United States
Environmental Protection
Agency

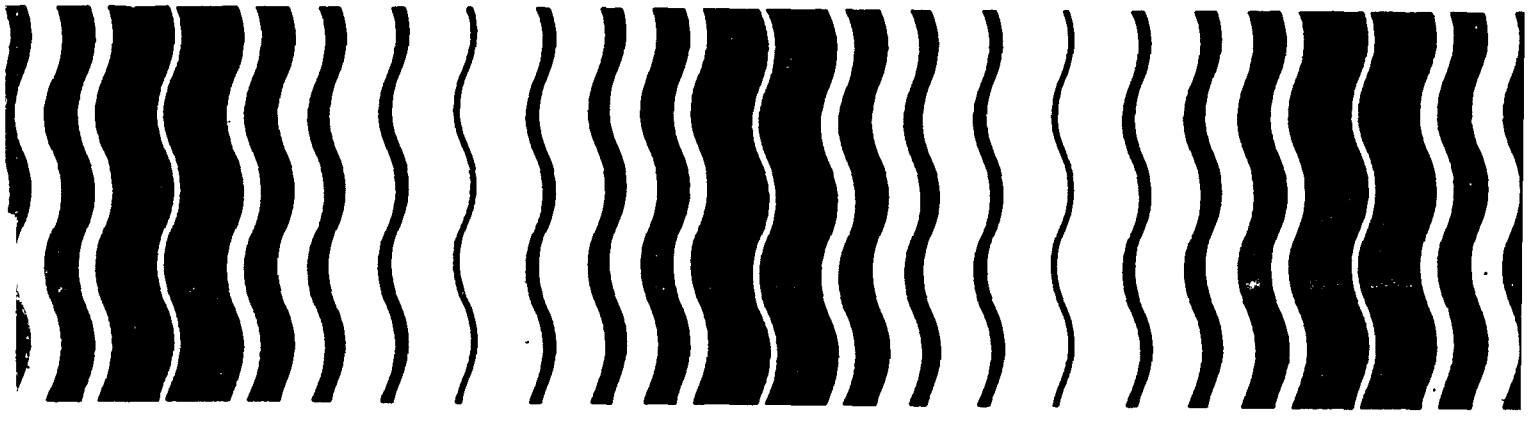
Office of
Pesticides and Toxic Substances
Washington DC 20460

Pesticides

540/RS-89-034

EPA

Guidance for the Reregistration of Pesticide Products Containing DIFENZOQUAT METHYL SULFATE as the Active Ingredient



OMB Control No. 2070-0057
Expires November 1989

GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

DIFENZOQUAT METHYL SULFATE

AS THE ACTIVE INGREDIENT

OPP Chemical Number: 106401

GS 0223

CAS (DOCKET) NUMBER : 43222-48-6 (SALT)

December 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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APPENDICES

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	An acceptable daily intake of pesticide residue based on a complete data base.
a.i.	Active ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial or aquatic ecosystem.
EP	End Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest dose tested in a toxicity study.
LC50	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 or feed, e.g., mg/l or ppm.
LD50	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). It is usually expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LDT	Lowest dose tested in a toxicity study.
LEL	Lowest Effect Level from a toxicity test in animals.
MPI	Maximum Permissible Intake of residues.

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing Use Product
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level from a toxicity study.
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake is an acceptable daily intake of pesticide residue that is based on a limited data base.
ppm	Parts per million
RfD	Reference Dose is an estimate of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The reference dose is a replacement term for the term acceptable daily intake (ADI).
TMRC	Theoretical Maximum Residue Contribution is an estimate of dietary exposure obtained by multiplying residue tolerance levels for a given pesticide by the average daily per capita food consumption figure, then adding the exposure figure for each crop. The TMRC is usually expressed in terms of mg/kg of food.

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program 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" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request,[1] focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review

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[1]The scientific reviews and Compendium of Acceptable Uses may be obtained from the OPP Public Docket. Write to OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, D.C. 20460

of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment. EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submittal of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submittal of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICALS COVERED BY THIS STANDARD

A. Description of Chemical

Difenzoquat is the American National Standards Institute (ANSI) common chemical name for 1,2-dimethyl-3,5-diphenyl-1 H-pyrazolium. It is marketed under the trade name AVENGE by American Cyanamid Company. AVENGE contains the methyl sulfate salt of difenzoquat.

Other identifying characteristics and codes are:

Empirical Formula: $C_{18}H_{20}N_2O_4S$ (Salt)

Molecular weight: 360.4 (Salt)

CAS Registry No.: 43222-48-6 (Salt)

OPP (Shaughnessy) No.: 106401 (Salt)

General Description of Chemical

Difenzoquat is a white, odorless, crystalline solid with a bulk density of 41 lb/cu.ft.. Difenzoquat is soluble in water; 76.5% at 23°C. It is poorly soluble in most organic solvents. This chemical is very stable under most conditions.

B. Use Profile

Difenzoquat or AVENGE is a postemergent herbicide for control of wild oats in alfalfa (seed crop in CA), wheat and barley. It is readily absorbed by plants and is not significantly metabolized or further degraded. The exact herbicidal mode of action of difenzoquat is not currently understood.

The only pest claim on the end-use products is for control of wild oats (*Avena fatua*) which is one of the most serious annual weeds in the hard red spring wheat growing areas of Montana, North Dakota, and Minnesota. Wild oats is an annual grassy weed with growth habits that out-compete wheat and barley and create serious yield losses.

Difenzoquat is applied postemergence broadcast by ground or aerial equipment when wild oats are in the three to five leaf stage (tillering). The rates of application range from 0.6 to 1.0 lbs./acre. This herbicide may be used on all varieties of barley and certain varieties of wheat. Since difenzoquat is highly selective in its weed control, it is usually tank mixed with broadleaf herbicides such as the amine salts or esters of MCPA (2-methyl-4-chlorophenoxyacetic acid) or 2,4-D (2,4-dichlorophenoxyacetic acid), metsulfuron methyl, bromoxynil, or chlorsulfuron.

Table I. Listing of Registered Products Containing Difenzoquat Methyl Sulfate

Formulation and Registration No.	Product Name	Manufacturer
96% Technical Chemical EPA Reg. No. 241-239	AVENGE Technical Herbicide	American Cyanamid Company
31.2% Soluble Concentrate Liquid (2 lb./gal) EPA Reg. No. 241-266	AVENGE Wild Oat Herbicide	American Cyanamid Company
31.8% Soluble Concentrate Liquid (2 lb./gal) EPA Reg. No. 241-250	AVENGE 2AS Wild Oat Herbicide	American Cyanamid Company
62.5% Soluble Concentrate/ Solid EPA Reg. No. 241-262	AVENGE S Wild Oat Herbicide	American Cyanamid Company

II. AGENCY ASSESSMENT

The Agency has reviewed all data in Agency files as of June 14, 1988 supporting the registration of difenzoquat. Data received by the Agency after this date have not been reviewed for the purposes of this standard. This section discusses the Agency's scientific findings and conclusions based on these reviewed data.

A. SUMMARY

The Agency has reviewed all available data for difenzoquat and determined that there are data gaps in the areas of residue chemistry, environmental fate, and toxicology.

A summary of these data gaps appears in Table II. Note that this list contains only summary information on the data gaps. More detailed information relating to the issues can be found in the Data Tables in Appendix I.

Table II. Summary of Data Gaps for Difenzoquat

Toxicology

Acute Oral Toxicity in one sex (females)
Acute Dermal Toxicity in one sex (females)
Acute Inhalation Toxicity in one sex (females)
Dermal Sensitization
Subchronic Dermal (21-day)
Chronic Toxicity in one species (nonrodent)
Teratogenicity in one species (rat)
Oncogenicity in one species (mouse)
Mutagenicity
(Gene mutation, chromosomal aberration, and direct DNA damage studies).
Metabolism

Ecological Effects

(None identified)

Environmental Fate

Hydrolysis
Photodegradation in water and on soil
Aerobic and anaerobic soil metabolism
Leaching and Adsorption/Desorption
Volatility (Lab)
Terrestrial field dissipation (soil)
Accumulation rotational crops (confined)
Fish accumulation

Product Chemistry
Product Identity and Disclosure of Ingredients
Description of Manufacturing Process
Discussion of Formulation and Impurities
Preliminary Analysis of Product Samples
Certification of Ingredient Limits
Analytical Methods to Verify Certified Limits
Physical and Chemical Characteristics

Residue Chemistry: Tolerance Reassessment

Nature of the Residue (Metabolism) in Livestock
Residue Analytical Methods
Storage Stability Data
Magnitude of Residue in Plants,
Fat/Meat/Meat Byproducts

B. Health Effects Assessments

1. Acute Toxicity

In studies with male rodents difenzoquat is moderately toxic by the oral route and only slightly toxic via the dermal route of exposure in rabbits. It has an extremely low toxicity via the inhalation route of exposure. Difenzoquat was found to be only slightly irritating to rabbits' eyes and moderately irritating to abraded skin while non-irritating to intact skin.

No data on the oral, dermal, inhalation toxicity and dermal sensitization of difenzoquat in female test animals available for review. These studies are required.

2. Subchronic Toxicity

In a 21-day subchronic dermal exposure study with difenzoquat, rabbits were dosed dermally for 21 days at doses of 0.25, 0.5, and 1.0 g/kg. The test material was applied for six hours a day, five days a week, and half of application sites were abraded. No toxic signs were exhibited in male rabbits at 0.5 g/kg level and in female rabbits at 1.0 g/kg level. Decreased body weight gain was the only toxic effect noted in males at the 1.0 g/kg level. However, the study reviewed was judged to be inadequate because it failed to note basic test parameters such as: application sites; food consumption; clinical biochemistry tests; organ weights; and an insufficient number of test animals from the high-dose group were microscopically examined. A new study is required.

No compound related effects were observed in male and female dogs in a 90-day oral feeding study. The systemic NOEL in that study is 2500 ppm (62.5 mg/kg:HDT).

3. Chronic Toxicity

There are no chronic feeding studies conducted with difenzoquat in non-rodents. This study is required.
The only toxic sign noted in a 2 year chronic feeding study in rats was a decrease in body weight gain in both sexes at the 2500 ppm level (125 mg/kg). A systemic NOEL was established at the 500 ppm level (25 mg/kg) for males and females.

4. Developmental Effects and Teratology

Teratogenic, fetotoxic and maternal toxic effects were not observed in rabbits at the 100 mg/kg level. However, high mortality and high percentage of animals with resorptions were observed at the high level (250 mg/kg:HDT).

Difenzoquat was negative for teratogenicity, fetotoxicity and maternal toxicity in the rat at the 2500 ppm (125 mg/kg; HDT) level. However, the test material was incorrectly administered, thus invalidating the test. No maternal toxicity was observed at the highest level tested. Another rat teratology study is required.

5. Reproduction

In a 3-generation rat reproduction study, the parental NOEL was equal to or greater than 2500 ppm (125 mg/kg:HDT) and reproductive/ developmental NOEL was 500 ppm (25 mg/kg). Decreased body weights of male and female pups at weaning in all generations and decreased body weights of male and female pups at birth in the second and third generation, respectively, were observed at the 2500 ppm level.

6. Oncogenicity

In a 2-year oncogenicity study in rats, difenzoquat was administered in the diet at levels of 100 ppm (5 mg/kg), 500 ppm (25 mg/kg), 2500 ppm (125 mg/kg), and 5000 ppm (250 mg/kg). No oncogenic effects were observed at any dose level. However, the oncogenic potential of difenzoquat in mice could not be determined because too few animals (tissues) were examined microscopically at all dose levels and particularly at the 2500 ppm (375 mg/kg:HDT) level in an 18-month feeding study. A new mouse oncogenicity study is required.

6. Mutagenicity

Insufficient data are available to evaluate the mutagenicity potential of difenzoquat. The following studies are required: gene mutation; chromosomal aberration; and direct DNA damage.

The only mutagenic study available is a dominant lethal study. Difenzoquat was judged not to be mutagenic in this study because of the low incidence of embryonic mortality when females were mated with treated males as compared with females mated with untreated males. This study has been provisionally classified as unacceptable because a positive control was not reported. This study may be upgraded upon receipt of information regarding the positive control.

C. Environmental Characteristics and Effects

1. Environmental Fate

The review of the environmental fate data indicates that difenzoquat is stable to hydrolysis. Difenzoquat is not likely to leach because it remains bound to soil particles and thus is not expected to contaminate groundwater.

While the studies available to the Agency have not been conducted according to the Agency's guidelines they have been deemed good studies following generally sound scientific practice. They have been classified as "supplemental" information on which to base the characterization of the fate of difenzoquat.

Hydrolysis study: This study does not fulfill data requirements because the test substance and the buffer solutions were incompletely characterized. However, the data suggest that difenzoquat is stable to hydrolysis. This study may be made acceptable if the appropriate information can be supplied.

Photodegradation studies in water: Two studies are available. One study is unacceptable because it was done in pond water. In addition the sampling protocol was inadequate (sampling was too infrequent and >90% of the difenzoquat dissipated between the first and second samplings) to precluding an accurate characterization of the photodegradation half-life of difenzoquat in water. The second study is also unacceptable because there were no dark controls, it was not specified that the solutions were sterile, and the sampling protocol (sunlight-irradiated solutions were analyzed at 58 days posttreatment only) was inadequate to accurately establish the photodegradation of difenzoquat in aqueous solutions.

Photodegradation studies on soil: One study is available. This study does not fulfill data requirements because the natural sunlight, the test substance and test soil were incompletely characterized. Also the incubation temperature was too high, ranging from 22-42°C.

Aerobic soil metabolism studies: No data were available for review.

Anaerobic soil metabolism studies: No data were available for review.

Leaching and adsorption/desorption study: This study does not fulfill data requirements because the unaged and aged portion of the test substance does not fully characterize the test substance, the description of incubation conditions during the aging period was inadequate, and [^{14}C]residues in the soil before and after leaching were not characterized.

Terrestrial field dissipation studies: Twelve studies are available. Six studies are unacceptable because they do not meet EPA Guidelines. Six studies provide supplemental information that suggests difenzoquat dissipates with a half-life of 7 to 180 days depending on soil type. These six studies do not fulfill data requirements because freezer storage stability data were not provided.

Confined accumulation studies on rotational crops: No data were available for review.

Laboratory studies of pesticide accumulation in fish: No data were available for review.

The following data requirements are deferred until the submission and evaluation of all of the previously identified environmental fate data requirements: photodegradation in air, aerobic and anaerobic aquatic metabolism, field volatility, aquatic field dissipation, forest dissipation, dissipation for combination products and tank mixes, long-term field accumulation on irrigated crops, and field accumulation in fish (laboratory).

Reentry

Reentry data are not required based on current use patterns of difenzoquat; postemergent applications to wheat and barley are at a time when workers are not expected to be in treated fields. Wheat and barley are harvested by machine and workers are not expected to be exposed to difenzoquat during harvest.

2. Ecological Effects

The available data were adequate to fully assess the potential hazards relating to the ecological effects for difenzoquat. No adverse effects to birds and mammals from the currently registered uses of difenzoquat are anticipated.

Difenzoquat is slightly toxic to mallard ducks (LD_{50} - 10,388 ppm) and bobwhite quail (LD_{50} -4640 ppm). Difenzoquat was found to be slightly toxic to fish (bluegill $LC5_0$ - 90.4 ppm and rainbow trout LC_50 - 76-99 ppm). Aquatic invertebrates were found to be the most sensitive test group to difenzoquat. Technical difenzoquat was found to be moderately toxic to freshwater invertebrates (Daphnia LC_{50} - 2.63 ppm).

A worst case scenario model for exposure of aquatic species would be a direct application to a farm pond using the maximum application rate applied to wheat and barley, 1 lb/ai/A. This type of application can be expected to result in a concentration of 0.061 ppm. This concentration is 43 times lower than the LC_{50} for Daphnia (2.63 ppm). Since this worst case scenario model does not indicate concern for aquatic invertebrates, additional modeling of runoff and drift is unnecessary.

Adverse chronic effects on terrestrial and aquatic species from difenzoquat are not anticipated because of its low toxicity and use restriction to a single application per season.

No data relating to nontarget insects are required. The uses for this herbicide, single postemergent applications to wheat and barley, do not represent significant exposure routes for honey bees.

3. Endangered Species

The uses of difenzoquat will have a low potential for hazard to endangered plant and animal species. These uses, are not expected to result in difenzoquat entering the habitat of susceptible aquatic and terrestrial organisms in significant concentrations. Since the only uses of this chemical are applications to cultivated crops, difenzoquat is not expected to have an adverse impact on endangered plant species. Risks to endangered plant and animal species have been deemed to be minimal and no additional data are needed.

D. Tolerance Reassessment

Residue Data

Tolerances have been established on a number of raw agricultural commodities and in meat, fat, and meat byproducts (40 CFR 180.369) for difenzoquat at levels ranging from 0.05 to 20.0 ppm. A Canadian maximum residue limit (MRL) of 0.1 ppm (negligible residue) has been established for difenzoquat in or on wheat and barley grain. There are no Mexican tolerances or Codex MRL for residues of difenzoquat in or on wheat grain. There are no Canadian or Mexican tolerances or Codex Maximum Residue Levels (MRL) for difenzoquat in or on barley or wheat straw. A listing of the established tolerances and MRLs is located at the end of this section.

The Agency has evaluated the residue and toxicology data supporting the tolerances and reviewed all uses of difenzoquat. Based on the available data the Agency has reached the following conclusions:

- The metabolism of difenzoquat in ruminants and poultry is not adequately understood. The tolrances for residues in animal commodities cannot be assessed at this time until the required animal metabolism, storage stability and method validation studies have been submitted and reviewed.

- The metabolism of difenzoquat in small grains is adequately understood. In barley plants difenzoquat remains almost entirely unmetabolized (96% of radiolabelled residues consisted of unaltared difenzoquat). One possible metabolites is 1-methyl-3,5-diphenyl pyrazole. Other metabolites present in trace amounts of those found in soil and photodegradation studies.

- Adequate methods exist for data collection and enforcement.

- Data adequately support the tolerances for residues of difenzoquat in barley and wheat grain, and straw. However, storage stability data are needed to validate these data.

Tolerance Assessment System (TAS) Tolerance Reassessment

A Reference Dose (Rfd) was established for difenzoquat based on a NOEL of 25 mg/kg from a two-year rat feeding study, using a safety factor of 300 to account for the lack of a chronic study in the most sensitive species, the dog. The Rfd is 0.08 mg/kg/day. It is considered a Provisional Allowable Daily Intake (PADI) because of the data gaps. The study from which the NOEL is taken is considered of only fair quality and is given a low confidence rating; the highest dose tested produced only marginal decrease in weight gain, but the change was consistent during a significant part of the study.

Dietary exposure was calculated using the published tolerances. The TAS Routine Chronic Analysis estimated a daily intake of 0.000219 mg/kg/day for the average U.S. population, 0.27% of the RfD. No population subgroup consumed more than 0.52% of the RfD.

Table IV. Summary of Tolerances Issued for Difenzoquat

Commodities	Tolerances (ppm) US[1]	MRL Canada[2]	MRL International[3]
Barley, grain	0.2	0.1(N)	
Barley, straw	20		
Cattle, fat	0.05		
Cattle, meat	0.05		
Cattle, meat byproducts	0.05		
Goats, fat	0.05		
Goats, meat	0.05		
Goats, meat byproducts	0.05		
Hogs, fat	0.05		
Hogs, meat	0.05		
Hogs, meat byproducts	0.05		
Horses, fat	0.05		
Horses, meat	0.05		
Horses, meat byproducts	0.05		
Poultry, fat	0.05		
Poultry, meat	0.05		
Poultry, meat byproducts	0.05		
Sheep, fat	0.05		
Sheep, meat	0.05		
Sheep, meat byproduct	0.05		
Wheat, grain	0.05	0.1(N)	
Wheat, straw	20		

1/ The United States tolerances are expressed as residues of difenzoquat (calculated as cation).

2/ Canadian MRLs are expressed in terms of residues of difenzoquat *per se*.

3/ No Mexican tolerances or Codex Maximum Residue Level (MRL) have been established for difenzoquat.

N - negligible.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on the review and evaluation of the available data on difenzoquat, the Agency has made the following determinations. Where label revisions are imposed, specific language is set forth in Section C of this Chapter.

1. The Agency will not initiate a Special Review of difenzoquat.

Rationale: Based on the data available to the Agency, difenzoquat does not exceed any of the risk criteria for Special Review specified in 40 CFR 154.7.

2. The Agency is not imposing restricted use classification on difenzoquat.

Rationale: At present, there is no indication that difenzoquat meets the criteria for restricted use in 40 CFR 152.170.

3. The Agency is not requiring registrants to place endangered species labeling on end-use products containing difenzoquat.

Rationale: The principal use patterns for difenzoquat are single postemergent applications to barley and wheat. The low toxicity to fish, mammals, and aquatic invertebrates combined with the limited use patterns is not expected to result in any adverse impact on endangered or threatened species.

Since the only federally registered uses of this pesticide are applications to cultivated crops, it is not expected to have an adverse impact on endangered plant species.

4. The available residue chemistry data are insufficient to permit the Agency to conduct a full tolerance reassessment.

Rationale: Data gaps exist for animal metabolism and magnitude of residue for difenzoquat in ruminants and poultry.

5. No new/additional tolerances for feed items treated with difenzoquat will be issued until the animal data have been submitted and reviewed by the Agency. Until these data gaps are filled, the Agency believes that it is prudent not to issue any new/additional tolerances for difenzoquat.

Rationale: Available animal metabolism and magnitude of residues in livestock data, are insufficient and/or lacking. These data deficiencies preclude the Agency from conducting a full tolerance reassessment.

6. The Agency is not requiring the use of personal protective clothing or establishment of reentry intervals for difenzoquat.

Rationale: Based on the available toxicological information, there are no concerns with human exposure which would require personal protective clothing and specific field reentry intervals.

7. The Agency is not requiring the addition of a groundwater advisory statement to difenzoquat labels.

Rationale: No acceptable environmental fate data are available to fully assess this issue. The Agency is requiring the submission of environmental fate data. Refer to Appendix I, Table A for the specific data requirements. While certain environmental fate data are lacking, a preliminary review of the available data indicates that difenzoquat is not persistent and does not leach. Rather, it remains bound in nearby soil particles and is not expected to contaminate groundwater. After a review of the data sufficient to evaluate groundwater hazards, the Agency will take the appropriate steps to protect groundwater if necessary.

8. No studies have been identified for priority review. The Agency will review the studies submitted under this Registration Standard when it schedules difenzoquat for a second round review.

Rationale: There are no human health or environmental concerns that warrant early review of these studies.

9. Data in support of tolerances on alfalfa hay and seed must be submitted, and pre-harvest intervals proposed. If the registrant of this use, permitted only in California under SLN CA 770540, can demonstrate to the Agency's satisfaction that treated alfalfa seed and hay will not be used for food or animal feed purposes, the Agency will consider this use to be a non-food, non-feed use not requiring the establishment of a tolerance. The State of California, California Department of Food and Agriculture (CDFA), must establish the following restrictions regarding alfalfa treated with difenzoquat, as well as provide evidence of ability to enforce these restrictions.

a. All screenings must be disposed of in such a way that they cannot be distributed or used for food or feed. The seed conditioner must keep records of screening disposal for three years from the date of disposal and shall furnish the records to the director of the California Department of Food and Agriculture upon request. Disposal records shall consist of documentation from a controlled dump site, incinerator, or other equivalent disposal cite and shall show the amount of material disposed of, its grower, and the date of disposal.

b. No portion of the seed alfalfa plant, including but to limited to green chop, hay, pellets, meal, whole seed, and cracked seed, may be used or distributed for food or feed purposes.

c. All alfalfa seed conditioned in the state of California must be bear a label tag which prohibits the use of the seed for human consumption or animal feed.

d. No alfalfa seed conditioned in California may be distributed for human consumption or animal feed.

Rationale: No tolerances have been established for difenzoquat in or on alfalfa seed and hay. Restrictive provisions upon the use of treated alfalfa, however, will permit a determination that tolerances are not necessary.

10. While data gaps are being filled, currently registered manufacturing use products (MPs) and end use products (EPs) containing difenzoquat may be sold, formulated and used, subject to the terms and conditions specified in this Standard. Registrant must provide or agree to develop additional data, as specified in the Data Appendicies, in order to maintain existing registrations.

Rational: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or inadequate (see FIFRA section 3(c)(2)(B) and 3(c)(7)). The issuance of this Standard provides the mechanism for obtaining necessary data. The data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain difenzoquat, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this registration standard.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain this pesticide. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing this pesticide provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the commodities listed below. The EPA Compendium of Acceptable Uses (for availability, see page 1) lists all registered uses, as well as approved maximum application rates and frequencies.

Terrestrial, non-domestic, food uses on:

Barley
Wheat
Alfalfa (seed crop only under SLN in CA)

D. LABELING

In order to remain in compliance with FIFRA, products must bear appropriate labeling as specified in 40 CFR 156.10 and this Standard, or must be revised to conform to those specifications. Appendix II contains information on label requirements.

No pesticide product containing this pesticide may be released for shipment by the registrant after December 31, 1988, unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing this pesticide may be distributed or sold after December 31, 1988, unless the product bears an amended label which complies with the requirements of this Standard.

The following specific information must appear on the labeling in order for products to remain in compliance with FIFRA:

1. Ingredients Statement

The ingredient statement for products must list the active ingredient as:

ACTIVE INGREDIENT
difenzoquat methyl sulfate....._____%

INERT INGREDIENTS....._____%

2. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Compendium of Acceptable Uses. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

3. Precautionary Statements:

Environmental Hazard Statements

a. Statements for Manufacturing-Use Product

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

b. Statements for End-Use Products

"Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

   1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

   2. The data requirements listed in Tables A and B.[2]

   3. The labeling requirements specified for manufacturing use products in Section IV.

   4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

   1. The data requirements listed in Table A.

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[2]Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end-use products at this time. Therefore, most Registration Standards do not contain a Table C.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption, [3]e data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

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[3]If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

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 registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4]Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be

submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

[Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit 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 in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with 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 Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of 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 or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6. (cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: Difenzoquat Registration Standard

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

TGUIDE-1

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to 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 out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Prot Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure Active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food

F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). 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 Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column e indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column t requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

Table A
Generic Data Requirements for Products Containing Difenzoquat

Data Requirement	Test Substance[1]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission
Part 158.190, Subpart C, Product Chemistry					
Product Identity and Composition					
61-1 - Product Identity and Disclosure of Ingredients	MP	No[2]		Yes[3]	9 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No[2]		Yes[4]	9 Months
61-3 - Discussion of Formation of Impurities	TGAI	No[2]		Yes[5]	9 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	TGAI	No[2]		Yes[6]	12 Months
62-2 - Certification of Ingredient Limits	MP	No[2]		Yes[7]	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	No[2]		Yes[8]	12 Months
Physical and Chemical Characteristics					
63-2 - Color	TGAI	No[2]		Yes[9]	9 Months
63-3 - Physical State	TGAI	No[2]		Yes[9]	9 Months

Table A
Generic Data Requirements for Products Containing Difenzoquat

Data Requirement	Test Substance[1]	Does EPA Have Data to Satisfy This Requirement	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)	Timeframe for Submission
Part 158.190, Subpart C, Product Chemistry (cont'd)					
Physical and Chemical Characteristics (cont'd)					
63-4 - Odor	TGAI	No[2/]		Yes[9/]	9 Months
63-5 - Melting Point	TGAI	No[2/]		Yes[9/]	9 Months
63-6 - Boiling Point	TGAI	No[2/]		No[10/]	
63-7 - Density, Bulk Density or Specific Gravity	TGAI	No[2/]		Yes[9/]	9 Months
63-8 - Solubility	TGAI or PAI	No[2/]		Yes[9/]	9 Months
63-9 - Vapor Pressure	TGAI or PAI	No[2/]		Yes[9/]	9 Months
63-10 - Dissociation Constant	TGAI or PAI	No[2/]		Yes[9/]	9 Months
63-11 - Octanol/Water Partitioning	PAI	No[2/]		Ass/	9 Months
63-12 - pH	TGAI	No[2/]		Yes[9/]	9 Months

Part 158.190, Subpart C, Product Chemistry (cont'd)

Physical and Chemical Characteristics (cont'd)					
63-13 -	Stability	TGAI	No[2/]	Yes[9/]	9 Months
63-14 -	Oxidizing or Reducing Agent	MP	No[2/]	Yes[9],	9 Months
63-15 -	Flammability	MP	No[2/]	No[9,11/]	9 Months
63-16 -	Explodability	MP	No[2/]	Yes[9,12/]	9 Months
63-17 -	Storage Stability	MP	No[2/]	Yes[9/]	15 Months
63-18 -	Viscosity	MP	No[2/]	No[9,13/]	9 Months
63-19 -	Miscibility	MP	No[2/]	No[9,14/]	9 Months
63-20 -	Corrosion Characteristics	MP	No[2/]	Yes[9/]	15 Months
Other Requirements:					
64-1 -	Submittal of Samples	N/A	N/A	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR PRODUCTS CONTAINING DIFENZOQUAT

Part 158.190, Subpart C, Product Chemistry - Footnotes

1/ Because the 96% T is also a manufacturing-use product, product chemistry data requirements applicable to both technical and manufacturing use products are covered in this table .

2/ Although product chemistry may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New data requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

3/ The chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common and trade names; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned code numbers.

4/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

5/ A detailed discussion of all impurities that are or may be present at $\geq$0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

6/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used. Specific analyses for the potential impurity, hydrazine, must be included.

7/ Upper and lower limits for the active ingredients and each intentionally added inert, and upper limits for each impurity present at $\geq$ 0.1% (w/w) and each "toxicologically significant" impurity present at <0.1% (w/w) must be provided and certified. Also, an explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimate based on amounts of ingredients used, etc.). Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certification must be submitted on EPA form 8570-4 Rev. 2-85.

TABLE A.
GENERIC DATA REQUIREMENTS FOR PRODUCTS CONTAINING DIFENZOQUAT

Part 158.190, Subpart C, Product Chemistry - Footnotes (cont'd)

8/ Analytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

9/ As required in the 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, quantitative data are required on color, physical state, odor, melting point, specific gravity, solubility, vapor pressure, dissociation constant, octanol/water partitioning coefficient, pH, and stability. Because the 96% T is also a manufacturing-use product, quantitative data are also required on oxidizing/reducing action, expodability, storage stability, and corrosion characteristics.

10/ Data on boiling point are not required because the 96% T is a solid at room temperature.

11/ Data on flammability are not required because the 96% T is not a combustible liquid.

12/ Data are required if the product contains potentially explosive ingredients.

13/ Data on viscosity are not required because the 96% T is a solid.

14/ Data on miscibility are not required because the 96% T is a solid.

TABLE A
GENERIC DATA REQUIREMENTS FOR DIFENZOQUAT

Data Requirement		Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for Submission[1]
158.240 Residue Chemistry						
171-2.	Chemical Identity					
171-3.	Directions for use		(See Index)			
171-4.	Nature of the residue (Metabolism) - Plants	PAIRA	Yes	00037957. 00037958. 00042200.	No	
171-4.	Nature of the residue (Metabolism) - Livestock	PAIRA and plant metabolites	Partially	00110347.	Yes[2,3]	18 months
171-4.	Residue analytical methods	TGAI and metabolites	Partially	00004614. 00004630. 00037959. 00038488. 00052480. 00052481.	Yes[4,5,6]	15 months
171-4.	Storage stability	TEP and metabolites	No		Yes[7]	18 months

(Continued).

TABLE A. GENERIC DATA REQUIREMENTS FOR DIFENZOQUAT (Continued).

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission[1]
171-4. Magnitude of the residue in plants					
Cereal Grains					
-Barley	TEP	Partially	00004610. 00004611.	Yes[7]	18 months
-Processed Barley			00004612. 00004613. 00005567. 00052478. 00060117. 00060118. 00108772. 00110331. 00110349. 00110355.	Yes[8]	24 months
-Wheat	TEP	Partially	00004637. 00004641.	Yes[7]	18 months
-Processed Wheat			00004647. 00004648. 00004652. 00004653. 00004654. 00004655. 00004656. 00004657. 00004658. 00004659. 00004660. 00060111. 00110347. 00110349.	Yes[9]	24 months
Forage, Fodder, and Straw of Cereal Grains					
- Barley Straw	TEP	Partially	(see Barley Grain listing)	Yes[7]	18 months
- Wheat Straw	TEP	Partially	(See Wheat Grain listing)	Yes[7]	18 months

(Continued).

TABLE A. GENERIC DATA REQUIREMENTS FOR DIFENZOQUAT (Continued).

Data Requirement		Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission[1]
	Crops Grown Solely for Seed --Alfalfa	TEP	No		Yes[10]	18 months
171-4.	Magnitude of residue in Meat/Milk/Poultry/Eggs					
	Milk, Fat, meat, and meat by-products of cattle, goats, hogs, and sheep	TGAI or plant metabolites	Partially	00052481.	Yes[11]	18 months
	Poultry and eggs	TGAI or plant metabolites	Partially	00037959.	Reserved[11]	18 months

1. Data must be submitted within the indicated time frame, based on the date of this Guidance Document.

2. Metabolism studies characterizing the total terminal residue of difenzoquat in milk, eggs and the tissues of ruminants and poultry. Animals must be dosed orally for a minimum of 3 days with 3-pyrazolyl-[^{14}C]difenzoquat fed in the diet at a level sufficient to make residue identification and quantification possible. Eggs and milk must be collected twice a day during the dosing period. Animals must be slaughtered within 24 hours of the final dose. The distribution and identity of residues must be determined in eggs, milk, liver, kidney, muscle, and fat. Representative samples from these studies must also be analyzed using Method II in the PAM, Volume II to ascertain that the method is capable of adequately recovering and identifying all residues of concern.

3. If the metabolism of difenzoquat in ruminants or poultry differs significantly from that in the rat, swine metabolism studies may be required.

TABLE A. Footnotes (continued).

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4. Validation data are required for method M-504 to determine recovery efficiency from poultry tissue samples fortified at the tolerance level of 0.05 ppm.

5. The nature of the residue in livestock has not been adequately described. If the metabolism studies required in the "Nature of the Residue in Animals" section reveal the presence of additional metabolites of toxicological concern, additional validated methods for data collection and tolerance enforcement will be required.

6. Representative plant samples and samples of meat and poultry bearing residues of difenzoquat must be analyzed by multiresidue protocols I and III, which are available from the National Technical Information Service under Order No. PB 203734/AS.

7. The sample storage conditions and intervals must be supplied for all required and previously submitted residue data for plant and animal commodities. Storage stability data in support of previously submitted residue data are required only for those samples deemed to be useful in evaluation of the tolerance. Data are also required which depict the decline in difenzoquat residue levels in commodities stored under the range of conditions and for the range in intervals specified. Crop samples bearing measurable weathered residues or fortified with difenzoquat and fortified meat, milk, and egg samples must be analyzed immediately after harvest or fortification and again after storage intervals that represent actual residue sample storage conditions and allow for reasonable unforseen delays in sample analysis. For additional guidance on conducting storage stability studies, the registrant is referred to an August 1987 "Position Document on the Effects of Storage on Validity of Pesticide Residue Data" available from NTIS under order no. PB88112362/AS.

8. The processing data requested for wheat will be translated to determine the potential for concentration of residues in milled products and grain dust of barley.

9. Data depicting the potential for concentration of difenzoquat residues in milled products (bran, flour, middlings, and shorts) and grain dust processed from wheat grain bearing measurable weathered residues. Exaggerated field use rates may be needed to obtain these residues. If residues concentrate in any of these products, appropriate food/feed additive tolerances must be proposed.

10. Data depicting difenzoquat residues in or on alfalfa hay and seed following a single foliar application of the 2 lb/gal SC/L formulation at 1 lb ae/A in 5 gal of water/A. Plants must be sprayed at the 5-leaf stage. Tests must be conducted in King's County, CA where this use is permitted by EPA SLN No. CA770540. A

TABLE A. Footnotes (continued).

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11. The nature of the residue in livestock is not adequately understood. On receipt of the required livestock metabolism, storage stability, and method validation data, the adequacy of available feeding studies and established tolerances will be determined.

Table A
Generic Data Requirements for Difenzoquat

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission
Sec. 158.290 Environmental Fate						
Degradation Studies - Lab						
161-1 - Hydrolysis	TGAI or PAIRA	A	Partially	00036788	Yes[1/]	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	A	No		Yes	9 Months
161-3 - On Soil	TGAI or PAIRA	A	Partially	00036788	Yes[1/]	9 Months
161-4 - In Air	TGAI or PAIRA	A	No		No	
Metabolism Studies - Lab						
162-1 - Aerobic Soil	TGAI or PAIRA	A	No		Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	N.A.	No		No[5/]	
162-4 - Aerobic Aquatic	TGAI or PAIRA	N.A.	No		No[5/]	
Mobility Studies						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A	Partially	00043775	Yes[1/]	12 Months

Table A
Generic Data Requirements for Difenzoquat (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Sec. 158.290 Environmental Fate (cont'd)						
163-3 - Volatility (Field)	TEP	A	No		No[4/]	
Dissipation Studies - Field						
164-1 - Soil	TEP	A	Partially	00045626 00045627 00045628 00045629 00045631 00045632	Yes[8/]	27 Months
164-2 - Aquatic (Sediment)	TEP	N.A.	No		No[5/]	
164-3 - Forestry	TEP	N.A.	No		No[5/]	
164-4 - Combination and Tank Mixes	TEP	N.A.	No		No[2/]	
164-5 - Soil, Long-Term	TEP	A	No		No[7/]	

Table A
Generic Data Requirements for Difenzoquat (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Sec. 158.290 Environmental Fate (cont'd)						
Accumulation Studies						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes[6/]	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No		Reserved[6/]	
165-3 - Irrigated Crops	TEP	N.A.	No		No[5/]	
165-4 - In Fish	TGAI or PAIRA	A	No		Yes	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP	A	No		No[7/]	

Table A
Generic Data Requirements for Difenzoquat (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Sec. 158.390 Reentry Protection						
132-1 - Foliar Dissipation	TGAI	N.A.	No		No[5/]	
132-1 - Soil Dissipation	TGAI	N.A.	No		No[5/]	
133-3 - Dermal Exposure	TGAI	N.A.	No		No[5/]	
133-4 - Inhalation	TGAI	N.A.	No		No[5/]	
Sec. 158.440 Spray Drift						
202-1 Drift Field Evaluation	TGAI	A	No		No	
202-1 Drift Size Spectrum	TGAI	A	No		No	
Ground Water Monitoring	TGAI	A	No		Reserved[9/]	

Table A

Generic Data Requirements for Difenzoquat (cont'd)

Sec. 158.290 Environmental Fate
Footnotes

1/ Additional data are required. This study does not fulfill the data requirements because the test substance and buffer solutions were incompletely characterized. This study may be made acceptable if appropriate information can be supplied.

2/ This data requirement is not being imposed at this time.

3/ This data will be required if the compound has a vapor pressure of 10^{-7} Torr or greater.

4/ These data may be required, pending examination of laboratory volatility data.

5/ These data are not required based on current use patterns because there is no anticipated human exposure.

6/ The soil metabolism data necessary for correct interpretation of rotational crops studies are not available. With properly done metabolism studies and an acceptable confined rotational crop study, the field studies may not need to be be repeated.

7/ These data are reserved. The requirements may be imposed if validated short term dissipation studies indicate the need for longer studies.

8/ These studies may be made acceptable if satisfactory freezer storage stability data are submitted. Otherwise they will need to be repeated.

9/ These data are reserved. Currently available information indicates that difenzoquat will not migrate to groundwater.

Table A
Generic Data Requirements for Difenzoquat

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Time Frame for Submission
§158.340 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral - Rat	TGAI	A	Partially	00041883	Yes[1/]	9 Months
81-2 - Acute Dermal	TGAI	A	Partially	00041883	Yes[2/]	9 Months
81-3 - Acute Inhalation - Rat	TGAI	A	Partially	00045641	Yes[3/]	9 Months
81-4 - Eye Irritation - Rabbit	TGAI	A	Yes	00041883	No	
81-5 - Dermal Irritation - Rabbit	TGAI	A	Yes	--	No	
81-6 - Dermal Sensitization - Guinea Pig	TGAI	A	No	--	Yes	9 Months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A	No	--	No[4/]	
SUBCHRONIC TESTING						
82-1 - 90-Day Feeding						
- Rodent	TGAI	A	No	--	No[5/]	
- Nonrodent	TGAI	A	Yes	00037922	No	

Table A
Generic Data Requirements for Difenzoquat

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Time Frame for Submission
§158.340 Toxicology						
SUBCHRONIC TESTING (cont'd)						
82-2 - 21-Day Dermal	TGAI	A	Partially	00041893	Yes[6/]	9 Months
82-3 - 90-Day Dermal	TGAI	A	No	--	No[7/]	
82-4 - 90-Day Inhalation	TGAI	A	No	--	No[8/]	
82-5 - 90-Day Neurotoxicity	TGAI	A	No	--	No[9/]	
CHRONIC TESTING						
83-1 - Chronic Toxicity						
- Rodent	TGAI	A	Yes	00036710	No	
- Nonrodent	TGAI	A	No	--	Yes	50 Months
83-2 - Oncogenicity Study						
- Rat	TGAI	A	Yes	00036710	No	
- Mouse	TGAI	A	Partially	00037923	Yes[10/]	50 Months
83-3 - Teratogenicity						
- Rat	TGAI	A	Partially	00037925	Yes[11/]	15 Months
- Rabbit	TGAI	A	Yes	00144522 00144521	No	
83-4 - Reproduction	TGAI	A	Yes	00037924	No	

Table A
Generic Data Requirements for Difenzoquat

Data Requirement	Composition	Use Pattern	Does EPA Have Data To Satisfy Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Time Frame for Submission
§158.135 Toxicology						
MUTAGENIC TESTING						
84-2 - Gene Mutation	TGAI	A	No	--	Yes	9 Months
84-2 - Chromosomal Aberration	TGAI	A	No	00030577	Yes[12/]	12 Months
84-2 - Other Mechanisms of Mutagenicity	TGAI	A	No	--	Yes	12 Months
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A	No	--	Yes	24 Months
85-2 - Domestic Animal Safety	Choice	A	No	--	No[13/]	

Table A
Generic Data Requirements for Difenzoquat

§158.340 Toxicology Footnotes

1/The existing study is inadequate because only male rats were tested. A study with female rats is required.
2/The existing study is inadequate because only male rabbits were tested. A study with female rabbits is required.
3/The existing study is inadequate because only male rats were tested and concentration of the test material in the inhalation chamber and the size of particles were not determined. A full study is required.
4/This study is not required because Difenzoquat is not an organophosphate.
5/The acceptable 2-year rat study available fulfills this requirement.
6/The existing study is inadequate because of deficiencies in experimental procedures.
7/This study is not needed because the existing acceptable end-uses should not result in repeated human skin contact for extended periods.
8/This study is not needed because the existing acceptable end-uses should not result in repeated inhalation exposure.
9/This study is not required because an acute delayed neurotoxicity study is not required.
10/The available study is inadequate.
11/The existing study has deficiencies in experimental procedures and does not satisfy the regulatory requirement.
12/The existing study can be upgraded from Unacceptable to Acceptable by submitting appropriate positive control data.
13/Considering the use pattern, these data are not required.

Table A
Generic Data Requirements for Difenzoquat

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA 3(c)(2)(B)?	Timeframe For Submission
Sec. 158.1490 -Wildlife and Aquatic Organisms						
Avian and Mammalian Testing						
71-1 -Avian Acute Oral Toxicity						
- Upland game bird	TGAI	A	Yes	00058830	No	
71-2 - Avian Dietary LC_{50}						
- Upland Game Bird	TGAI	A	Yes	00052458	No	
- Waterfowl	TGAI	A	Yes	00037928	No	
71-3 - Wild Mammal Toxicity	TGAI	A	No		No[1/]	
71-4 - Avian Reproduction	TGAI	A	No		No	
- Upland Game Bird	TGAI	A	No		No	
- Waterfowl	TGAI	A	No		No	
71-5 - Actual Field Testing for Birds and Mammals	TEP	A	No		No	

Table A
Generic Data Requirements for Difenzoquat (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Sec. 158.490 Wildlife and Aquatic Organisms						
Aquatic Organism Testing						
72-1 - Freshwater Fish LC_{50}						
- Warmwater	TGAI	A	Yes	00037926	No	
	TEP	A	Yes[2/]	00037927		
- Coldwater	TGAI	A	Yes	00037926	No	
	TEP	A	Yes[2/]	00037927	No	
72-2 - Freshwater Invertebrate LC_{50}	TGAI	A	Yes	00057909	No	
72-3 - Estuarine and Marine Organisms LC_{50}	TGAI	A	No			
72-4 - Fish Early Life Stage and Invertebrate Life Cycle						
- Freshwater						
- Fish	TGAI	A	No		No	
- Invertebrates	TGAI	A	No		No	

Table A
Generic Data Requirements for Difenzoquat

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
72-5 - Fish Life Cycle	TGAI	A	No		No	
72-6 - Aquatic Organisms Accumulation	TGAI	A	No		No	
72-7 - Simulated or Actual Field Testing						
-Aquatic Organisms	TEP	A	No		No	
Sec. 158.540 Plant Protection						
121-1 - Target Area Phytotoxicity	TEP	A	No[3]		No	
Nontarget area Phytotoxicity						
Tier I						
122-1 - Seedling Germination Seedling Emergence	TGAI	A	No		No[4]	
122-1 - Vegetative Vigor	TGAI	A	No		No[4]	
122-2 - Aquatic Plant Growth	TGAI	A	No		No[4]	

Table A
Generic Data Requirements for Difenzoquat

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Tier II						
123-1 - Seedling Germination/ Seedling Emergence	TGAI	A	No		No	
123-2 - Aquatic Plant Growth	TGAI	A	No		No	
TIER III						
124-1 - Terrestrial Field	TEP	A	No		No	

1/ The rat LD_{50} = 270 mg/kg.

2/ The studies on Avenge 2A-S (32%ai) would fulfill Guideline requirements for that TEP, however, there is no requirement for these data at this time.

3/ Not currently a requirement.

4/ Phytotoxicity testing is not required because difenzoquat has a negligible vapor pressure and is strongly absorbed to soil particles.

Table A
Generic Data Requirements for Difenzoquat

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Sec. 158.590 Nontarget Insects						
NONTARGET INSECT TESTING - POLLINATORS						
141-1 - Honey Bee Acute Contact LD50	TGAI	A,	No		No[1/]	
141-2 - Honey Bee - Toxicity Residues on Foliage	TEP	A	No		No[2/]	
141-4 - Honey Bee Subacute Feeding Study	Reserved[1/]					
141-5 - Field Testing for pollinators	TEP	A	No		No[2/]	
NONTARGET INSECT TESTING - AQUATIC INSECTS						
142-1 - Acute Toxicity to Aquatic Insects	TEP	A	No		No[2/]	
142-2 - Aquatic Insect Life Cycle Study	TEP	A	No		No[2/]	
142-3 - Simulated or Actual Field Testing for Aquatic Insects	TEP	A	No		No[2/]	

Table A
Generic Data Requirements for Difenzoquat

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
NONTARGET INSECT TESTING - PREDATORS AND PARASITES						
143-1 thru 143-3	Reserved[2/]	A	No		No	

Table A
Generic Data Requirements for Difenzoquat (cont'd)

#158.590 - Nontarget Insects Footnotes

1/ Data is not required since applications to currently registered uses do not represent a significant exposure to nontarget insects.
2/ This requirement is reserved pending Agency decision as to whether the data requirement should be established.

TABLE B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING [NAME OF CHEMICAL]

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission
Part 158.190, Subpart C, Product Chemistry						
Product Identity and Composition						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	1/	1/	Yes2/	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	1/	1/	Yes3/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	TGAI	All	1/	1/	Yes4/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	1/	1/	Yes	6 Months
63-3 - Physical State	TGAI	All	1/	1/	Yes	6 Months
63-4 - Odor	TGAI	All	1/	1/	Yes	6 Months
63-5 - Melting Point	TGAI	All	1/	1/	Yes	6 Months
63-6 - Boiling Point	TGAI	All	1/	1/	Yes	6 Months

TABLE B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING [NAME OF CHEMICAL]

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission
Part 158.190, Subpart C, Product Chemistry (cont'd)						
Physical and Chemical Characteristics (cont'd)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	1/	1/	Yes	6 Months
63-8 - Solubility	TGAI or PAI	All	1/	1/	Yes	6 Months
63-9 - Vapor Pressure	TGAI or PAI	All	1/	1/	Yes	6 Months
63-10 - Dissociation Constant	TGAI or PAI	All	1/	1/	Yes	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	All	1/	1/	Yes	6 Months
63-12 - pH	TGAI	All	1/	1/	Yes	6 Months
63-13 - Stability	TGAI	All	1/	1/	Yes	6 Months
Other Requirements:						
64-1 - Submittal of Samples	N/A	N/A	N/A	N/A	No	

TABLE B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING [NAME OF CHEMICAL]

Part 158.190, Subpart C, Product Chemistry - Footnotes

1/ Although product chemistry may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New data requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

3/ A detailed discussion of all impurities that are or may be present at $\geq$0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

4/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Difenzoquat

Data Requirement	Test Siubstance	Use Pattern	Does EPA Have Data To Satisfy Requirements? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral - Rat	MP		Partially	00041883	Yes[1/]	9 Months
81-2 - Acute Dermal	MP		Partially	00041883	Yes[2/]	9 Months
81-3 - Acute Inhalation - Rat	MP		Partially	00045641	Yes[3/]	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP		Yes	00041883	No	
81-5 - Primary Dermal Irritation - Rabbit	MP		Yes	00041883	No	
81-6 - Dermal Sensitization - Guinea Pig	MP		No	--	Yes	9 Months

1/The existing study is inadequate because only male rats were tested. A study with female rats is required.
2/The existing study is inadequate because only male rabbits were tested. A study with female rabbits is required.
3/The existing study is inadequate because only male rats were tested, the concentration of the test material in the inhalation chamber, and the size of particles were not determined. A full study is required.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely.
[40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement.
[40CFR 156.10(h)(1)(i)].

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON.
[40 CFR 156.10(h)(1)(i)].

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv).

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-7

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by . . . ," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units.
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage is given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-8

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all	
7E	Referral statement	All products where precautionary labeling appears on other than front panel	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-9

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposu to temperatures above 130°F may cause bursting
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261 Subpart C for a hazardous waste must bear the following pesticid disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1]/, dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. 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, will be 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 attempted also 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 at any time 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 a 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 identifier 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 standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, 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 author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence 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 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, following the phrase "submitted by." 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," standing 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. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Difenzoquat Methyl Sulfate Standard

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 (3,5-Dibromo-4-hydroxylbenzonitrile) Residues in Barley Straw and Grain Following Ground Application (California): Report No. C-592. (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 (R) (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 Cyanamide Co. Princeton, N.J.

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Citations Considered to be Part of the Data Base Supporting
Registrations Under the Difenzoquate Methyl Sulfate Standard

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): R4eport 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)

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Registrations Under the Difenzoquat Methyl Sulfate Standard

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 Duru 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

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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)

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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. C-820. (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)

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V. FORMS APPENDICES

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO

PRODUCT NAME

APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

Attach separate page with a list of the data requirements your company agrees to satisfy.

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

Attach list of data requirements

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products)

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-6

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) 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	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No._____ Date_____

Guidance Document for_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	I am complying with data requirements by Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

PRODUCT SPECIFIC DATA REPORT (cont'd)

EPA Reg. No._____ Date_____

Guidance Document for_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	I am complying with data requirements by Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
Subpart C PRODUCT CHEMISTRY (cont'd)					
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.340 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization,				
81-7	Acute Delayed neurotoxicity, hen				

OMB Approval No. 207(
Expiration Date 11/3(

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number:_____

Registrant's Name and Address: _____

_____

As an authorized representative of the registrant of the product identified abc certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _____ concerning a requirement for submission of "generic" data on the a ingredient _____ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, de our lack of intent to submit the generic data in question, on the grounds that the pr contains the active ingredient solely as the result of the incorporation into the pr of another product which contains that active ingredient, which is registered under Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula (CSF) for the above-iden product is attached to this statement. That formula statement indicates, by company registration number, and product name, the source of the subject active ingredient firm's product, or

The CSF dated_____ on file with EPA is complete, current and accura contains the information requested on the current CSF Form 8570-4. The regi source(s) of the above named active ingredient in my product(s) is/are _____ and their registration number(s) is/are _____.

My firm will apply for an amendment to the registration prior to changing the so of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portic this Statement is no longer true, or if my firm fails to comply with the undertakings in this Statement, my firm's product's registration may be suspended under FIFRA Sec 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for product, my firm relies on the efforts of other persons to provide the Agency with required generic data. If the registrant(s) who have committed to generate and submit required data fail to take appropriate steps to meet requirements or are no longe compliance with this Notice's data requirements, the Agency will consider that both and my firm are not in compliance and will normally initiate proceedings to suspend registrations of my firm's product(s) and their product(s), unless my firm commits submit and submits the required data in the specified time frame. I understand that such cases, the Agency generally will not grant a time extension for submitting the dat

Registrant's authorized representative:_____
(Signature

Dated: _____ _____
(Typed)

EPA Form 8570-27