID 00145855), (MRID 00155474 - amended pages to replace pages 145 and 146 of the original report, MRID 00145855), (MRID 00160673 - historical control data for neoplastic lesions) and (MRID 40185602 - registrant's comments on the incidence of osteosarcoma).

Groups of CD-1 mice (60/sex/dose) were administered technical diquat dibromide in the diet for at least 104 weeks. The dose levels used were 0, 30, 100 or 300 ppm, expressed as diquat cation, and were based on the results from previous feeding studies with the same strain of mice. These levels, expressed as diquat cation, were equivalent to 0, 3.56, 11.96 or 37.83 mg/kg/day for males and 0, 4.78, 16.03 or 48.27 mg/kg/day for females. Nothing remarkable was observed in the 30 ppm male and female group. Treatment-related effects in the 100 ppm group were: increased number of males (25%) with eye discharge; decreased body weight gains (11-13%; $p < 0.01$) in the males during weeks 93-105; increased kidney weight, adjusted for body weight, in the males (6%; $p < 0.01$); slight increase in the incidence of tubular dilatation of the kidneys in the males (3/60) and females (4/60) when compared with the controls (1/60, males and females); increased incidence of tubular hyaline droplet formation in the kidneys of the females (10/60; controls: 3/60); and increased incidence of lymphoid proliferation in the mesenteric lymph node of the females (13/59; controls: 9/60). Based on the above findings, systemic NOEL (diquat cation) for both sexes is 30 ppm (males: 3.56 mg/kg/day and females: 4.78 mg/kg/day). The systemic LOEL (diquat cation), therefore, is 100 ppm (males: 11.96 mg/kg/day and females: 16.03 mg/kg/day). Diquat was not carcinogenic in this study. The number of tumor-bearing mice was the same in the control and diquat-treated male groups. In the females, there was a reduction in the number of tumor-bearing mice in the mid-dose (100 ppm) and high-dose (300 ppm) groups, relative to the controls. Most of the tumor-bearing mice in each group, including the controls, had single, malignant and metastatic tumors. (MRID 42219801 - main study) and (MRID 42880701, 42905901, and 42919501 - supplemental data).

The carcinogenic potential of diquat dibromide was evaluated by the Health Effects Division Reference Dose (RfD)/Peer Review Committee on March 31, 1994. The Committee classified diquat dibromide into Group E (evidence of noncarcinogenicity for humans), based on a lack of evidence of carcinogenicity in acceptable studies with two animal species, rat and mouse. The dose levels tested in both studies were considered to be adequate for carcinogenicity testing. This conclusion was based on moderate reduction in body weight gain in both rats and mice, and on histopathological changes (lens opacity, severe cataracts and extralenticular lesions) in the eyes of rats. The slight increase in the incidence of osteosarcoma of the bone in the high-dose male rats above the concurrent and historical control incidence was regarded as spontaneous rather than diquat-related. This increase attained a statistically significant positive trend, but was not statistically significant in the pair-wise comparison with the concurrent controls.

e. Developmental Toxicity

A developmental study was conducted in which diquat dibromide was administered to pregnant Sprague-Dawley rats (18-20/ group) in their diets throughout gestation (days 1-20). The dose levels used were 0, 125 or 500 ppm, expressed as diquat cation. Based on calculations from the actual food consumption and body weight data, these values were equivalent to 0, 8-14 or 32-56 mg of diquat cation/kg/day, respectively. Maternal toxicity was observed only in the 500 ppm group and included decreases in mean total body weight gain

(31%; $p < 0.01$), mean total food consumption (20%; $p < 0.01$) and food efficiency (4%), when compared with the controls. Developmental toxicity was also observed only in the 500 ppm group and included decreased fetal weight (8%; $p < 0.01$) and instances of various external, visceral and skeletal alterations. Based on these findings, the NOEL and LOEL for maternal toxicity are 8-14 mg/kg/day and 32-56 mg/kg/day, respectively. The NOEL and LOEL for developmental toxicity are also 8-14 mg/kg/day and 32-56 mg/kg/day, respectively. Because of various deficiencies in the reporting of this study (no data on the number of corpora lutea per dam, pregnancy status and preimplantation losses; and no individual data for maternal, fetal and litter weights, number of implantation, live fetuses, early and late resorptions, and incidences of external, visceral and skeletal alterations), this study should be classified as supplementary. However, this study could be used in conjunction with other developmental toxicity studies with diquat to support reregistration of the pesticide. (Accession No. 224405)

In another recently submitted developmental toxicity study, diquat dibromide was administered by gavage, in deionized water, to pregnant Wistar-derived rats (23-24/group) from gestation day 7 through 16. The dose levels used were 0, 4, 12 or 40 mg/kg/day, expressed as diquat cation. Animals were sacrificed on gestation day 22 and uteri were examined for live fetuses and intrauterine deaths. The lowest dose (4 mg/kg/day) was associated with decreased maternal body weight gain (22%; $p < 0.05$) and food consumption (7%; $p < 0.05$) during the first three days of dosing only, when compared with the controls. Treatment-related findings in the high-dose group were: decreases in fetal (9%; $p < 0.01$) and litter (12%; $p < 0.05$) weights; increased incidence of fetuses with hemorrhagic kidney (5 in 4 litters; $p < 0.05$), compared with none in the control group; partially ossified second sternebra in 26 fetuses from 6 litters ($p < 0.01$), compared with 2 fetuses in 2 litters in the control group; partially ossified fifth sternebra in 89 fetuses from 19 litters ($p < 0.01$), compared with 69 fetuses in 19 litters in the control group; unossified ventral tubercle in 26 fetuses from 11 litters ($p < 0.05$), compared with 17 fetuses in 8 litters in the control group; and unossified centra of the second through fifth cervical vertebrae, as follows (number of fetuses affected/number of litters involved in the high-dose group versus (vs) those in the controls): 2nd vertebrae -- 180/23 ($p < 0.05$) vs 162/24; 3rd vertebrae -- 88/18 ($p < 0.05$) vs 39/16; 4th vertebrae -- 56/17 ($p < 0.01$) vs 21/11; and 5th vertebrae -- 23/10 ($p < 0.01$) vs 12/7. Based on the above findings, the NOEL for maternal toxicity is not established and the LOEL is < 4 mg/kg/day, expressed as diquat cation (lowest dose tested). The developmental toxicity NOEL and LOEL are, respectively, 12 mg/kg/day and 40 mg/kg/day (highest dose tested), expressed as diquat cation. (MRID 41198902)

Pregnant Dutch rabbits (15-20/group) were treated with diquat dibromide on gestation days 1 through 28. The test material was administered by gavage at dose levels of 0, 1.25, 2.5 or 5.0 mg/kg/day, expressed as diquat cation. The animals were sacrificed on gestation day 29 and examined to determine the numbers of implantation sites, resorptions, and live and dead fetuses. Decreased body weight gain in the 5 mg/kg group was the only maternal toxicity observed in this study. The food consumption data were not reported. There was no indication of a dose-related effect of diquat administration on fetal development, but there

appeared to be a treatment-related increase in the early resorption rate. Historical control data were not submitted to determine if the early resorption rate reported for the concurrent control group was unusually low for the Dutch strain of rabbit. Based on these findings, the NOEL and LOEL for maternal toxicity are 2.5 mg/kg/day and 5.0 mg/kg/day, respectively, expressed as diquat cation, but the NOEL for developmental toxicity cannot be clearly established. Because of the marginal number of pregnancies available for evaluation in this study (10 or 11 per group) and the reporting deficiencies (no data on the number of corpora lutea per doe, pregnancy status and preimplantation losses; no individual data, by litter, on the incidences of external, visceral and skeletal alterations; and no statistical analyses and historical control data), this study should be classified as supplementary. However, this study could be used in conjunction with other developmental toxicity studies with diquat to support reregistration of the pesticide. (MRID 00061635)

In another recently submitted developmental toxicity study, diquat dibromide in deionized water, was administered by gavage, to pregnant New Zealand white rabbits (20/group) from gestation day 7 through 19. The dose levels used were 0, 1, 3 or 10 mg/kg/day, expressed as diquat cation. Animals were sacrificed on gestation day 30 and uteri were examined for live fetuses and intrauterine deaths. Nothing remarkable was observed in the low-dose (1 mg/kg/day) group. The mid-dose group (3 mg/kg/day) was associated with decreased maternal body weight gain (229% less than controls; $p < 0.01$) and food consumption (45% less than controls; $p < 0.01$) which were observed only during the first three days of dosing. The high-dose group (10 mg/kg/day) showed greater decreases in body weight gain (343%; $p < 0.01$) and food consumption (74%; $p < 0.01$) than the mid-dose group during the first three dosing days and the decreases continued throughout the dosing period. Developmental effects were observed only in the high-dose group and included an increased incidence of fetuses with friable livers (14 in 3 litters, $p < 0.05$, compared with 8 in 5 litters in the control group) and mottled livers (12 in 3 litters, $p < 0.05$, compared with 8 in 6 litters in the controls). Fetuses from the high-dose group also exhibited poorer ossification as indicated by higher incidences of minor skeletal alterations, including partially ossified ventral tubercle of cervical vertebrae (10 fetuses in 5 litters, $p < 0.01$, compared with 1 fetus in 1 litter in the control group); partially ossified sixth sternebra (16 fetuses in 8 litters, $p < 0.01$, compared with 9 fetuses in 6 litters in the controls); and unossified sixth sternebra (6 fetuses in 5 litters, $p < 0.01$, compared with zero incidence in the control group). Also, the frequency of the skeletal variant, 27 presacral vertebrae, was increased in the high-dose group (49 fetuses in 12 litters, $p < 0.01$, compared with 46 fetuses in 14 litters in the controls), but this increase was within recent historical control incidence. Based on the above findings, the NOEL and LOEL for maternal toxicity are 1 mg/kg/day and 3 mg/kg/day, respectively, expressed as diquat cation. The developmental toxicity NOEL and LOEL are, respectively, 3 mg/kg/day and 10 mg/kg/day (highest dose tested), expressed as diquat cation. (MRID 41198901)

A developmental study was conducted in which an aqueous solution of diquat dibromide was administered by gavage to pregnant Alderley Park strain SPF albino mice (32-34/group) from gestation day 6 through 15. The dose levels used were 0, 1, 2 or 4

mg/kg/day, expressed as diquat cation. Animals were sacrificed on gestation day 17. Nothing remarkable was observed in the low-dose group. Toxic signs noted in the mid-dose and high-dose groups were piloerection, dyspnea, respiratory noise and abnormal posture (hunched or tail raised), whereas none of these signs were observed in the control group. Relative to the control value, a decreased body weight gain was also reported for the mid-dose (23%) and high-dose (29%) group. Excluding the intubation errors, there were no unscheduled deaths in the control group, but 3/33 (9%) and 5/34 (15%) animals died in the mid-dose and high-dose groups, respectively. Developmental toxicity was observed only in the high-dose group and included statistically significant ($p < 0.05$) decreased fetal body weight (12% below the control group mean) and increased incidence of overall skeletal alterations (16/23 affected litters, compared with 9/27 litters in the control group). Based on these findings, the NOEL and LOEL for maternal toxicity are 1 mg/kg/day and 2 mg/kg/day, respectively, expressed as diquat cation. The developmental toxicity NOEL and LOEL are, respectively, 2 mg/kg/day and 4 mg/kg/day (highest dose tested), expressed as diquat cation. (MRID 00061637)

f. Reproductive Toxicity

Wistar-derived rats (30 males and 30 females/group) were fed diets containing diquat dibromide at dose levels equivalent to 0, 16, 80 or 400/240 ppm of diquat cation. Based on the commonly used conversion factor of 1 ppm = 0.05 mg/kg for an older rat these levels were equivalent to 0, 0.8, 4 or 20/12 mg/kg/day, respectively. The F_0 high-dose group received diets containing 400 ppm of diquat cation. Due to adverse effects in the F_1 animals, the dose was reduced from 400 ppm to 240 ppm approximately four weeks after selection. The feeding of the test material was started 12 weeks (11 weeks for the F_1 generation) before mating and was continued through the mating, gestation and lactation periods. Parental toxicity was observed mostly in the high-dose group, in both generations, as increased incidences of clinical signs (red/brown urine, piloerection, and ulcers on palate and tongue); increased incidences of ophthalmoscopic signs (eye opacity, partial or total lenticular cataracts, and iritis); statistically significant ($p < 0.01$) decreased body weight gains during the pre-mating (males, 15-40% and females, 10-37%), gestation (20-23%) and lactation (32-80%) periods; and statistically significant ($p < 0.05$ or 0.01) decreased food consumption during the pre-mating (males, 7-40% and females, 5-33%), gestation (8-14%) and lactation (16-28%) periods. The clinical signs were confirmed by gross and microscopic pathology. Reproductive toxicity was observed only at the 400/240 ppm level in both generations as decreased numbers of the live F_1 pups/litter on days 1-22 (15-16% fewer than in the control group; $p < 0.05$); and as decreased body weight gain, on day 22, of the F_1 pups (males, 21% and females, 18%; $p < 0.05$) and of the F_2 pups (13%, males and females; $p < 0.01$), when compared with the respective controls. Based on the above findings, the NOEL and LOEL for systemic toxicity are 16 ppm (0.8 mg/kg/day) and 80 ppm (4 mg/kg/day), respectively, expressed as diquat cation. The NOEL and LOEL for reproductive toxicity are 80 ppm (4 mg/kg/day) and 400/240 ppm (20/12 mg/kg/day), respectively, expressed as diquat cation. (MRID 41531301)

g. Mutagenicity

Diquat dibromide was negative for mutagenicity in the following tests: 1 gene mutation (Ames), 2 structural chromosome aberration (mouse micronucleus and dominant lethal in mice) and 1 other genotoxic effects (unscheduled DNA synthesis in rat hepatocytes *in vitro*). Diquat dibromide was positive in 1 gene mutation test (mouse lymphoma cell assay) and in 1 chromosome aberration test (human blood lymphocytes, depending on the concentration of diquat dibromide and the presence or absence of the metabolic activation system).

Technical diquat dibromide was not mutagenic in the Ames test. In two separate experiments, diquat dibromide (0.01-100 ug/plate) did not induce any significant increase in the observed numbers of revertant colonies in any of the five strains of *Salmonella typhimurium* (TA1535, TA1537, TA1538, TA98 and TA100) and one strain of *Escherichia coli* (WP2uvrA pKM 101) used, with or without the metabolic activation system (rat liver postmitochondrial fraction, S9, plus cofactors). An appropriate positive control was used with each strain. This study satisfies guideline requirements for genetic effects Category I, Gene Mutations. (MRID 40323103)

Technical diquat dibromide was mutagenic in the mouse lymphoma cell assay. It induced forward mutation in the L5178Y mouse lymphoma cell line as monitored by cell growth in the presence of trifluorothymidine (TFT), with and without the metabolic activation system (S9 mix). Positive results were obtained with known mutagens, N-nitrosodimethylamine (DMN) requiring metabolic activation and ethylmethanesulphonate (EMS) not requiring activation. Concentration-dependent cytotoxicity was observed at all levels tested with and without the S9 mix. Mouse lymphoma cells L5178Y were exposed to diquat dibromide (6.25-100 ug/mL and 3.12-50 ug/mL without and with the S9 mix, respectively) for 2 hours, centrifuged, washed, and a sample was examined for survival (cytotoxicity). The remaining cells were maintained in exponential growth for 72 hours and then were grown in the presence of TFT. Negative (solvent) and positive controls were treated in the same manner. This study satisfies guideline requirements for genetic effects Category I, Gene Mutations. (MRID 40323101)

Technical diquat dibromide, at two levels tested, was not clastogenic in the mouse micronucleus test. Bone marrow was obtained from the C57Bl/6J/Alpk male and female mice which were treated with single intragastric doses of diquat dibromide. The dose levels used were 62.5 mg or 100 mg (expressed as diquat cation)/kg of body weight. These levels were equivalent to 50% and 80%, respectively, of the Median Lethal Dose (MLD; 125 mg/kg) determined in a preliminary study. Positive results were obtained with cyclophosphamide, a known clastogen. Diquat dibromide reached the target organ (bone marrow), as indicated by the cytotoxicity observed at both doses. This study satisfies guideline requirements for genetic effects Category II, Structural Chromosome Aberrations. (MRID 40323104)

Another chromosomal aberration study was conducted with human blood lymphocytes obtained from two donors, Donor 1 (male) and Donor 2 (female). Cell cultures of both donors were exposed to the concentrations of technical diquat dibromide ranging from 2.58 to 258 ug/mL of growth medium, but the following concentrations were selected for analysis of the cytogenetic potential of the chemical: 12.9, 64.5 or 129 ug/mL for Donor 1 and 12.9, 25.8 or 129 ug/mL for Donor 2. The concentration of 129 ug/mL, with or without the metabolic activation system (S9), was the maximum tolerated dose (MTD) for each donor, based on a preliminary study in which diquat dibromide concentrations ranging from 2.58 to 2580 ug/ml (\pm S9) were tested. MTD was defined as an *in vitro* exposure level which reduces mitosis by 50-80%. Diquat dibromide was not clastogenic at concentrations of 12.9 ug/mL (\pm S9) and 25.8 ug/mL (+ S9), when the treated cultures were compared with the negative controls. Other concentrations of diquat dibromide tested induced statistically significant ($p < 0.05$ or 0.01) increases in chromosomal damage (4.5-30% above the control values, depending on the concentration of diquat and the presence or absence of S9). Positive results were also obtained with known clastogens, mitomycin C and cyclophosphamide. This study satisfies guideline requirements for genetic effects Category II, Structural Chromosome Aberrations. (MRID 40323106)

Technical diquat dibromide, administered by gavage to Charles River CD-1 male mice for 5 consecutive days, did not produce dominant lethal effects at any of the levels tested. The levels of diquat used were 0, 0.1, 1.0 or 10 mg/kg, expressed as diquat cation. Positive controls used were ethylmethanesulphonate (EMS; 100 mg/kg, administered by gavage for 5 consecutive days) or cyclophosphamide (Endoxana; 200 mg/kg given once intraperitoneally one day before mating). This study satisfies guideline requirements for genetic effects Category II, Structural Chromosome Aberrations. (MRID 00061636)

Technical diquat dibromide at dose levels of 225, 450 or 900 mg/kg of body weight did not induce unscheduled DNA synthesis in rat hepatocytes exposed *in vitro*. Unscheduled DNA synthesis was induced under the same conditions by 6-p-dimethylaminophenylazo-benzthiazole (6BT), the positive control, tested at 40 mg/kg of body weight. The selection of dose levels was governed by the need to evaluate diquat at adequate concentrations and that these levels should not induce toxicity in the hepatocytes. Although hepatocytes from animals in each group treated with diquat dibromide showed signs of toxicity, as evidenced by pyknotic and deeply stained nuclei, sufficient cells of normal morphology were available at each dose level to be examined for unscheduled DNA synthesis. This study satisfies guideline requirements for genetic effects Category III, Other Genotoxic Effects. (MRID 40323107)

h. Metabolism

Rats were dosed orally with [14 C]-diquat dibromide and their urine and feces were quantitated for radioactivity at selected time intervals following dose administration. About 90% of the radioactivity was eliminated in feces, indicating that diquat was poorly absorbed from the gastrointestinal tract. Following a subcutaneous injection of [14 C]-diquat to

circumvent the intestine, nearly all of the labeled material was recovered in the urine within 2 days. (MRID 00055107)

Diquat dibromide was slowly absorbed from the gastrointestinal tract of male and female rats. Irrespective of the type of dosing (oral or intravenous), diquat did not accumulate in tissues of rats or mice. Following a single oral dose of [¹⁴C]-diquat dibromide (60 mg/kg, expressed as diquat cation), only 5.5% of the administered radioactivity was excreted in the urine of rats within 7 days. Following an oral feeding of unlabeled diquat dibromide (250 ppm, expressed as diquat cation) to male and female rats for 2, 4 or 8 weeks, there was no retention of diquat (as determined colorimetrically) in the brain, liver, lung, stomach, small and large intestines, muscle and blood, and little retention in the kidneys (0.18, 0.25 and 1.17 ppm during weeks 2, 4 and 8, respectively). Ten minutes after an intravenous injection of [¹⁴C]-diquat dibromide (60 mg/kg, expressed diquat cation), there were indications (whole body autoradiography), that diquat concentrated in the cartilaginous tissues, the liver and the urinary bladder. Most of other tissues also showed the presence of radioactivity, including small amounts in the brain and spinal cord. After 1 hour, the amounts of radioactivity declined in most tissues. After 24 hours, radioactivity was detected only in the urinary bladder, and in the small and large intestines. There was still some radioactivity in the intestines, but none in the bladder, at 72 hours after dosing. (MRID 00065592)

Rats were dosed with [¹⁴C]-diquat dibromide (doses were not specified in the review) either by stomach tube or by subcutaneous injection and their urine and feces were monitored at 24-hour intervals for 4 days. Following oral administration of [¹⁴C]-diquat, the rats excreted 6.3% and 89.3% of the administered radioactivity in the urine and feces, respectively, within 4 days. Most of this radioactivity was excreted during the first 48 hours. In the urine, most of the excreted radioactivity (5.3%) was unchanged diquat, whereas the remaining 1% was associated with the following metabolites: diquat monopiridone (0.2%), diquat dipiridone (0.1%) and unidentified metabolites (0.3). In the feces, 65.5% of the excreted radioactivity was detected in the sulfuric acid-extractable fraction and 15.7% in the ammonium sulfate-unextractable fraction. In the sulfuric acid fraction, the radioactivity was distributed as follows: unchanged diquat (57.1%), diquat monopiridone (4.3%) and unidentified material (4.1%). The ammonium sulfate fraction was not analyzed for metabolites. Following subcutaneous administration of [¹⁴C]-diquat, 87.1% of the dose was recovered in the urine during 4 days, but only 4.8% was recovered in the first 24 hours. Most of this radioactivity (78.8%) was unchanged diquat. The amount of radioactivity recovered in feces and the percent distribution of monopiridone and dipiridone in urine and feces, after the subcutaneous dose, was not reported in the available review. (MRID 00065593)

i. Neurotoxicity

In an acute neurotoxicity study, diquat dibromide (technical grade) was administered in a single gavage dose to 10 male and 10 female Sprague-Dawley rats at doses of 0, 25, 75 or 150 mg/kg, expressed as diquat cation. These rats were assessed for reactions in functional observational battery (FOB) and motor activity measurements at 6 hours postdosing and on

days 8 and 15. Evidence for neurotoxicity was observed only during the daily clinical observations. In the 75 mg/kg group, females had an increased incidence of diarrhea (2/10) and staining of the nose (3/10), compared with the controls (0/10). Females in the 150 mg/kg group also had piloerection (7/10), urinary incontinence (3/10), mouth staining (3/10), upward curvature of the spine (3/10), tip toe gait (3/10), hunched posture (2/10), subdued behavior (2/10) and sides pinched in (1/10). One female in the 150 mg/kg group, with all of the above signs, was sacrificed *in extremis* on study day 6. Males were less affected than females. The Agency has concluded that symptoms observed in this study may not be due to direct neurotoxicity. Based on the clinical signs observed in females, the NOEL and LOEL for the study are 25 mg/kg/day and 75 mg/kg/day, respectively, expressed as diquat cation. (MRID 42666801)

In a subchronic neurotoxicity study, diquat dibromide (technical grade) was administered in the diet to 12 male and 12 female Alpk:APfSD rats for up to 14 weeks, at dietary levels of 0, 20, 100 or 400 ppm, expressed as diquat cation. These doses were equivalent to 0, 1.6, 8.0 and 32.4 mg/kg/day (males) and 0, 1.9, 9.5 and 38.5 mg/kg/day (females), expressed as diquat cation. Of these 12 rats/sex/dose, 5/sex/dose were used for a neurohistopathological examination at the end of the study. Toxic signs were observed only in the 400 ppm group, as follows: decreased body weights in males and females (10%; $p < 0.01$), decreased body weight gains in males (20%; $p < 0.01$) and females (18%; $p < 0.01$), and high incidence of total cataracts (males, 5/12 and females, 7/12) and posterior opacities of the lens (males, 8/12 and females, 6/12). In addition, food utilization was decreased in the 400 ppm males, at several intervals (14-17%; $p < 0.05$ or 0.01) and in the females, at weeks 1-4 (19%; $p < 0.05$). Based on the evidence of cataracts and decreased body weight gain and food utilization in males and females, the NOEL and LOEL for systemic toxicity are 100 ppm (mg/kg/day: 8.0 for males and 9.5 for females) and 400 ppm (mg/kg/day: 32.4 for males and 38.5 for females), respectively. No evidence of neurotoxicity was observed in the functional observational battery, motor activity measurement or neurohistopathology. (MRID 42616101)

j. Other Toxicological Considerations

Dermal Absorption Studies - Application of the aqueous solutions of [^{14}C]-diquat dibromide to the 10 cm² shaved areas on the rats' backs resulted in the following absorption after a 24-hour exposure: 2.3, 2.1 or 3.3% for dose levels of 0.05, 0.5 or 5.0 mg diquat cation/rat, respectively. The unabsorbed diquat was recovered from the application sites. Based on these findings, the absorption of diquat through an intact skin was very low. Male Sprague-Dawley rats, 4 per group, were used in this study. (MRID 41238701)

Diquat dibromide is readily soluble in water and it ionizes in aqueous solutions. Such compounds can be expected to be absorbed very slowly and in small amounts through the skin. The very low absorption of diquat through an intact skin, observed in the above *in vivo* study, was confirmed in the *in vitro* studies. In these studies, the absorption of [^{14}C]-diquat dibromide through the human and animal whole skins (dermis and epidermis; 2.54 cm²) was

studied. In one study, the absorption rate (ug diquat cation/cm²/hr) for the human, rat, rabbit, mouse and guinea pig skins was 0.058, 0.231, 0.333, 0.431 and 0.455, respectively. According to these data, all skins studied were very poorly permeable to diquat cation, and human skin was least permeable. Similar results were obtained in other studies in which only human and rat skins were used. Human abdominal skins were obtained *post mortem* from subjects of varying ages, the majority being 60 years old or older. The animal skins were obtained *post mortem* from the dorsal area. (MRID 41247201, 41247202, 41247203 and 41247204)

(1) Reference Dose

The RfD/Peer Review Committee determined the RfD (ADI) to be 0.005 mg/kg/day, expressed as diquat cation, based on the chronic toxicity study in dogs with a NOEL of 0.5 mg/kg/day, with an uncertainty factor (UF)/safety factor (SF) of 100 (5/12/94). This was based on unilateral cataracts in females and decreased weight of epididymides and adrenals in males at 2.5 mg/kg/day. The chronic toxicity study in rats, with a NOEL of 0.58 mg/kg/day, was identified as a supportive or co-critical study. The uncertainty factor (UF) of 100 was used in estimating the RfD to account for inter-species extrapolation and intra-species variability. This RfD (ADI) is consistent with the revised ADI established by the Food and Agriculture Organization/World Health Organization (FAO/WHO) joint meeting on pesticide residues (JMPR) in 1993.

2. Exposure Assessment

a. Dietary Exposure

The established tolerances for residues of diquat dibromide in/on raw agricultural commodities and in animal products are presently expressed in terms of the diquat cation (40 CFR 180.226 (a) and (b)). Tolerance levels of 0.02-0.1 ppm are established for crop commodities and 0.02 ppm for animal commodities. A food additive tolerance for residues in potable water is expressed in terms of the diquat cation (40 CFR 185.2500 (a) and (b)), as is a feed additive tolerance for residues in processed dried potato waste (40 CFR 186.2500). A food additive tolerance for residues in processed potato (including potato chips) is currently expressed in terms of diquat *per se* (40 CFR 185.2500 (c)). Adequate enforcement methods are available for the determination of diquat dibromide residues in/on plant and in animal commodities.

Plant Metabolism

The reregistration data requirements for plant metabolism are fulfilled. The qualitative nature of the residue in plants is adequately understood based on an acceptable potato metabolism study and a rat bioavailability study. The terminal residue of concern in plants is diquat *per se*. The established tolerance expression for residues of diquat dibromide in/on plant commodities is appropriate and no changes are required.

The potato metabolism study indicated that no metabolism of diquat occurred in potato tubers following preharvest application of [¹⁴C]diquat as a desiccant to potato stalks and stems. Soybean and wheat metabolism studies had also been previously submitted but were deemed marginal because of inadequate characterization and identification of ¹⁴C-residues in the commodities of concern. Attempts to further characterize ¹⁴C-residues from these studies were unsuccessful. In lieu of the requirements for additional crop metabolism studies, the Agency recommended several options to satisfy reregistration data requirements. The registrant opted to conduct a bioavailability study. The results of the bioavailability study showed that diquat plant residues are largely not bioavailable; < 5% of the ¹⁴C is absorbed as a result of feeding diquat field residues in/on wheat chaff to rats. The retention of diquat residues in tissues was negligible (≤0.004 ppm diquat equivalents) following dosing at ≥ 25X the maximum human dietary intake.

Animal Metabolism

The reregistration requirements for animal metabolism are fulfilled. The qualitative nature of the residue in animals is adequately understood based on acceptable poultry, ruminant, and fish metabolism studies. The terminal residue of concern in animals is diquat *per se*. The established tolerance expression for residues of diquat dibromide in animal commodities is appropriate and no changes are required.

In the poultry metabolism study, laying hens were dosed with ring-labeled [¹⁴C]diquat at 32 ppm (~36X the maximum dietary burden for poultry) in the diet for 4 consecutive days. The total radioactive residues (TRR; expressed as diquat equivalents) were < 0.001 ppm in egg yolks, 0.004 ppm in egg whites, 0.004 ppm in fat, 0.003 ppm in muscle, 0.042-0.058 ppm in kidney, and 0.030-0.045 ppm in liver. The predominant metabolites identified were diquat *per se* which accounted for 48% of TRR in liver, and diquat monopyridone which accounted for 15.1% of TRR in kidney; diquat dipyrindone and TOPPS [1,2,3,4-tetrahydro-1-oxo-pyrido(1,2-a)-5-pyrazinium salt] were additional minor (≤6.6% of TRR) metabolites identified in these poultry tissues. The unidentified radioactive residues were presumed to have been incorporated into cell constituents. The Agency has determined that diquat monopyridone is not a residue of toxicological concern.

The metabolism of diquat dibromide in ruminants had been extensively investigated. Ethylene bridge-labeled [¹⁴C]diquat dibromide was administered at 5 ppm to a Friesian cow and two Guernsey cows using a drenching bottle. One of these Guernsey cows was additionally dosed with ethylene bridge-labeled [¹⁴C]diquat dibromide at 20 ppm by the same method and with bipyridyl-labeled [¹⁴C]diquat dibromide at 5 ppm; at least one month was allowed between repeat dosings. A Guernsey bull calf was also administered ethylene bridge-labeled [¹⁴C]diquat dibromide at 8 ppm. The radioactivity levels in milk were found to be dose-related, and were not affected by the radiolabel position. The highest TRR value in milk was 0.077 ppm and was observed in the 72-hour milk sample from the cow dosed at 20 ppm. In milk samples from the high-dose cow, residues of diquat *per se* were quantitated at

< 0.002 ppm (determined by colorimetry, limit of detection not provided), and did not concentrate in the fat, casein or whey. No residues (< 0.01 ppm) were found in the leg muscle samples from the Friesian cow dosed at 5 ppm. In the bull calf sacrificed 24 hours after dosing at 8 ppm, the TRR were 1.071 ppm in kidney, 0.033 ppm in liver and < 0.04 ppm in other tissues. Residues of diquat *per se* were 0.03 ppm and < 0.01 ppm in the kidney and liver samples, respectively. In addition to the studies briefly summarized above, other cow and goat metabolism studies had been submitted but were deemed marginally adequate because the test animals were preconditioned, were not sacrificed within 24 hours of dosing, or the radioactive residues in tissues were incompletely characterized. Nonetheless, these ruminant data confirm that the residue of concern in ruminant milk and tissues is diquat *per se*.

In the fish metabolism study, trout and carp were exposed to an initial concentration of 1 ppm of bridge-labeled [¹⁴C]diquat in the water for 7 days. The TRR (expressed as diquat equivalents) in carp head and tail, viscera, and body with skin were 0.025-0.077 ppm, 0.135-0.946 ppm, and 0.013-0.024 ppm, respectively. The TRR in skin and in flesh without skin were 0.015-0.023 ppm and 0.006-0.016 ppm, respectively. The TRR in trout head, tail, and flesh were 0.025-0.051 ppm, 0.059-0.239 ppm, and 0.008-0.01 ppm, respectively. Approximately 65% of the radioactivity in carp flesh and trout viscera was identified as diquat *per se*.

Residue Analytical Methods-Plants and Animals

Enforcement methods: The Pesticide Analytical Manual (PAM) Vol. II. lists a spectrophotometric method, designated as Method A (also referenced as Chevron Chemical Company RM-8-7) as available for the enforcement of tolerances for residues of diquat *per se* in/on plant and in animal commodities. In this method, residues are extracted with sulfuric acid to free diquat from the bound state, absorbed on cation exchange resin, and eluted with saturated ammonium chloride. The diquat in the eluate is reduced by sodium dithionite, forming an intense green color and is measured spectrophotometrically at 337 m μ . The limit of detection is 0.01 ppm.

The registrant has proposed new enforcement methods, RM-5B-1 and RM-5C (replaces RM-5X-1), for plant and animal commodities, respectively. Both methods involve extraction of residues by acid hydrolysis, concentration, and cleanup on an ion-exchange column, reduction with sodium borohydride, selective pH partitioning, and measurement of the diquat reduction product by gas chromatography using a nitrogen/phosphorus flame ionization detector. The stated limit of detection is 0.005 ppm for RM-5B-1; the limit of detection for RM-5C is not clearly specified. Both methods have been adequately validated by the registrant; however, an independent laboratory validation must be conducted followed by validation by the Agency's Analytical Chemistry Section before they can be deemed fully adequate for enforcement purposes. Once a successful Agency method validation has been performed, these methods will be sent to FDA for inclusion in PAM Vol. II.

Data collection: Residue data submitted for tolerance reassessment were collected using the current or proposed enforcement methods. The registrant provided adequate method validation data to verify the suitability of these methods for data collection.

Multiresidue method: The FDA's PESTDATA dated 11/6/90 (Pam Vol. I, Appendix) indicates that recovery of diquat dibromide using Multiresidue Protocols is unlikely. The updated PESTDATA dated 08/93 does not have an entry for diquat dibromide.

Storage Stability

The requirements for storage stability data are fulfilled for purposes of reregistration. Adequate storage stability data on diquat dibromide are available to support the storage conditions and intervals of samples from magnitude of the residue studies in plants and animals. Residues of diquat *per se* are stable under frozen (-20°C) storage conditions for: (i) up to six months in/on bell pepper, carrot roots, clover (hay and seed), lettuce, potato, rice (grain and straw), sorghum grain, soybean, tomato and tomato processed fractions, and wheat (grain and straw); (ii) up to 8 months in processed fractions of sorghum grain and soybean; and (iii) up to 2 months in water and seafood samples.

Magnitude of the Residue in Plants

All data for magnitude of the residue in plants have been evaluated and deemed adequate. All field residue data have been re-evaluated and plant commodity tolerances reassessed for reregistration purposes.

The registered uses of diquat dibromide on potato for preplant/preemergence or for preharvest desiccation are supported by acceptable residue field data reflecting maximum label rates. Sufficient data are available to ascertain that the established tolerance of 0.1 ppm in/on potato and the feed additive tolerance of 1 ppm for residues in processed potato waste are adequate. In accordance with Agency evaluation of the available data, a petition to increase the food additive tolerance of 0.5 ppm for residues in/on processed potato to 1 ppm was submitted to reflect the higher concentration factor which occurred in processed potatoes from potato bearing measurable weathered residues in some of the submitted tests. The tolerances are expressed in terms of potato granules/flakes and potato chips.

The registered uses of diquat dibromide on sorghum and soybean grown for seed as a preharvest desiccant are supported by adequate field residue data reflecting maximum label rates. Because there are no established tolerances for residues of diquat in/on sorghum and soybeans, the registrant has proposed a tolerance on sorghum and has committed to do so for soybeans. Tolerances of 2.0 ppm and 0.2 ppm appear to be appropriate for sorghum and soybeans, respectively.

The registered uses of diquat dibromide on alfalfa and clover grown for seed as a preharvest desiccant are supported by acceptable field residue data. The available data indicate that residues did not exceed 2.4 ppm in/on alfalfa seed and 1.7 ppm in/on clover seed following tests conducted at label rates. The registrant has proposed tolerances of 5.0 ppm for residues of diquat dibromide in/on both alfalfa and clover seed. The proposed tolerance level for alfalfa was too high and a new petition for a lower tolerance levels has been submitted. A tolerance of 3.0 ppm would be more appropriate for alfalfa seeds. Clover seed are no longer considered to be a significant food or feed item and, therefore, a tolerance is not required. Furthermore, the registrant must propose a true PHI before which seed may not be harvested, i.e., a label restriction rather than an efficacious interval. Based on the available data, a 3-day PHI would be appropriate.

The registered uses of diquat dibromide (i) as a preharvest desiccant on carrot, radish, and turnip grown for seed, and (ii) as a postharvest desiccant on cantaloupe, cucumber, pepper, squash, tomato, and watermelon are considered to be non-food uses. No residue data are required and no tolerances are needed. The raw agricultural commodities associated with these uses are not likely to be consumed by humans or animals.

Since there are no registered uses of diquat dibromide on sugarcane and vetch, field residue data for these crops are no longer required. The established tolerance for residues in/on sugarcane will be revoked.

Magnitude of the Residue in Processed Food/Feed

The data for magnitude of the residue in processed food/feed have been evaluated and deemed adequate to determine the extent to which residues of diquat concentrate in food/feed items upon processing of raw agricultural commodities. Acceptable potato, soybean, and sorghum processing studies have been submitted and evaluated.

The potato processing data indicate that residues of diquat concentrated 5x and 12x in potato chips and dried potato, respectively. A petition has been submitted to increase the existing food additive tolerance of 0.5 ppm for residues of diquat in processed potato (which includes dried potato, granules, and chips) to 1 ppm for potato, granules/flakes and potato chips. Data depicting residues in dried potato processed from potato bearing measurable residues may be translated to processed potato waste. The established feed additive tolerance for residues of diquat in processed potato waste has been reassessed and found to be appropriate.

The soybean processing data indicate that residues of diquat concentrated 2.6x in soybean hulls processed from soybean bearing detectable residues. No concentration of residues was observed in other soybean processed fractions. The registrant has committed to propose a feed additive tolerance for residues of diquat in soybean hulls; a feed additive tolerance of 0.6 ppm would be appropriate based on a recommended tolerance of 0.2 ppm for soybean and a concentration factor of ~3x in soybean hulls.

The sorghum processing data indicate that residues of diquat concentrated 4x in sorghum dry milling bran fraction processed from sorghum bearing detectable residues. According to the revised Table II of Subdivision O's Pesticide Assessment Guidance (PAG), the only processed commodity entry for sorghum is flour. Residue data are not needed for flour at this time since sorghum flour is used exclusively in the U.S. as a component of drywall, and not as either a human or animal feed item. However, because 50% of the worldwide sorghum production goes toward human consumption, the Agency reserves the right to require data if needed at a later date.

Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

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

The maximum dietary burden for beef and dairy cattle had been calculated previously. The past dietary burden estimate was based on tolerances of commodities for which tolerances are no longer established. For reregistration purposes, a new burden estimate, based on reassessed established/proposed tolerances of feed commodities and revised Table II of Subdivision O's PAG, is presented below.

Estimate of Maximum Ruminant Dietary Burden for Diquat Dibromide.

Commodity	Tolerance (ppm)	% Dry Matter	Beef Cattle		Dairy Cattle	
			% of Diet	Burden (ppm)	% of Diet	Burden (ppm)
Alfalfa seed	3.0 ^a	88	25	0.85	25	0.85
Potato processed waste	1.0	12	75	6.25	50	4.17
Soybean hulls	0.6 ^b	90	--	--	25	0.17
Total			100	7.10	100	5.19

^a Recommended tolerance level for alfalfa seed. ^b Recommended tolerance level for soybean hulls.

In a cattle feeding study, residues of diquat were non-detectable (< 0.003 ppm) in milk and tissues following feeding of diquat-treated rye grass silage to cattle at 3.6 ppm (~0.7x and 0.5x the maximum dietary intake for dairy and beef cattle, respectively) for 30 days. In another study, residues of diquat were non-detectable (< 0.01 ppm) in milk following feeding of diquat-treated clover hay to cattle at 11 ppm (~2.1x) for 34 days. The established 0.02-ppm tolerance level for diquat residues in milk is adequate. The established tolerances of 0.02 ppm for diquat residues in the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep may be raised to 0.05 ppm to achieve compatibility with the Codex maximum residue limit (MRL).

The maximum dietary burden for poultry is 0.881 ppm; the calculation of the poultry burden is presented below. In a poultry feeding study, residues of diquat were mostly non-detectable (< 0.005 ppm) in samples of eggs, fat, muscle, liver, and skin from chickens fed diquat at 1, 4.3, and 8.2 ppm diquat cation (~1.1x, 4.9x, and 9.3x, respectively, the estimated dietary burden) in the diet for 28 days. A single skin sample from the day-21, 8.2 ppm treatment group bore residues of 0.006 ppm. Residues in gizzard ranged from non-detectable to 0.022 ppm. The established 0.02-ppm tolerance level for diquat residues in poultry fat, meat, meat byproducts and eggs may be raised to 0.05 ppm to achieve compatibility with the Codex maximum residue limit (MRL).

Estimate of Maximum Poultry Dietary Burden for Diquat Dibromide.

Commodity	Tolerance	% of Diet	Burden (ppm)
Alfalfa seed	3.0 ^a	25	0.75
Soybean hulls	0.6 ^b	20	0.12
Cereal grain (e.g., corn)	0.02	55	0.011
Total		100	0.881

^a Recommended tolerance level for alfalfa seed. ^b Recommended tolerance level for soybean hulls.

Magnitude of the Residue in Potable Water

The Agency no longer establishes tolerances for residues in potable water (47 FR 25746, 12/15/82); the tolerance for diquat dibromide has been replaced with a designated maximum contaminant level goal (MCLG). An MCLG of 0.02 mg/L for residues of diquat in potable water has been established (57 FR 31776, 7/17/92).

Magnitude of the Residue in Fish and Shellfish

All data requirements for magnitude of the residue in fish and shellfish have been evaluated and deemed adequate to reassess the tolerances for diquat; no additional data are required regarding this topic. The available data indicate that residues of diquat in fish and shellfish will exceed the established tolerances following tests reflecting the current maximum registered use patterns. The registrant has submitted a petition requesting tolerances of 2.0 ppm for fish and 20 ppm for shellfish to cover all residues of diquat which may occur as a result of the currently registered uses.

Magnitude of the Residue in Irrigated Crops

The available data concerning diquat residues following irrigation of bean, blackberry, carrot, corn (sweet), cowpea, pasture grass, peach, rice, and strawberry are adequate to support the established 0.02 ppm tolerances for diquat residues in/on all members of the crop groups containing these commodities. However, the data also indicate that residues in/on mustard greens and tomato may exceed the tolerances for the respective crop groups. A

higher tolerance level of 0.05 ppm for fruiting vegetables and Brassica leafy vegetables has been proposed by the registrant in accordance with Agency recommendations.

At the Agency's recommendation, the registrant has petitioned to increase tolerances from 0.02 to 0.1 ppm for residues of diquat in/on the following miscellaneous commodities: avocado, cottonseed, hops and sugarcane irrigated with water treated with diquat dibromide. In the absence of adequate supporting data, the Agency translated available data on other crops. If the registrant desires lower tolerances, data may be submitted specifically for these miscellaneous commodities.

Confined/Field Rotational Crops

The data requirements for confined rotational crops have been reviewed and deemed adequate. The requirements for limited and extensive field rotational crop studies have been waived at this time.

b. Occupational and Residential

Mixers, Loaders, Applicators (Handlers) Exposure

There is an exposure potential for mixers, loaders, applicators, or other handlers during the ordinary use-patterns associated with diquat. The mixing, loading, and application methods include open pouring, broadcast (aerial and ground) application and application with hand-held equipment.

M/L/A Exposure Studies

Requirements for mixer/loader/applicator (i.e., handler) exposure studies are addressed in Subdivision U of the Pesticide Assessment Guidelines. An assessment of diquat dibromide dermal and inhalation exposure data was conducted, based on the findings in the Toxicology Endpoint Selection Document for diquat dibromide.

To assess mixer/loader/applicator (handler) exposure to the adverse effects of diquat, data provided in the Pesticide Handlers Exposure Database (PHED) were used. The data in PHED are normalized by pounds of active ingredient handled, and are referred to as unit exposures. Whenever possible, surrogate unit exposures are chosen from studies having the same (baseline) PPE required for the active ingredient being evaluated. When label specific PPE data are not available, existing data points are adjusted using a 50% protection factor based on the type of PPE. For example hand exposure is reduced by 50 percent, if the Agency assumes chemical-resistant gloves are worn. The diquat handler assessment assumes the use of coveralls worn over a long-sleeved shirt and long pants, chemical-resistant gloves and a respirator as required on product labels.

Based on the use patterns and potential exposures described above, ten exposure scenarios were identified for diquat. Seven scenarios were identified for large scale applications: (1) open mixing/loading, (2) closed mixing/loading, (3) applying with a ground-boom sprayer, (4) applying with a hand-held sprayer, (5) applying aerially, (6) applying to aquatic sites using direct pouring, and (7) applying to aquatic sites using handguns. Three scenarios were identified for smaller-scale applications: (1) applying (including mixing and loading) using backpack equipment, (2) applying (including mixing and loading) using low-pressure handwand equipment, and (3) applying (including mixing and loading) for spot treatments at residential sites using small, low-pressure spray equipment.

The exposure scenarios are presented in Table 1, which summarizes the caveats and parameters specific for each exposure scenario. The actual clothing and equipment worn by persons being monitored in the exposure studies are described.

In this exposure assessment, the amount of diquat applied and the potential exposure are estimated based on the cation, not the entire diquat dibromide molecule, with the exception of the 1983 study by Wojcek, which appears to consider the salt.

These assessments assumed the maximum agricultural use-rate. In non-crop situations, a higher use-rate is allowed for application on Bermuda grass. However, since these applications would likely be to golf courses and the typical golf course acreage (45 acres) is less than is assumed for a typical crop acreage (80 acres), the potential exposure is expected to be similar.

M/L/A Incidence Data

As of August 18, 1994, the following diquat dibromide poisoning data were available:

- A. California Department of Food and Agriculture reported 19 systemic cases of diquat dibromide poisoning during 1982-89. There were 4 hospitalized cases (1 agricultural poisoning ranked definite/probable; 2 non-agricultural occupational cases, 1 ranked definite/probable and 1 ranked possible. These 4 cases required a total of 40 days of hospitalization. This chemical ranked 9th in California for days hospitalized.
- Also, for the same time period California reported 19 agricultural cases, all ranked definite/probable. In addition, there were 8 non-agricultural cases ranked definite/probable and 3 possible; plus 10 non-agricultural, non-occupational cases, all ranked definite/probable.
- For 1990, 8 additional systemic diquat dibromide poisoning incidents (5 definite/probable and 3 possible) were reported to the California Illness

Surveillance System. These included 1 systemic poisoning incident, 2 eye and 2 skin, all rated definite/probable.

- According to the draft (8/94) California risk characterization document for diquat, "virtually all illnesses reported during agricultural use occurred as the result of equipment failure, accidental exposure, or violations of label requirements"
- B. Diquat dibromide was not included in the Acute Worker Risk Strategy, therefore there are no data available from the American Association of Poison Control Centers.
- C. For diquat (only listing), the National Pesticide Telecommunication Network reports from 1984-1991 inclusive, show 74 human poisoning incidents and 8 animal poisoning incidents, 15 rated other, and 97 total incidents among 345 calls to the EPA hotline.
- D. The EPA Incident Data System (June, 1992 to July, 1994) contains reports for two submissions reported under 6 (a) (2), including 1 probable incident for a three year old child who ingested diquat from a bottle, and 1 wildlife episode (unknown certainty).

Post-Application Exposure

There is an exposure potential for persons entering treated sites after application is completed. These exposures included persons swimming in diquat treated aquatic sites, persons (such as maintenance personnel) exposed to treated non-crop sites (golf courses, rights-of-way, residential sites), and persons (such as crop advisors and harvesters) exposed to treated crop sites. Seed-crops are harvested 5 to 10 days after application; potatoes are harvested 7 or more days after application.

Post-Application Exposure Studies

Requirements for post-application exposure studies are addressed by Subdivision K of the Pesticide Assessment Guidelines. Post-application exposure data submitted to support reregistration consist of soil and foliar dislodgeable residue studies (MRID 40917401 and 40917402, respectively).

The soil dislodgeable study conducted by the registrant indicates levels of diquat in the soil after the digger machines have buried the potato tops and exposed the potato tubers at 0.5 ppm (MRID 40917401). Surrogate data were used to estimate human exposure to these residue levels. To estimate the rate of transfer (soil to hand), the exposure rate per hour was adjusted from the surrogate study (1 ppm) to the levels of diquat observed in the registrant's study (0.5 ppm). Thus, a rate of transfer was estimated to be 1.9 µg/hr or 15.2 µg/day. By

assuming the weight of the exposed individual was 48 kg, the average daily exposure was estimated to be 3.2×10^{-4} mg/kg/day.

The potential for postapplication/reentry exposure for golfers is anticipated to be low, following applications to golf courses, because the applications to the turf and exposure to golfers is primarily limited to the shoes from walking over treated surfaces. Exposure to golf-course maintenance personnel, however, is a concern, because their routine tasks may require exposure to the treated turf through such activities as bagging/disposing grass clippings and relocating the flag-holes on the greens.

The potential for post-application/reentry exposure following application as a spot treatment in residential gardens, driveway edges, and patios is low due to the limited frequency and duration of exposure. However, potential post-application broadcast applications at residential sites is expected to be similar to that of golf-course maintenance personnel.

There is a potential for post-application exposure to swimmers following applications to aquatic sites such as lakes and ponds. There are no diquat specific exposure data to assess swimmer exposure. However, an assessment was conducted using information provided in EPA's Dermal Exposure Assessment: Principles and Applications, Interim Report, January 1992.

To estimate the flux rate for diquat for one hour through skin, the permeability constant for ethylene dibromide (3.3×10^{-3}) was used since this compound is used to produce diquat, and a permeability constant (K_p) for diquat is not available. The assessment of swimmer exposure is based on the following:

$$\begin{aligned} \text{Fick's Law : } dm/dt &= K_p * \text{concentration } (1.5 \times 10^{-3}) \\ &= 3.3 \times 10^{-3} * 1.5 \times 10^{-3} \\ &= 4.95 \times 10^{-6} \end{aligned}$$

The body weight of an average six-year old boy is assumed to be 21.9 kg and to have a surface area of 0.88 square meters. The swimming period is assumed to be 3 hours.

Exposure Time (hr)	Surface Area	$\text{cm}^2 \times 10^4$	dm/dt ($\text{mg}/\text{cm}^2/\text{hr}$) $\times 10^{-6}$	Total Dermal Exposure (mg) 10^{-2}
3	0.88	1	4.95	12.9

Oral absorption will also account for a portion of the exposure. It is assumed that 1% of the water in residence in the mouth while breathing will be swallowed. Oral exposure is as follows:

Exposure Time (hr)	Contact Rate (1/hr)	Concentration (mg/L)	Total Oral Exposure (mg)
3	.05	1.5	0.225

Due to diquat's low vapor pressure and the fact that it is a large molecule, exposure via the inhalation route or penetration through ear wax was not considered.

3. Risk Assessment

a. Dietary Chronic Risk Analysis

This chronic dietary risk analysis is based on the Reference Dose (RfD) for chronic oral exposure as determined by the Agency's RfD/Peer Review Committee. The diquat dibromide RfD is 0.005 mg/kg/day. Percent crop treated data were included in this dietary risk analysis.

The DRES chronic analysis used tolerance level residues to calculate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. Refinements in percent crop treated information were considered in calculating the Anticipated Residue Contribution (ARC) for the same population groups. The ARC is considered the more accurate estimate of dietary exposure. These exposure estimates were then compared to the RfD for diquat dibromide to calculate estimates of chronic dietary risk.

Using Tolerances

The Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population from published and proposed uses recommended through reregistration are listed below:

<u>Subgroup</u>	<u>Exposure (mg/kg/day)</u>	<u>%Reference Dose</u>
U.S. population	0.002675	54
Children (1-6)	0.004590	92
Non-Nursing infants < 1yr.	0.004519	90

Using Anticipated Residues

The Anticipated Residue Contribution (ARC) for the overall U.S. population from published and proposed uses recommended through reregistration are listed below:

<u>Subgroup</u>	<u>Exposure (mg/kg/day)</u>	<u>%Reference Dose</u>
U.S. population	0.001529	31
Children (1-6)	0.002339	47
Non-Nursing infants < 1 yr.	0.002471	49

The U.S. population and all the subgroups have ARCs for chronic dietary risk below the RfD when published and proposed tolerances for reregistration are considered. It appears that chronic dietary risk is minimal for diquat dibromide for published and proposed tolerances.

b. Occupational and Residential

Toxicity Endpoints

Diquat is classified as Toxicity Category II for acute dermal toxicity and primary eye irritation; Category III for acute oral and acute inhalation toxicity; and Category IV for dermal irritation.

The short term (1 to 7 days) and intermediate term (1 week to several months) toxicological endpoints for occupational and residential risk assessment are based on systemic toxicity resulting from dermal and inhalation exposures. These endpoints were derived from a 21-Day dermal toxicity study in rabbits (MRID 00140576) and a 21-day inhalation study in rats (MRID 40640801), respectively. For both short and intermediate term occupational/residential exposures, the systemic NOEL = 20 mg/kg/day and the LOEL = 40 mg/kg/day for dermal toxicity; the NOEL = 0.1 microgm/l and LOEL = 0.49 microgm/l for inhalation toxicity.

The Agency has previously used two endpoints, one inhalation and one dermal, to assess both short-term and intermediate occupational and/or residential exposure to diquat dibromide. The endpoints for dermal exposure and inhalation exposure are:

21-day dermal toxicity study in rabbits (MRID 00140576) - Systemic NOEL = 20 mg/kg/day based on weakness, unsteadiness, and weight loss.

21-day inhalation toxicity in rats (MRID 40640801) - NOEL = 0.1 µg/L, based on lung lesions. To convert this NOEL to mg/kg/day, the following is assumed:

$$[0.1 \mu\text{g/L} * 29 \text{ l/min} * 60 \text{ min/hr} * 8 \text{ hr/day}] / 70 \text{ kg}$$

Ethylene dibromide (EDB) is used in the manufacture of diquat dibromide and occurs as an impurity in diquat dibromide products. The possibility for exposure to EDB was addressed in the 1986 Guidance for the Reregistration of Diquat Dibromide. According to that document, 10 ppm is the certified maximum EDB level permitted in the formulated products. The Agency concluded that the presence of EDB as an impurity does not pose significant risk to human health, either to the public or to applicators.

In this risk assessment for occupational/residential exposure protection factors were applied to the exposure data to simulate use of the following personal protective equipment (PPE) for dermal protection: chemical-resistant gloves and coveralls over long-sleeved shirt and long pants. In addition, a dust/mist filtering respirator was assumed for most mixer, loader, and application exposure scenarios. A summary of MOEs and exposure scenarios are provided in Table 1.

Mixers, Loaders, Applicators (Handlers) Risk

In large-scale applications, the highest potential exposure and risks are to mixers and loaders supporting aerial applications. For mixers and loaders using open systems to support aerial applications, the dermal MOE is 71 and the inhalation MOE (assuming the use of a respirator) is 100, where the $MOE = NOEL \div Exposure$. For mixers and loaders supporting aerial applications using closed systems, the dermal MOE is 400 and the inhalation MOE (assuming no use of a respirator) is 133. These MOE assessments assumed the maximum agricultural application-rate. In non-crop situations, a higher application-rate is allowed for use on Bermuda grass. However, since these applications would likely be to golf courses and the typical golf course acreage (45 acres) is less than is assumed for a typical crop acreage (80 acres), the MOE's should not be lower.

For applicators participating in large-scale applications, the dermal MOE's are greater than 100.

For mixers, loaders, and applicators participating in small-scale applications (including spot treatments by homeowners), the MOE's are all greater than 100. For occupational users, the MOE's are calculated using baseline PPE coveralls worn over a long-sleeved shirt and long pants, and chemical-resistant gloves. No PPE was assumed for homeowner users. A summary of MOEs for each exposure scenario is provided below:

Table 1. DIQUAT DIBROMIDE EXPOSURE SCENARIOS AND MOEs^a

Exposure Scenario (Scenario #)	Unit Dermal Exposure ^b (mg/lb ai)	Unit Inhalation Exposure ^b (µg/lb ai)	Maximum Label Application Rate ^c (lb ai/acre)	Daily Maximum Treated ^d (acres)	Daily Dermal Dose ^e (mg/kg/day)	Dermal MOE ^f	Daily Inhalation Dose ^g (mg/kg/day)	Inhalation MOE ^h
Mixer/Loader^g								
Closed Mixing liquids for Aerial Application (I)	0.02	0.06	0.50	350	0.05	400	0.00015	133
Open Mixing Liquids For Aerial Application (II)	0.113	0.08 w/respirator	0.50	350	0.28	71	0.0002	100
Open Mixing Liquids For Ground-Boom Applications (II)	0.113	0.08 w/respirator	0.50	80	0.06	307	0.00005	400
Applicator								
Fixed-Wing Aerial Application (III)	0.005	0.04 w/respirator	0.50	350	0.013	1539	0.0001	200
Groundboom Application (IV)	0.01	0.08 w/respirator	0.50	80	0.0057	3508	0.000046	435
High Pressure Handwand Application (V)	0.53	0.09	2.0	10	0.15	132	0.000026	769
Water Hyacinth Control - Handgun (Wojeck 1983)	2.80 mg/hr	No Data	1.5	5 hr/day	0.20	100	No Data	--
Water Hyacinth Control - Driver (Wojeck 1983)	0.60 mg/hr	No Data	1.5	5 hr/day	0.05	400	No Data	--
Hydrilla Control - Applicator (Wojeck 1983)	0.17 mg/hr	No Data	4.0	5 hr/day	0.012	1666	No Data	--
Hydrilla Control - Mixer (Wojeck 1983)	0.47 mg/hr	No Data	4.0	5 hr/day	0.034	588	No Data	--
Mixer/Loader/Applicator								
Mixing/Loading and Application With a Backpack Sprayer (VI)	1.3	6 w/respirator	1.0	2.0	0.037	540	0.00017	117
Mixing/Loading and Application With a Low Pressure Handwand Sprayer -- Residential Uses (VII)	103.0	31.0	1.0	1000 sq. ft.	0.034	588	0.00001	2000

a All application types for diquat dibromide are foliar/broadcast in nature except for a few spot treatments for ornamentals. No banding, in-furrow or soil injection type techniques are noted.

b All unit exposure values presented in Table 1 have been "normalized" to reflect the appropriate PPE clothing scenario recommended in this RED.

c Values representing the maximum application rate allowable by the label unless specifically noted (i.e., lb ai/acre). Mixing/loading scenarios were based on the highest potential cumulative chemical use for all application methods included in this table in conjunction with the maximum number of acres treated for that application technique.

d Values representing the maximum area (acres) which would be used in a typical work day to complete treatments for each equipment type/exposure scenario of interest.

e Daily Dermal Dose (mg/kg/day) = [(Unit Exposure (mg/lb ai) * Max. Appl. Rate (lb ai/treatment) * Max. Treated)/70 kg]. For Wojeck et al, Daily Dermal Dose = [(mg/hr * hours exposure/day)/70 kg].

f Dermal MOE values calculated using the following equation: MOE = Dermal NOEL (mg/kg/day)/Daily Dermal Dose (mg/kg/day); 21 day rabbit dermal NOEL = 20.0 mg/kg/day.

g Daily Inhalation Dose (mg/kg/day) = [(Unit Exposure (mg/lb ai) * Max. Treated)/70 kg]. In some cases respirators have been added, which are noted in the table.

h Inhalation MOE values calculated using the following equation: MOE = [NOEL (µg/L) * 29 L/min * 60 min/hr * 8 hr/day]/Daily Inhalation Dose; 21 day rabbit inhalation NOEL= 0.1 µg/L.

Post-Application Risk and REI Entry

Post-application exposure data were submitted to support reregistration and consist of soil and foliar dislodgeable residue studies (MRID 40917401 and 40917402, respectively).

Golf Course Postapplication Risk

There is a low potential for post-application/reentry exposure following applications to golf courses because exposure is primarily limited to walking over treated surfaces rather than full contact that is possible in a residential situation. Full contact with residues based on dissipation data (24 hours postapplication) submitted by the registrant (MRID 409174-02) would be as follows:

$$\frac{1.3 \mu\text{g}/\text{cm}^2 * 10,000 \text{ cm}^2/\text{hr} * 8 \text{ hours}}{70 \text{ kg}} = 1.5 \text{ mg}/\text{kg}/\text{day}$$

This would result in an MOE of 13. At day 4 postapplication the MOE would be 105. Therefore, a four day postapplication reentry interval (4 day REI) is recommended for workers at golf courses, when worker activities involve substantial physical contact with the treated turf. This does not apply to activities such as mowing.

Residential Postapplication Risk

The potential for postapplication/reentry exposure, following application as a spot treatment in residential gardens, driveway edges, and patios, is low due to the expected contact pattern and duration of exposure. Based on the MOE's calculated for the golf course workers discussed above, broadcast treatments to residential turf are not recommended.

Aquatic Site Postapplication Risk

There is a potential for postapplication exposure to swimmers, following applications to aquatic sites such as lakes and ponds. There are no diquat specific exposure data to assess swimmer exposure risk. However, an assessment was conducted, using information provided in EPA's Dermal Exposure Assessment: Principles and Applications, Interim Report, January 1992 as indicated above in the exposure assessment section.

Due to diquat's low vapor pressure and the fact that it is a large molecule, exposure via the inhalation route or penetration through ear wax was not considered. Total swimmer exposure is estimated to be $[0.354 \text{ mg}/\text{day}]/\text{body weight} = 0.016 \text{ mg}/\text{kg}/\text{day}$ or an MOE of 1250, for a 21.9 kg 6 year old person.

Additional Occupational/Residential Exposure Studies

Handler Studies

Additional handler exposure studies are not required at this time.

Post-Application Studies

Additional post-application exposure studies are not required at this time.

C. Environmental Assessment

1. Ecological Toxicity Data

The ecotoxicological data base is adequate to characterize the toxicity of diquat dibromide to nontarget terrestrial and aquatic organisms when used on terrestrial food, feed and nonfood sites, and on aquatic nonfood sites.

a. Toxicity to Terrestrial Animals

In order to establish the toxicity to birds, the following tests are required using the technical grade material: an avian single-dose oral acute study (71-1) on one species (preferably mallard duck or bobwhite quail); two subacute dietary studies (71-2) on one species of waterfowl (preferably mallard duck) and on one species of upland game bird (preferably bobwhite quail); and because of persistence and multiple applications, two avian reproduction studies (71-4) on mallard duck and bobwhite quail.

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics.

A honey bee acute contact LD₅₀ study is required if the proposed use will result in honey bee exposure.

(1) Birds, Acute and Subacute

Effects on Non-target Birds

Nine studies were evaluated under this topic. The activity of diquat dibromide herbicide is expressed in units of cations. In the tables below, the cation will be used for risk assessment purposes for birds since the use information is in lb cation per acres in the terrestrial environment. The cation value in ppm is extrapolated from the test values whether it be in diquat formulation or cation, or active ingredient. The acceptable toxicity studies for use in a hazard assessment are listed below:

Avian Acute Toxicity

Avian Acute Oral Toxicity Findings			
Species	% Test Material (TGAI)	LD ₅₀ in mg/kg cation per kg	Conclusions
Mallard	45.6	60.6 mg/kg	Moderately toxic
Mallard	30.0	89.6 mg/kg	

For hazard assessment, these data indicate that diquat dibromide is moderately toxic in acute studies to birds. Typically, toxicity testing is to be done with technical grade active ingredients, usually having relatively high per cent purity. In the case of diquat dibromide, a test material containing 35 to 37 percent represents, apparently, the highest purity produced. The guideline requirement for the avian acute oral LD₅₀ study is fulfilled. (MRID 00106559)

Avian Subacute Dietary Toxicity

Avian Subacute Dietary Toxicity Findings			
Species	% Test Material	LC ₅₀ cation per kg	Conclusions
Bobwhite quail	37.0	575 ppm	Slightly to moderately toxic
Mallard	37.0	980* ppm	
Japanese quail	37.0	264 ppm	
Ring-neck pheasant	37.0	734 ppm	
Bobwhite quail	35.3	106 ppm	

* 30 percent mortality at 980 ppm cation.

On a subacute dietary basis, diquat dibromide ranges from slightly to moderately toxic to birds. The guideline requirement for the avian subacute dietary study is fulfilled. (MRID 00034769, and 00116565)

Avian Reproduction

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Present product labeling of diquat dibromide allows several applications of the end-use product per growing season.

Avian Reproduction Findings			
Species	% A.I.	Reproductive Impairment	Conclusions (ppm cations)
Bobwhite Quail	35.3	None	NOEL > 19.6
Mallard Duck	35.3	Number of eggs laid, hatching and 14-day old survival	NOEL = 5 LOEL = 25

The avian reproductive study found the NOEL to be 5 ppm cation and LOEL to be 25 ppm cation. These findings were based on number of eggs laid, hatching and 14-day old survival. (MRIDs 00119988, 00114230)

(2) Insects

The minimum data required to establish the acute toxicity to honey bees is an acute contact LD₅₀ study with the technical material.

Nontarget Insect Acute Contact Toxicity Findings			
Species	% Test Material	LD₅₀	Conclusion
Honey bee	99.6	100 µg/bee	practically non-toxic to bees
Honey bee		47 µg/bee*	

* This was tested as "Reglone" with an LD₅₀ = 171 µg/bee and as "Reglone + Agral" with an LD₅₀ = 66 µg/bee for acute contact toxicity. This was also tested for oral acute with "Reglone" (LD₅₀ = 47µg/bee) and "Reglone + Agral" (LD₅₀ = 35 µg/bee). Agral is a liquid non-ionic wetting and spreading agent.

There is sufficient information to characterize diquat dibromide as practically nontoxic to bees. The guideline requirement is fulfilled. (MRIDs 072012, 40208001)

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity to fish, the following tests are required using the technical grade material: two 96-hour acute fish studies (72-1); one on a species of coldwater fish (preferably rainbow trout) and one on a species of warmwater fish (preferably bluegill sunfish); and because of persistence one fish early life stage study.

In the table below, the diquat cation will be used for risk assessment purposes for aquatic organisms since the availability of diquat dibromide is as a cation in aquatic environments. The value in ppm cation is extrapolated from the test values whether it be in diquat formulation, cation, or active ingredient. The acceptable toxicity studies for use in a hazard assessment are listed below:

Freshwater Fish Acute Toxicity Findings			
Species	% Test Material (TGAI)	LC₅₀ in ppm cations	Conclusions
Brown trout	35.3	17.8	slightly to moderately toxic
Bluegill	35.3	12.1**	
Rainbow trout	35.3*	14.8	
Bluegill	35.3	13.9	
Rainbow trout	35.3	> 18.7	
Bluegill	35.3	21.5	
Yellow Perch	35.3	4.4	
Black Bullhead	35.3	4.6	

* The study cites the percentage formulation as 19.8 percent cation and having 2 lb cation per gallon. According to the LUIS report, the 2 lb cation per gallon is similar to the 35.3 percent ai formulation (diquat dibromide is made up of about 53 percent cation).

** Results based on 72 hour test rather than 96 hour test.

The results of the acute toxicity studies indicate that diquat dibromide is slightly to moderately toxic to both cold and warm water fish. The guideline requirement for acute toxicity testing of the technical on freshwater fish is fulfilled. (MRID 00115858, 0027203, 00115572, 00138961, and 00003503)

Fish Early Life Stage Study

The MATC below is derived from the geometric mean of the fish early life cycle study which resulted in a NOEL of 0.58 ppm and LOEL of 1.5 ppm of the test material. The effects at the 1.5 ppm level were reduction in wet weight and length of the larvae. Note that the NOEL and LOEL are in ppm of test material, which was a 41.4% ai formulation. Furthermore, the active ingredient is comprised of an active and inactive cation, with only 50.9% active cation. The NOEL and LOEL, expressed in ppm active cation, would be 0.122 ppm and 0.316 ppm respectively. Since exposure values for risk assessment are calculated in units of active cation, the MATC (reported below) will also be reported in units (ppm) of active cation.

Fish Early Life Stage Findings			
Species	% Test Material (TGAI)	MATC in ppm cations	Conclusions
Channel Catfish	unknown	> 1.0	NOEL = 0.122 ppm cation LOEL = 1.316 ppm cation
Fathead Minnow	41.4	0.197	

For hazard assessment, these data indicate that diquat dibromide ranges in toxicity to fish from slightly to moderately toxic. Data requirements for freshwater fish are fulfilled.

Typically, toxicity testing is to be done with technical grade active ingredients, usually having relatively high percent purity. In the case of diquat dibromide, a test material containing 35 to 37 percent represents the highest purity obtainable. (MRIDs 090862, 40380703)

(2) Freshwater Invertebrates

In order to establish the toxicity to aquatic invertebrates, a 48-hour aquatic invertebrate acute toxicity test is required using the technical grade material on first instar *Daphnia magna* or early instar amphipods, stoneflies or mayflies; and because of persistence one aquatic invertebrate life cycle study.

Seven studies were evaluated under this topic. In the table below, the diquat cation will be used for risk assessment purposes for aquatic organisms since the availability of diquat dibromide is as a cation in aquatic environments. The value in ppm cation is extrapolated from the test values whether it be in diquat formulation, cation, or active ingredient. The acceptable toxicity studies for use in a hazard assessment are listed below:

Freshwater Invertebrate Toxicity Findings			
Species	% Test Material (TGAI)	EC ₅₀ or MATC ppm cation	Conclusions
<i>Daphnia magna</i> *	46.6	EC ₅₀ = 1.03	Slightly to highly toxic
<i>Daphnia magna</i> *	46.6	EC ₅₀ = 1.19	
<i>Daphnia magna</i> *	35.2	EC ₅₀ = 0.77	
<i>Gammarus fasciatus</i> *	35.3	EC ₅₀ = 18.7	
<i>Hyalella</i> *	unknown	EC ₅₀ = 0.14	
Apple Snail*	35.3	EC ₅₀ = 0.34	
<i>Daphnia magna</i> **	41.4	MATC = 0.044	

* Acute toxicity Study

** Life Cycle Study

There is sufficient information to characterize diquat dibromide as slightly to highly toxic to aquatic invertebrates. The guideline requirement is fulfilled. (MRIDs 235179, 00115576, 00003530, and 00115862)

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. The terrestrial nonfood use of diquat dibromide may result in exposure to the estuarine environment.

In order to establish the toxicity to estuarine and marine organisms, the following tests are required using the technical grade material: either a Mollusc 48-hour embryo larvae study using Pacific oyster, Eastern oyster, mussel (preferably *Mytilus edulis*) or Quahog

(*Mercenaria*) or a Mollusc 96-hour Flow-Through Shell Deposition study using Pacific oyster or Eastern oyster; and a Shrimp 96-hour acute toxicity test using white, pink, brown, grass or mysid shrimp species; an estuarine fish (preferably silverside or sheepshead minnow).

Four studies were evaluated under this topic. In the table below, the diquat cation will be used for risk assessment purposes for aquatic organisms since the availability of diquat dibromide is as a cation in aquatic environments. The value in ppm cation is extrapolated from the test values whether it be in diquat formulation, cation, or active ingredient. The acceptable toxicity studies for use in a hazard assessment are listed below:

Estuarine/Marine Acute Toxicity Findings			
Species	% Test Material (TGAI)	LC₅₀ ppm cation	Conclusions
Mysid Shrimp	41.1	0.42	slightly to highly toxic
Eastern Oyster	41.4	54.8	
Sheepshead Minnow	41.4	48	
Striped Bass	35.3	43.2	

There is sufficient information to characterize diquat dibromide as slightly to highly toxic to estuarine species. The guideline requirement is fulfilled. (MRID 40315701, 40316001, 40316101, 090862, and 00028002)

c. Toxicity to Plants

Terrestrial plant testing (seed germination, seedling emergence and vegetative vigor) is required for herbicides which have terrestrial nonfood/feed or aquatic nonfood (except residential) use patterns and which have endangered or threatened plant species associated with the site of application.

(1) Aquatic Plants

Aquatic plant testing is required for any herbicide applied to terrestrial nonfood or aquatic nonfood sites (except residential). In order to establish the toxicity to aquatic plants, an aquatic plant growth study (123-2) comprising of *Selenastrum capricornutum*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom is required using the technical grade material. The registrant has submitted a *Selenastrum capricornutum* study.

Two aquatic plant studies were evaluated under this topic. In the table below, the diquat cation will be used for risk assessment purposes for plants since the availability and activity of diquat dibromide is as a cation with plants. The value in ppb cation is extrapolated from the test values whether it be in diquat formulation, cation, or active ingredient. The acceptable toxicity studies for use in a hazard assessment are listed below:

Nontarget Aquatic Plant Toxicity Findings				
Species	% A.I.	Toxicity		Conclusions
Tier I, several species of filamentous algae and aquatic vegetation	---	Controlled by 0.25 cation ppm of diquat		information insufficient to assess the toxicity, but sufficient to require Tier II testing
Tier II vascular plants: Giant Duckweed Water Hyacinth Azolla Hydrilla	35.3	EC ₅₀ * 0.0036 0.0198 0.0277 N/A	EC ₅₀ ** 0.75 114.0 11.6 9.9	Vascular plant requirements (<i>Lemna gibba</i>) are satisfied, but <i>Skeletonema costatum</i> , <i>Anabaena flos-aquae</i> , <i>Selenastrum capricornutum</i> , and a freshwater diatom needs to be tested to satisfy the requirements under 123-2 and to provide a complete risk assessment of diquat to non-target aquatic plants.

* Foliar applied, lb cation/A

** Rootzone, ppb cation

(MRID 40165103, 40165104, 40165105, and 41883002)

(2) Terrestrial Plants

Three terrestrial plant studies were evaluated under this topic. In order to establish the toxicity to terrestrial plants, a germination, seedling emergence (123-1a) and vegetative vigor study (123-1b) is required. The acceptable toxicity studies for use in a hazard assessment are listed below:

Nontarget Terrestrial Plant Toxicity Findings			
Test and Species	% A.I.	EC ₂₅	Conclusions
Seedling emergence & Germination (10 species)	--	> 7.49 lbs ai/Acre	No effect to plants at 8.4 ai kg/ha or 7.49 lb ai/A*
Vegetative Vigor (corn, sweet corn, & wheat)	--	rates as low as 0.016 lb cation/A resulted in desiccation of certain plants	Tier II vegetative vigor testing needed
Vegetative Vigor, Sensitive species: Cotton Soybean Corn	35.3	0.00470 cation lb/A 0.00738 cation lb/A 0.01064 cation lb/A	Untreated seeds of wheat and sweet corn should be tested for tier II Vegetative Vigor.**

* Tier II seed emergence and seed germination studies do not need to be done.

** Only one grass species was tested. According to earlier study (40165102), sweet corn and wheat were found to be sensitive. Two more grass species should be tested to fulfill guidelines. If there are difficulties in finding untreated seeds of sweet corn or wheat, the treated seeds could be washed in methanol to remove most of the treatment and then tested after drying.

There are outstanding data requirements for terrestrial plants. (MRID 40165101, 40165102, and 41883001)

2. Environmental Fate

There is sufficient data for comprehensive qualitative and quantitative environmental fate, ground and surface water assessments for diquat dibromide.

a. Environmental Fate Assessment

The primary route of environmental dissipation of diquat is strong adsorption to soil particles. Diquat does not hydrolyse or photodegrade and is resistant to microbial degradation under aerobic and anaerobic conditions. There were no major degradates isolated from any of the environmental fate studies. When used as an aquatic herbicide, diquat is removed from the water column by adsorption to soil sediments, aquatic vegetation, and organic matter. Adsorbed diquat is persistent and immobile, and is not expected to be a ground-water contaminant.

The environmental fate data base for diquat is complete for reregistration of diquat dibromide.

Pesticide Runoff Simulation Modeling:

An estimate of diquat runoff and its effect on surface water quality was evaluated using PRZM-EXAM models from a typical crop use on potatoes with data from a silt loam soil in Maine.

Model simulations indicate that a 10 percent exceedance probability of the maximum of 0.33 kg/ha/year diquat could potentially be found in surface water systems. This estimate is a high exposure scenario of the entire yearly application of 0.5 lb ai/A to soil on a highly eroded soil for 36 years. This assessment includes diquat adsorbed onto eroded soil particles as well as diquat in the runoff water. Estimated environmental concentrations (EEC's) at 10 percent exceedance probabilities in a one hectare water body, 2 meters deep, are shown in the table below.

Annual Average EEC of Dissolved Diquat in Maine with 10 percent Exceedance Probability.				
Maximum	96 hour	21 day	60 day	90 day
48.4 ppb	47.8 ppb	45.1 ppb	45.3 ppb	43.6 ppb

While these predictions are higher than expected from the environmental assessment of diquat, the PRZM-EXAM model is predicting a high exposure scenario for diquat applied to potatoes.

b. Surface Water Assessment

Diquat dibromide is persistent and binds nearly irreversibly to soil. It does not appear to be biologically available to aquatic organisms in surface water. Therefore, the Agency does not require a surface water advisory.

c. Environmental Fate and Transport

Hydrolysis

Diquat dibromide was stable to hydrolysis in water at all pHs (tested at pH 5, 7, and 9). (MRIDs 154100 and 154101)

Photodegradation in water

Diquat can be considered to be photolytically stable in the environment; diquat degraded with a calculated half-life of 74 days of Florida spring sunlight. Radiolabeled diquat in pH 7 buffer was continuously irradiated with a xenon lamp for a period of time that approximated 32 days of Florida spring sunlight. One degradate, 1,2,3,4-tetrahydro-1-oxopyrido (1,2-a)pyrazin-5-ium ion, comprised 12 percent of the radioactivity at the conclusion of the study. (MRID 40418801)

Photodegradation on soil

[¹⁴C]Diquat did not photodegrade on loam soil irradiated with a xenon arc lamp at 20.5-29.1 °C for 107.42 hours (equivalent to approximately 32 days of natural sunlight). Diquat was the only compound identified in the extracts. (MRID 40246101)

Aerobic soil metabolism

Diquat at approximately 3 ug/g did not degrade in an aerobic sandy loam soil incubated at 25 °C in the dark for 9 months. (MRID 40972301)

Anaerobic aquatic metabolism

[¹⁴C]Diquat did not degrade when incubated under anaerobic aquatic conditions for 9 months at 25 °C. After 9 months, one unidentified degradate comprised approximately 5 percent of the applied radioactivity. Throughout the study 89 to 100 percent of the diquat residues were associated with the soil sediment portion of the system. No anaerobic aquatic half-life could be calculated. (MRID 40972302)

Aerobic aquatic metabolism

[¹⁴C]Diquat did not degrade when incubated under aerobic aquatic conditions for 31 days at 25 °C. Between 95 to 99 percent of the diquat residues were associated with the soil sediment portion of the system. No aerobic aquatic half-life could be calculated. (MRID 40927601)

Mobility -- adsorption/desorption

Diquat is immobile with Freundlich K_{ads} values of 15 in sand sediment, 36-42 in two sand soils, and Freundlich K_{ads} values of 1882-10740 in sandy loam, sandy clay loam, and loam soils. (MRID 40348601)

Laboratory volatility

Diquat has a vapor pressure of $< 4 \times 10^{-9}$ mm Hg at 25 °C; therefore, volatility is not expected to be a route of dissipation. There was no evidence of volatility in any study submitted to satisfy environmental fate requirements. (MRID 40245101)

Dissipation -- Terrestrial field and Long-term field

Diquat did not degrade for 3 years after application to two plots in New York; concentrations of diquat ion ranged from 0.01 to 0.32 ppm in the upper 15-cm soil depth. The two plots were planted to potatoes; the potato vegetation from the clay loam soil plot was removed prior to application to represent bare ground application, the other plot was on a loam soil and diquat was sprayed on the vegetation. There were two applications of diquat dibromide (2 lb ai/gal SC/L) at 0.25 lb diquat ion/A/application (total 0.5 lb ai/A). In general, there was no pattern of leaching; diquat was recovered at 0.01-0.03 ppm from individual soil cores from the 15- to 22.5-cm soil depth.

Diquat did not degrade for 3 years after application to two plots of loam soil in Idaho; concentrations of diquat ion ranged from 0.01 to 0.13 ppm in the upper 35-cm soil depth. Application was made to bare ground and to potato vegetation. The plots were cultivated to 35 cm and in subsequent years cropped to a rotation of sugarbeets, wheat and potatoes. There were two applications of diquat dibromide (2 lb ai/gal SC/L) at 0.25 lb diquat ion/A/application (total 0.5 lb ai/A). There were no residues recovered from below 35 cm. (MRIDs 42060301, 42060302, 40335201)

(1) Field Dissipation

Aquatic and Aquatic Impact

Diquat dissipated with half-lives of 1-2 days from Florida pondwater that was treated four times at 4 lb ai/A/application at approximately monthly intervals with diquat dibromide

(Ortho Diquat Herbicide-HA). Diquat was removed from the water column by adsorbing to sediment. The diquat concentrations in the sediment were variable ranging to a maximum of 1.2 ppm in the 0- to 5-cm depth with no discernible pattern of decline. In the aquatic dissipation study, the sites chosen were both near Gainesville, FL. Although the pond sites were treated under the same climatic conditions, the sediments were of different textures; one was sandy clay loam and the other was a sand sediment. The findings from these two sites were in agreement with findings from field dissipation studies conducted under a variety of climatic conditions and also were comparable to predictions from laboratory results. (MRID 40917403)

(2) Accumulation

Laboratory Accumulation - Fish

Diquat residues did not significantly accumulate in bluegill sunfish exposed to [¹⁴C]diquat dibromide at approximately 1030 ppb diquat ion for 14 days under flow-through conditions. The maximum mean bioconcentration factors were 0.7X for edible tissues (muscle, skin, skeleton), 2.5X for nonedible tissues (viscera) and 1.03X for whole fish. Depuration was rapid, with approximately 50 percent of the accumulated [¹⁴C]residues eliminated from the fish tissues by day 3 of the depuration period. (MRID 40326901)

Laboratory Accumulation - Non-target organisms

a. *Daphnia magna*. Diquat residues did not significantly accumulate in *Daphnia magna* exposed to diquat dibromide at 10 ug/L in a laboratory flow-through system. The reported maximum bioconcentration factor was 8.3X, at 1 day post-exposure.

b. Mayfly nymph Diquat residues did not significantly accumulate in mayfly nymphs exposed to diquat dibromide at 1 mg/L in a laboratory flow-through system. The reported maximum bioconcentration factor was 32X, at 1 day post-exposure.

c. Oysters Diquat residues did not significantly accumulate in the soft tissue of Pacific oysters which were exposed to diquat dibromide monohydrate at 0.1 mg/L in a laboratory flow-through system for up to 28 days. The soft tissue bioconcentration factor for organisms exposed for 14 days was 5.5X; for those exposed for 28 days, the soft tissue bioconcentration factor was 10.5X.

Field Accumulation - Fish

Diquat did not significantly accumulate in tissues of tilapia and catfish from two fish ponds in Florida which were treated with diquat dibromide in four monthly applications at 4 lb diquat ion/A/application (total 16 lb diquat ion/A). Each application was equivalent to 0.36 ug diquat ion/mL. In tilapia, maximum concentrations of diquat ion were 8.5 and 0.30 ppm in nonedible (head, tail, and

viscera) and edible (fillet plus skin) tissues, respectively. In catfish, the maximum concentrations of diquat ion were 0.06 and 0.15 ppm in edible (fillet) and nonedible (head, skin, tail, and viscera) tissues, respectively. Diquat ion concentrations in fish tissues did not increase with repeated applications. Diquat ion dissipated from the pond water with half-lives of 0.72-2.3 days. (MRIDs 40326903, 40326902, 40326904, 40380701)

(3) Spray Drift

Spray drift data are required by 40 CFR § 158.142 when aerial application and/or mist blower or other ground application are proposed and it is expected that the detrimental effect level of nontarget organisms expected to be present are exceeded.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC): The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine if an LOC has been exceeded, a risk quotient must be derived and compared to the LOC's. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration, (EEC) by an appropriate toxicity test effect level, e.g. the LC₅₀. The acute effect levels typically are:

- EC₂₅ (terrestrial plants),
- EC₅₀ (aquatic plants and invertebrates),
- LC₅₀ (fish and birds), and
- LD₅₀ (birds and mammals)

The chronic test results are the:

- NOEL (sometimes referred to as the NOEC) for avian and mammal reproduction studies, and either the NOEL for chronic aquatic studies, or the Maximum Allowable Toxicant Concentration (MATC), the geometric mean of the NOEL and the LOEL (sometimes referred to as the LOEC) for chronic aquatic studies.

When the risk quotient exceeds the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented along with the corresponding LOC's.

Levels of Concern (LOC) and associated Risk Presumption

Mammals, Birds

<u>IF THE</u>	<u>LOC</u>	<u>PRESUMPTION</u>
acute RQ>	0.5	High acute risk
acute RQ>	0.2	Risk that may be mitigated through restricted use
acute RQ>	0.1	Endangered species may be affected acutely
chronic RQ>	1	Chronic risk, endangered species may be affected chronically,

Fish, Aquatic invertebrates

<u>IF THE</u>	<u>LOC</u>	<u>PRESUMPTION</u>
acute RQ>	0.5	High acute risk
acute RQ>	0.1	Risk that may be mitigated through restricted use
acute RQ>	0.05	Endangered species may be affected acutely
chronic RQ>	1	Chronic risk, endangered species may be affected chronically

Plants

<u>IF THE</u>	<u>LOC</u>	<u>PRESUMPTION</u>
RQ>	1	High risk
RQ>	1	Endangered plants may be affected

Currently, no separate criteria for restricted use or chronic effects for plants exist.

Established Levels of Concern (LOC's)

<u>Endpoint/Scenario</u>	<u>Risk Quotient</u>	<u>Non-Endangered LOC</u>	<u>Endangered LOC</u>
Mammalian acute	EEC/LC ₅₀	0.5	0.1
Mammalian chronic	EEC/LEL*	1.0	1.0
Avian acute	EEC/LC ₅₀	0.5	0.1
Avian chronic	EEC/LEL	1.0	1.0
Aquatic acute	EEC/LC ₅₀	0.5	0.05
Aquatic chronic	EEC/LEL	1.0	1.0
Non-target insects	NOT QUANTIFIED	N/A	N/A
Non-target plants	EEC/EC ₂₅ or EC ₅₀	1.0	1.0

LEL: Lowest Effect Level. The LEL is a theoretical level which is a value somewhere between the NOEL and the LOEL. The Agency uses the NOEL to calculate the risk quotients for the mammalian and avian chronic risks and the MATC to calculate the risk quotients for the aquatic chronic risk.

(1) Exposure and Risk to Nontarget Terrestrial Animals

(a) Birds

Residues found on dietary food items following diquat dibromide application may be compared to LC₅₀ values to predict hazard. The maximum concentration of residues of diquat dibromide which may be expected to occur on selected avian or mammalian dietary food items following a single foliar application at different application rates is provided in the table below:

Residues on Avian and Mammalian Dietary Food Items in PPM					
Use Sites		Application Rates (lb a.i./A)			
		0.25 ^a	0.375 ^b	0.5 ^c	0.8923 ^d
Range Grasses (short)	Maximum residue	60	90	120	214
	Typical residue	31	47	63	112
Fruit/Vegetable Leaves (other than legumes)	Maximum residue	31	47	63	111
	Typical residue	9	13	18	31
Forage Legumes and small insects	Maximum residue	15	22	29	52
	Typical residue	8	12	17	29
Seeds, large insects	Maximum residue	3	5	6	11
	Typical residue	1	1	1.5	2.7
Long Grass	Maximum residue	28	90	120	214
	Typical residue	23	47	63	112

^a Cantaloupe

^b Cucumber and tomato

^c Alfalfa, carrot, clover, pepper, squash, potato, radish, turnip, soybean, and sorghum

^d Turf, golf courses, ornamental uses

Acute Risks

Regarding acute avian dietary risks, the table below indicates the risk quotients for each of the following application rates:

Acute Avian Dietary Risk Quotients				
(Dietary RQ = EEC (Maximum residue value)/LC₅₀)LC₅₀ = 575 ppm ai for bobwhite quail				
<i>Use Sites</i>	<i>Application Rates in lbs. A.I./A</i>			
	0.25 ^a	0.375 ^b	0.5 ^c	0.8923^d
<i>Range(short) grasses</i>	0.10	0.16	0.21	0.37
<i>Small insects</i>	0.03	0.04	0.05	0.09
Leafy crops	0.05	0.08	0.11	NA

^a Cantaloupe

^b Cucumber and tomato

^c Alfalfa, carrot, clover, pepper, squash, potato, radish, turnip, soybean, and sorghum

^d Turf, golf courses, ornamental uses

High acute risk to birds is not expected from the use of diquat dibromide. However, level of concern for restricted use has been exceeded (LOC = 0.2) primarily for the turf use. The LOC for endangered bird species (LOC = 0.1) has been exceeded for those avian species feeding on short grass, primarily the turf use.

Chronic Risks

The risk quotients for chronic risk to birds were based on both maximum **and** typical residues expected to occur immediately after treatment. Diquat is extremely persistent, but neither the rate of decline on food items, nor rate at which diquat becomes biologically unavailable to birds is known.

Based on available data, there is moderate to high certainty that some reproductive effects will occur to birds. The likelihood that this impact will occur frequently, or be of ecological significance is less certain.

Regarding chronic avian risks, the table below indicates the risk quotients for each of the following application rates:

Chronic Avian Risk Quotients					
(Chronic RQ = EEC (Maximum or typical residue value)/NOEL (5 ppm cation) NOEL = 5 ppm cation from the mallard reproduction study)					
Use Sites ⁰		Application Rates in lbs. A.I./A			
		0.25 ^a	0.375 ^b	0.5 ^c	0.8923 ^d
Range (short) grasses	Maximum	12	18	24	42.8
	Typical	6.3	9.5	12.6	22.3
Small insects	Maximum	3	4	5.9	10
	Typical	1.7	2.4	3.3	5.9
Leafy crops	Maximum	6.3	9.5	12.5	NA
	Typical	4.6	6.9	9.1	NA

^aCantaloupe

^bCucumber and tomato

^cAlfalfa, carrot, clover, pepper, squash, potato, radish, turnip, soybean, and sorghum

^dTurf, golf courses, ornamental uses

A NOEL of 5 ppm cation and LOEL of 25 ppm cation was determined from the mallard reproduction study. These findings were based on the number of eggs laid, hatching and 14-day old survival. The level of concern for chronic risk to avian species has been exceeded (LOC = 1). Therefore, birds feeding on diquat dibromide contaminated food items may experience reproductive problems. It is recognized that in some field crops such as alfalfa, clover and soybean, there may be few short grasses, so residues on leafy crops and insects may be more representative of actual exposure.

(b) Mammals

Small mammal exposure is estimated using the rat acute oral LD₅₀ values converted to a LC₅₀ value for dietary exposure. The estimated LC₅₀ = $\frac{LD_{50} \times \text{body weight (g)}}{\text{food. cons. per day (g)}}$

Small Mammal Food Consumption in PPMs (Based on an LD ₅₀ = 600 mg/kg) ^a				
Small Mammal	Body Weight in Grams	% of Weight Eaten Per Day	Food Consumed Per Day in Grams	Estimated LC ₅₀ Per Day in PPMs
Herbivore	26 gms	16 %	4.3 gms	701 ppm cation
Insectivore	5 gms	110 %	5.5 gms	105 ppm cation

The above table is based on information contained in Principles of Mammology by D. E. Davis and F. Golly, published by Reinhold Corporation, 1963.

^a An LD₅₀ in mg diquat dibromide cation/kg was calculated to be 116. This takes into account that this formulation was 19.3% cationic. Calculation: 600 mg/kg X 0.193 = 116 mg cation/kg.

Discussion of Overall Risk to Mammals:

Diquat dibromide will pose only a low risk to mammals considering the use patterns, environmental fate characteristics and toxicity. Effects, if they occur should not result in significant ecological damage.

Acute Risks

Regarding acute mammalian dietary risks, the table below indicates the risk quotients for each of the following application rates:

Acute Mammalian Dietary Risk Quotients (Dietary RQ = EEC (Maximum residue value)/Lowest 1-day LC ₅₀)				
	Application Rates in lbs. Cation/A			
	0.25 ^a	0.375 ^b	0.5 ^c	0.8923 ^d
Small Mammal				
Herbivore consuming range (short) grasses	0.08	0.13	0.17	0.30
Insectivores consuming small insects	0.14	0.21	0.28	0.49
Herbivores consuming leafy crops	NA	NA	0.09	NA

^a Cantaloupe

^b Cucumber and tomato

^c Alfalfa, carrot, clover, pepper, squash, potato, radish, turnip, soybean, and sorghum

^d Turf, golf courses, ornamental uses

None of the acute risk quotients exceed the LOC for high acute risk. The LOC for restricted use is exceeded by all uses **except cantaloupe**. The LOC for endangered species has been exceeded for all use patterns.

Some additional factors influencing acute exposure are presented below, and reduce the certainty of the risk assessment conclusions. These are as follows:

- 1). Small herbivores such as mice feed on a variety of food items ranging from short grass to seeds and fruits. The residues on these other food items would be less, yielding lower risk quotients.
- 2). Small insectivores feed on insects in a variety of habitats, not just those on the surface exposed to direct spray. Insects that were underground, or otherwise protected during spraying may have lower residue levels, also yielding lower risk quotients. Also, the estimated residues were for small insects. Large insects would have smaller residue levels.
- 3). The residues used in calculating the above risk quotients represented the maximum expected exposure levels. It should be noted that typical exposure levels would likely be less.

- 4). The entire risk assessment for mammals is based on one LD₅₀ value for laboratory rats. It is not known how sensitive wild mammals may be to diquat dibromide. If they are substantially more sensitive, they may be at greater risk than indicated by the risk quotients above.
- 5). The acute oral LD₅₀ may not be the best indicator of actual toxicity of diquat dibromide as might occur when ingested as a dietary concentration. Diquat dibromide binds tightly to organic matter such as food items, and may not be as biologically available. Whereas, when intubated directly, as is done during the acute oral test, the test animal is more likely to receive the full impact of the test material.
- 6). The acute risk quotient for insectivores in turf and ornamental areas was 0.49, which is very close to the LOC of 0.5.

Therefore, it is only with moderate certainty that the Agency concludes that nonendangered mammals are **not at acute risk** from diquat dibromide. Based on risk to mammals, diquat dibromide does exceed the restricted use LOC for all uses except cantaloupe (application rate of 0.25 lb cation/acre).

Information that could reduce uncertainty in the acute risk assessment for mammals would be toxicity tests with wild mammals providing actual LC₅₀ values. This testing is **not required** for risk assessment.

Chronic Risks

Regarding chronic mammalian risks, the table below indicates the risk quotients for each of the following application rates:

Chronic Mammalian Risk Quotients					
(Chronic RQ = EEC (Maximum or typical residue value)/NOEL (80 ppm cation))					
Small Mammal		Application Rates in lbs. A.I./A			
		0.25 ^a	0.375 ^b	0.5 ^c	0.8923 ^d
Herbivores consuming range (short) grasses	Maximum	0.7	1.1	1.5*	2.7
	Typical	0.4	0.6	0.8*	1.4
Insectivores consuming small insects	Maximum	0.2	0.3	0.4	0.6
	Typical	0.1	0.2	0.2	0.4
Herbivores consuming leafy crops	Maximum	0.4	0.6	0.8	NA
	Typical	0.1	0.2	0.2	NA

^a Cantaloupe

^b Cucumber and tomato

^c Alfalfa, carrot, clover, pepper, squash, potato, radish, turnip, soybean, and sorghum

^d Turf, golf courses, ornamental uses

* There may be relatively few short grasses in alfalfa, clover, or soybean fields, or in some other vegetable growing fields.

Chronic risk for mammals is based on maximum and typical residues on small insects or leafy crops, except for the turf use, where short grasses would likely predominate. The 2-generation rat reproduction study showed the NOEL = 80 ppm cation and the LOEL = 240 ppm cation.

Using maximum and typical residues on food items for mammals, the risk quotients exceed the chronic LOC for turf and ornamental use only. However, other factors must be considered when considering the extent of risk and the probability that chronic risk will occur such as:

- 1). Diquat is very persistent in the environment shown by data from terrestrial Field Dissipation studies showing diquat does not degrade after 3 years. However, it is bound to the soil and not taken up by plants.
- 2) Small herbivores such as mice actually feed on a variety of food items ranging from short grass to seeds and fruits. These mammal species may move about, choosing a variety of food items, not just the food items with the maximum residues.
- 3). The RQ values were derived using the No Effect Level (NOEL) of 80 ppm cation. The Lowest Effect Level (LOEL), where adverse effects were known to occur was at the extrapolated 240 ppm cation. It is not known at what concentration, between 80 and 240 ppm, adverse chronic effects may start to occur. Again, including the turf use, even maximum residues on food items did not exceed the 240 ppm.
- 4). Small insectivores feed on insects in a variety of habitats, not just those who are on the surface exposed to direct spray. Insects that were underground, or otherwise protected during spraying may have lower residue levels, also yielding lower risk quotients. Also, the estimated residues were for small insects. Large insects would have smaller residue levels.

These factors lead to a conclusion that while the possibility of chronic risk exists, the probability that it will occur may be relatively low. **The extent, or significance, of chronic impact to non-endangered mammals appears to be low.**

(c) Insects

Diquat dibromide poses only minimal risk to non-target insects and because it is practically non-toxic to honey bees, LD₅₀ 100 and 47 µg/bee, there is little direct exposure to it.

(2) Exposure and Risk to Nontarget Aquatic Animals

A refined EEC was done by the Agency. This EEC is determined using environmental fate and transport computer models. The Pesticide Root Zone Model (PRZM1) was used to simulate pesticides in field runoff and the Exposure Analysis Modeling System (EXAMS II) to simulate pesticide fate and transport in an aquatic environment (one acre body of water). An estimate of diquat runoff and its effect on surface water quality was evaluated using PRZM-EXAM models from a typical crop use on potatoes with data from a silt loam soil in Maine. This estimate is a worst case scenario of the entire yearly application of 0.5 lb ai/A (cation ai/A) to highly eroded soil for 36 years. This assessment includes diquat adsorbed onto eroded soil particles as well as diquat in the runoff water. Below is runoff as computed by EFED's PRZM-EXAM model showing annual average Environmental Exposure Concentration of diquat in Maine with 10% exceedance. The values are in cations ppb and the time period is after application.

Maximum	96 hour	21 days	60 days	90 days
48.4 ppb	47.8 ppb	45.1 ppb	45.3 ppb	43.6 ppb

Diquat dibromide binds very strongly to clay and organic matter in the soil ($K_{OC} = 100,000$ in soil). The LC_{50} values of the aquatic organisms are from laboratory conditions, in which there are no soil particles or plant material to bond. Therefore, the availability of diquat to aquatic organisms in the test system would be much higher than in a environmental setting where matter was available to "bind" with diquat dibromide. Data from the Aquatic Dissipation study shows that diquat dissipates from the water column in Florida ponds with half-lives of 1-2 days. Since diquat bonds very tightly to organic matter and soil and the diquat is very stable (does not degrade); **the diquat in the runoff would dissipate rapidly to the soil bottom and not be readily available to aquatic organisms. These factors lead to a conclusion that while the possibility of acute or chronic risk to aquatic organisms exist, the probability that it will occur is relatively low. Therefore, it is expected that diquat dibromide will pose only a minimal risk to aquatic organisms from exposure to runoff.**

Estimated Residues (cations ppb) and RQ for Single Event/Single Application from Spray Drift		
Contamination Rates	5% Direct Drift to 1 A Surface	Risk Quotient
0.25 lb cation/A	0.0125 lb cation/A 0.76 ppb cation/2M	Invertebrates Acute: 0.002 Fish Acute: 0.00001 Fish Chronic: 0.003
0.375 lb cation/A	0.0188 lb cation/A 1.15 ppb cation/2M	Invertebrates Acute: 0.003 Fish Acute: 0.00008 Fish Chronic: 0.003
0.5 lb cation/A	0.0250 lb cation/A 1.53 ppb cation/2M	Invertebrate Acute: 0.0036 Fish Acute: 0.0001 Fish Chronic: 0.008
0.892 lb cation/A	0.0446 lb cation/A 2.72 ppb cation/2M	Invertebrate Acute: 0.006 Fish Acute: 0.0002 Fish Chronic: 0.014
4.0 lb cation/A	0.2000 lb cation/A 12.2 ppb cation/2M	Invertebrate Acute: 0.03 Fish Acute: 0.0009 Fish Chronic: 0.062

MEAN CHRONIC MATC= PPB, High acute risk RQ ≥ 0.5, Restricted use RQ ≥ 0.1,
Endangered Species RQ ≥ 0.05 and Chronic RQ ≥ 1

Estimated Residues (cations ppb) and RQ from Direct Application to Aquatic Weed Control		
Contamination Rates	Residues (EEC)	Risk Quotient
4.0 lb cation/A from aerial or boat	244.0 ppb cation in 2 meters	Estu. Invertebrates Acute: 0.6 Invertebrate Acute: 0.3 Fish Acute: 0.02 Fish Chronic: 1.24 Invertebrate Chronic: 5.5

MEAN CHRONIC MATC= PPB, High acute risk RQ ≥ 0.5, Restricted use RQ ≥ 0.1, Endangered Species RQ ≥ 0.05 and Chronic RQ ≥ 1

(a) Freshwater Fish

As indicated in the above estimated residue table, High Acute Risk and Endangered Species acute LOCs for freshwater fish have **not** been exceeded at the maximum application rate and for the refined EEC. The Restricted Use LOC for freshwater fish has **not** been exceeded for all application rates and for the refined EEC. This indicates that the use of diquat dibromide **does not** cause adverse effects to freshwater fish when exposed to the chemical and/or residues.

As indicated in the above estimated residue table, the freshwater fish chronic LOC **has been exceeded for aquatic weed control use only** and the refined EEC by 1.24 times. Adverse impacts are **not** expected to freshwater fish reproductive success from the use of - diquat dibromide.

b. Freshwater Invertebrates

As indicated in the above estimated residue table, the freshwater invertebrate acute LOC has **not** been exceeded at all application rates and the refined EEC. Therefore, freshwater aquatic invertebrates are **not** likely to be adversely affected by the use of diquat dibromide.

As indicated in the above estimated residue table, the invertebrate chronic LOC **has been exceeded** at application rates for aquatic weed control use only by 5.5 times. Adverse impacts are expected to invertebrate reproductive success from the use of diquat dibromide.

c. Estuarine and Marine Animals

As indicated in the above estimated residue table, the High Risk and Endangered Species acute LOCs for fish have **not** been exceeded for the maximum application rate and for the refined EEC. The Restricted Use LOC for fish has **not** been exceeded for all application rates and for the refined EEC. This indicates that the use of diquat may **not** cause adverse effects to fish when exposed to the chemical and/or its' residues.

4. Exposure and Risk to Nontarget Plants

There is relatively high certainty that drift from aerial spraying of diquat dibromide will result in adverse effects to plants. There is an element of uncertainty in the terrestrial plant risk assessment because data from the more sensitive plant species is probably not available. It is likely that sweet corn and wheat would yield lower EC25's.

Non-target terrestrial plants inhabit non-aquatic areas. Non-target "semi-aquatic" plants are plants that usually inhabit low-lying wet areas that may or may not be dry at certain times of the year. These plants are not obligatory aquatic plants in that they do not live in a continuously aquatic environment. The terrestrial and "semi-aquatic" plants are exposed to pesticides from runoff, drift or volatilization.

Exposure to non-target aquatic plants may occur through either runoff from terrestrial sites, or drift from aerial application. Of course, aquatic plants are directly exposed from the aquatic weed control use. However, since they are the "target area" for that use, risk from such exposure is not estimated. For the aquatic weed control use, only risk caused by spray drift from aerial treatment of aquatic weeds is assessed for the non-targets.

Spray drift exposure is determined by assuming 5% of the pesticide application will drift over to an adjacent acreage or to a much longer distance. Runoff exposure is determined from refined EEC from the Agency using PRZM-EXAM with conversions to lb ai/A. This runoff is characterized as a channelized runoff from 10 acres to a low lying areas (one acre) some distance away that impacts "semi-aquatic" and terrestrial plants. An estimate of diquat runoff and its effect on surface water quality was evaluated using PRZM-EXAM models from

a typical crop use on potatoes with data from a silt loam soil in Maine. This estimate is a worst case scenario of the entire yearly application of 0.5 lb ai/A (cation ai/A) to highly eroded soil for 36 years. This assessment includes diquat adsorbed onto eroded soil particles as well as diquat in the runoff water. The Estimated Environmental Concentrations are 48.4 ppb cation (0.7934 lb cation/A) just after application and 43.6 ppb cation 90 days after application.

However, according to the environmental fate data, diquat dibromide binds very strongly to clay and organic matter in the soil ($K_{OC} = 100,000$ in soil). Diquat is not expected to be bioavailable to plants once it is attached to soil particles. **Therefore, it is assumed that diquat dibromide once attached to soil particles from runoff will not affect plants. Furthermore, no EEC will be made for runoff from terrestrial treatment to non-target terrestrial plants since it is assumed that impact to terrestrial plants will be minimal.**

The EC_{50} values of the aquatic plants are from laboratory conditions, in which there are no soil particles to bond. Therefore, the availability to aquatic plants would be much higher than in an environmental setting. Data from the Aquatic Dissipation study shows that diquat dissipates from the water column in Florida ponds with half-lives of 1-2 days. Since diquat bonds very tightly to organic matter and soil and the diquat is very stable (does not degrade); **the diquat in the runoff would dissipate rapidly to the soil bottom and not be readily available to aquatic plants. Therefore, any impact on aquatic plants will come from aerial application.**

The EC_{25} value of the most sensitive species in the vegetative vigor study is used for the drift exposure to terrestrial plants. For the aquatic plants, the endpoints are in EC_{50} values. The risk quotient is derived from the following:

- the most sensitive EC_{25} value (from cotton) for terrestrial plants is 0.0047 lb cation/A.
- the most sensitive EC_{50} value (from giant duckweed) for vascular aquatic plants is 0.0036 lb cation/A when applied at surface of water as in aerial drift.
- the risk quotient is derived from dividing the exposure (EEC) by the toxicity value (EC_{25} or EC_{50})

The following aerial EECs have been determined for non-target plants that are exposed from the labeled application of diquat:

Non-Target Vascular Aquatic and Terrestrial Plants Exposure to Diquat

Maximum Application Rate (lb cation/A)	Use Sites	Spray Drift EEC (lb cation/A)	Non-Target Plant Risk Quotients		LOC
			Aquatic	Terrestrial	
0.25	cantaloupe	0.0125	3.5	2.7	1.0
0.375	cucumber, tomato, watermelon	0.0188	5.2	4.0	1.0
0.500	pepper, squash, potato, radish, turnip, soybean, sorghum	0.0250	6.9	5.3	1.0
0.892	turf, ornamental	0.0446	12.4	9.5	1.0
4.0	aquatic weed control	0.2000	55.6	42.5	1.0

Endangered and non-endangered plants species have the same LOC which is 1.0.

The possibility of risk to non-target aquatic and terrestrial plants from aerial application from all sites is relatively high. The data also suggest that exposure from drift settling on the foliage of aquatic plants represents a greater hazard than if the drift settles on the water first before exposure to the plants occur.

(1) Endangered Species

Levels of Concern have been exceeded for endangered species of mammals and birds from all terrestrial use sites.

Levels of Concern have been exceeded for endangered species of aquatic invertebrates, estuarine species, and fish from the use of diquat for aquatic weed control. It is recognized that in places where aquatic weed control is done year after year, endangered species may have already been eliminated. This cannot be assumed, however. Alternatively, the possibility of future threat to endangered species may exist if diquat dibromide were to be applied in new (previously untreated) aquatic ecosystems.

Although Levels of Concern have been exceeded for endangered species of aquatic and estuarine invertebrates and aquatic plants by runoff exposure from fields of alfalfa, clover, carrot, pepper, radish, potato, squash, turnip, soybean, or sorghum for endangered species of aquatic organisms; there is a **high degree of uncertainty** that endangered species in these habitats may actually be affected **by runoff**. The risk quotient was based on exposure provided by the Agency's EEC model based on erodible potato fields in Maine. However, other environmental fate data, which the model does not take into account, indicate that the diquat that moves with the water will actually become biologically unavailable quickly as it becomes tied up by soil and organic particles. This reduces, significantly, the possibility of acute effects, and makes chronic exposure extremely unlikely. Therefore, it is unlikely, in spite of the relatively large risk quotient, that endangered aquatic organisms (fish, invertebrates or plants) would be affected from exposure due to runoff alone.

Endangered species of aquatic plants may be affected from drift coming from aerial application of all terrestrial use sites and from aerial application of aquatic weed control. Endangered species of aquatic plants in close proximity to aquatic weed control sites that use diquat may be affected.

Endangered species of terrestrial plants may be affected by drift from aquatic weed control or turf/ornamental use sites only.

However, the Endangered Species Protection Program has been postponed pending national assessment. Limitations in the use of diquat dibromide will be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

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 ingredients 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 diquat dibromide active ingredients. 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 diquat dibromide. Appendix A lists the registered uses. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of diquat dibromide, 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 diquat dibromide and to determine that diquat dibromide can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing diquat dibromide as the active ingredients 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 data base 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 diquat dibromide 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 diquat dibromide, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients diquat dibromide, the Agency has sufficient information on the health effects of diquat dibromide and on its potential for causing adverse effects in fish and wildlife and the environment.

Therefore, the Agency concludes that products containing diquat dibromide for all uses are eligible for reregistration. The Agency has determined that diquat dibromide products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of diquat dibromide are eligible for reregistration.

B. Regulatory Position

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

1. Tolerance Reassessment

Tolerances Listed Under 40 CFR §185.226(a)

The tolerances listed in 40 CFR §180.226(a) are for residues of the plant growth regulator diquat (6,7-dihydrodipyrido(1,2-a:2', 1'-c)pyrazinediium) derived from application of the dibromide salt and calculated as the cation. We recommend that this 40 CFR subsection be amended to read "...residues of the plant growth regulator **and herbicide** diquat...".

A tabular outline of tolerance reassessment summary and recommended modifications in commodity definitions is presented in Table A. Refer to Table B for recommendations concerning harmonization of U.S. tolerances with Codex MRLs. Based on the available data, the following conclusions have been made regarding residues of diquat dibromide:

- Sufficient data are available to ascertain the adequacy of all established tolerances listed in 40 CFR §180.226(a) except for sugarcane. The tolerance for sugarcane was established to support direct application of the dibromide salt formulation on sugarcane. There are presently no registered direct application

uses of diquat dibromide on sugarcane. Therefore, the tolerance for sugarcane should be revoked.

- The established tolerances of 0.1 ppm for potato and 0.02 ppm for milk are adequate.
- The established tolerances of 0.02 ppm for the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep should be raised to 0.05 ppm to achieve compatibility with the Codex MRL.
- The established 0.02 ppm tolerance level for poultry fat, meat, meat byproduct and eggs should be raised to 0.05 ppm to achieve compatibility with the Codex MRL.
- The registrant has proposed tolerances of 5.0 ppm for both alfalfa and clover seeds. The proposed tolerance level for residues in alfalfa seed appears to be too high and a new petition with a lower tolerance level of 3.0 ppm has been submitted. Clover seed are no longer considered to be significant food or feed items; therefore a tolerance is not required.
- The registered uses of diquat dibromide on sorghum and soybean grown for seed as a preharvest desiccant are supported by adequate field residue data. The registrant has proposed a tolerance in/on sorghum seed and has committed to do so for soybeans. The available data support tolerances of 2.0 ppm and 0.2 ppm for sorghum and soybean seed.
- The registered uses of diquat dibromide (i) as a preharvest desiccant on carrot, radish, and turnip grown for seed, and (ii) as a postharvest desiccant on cantaloupe, cucumber, pepper, squash, tomato, and watermelon are considered to be non-food uses. No residue data are required and no tolerances are needed.

Tolerances Listed Under 40 CFR §185.226(b)

The tolerances listed in 40 CFR §180.226(b) are for residues of diquat calculated as the cation derived from application of the dibromide salt to ponds, lakes, reservoirs, marshes, drainage ditches, canals, streams, and rivers which are slow-moving or quiescent in programs of the Corps of Engineers or other Federal or State public agencies and to ponds, lakes, and drainage ditches only where there is little or no outflow of water and which are totally under the control of the user.

- Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.226(b) for cucurbits vegetables, citrus fruits, pome fruits, small fruits and berries, stone fruits, cereal grains, forage, fodder,

and straw of cereal grains, grass forage, fodder, and hay, foliage of legume vegetables, tree nuts, root and tuber vegetables, legume vegetables (succulent/dried); see Table A for modifications in commodity definitions.

- The available data indicate that residues of diquat will exceed the established tolerances of 0.02 ppm for residues in/on Brassica leafy vegetables (represented by mustard green) and fruiting vegetables (represented by tomato). The registrant has appropriately proposed higher tolerance levels of 0.05 ppm for diquat residues in/on fruiting vegetables and Brassica leafy vegetables.
- No data are available for the miscellaneous commodities avocado, cottonseed, hops, and sugarcane for which tolerances currently exist. However, we have translated from data for other crops. Based on the highest residues found in other irrigated crops resulting from irrigation with water containing diquat residues, we have recommended that the registrant propose increased tolerances from 0.02 ppm to 0.1 ppm for these crops; a petition to this end has been submitted. If lower tolerances are desired, additional data will be required.
- The established tolerances for diquat residues in fish and shellfish at 0.1 ppm have, as per Agency recommendation, been proposed to be increased to 2 ppm and 20 ppm, respectively, based on data reflecting residues of diquat in fish and shellfish from currently registered uses.

Tolerances Listed Under 40 CFR §185.2500 (a) and (b)

The tolerance listed in 40 CFR §185.2500(a) is for residues of diquat derived from application of the dibromide salt in potable water of ponds, lakes, reservoirs, marshes, bayous, drainage ditches, canals, streams, and rivers which are slow-moving or quiescent in programs of the Corps of Engineers or other Federal and State public agencies.

The tolerance listed in 40 CFR §185.2500(b) is for residues of diquat derived from application of the dibromide salt and calculated as the cation in potable water of ponds, lakes, and drainage ditches where there is little or no outflow of water and which are totally under control of the user.

- Since the Agency no longer establishes tolerances for residues in potable water (47 FR 25746, 12/15/82), the tolerance for diquat dibromide has been replaced with a designated maximum contaminant level (MCLG). An MCLG of 0.02 mg/L for residues of diquat in potable water has been established (57 FR 31776, 7/17/92). The established tolerance for residues of diquat in potable water should be revoked.

Tolerance Listed Under 40 CFR §185.2500(c)

The tolerance listed in 40 CFR §185.2500(c) is for residues of diquat derived from application of the dibromide salt and calculated as the cation.

- Based on the 12x concentration factor observed in processed potatoes, a higher tolerance of 1.0 ppm is appropriate for potatoes, granules/flakes and 0.5 ppm potato chips. The registrant has submitted a petition to this end.

Tolerance Listed Under 40 CFR §186.2500

The tolerance listed in 40 CFR §186.2500 is for residues of diquat derived from application of the dibromide salt and calculated as the cation.

- The potato processing data indicate that the established feed additive tolerance for processed potato waste is appropriate.
- The soybean processing data indicate that residues of diquat concentrated 2.6x in soybean hulls processed from soybean bearing detectable residues. No concentration of residues was observed in other soybean processed fractions. In accordance with Agency recommendations, the registrant has proposed a feed additive tolerance for residues of diquat in soybean hulls; a feed additive tolerance of 0.6 ppm would be appropriate based on a recommended tolerance of 0.2 ppm for soybean and a concentration factor of ~3x in soybean hulls.
- The sorghum processing data indicate that residues of diquat concentrated 4x in sorghum dry milling bran fraction processed from sorghum bearing detectable residues. According to the revised Table II of Subdivision O's Pesticide Assessment Guideline (PAG), the only processed commodity entry for sorghum is flour. Residue data are not needed for flour at this time since sorghum flour is used exclusively in the U.S. as a component of drywall, and not as either a human or animal feed item. However, because 50% of the worldwide sorghum production goes toward human consumption, the Agency reserves the right to require data if needed at a later date.

Table A. Tolerance Reassessment Summary.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/[Correct Commodity Definition]
Tolerances Listed Under 40 CFR §180.226(a)			
Cattle, fat	0.02	0.05	The established tolerance for ruminant and swine commodities may be raised to achieve compatibility with the Codex MRL.
Cattle, mby	0.02	0.05	
Cattle, meat	0.02	0.05	
Eggs	0.02	0.05	The established tolerance for eggs may be raised to achieve compatibility with the Codex MRL.
Goats, fat	0.02	0.05	
Goats, mby	0.02	0.05	
Goats, meat	0.02	0.05	
Hogs, fat	0.02	0.05	
Hogs, mby	0.02	0.05	
Hogs, meat	0.02	0.05	
Horses, fat	0.02	0.05	
Horses, mby	0.02	0.05	
Horses, meat	0.02	0.05	
Milk	0.02	0.02	
Potatoes	0.1	0.1	<i>[Potato]</i>
Poultry, fat	0.02	0.05	The established tolerance for poultry fat, meat and meat byproducts may be raised to achieve compatibility with Codex.
Poultry, mby	0.02	0.05	
Poultry, meat	0.02	0.05	
Sheep, fat	0.02	0.05	The established tolerance for ruminant commodities may be raised to achieve compatibility with Codex.
Sheep, mby	0.02	0.05	
Sheep, meat	0.02	0.05	
Sugarcane	0.05	Revoke	No registered direct application uses of diquat dibromide on sugarcane exist.
Additional Tolerances That Have Been Proposed Under 40 CFR §180.226(a)			
Alfalfa seed	None	3.0	
Sorghum, grain	None	2.0	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/[Correct Commodity Definition]
Additional Tolerance that Needs to be Proposed Under 40 CFR §180.226(a)			
Soybean, seed	None	0.2	
olerances Listed Under 40 CFR §180.226(b)			
Avocados	0.02	0.1	A higher tolerance has been proposed based on available data.
Cottonseed	0.02	0.1	
Cucurbits	0.02	0.02	<i>[Cucurbits vegetables group]</i>
Fish	0.1	2.0	A higher tolerance has been proposed based on available data.
Fruits, citrus	0.02	0.02	<i>[Citrus fruits group]</i>
Fruits, pome	0.02	0.02	<i>[Pome fruits group]</i>
Fruits, small	0.02	0.02	<i>[Small fruits and berries group]</i>
Fruits, stone	0.02	0.02	<i>[Stone fruits group]</i>
Grain, crops	0.02	0.02	<i>[Cereal grains group]</i> and <i>[Forage, fodder, and straw of cereal grains group]</i>
Grasses, forage	0.1	0.1	<i>[Grass forage, fodder, and hay group]</i>
Hops	0.02	0.1	A higher tolerance has been proposed based on available data.
Legumes, forage	0.1	0.1	<i>[Foliage of legume vegetables group]</i>
Nuts	0.02	0.02	<i>[Tree nuts group]</i>
Shellfish	0.1	20	A higher tolerances has proposed based on available data.
Sugarcane	0.02	0.1	A higher tolerance has been proposed based on available data.
Vegetables, fruiting	0.02	0.05	A higher tolerance has been proposed based on available data. <i>[Fruiting vegetables (except cucurbits) group]</i>
Vegetables, leafy	0.02	0.05	A higher tolerance has been proposed based on available data. <i>[Leafy except Brassica group]</i> and <i>[Brassica leafy vegetables group]</i>
Vegetables, root crop	0.02	0.02	<i>[Root and tuber vegetables group]</i>
Vegetables, seed and pod	0.02	0.02	<i>[Legume vegetables (succulent/dried) group]</i>
Tolerance Listed Under 40 CFR §185.2500 (a) and (b)			
Potable water	0.01	Revoke	A maximum contaminant level of 0.02 mg/L for residues of diquat in potable water has been established.
Tolerances Listed Under 40 CFR §185.2500(c)			

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/[Correct Commodity Definition]
Processed potatoes (including potato chips)	0.5	1.0	A higher tolerance is needed based on the 12x concentration factor observed in dried potato. [Expressed in terms of potatoes, granules/flakes at 1.0 ppm and potato chips at 0.5 ppm]
	0.5	0.5	
Tolerance Listed Under 40 CFR §186.2600			
Processed potato waste	1.0	1.0	
Additional Tolerance That Needs To Be Proposed Under 40 CFR §186.2600			
Soybean, hulls	None	0.6	A tolerance is needed based on a concentration factor of ~3x in soybean hulls.

CODEX HARMONIZATION

Several maximum residue limits (MRLs) for diquat have been established by Codex in various commodities. The diquat residues regulated by Codex and the U.S. are equivalent. The Codex MRLs (currently expressed as the diquat cation) and U.S. tolerances derived from application of the dibromide salt (calculated as the cation) are listed in Table D.

The U.S. tolerance for eggs, poultry, meat, and offal (mammalian) may be raised to 0.05 ppm to achieve harmonization. Further harmonization of U.S. tolerances and Codex MRLs on other commodities are not feasible at this time because of differences in agricultural practices.

Table B. Codex MRLs and applicable U.S. tolerances. Recommendations for compatibility are based on conclusions following reassessments of U.S. tolerances (see Table A).

Commodity	MRL (mg/kg) ^a	Reassessed U.S. Tolerance (ppm)	Recommendation
Barley	5	0.02	Incompatible. In U.S. tolerance is for cereal grains resulting from inadvertant water exposure
Beans, shelled	0.5	0.02	Incompatible. As per barley except legume vegetable group
Cotton seed	1	0.02, (0.1) ^d	Incompatible. U.S. use is inadvertant irrigation
Cotton seed oil, edible	0.1	None	--
Edible offal (Mammalian)	0.05 ^b	0.05	Compatibility will exist when current U.S. tolerance is raised.
Eggs	0.05 ^b	0.05	Compatibility will exist when current U.S. tolerance is raised.
Maize	0.1	0.02	same as barley note
Meat	0.05 ^b	0.05	Compatibility will exist when current U.S. tolerance is raised.
Milks	0.01 ^b	0.02	--
Onion, Bulb	0.1	0.02	same as barley but root and tuber vegetables group
Peas, shelled	0.1	0.02	same as barley but root and tuber vegetables group
Poppy seed	5	None	--
Potato	0.2	0.1	--
Rape seed	2	None	--
Rapeseed oil, edible	0.1	None	--
Rice	5	0.02	same as barley
Rice, husked	0.2	None	--
Rice, polished	0.2	None	--
Sesame seed oil, edible	0.1	None	--
Sorghum	2	(2)	compatible as proposed
Sugar beet	0.1	0.02	same as onion, bulb
Sunflower seed	0.5	None	---
Sunflower seed oil, edible	0.1	None	--
Vegetables (except...) ^c	0.05 ^b	0.02, 0.05	Potentially compatible if <u>all</u> U.S. tolerances are increased to 0.05 ppm, provided those with <u>higher</u> tolerances are excluded
Wheat	2	0.02	same as barley
Wheat bran, unprocessed	5	None	--
Wheat flour	0.2	None	--
Wheat whole meal	2	None	--

^a All diquat MRLs are final (CXL).

^b At or about the limit of detection.

^c Except as otherwise listed.

^d Parenthetic values as proposed.

2. Risk Mitigation Measures

Aquatic Risk Mitigation Measure

The Agency maintains that the current labels for aquatic use of diquat dibromide are satisfactory to protect aquatic organisms.

For aquatic use: Apply diquat dibromide to one-third or one-half of the dense weed areas in a water body to be treated at any one time and recommend subsequent applications should not be made for a further two weeks.

If diquat dibromide is applied in this fashion, the untreated part of the water body will act as a refuge for aquatic organisms and allows time for oxygen levels to recover before further applications are made.

Spray-Drift Risk Mitigation Measure (Non-target plants)

The possibility of risk to non-target aquatic and terrestrial plants from aerial application for all sites is relatively high. The Agency recommends the use of the best management practices to minimize Spray Drift.

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 Spray Drift Task Force completes their studies, submits data, and the Agency evaluation is complete, there may be further refinement in spray drift management practices.

3. Endangered Species Statement

The Agency has concerns about the exposure of threatened and endangered mammals and birds to diquat dibromide in terrestrial use sites as discussed above in the environmental assessment chapter. In addition, Levels of Concern have been exceeded for endangered species of aquatic and estuarine invertebrates and aquatic plants by runoff exposure to diquat dibromide. However, since diquat dibromide binds with soil and organic particles, chronic exposure seems unlikely.

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service may be necessary to assess risks to

newly listed species or from proposed new uses. In the future, the Agency plans to publish in the Federal Register a description of the program and have available enforceable county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

4. Labeling Rationale

Uses within Scope of the Worker Protection Standard

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research used on farms, forests, nurseries, and greenhouse to produce agricultural plants (including food, feed, and fiber plants, trees, turfgrass, flowers, shrubs, ornamentals, and seedlings). Uses within the scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in.

At this time some of the registered uses of diquat are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) and some uses are outside the scope of the WPS. Those uses that are outside the scope of the WPS include:

Use on sites, such as ornamental gardens, parks, golf courses, and public or private lawns and grounds that are intended only for decorative or environmental benefit. (However, pesticides used on sod farms ARE covered by the WPS).

Uses not directly related to the production of agricultural plants, for example, involve control of vegetation along rights-of-way and in other non-crop areas or aquatic weed control in non-crop sites.

Compliance With The WPS

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)", and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

- After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.
- After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person.

Personal Protective Equipment/Engineering Controls for Handlers

Occupational-Use Products (WPS and NonWPS Uses)

For each end-use product, PPE requirements for pesticide handlers will be set during reregistration in one of two ways:

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent Agency guidelines.
2. If the Agency has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc):
 - In the RED for that active ingredient, the Agency may establish minimum or "baseline" handler PPE requirements that pertain to all or most occupational end-use products containing that active ingredient.
 - These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.
 - The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

There are special toxicological concerns about diquat dibromide that warrant the establishment of active-ingredient-based PPE requirements for occupational handlers. The MOE's were calculated as being acceptable using the assumption that coveralls over a long-sleeved shirt and long pants, and chemical-resistant gloves were worn by all occupational handlers, including mixers, loaders, and applicators. The use of PPE was not sufficient to reduce the MOE's to an acceptable level for mixers and loaders using open mixing systems to support aerial applications. Those MOE's were acceptable only with the use of closed mixing systems. There are also special toxicological concerns about diquat dibromide stemming from the considerable epidemiological data (mostly from California) documenting poisoning incidents resulting from use of diquat dibromide.

Homeowner-Use Products

EPA is not establishing minimum (baseline) handler PPE for diquat dibromide end-use products that are intended primarily for homeowner use, since the Agency anticipates that the frequency, duration, and degree of exposure by such users do not warrant the risk mitigation measures imposed for occupational handlers. Personal protective equipment, if appropriate, will be established based on the acute toxicity of the end-use product.

Post-Application/Entry Restrictions

Occupational-Use Products (WPS Uses)

Restricted Entry Interval

Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are established based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data and (2) interim REI's that are longer than those that would be established under the WPS.

Occupational Uses (WPS Uses)

For occupational end-use products containing diquat as an active ingredient, the Agency is requiring a 7-day interim REI pertaining to each use of the product that is within the scope of the Worker Protection Standard for Agricultural Pesticides. The basis for this recommendation are the low MOE's following certain exposure scenarios of diquat, the limited dissipation data regarding post-application exposure and risk from these uses, and incidence data.

It should be noted that the WPS requirements place very specific restrictions on entry during restricted-entry intervals, when that entry involves contact with treated surfaces. The Agency believes that these existing WPS protection measures are sufficient to mitigate post-application exposures of workers who have contact with surfaces treated with diquat. A 7-day REI should not pose a significant hardship, since seed-crops are generally treated 5 to 10 days before harvest and potatoes are treated 7 or more days before harvest. In addition, if the crops are mechanically harvested and the harvesters and harvest-equipment operators have no contact with the treated surfaces (soil, foliage, seed or crop being harvested, etc.), the WPS permits them to enter the treated area during the restricted-entry interval without personal protective equipment or any other restriction.

The WPS REI for diquat dibromide, in effect until now, was 24 hours. The 24-hour reentry interval was established for these uses by the 1986 Guidance for the Reregistration of Diquat Dibromide. That reentry interval was converted into a 24-hour restricted-entry interval through modifications specified in PR Notice 93-7, which implemented the labeling requirements of the 1992 Worker Protection standard for Agricultural Pesticides.

Early-Entry PPE: The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry by workers if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and the requirement that personal protective equipment be worn. Personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the toxicity concerns about the active ingredient. The requirements are set in one of two ways.

1. If the Agency has no special concerns about the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements based on the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient.
2. If the Agency has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects, cancer, developmental toxicity, or reproductive effects, it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Since the 21-day dermal toxicity studies for diquat dibromide indicate toxicity endpoints of concern and the MOEs for certain handlers tasks are low, the Agency is requiring more stringent PPE requirements than would be established otherwise. In addition, since diquat is classified as toxicity category II for eye irritation potential, protective eyewear is also required. The Agency will not require a respirator for early-entry workers, since the WPS places very specific restrictions on early entry and these existing WPS protection measures are sufficient to mitigate post-application inhalation exposures of workers.

Occupational-Use Products (NonWPS Uses)

For occupational end-use products containing diquat as an active ingredient, the Agency is establishing a 4-day entry restriction for turf uses of the product on nonWPS sites, other than aquatic sites and spot-treatments at residential sites. The basis for this requirement is the low MOEs for certain applications of diquat and the post-application exposure assessment for these uses. Employees (i.e., maintenance workers) at these sites are prohibited for 4 days from contacting the treated area after application. After the sprays have settled following application, respiratory protection should not be necessary. The entry restriction in effect until now was 24 hours, since a 24-hour reentry interval was established for these uses by the 1986 Guidance for the Reregistration of Diquat Dibromide.

For occupational end-use products containing diquat as an active ingredient, the Agency is retaining the 24-hour swimming prohibition for each use of the product on aquatic sites. The

basis for this recommendation is the post-application exposure assessment for swimmers following aquatic applications. Data demonstrates an aquatic half-life of 1 - 2 days. After that diquat will be bound to sediment. Swimmers are prohibited from swimming in the treated water for 24 hours.

Homeowner-Use Products

For non-occupational (homeowner) end-use products containing diquat as an active ingredient, the Agency is establishing an entry restriction for spot-treatment applications of the product. Although the Agency considers the potential for post-application exposures following spot treatments at residential sites to be low, the Agency intends to further minimize the potential for such exposures by prohibiting broadcast applications at residential sites. The basis for this prohibition is the low MOEs for certain applications of diquat and the post-application exposure assessment for golf-course maintenance personnel following broadcast applications to turfgrass. The Agency does not consider entry restrictions of specified hours or days feasible for applications at residential sites.

V. ACTIONS REQUIRED BY 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

The generic data base supporting the reregistration of diquat dibromide for the above eligible uses has been reviewed and determined to be substantially complete. However, confirmatory data are needed to fulfill requirements for the studies listed below:

Enforcement method - plant and animal commodities (Independent Laboratory Validation)

Certain data, which are not part of the target database for diquat, are required to support the continued registration of diquat dibromide. These data include:

Terrestrial plant studies: vegetative vigor

2. Labelling 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 herbicide, dessicant and plant growth regulator or the applicable term which describes the type of pesticide uses(s)] for the

following uses(s): aquatic, indoor and terrestrial food and non-food, feed crops, outdoor residential, aquatic non-food industrial uses."

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 the support of such uses(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 the support of such uses(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. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) 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

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

Occupational/Residential Labeling

PPE Requirements for Pesticide Handlers

Sole-active-ingredient end-use products that contain diquat dibromide must be revised to adopt the handler personal protective equipment requirements set forth in this section. Any conflicting PPE requirements on their current labeling must be removed.

Multiple-active-ingredient end-use products that contain diquat dibromide must compare the handler personal protective equipment requirements set forth in this section to the

PPE requirements on their current labeling and retain the more protective. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Products Intended Primarily for Occupational Use

Minimum (baseline) PPE requirements -- Some of the registered uses of diquat dibromide are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) and some are outside the scope of the WPS. The minimum (baseline) PPE requirements pertain to both the WPS and nonWPS uses by occupational handlers, since the potential exposure to occupational handlers is similar for WPS and nonWPS uses.

The minimum (baseline) PPE for all WPS and nonWPS occupational uses of diquat dibromide end-use products is:

"Applicators and other handlers must wear:
--Coveralls over long-sleeved shirt and long pants
--Chemical-resistant gloves (see instructions * below)
--Chemical-resistant footwear plus socks
--Chemical-resistant headgear for overhead exposure
--Chemical-resistant apron when cleaning equipment, mixing, or loading" (see instructions ** below)
--A dust/mist filtering respirator (MSHA/ NIOSH approval number prefix TC-21C)

* The glove statement for diquat dibromide is the statement established through the instructions in Supplement Three of PR Notice 93-7.

** The words "mixing, or loading" may be removed if the product is formulated as "ready-to-use."

Actual end-use product PPE requirements -- The PPE that would otherwise be established based on the acute toxicity of each end-use product must be compared to the minimum (baseline) personal protective equipment, if any, specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Placement in labeling -- 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 PR Notice 93-7.

Products Intended Primarily for Homeowner Use

Personal protective equipment requirements -- EPA is not establishing minimum (baseline) handler PPE for diquat dibromide end-use products that are intended primarily for homeowner use. Personal protective equipment, if appropriate, will be established based on the acute toxicity of the end-use product.

Placement in labeling -- The personal protective equipment requirements, if any, must be placed on the end-use product labeling immediately following the precautionary statements in the labeling section "Hazards to Humans (and domestic animals)."

Entry Restrictions

Sole-active-ingredient end-use products that contain diquat dibromide must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on their current labeling must be removed.

Multiple-active-ingredient end-use products that contain diquat dibromide must compare the entry restrictions set forth in this section to the entry restrictions on their current labeling and retain the more protective. A specific time-period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

Products Intended Primarily for Occupational Use

WPS uses

Restricted-entry interval -- A 7-day entry interval (REI) is required for uses within the scope of the WPS (see PR Notice 93-7) on all end-use products (see tests in PR Notices 93-7 and 93-11). This REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7.

Early-entry personal protective equipment (PPE) --

The PPE required for early entry is:

- coveralls over long-sleeve shirt and long pants,
- chemical-resistant gloves,
- chemical-resistant footwear plus socks,
- chemical-resistant headgear for overhead exposures,
- protective eyewear.

Placement in labeling -- The REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7. The PPE required for early entry must be inserted into the standardized early entry PPE statement required by Supplement Three of PR Notice 93-7.

NonWPS uses

Entry restrictions --

For applications to nonWPS sites (other than aquatic sites residential sites), such as golf courses, parks, etc:

"For 4 days following applications to non-crop areas (other than aquatic or residential sites), do not allow employees to have contact with the treated plants, except for contact with their footwear."

For spot-treatment applications to residential sites:

"Do not allow people or pets to touch treated plants until the sprays have dried."

Placement in labeling --

If WPS uses are also on label: Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box and place the appropriate nonWPS entry restriction in that box.

If no WPS uses are on label: Add the appropriate nonWPS entry restriction to the labels of all end-use products, except products primarily intended for homeowner use, in a section in the Directions For Use with the heading: "Entry Restrictions:"

Products Intended Primarily for Home Use

Entry restrictions --

"Do not allow people or pets to touch treated plants until the sprays have dried."

Placement in labeling -- Add the entry restriction to the labels of products primarily intended for homeowner use in a section in the Directions For Use with the heading: "Entry Restrictions:"

Other Labeling Requirements

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing diquat dibromide that are intended primarily for occupational use.

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."

Engineering Controls:

"Mixers and loaders supporting aerial applications are required to use closed systems. The closed system must be used in a manner that meets the requirements listed in the Worker Protection

Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4). When using the closed system, the mixers' and loaders' PPE requirements may be reduced or modified as specified in the WPS."

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements:

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

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."

Products Intended Primarily for Homeowner Use

The Agency is requiring the following labeling statements to be located on all end-use products containing diquat dibromide that are intended primarily for homeowner use.

Application Restrictions:

"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Only persons applying this product may be in the area during application."

User Safety Recommendations:

- "Clothing and protective equipment exposed to this product should be washed in detergent and hot water. Such items should be kept and washed separately from other laundry."

- "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."

Environmental Hazard

Environmental hazard requires the following label statements:

For products that are for terrestrial nonfood sites, use this precautionary statement: "This pesticide is toxic to aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."

For products that are for outdoor residential sites, use this precautionary statement: "This pesticide is toxic to aquatic invertebrates. Do not apply directly to water."

C. Spray Drift Label Advisory

Aerial Spray Drift Management

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

SPRAY DRIFT MANAGEMENT

AVOIDING SPRAY DRIFT AT THE APPLICATION SITE IS THE RESPONSIBILITY OF THE APPLICATOR AND THE GROWER.

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 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.

Aerial Drift Reduction Advisory Information

The following aerial drift 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 target 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 downwind. 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 winds speeds of 3 - 10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 3 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 wind is blowing away from adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops).

D. Labeling for Endangered Species

No use limitations to protect endangered plant species will be suggested until the OPP Endangered Species Protection Program is complete.

E. 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 products bearing old labels/labeling, i.e., labels absent the modifications specified in this RED document, except as noted below, 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. Table of Use Patterns Subject to Reregistration

**APPENDIX B. Table of the Generic Data Requirements
and Studies Used to Make the Reregistration Decision**

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Diquat Dibromide covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Diquat Dibromide 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 Diquat Dibromide

REQUIREMENT	USE PATTERN	CITATION(S)
Registrant: Zeneca Ag Products		
Product: 10182-376 and 10182-378		
PRODUCT CHEMISTRY		
61-1	Chemical Identity	Data gap
61-2A	Start. Mat. & Mnfg. Process	No MRID no.
61-3	Formation of Impurities	No MRID no.
62-1	Preliminary Analysis	40323601,40429601
62-2	Certification of Ingredient limits	40323601,40429601, Data gap
62-3	Analytical Method	40323601, 40429601
63-2	Color	00038627
63-3	Physical State	00038627
63-4	Odor	00136329
63-5	Melting Point	00115555
63-7	Density	00115555
63-8	Solubility	00136329,40302701
63-10	Dissociation Constant	00138938
63-12	pH	Data gap

Data Supporting Guideline Requirements for the Reregistration of Diquat Dibromide

REQUIREMENT	USE PATTERN	CITATION(S)
63-13	Stability	00038627, 00138928
63-14	Oxidizing/Reducing Action	40069304
63-16	Explodability	40069304
63-17	Storage stability	40069304
63-18	Viscosity	40069304
63-20	Corrosion characteristics	40069304
ECOLOGICAL EFFECTS		
71-1A	Acute Avian Oral - Quail/Duck	A,B,C,E 00106559, G59999001
71-2A	Avian Dietary - Quail	A,B,C,E 00022923, 00116565
71-2B	Avian Dietary - Duck	A,B,C,E 0002293
71-4A	Avian Reproduction - Quail	A,B,C,E 00119988
71-4B	Avian Reproduction - Duck	A,B,C,E 00114230
72-1B	Fish Toxicity - Bluegill - TEP	A,B,C,E 00138963,00115572,00027203,00138962, 00003503
72-1D	Fish Toxicity - Rainbow Trout-TEP	A,B,C,E 00138963,00115858,00028002, 00003503,00138961
72-2A	Invertebrate Toxicity	A,B,C,E 00003503.00115576,00115862
72-3A	Estuarine/Marine Toxicity - Fish	A,B,C,E 40316001,00028002
72-3B	Estuarine/Marine Toxicity - Mollusk	A,B,C,E 40316001
72-3C	Estuarine/Marine Toxicity - Shrimp	A,B,C,E 40315701

Data Supporting Guideline Requirements for the Reregistration of Diquat Dibromide

REQUIREMENT	USE PATTERN	CITATION(S)
72-4A	Early Life Stage Fish	A, B, C, E 4030703
72-4B	Life Cycle Invertebrate	A, B, C, E 40380702
122-1B	Vegetative Vigor	A, B, C, E 40165102
122-2	Aquatic Plant Growth	A, B, C, E 40165103, 40165104, 40165105
123-1B	Vegetative Vigor	41883001, another study reqd
123-2	Aquatic Plant Growth	41883002, D212863 in rev.
141-1	Honey Bee Acute Contact	A, B, C, E 00131562, 40208001
<u>TOXICOLOGY</u>		
81-1	Acute Oral Toxicity - Rat	A, B, C, E 00081506
81-2	Acute Dermal Toxicity - Rabbit/Rat	A, B, C, E 00100614
81-3	Acute Inhalation Toxicity - Rat	A, B, C, E
81-4	Primary Eye Irritation - Rabbit	A, B, C, E 00081507
81-5	Primary Dermal Irritation - Rabbit	A, B, C, E 00107903
81-6	Dermal Sensitization - Guinea Pig	A, B, C, E 00155475
81-8	Acute Neurotoxicity - Rat	42666801
82-1A	90-Day Feeding - Rodent	A, C, E 40185601
82-2	21-Day Dermal - Rabbit/Rat	00145056
82-4	90-Day Inhalation - Rat	40301701
82-4B	21-Day Inhalation - Rat	40440801
82-7	Subchronic Neurotoxicity - Rats	42616101

Data Supporting Guideline Requirements for the Reregistration of Diquat Dibromide

REQUIREMENT	USE PATTERN	CITATION(S)
83-1A	Chronic Feeding Toxicity - Rodent	00145855, 00155474
83-1B	Chronic Feeding Toxicity - Non-Rodent	41730301
83-2A	Oncogenicity - Rat	00145855, 00160673
83-2B	Oncogenicity - Mouse	42219801
83-2B	Oncogenicity - Mouse	42880701, 42905901, 42919501
83-3A	Developmental Toxicity - Rat	224405, 41198902, 00061637
83-3B	Developmental Toxicity - Rabbit	00061635, 41198901
83-4	2-Generation Reproduction - Rat	41531301
84-2A	Gene Mutation (Ames Test)	40323103, 40323101
84-2B	Structural Chromosomal Aberration	40323106, 40323107, 40323104, 00061638
85-1	General Metabolism	00055107, 00065592, 00065593
85-2	Dermal Penetration	41238701
85-2 (sp)	Dermal Absorption	41247201, 41247202 41247203, 41247204
ENVIRONMENTAL FATE		
161-1	Hydrolysis	A,B,C,E 000154100
161-2	Photodegradation - Water	A,B,C,E 40418801
161-3	Photodegradation - Soil	A,B,C,E 40246101
162-1	Aerobic Soil Metabolism	A,B,C,E 40972301
162-2	Anaerobic Soil Metabolism	A,B,C,E 40972302

Data Supporting Guideline Requirements for the Reregistration of Diquat Dibromide

REQUIREMENT	USE PATTERN	CITATION(S)
162-3 Anaerobic Aquatic Metabolism	A, B, C, E	40972302
162-4 Aerobic Aquatic Metabolism	A, B, C, E	40927601
163-1 Leaching/Adsorption/Desorption	A, B, C, E	40348601
163-2 Volatility - Lab	A, B, C, E	40245101
164-1 Terrestrial Field Dissipation:soil	A, B, C, E	42060301, 4260302
164-2 Aquatic Field Dissipation	A, B, C, E	40917403
164-5 Long Term Soil Dissipation	A, B, C, E	40335201
165-4 Bioaccumulation in Fish	A, B, C, E	40326901
165-5 Bioaccumulation - Aquatic NonTarget	E	40326903 40326902 40326904 40380701

RESIDUE CHEMISTRY

171-4A Nature of Residue - Plants	A, B, D	00055086, 00056905, 00065600, 00065602, 00067157, 00067162, 00068221, 00115563, 00115583, 00116728, 00121305, 00121307, 40001301, 40391501, 41149401, 43028401
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Data Supporting Guideline Requirements for the Reregistration of Diquat Dibromide

REQUIREMENT	USE PATTERN	CITATION(S)
171-4B	Nature of Residue - Livestock	00065594, 00065595, 00065596, 00065597, 00065599, 00065560, 00068229, 00071328, 00114410, 00122705, 40535001, 40555501
171-4C/D	Residue Analytical Method - Plants	00071325, 00071326, 00114449, 00115546, 00115547, 00115559, 00116728, 00116736, 00116739, GS0288002, 40308001, 40308002, 40555501, data gap
171-4E	Storage Stability	40427601, 40811101, 40811102, 40811103, 41940905
171-4F	Magnitude of the Residue in Potable Water	00068228, 00068229
171-4G	Magnitude of the Residue in Fish and Shellfish	PP#1F1101, 00068228, 00135717, 40427601
171-4H	Magnitude of the Residue in Irrigated Crops	00031836, 40535905
171-4J	Magnitude of the Residue in Poultry and Eggs	No MRID no.
	Cattle, goats, hogs, horses, and sheep	00031841, 00140582
	Poultry and Eggs	00116739

Data Supporting Guideline Requirements for the Reregistration of Diquat Dibromide

REQUIREMENT	USE PATTERN	CITATION(S)
Milk		00031841, 00140582
171-4k Magnitude of Residues -Plants		42822002, 40535901
 <u>Root and Tuber Vegetables Group</u>		
Potato		00116728, 00140590
<u>Fruiting Vegetables Group</u>		
Pepper		No MRID no.
Tomato		No MRID no.
<u>Curcubit Vegetables Group</u>		
Cantaloupe		
Cucumber		
Squash		
Watermelon		
 <u>Miscellaneous Commodities</u>		
Sugarcane		00100410, 00140586
 <u>Crops Grown Solely for Seed</u>		
Alfalfa		40535901, 42822002
Carrot		00067154
Clover		40535902, 42822001
Radish		No MRID no.

Data Supporting Guideline Requirements for the Reregistration of Diquat Dibromide

REQUIREMENT	USE PATTERN	CITATION(S)
	Sorghum	00115575, 40535903
	Soybean	00115575, 40535904
	Turnip	No MRID no.
	Vetch	No MRID no.
171-4I	Magnitude of Residues - Processed Food/Feed	

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Diquat Dibromide

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.

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APPENDIX D. List of Available Related Documents

The following is a list of available documents related to Diquat Dibromide. It's purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for Diquat Dibromide and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters
2. Detailed Label Usage Information System (LUIS) Report
3. Diquat Dibromide RED Fact Sheet
4. PR Notice 86-5 (included in this appendix)
5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement

APPENDIX E. PR Notices 86-5 and 91-2

PR Notice 86-5



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

PR NOTICE 86-5

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

- INDEX-

	Text Page	Example Page
A. Organization of the Submittal Package	3	17
B. Transmittal Document	4	11
C. Individual Studies	4	
C. 1 Special Considerations for Identifying Studies	5	
D. Organization of each Study Volume	6	17
D. 1 Study Title Page	7	12
D. 2 Statement of Data Confidentiality Claims (based on FIFRA §10(d)(1))	8	13
D. 3 Confidential Attachment	8	15
D. 4 Supplemental Statement of Data Confidentiality		

Claims (other than those based on FIFRA §10(d)(1))	8	14
D. 5 Good Laboratory Practice Compliance Statement	9	16
E. Reference to Previously Submitted Data	9	
F. Physical Format Requirements & Number of Copies	9	
G. Special Requirements for Submitting Data to the Docket	10	

A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.
- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,.... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, ...250 of 250).

- Include a company name or mark and study number on each page of the study, e.g., Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. **Safety Studies.** Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. **Product Chemistry Studies.** All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

<u>Element</u>	<u>When Required</u>	<u>Example</u>
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or ©	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE.** An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

- a. **Study title.** The study title should be as descriptive as possible. It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.
- b. **Data requirement addressed.** Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.
- c. **Author(s).** Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.
- d. **Study Date.** The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.
- e. **Performing Laboratory Identification.** If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.
- f. **Supplemental Submissions.** If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).
- g. **Facts of Publication.** If the study is a reprint of a published document, identify on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning

with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d) (1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.
- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.
- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.

- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided in three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact John Carley, Chief, Information Services Branch,
Program Management and Support Division, (703) 305-5240.

/S/

James W. Akerman
Acting Director,
Registration Division

Attachment 1.	Sample Transmittal Document
Attachment 2.	Sample Title Page for a Newly Submitted Study
Attachment 3.	Statements of Data Confidentiality Claims
Attachment 4.	Supplemental Statement of Data Confidentiality Claims
Attachment 5.	Samples of Confidential Attachments
Attachment 6.	Sample Good Laboratory Practice Statements
Attachment 7.	Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

+Smith Chemical Corporation
1234 West Smith Street
Cincinnati, OH 98765

-and-

Jones Chemical Company
5678 Wilson Blvd
Covington, KY 56789

+ Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

Vol n Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official:

Name

Signature

Company Name

Company Contact:

Name

Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ Signature _____

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information is voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

<u>CROSS REFERENCE NUMBER 1</u>		This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.	
DELETED WORDS OR PHRASE:		<u>Ethylene Glycol</u>	
<u>PAGE REFERENCE</u>	<u>LINES</u>	<u>REASON FOR THE DELETION</u>	<u>FIFRA</u>
6	14	Identity of Inert Ingredient	§10(d)(C)
28	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

<u>CROSS REFERENCE NUMBER 5</u>		This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.	
DELETED PARAGRAPH(S):			
()	
(Reproduce the deleted paragraph(s) here)	
()	
<u>PAGE</u>	<u>LINES</u>	<u>REASON FOR THE DELETION</u>	<u>FIFRA REFERENCE</u>
20.	2-17	Description of the quality control process	§10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

<u>CROSS REFERENCE NUMBER 7</u>		This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.	
DELETED PAGES(S): are attached immediately behind this page			
<u>PAGES</u>	<u>REASON FOR THE DELETION</u>	<u>FIFRA REFERENCE</u>	
35-41.	Description of product manufacturing process	§10(d)(1)(A)	

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1. _____
2. _____
3. _____

Submitter _____

Sponsor _____

Study Director _____

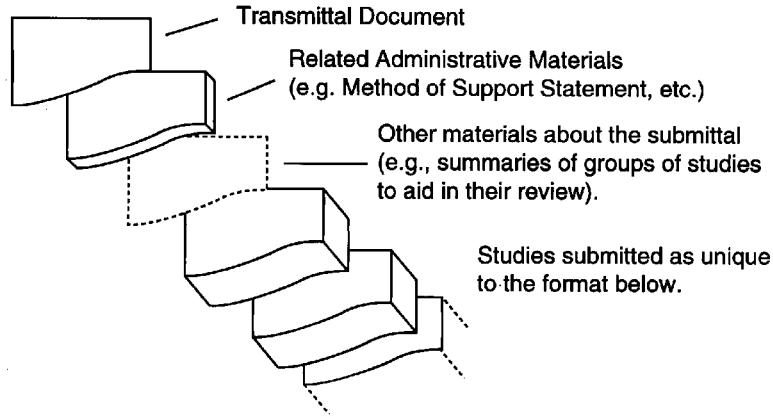
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

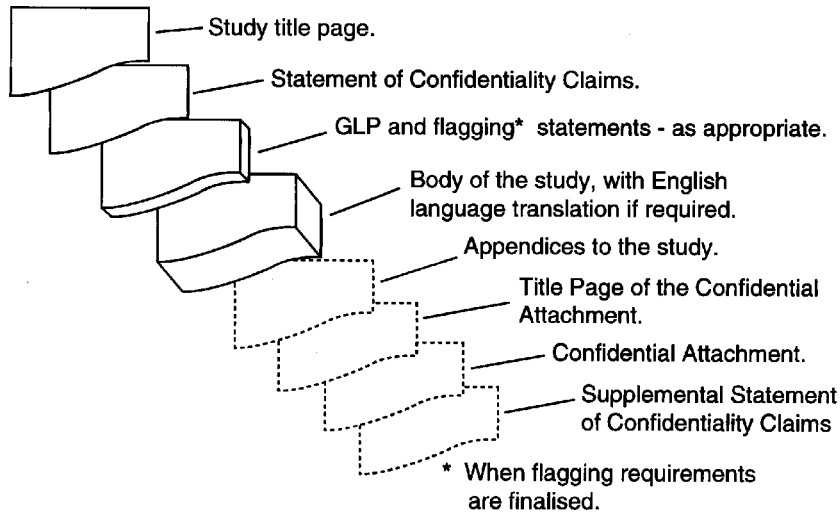
Submitter _____

ATTACHMENT 7.

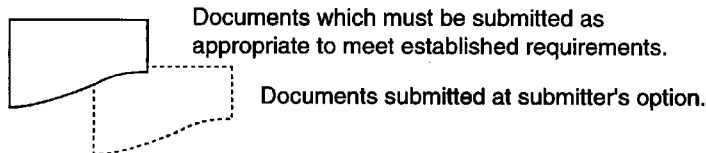
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



PR Notice 91-2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients
Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section 10(b). In this respect the

certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE**," all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be **set based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient Statements must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower than the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B)). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

- (1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.
- (2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

- (3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 308-7031.

/s/
Anne E. Lindsay, Director
Registration Division (H-7505C)

**APPENDIX F. Combined Generic and Product Specific
Data Call-In**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC
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 A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain 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 7; or
2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Registrant's Response Form, (see section III-B); or
3. Why you believe EPA should not require your submission of 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. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is 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 3-31-96).

This Notice is divided into six sections and seven 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 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
- 3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - EPA Acceptance Criteria
- 6 - List of Registrants Receiving This Notice
- 7 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredients.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/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 the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes 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 (Telephone number: 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].

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

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and 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

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic 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.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (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.

a. 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 completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms 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.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7

under item 9 in the instructions for the Requirements Status and Registrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

- (i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;
- (ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and
- (iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data

pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for 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.

2. Product Specific Data Requirements

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 choose 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.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). 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 also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. 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.

a. 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 both the Generic and Product Specific Data Call-In Response Forms. If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose 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.

b. 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.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Registrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic 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 you to additional instructions provided in this Section. The options are:

- (1) I will generate and submit data within the specified timeframe (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. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

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 or protocols. 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

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

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 the 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 to 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 burden 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 normally will 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 '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, means "any material derived from a test system for examination or analysis."

- b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must 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 usually are 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 EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

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 also should 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 ecological effects studies, the classification generally would be a rating of "core." 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.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 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 -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, 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.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.1., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

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, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be

granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i) Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the

environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

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 product specific 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.

SECTION 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:
 - i. 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.
 - ii. Fulfill the commitment to develop and submit the data as required by this Notice; or
 - iii. 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 generally would 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 also must 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 a 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 must include completed Data Call-In Response Forms (Attachment 2) and completed Requirements Status and Registrant's Response Forms (Attachment 3), for both (generic and 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 Generic and Product Specific Data Call-In Response Forms need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois Rossi, Division Director
Special Review and Reregistration Division

Attachments

The Attachments to this Notice are:

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

Attachment 1. Chemical Status Sheets

DIQUAT DIBROMIDE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing Diquat Dibromide.

This Generic 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 Diquat Dibromide. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this Diquat Dibromide Generic Data Call In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Diquat Dibromide are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Diquat Dibromide are needed. These data are needed to fully complete the reregistration of all eligible Diquat Dibromide products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Kylie Rothwell at (703) 308-8055.

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

Kylie Rothwell, Chemical Review Manager
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Diquat Dibromide

DIQUAT DIBROMIDE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Diquat Dibromide. 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 Diquat Dibromide 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 Diquat Dibromide are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Diquat Dibromide 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 Diquat Dibromide products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Diquat Dibromide, please contact Kylie Rothwell at (703) 308-8055.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Frank Rubis at (703) 308-8184.

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

Frank Rubis
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: Diquat Dibromide

**Attachment 2. Combined Generic and Product Specific
Data Call-In Response Forms (Form A inserts) Plus
Instructions**

Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of data call-in (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form. BOTH "Data Call-In Response" forms must be completed.**

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The 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, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

NOTE: Item 6a and 6b are not applicable for Product Specific Data.

Item 7a. ON THE PRODUCT SPECIFIC DATA FORM: 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."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do 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.

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.

NOTE: Item 7a and 7b are not applicable for Generic Data.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS Generic and Product Specific Data Call-In

Item 8. ON BOTH FORMS: This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialed and dated in the space provided for the certification.

Item 9. ON BOTH FORMS: Enter the date of signature.

Item 10. ON BOTH FORMS: Enter the name of the person EPA should contact with questions regarding your response.

Item 11. ON BOTH FORMS: Enter the phone number of your company contact.

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

**Attachment 3. Generic and Product Specific Requirement
Status and Registrant's Response Forms (Form B inserts)
and Instructions**

**Instructions For Completing The
"Requirements Status and Registrant's Response Forms"
For The Generic and Product Specific Data Call-In**

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.** Both "Requirements Status and Registrant's Response" forms must be completed.

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 30 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, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

- Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.
- Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.
ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.
- Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.
ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.
- Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In 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. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

- Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:
- 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 crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the

date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. 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 and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency 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.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. 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 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 apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

Option 5. **ON BOTH FORMS: (Upgrading a Study)** I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

Option 6. **ON BOTH FORMS: (Citing a Study)** I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, 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 the Agency 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). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" for generic data.

Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low-volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" for product specific data.

- Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. 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" form specifying 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.
- Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.
- Item 11. **ON BOTH FORMS:** Enter the date of signature.
- Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.
- Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled

Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

EPA'S BATCHING OF DIQUAT DIBROMIDE END-USE 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 end-use products containing the active ingredient diquat dibromide [6,7-dihydrodipyrido (1,2-a:2',1'-c) pyrazinediium dibromide], 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.

Batching has been accomplished using the readily available information described above. Frequently acute toxicity data on individual end-use products has been found to be incomplete. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual end-use product should the need arise.

Registrants of end-use 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 cited, the registrant must clearly identify the material tested by its EPA registration number. If more than one Confidential Statement Of Formula (CSF) exists for a product registration, 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.

The following information (Table I) lists thirty five products (four batches) containing diquat dibromide.

Table I: Batched Products.

Batch No.	EPA Reg. No.	% Diquat dibromide	Formulation Type
1.	192-177	.23	Ready-To-Use Solution (RTUS)
	478-114	.23	RTUS
	769-945	.23	RTUS
	802-572	.23	RTUS
	9404-75	.23	RTUS
	10583-10	.23	RTUS
	46515-14	.09	RTUS
	46515-15	.19	RTUS
	46515-16	.23	RTUS
2.	192-178	1.84	Emulsifiable Concentrate (EC)
	802-582	1.84	RTUS
	1685-64	2.36	EC
	1769-174	1.85	EC
	2155-43	1.85	EC
	2155-63	1.85	EC
	2155-64	1.85	EC
	8123-37	1.85	EC
	10088-13	1.85	SC
	10088-35	1.85	SC
	10663-11	1.85	SC
	11515-29	1.85	SC
	37347-6	1.85	SC
	48211-23	1.85	SC
3.	8123-102	4.35	SC
	9250-16	4.35	SC
	10182-356	4.35	SC
	10182-377	4.35	SC
	10827-78	4.35	SC
	34704-589	4.35	SC
	4.	10182-353	36.4
10182-354		37.45	Formulation Intermediate (FI)
10182-355		35.3	FI
10182-375		35.3	SC
10182-376		35.3	FI
10182-378		37.45	FI

Seven products (Table II) were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making, and not placed in any batch. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Table II: Products Not Batched

EPA Reg. Number	% Diquat dibromide plus other active ingredient	Formulation Type
228-201	.154 diquat dibromide 2.3 sodium chlorate	RTUS
491-201	2.38 diquat dibromide	EC
5080-4	8.54 diquat dibromide	SC
5197-37	2.16 diquat dibromide	EC
8959-9	8.53 diquat dibromide	SC
9688-93	2.3 diquat dibromide	SC
10583-22	2.7 diquat dibromide	SC

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ___ Name of technical material tested (include product name and trade name, if appropriate).
2. ___ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.
3. ___ Name and upper certified limit for each impurity or each group of impurities present at $> 0.1\%$ by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at $< 0.1\%$.
4. ___ Purpose of each active ingredient and each intentionally-added inert.
5. ___ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.
6. ___ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.
7. ___ Description of each beginning material in the manufacturing process.
 - ___ EPA Registration Number if registered;
 - ___ for other beginning materials, the following:
 - ___ Name and address of manufacturer or supplier.
 - ___ Brand name, trade name or commercial designation.
 - ___ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.
8. ___ Description of manufacturing process.
 - ___ Statement of whether batch or continuous process.
 - ___ Relative amounts of beginning materials and order in which they are added.
 - ___ Description of equipment.
 - ___ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
 - ___ Statement of whether process involves intended chemical reactions.
 - ___ Flow chart with chemical equations for each intended chemical reaction.
 - ___ Duration of each step of process.
 - ___ Description of purification procedures.
 - ___ Description of measures taken to assure quality of final product.
9. ___ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq 0.1\%$ or was found at $\geq 0.1\%$ by product analyses and (2) certain toxicologically significant impurities (see #3).

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1. ___ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at $> 0.1\%$.
2. ___ Degree of accountability or closure $> ca 98\%$.
3. ___ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.].
4. ___ Complete and detailed description of each step in analytical method used to analyze above samples.
5. ___ Statement of precision and accuracy of analytical method used to analyze above samples.
6. ___ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7. ___ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8. ___ Upper certified limit proposed for each impurity present at $> 0.1\%$ and for certain toxicologically significant impurities at $< 0.1\%$ along with explanation of how limit determined.
9. ___ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10. ___ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color

- Verbal description of coloration (or lack of it)
- Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State

- Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
- Based on visual inspection at about 20-25° C

63-4 Odor

- Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
- Observed at room temperature

63-5 Melting Point

- Reported in °C
- Any observed decomposition reported

63-6 Boiling Point

- Reported in °C
- Pressure under which B.P. measured reported
- Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity

- Measured at about 20-25° C
- Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft³ or lbs/gallon.]

63-8 Solubility

- Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
- Measured at about 20-25° C
- Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure

- Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
- Experimental procedure described
- Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant

- Experimental method described
- Temperature of measurement specified (preferably about 20-25° C)

63-11 Octanol/water Partition Coefficient

- Measured at about 20-25° C
- Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
- Data supporting reported value provided

63-12 pH

- Measured at about 20-25° C
- Measured following dilution or dispersion in distilled water

63-13 Stability

- Sensitivity to metal ions and metal determined
- Stability at normal and elevated temperatures
- Sensitivity to sunlight determined

SUBDIVISION F

<u>Guideline</u>	<u>Study Title</u>
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ___ Identify material tested (technical, end-use product, etc).
2. ___ At least 5 young adult rats/sex/group.
3. ___ Dosing, single oral may be administered over 24 hrs.
4. ___ Vehicle control if other than water.
5. ___ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6. ___ Individual observations at least once a day.
7. ___ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8. ___ Individual daily observations.
9. ___ Individual body weights.
10. ___ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. Identify material tested (technical, end-use product, etc).
2. At least 5 animals/sex/group.
3. * Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4. Dosing, single dermal.
5. Dosing duration at least 24 hours.
6. * Vehicle control, only if toxicity of vehicle is unknown.
7. Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8. Application site clipped or shaved at least 24 hours before dosing.
9. Application site at least 10% of body surface area.
10. Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11. Individual observations at least once a day.
12. Observation period to last at least 14 days.
13. Individual body weights.
14. Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ___ Identify material tested (technical, end-use product, etc).
2. ___ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 μm or less).
3. ___ At least 5 young adult rats/sex/group.
4. ___ Dosing, at least 4 hours by inhalation.
5. ___ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6. ___ Chamber temperature, 22° C (+ 2°), relative humidity 40-60%.
7. ___ Monitor rate of air flow.
8. ___ Monitor actual concentrations of test material in breathing zone.
9. ___ Monitor aerodynamic particle size for aerosols.
10. ___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11. ___ Individual observations at least once a day.
12. ___ Observation period to last at least 14 days.
13. ___ Individual body weights.
14. ___ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ___ Identify material tested (technical, end-use product, etc).
2. ___ Study not required if material is corrosive, causes severe dermal irritation or has a pH of ≤ 2 or ≥ 11.5 .
3. ___ 6 adult rabbits.
4. ___ Dosing, instillation into the conjunctival sac of one eye per animal.
5. ___ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6. ___ Solid or granular test material ground to a fine dust.
7. ___ Eyes not washed for at least 24 hours.
8. ___ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
- 9.* ___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ___ Identify material tested (technical, end-use product, etc).
2. ___ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5 .
3. ___ 6 adult animals.
4. ___ Dosing, single dermal.
5. ___ Dosing duration 4 hours.
6. ___ Application site shaved or clipped at least 24 hours prior to dosing.
7. ___ Application site approximately 6 cm².
8. ___ Application site covered with a gauze patch held in place with nonirritating tape.
9. ___ Material removed, washed with water, without trauma to application site.
10. ___ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
- 11.* ___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. Identify material tested (technical, end-use product, etc).
2. Study not required if material is corrosive or has a pH of < 2 or > 11.5.
3. One of the following methods is utilized:
 - Freund's complete adjuvant test
 - Guinea pig maximization test
 - Split adjuvant technique
 - Buehler test
 - Open epicutaneous test
 - Mauer optimization test
 - Footpad technique in guinea pig.
4. Complete description of test.
5. * Reference for test.
6. Test followed essentially as described in reference document.
7. Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an * are supplemental and may not be required for every study.

**Attachment 6. List of All Registrants Sent This Data Call-In (insert)
Notice**

**Attachment 7. Cost Share, Data Compensation Forms, Confidential
Statement of Formula Form and Instructions**

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

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 % by Weight
 b. % by Weight

14. Certified Limits % by Weight
 a. Upper Limit
 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

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.
- l. 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 all 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.



United States Environmental Protection Agency
Washington, DC 20460

**CERTIFICATION OF OFFER TO COST
SHARE IN THE DEVELOPMENT OF DATA**

Form Approved

OMB No. 2070-0106
2070-0057

Approval Expires 3-31-96

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-223, 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 firm(s) 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)	



**CERTIFICATION WITH RESPECT TO
DATA COMPENSATION REQUIREMENTS**

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:

1. For each study cited in support of registration or reregistration 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)

APPENDIX G. FACT SHEET



R.E.D. FACTS

Pesticide Reregistration

Diquat Dibromide

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0288, diquat dibromide.

Use Profile

Diquat dibromide is a non-selective contact herbicide, algicide, desiccant, and defoliant. As a herbicide/algicide, it is used to control broadleaf and grassy weeds in non-crop (including residential) and aquatic areas. As a desiccant/ defoliant, it is used in seed crops and potatoes. Its largest use is as a desiccant on potato crops.

Diquat dibromide is formulated as a soluble concentrate and ready-to-use liquid. As a herbicide, it is applied using a hand-held or mechanical sprayer; as an algicide, it is injected below the water surface to control submerged weeds. When used as a desiccant, it may be applied by aircraft or ground equipment. Applications in crop areas are made five days to two weeks before harvest.

Use practice limitations include...

Regulatory History

Diquat dibromide is the common name for 6,7-dihydrodipyrido (1,2-a:2',1'-c) pyrazinediium dibromide. The manufacture of diquat dibromide may result in the formation of ethylene dibromide (EDB) as a process impurity. EDB is considered a carcinogen, and all pesticide uses have been cancelled. EPA assessed the potential exposure risks of diquat dibromide and concluded in June 1986 that the presence of EDB does not pose a significant dietary risk, based on worst case assumptions. In addition, the registrant certified an upper limit of 10 parts per billion for EDB in diquat dibromide, and demonstrated that EDB does not persist and will slowly dissipate over time in diquat dibromide.

EPA issued a Registration Standard for diquat dibromide in June 1986 (NTIS #PB87-105490). A 1991 Data Call-In required additional toxicology, ecological effects, environmental fate, and residue chemistry data. Currently, 43 products containing the active ingredient diquat dibromide are registered and marketed under the trade name Diquat.

Human Health Assessment

Toxicity

In studies using laboratory animals, diquat dibromide has been shown generally to be of moderate toxicity. It can cause slight to severe eye irritation and has been placed in Toxicity Category II (the second highest of four categories) for acute dermal and eye irritation effects. It is slightly acutely toxic by the oral and inhalation routes and has been placed in Toxicity Category III for these effects. Diquat dibromide causes slight dermal irritation and has been placed in Toxicity Category IV for this effect. It is not a skin sensitizer.

A supplemental subchronic dermal toxicity study using rabbits indicated that diquat dibromide is toxic via repeated dermal exposure. A second dermal study using rats resulted in high mortality, decreased food consumption and weight gain, congestion in the lungs, liver and kidneys, and dermal irritation at the application site. An inhalation study using rats resulted in increases in lung weight, lung/body weight and lung/brain weight, lung lesions, and mottling and reddening of the lungs in females; however, all effects except the latter were reversible. A second inhalation study using rats showed no effects on any of the parameters examined.

A chronic feeding/carcinogenicity study using rats resulted in eye effects including lens opacity and severe cataracts. A feeding study using beagle dogs showed some incidence of cataracts, and decreased adrenal and epididymide weights in males.

Another chronic feeding/cancer study using rats resulted in evidence of bone tumors. The Agency's Health Effects Division Reference Dose/Peer Review Committee evaluated the carcinogenic potential of diquat dibromide in March 1994 and classified it as a Group E carcinogen --a chemical for which there is evidence of non-carcinogenicity for humans--based on a lack of

evidence in studies with two species, rat and mouse. In a study using mice, diquat was not carcinogenic.

A supplemental developmental toxicity study using rats resulted in maternal toxicity and developmental toxicity only at the highest dose level. Another more recent study using rats resulted in effects at high dose levels including decreases in fetal and litter weights, kidney effects, and incomplete development of certain bones. In a supplementary study using rabbits, decreased body weight gain in the high dose group was the only maternal toxicity observed. A recent study using rabbits resulted in developmental effects only in the high dose group, including liver effects and poor ossification. A study using mice resulted in developmental toxicity only in the high dose group, including decreased fetal body weight and increased skeletal alterations.

A reproductive toxicity study using rats resulted in effects at the highest dose level including decreased numbers of live pups per litter and decreased body weight gain. Diquat dibromide was negative in four mutagenicity studies and positive in two other studies. Metabolism studies indicate that it is poorly absorbed from the gastrointestinal tract and primarily excreted in urine. An acute neurotoxicity study using rats resulted in symptoms that may not be due to direct neurotoxicity. In a subchronic neurotoxicity study, toxic signs observed only in the high dose group included cataracts and decreased body weight gain and food utilization.

Dietary Exposure

People may be exposed to residues of diquat dibromide through the diet. Tolerances or maximum residue limits have been established for a variety of crop and animal commodities (please see 40 CFR 180.226 (a) and (b)). A food additive tolerance is established for residues in potable water (40 CFR 185.2500 (a) and (b)). Food and feed additive tolerances also are established for residues in processed potatoes (including potato chips) (40 CFR 185.2500 (c)) and processed potato waste (40 CFR 186.2600).

The registrant has proposed revised tolerances for many commodities, some at EPA's recommendation. A tolerance for sugarcane must be revoked since this use is no longer registered. A tolerance for potable water also will be revoked since it has been replaced with a Maximum Contaminant Level Goal (MCLG) under the Safe Drinking Water Act. The U.S. tolerances for eggs, poultry, meat, and offal may be raised to achieve harmonization with Codex Maximum Residue Levels (MRLs). With these changes, diquat dibromide tolerances are considered appropriate.

EPA has assessed the dietary risk posed by diquat dibromide considering both published and proposed tolerances. The Anticipated Residue Concentration (ARC) for the overall U.S. population and 22 subgroups represents 31% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The most highly

exposed subgroup, non-nursing infants less than one year old, has an ARC which represents 49% of the RfD. Diquat dibromide's chronic dietary risk is therefore considered minimal.

Occupational and Residential Exposure

Based on current use patterns, workers (mixers, loaders, applicators, and other handlers) may be exposed to diquat dibromide during and after application in agricultural and other settings. During large-scale applications, the highest potential exposure and risks are to mixers and loaders using open systems to support aerial applications (their dermal Margin of Exposure (MOE) is 71, less than the 100-fold margin considered acceptable). Using closed systems, their dermal MOE is 400. EPA therefore is requiring closed mixing/loading of diquat dibromide for aerial applications.

For applicators participating in large-scale applications and for all workers (including homeowners) participating in small-scale applications, MOEs are greater than 100.

Post-application exposure to diquat dibromide residues on treated foliage is a concern. For uses within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS), EPA is requiring a longer interim Restricted Entry Interval (REI) and more stringent personal protective equipment (PPE) than usual, to reduce potential exposure and risk (see Risk Mitigation below).

For uses outside the scope of the WPS, post-application exposure risks also are posed. For example, golf course workers who have substantial physical contact with treated turf have a MOE of 13, 24 hours after application. At four days post-application, the MOE rises to 105. Therefore, a four-day reentry interval is being recommended for these workers. To reduce the potential for post-application residential exposure, spot treatments will be acceptable but broadcast treatments will be prohibited. Swimmers may be exposed to diquat dibromide residues in treated lakes and ponds, however their estimated MOE of 1,250 is acceptable.

Human Risk Assessment

Diquat dibromide is of moderate acute toxicity causing acute dermal toxicity and primary eye irritation (Toxicity Category II). It is classified as a Group E carcinogen, indicating that it poses no known cancer risk for humans. Diquat dibromide causes developmental and reproductive toxicity at the highest dose levels tested. Human incident data from California and other sources were considered in evaluating diquat dibromide's risks.

Although people may be exposed to residues of diquat dibromide through their diets, the chronic dietary risk from such exposure is minimal. EPA is concerned about worker exposure to diquat dibromide during aerial spray operations, and is requiring use of closed systems to mitigate potential risks. The Agency also is concerned about post-application/reentry exposure for uses both within and outside the scope of the WPS. EPA therefore is imposing stringent reentry restrictions and protective clothing requirements

for commercial uses, and is limiting residential use to spot treatments with label directions warning these users not to touch treated plants until sprays have dried.

Environmental Assessment

Environmental Fate

Diquat dibromide's primary route of environmental dissipation is strong adsorption to soil particles. Diquat does not hydrolyse or photodegrade and is resistant to microbial degradation under aerobic and anaerobic conditions. No major degradates have been isolated. When used as an aquatic herbicide, diquat dibromide is removed from the water column by adsorption to soil sediments, aquatic vegetation, and organic matter. Adsorbed diquat dibromide is persistent and immobile, and is not expected to be a ground-water contaminant.

Ecological Effects

Diquat dibromide is moderately toxic to birds in acute studies, and is slightly to moderately toxic on a subacute dietary basis. It is practically non-toxic to bees. In acute studies, diquat dibromide is slightly to moderately toxic to both cold and warm water fish. In fish early life stage studies, it ranges in toxicity from slightly to moderately toxic. It is slightly to highly toxic to both aquatic invertebrates and estuarine species. Additional studies are required to determine diquat dibromide's toxicity to nontarget aquatic and terrestrial plants.

Ecological Effects Risk Assessment

High acute risk to birds is not expected from use of diquat dibromide. However, the turf use exceeds EPA's level of concern for restricted use, and for endangered bird species feeding on short grass. Regarding chronic effects, birds feeding on diquat dibromide-contaminated food items may experience reproductive problems.

Diquat dibromide will pose only a low overall risk to mammals. Effects, if they occur, should not result in significant ecological damage. However, the Agency is only moderately certain that nonendangered mammals are not at acute risk from diquat dibromide, which exceeds the restricted use level of concern for all uses except cantaloupes. The level of concern for endangered species is exceeded for all use patterns. Chronic risks to mammals are believed to be low.

Diquat dibromide may pose acute or chronic risk to aquatic organisms, but the probability that exposure will occur is relatively low. It is therefore expected to pose only a minimal risk to aquatic organisms from exposure to runoff. Diquat dibromide does not cause adverse effects to freshwater fish. Freshwater invertebrates are not likely to be adversely affected by its use in the short term, but their reproductive success may be adversely effected.

Drift from aerial spraying of diquat dibromide is likely to result in adverse effects to plants. The possibility of risk to non-target aquatic and terrestrial plants from aerial application from all sites is relatively high.

Diquat dibromide poses only minimal risk to non-target insects. However, levels of concern have been exceeded for endangered species of mammals and birds from all terrestrial use sites.

Risk Mitigation

EPA is requiring the following risk mitigation measures for diquat dibromide:

Aquatic Risk Mitigation - To protect aquatic organisms, EPA is requiring labeling that limits application of diquat dibromide to one-third or one-half of the dense weed areas in a water body, and prohibits subsequent applications for two weeks. The untreated part of the water body will act as a refuge for aquatic organisms, and the two-week waiting period allows time for oxygen levels to recover before further applications are made.

Spray Drift Risk Mitigation - Since the possibility of risk to non-target aquatic and terrestrial plants from aerial application is high, EPA is requiring that a Spray Drift Advisory which recommends best management practices to minimize spray drift appear on labels of products that can be applied aerially.

Application and Post-Application Risk Mitigation - To protect handlers during agricultural use, EPA is requiring closed mixing/loading of diquat dibromide liquid formulations for aerial applications, in keeping with WPS provisions. EPA also is requiring a 7-day interim Restricted Entry Interval (REI) for all uses within the scope of the WPS, as well as more stringent Personal Protective Equipment (PPE) including protective eyewear for early-entry workers.

For occupational uses that are not within the scope of the WPS (primarily the turf use), EPA is establishing a 4-day entry restriction for workers.

EPA is retaining the 24-hour swimming prohibition on diquat dibromide products with aquatic uses. Swimmers are prohibited from swimming in treated water for 24 hours.

To protect home users, EPA is establishing an entry restriction for spot treatment applications (label directions warning people and pets not to touch treated plants until sprays have dried), and is prohibiting broadcast applications at residential sites.

Additional Data Required

EPA is requiring the following additional generic data for diquat dibromide to confirm its regulatory assessments and conclusions:

- Enforcement method for plant and animal commodities (independent laboratory validation);
- Product chemistry.

Although not part of the target data base, the following studies also are required:

- Terrestrial plant studies; vegetative vigor.

The Agency is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All diquat dibromide end-use products must comply with EPA's current pesticide product labeling requirements, and with the additional requirements summarized below. Please see the RED document for a complete list of labeling requirements.

Personal Protective Equipment (PPE) Requirements

For Occupational Use

The minimum, baseline PPE for all diquat dibromide WPS and nonWPS occupational end-use products is:

"Applicators and other handlers must wear:

- Coveralls over long-sleeved shirt and long pants;
- Chemical-resistant gloves;
- Chemical-resistant footwear plus socks;
- Chemical-resistant headgear for overhead exposure;
- Chemical-resistant apron when cleaning equipment, mixing, or loading;
- A dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C).

The PPE that would normally be established based on the toxicity of the end-use product must be compared to the minimum PPE specified above, and the more protective PPE must be placed on the product labeling.

Entry Restrictions

For Occupational Use

A 7-day restricted entry interval (REI) is required for uses within the scope of the WPS. The PPE required for early entry is:

- Coveralls over long-sleeved shirt and long pants;
- Chemical-resistant gloves;
- Chemical-resistant footwear plus socks;
- Chemical-resistant headgear for overhead exposures;
- Protective eyewear.

For products with non-WPS sites such as golf courses, parks, etc., the following statement is required:

"For 4 days following applications to non-crop areas (other than aquatic or residential sites), do not allow employees to have contact with the treated plants, except for contact with their footwear."

For Home Use

For spot treatments to residential sites, the following statement is required:

"Do not allow people or pets to touch treated plants until the sprays have dried."

Other Labeling Requirements

For Occupational Use

- 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."

- Engineering Controls:

"Mixers and loaders supporting aerial applications are required to use closed systems. The closed system must be used in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for Agricultural Pesticides (40 CFR 170.240(d)(4)). When using the closed system, the mixers' and loaders' PPE requirements may be reduced or modified as specified in the WPS."

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for Agricultural Pesticides (40 CFR 170.240(d)(4-6)), the handler PPE requirements may be reduced or modified as specified in the WPS."

- User Safety Requirements:

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

- 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."

For Home Use

- Application Restrictions:

"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Only persons applying this product may be in the area during application."

- User Safety Recommendations:

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- "Clothing and protective equipment exposed to this product should be washed in detergent and hot water. Such items should be kept and washed separately from other laundry."
 - "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."

Environmental Hazard -

For products intended for terrestrial nonfood sites, use this precautionary statement:

"This pesticide is toxic to aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."

For products intended for outdoor residential sites, use this precautionary statement:

"This pesticide is toxic to aquatic invertebrates. Do not apply directly to water."

Spray Drift Label Advisory

See the diquat dibromide RED document for the complete text of this Label Advisory, which must be placed on the labeling of each product that can be applied aerially.

Regulatory Conclusion

The use of currently registered products containing diquat dibromide in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Diquat dibromide products will be reregistered once the required product specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for diquat dibromide during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet 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*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the diquat dibromide RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the diquat dibromide RED, or reregistration of individual products containing diquat dibromide, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 8:00 pm Eastern Standard Time, Monday through Friday.