United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA 738-R-94-018
September 1994

Reregistration Eligibility Decision (RED)

Difenzoquat

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 active ingredient difenzoquat. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED". This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses 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 Gee at (703) 308-8008. Address any questions on required **generic** data to the Special Review and Reregistration Division representative Andrew Ertman at (703) 308-8063.

Sincerely yours,

Louis P. True, Jr., Acting 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, another DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); 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 should be submitted in the 90-day response, but certainly no later than the 8-month response date. 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

DIFENZOQUAT

LIST A

CASE 0223

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

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DIFENZOQUAT REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

George W. Keitt, Jr.	Biological Analysis Branch
Arthur Grube	Economic Analysis Branch
Ghulam Ali	Economic Analysis Branch
Margaret Cogdell	LUIS Staff

Environmental Fate and Effects Division

Sharlene Matten	Science Analysis and Coordination Staff
Mike Rexrode	Ecological Effects Branch
Richard Mahler	Environmental Fate and Groundwater Branch

Health Effects Division

Charles Frick	Chemical Coordination Branch
Krystyna Locke	Toxicology Branch I
Susan Hummel	Reregistration Support Chemistry Branch
Jeff Evans	Occupational and Residential Exposure Branch
Steven Schaible	Science Analysis Branch

Registration Division

Dan Kenny	Fungicide-Herbicide Branch
Mark J. Perry	Registration Support Branch

Special Review and Reregistration Division

Andrew Ertman	Reregistration Branch
Walt Waldrop	Reregistration Branch
Carol Stangel	Policy, Planning and Operations Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid equivalent
a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
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
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.

GLOSSARY OF TERMS AND ABBREVIATIONS

LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOC	Level of Concern
LOEL	Lowest Observed Effect Level
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.
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MOE	Margin Of Exposure
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
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts Per Million
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RED	Reregistration Eligibility Decision

GLOSSARY OF TERMS AND ABBREVIATIONS

RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TGAI	Technical Grade Active Ingredient
TMRC	Theoretical Maximum Residue Contribution

EXECUTIVE SUMMARY

This Reregistration Eligibility Decision document (RED) addresses the reregistration eligibility of the pesticide difenzoquat, 1,2-dimethyl-3,5-diphenyl-1H-pyrazolium.

Difenzoquat is a postemergent herbicide that is produced by American Cyanamid Company and marketed under the trade name Avenge®. Difenzoquat is used to control wild oats (*Avena fatua*) in barley and wheat. Wild oats is an annual grassy weed with growth habits that out-compete wheat and barley and create serious yield losses. There is one manufacturing use product and one end-use formulation of difenzoquat; a soluble concentrate/liquid (SC/L). This formulation is applied postemergence as a ground or aerial broadcast treatment.

Difenzoquat was first registered as a pesticide in July, 1975. A Registration Standard was issued in December, 1988 (NTIS# PB89-162127). This Registration Standard summarized available data supporting the registration of products containing difenzoquat used as a herbicide for control of wild oats in alfalfa (seed crop in CA), barley and wheat. The use on alfalfa is no longer registered. The Registration Standard also required additional product chemistry, residue chemistry, toxicology, and environmental fate data.

The Agency has now completed its review of the difenzoquat target data base including data submitted in response to the 1988 Registration Standard and has determined that the uses of difenzoquat as currently registered will not cause unreasonable adverse effects to humans or the environment. All currently registered uses of difenzoquat are eligible for reregistration. The Agency is requiring additional studies in the residue chemistry, toxicology, environmental fate and ecological effects disciplines that will be called in on a confirmatory basis. The following data are required: an acute neurotoxicity screening battery in the rat, a 90-day neurotoxicity screening battery in the rat, additional data to upgrade a previously submitted confined rotational crop study, a non-guideline bridging study in lieu of additional terrestrial field dissipation studies, spray drift studies and phytotoxicity data.

Difenzoquat was classified "Group E" as to its carcinogenic potential (Evidence of non-carcinogenicity for humans) by the Office of Pesticide Programs (OPP) Reference Dose RfD/Peer Review Committee on 2/24/94. The Committee recommended that the RfD for difenzoquat be established at 0.2 mg/kg/day. This value was based on the systemic NOEL of 20 mg/kg/day from the one-year dog feeding study and an uncertainty factor (UF) of 100. The Theoretical Maximum Residue Contribution (TMRC) for the over all U.S. population from existing and proposed tolerances is 0.1% of the RfD. The subgroup most highly exposed, children aged one through six has an Anticipated Residue Contribution (ARC) of 0.2% of the RfD. All existing difenzoquat tolerances have been reassessed and no changes are required. New tolerances must be established for wheat bran wheat shorts, barley hulls, and barley bran.

There are no toxicological endpoints of concern for workers with the exception of acute eye irritation (Toxicity Category I). Because difenzoquat does not meet the Agency's

toxicity criteria, neither handler (mixer/loader/applicator) nor postapplication/reentry data are required to support the reregistration of difenzoquat. Because difenzoquat is in toxicity category I for primary eye irritation, the 48 hour restricted entry interval (REI) imposed by the Worker Protection Standard (WPS) will be maintained.

Based on the existing data base, it is the Agency's conclusion that the use of difenzoquat as a herbicide will not pose a serious acute or chronic environmental threat. Difenzoquat only poses minimum acute and chronic risks to avian, mammalian and aquatic species, and non-target insects. Since difenzoquat is an herbicide, it is anticipated that the risk to non-target aquatic and terrestrial plants will be high. Additional data on phytotoxicity to non-target plants are being required.

Difenzoquat has been shown to be persistent and relatively immobile. However, the environmental fate assessment is not comprehensive because the route of dissipation has not been determined. The field dissipation studies contrast with laboratory data and indicate that difenzoquat residues decline with time. It appears from the laboratory data that difenzoquat is immobile in soil and the potential for ground water contamination is minimal. Additional data are required on a confirmatory basis comparing the recovery of difenzoquat between the methods used in laboratory and field studies.

Confirmatory data are required on confined rotational crops, terrestrial field dissipation, and spray drift. Data that are not part of the target data base are also required on neurotoxicity and phytotoxicity. The neurotoxicity data are required based on the results of the one-year dog feeding study and the developmental toxicity study in rats. Additional data are required to upgrade an existing confined rotational crop study. The dissipation data are required to determine the actual route of dissipation of difenzoquat in the field. The phytotoxicity data are required to refine the Agency's assessment that difenzoquat, as an herbicide, will be harmful to non-target aquatic and terrestrial plants. The spray drift data are required because difenzoquat is applied aerially.

Before reregistering the products containing difenzoquat, 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 registration" 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 difenzoquat. The document consists of six sections. Section I is the introduction. Section II describes difenzoquat, 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 difenzoquat. Section V discusses the reregistration requirements for difenzoquat. 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 Document:

- **Common Name:** Difenzoquat
- **Chemical Name:** 1,2-dimethyl-3,5-diphenyl-1H-pyrazolium
- **Chemical Family:** Pyrazolium
- **CAS Registry Number:** 43222-48-6 (salt)
- **OPP Chemical Code:** 106401 (salt)
- **Empirical Formula:** $C_{18}H_{20}N_2O_4S$ (salt)
- **Trade and Other Names:** Avenge®
- **Basic Manufacturer:** American Cyanamid Company

B. Use Profile

The following is information on the current registered uses with an overview of use sites and application methods. A detailed table of the uses of difenzoquat can be found in Appendix A.

For Difenzoquat:

Type of Pesticide: Herbicide

Use Sites: Barley and Wheat

Target Pests: Wild Oats

Formulation Types Registered: Soluble Concentrate/Liquid (SC/L)

Method and Rates of Application:

Equipment	Aerial and ground equipment
Method and Rate	Broadcast 0.6 - 1.0 lb cation/acre
Timing	Postemergence treatment

C. Estimated Usage of Pesticide

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

Name of Site	Acres Planted[1] (000)	Acres Treated (000)	Percentage of Acres[2]	Active Ingredient[2] lbs a.i. (000)	Percentage of Total Difenzoquat Use
BARLEY	8,321	< 416	< 5	30 - 85	23 - 36
WHEAT[3]	73,141	200 - 300	< 0.5	100 - 150	64 - 77
TOTAL	81,462	200 - 716		130 - 235	

1 Three years 1990 - 1992 average is reported.
2 Sources: EPA Proprietary Sources
USDA
Agricultural Chemical Usage, 1992 Field Crops Summary, March, 1993
3 For wheat 1992 usage data is reported.

D. Data Requirements

Data requested in the December, 1988 Registration Standard for difenzoquat included studies on product chemistry, residue chemistry, toxicology, ecological effects, and environmental fate. These data were required to support the uses listed in the Registration Standard. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Difenzoquat is the accepted common name for 1,2-dimethyl-3,5-diphenyl-1H-pyrazolium. It is manufactured by American Cyanamid Company and is marketed under the trade name Avenge®. Avenge® contains the methyl sulfate salt of difenzoquat.

Difenzoquat was first registered in July, 1975 for use on wheat and barley to control wild oats (*Avena fatua*). Currently wheat and barley are the only crops upon which difenzoquat is used. Difenzoquat is a postemergent herbicide that is readily absorbed by plants and is not significantly metabolized or further degraded.

In December, 1988, EPA issued a Registration Standard for products containing difenzoquat methyl sulfate as an active ingredient (NTIS# PB89-162127). A Pesticide Fact Sheet for difenzoquat was also issued in December, 1988 (NTIS# PB89-162119). These documents provide a summary and the rationale of the regulatory position for difenzoquat at that time.

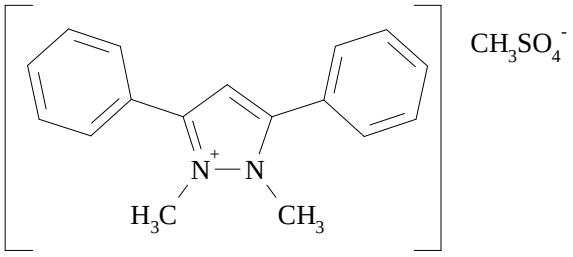
Currently, there are two active products containing difenzoquat methyl sulfate which are registered under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act. They consist of a 96% technical (manufacturing use) product and a 31.2% soluble concentrate end-use product.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

DESCRIPTION OF CHEMICAL

Difenzoquat (1,2-dimethyl-3,5-diphenyl-1*H*-pyrazolium ion) is formulated as a methyl sulfate salt for use as a selective herbicide for the postemergence control of wild oats in barley and wheat.



Empirical Formula:	$C_{17}H_{17}N_2$(ion)
	$C_{18}H_{20}N_2O_4S$ (salt)
Molecular Weight:	249.3 (ion)
	360.4 (salt)
CAS Registry No.:	49866-87-7 (ion)
	43222-48-6 (salt)
Shaughnessy No.:	106402 (ion)
	106401 (salt)

IDENTIFICATION OF ACTIVE INGREDIENT

Technical difenzoquat methyl sulfate is an odorless, colorless to pale yellow crystalline solid with a melting point of 156-158^0 C and bulk density of 0.796 g/mL.

Difenzoquat methyl sulfate is soluble in water and methanol, slightly soluble in acetone and ethylene dichloride, and nearly insoluble in most organic solvents.

MANUFACTURING-USE PRODUCTS

There is one manufacturing-use product (MP) registered for difenzoquat methyl sulfate, which is the American Cyanamid 96% technical (T; EPA Reg. No. 241-239). There are no registered MPs for the difenzoquat ion (Shaughnessy No. 106402). The American Cyanamid 96% T is the only MP subject to a reregistration eligibility decision.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base in support of the food uses for difenzoquat methyl sulfate is adequate and will support reregistration eligibility.

a. Acute Toxicity

Test	Citation	Results	Toxicity Category
Acute Oral LD_{50} Rat	MRID 41325406 Duplicate: 41300502	617 mg/kg male 373 mg/kg female 484 mg/kg male and female	III II II
Acute Dermal LD_{50} Rabbit	MRID 41325407	> 2000 mg/kg	III
Acute Inhalation LC_{50} Rat	MRID 41325408	0.62 mg/L male 0.36 mg/L female 0.50 mg/L male and female	III II II
Eye Irritation Rabbit*	MRID 41300501	Severe irritation	I
Dermal Irritation Rabbit*	MRID 00041883	No irritation (intact skin) Severe irritation (abraded skin)	IV II
Skin Sensitization Guinea Pig*	MRID 41325409	Negative	N/A[1]

[1] N/A = Not Applicable

* 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 following toxic signs were observed in the above studies:

Acute Oral LD_{50} Rat: Salivation, decreased activity, prostration and diuresis. Salivation was observed in all groups (200, 400 and 800 mg/kg); decreased activity and prostration, in the mid-dose and high-dose groups; and diuresis, only in the high-dose group. Signs of toxicity generally occurred during the first 24 hours following dosing and disappeared completely, in the surviving animals, within 1-2 days. Necropsy was unremarkable in the survivors. Most of the non-survivors had congested livers and kidneys and enlarged, fluid-filled, pale intestines (MRID 41325406).

Acute Dermal LD_{50} Rabbit: Severe skin irritation (erythema, edema, small sores, subdural hematoma, fissuring, dark red welts and necrosis) at the application site, anorexia, diarrhea, emaciation and nasal discharge; weight loss in males (99 g in 14 days) and little weight gain in females (16 g in 14 days); and pale kidneys and congested lungs in the non-surviving females (MRID 41325407).

Acute Inhalation LC_{50} Rat: Inactivity, eye irritation (treated animals closed their eyes and controls did not) and nasal discharge at all concentrations tested (0.255, 0.438, 0.579, 1.14 and 1.72 mg/L) during exposure; deaths (all animals) in the last two groups during the first 3 hours of exposure and in the 0.579 mg/L group (4/10 males and 9/10 females) during the first hour after exposure; ruffled appearance, brown discharge (ocular, oral, nasal), unsteady gait and tremors, in most animals, for 4 to 6 days after exposure; and dark red lungs with free flowing dark red liquid on the cut surface of the lungs, noted at necropsy, in the 1.72 mg/L group (MRID 41325408).

Primary Eye Irritation Rabbit: Corneal opacity persisted in 1/6 male rabbits (females were not tested) until the termination of the study (day 21 after exposure). Other toxic signs (conjunctival redness, chemosis and discharge) were present in 1-2 rabbits on day 7, but not on day 14 (MRID 41300501).

Primary Dermal Irritation Rabbit: The intact test sites completely recovered from slight erythema and edema by 72 hours, whereas the abraded test sites did not show recovery from severe erythema and edema by 72 hours (last observation time) (MRID 00041883).

b. Subchronic Toxicity

90-Day Feeding Non-Rodent: In a subchronic (non-rodent) feeding study, young purebred beagle dogs (4-6/sex/group) were dosed with technical AC 84,777 (difenzoquat) orally for 90 days at doses of 0, 100, 500 or 2500 ppm, which were equivalent to 0, 2.5, 12.5 or 62.5 mg/kg/day, respectively (1 ppm = 0.025 mg/kg). The diets containing AC 84, 777 were offered to each dog for 1 hour daily, 6 days a week. Parameters examined included clinical signs of toxicity, mortality, ophthalmology, body weights, food consumption, hematology, clinical chemistry, urinalysis, necropsy, organ weights (kidney, adrenals, heart, testes and ovaries), organ/body weight ratios and histopathological examination of organs/tissues. Compound related effects were not observed. Systemic NOEL for both sexes is, therefore, 2500 ppm (25 mg/kg/day; HDT) (MRID 00037922; duplicate MRID 00069540, 00075774).

21-Day Dermal Toxicity Rabbit: In a repeated dose dermal toxicity study, New Zealand rabbits, 5-7/sex/group, were exposed dermally to technical AC 84,777 (difenzoquat) for 3 weeks (5 days/week, 6 hours/day). The exposure of females was delayed by 21 days to allow for replacement of the animals due to the poor health of the initial shipment of females. The dose levels of AC 84,777 used were 0, 250, 500 or 1000 (limit dose) mg/kg/day. Parameters examined included clinical signs of toxicity, mortality, body weights, food consumption, hematology, clinical chemistry, necropsy, organ weights (liver, kidneys, adrenals and gonads), organ/body weight ratios and histopathological examination of selected organs/tissues from the control and high-dose groups. Tissues with gross lesions and skin (treated areas) were also examined histopathologically from all rabbits in the low-dose and mid-dose groups. Treatment-related skin reactions/effects included very slight erythema in 1/6 mid-dose females; very slight edema in 5/7 high-dose males; eschar in 1/7 mid-dose males, 7/7 high-dose males, 2/6 mid-dose females and 4/5 high-dose females; epithelial hyperplasia at the application sites in 5/7 high-dose males, 2/5 high-dose females and 1/6 mid-dose females; and necrosis at the application site in 4/7 high-dose males. Therefore, the NOEL and LOEL for dermal toxicity are 250 mg/kg/day and 500 mg/kg/day, respectively. The NOEL and LOEL for systemic toxicity are both $ 1000 mg/kg/day (MRID 41325410).

c. Chronic toxicity

Chronic Toxicity/Oncogenicity Rodent: A chronic feeding/ carcinogenicity study was conducted using Wistar-derived rats which

were fed diets containing 0, 100, 500 or 2500/5000 ppm of technical AC 84,777 (difenzoquat) for 104 weeks. These dose levels were equivalent to 0, 5, 25 or 125/250 mg/kg/day (1 ppm = 0.05 mg/kg). The 2500/5000 ppm group was dosed with 2500 ppm of difenzoquat for 30 weeks and 5000 ppm until the termination of the study. No reason was given for the dose increase, especially since decreased body weight gains were already observed at the 2500 ppm level. There were 100 rats/sex in the control group and 60/sex in each of the treated groups. Interim sacrifice (10 rats/sex/group) took place at 90 days. Parameters examined included clinical signs of toxicity, mortality, ophthalmology, hematology, clinical chemistry, urinalysis, necropsy, organ weights, organ/body weight ratios and histopathological examination of organs/tissues. With the exception of decreased body weight gains, difenzoquat had no effect on any of the parameters examined. Compared with the concurrent controls, body weight gains were slightly but consistently decreased in the high-dose males (4-9%) and females (8-16%). For male rats, the decreased weight gains were statistically significant ($p = 0.05$) during weeks 4, 13 and 26; and for female rats, only at week 26. Based on the above findings, systemic NOEL for both sexes is 500 ppm (25 mg/kg/day) and systemic LOEL is 2500 ppm (125 mg/kg/day) (MRID 00036710).

Chronic Toxicity Non-Rodent: Groups of purebred beagle dogs (4-6/sex/dose) were administered technical AC 84,777 (difenzoquat) in capsules for 52 weeks. Group I (controls) received empty gelatin capsules and Group II, 12.5 mg/kg/day of difenzoquat. The remaining groups were dosed with difenzoquat as follows: Group III - 37.5 mg/kg/day for the first 28 days and 20 mg/kg/day from day 29 through week 52; Group IV - 75 mg/kg/day for the first 6 days, 50 mg/kg/day during days 7 and 8, 44 mg/kg/day during days 9-28 and 30 mg/kg/day from day 29 through week 52; and Group V - 125 mg/kg/day for the first 4 days, 100 mg/kg/day during days 5 and 6, and 75 mg/kg/day until day 9 when all dogs died or were sacrificed moribund. It was not reported how the initial doses were selected. However, due to mortality, poor health and lack of food consumption observed in Groups IV and V, doses for these groups were decreased until the dogs could tolerate them. Due to continued poor food consumption in Group III, difenzoquat level was also decreased in that group. Therefore, the final dose levels of difenzoquat administered to dogs in Groups I through IV, from day 29 (week 5) until the termination of the study (week 52) were 0, 12.5, 20 and 30 mg/kg/day, respectively. Parameters examined included clinical signs of toxicity, mortality, ophthalmoscopy, body weights, food consumption, hematology, clinical chemistry, urinalysis, necropsy, organ weights, organ/body weight and organ/brain weight

ratios and histopathological examination of organs/tissues. Toxic signs were not observed in male and female dogs which were dosed with difenzoquat at levels of 12.5 and 20 mg/kg/day, and in male dogs treated with 30 mg/kg/day of difenzoquat. However, female dogs dosed with 30 mg/kg/day of difenzoquat gained significantly less weight than did the controls throughout the study (40-60% of the control values; p = 0.05 or 0.01). No other toxic signs were observed. Toxic signs were observed mostly at difenzoquat levels of 44-125 (HDT) m/kg/day, which were administered to dogs during the first 28 days of the study, and included:

1. High mortality - 4 dogs (1/6 males and 3/6 females) died in Group IV and all dogs (4/4 males and 4/4 females) died in Group V.
2. Watery stools, emesis, salivation, tremors, lethargy, irregular gait, lateral recumbency, dilated pupils, and partially or completely closed eyes.
3. Weight loss during weeks 1-2 and decreased weight gain (by 38% for males and 89% for females) during weeks 3-4, relative to the control values.
4. Decreased food consumption for Group IV males (25-36%) and females (35-50%), and for Group V males (54-99.55) and females (50-99.5%), relative to the control values.
5. Macroscopic findings in the non-surviving dogs: discoloration and/or abnormal contents of the esophagus, stomach, and small and large intestines.
6. Microscopic findings in the non-surviving dogs: myocardial degeneration (6 dogs), myocardial necrosis (1 dog), and lesions in the gastrointestinal tract (necrotic ulcer and acute inflammation of the esophagus; luminal or mucoid exudate, necrotic ulcer and congestion of the stomach; and congestion, exudate and necrotic ulcer in the large and small intestines).

Based on the decreases in body weight gain during weeks 5 through 52, the systemic NOEL is 20 mg/kg/day for the female dogs and 30 mg/kg/day for the male dogs (MRID 42800401).

d. Carcinogenicity

Chronic Toxicity/Oncogenicity Rodent: A chronic feeding/ carcinogenicity study was conducted using Wistar-derived rats which were fed diets containing 0, 100, 500 or 2500/5000 ppm of technical AC 84,777 (difenzoquat) for 104 weeks. These dose levels were equivalent to 0, 5, 25 or 125/250 mg/kg/day (1 ppm = 0.05 mg/kg). The

2500/5000 ppm group was dosed with 2500 ppm of difenzoquat for 30 weeks and 5000 ppm until the termination of the study. No reason was given for the dose increase, especially since decreased body weight gains were already observed at the 2500 ppm level. There were 100 rats/sex in the control group and 60/sex in each of the treated groups. Interim sacrifice took place at 90 days. Predominant neoplastic lesions were observed in the adrenals (cortical adenoma), lungs (reticulum cell sarcoma), pituitary (adenoma), thyroid (follicular adenoma and adenocarcinoma), mammary glands (adenocarcinoma and fibroadenoma), ovaries (adenoma) and uterus (polyps). With the exception of thyroid follicular adenocarcinoma in the mid-dose and high-dose male rats, none of the other neoplasms were treatment-related. The percent incidence of thyroid follicular adenocarcinoma in the control, low-dose, mid-dose and high-dose male rats was 4.1, 2.9, 6.3 and 10.2, respectively. According to Dr. Lynnard Slaughter, Consulting Pathologist, Toxicology Branch, Health Effects Division, the historical incidence of thyroid follicular adenocarcinoma in the male Wistar-derived rats is about 19%. The incidence of thyroid follicular adenocarcinoma observed in this study was, therefore, within normal limits and difenzoquat was not considered to be carcinogenic under the conditions of this study. Based on decreased body weight gains in the high-dose males and females, it appeared that the Maximum Tolerated Dose (MTD) was reached (MRID 00036710).

Oncogenicity Mouse: Groups of CD-1 mice (55/sex/dose) were administered technical AC 84,777 (difenzoquat) at dietary levels of 0, 200, 500 or 1000 ppm for 79/80 weeks. These levels were equivalent to 0, 26.9, 69.4 and 150.1 mg/kg/day for males and 0, 39.7, 97.9 and 202.4 mg/kg/day for females. In addition, 10 mice/sex/dose, receiving the same diets, were sacrificed during weeks 53-54. Parameters examined included clinical signs of toxicity, mortality, body weights, food consumption, hematology, necropsy, organ weights, organ/body weight and organ/brain weight ratios, and histopathological examination of organs/tissues. The only treatment-related and statistically significant ($p = 0.05$) toxic sign observed was a decrease in body weight gain in the high-dose males (62% maximum) and females (54% maximum), and in the mid-dose males (34% maximum). The systemic NOEL was, therefore, 200 ppm (26.9 mg/kg/day) for males and 500 ppm (97.9 mg/kg/day) for females. The systemic LOEL was 500 ppm (69.4 mg/kg/day) for males and 1000 ppm (202.4 mg/kg/day) for females. The number of tumor-bearing male and female mice was lower in the treated groups than in the controls, and pulmonary adenoma was the most common neoplasm. Difenzoquat was, therefore, not carcinogenic under the conditions of this study. Based on decreased body weight

gains in the high-dose and mid-dose groups, it appeared that the MTD was reached (MRID 42800402).

e. Developmental Toxicity

Teratogenicity Rat: A developmental study was conducted with pregnant Charles River rats (25/group) which were given daily doses of technical AC 84,777 (difenzoquat) by gavage on gestation days 6 through 15. The dose levels used were 0, 30, 60, 120 or 240 mg/kg/day. The dams were sacrificed on day 20 and the fetuses examined. Maternal toxicity was observed in the last two groups and included long-lasting, recurrent and statistically significant (p # 0.01) excessive salivation in 72-76% of the animals; decreased body weight gain during the dosing period (82.6% and 84.1%, respectively, of the control group value; p # 0.05); and decreased food consumption during the dosing period (93.8% and 89.7%, respectively, of the control group value; p # 0.05 and p # 0.01, respectively). One rat in the 240 mg/kg group had decreased motor activity, head-tilt and tremors, and another rat from the same group had red urine. A slight, statistically insignificant, decrease in the mean fetal weights (96.9% of the control value, males and females), in the 240 mg/kg group, was the only developmental toxicity observed in this study. Therefore, the NOEL and LOEL for maternal toxicity are 60 mg/kg/day and 120 mg/kg/day, respectively. The NOEL and LOEL for developmental toxicity are 120 mg/kg/day and 240 mg/kg/day, respectively (MRID 41521203).

Teratogenicity Rabbit: Artificially inseminated New Zealand rabbits (18/group) were treated with technical AC 84,777 (difenzoquat) on gestation days 7 through 17. The test material was administered by gavage at dose levels of 0, 50, 100 or 250 mg/kg. The does were sacrificed on day 29 and the fetuses examined for external, visceral and skeletal abnormalities. Maternal toxicity was observed only in the 250 mg/kg group and included high mortality (61%) and high percentage of does with resorptions only (33%, compared with 6% in the control group). Developmental toxicity (malformation of the vertebrae) was observed mostly in the high-dose group. Relative to the concurrent control incidence, there was a small and possibly treatment-related increase in the number of fetuses with vertebrae centra abnormalities in the 250 mg/kg group. The fetal percent incidence of this skeletal malformation in the control, low-dose, mid-dose and high-dose groups was 0, 0, 1 and 12, respectively. However, maternal mortality of 61% in the 250 mg/kg group resulted in an insufficient number of fetuses (only 17) to permit a meaningful evaluation of the developmental effects in that group. Considering the above findings, the NOEL and LOEL

for maternal toxicity are 100 mg/kg/day and 250 mg/kg/day, respectively. The NOEL and LOEL for developmental toxicity are also 100 mg/kg/day and 250 mg/kg/day, respectively (MRID 00142521).

f. Reproductive Toxicity

3-Generation Reproduction Rat: Charles River rats (10 males and 20 females/group) were fed diets containing 0, 500 or 2500 ppm of technical AC 84,777 (difenzoquat) for three successive generations. These dose levels were equivalent to 0, 25 and 125 mg/kg/day of difenzoquat (1 ppm = 0.05 mg/kg). The feeding of the test material was started 14 weeks (P_1 parents) or 9 weeks (P_2 and P_3 parents) before mating and was continued through the mating, gestation and lactation periods. One litter was produced per generation. The only parental effect observed in all three generations was a decreased body weight gain in the high-dose females during the pre-mating period (the only time when body weights were recorded in this study). Although, compared with the controls, these weight decreases were statistically significant (p # 0.05), they were either small (5 or 6%) and probably biologically insignificant or occurred in animals which were smaller (20%) than controls at the start of the treatment. Male and female pups in the high-dose group weighed less at birth in the second (F_{2A}) and third (F_{3A}) generations, and at weaning in all generations, than did those in the control group. The mean weight decreases at birth were statistically significant (p # 0.05) and ranged from 6.2 to 7.0% (males) and 6.0 to 8.2% (females). The mean weight decreases at weaning were also statistically significant (p # 0.05) and ranged from 14.0 to 15.2% (males) and 13.9 to 15.5% (females). In the low-dose group, a statistically significant (p # 0.05) mean body weight decrease (8.7%) was observed only at weaning in the F_{3A} female pups. The mean body weight decrease (6.7%), observed at weaning in the low-dose F_{3A} male pups, was statistically insignificant. The mean body weight decreases, observed in the low-dose F_{1A} and F_{2A} male and female pups, were small (2.1-4.3%) and also statistically insignificant. Based on these findings, the parental NOEL is $ 2500 ppm (125 mg/kg/day). The reproductive/developmental NOEL and LOEL are 500 ppm (25 mg/kg/day) and 2500 ppm (125 mg/kg/day), respectively (MRID 00037924; duplicate MRID 00030578).

g. Mutagenicity

Gene Mutation: Under the conditions of the Chinese hamster ovary (CHO) cell HGPRT forward gene mutation assay, doses of non-activated difenzoquat (500 - 1600 ug/mL), and doses of S9-activated difenzoquat

(500 - 1250 ug/mL) did not induce a mutagenic response. Higher levels (2000 ug/mL without S9 and 1600-2000 ug/mL with S9) were severely cytotoxic. Based on these findings, it was concluded that difenzoquat was tested over an appropriate range of concentrations with no evidence of a mutagenic effect (MRID 41325411).

Structural Chromosomal Aberration: Difenzoquat was assessed for its potential to induce structural chromosome aberrations in late, middle and early stages of the Chinese hamster ovary (CHO) cell cycle at five non-activated nominal doses of 100 to 10,000 ug/mL (actual concentrations: $ 65 to 5700 ug/mL) and five S9-activated nominal doses of 33 to 3330 ug/mL (actual concentrations: $ 24 to 1900 ug/mL). Nominal doses $ 3330 ug/mL +/- S9 (analytically, $ 1900 ug/mL) were cytotoxic. A significant increase in the percentage of cells with aberrations was seen at 3330 ug/mL - S9 (1900 mg/mL) 3 hours posttreatment. However, the significant effect was confined to one dose, was not reproduced in a repeat 3 hour treatment, and was not observed in cultures 8 or 12 hours following treatment. There were no significantly increased aberration frequencies in cells recovered 3, 8 or 12 hours post-exposure to the S9-activated test material. It was, therefore, concluded that AC 84,777 was adequately tested and found to be non-clastogenic in this series of experiments (MRID 41415303).

Other Genotoxic Effects: At concentrations ranging from 0.8 to 80 ug/well, difenzoquat did not induce unscheduled DNA synthesis (UDS) in primary rat hepatocytes. Higher levels ($ 266 ug/well) were cytotoxic. Positive response was obtained with 2-acetamidofluorene (2-AAF), a positive control. Based on these findings, it was concluded that difenzoquat was tested over an appropriate range of concentrations with appropriate controls and showed no evidence of USD (MRID 41415304).

h. Metabolism

General Metabolism: The absorption, distribution, metabolism and excretion of difenzoquat were studied in groups of male and female Sprague Dawley rats administered a single oral gavage dose of 5 or 125 mg/kg [^{14}C]-difenzoquat, or a 14-day repeated oral dosing of 5 mg/kg unlabeled difenzoquat followed by a single dose of 5 mg/kg [^{14}C]-labeled difenzoquat on day 15. An additional group of rats received an intravenous injection of 5 mg/kg [^{14}C]-difenzoquat. [^{14}C]-Difenzoquat was poorly absorbed, distributed, and metabolized in rats for all dosing regimens. Most of the radioactivity (63-80% of the administered dose) was rapidly eliminated in the feces within 24 hours while recoveries

were low in the urine (1.3-6.9% of the administered dose) of all oral dose groups. Rats dosed intravenously with 5 mg/kg [^{14}C]-difenzoquat excreted 23.6-25.3% of the administered dose in the urine and 30.1-32.2% in the feces after 24 hours. The results from the pilot study conducted on 4 rats exposed orally to radiolabeled 5 mg/kg difenzoquat indicated that there was no detectable amount of radioactivity in the expired air as [^{14}C]-CO_2. The study indicates that difenzoquat and/or its metabolites do not bioaccumulate to an appreciable extent following oral and intravenous exposure. The distribution of difenzoquat after oral dosing was minimal; the tissues contained negligible levels of radioactivity. Tissue levels were usually less than 0.01 ppm in the single and repeated 5 mg/kg [^{14}C]-difenzoquat-dosed groups and usually less than 0.1 ppm in the 125 mg/kg group. Following intravenous dosing, most radioactivity in the tissues was also less than 0.01 ppm; the highest levels were in the heart (0.22 - 0.26 ppm) and muscle (0.35-0.37 ppm). The metabolism of difenzoquat is minimal because most of the radioactivity was detected in the feces as unmetabolized parent compound. There were 6 minor bands quantitated on HPLC following oral and/or intravenous dosing; however, no attempt was made to identify any of these metabolites. Based on these results, there were no remarkable sex, dose or treatment related differences in the absorption, distribution, metabolism, and elimination of [^{14}C]-difenzoquat in rats. The study also showed that oral administration of 5 and 125 mg/kg difenzoquat, as well as intravenous dosing with 5 mg/kg, did not induce any apparent treatment-related clinical effects (MRID 41844501).

i. Neurotoxicity

Based on the clinical findings observed in the one-year dog feeding study with difenzoquat (MRID 42800401; emesis, salivation, tremors, lethargy, irregular gait, lateral recumbency, dilated pupils, and partially or completely closed eyes) and the developmental toxicity study in rats (MRID 41521203; recurrent extensive salivation at two highest doses tested; one rat at the highest dose tested had decreased motor activity, head-tilt and tremors), the Agency concluded that the following studies are required for difenzoquat: Acute Neurotoxicity Screening Battery in the Rat (81-8) and 90-Day Neurotoxicity Screening Battery in the Rat (82-7). Should these studies be positive, a Developmental Neurotoxicity Study (83-6) would also be required.

j. Other Toxic Endpoints

A Dermal Penetration/Absorption Study (85-2) with technical difenzoquat is not needed because there are no toxicological endpoints to indicate that this study should be required.

Domestic Animal Safety Studies (86-1) are not required due to the use pattern of difenzoquat (a selective postemergence herbicide for control of wild oats in barley and wheat).

k. Peer Review

The carcinogenic potential of difenzoquat was evaluated by the OPP Reference Dose RfD/Peer Review Committee on February 24, 1994. The Committee classified difenzoquat into "Group E" (evidence of non-carcinogenicity for humans), based on a lack of evidence of carcinogenicity in adequate studies with two animal species, rat and mouse.

l. Reference Dose

On February 24, 1994, the OPP Reference Dose RfD/Peer Review Committee recommended that the RfD for difenzoquat be established at 0.2 mg/kg/day. This value was based on the systemic NOEL of 20 mg/kg/day from the one-year dog feeding study (83-1b; MRID 42800401) and an uncertainty factor (UF) of 100. There are no Codex MRLs established or proposed for residues of difenzoquat.

2. Exposure Assessment

a. Dietary Exposure

Plant Metabolism: The qualitative nature of the residue in plants is adequately understood based on acceptable cereal grain (barley and wheat) metabolism studies. These studies indicated that difenzoquat was absorbed from the foliage and translocated throughout the plant but was not extensively metabolized. The terminal residue of concern in plants is difenzoquat (MRIDs 00037957, 00037958, 00042200).

Animal Metabolism: The qualitative nature of the residue in animals is adequately understood based on acceptable poultry and ruminant metabolism studies. The residue of concern in both poultry and ruminant is difenzoquat. In the poultry metabolism study, laying hens were dosed with [^{14}C]difenzoquat at levels equivalent to 1, 10, or 12

ppm in the diet (4x, 35x, or 42x the maximum theoretical dietary burden, respectively). Residues were non-detectable in eggs, muscle, and fat; difenzoquat was the only residue detected in liver and kidney accounting for > 90% of the total radioactive residue in each tissue. In the ruminant metabolism study, goats were administered with [^{14}C]difenzoquat at 23 or 98 ppm in the diet (10x or 41x the maximum theoretical dietary burden, respectively). Residues were non-detectable in the milk, fat, and muscle of goats. Difenzoquat was the predominant residue in liver and kidney; the O-4-glucuronide of parent difenzoquat was present as a minor metabolite (MRIDs 00110347, 41634802, 41634803, 42141601, and 42141602).

Residue Analytical Methods - Plants and Animals: Adequate residue analytical methods are available for purposes of reregistration. For tolerance enforcement, two GLC/FID methods (Methods I for plant and II for animal commodities) are listed in the Pesticide Analytical Manual (PAM, Vol. II). For residue data collection, methods based on the enforcement methods and with acceptable method validation data, were used for plant (American Cyanamid methods M-411 and M-1417) and animal matrices (American Cyanamid methods M-457 and M-504). The registrant has submitted adequate validation data for analytical methods M-457 (ruminant) and M-504 (poultry), using liver and kidney samples from metabolism studies. In addition, the registrant has satisfied the requirements for data on the recovery of difenzoquat using FDA Multi-residue protocols, and these data have been forwarded to FDA for review (MRIDs 00004614, 00004630, 00037959, 00038488, 00052480, 00052481, PP#6F1703, 41521201, 41521202, 41634802, 41634803, 41921101, and 41921102).

Storage Stability: Adequate storage stability data on difenzoquat are available to support the storage conditions and intervals of samples from metabolism and magnitude of the residue studies in plants and animals. Residues of difenzoquat *per se* are stable under frozen (-10 C) storage conditions for up to 24 months in/on wheat grain and wheat straw. No storage stability data are needed for livestock tissues since the samples were analyzed within one month of collection (MRIDs 41634801 and 42323201).

Magnitude of the Residue in Plants: All data requirements for magnitude of difenzoquat residue in plants have been evaluated and deemed adequate. The registered uses of difenzoquat on barley and wheat along with the established tolerances on these commodities are supported by acceptable field residue data from trials reflecting the maximum registered use patterns (MRIDs 00004610, 00004611,

00004612, 00004613, 00004637, 00004641, 00004647, 00004648, 00004652, 00004653, 00004654, 00004655, 00004656, 00004657, 00004658, 00004659, 00004660, 00005567, 00052478, 00060111, 00060117, 00060118, 00108772, 00110331, 00110347, 00110349, and 00110355).

Magnitude of the Residue in Processed Food/Feed: The data requirements for magnitude of the residue in processed food/feed have been evaluated and deemed adequate. Acceptable wheat grain processing and grain dust data have been submitted; the wheat processing data will be translated to barley. The wheat grain processing data indicated that residues of difenzoquat concentrated 4x and 4.6x in wheat bran and shorts, respectively, and minimal concentration occurred in middlings. Residues did not concentrate in flour or grain dust. The registrant has submitted a petition for the establishment of food/feed additive tolerances as a result of the wheat processing study. The Agency has reviewed these tolerance proposals and recommended the establishment of: (i) food additive tolerance in wheat bran at 0.25 ppm; and (ii) feed additive tolerances in wheat shorts at 0.25 ppm, barley hulls at 1 ppm, and barley bran at 1 ppm (MRIDs 41895301 and 42243500, FAP#2H5638).

Magnitude of the Residue in Meat, Milk, Poultry and Eggs: Acceptable animal feeding studies have been conducted. The results of these studies indicate that the established tolerances of 0.05 ppm (based on the limit of detection of the analytical method) for difenzoquat residues in the fat, meat, and meat byproducts of cattle, goats, hogs, sheep, and poultry are adequate. The cattle feeding study showed no detectable residues of difenzoquat in the muscle, fat, and kidney of beef cattle fed up to 10 ppm (4x the estimated dietary burden calculated from feed commodities with established and proposed tolerances). The poultry feeding study showed no detectable residues of difenzoquat in the eggs, muscle, liver, kidney, fat, and skin of laying hens administered with up to 0.5 ppm (2x the estimated dietary burden). Finite residues were detected only in the cattle liver; this observation is consistent with the ruminant metabolism study where finite residues were detected only in the liver and kidney of animals dosed at 41x the estimated dietary burden. No tolerances are needed for residues of difenzoquat in milk and eggs; the presently registered uses of difenzoquat are classified as Category 3 of 40 CFR §180.6(a) with respect to the need for tolerances in milk and eggs. Category 3 of 40 CFR §180.6(a) states "that it is not possible to establish with certainty whether finite residues will be incurred, but there is no reasonable expectation of finite residues" (MRIDs 00037959 and 00052481, FAP#2H5638).

Confined/Field Rotational Crops: A confined rotational crop study has been reviewed and requires additional data to upgrade the study to an acceptable status. The registrant is required to perform additional characterization/identification of ^{14}C-residues in/on selected fractions and submit supporting storage stability data. The requirements for limited field trials and for establishment of plantback intervals, if needed, remain, but may be waived, pending resolution of the deficiencies from the confined rotational crop study. (MRID 42811001).

b. Occupational and Residential Exposure

Handler (Mixer/Loader/Applicator) Exposure

The need for handler data is determined by both the toxicity and exposure potential of a chemical. Handler exposure monitoring data were not required in the Difenzoquat Registration Standard. The Agency has determined that additional exposure data for handlers are not required to support the reregistration of difenzoquat due to its low acute toxicity and lack of other adverse effects with the exception of primary eye irritation.

Postapplication/Reentry Exposure (Workers) and REI

The need for postapplication/reentry data is determined by both the toxicity and exposure potential of a chemical. Difenzoquat does not meet the Agency's toxicity or exposure criteria for requiring reentry data. However, because difenzoquat is in toxicity category I for primary eye irritation, **the 48 hour restricted entry interval (REI) imposed by the Worker Protection Standard (WPS) will be maintained.**

Personal Protective Equipment (PPE) Requirements

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

1. If the Agency has no special concerns regarding other adverse effects of an active ingredient, the PPE for pesticide handlers will be established 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 EPA guidelines.

2. If the Agency has special concerns about an active ingredient due to very high acute toxicity or the certain adverse effects, such as allergic

effects or other effects (cancer, developmental toxicity, reproductive effects, etc):

- the Agency may establish in the RED minimum or "baseline" handler PPE requirements for that active ingredient 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, and
- 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 no special toxicological concerns about difenzoquat that warrant the establishment of active-ingredient-based PPE requirements for pesticide handlers.

Early Entry PPE 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 additional concerns about an active ingredient, it establishes the early-entry PPE requirements RED 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 other adverse effects, such as allergic effects or cancer, developmental toxicity, reproductive effects, etc., it may establish early-entry PPE requirements that are more stringent than would be established on the basis of acute toxicity concerns.

For all products containing difenzoquat, the PPE required for entry permitted during a restricted entry interval when there will be contact with pesticide residues is: coveralls, chemical-resistant gloves, shoes plus socks, and protective eyewear.

3. Risk Assessment

a. Dietary

Toxicological Endpoints: Exposure calculated in the DRES chronic analysis was compared to a Reference Dose (RfD) of 0.20 mg/kilograms body weight/day, based on a No Observed Effect Level (NOEL) of 20 mg/kg bwt/day and an uncertainty factor of 100. The NOEL was taken from a 1 year feeding study in dogs in which there was decreased body weight gain in females at the LOEL. There are no data gaps in the studies supporting the RfD. An acute dietary risk assessment was performed for difenzoquat in which exposure was compared to a NOEL of 37.5 mg/kg/day for difenzoquat methyl sulfate. The NOEL was taken from a chronic dietary study in dogs, with mortality being the effect upon which the endpoint was based.

Residue Information: Food uses evaluated in this analysis were the published tolerances listed in 40 CFR 180.369 and in the Tolerance Index System (TIS) for residues of difenzoquat derived from application of its methyl sulfate salt, and the proposed food additive tolerance of 0.25 ppm for difenzoquat on wheat bran (FAP#2H5638).

Chronic Exposure: The DRES chronic exposure analysis assumed tolerance level residues and 100 percent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. These exposure estimates were then compared to the RfD to estimate chronic dietary risk. The TMRC for the overall U.S. population from uses supported through reregistration is 0.000219 mg/kg bwt/day, which represents 0.1% of the RfD. The proposed food additive tolerance for "wheat, bran" contributes an additional 0.000003 mg/kg bwt/day, which does not raise the TMRC as a percentage of the RfD. The subgroup most highly exposed, children aged one through six, has a TMRC from supported uses of 0.000416 mg/kg bwt/day, or 0.2% of the RfD. The proposed tolerance contributes an additional exposure of 0.000005 mg/kg bwt/day, which does not cause any increase in the TMRC as a percentage of the RfD.

Acute exposure The DRES detailed acute exposure analysis evaluates individual food consumption as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey (NFCS) and estimates the distribution of single day exposures through the diet for the U.S. population and certain subgroups. The analysis reflects consumers only and assumes a uniform distribution of difenzoquat in the commodity

supply. Since the toxicological effect to which high end exposure is being compared in this analysis is mortality, and no particular age or sex category was specified, Margins of Exposure (MOEs) were calculated for the overall population and all subgroups offered in the analysis (Infants < 1 yr, Children 1 through 6 years, Males 13 yrs and older, Females 13 years and older).

The MOE is a measure of how closely the high end exposure approaches the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL/Exposure = MOE).

In this analysis, the calculated exposure for the highest exposed individual for each of the subgroups was compared to the NOEL of 37.5 mg/kg bwt/day. The lowest MOE of all of the subgroups was 16,667, for the subgroup infants less than one year old. This means that for that subgroup, those infants most highly exposed to difenzoquat in their diet would receive 1/16,667 the dose that represents the NOEL in animals for acute toxicity. MOEs ranged from 16,677 to 50,000.

Acute risk is probably overestimated by this analysis, since it is very unlikely that tolerance level residues would exist on all of the food items considered in this analysis and eaten in one day by an individual.

b. Occupational and Residential

Workers are potentially at risk for eye irritation (Toxicity Category I). The Agency concluded that there were no additional toxicological endpoints of concern for workers.

4. Data Requirements

The following data required for the reregistration of difenzoquat are considered confirmatory:

Toxicology: An Acute Neurotoxicity Screening Battery in the rat (81-8) and 90-Day Neurotoxicity Screening Battery in the rat (82-7). Should these studies be positive, a Developmental Neurotoxicity study (83-6) would also be required.

Residue Chemistry: Additional data are required to update the rotational crop study (MRID 42811001). The field rotational crop study is reserved.

C. Environmental Assessment

1. Environmental Fate

a. Environmental Chemistry, Fate and Transport

The following environmental fate studies submitted in support of reregistration have been reviewed and are included in the RED:

Hydrolysis: A study showed that difenzoquat did not hydrolyze in sterile aqueous buffered solutions (pH 5, 7, and 9) that were incubated in the dark at 25 ^{0}C for 28 days. Using three different thin-layer chromatography systems, [^{14}C]difenzoquat was the only compound detected in the treated solutions at 28 days posttreatment. During the study, material balances ranged from 98.2 to 101.1% of the applied with no discernable pattern of decline (MRID 41325403).

Photolysis in Water: Difenzoquat did not degrade in sterile aqueous buffered (pH 7) solutions that were continuously irradiated with a xenon arc lamp at 25 ^{0}C for 28 days. Using three different TLC systems, [^{14}C]difenzoquat was the only compound detected in the irradiated and dark control solutions at 28 days posttreatment. During the study, material balances ranged from 98.6 to 101.6% of the applied with no discernable pattern of decline (MRID 41325404).

Photolysis on Soil: Difenzoquat did not degrade on sandy loam soil that was continuously irradiated with a xenon arc lamp for 28 days at 25 ^{0}C. Based on data from three different TLC systems, [^{14}C]difenzoquat comprised 98.0-99.8% of the applied radioactivity in the irradiated and dark control solutions at 28 days posttreatment. Two unidentified [^{14}C]compounds were each $< 1.4\%$ of the applied in the irradiated and dark control solutions; unidentified "1" was detected at all sampling intervals, and unidentified "2" was detected only at 3 and 4 weeks posttreatment. During the study, the material balances ranged from 99.07 to 106.23% of the applied with no discernable pattern of decline (MRID 41325405).

Aerobic Soil Metabolism: Difenzoquat did not degrade in aerobic sandy loam soil that was incubated for 1 year in the dark at 20 ^{0}C and 75% of 0.33 bar moisture. During the study, extractable [^{14}C]residues totaled 96.9-98.9% of the applied; [^{14}C]difenzoquat was the only compound detected in the soil extracts at 12 months posttreatment. Unextracted [^{14}C]residues in the soil were 1.1-3.1% of the applied at all sampling intervals, and [^{14}C]volatiles (organic and $^{14}CO_2$) totaled $< 1\%$ at 12

months posttreatment. During the study, the material balances ranged from 97.10 to 107.68% of the applied with no discernable pattern of decline (MRID 41903701).

Anaerobic Soil Metabolism: Difenzoquat did not degrade in anaerobic (flooded plus oxygen-free atmosphere) sandy loam soil that was incubated in the dark at 20 ^{0}C for 2 months. During the study, extractable [^{14}C]residues associated with the soil totaled 96.5-102.2% of the applied; during anaerobic incubation, only 0.14-0.21% was associated with the floodwater. [^{14}C]Difenzoquat was the only compound detected in the soil extracts. Unextracted [^{14}C]residues in the soil were 1.18-2.48% of the applied at all sampling intervals. [^{14}C]Volatiles (organic and $^{14}CO_2$) were not detected during the aerobic portion of the experiment, and were not measured during the anaerobic portion of the experiment. During the study, the material balances ranged from 99.06 to 104.23% of the applied with no discernable pattern of decline (MRID 41903702).

Leaching and Adsorption/Desorption: Based on batch equilibrium experiments, difenzoquat was immobile in sandy loam, sandy clay loam, silt loam, and clay loam soils, with Freundlich $K_{adsorption}$ values of 124-685 in calcium chloride solutions and 181-2680 in water (MRID 41703401).

Terrestrial Field Dissipation: Freezer storage stability data were submitted to support six previously submitted and reviewed field dissipation studies. The Difenzoquat Registration Standard required freezer storage stability data to support these data and fulfill the guideline data requirement. The freezer storage stability data are adequate to support the existing data. However, under present day review criteria these six studies are no longer acceptable primarily because differences in extraction technique do not allow determination of the extent of mobility. In addition, many details needed to judge the validity of the studies were lacking. In these field studies, half-lives varied from 49-75 days in California to 254-354 days in Oregon. Furthermore, the registrant must determine a route of dissipation of difenzoquat and its residues, and whether difenzoquat binds to soil or not. The Agency is requiring a non-guideline laboratory study comparing the recovery of ^{14}C-difenzoquat between the methods used in laboratory and field studies. This added bridging information is needed to assist the Agency in determining if the major route of difenzoquat dissipation is soil binding (00045626, 00045627, 00045628, 00045629, 00045631, 00045632, 41903703, 42327501).

b. Environmental Fate Assessment

Except for field dissipation studies (164-1), all of the required environmental fate data requirements are fulfilled at this time.

Difenzoquat is persistent (the chemical did not degrade in any of the laboratory studies performed: hydrolysis, aqueous and soil photolysis, and aerobic and anaerobic soil metabolism). This chemical is relatively immobile (K_ds ranged from 124 to 685, K_{oc}s ranged from 23,071 to 36,231). In aged and unaged soil column leaching studies with sand, sandy loam and silt loam soils, 90.88 and 96.7% of the applied radioactivity remained in the top 3.5 inches of the columns after 20 inches of water was applied, respectively, and 0.47-2.59 % was recovered in the leachates.

A preliminary assessment of the environmental fate of difenzoquat indicates that soil binding appears to be the principal route of dissipation. This assessment is supported by laboratory data which shows a high degree of adsorption to soil but no degradation of the parent material.

However, the field dissipation studies contrast sharply with laboratory data and indicate that difenzoquat residues decline with time. Because different methods were used in the laboratory and field studies to extract difenzoquat from soil, it is not possible to conclude at this time that difenzoquat is bound in the field soils. The submitted laboratory and field studies do not provide a coherent description of the environmental fate of difenzoquat nor explain the discrepancies between laboratory data, which indicate persistence, and field data, which indicate slow to moderate dissipation. It appears from the laboratory data that difenzoquat is immobile in the soil and the potential for ground water contamination is minimal.

Typically, results from the field dissipation studies along with data from the other environmental fate studies would be used to determine the leaching potential of difenzoquat and whether groundwater monitoring studies are needed. However, it cannot be determined based solely on laboratory data how far through field soil difenzoquat or its degradates will move by leaching. Therefore, without acceptable terrestrial field studies, the potential for contamination of groundwater cannot be assessed. The information gained from further field terrestrial dissipation studies may enable the Agency to determine the persistence, potential mobility and route of dissipation of difenzoquat under actual use conditions.

A non-guideline laboratory study is required comparing the recovery of ^{14}C-difenzoquat between the methods used in laboratory and field studies. This added bridging information is needed to assist the Agency in determining if the major route of difenzoquat dissipation is soil binding. The soils in these new studies should be the same as used in the field studies.

Upon review of data bridging laboratory and field extraction methodologies, the Agency will reevaluate the need for further terrestrial field dissipation studies.

2. Ecological Effects

a. Ecological Effects Data

(1) Terrestrial Data

Effects to Birds All avian dietary studies show that the compound is practically non-toxic to birds, while the oral toxicity study shows that the compound is slightly toxic to birds. Avian toxicity requirements have been fulfilled with two dietary studies, 71-2(a) Bobwhite quail LC_{50} = 4,640 ppm (MRID 00052458), 71-2(b) Mallard LC_{50} = 10,388 ppm (MRID 00037928), and one oral study, 71-1(a) Bobwhite quail LD_{50} = 1,577 mg/kg (MRID 00058830).

(2) Aquatic Data

Effects on Freshwater Fish Aquatic testing on freshwater fish show that difenzoquat is slightly to practically non-toxic to fish. The guideline requirements for freshwater fish, 72-1(a) and 72-1(c), are fulfilled for this compound. Test results for freshwater fish include 72-1(c) Acute Fish (rainbow trout) LC_{50} = 694 mg/L (MRID 00037926) and 72-1(a) Acute Fish (bluegill) LC_{50} = 46.5 -696 mg/L (MRID 00037926; MRID DIF0601).

Effects on Freshwater Invertebrates Aquatic testing on freshwater invertebrates indicated that difenzoquat is moderately toxic to invertebrates. Guideline requirement 72-2(a) is fulfilled for this compound. Acute studies on freshwater invertebrates include 72-2(b) *Daphnia magna* EC_{50} = 2.63 ppm (MRID 00057909).

(3) Insect Data

Difenzoquat is non-toxic to honey bees (no deaths when a dose equivalent of 36 lb/A was administered).

(4) Non-Target Plants Data

Non-target plant data are required. These studies are required because difenzoquat i) is used on terrestrial food and feed sites, ii) is applied by ground rigs, iii) has a water solubility greater than 10 ppm (difenzoquat solubility is 7.65×10^5 ppm) or a vapor pressure greater than 1.0×10^5 mg Hg at 25^0C, and iv) the Typical End-Use Product (TEP) is not thoroughly incorporated immediately after application (aerial application and chemigation).

The Agency is requiring Tier II Plant Testing:

123-1a Seed Germination/Seedling Emergence
123-1b Vegetative Vigor
123-2 Aquatic Plant Growth (The study should be conducted on each of the following species: *Selenastrum capricornutum*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.)

b. Ecological Effects Risk Assessment

Difenzoquat is applied to crops once per growing season at rates of 0.6 to 1.0 lbs ai/A. Difenzoquat is readily absorbed but not metabolized or degraded by plants. The only pest claim for this compound is for the control of wild oats (*Avena fatua*).

(1) Terrestrial Organisms

Difenzoquat acute toxicity values to birds suggest that difenzoquat presents a slight to moderate potential for toxicity to wildlife. These acute values are as follows: mallard ducks (LC_{50} = 10,388 ppm) and bobwhite quail (LC_{50} = 4,640 ppm).

The available data show that difenzoquat is slightly to practical non-toxic to birds. In order to predict plant residues, the maximum application rate of 1 lb ai/A at one application per season was used as follows:

short grass	240 ppm
long grass	110 ppm
leafy crops	125 ppm
small insects	58 ppm
large insects	12 ppm
grain	10 ppm
fruit	7 ppm

The expected residues do not trigger adverse effects to avian or mammalian species from the present registered uses of difenzoquat. Adverse chronic effects to birds are not expected from exposure to this compound because of its low acute avian toxicity values, the low mammalian toxicity and the use restriction of one application per season.

Chronic toxicity to wildlife has not been evaluated directly, but appears to be slight as noted by mammalian chronic testing. No further testing on wildlife will be required at this time. Difenzoquat chronic toxicity to wildlife appears to be slight. Testing conducted on mammalian species (rats) showed that through the major routes of exposure (dermal and inhalation), the following toxicological characteristics were noted:

Subchronic toxicity: Systemic NOEL was 2,500 ppm. No compound related effects were observed in 90-day feeding study (MRID 00037922 duplicate MRID 00069540, 00075774).

Oncogenicity: Negative at the 5,000 ppm level in rats (MRID 00036710).

Teratogenicity: Negative for teratogenicity, fetotoxicity and maternal toxicity in rats at 2,500 ppm (MRID 41521203).

Reproduction: A 3-generation rat reproduction study found the parental NOEL was equal to or greater than 2,500 ppm and reproductive/developmental NOEL was 500 ppm (MRID 00037924; duplicate MRID 00030578).

(2) Aquatic Organisms

Difenzoquat acute toxicity values to aquatic species suggest that difenzoquat presents a slight to moderate potential for toxicity. These acute values are as follows: rainbow trout

(LC_{50} = 694 mg/L), acute bluegill (LC_{50} = 46.5-696 mg/L) and Daphnia (LC_{50} = 2.6 ppm).

The aquatic risk from difenzoquat exposure was evaluated by comparing the preliminary estimated environmental concentrations (EEC) with the level of concern for acute aquatic risk (i.e. runoff or drift EEC > 0.5 LC_{50} Daphnia; 3.05 - 12.2 ppb < 1.3 ppm) as well as difenzoquat toxicity and use pattern information. Difenzoquat appears to pose minimal acute risk to aquatic organisms because the EEC is < 0.5 LC_{50} value.

The preliminary EEC's for this herbicide were calculated by using a water body scenario at a maximum rate of 1.0 lb ai/A for simulated ground and aerial application to 6 feet of water. These values are summarized as follows:

1) Ground Application = runoff 12.2 ug/L (0.012 ppm)

2) Aerial Application = runoff 7.3 ug/L (0.007 ppm)
drift 3.05 ug/L (0.003 ppm)

Chronic risk to fish is unlikely because expected exposure is < 0.01 the lowest LC_{50} values and only one application per season is permitted. No additional data are required.

The current uses of difenzoquat on wheat and barley appear to result in low toxic impact on aquatic organisms. This conclusion is based upon the following information:

1) moderate to slight toxicity of difenzoquat to fish and aquatic invertebrates;
2) Preliminary EEC values that suggest no risk (these values are at least 2 orders of magnitude below the acute risk criteria);
3) Restriction of one application per season;
4) Mammalian data do not indicate chronic effects.

(3) Nontarget Insects

Difenzoquat is non-toxic to honey bees (no deaths when a dose equivalent of 36 lb/A was administered).

(4) Nontarget Plants

Difenzoquat is an herbicide that is applied aerially. There is a potential for direct exposure of the toxicant to terrestrial and aquatic plants. In order to evaluate toxicity of this compound to plants, Tier II Plant Testing is required (see section III(C)(3)).

Although there are no data available on effects to non-target plants, it is anticipated that, since difenzoquat is an herbicide, risk to non-target aquatic and terrestrial plants will be high. The required plant data are necessary in order to assess risks to non-target plants. Phytotoxicity data are not part of the target data base for reregistration.

(5) Spray-Drift Label Advisory

In order to inform the user of best management practices that would minimize spray drift from the target site, the Agency is currently preparing spray drift labeling statements. This future labeling may be required for all difenzoquat products that may be applied aerially to agricultural crops.

c. Endangered and Threatened Species

EPA has been working with the U.S. Fish and Wildlife Service and other federal and state agencies to develop a program to avoid jeopardizing the continued existence of listed species from the use of pesticides. The Endangered Species Protection Program is expected to become final in 1994. Limitations on the use of difenzoquat may be required to protect endangered and threatened species, but these limitations have not yet been defined, and they may be formulation specific. OPP anticipates that 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 the 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.

Although the Endangered Species Protection Program has not been finalized, it can be assumed that endangered plant species occurring in counties where wheat and barley are grown may be affected from exposure to this herbicide.

d. Risk Mitigation

The Agency has determined that the current uses of difenzoquat do not pose any unreasonable threat to the environment, and based on available data, no levels of concern (LOCs) have been exceeded. However, it can be anticipated that difenzoquat, as an herbicide, will pose some risk to non-target plants. The Agency remains concerned and is exploring risk mitigation for all herbicides.

3. Data Requirements

Environmental Fate:

164-1 Non-guideline laboratory study comparing the recovery of ^{14}C-difenzoquat between the methods used in laboratory and field dissipation studies
165-1 Confined Rotational Crop (supplemental data)
201-1 Droplet Size Spectrum
202-1 Drift Field Evaluation

Ecological Effects:

123-1a Seed Germination/Seedling Emergence
123-2b Vegetative Vigor
123-2 Aquatic Plant Growth (*Selenastrum capricornutum*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom)

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 difenzoquat as the active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing difenzoquat. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of difenzoquat, and lists the submitted studies that the Agency found acceptable.

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 and the data identified in Appendix B. Although the Agency has found that all uses of difenzoquat 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 difenzoquat, 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

The Agency has determined that difenzoquat products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment.

Based on the reviews of the generic data for the active ingredient difenzoquat, the Agency has sufficient information on its health effects and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency concludes that products containing difenzoquat for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

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

B. Regulatory Position

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

1. Tolerance Reassessment

Tolerances Listed Under 40 CFR §180.369

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.369 for the following commodities: barley grain; barley straw; wheat grain; wheat straw; fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep; and fat, meat and meat byproducts of poultry. No tolerances are needed for residues of difenzoquat in milk and eggs; the presently registered uses of difenzoquat are classified as Category 3 of 40 CFR §180.6(a) with respect to the need for tolerances in milk and eggs.

Category 3 of 40 CFR §180.6(a) states "that it is not possible to establish with certainty whether finite residues will be incurred, but there is no reasonable expectation of finite residues."

Proposed Food (40 CFR §185.xxx) and Feed (40 CFR §186.xxx) Tolerances

No food/feed additive tolerances have been established for difenzoquat derived from application of the methyl sulfate salt and calculated as the cation. The registrant has submitted a petition (FAP#2H5638) proposing the establishment of food/feed additive tolerances as a result of an adequate wheat processing study. The Agency has reviewed these tolerance proposals and recommended for the establishment of: (i) food additive tolerance in wheat bran at 0.25 ppm; and (ii) feed additive tolerances in wheat shorts at 0.25 ppm, barley hulls at 1 ppm, and barley bran at 1 ppm.

A summary of the difenzoquat tolerance reassessment is presented in the table below. There are no changes required in existing tolerances.

Dietary Exposure Estimates

The dietary exposure assessment for difenzoquat will be based on tolerance level residues and proposed tolerance levels for processed commodities. Tolerance level residues will greatly overestimate the dietary exposure to residues of difenzoquat.

Codex Harmonization

There are no Codex MRLs established or proposed for residues of difenzoquat. Therefore, there are no questions with respect to compatibility of U.S. tolerances with Codex MRLs.

Tolerance Reassessment Summary for Difenzoquat

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment
Tolerances listed under 40 CFR §180.369			
Barley, grain	0.2		All established tolerances are supported by adequate residue chemistry data.
Barley, straw	20		
Cattle, fat	0.05		
Cattle, mbyp	0.05		
Cattle, meat	0.05		
Goats, fat	0.05		

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment
Goats, mbyp	0.05		
Goats, meat	0.05		
Hogs, fat	0.05		
Hogs, mbyp	0.05		
Hogs, meat	0.05		
Horses, fat	0.05		
Horses, mbyp	0.05		
Horses, meat	0.05		
Poultry, fat	0.05		
Poultry, mbyp	0.05		
Poultry, meat	0.05		
Sheep, fat	0.05		
Sheep, mbyp	0.05		
Sheep, meat	0.05		
Wheat, grain	0.05		
Wheat, straw	20		
Proposed Food Additive Tolerances (40 CFR §185.xxx)			
Wheat, bran	None	0.25	Tolerance pending (FAP#2H5638)
Proposed Feed Additive Tolerances (40 CFR §186.xxx)			
Barley, hulls	None	1	Tolerance pending (FAP#2H5638)
Barley, bran	None	1	
Wheat, shorts	None	0.25	

2. Restricted Use Classification

Difenzoquat is not currently classified for restricted use. The Agency has determined that difenzoquat products should not be classified for restricted use at this time. After an analysis of additional data submitted, the Agency will reassess whether any difenzoquat uses warrant a restricted use classification.

3. Reference Dose (RfD)

Difenzoquat is not a RfD exceeder. The reference dose for difenzoquat was determined to be 0.2 mg/kg/day. This value was based on the systemic NOEL of 20 mg/kg/day from the one-year dog feeding study (MRID 42800401) and an uncertainty factor (UF) of 100. The TMRC for the overall U.S. population from uses supported through reregistration is 0.000219 mg/kg

bwt/day, which represents 0.1% of the RfD. The proposed food additive tolerance for "wheat, bran" contributes an additional 0.000003 mg/kg bwt/day, which does not raise the TMRC as a percentage of the RfD. The subgroup most highly exposed, children aged one through six, has a TMRC from supported uses of 0.000416 mg/kg bwt/day, or 0.2% of the RfD. The proposed tolerance contributes an additional exposure of 0.000005 mg/kg bwt/day, which does not cause any increase in the TMRC as a percentage of the RfD.

4. Spray Drift Label Advisory

In order to inform the user of best management practices that would minimize spray drift from the target site, the Agency is currently preparing spray drift labeling statements. This future labeling may be required for all difenzoquat products that may be applied aerially to agricultural crops.

5. Endangered Species Statement

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 mitigation measures that will eliminate the adverse impacts. The program would require use modifications or a generic product label statement, requiring users to consult county-specific bulletins. These bulletins would provide information about specific use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses.

The Agency plans to publish a description of the Endangered Species Program in the Federal Register in 1994 and by 1995 have enforceable county-specific bulletins available. 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.

6. Labeling Rationale

a. Compliance with Worker Protection Standard

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.

Post-application Reentry

Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are established on the basis of 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: product-specific REI's established on the basis of adequate data and interim REI's that are longer than those that would be established under the WPS.

The technical grade of difenzoquat is in toxicity category I for acute eye irritation, and the REI imposed by the WPS was 48 hours. The RED evaluation of the REI established by the WPS concluded that no changes were warranted and the REI should remain at 48 hours. The

48 hour REI established by the WPS applies to all registered uses of difenzoquat since all the registered uses fall under the scope of the WPS.

Personal Protective Equipment (PPE) Requirements

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

1. If the Agency has no special concerns regarding other adverse effects of an active ingredient, the PPE for pesticide handlers will be established 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 EPA guidelines.

2. If the Agency has special concerns about an active ingredient due to very high acute toxicity or certain adverse effects, such as allergic effects or other effects (cancer, developmental toxicity, reproductive effects, etc):

- the Agency may establish in the RED minimum or "baseline" handler PPE requirements for that active ingredient 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, and
- 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 no special toxicological concerns about difenzoquat that warrant the establishment of active-ingredient-based PPE requirements for pesticide handlers.

Early Entry PPE 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 additional concerns about an active ingredient, it establishes the early-entry PPE requirements RED 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 other adverse effects, such as allergic effects or cancer, developmental toxicity, reproductive effects, etc., it may establish early-entry PPE requirements that are more stringent than would be established on the basis of acute toxicity concerns.

For all products containing difenzoquat, the PPE required for entry during a restricted entry interval is: coveralls, chemical-resistant gloves, shoes plus socks, and protective eyewear.

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 difenzoquat for the above eligible uses has been reviewed and determined to be substantially complete. Data are required for the following guidelines:

- 81-8 Acute Neurotoxicity Screening Battery Rat
- 82-7 90-Day Neurotoxicity Screening Battery Rat
- 123-1a Seed Germination/Seedling Emergence
- 123-1b Vegetative Vigor
- 123-2 Aquatic Plant Growth (*Selenastrum capricornutum*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom)
- 164-1 Non-guideline laboratory study comparing the recovery of 14C-difenzoquat between the methods used in laboratory and field dissipation studies
- 165-1 Confined Rotational Crop (supplemental data)
- 201-1 Droplet Size Spectrum
- 202-1 Drift Field Evaluation

2. Labeling Requirements for Manufacturing-Use Products

No additional labeling requirements are being required for manufacturing use products at this time.

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

No additional labeling requirements are being required for end-use products at this time.

3. Worker Protection Standard (WPS)

The RED evaluation of the REI established by the WPS concluded that no changes were warranted and **the REI should remain at 48 hours**. This REI must be inserted into the standardized REI statement required by PR Notice 93-7. The PPE for early entry for difenzoquat includes coveralls, chemical resistant gloves, shoes plus socks, and protective eyewear. These PPE must be inserted into the early entry PPE statement required by PR Notice 93-7.

C. 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 difenzoquat products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED.

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

APPENDIX A - CASE 0223, [Difenzoquat] Chemical 106401 [Difenzoquat methyl sulfate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year		Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES													
BARLEY				Use Group: TERRESTRIAL FOOD+FEED CROP									
Spray., Postemergence., Aircraft.	SC/L	NA	1 lb (CI) A	*	1	NS	NS	NS	NS	NS			C46
Spray., Postemergence., Ground.	SC/L	NA	1 lb (CI) A	*	1	NS	NS	NS	NS	NS			C46
WHEAT				Use Group: TERRESTRIAL FOOD+FEED CROP									
Spray., Postemergence., Aircraft.	SC/L	NA	1 lb (CI) A	*	1	NS	NS	NS	NS	NS			C46
Spray., Postemergence., Ground.	SC/L	NA	1 lb (CI) A	*	1	NS	NS	NS	NS	NS			C46

LEGEND

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Restr. Entry Interv (days)	: Restricted Entry Interval (days)

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

SC/L	: SOLUBLE CONCENTRATE/LIQUID

ABBREVIATIONS

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

APPLICATION RATE

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

USE LIMITATIONS CODES

C46 : Do not apply through any type of irrigation system.

* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

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 Difenzoquat covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Difenzoquat 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 Difenzoquat

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	41325401
61-2A	**Starting Materials & Manufacturing Process**	All	41325401
61-2B	**Formation of Impurities**	All	41325401
62-1	**Preliminary Analysis**	All	41415301
62-2	**Certification of limits**	All	41415301
62-3	**Analytical Method**	All	41415301
63-2	**Color**	All	41325402
63-3	**Physical State**	All	41325402
63-4	**Odor**	All	41325402
63-5	**Melting Point**	All	41325402
63-6	**Boiling Point**	N/A	
63-7	**Density**	All	41325402
63-8	**Solubility**	All	41325402
63-9	**Vapor Pressure**	All	41325402
63-10	**Dissociation Constant**	All	41325402, 42243501
63-11	**Octanol/Water Partition**	All	41325402
63-12	**pH**	All	41325402
63-13	**Stability**	All	41325402

Data Supporting Guideline Requirements for the Reregistration of Difenzoquat

REQUIREMENT		USE PATTERN	CITATION(S)
63-14	**Oxidizing/Reducing Action**	All	41325402
63-15	**Flammability**	N/A	
63-16	**Explodability**	All	41325402
63-17	**Storage stability**	All	41593501
63-18	**Viscosity**	N/A	
63-19	**Miscibility**	N/A	
63-20	**Corrosion characteristics**	All	41593501
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	AB	00058830
71-2A	**Avian Dietary - Quail**	AB	00052458
71-2B	**Avian Dietary - Duck**	AB	00037928
72-1A	**Fish Toxicity Bluegill**	AB	00037926
72-1C	**Fish Toxicity Rainbow Trout**	AB	00037926
72-2A	**Invertebrate Toxicity**	AB	00057909
123-1A	**Seed Germination/Seedling Emergence**	AB	**DATA GAP**
123-1B	**Vegetative Vigor**	AB	**DATA GAP**
123-2	**Aquatic Plant Growth**	AB	**DATA GAP**
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	AB	41325406, 41300502 (duplicate)
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	AB	41325407

Data Supporting Guideline Requirements for the Reregistration of Difenzoquat

REQUIREMENT		USE PATTERN	CITATION(S)
81-3	**Acute Inhalation Toxicity - Rat**	AB	41325408
81-4	**Primary Eye Irritation - Rabbit**	AB	41300501
81-5	**Primary Dermal Irritation - Rabbit**	AB	00041883
81-6	**Dermal Sensitization - Guinea Pig**	AB	41325409
81-8	**Acute Neurotoxicity - Rat**	AB	**DATA GAP**
82-1B	**90-Day Feeding - Non-Rodent**	AB	00037922 (00069540, 00075774; duplicates)
82-2	**21-Day Dermal - Rabbit/Rat**	AB	41325410
82-7	**90-Day Neurotoxicity - Rat**	AB	**DATA GAP**
83-1A	**Chronic Feeding Toxicity - Rodent**	AB	00036710
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	AB	42800401
83-2A	**Oncogenicity - Rat**	AB	00036710
83-2B	**Oncogenicity - Mouse**	AB	42800402
83-3A	**Developmental Toxicity - Rat**	AB	41521203
83-3B	**Developmental Toxicity - Rabbit**	AB	00144521
83-4	**2-Generation Reproduction - Rat**	AB	00037924 (00030578; duplicate)
84-2A	**Gene Mutation (Ames Test)**	AB	41325411
84-2B	**Structural Chromosomal Aberration**	AB	41415303
84-4	**Other Genotoxic Effects**	AB	41415304
85-1	**General Metabolism**	AB	41844501

Data Supporting Guideline Requirements for the Reregistration of Difenzoquat

REQUIREMENT		USE PATTERN	CITATION(S)
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	AB	41325403
161-2	**Photodegradation - Water**	AB	41325404
161-3	**Photodegradation - Soil**	AB	41325405
162-1	**Aerobic Soil Metabolism**	AB	41903701
162-2	**Anaerobic Soil Metabolism**	AB	41903702
163-1	**Leaching/Adsorption/Desorption**	AB	41703401
164-1	**Terrestrial Field Dissipation**	AB	00045626, 00045627, 00045628 00045629, 00045631, 00045632 41903703, 42327501, **(DATA GAP)**
165-1	**Confined Rotational Crop**	AB	42811001 **(DATA GAP)**
201-1	**Droplet Size Spectrum**	AB	**DATA GAP**
202-1	**Drift Field Evaluation**	AB	**DATA GAP**
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**		00037957, 00037958, 00042200
171-4B	**Nature of Residue - Livestock**		00110347, 41634802, 41634803 42141601, 42141602
171-4C	**Residue Analytical Method - Plants**		00004614, 00004630, 41521202 41921101, 41921102
171-4D	**Residue Analytical Method - Animal**		00037959, 00038488, 00052480 00052481, 41521201, 41521202 41634802, 41634803

Data Supporting Guideline Requirements for the Reregistration of Difenzoquat

REQUIREMENT		USE PATTERN	CITATION(S)
171-4E	**Storage Stability**		41634801, 42323201
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**		00037959, 00052481
171-4K	**Crop Field Trials**		
	- Barley		00004610, 00004611, 00004612 00004613, 00005567, 00052478 00060117, 00060118, 00108772 00110331, 00110349, 00110355
	- Wheat		00004637, 00004641, 00004647 00004648, 00004652, 00004653 00004654, 00004655, 00004656 00004657, 00004658, 00004659 00004660, 00060111, 00110347 00110349
171-4L	**Processed Food**		
	- Barley		41895301, 42243500
	- Wheat		41895301, 42243500

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

GUIDE TO APPENDIX C

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

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

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

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

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

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

BIBLIOGRAPHY

MRID	CITATION
00004610	Feeny, R.W.; Higham, J.W.; Snyder, E.H.; Colbert, D.R.; Agamalian, H. (1975) Avenge (CL 84,777): Determination of CL 84,777 (1,2-Dimethyl pyrazolium methyl sulfate) and Bromoxynil (3,5Dibromo-4-hydroxylbenzonitrile) Residues in Barley Straw and Grain Following Ground Application (California): Report No. C592. (Unpublished study received Jan 8, 1975 under 241-EX-64; prepared in cooperation with Lake Ontario Environmental Laboratory, submitted by American Cyanamid Co., Princeton, N.J.; CDL: 224170-R)
00004611	Higham, J.W.; Feeny, R.W.; Snyder, E.H; Kushnak, G.; O'Hare, T.R. (1975) Avenge (CL 84,777): Determination of CL 84,777 (1, 2-Dimethyl-3,5-diphenyl pyrazolium methyl sulfate), Bromoxynil (3,5-Dibromo-4-hydroxylbenzonitrile) and MCPA (2-Methyl-4 chlorophenoxyacetic acid) Residues in Barley Grain and Straw Following Ground Application of Avenge Alone and in Combination with MCPA, Bromoxynil, 2,4-D and Bromoxynil plus MCPA: Montana: Report No. C-593. (Unpublished study received Jan 8, 1975 under 241-EX-64; prepared in cooperation with Montana State Univ. and Lake Ontario Environmental Laboratory, submitted by American Cyanamid Co., Princeton, N.J.; CDL:224170-S)
00004612	Higham, J.W.; Feeny, R.W.; Poeppel, M.O.; O'Hare, T.R. (1975) Avenge (CL 84,777): Determination of CL 84,777 (1,2-Dimethyl-3,5-diphenyl pyrazolium methyl sulfate) and Bromoxynil (3,5-Dibromo-4- hydroxybenzonitrile) Residues in Barley Straw and Grain Following Ground Application (North Dakota): Report No. C-595. (Unpublished study received Jan 8, 1975 under 241-EX-64; prepared in cooperation with Lake Ontario Environmental Laboratory, submitted by American Cyanamid Co., Princeton, N.J; CDL:224170-U)
00004613	Higham, J.W.; Feeny, R.W; Cheston, K.G.; Snyder, E.H.; Nowatski, R.; O'Hare, T.R. (1975) Avenge (CL 84,777): Determination of CL 84,777 (1,2-Dimethyl-3,5-diphenyl pyrazolium methyl sulfate), Bromoxynil (3,5-Dibromo-4-hydroxylbenzonitrile) and MCPA (2-Methyl-4-chlorophenoxyacetic acid) Residues in Barley Grain and Straw Following Ground Application of Avenge Alone and in Combination with MCPA, Bromoxynil or 2,4-D (North Dakota): Report No. C-596. (Unpublished study received Jan 8, 1975 under 241-EX-64; prepared in cooperation with Lake Ontario Environmental Laboratory, submitted by American Cyanamid Co., Princeton, N.J.; CDL:224170-V)

BIBLIOGRAPHY

MRID	CITATION
00004614	Higham, J.W.; Steller, W.A. (1974) Avenge (CL 84,777): The Gas Chromatographic Determination of (1,2-Dimethyl-3,5-diphenyl pyrazolium methyl sulfate) in Fortified Barley Foliage, Grain and Straw: Report No. C-519. Includes method M-411 dated Apr 26, 1973. (Unpublished study received Jan 8, 1975 under 241-EX-64; submitted by American Cyanamid Co., Princeton, N.J.; CDL: 224170-W)
00004630	Higham, J.W.; Manuel, A.J.; Snyder, E.H. (1974) Avenge (CL 84,777): The Gas Chromatographic Determination of (1,2-Dimethyl-3,5-diphenyl pyrazolium methyl sulfate) in Fortified Wheat Foliage, Grain, and Straw: Report No. C-537. Includes method M-411 dated Apr 26, 1973. (Unpublished study received Nov 14, 1975 under 6F1703; submitted by American Cyanamid Co., Princeton, N.J.; CDL:094738-B)
00004637	Elenewski, C.A.; Wang, T. (1975) Avenge (CL 84,777): Determination of CL 84,777 (1,2-Dimethyl-3,3,5-diphenyl-1H-pyrazolium methyl sulfate) Residues in Wheat Grain and Straw Following Ground Application (California, 1975): Report No. C-842. (Unpublished study received Nov 14, 1975 under 6F1703; submitted by American Cyanamid Co., Princeton, N.J.; CDL:094738-K)
00004641	Elenewski, C.A.; Wang, T. (1975) Avenge (CL 84,777): Determination of CL 84,777 (1,2-Dimethyl-3,5-diphenyl-1H-pyrazolium methyl sulfate) Residues in Wheat Grain and Straw Following Ground Application (Oklahoma, 1975): Report No. C-794. (Unpublished study received Nov 14, 1975 under 6F1703; submitted by American Cyanamid Co., Princeton, N.J.; CDL:094738-O)
00004647	Elenewski, C.A.; Wang, T. (1975) Avenge (CL 84,777): Determination of CL 84,777 (1,2-Dimethyl-3,5-diphenyl-1H-pyrazolium methyl sulfate) Residues in Wheat Grain and Straw Following Ground Application (Texas, 1975): Report No. C-840. (Unpublished study received Nov 14, 1975 under 6F1703; submitted by American Cyanamid Co., Princeton, N.J.; CDL:094738-U)
00004648	Elenewski, C.A.; Wang, T. (1975) Avenge (CL 84,777): Determination of CL 84,777 (1,2-Dimethyl-3,5-diphenyl-1H-pyrazolium methyl sulfate) Residues in Wheat Grain and Straw Following Ground Application (Texas, 1975): Report No. C-841. (Unpublished study received Nov 14, 1975 under 6F1703; submitted by American Cyanamid Co., Princeton, N.J.; CDL:094738-V)

BIBLIOGRAPHY

MRID	CITATION
00004652	Elenewski, C.A.; Wang, T. (1975) Avenge (CL 84,777): Determination of CL 84-777 (1,2-Dimethyl-3,5-diphenyl-1H-pyrazolium methyl sulfate) and Bromoxynil (3,5-Dibromo-4-hydroxylbenzonitrile) Residues in Wheat Grain and Straw Following Aerial Application of Avenge Alone and in Combination with Bromoxynil, (Arizona): Report No. C-808. (Unpublished study received Nov 14, 1975 under 6F1703; prepared in cooperation with Biodynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL: 094738-AA)
00004653	Elenewski, C.A.; Wang, T. (1975) Avenge (CL 84,777): Determination of CL 84,777 (1,2-Dimethyl-3,5-diphenyl-1H-pyrazolium methyl sulfate) and Bromoxynil (3,5-Dibromo-4-hydroxylbenzonitrile) Residues in Wheat Grain and Straw Following Ground Application of Avenge Alone and in Combination with Bromoxynil, (California): Report No. C-807. (Unpublished study received Nov 14, 1975 under 6F1703; prepared in cooperation with Biodynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:094738-AB)
00004654	Elenewski, C.A.; Wang, T. (1975) Avenge (CL 84,777): Determination of CL 84,777 (1,2-Dimethyl-3,5-diphenyl-1H-pyrazolium methyl sulfate) and Bromoxynil (3,5-Dibromo-4-hydroxylbenzonitrile) Residues in Wheat Grain and Straw Following Aerial Application of Avenge Alone and in Combination with Bromoxynil, (California): Report No. C-814. (Unpublished study received Nov 14, 1975 under 6F1703; prepared in cooperation with Biodynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:094738-AC)
00004655	Elenewski, C.A.; Wang, T. (1975) Avenge (CL 84,777): Determination of CL 84,777 (1,2-Dimethyl-3,5-diphenyl-1H-pyrazolium methyl sulfate), Bromoxynil (3,5-Dibromo-4-hydroxylbenzonitrile) and MCPA (2-Methyl-4-chlorophenoxyacetic acid) Residues in Durum Wheat Grain and Straw Following Aerial Application of Avenge Alone and in Combination with MCPA or Bromoxynil, (Minnesota): Report No. C-823. (Unpublished study received Nov 14, 1975 under 6F1703; prepared in cooperation with Biodynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:094738-AD)

BIBLIOGRAPHY

MRID	CITATION
00004656	Elenewski, C.A.; Wang, T. (1975) Avenge (CL 84,777): Determination of CL 84,777 (1,2-Dimethyl-3,5-diphenyl-1H-pyrazolium methyl sulfate) and Bromoxynil (3,5-Dibromo-4-hydroxylbenzonitrile) Residues in Wheat Grain and Straw Following Ground Application of Avenge Alone and in Combination with Bromoxynil, (Montana): Report No. C-812. (Unpublished study received Nov 14, 1975 under 6F1703; prepared in cooperation with Biodynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL: 094738-AE)
00004657	Elenewski, C.A.; Wang, T. (1975) Avenge (CL 84,777): Determination of CL 84,777 (1,2-Dimethyl-3,5-diphenyl-1H-pyrazolium methyl sulfate) and Bromoxynil (3,5-Dibromo-4-hydroxylbenzonitrile) Residues in Wheat Grain and Straw Following Aerial Applications of Avenge Alone and in Combination with Bromoxynil, (Montana): Report No. C-813. (Unpublished study received Nov 14, 1975 under 6F1703; prepared in cooperation with Biodynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:094738-AF)
00004658	Elenewski, C.A.; Wang, T. (1975) Avenge (CL 84,777): Determination of CL 84,777 (1,2-Dimethyl-3,5-diphenyl-1H-pyrazolium methyl sulfate) and Bromoxynil (3,5-Dibromo-4-hydroxylbenzonitrile) Residues in Wheat Grain and Straw Following Ground Application of Avenge Alone and in Combination with Bromoxynil, (Oregon): Report No. C-806. (Unpublished study received Nov 14, 1975 under 6F1703; prepared in cooperation with Biodynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL: 094738-AG)
00004659	Elenewski, C.A.; Wang, T. (1975) Avenge (CL 84,777): Determination of CL 84,777 (1,2-Dimethyl-3,5-diphenyl-1H-pyrazolium methyl sulfate), Bromoxynil (3,5-Dibromo-4-hydroxylbenzonitrile) and MCPA (2-Methyl-4-chlorophenoxyacetic acid) Residues in Wheat Grain and Straw Following Ground Application of Avenge Alone and in combination with MCPA or Bromoxynil, (Oregon): Report No. C820. (Unpublished study received Nov 14, 1975 under 6F1703; prepared in cooperation with Biodynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:094738-AH)
00004660	Feeny, R.W.; Poeppel, M.O. (1974) Avenge (CL 84,777): Determination of CL 84,777 (1,2-Dimethyl-3,5-diphenyl-1H-pyrazolium methyl sulfate) Residues in Wheat Grain and Straw Following Ground Application, (Washington): Report No. C-780. (Unpublished study received Nov 14, 1975 under 6F1703; submitted by American Cyanamid Co., Princeton, N.J.; CDL:094738-AI)

BIBLIOGRAPHY

MRID	CITATION
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00030578	Reno, F.E. (1974) Three-Generation Reproduction Study in Rats: AC 84,777. Final rept. (Unpublished study received on unknown date under 4G1453; prepared by Hazleton Laboratories, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:094933-F)
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APPENDIX D. List of Available Related Documents

The following is a list of available documents related to Difenzoquat. 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 Difenzoquat 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. Difenzoquat 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

OFFICE OF

PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PR NOTICE 86-5

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-

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.

Element	When Required	Example
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 require-ments	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 Confi-dential 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 (C)	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 pub-lished document, identity 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 pet-itions 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 ln 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

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 6§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 in 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)

CROSS REFERENCE NUMBER 1 — 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: Ethylene Glycol

PAGE REFERENCE	LINES	REASON FOR THE DELETION	FIFRA
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)

CROSS REFERENCE NUMBER 5 — 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)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

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

CROSS REFERENCE NUMBER 7 — 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

PAGES	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
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 _____

Study Director _____

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_____

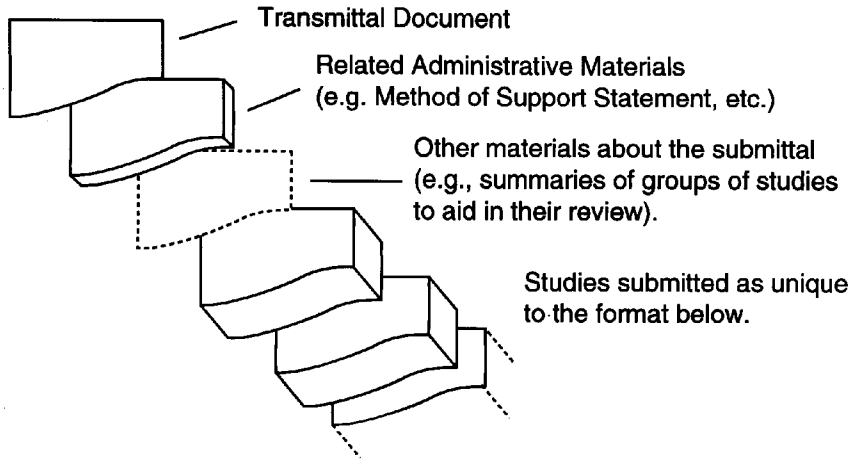
Example 3.

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.

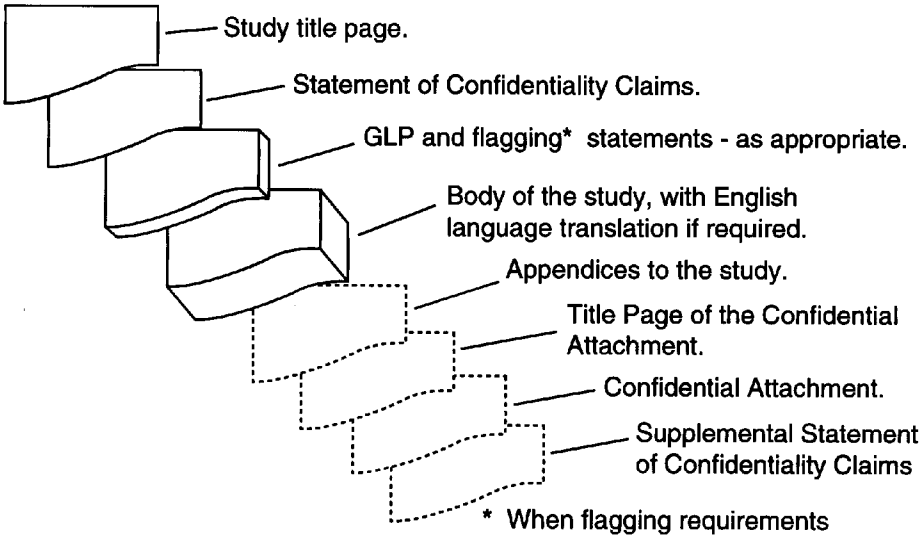
Submitter_____

ATTACHMENT 7.

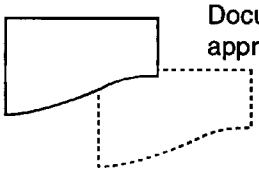
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



Documents which must be submitted as appropriate to meet established requirements.

Documents submitted at submitter's option.

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 l0(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 then 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:

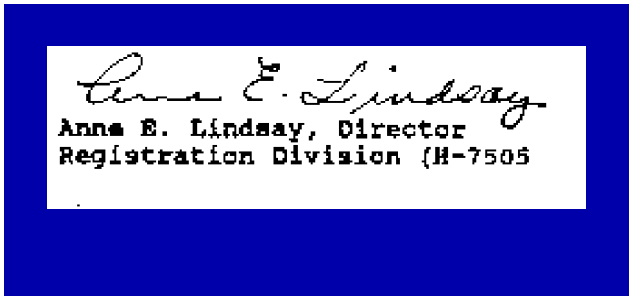
(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(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.



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 Grouping 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.I., 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,

Louis P. True, Jr., Acting 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 Grouping 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

Difenzoquat DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Difenzoquat. 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 Difenzoquat 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 Difenzoquat are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Difenzoquat are needed. These data are needed to fully complete the reregistration of all eligible Difenzoquat 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 Andrew Ertman at (703) 308-8063.

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

Andrew Ertman, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Difenzoquat

DIFENZOQUAT DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Difenzoquat, please contact Andrew Ertman at (703) 308-8063.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Franklin Gee at (703) 308-8008.

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

Veronica Dutch
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: **Difenzoquat**

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 reprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been reprinted 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.

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 initialled 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 "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 reprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been reprinted 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 initialled 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 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

EPA'S DECISION NOT TO BATCH PRODUCTS CONTAINING DIFENZOQUAT FOR PURPOSES OF 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 difenzoquat, the Agency considered batching end-use products. This process involves grouping similar products 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.).

However, batching of products containing difenzoquat was not possible after considering the available information described above. Table I lists the end-use products (2) containing difenzoquat. These products were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making purposes. The registrant is responsible for meeting the acute toxicity data requirements for each product.

Registrants must generate all the required acute toxicological studies for each of their products. 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).

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," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant 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). Since the products containing difenzoquat could not be batched, registrants cannot choose from the remaining options: Cost Sharing (Option 2) or Offers to Cost Share (Option 3).

Table I (No Batch)

EPA Reg. No.	% Active Ingredients	Formulation Type
241-239	96.5% difenzoquat	Solid
241-266	31.2% difenzoquat	Liquid

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 20-25E 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 EC
____ Any observed decomposition reported

63-6 Boiling Point
____ Reported in EC
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity
____ Measured at about 20-25E C
____ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20E C. [Note: Bulk density of registered products may be reported in lbs/ft^3 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 20-25E C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure
____ Measured at 25E C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25E 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 20-25EC)

63-11 Octanol/water Partition Coefficient
____ Measured at about 20-25E 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 20-25E 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

Guideline	Study Title
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, 22E 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 cm^2.
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

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

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

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 3-31-96

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)(D) 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)(D) 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 sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-90)

APPENDIX G. FACT SHEET

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-94-014 September 1994

R.E.D. FACTS

Difenzoquat

Pesticide Reregistration

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 for reregistration Case 0223, difenzoquat.

Use Profile

Difenzoquat is a selective, post-emergent herbicide used to control wild oats in barley and wheat. Wild oats is an annual grassy weed that out-competes barley and wheat, causing serious yield losses. Marketed under the trade name Avenge, difenzoquat is a soluble concentrate/liquid applied once per growing season as a ground or aerial broadcast treatment. Most of the product used in the U.S. is applied to wheat crops (64-77%).

Regulatory History

Difenzoquat was first registered as a pesticide in the U.S. in July 1975, for its current uses. EPA issued a Registration Standard for difenzoquat in December 1988 (NTIS #PB89-162127). Currently, two difenzoquat pesticide products are registered. One is a technical grade, manufacturing use product containing 96% of the active ingredient; the other is the end-use product Avenge, a soluble concentrate containing 31.2% active ingredient.

Human Health Assessment

Toxicity

In acute toxicity studies, difenzoquat has caused severe irritation to the eyes of rabbits. It has been placed in Toxicity Category I, indicating the greatest degree of acute toxicity, for eye irritation effects. Difenzoquat causes a moderate degree of acute toxicity administered orally, to the skin and by

inhalation, and has been placed in Toxicity Categories II and III for these effects.

In a subchronic feeding study using beagle dogs, difenzoquat caused no treatment-related effects. However, treatment-related skin reactions and effects were noted in a dermal toxicity study using rabbits.

A chronic toxicity study using rats resulted only in decreased body weight gains. A study using beagle dogs resulted in numerous toxic signs including high mortality, decreased food consumption, weight loss, tremors, lethargy and irregular gait. Difenzoquat is not carcinogenic in studies using rats and mice, and has been classified as a Group E carcinogen (a compound showing evidence of non-carcinogenicity for humans).

Developmental toxicity studies using rats and rabbits resulted in maternal toxicity in the higher dose groups, a decrease in fetal weights in rats, and vertebrae abnormalities in rabbit offspring. In a reproductive toxicity study using rats, difenzoquat caused maternal decreased body weight gain and weight decreases in pups at birth and weaning. Difenzoquat is not mutagenic. Neurotoxicity studies still are required.

Dietary Exposure

People may be exposed to low level residues of difenzoquat in the diet when consuming wheat, barley or the meat of poultry, cattle, hogs and sheep. Tolerances or maximum residue limits are established, and have been reassessed, for residues of difenzoquat in barley and wheat grain and straw, in the meat, fat and byproducts of cattle, goats, hogs, horses and sheep, and in poultry meat and meat byproducts (please see 40 CFR 180.369). Tolerances are not established or needed for milk or eggs, but food and feed additive tolerances must be established for wheat bran and shorts, and barley bran and hulls.

EPA estimates that the overall U.S. population is exposed to about 0.1% of the difenzoquat Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. Children aged one through six, the most highly exposed population subgroup, are exposed to about 0.2% of the RfD. The new food additive tolerance for wheat bran will not cause a measurable increase in these extremely low exposure levels.

Occupational and Residential Exposure

Pesticide handlers (mixers, loaders and applicators) may be exposed to difenzoquat during application. However, difenzoquat generally is of low acute toxicity and causes no toxicity concerns for workers, with the exception of primary eye irritation. Since difenzoquat is extremely acutely toxic to the eyes and is placed in Toxicity Category I for eye irritation, a 48 hour restricted entry interval (REI) imposed by the Worker Protection Standard (WPS) will be maintained. During this time period, workers who must enter treated areas will be required to wear personal protective equipment (PPE) including coveralls, chemical-resistant gloves, shoes plus socks, and protective eyewear.

Human Risk Assessment

Although difenzoquat is used on barley and wheat crops, consumers are exposed to extremely low level residues in their diets posing no known risks. Difenzoquat generally is of low acute toxicity but poses a risk of acute eye

irritation to workers. To mitigate this risk, a 48 hour restricted entry interval will be maintained. People who must enter treated areas during this time are required to wear designated protective clothing and equipment including protective eyewear.

Environmental Assessment

Environmental Fate

Difenzoquat is persistent and relatively immobile. However, the environmental fate assessment is not complete because the route of dissipation has not been established. Laboratory data indicate that difenzoquat binds with/is immobile in soil and has little potential for ground water contamination. However, field dissipation studies contrast sharply and indicate that residues decline with time. Additional, confirmatory data are required to compare the recovery methods used in laboratory and field studies.

Ecological Effects

Difenzoquat is slightly toxic to practically non-toxic to birds and freshwater fish, but is moderately toxic to freshwater invertebrates. It is non-toxic to honey bees.

Ecological Effects Risk Assessment

Current uses of difenzoquat do not pose any unreasonable threat to the environment. Difenzoquat is believed to present a slight to moderate potential for acute toxicity to wildlife and aquatic species. Actual acute risks, however, appear to be minimal. Chronic toxicity to wildlife appears to be slight, and chronic risk to fish is unlikely.

Since difenzoquat is a herbicide that is applied aerially, risk to non-target aquatic and terrestrial plants, including endangered plant species, is expected to be high. Additional, confirmatory data are required to assess these risks. In addition, EPA is exploring risk mitigation for all herbicides.

Additional Data Required

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

Acute and 90-Day Neurotoxicity Screening Studies;

Seed Germination/Seedling Emergence;

Vegetative Vigor;

Aquatic Plant Growth;

Confined Rotational Crop;

Droplet Size Spectrum;

Drift Field Evaluation;

Non-guideline laboratory study comparing recovery methods used in previous laboratory and field dissipation studies.

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

Product Labeling Changes Required

The labels of all registered pesticide products containing difenzoquat must comply with EPA's current pesticide labeling requirements. No additional labeling requirements are required for the end-use product at this time. However:

- The Restricted Entry Interval (REI) established by the Worker Protection Standard must remain at 48 hours. This REI must be inserted into the standardized REI statement required by PR Notice 93-7.
- Personal protective equipment (PPE) for early entry includes coveralls, chemical resistant gloves, shoes plus socks, and protective eyewear. These items must be inserted into the early entry PPE statement required by PR Notice 93-7.

Regulatory Conclusion

The use of currently registered pesticide products containing difenzoquat 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.

These difenzoquat products will be reregistered once the confirmatory generic data, 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 difenzoquat 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.

Following the comment period, the difenzoquat RED document 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 difenzoquat RED, or reregistration of individual products containing difenzoquat, 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 6:00 pm Central Time, Monday through Friday.