United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA 738-R-95-028
May 1996

Reregistration Eligibility Decision (RED)

Dimethoxane

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

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

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

If you have questions on the product specific or generic data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative C. P. Moran at (703) 308-8590.

Sincerely yours,

Lois Rossi, Director
Special Review
and Reregistration Division

Enclosures

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

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

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

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

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

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

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

DIMETHOXANE

LIST C

CASE 3064

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

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DIMETHOXANE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

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Special Review and Reregistration Division

C. P. Moran	Policy, Planning and Operations Branch
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Kevin Lee	Pesticides Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

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

GLOSSARY OF TERMS AND ABBREVIATIONS

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

EXECUTIVE SUMMARY

Based on the reviews of the generic data for the active ingredient dimethoxane (2,6-Dimethyl-m-dioxan-4-ol acetate), the Environmental Protection Agency has sufficient information on the health effects of dimethoxane and on its potential for causing adverse effects in fish and wildlife in the environment. The Agency has determined that the dimethoxane product, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonalble risks or adverse effects to humans or the environment. Therefore, the Agency concludes that all uses of the product containing dimethoxane are eligible for reregistration.

Dimethoxane (Giv-Gard DXN) is a fungicide, microbiocide/microbiostat formulated as a liquid soluble concentrate. As an industrial preservative/antimicrobial agent, Giv-Gard DXN, the only product containing dimethoxane currently registered, is used in the preservation of numerous types of emulsions and water-based industrial processes and is not used on or in finished products. This biocidal product offers protection against microbial spoilage or contamination of another product during its manufacture or processing (i.e., industrial preservative). It is used in the manufacturing process to control spoilage microorganisms encountered in industrial emulsions and specialty industrial products, textiles, jet fuels, adhesives and leather processing liquors.

The toxicological data base for dimethoxane suggests a low toxicity to mammals on an acute and subchronic basis. Due to the low toxicity, neither short term (1 to 7 days) nor intermediate term (1 week to several months) toxicological endpoints for occupational risk assessment were identified. Also, dimethoxane is slightly toxic to practically nontoxic to avian species on an acute oral and subacute dietary basis, and not more than slightly toxic to freshwater fish and invertebrates.

Before reregistering the product containing dimethoxane, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister the product.

I. INTRODUCTION

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

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

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of dimethoxane. The document consists of six sections. Section I is the introduction. Section II describes dimethoxane, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for dimethoxane. Section V discusses the reregistration requirements for dimethoxane. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Dimethoxane
- **Chemical Name:** 2,6-dimethyl-m-dioxan-4-ol acetate
- **CAS Registry Number:** 828-00-2
- **OPP Chemical Code:** 001001
- **Empirical Formula:** $C_8O_4H_{14}$
- **Trade and Other Names:** Dimethoxane, Acetomethoxane
- **Basic Manufacturer:** Givaudan-Roure Corporation

B. Use Profile

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

For dimethoxane:

Type of Pesticide: Microbiocide/Microbiostat (slime-forming bacteria and fungi), Bacteriostat, Fungicide

Use Sites:

INDOOR NON-FOOD:

The intent of this biocidal product is to offer protection against microbial spoilage or contamination of another product during its manufacture or processing (i.e. industrial preservative). As an industrial preservative/antimicrobial agent, Giv-Gard DXN has been found to be important in the preservation of numerous types of emulsions and water-based industrial processes. These registered uses include the following:

1) Emulsions (latex, PVA (polyvinyl alcohol), silicone, oil, acrylic, polyethylene, PVC (polyvinyl chloride), etc.).
2) Paints (emulsion)
3) Coatings, industrial, preservatives
4) Specialty industrial products/preservatives (e.g., pigment slurries, dyestuffs, inks, thickeners/gums, lignosulfonates)
5) Textile chemicals and finishes (such as dye levelers, textile auxiliaries, softeners, lubricants, antistats, sizings, print pastes, etc.)
6) Adhesives, industrial/preservatives
7) Leather processing liquors (e.g., wet processing leather finishes)
9) Distillate fuels

PVA

Giv-Gard DXN is added to PVA emulsions to protect these emulsions from damage caused by microbial organisms. The emulsions in turn are used as components in the manufacture of industrial adhesives.

Silicone

Giv-Gard DXN is added to silicone emulsions to protect these emulsions from damage caused by microbial organisms. The emulsions in turn are used in either the manufacture of caulks, sealants, etc. for the construction industry or incorporated into softeners, lubricants, etc., utilized by the textile industry during the manufacture of fibers/yarns.

Thickeners/Gums

Giv-Gard DXN is added to thickeners/gums to protect these materials from damage caused by microbial organisms. These materials are used in the production (i.e., manufacture) of carpets and fabrics as dyeing and printing auxiliaries such as print pastes, pigment pastes, or adhesives.

Textile Auxiliaries

Giv-Gard DXN is added to "auxiliaries" used in the production of textiles to protect these agents from damage caused by microbial organisms. These industrial auxiliaries include dyestuffs, softeners, sizings, print pastes and lubricants.

Target Pests: Spoilage microorganisms, gram positive and gram negative bacteria, yeast, and fungi.

Formulation Types Registered: Soluble concentrate/liquid; 87%

Method and Rates of Application:

Equipment - Not specified

Method and Rate - For industrial preservative treatment of emulsions, paints, coatings, specialty industrial products, textile chemicals and finishes, industrial adhesives and leather processing liquors - 870 ppm to 1740 ppm active ingredient by weight.

For preservative treatment of distillate fuels - 870 ppm to 1740 ppm active ingredient by weight.

Timing - During manufacture, not specified

Use Practice Limitations:

Compatibility with systems containing amides or amines warrants careful examination because product may cause discoloration in such systems.

C. Estimated Usage of Pesticide

The only source available which can provide a quantitative estimate of usage of dimethoxane is The Federal Insecticide, Fungicide, and Rodenticide Act as Amended, Section 7 data, which is Confidential Business Information and cannot be published since currently there is only one registrant. One source, Kline and Co. Inc., which addresses specialty biocides, gives usage estimates only for major active ingredients or products. Kline does not provide a quantitative estimate of dimethoxane use or list it as a major chemical on any site. Kline does state that dimethoxane's greatest usage is as a preservative of aqueous emulsions used in the textile industry.

D. **Regulatory History**

The first product containing dimethoxane, 2,6-Dimethyl-m-dioxan-4-ol acetate, as an active ingredient was registered in the United States in 1962. Currently, one product is registered for use. The 1987 antimicrobial Data Call-In (DCI) required the submission of a variety of subchronic and chronic toxicology and occupational exposure studies. The reregistration Phase IV DCI was issued in 1992.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Color:	Clear yellow to light amber
Physical State:	Liquid
Odor:	Characteristic halide odor. Strong odor at 25°C
Boiling Point:	66-68°C at 3 mm Hg
Density:	1.060 - 1.075 at 25°C
Solubility:	> 2 gm in Methanol, Hexane & Water @ 25°C. Not stable in water. The approximate saturation point of test sample: Methanol: 3.11×10^3 Hexane: 2.25×10^3 Water: 2.38×10^3
Vapor Pressure	0.111 mm Hg at 23°C
pH:	5.8 at 25°C
Stability:	Stable after exposure to Zinc foil (a reducing agent). Not stable at: (a) low temperatures (-2 to 9°C) after 48 hours (b) high temp. (53-54°C) for 2 weeks. (c) simulated sunlight (Xenon) for 24 hours.

B. Human Health Assessment

1. Toxicology Assessment

Adequate animal toxicological data on dimethoxane are available and will support reregistration eligibility as a non-food use pesticide. The data are reported below.

a. Acute Toxicity

TEST	RESULTS	CATEGORY
Oral LD_{50}-rat	>2000 mg/kg	III
Dermal LD_{50}-rat	>2000 mg/kg	III
Inhalation LC_{50}-rat	>4.0 mg/L	III
Eye Irritation-rabbit*	mild irritation	III
Dermal Irritation-rabbit*	slight irritation	IV
Dermal Sensitization-guinea pig*	strong sensitizer	--

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

An acute oral toxicity study in rats found the LD_{50} was greater than 2000 mg/kg which is toxicity category III (guideline 81-1, MRID 43528501). An acute dermal toxicity study with rats found the LD_{50} was greater than 2000 mg/kg, which is toxicity category III (guideline 81-2, MRID 42667701). In an acute inhalation study with rats, the LD_{50} was greater than 4.0 mg/L, which is toxicity category III (guideline 81-3, MRID 41936702).

In a primary eye irritation study, rabbits had mild transient ocular irritation, which is toxicity category III (guideline 81-4, MRID 41641102). In a primary dermal irritation study with rabbits, there was slight erythema, with irritation clearing in all but one animal by 48 hours. This is toxicity category IV (guideline 81-5; MRID 41641101).

When a dermal sensitization study was conducted with guinea pigs, dimethoxane was shown to be a strong sensitizer (guideline 81-6; MRID 41936703).

b. Subchronic Toxicity

Dimethoxane was administered dermally to Sprague Dawley rats for three months. The doses were 0, 100, 300, or 1000 mg/kg/day. Some dermal irritation was observed at the dose site in the 1000 mg/kg/day group. The two highest dose groups had, in males, reduced body weight gains and in females, an increased incidence of hepatic changes, including necrosis, inflammation, and hemorrhage. The NOEL was 100 mg/kg/day. The LOEL was 300 mg/kg/day, based on these effects (guideline 82-2; MRID 42952201).

c. Carcinogenicity

The National Toxicology Program (NTP) conducted carcinogenicity studies with commercial grade dimethoxane. With F344/N rats, the males were given 0, 62.5, or 125 mg/kg/day and the females were given 0, 125 or 250 mg/kg/day by gavage for two years. Acanthosis and hyperkeratosis were increased in the forestomach of high dose rats. With B6C3F1 mice, the males and females were given 0, 250, or 500 mg/kg/day by gavage for two years. Acanthosis, hyperkeratosis, focal hyperplasia, and chronic inflammation were increased in the forestomach of dosed mice. With an increased incidence of squamous cell papillomas of the forestomach in high dose male mice, NTP concluded that there was equivocal evidence of carcinogenicity for male mice. However, there was no evidence of dimethoxane carcinogenicity in female mice or in male or female rats. (NTP, 1989).

d. Developmental Toxicity

Sprague Dawley rats were given doses of 0, 60, 300, or 900 mg/kg/day of dimethoxane by gavage on gestation days 6-15. The NOEL for maternal toxicity was 300 mg/kg/day. The LOEL was 900 mg/kg/day, based on reduced body weight gain and reduced food consumption. The NOEL for developmental toxicity was 900 mg/kg/day, the highest dose tested (guideline 83-3; MRID 41151401).

e. Mutagenicity

Dimethoxane is not mutagenic in the standard Ames battery of bacterial strains, with or without activation (MRID 41144101). Dimethoxane did not cause DNA damage or induce repair in the rat hepatocyte unscheduled DNA synthesis assay (MRID 41144103). However, the chemical was clastogenic in Chinese hamster ovary cells with activation but was negative without activation (guideline 84-2; MRID 41144102).

f. Toxic Endpoints of Concern:

Based upon the review of the toxicology data base for dimethoxane, neither short term (1 to 7 days) nor intermediate term (1 week to several months) toxicological endpoints for occupational/residential risk assessment were identified due to low toxicity and minor effects. Therefore, no assessment is required for acute dietary risk or occupational risk.

g. Reference Dose

This chemical has no food uses, therefore, no RfD value has been identified for dimethoxane.

2. Exposure Assessment

a. Occupational and Residential

1. Use Patterns

As indicated, dimethoxane is a fungicide, microbiocide/microbiostat and bacteriostat formulated as a liquid soluble concentrate. It is used as a preservative in commercial/industrial formulation of in-can latex paints (approximate 0.1% by weight as maximum dosage), in fuel/oil storage tank bottom water (approximate 0.1% by weight as maximum dosage), emulsion paints and inks, specialty industrial products/preservatives, textile presevatives, adhesives, leather processing liquors, and distillate fuels.

Giv-Gard DXN, the only product containing dimethoxane currently registered (Reg. No. 824-7), contains 87% dimethoxane. This product is registered only for use in industrial settings. Both open-pour and closed delivery systems are acceptable application methods for dimethoxane. There are no residential uses registered for the dimethoxane product.

There are no registered uses of dimethoxane within the scope of the Agency's Worker Protection Standard for Agricultural Pesticides (WPS); i.e., no uses registered for use in the production of food, feed, fiber, ornamental, turf, or tree crops.

2. Handler (Mixer/Loaders and Applicators) Exposure

Dimethoxane exposure to handlers is possible when workers handle the preservative in industrial settings. For those handlers using open pouring application methods, there is the potential for respiratory, dermal, and eye exposure. By comparison, potential exposure to handlers using closed delivery systems is expected to be significantly reduced.

3. Post Application Exposure

There are several types of potential exposure to persons after application is complete. These include:

a. Potential exposure, especially inhalation exposure, to industrial/manufacturing workers immediately after dimethoxane use.

b. Potential exposure, including dermal and inhalation exposure, when substances (such as paints) containing dimethoxane are used.

Based on dimethoxane use patterns, exposure to workers in the industrial setting is possible immediately following dimethoxane use. Due to the chemical properties of dimethoxane (low vapor pressure, etc.), post-application inhalation exposure to workers is expected to be minimal. Also, exposure to individuals who use dimethoxane products (such as paints) is possible, but the amount of dimethoxane contained in these products is so small that resulting toxic effects are expected to be negligible.

3. Risk Assessment

a. Occupational and Residential

All uses of dimethoxane are outside of the scope of the Agency's Worker Protection Standard and there are no special toxicological concerns about dimethoxane that warrant the establishment of active-ingredient-based personal protective equipment (PPE).

Based on the available toxicity information and use patterns for dimethoxane, the Agency has completed a qualitative assessment of exposure and cancer risk based on the National Toxicology Program studies and conservative occupational exposure assumptions. The assessment indicates no significant human cancer risk.

Based on the existing use patterns of dimethoxane, post-application exposure data are not required. Due to the chemical properties of dimethoxane (low vapor pressure, etc.), post-application inhalation exposure to workers is expected to be minimal. Also, exposure to individuals who use dimethoxane products (such as paints) is possible, but

the amount of dimethoxane contained in these products is so small that resulting toxic effects are expected to be negligible.

C. Environmental Assessment

1. Ecological Toxicity Data

The ecotoxicological data base is adequate to characterize the toxicity of dimethoxane to nontarget terrestrial and aquatic organisms when used as an indoor, nonfood use microbiostat/fungistat. There is no direct use or application of this peticide outdoors. Any significant hazard would presumably result from a transportation accident, spill, or purposeful discharge into the environment. Any such environmental contamination would have minimal impact on avian and aquatic species given the results of the studies described below.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of dimethoxane to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); one subacute dietary study (LC_{50}) on one species of waterfowl (preferably the mallard duck) or one species of upland game bird (preferably bobwhite quail or ring-necked pheasant).

Avian Acute Oral Toxicity Findings			
Species	**% Test Material (TGAI)**	**LD_{50} mg/kg**	**Conclusion**
Bobwhite Quail	92.0	1585	slightly toxic

Avian Subacute Dietary Toxicity Findings			
Species	**% Test Material**	**LC_{50} ppm**	**Conclusions**
Bobwhite Quail	92.0	>5620	practically nontoxic
Mallard Duck	92.0	>5620	practically nontoxic

These results indicate that dimethoxane is slightly toxic to practically nontoxic to avian species on an acute oral and subacute dietary basis. The guideline requirements are fulfilled. (MRID 41962502, 41962503 and 41962504)

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of dimethoxane to freshwater fish, the minimum data required on the technical grade of the active ingredient is one freshwater fish toxicity study. The study should use a coldwater species (preferably the rainbow trout) or a warmwater species (preferably the bluegill sunfish).

Freshwater Fish Acute Toxicity Findings			
Species	**% Test Material (TGAI)**	**LC_{50} ppm a.i.**	**Conclusions**
Rainbow trout	88.5	> 37.0	not more than slightly toxic

Although the submitted 96-hour acute toxicity study did not define a precise LC_{50} value, the results did demonstrate that dimethoxane is not more than slightly toxic to both cold and warm water fish. The study was scientifically sound, but the test deviated from specified methods in the EPA standard guideline protocol such that in lieu of a calculated LC_{50}, the test indicated the LC_{50} to be greater than 37 ppm of active ingredient. A greater than 100 ppm toxicity category indicates that the pesticide's toxicity category is practically nontoxic to aquatic organisms. The No Observed Effect Concentration (NOEC) was

determined to be 1 ppm. The guideline requirement is not fulfilled; however, at this time, dimethoxane is registered only for indoor uses. As a result, minimal exposure to wildlife is expected. Therefore, the data are sufficient for the indoor use pattern such that the study does not need to be repeated. (MRID 41936701)

(2) Freshwater Invertebrates

The minimum testing required to assess the hazard of dimethoxane to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

Freshwater Invertebrate Toxicity Findings			
Species	**% Test Material (TGAI)**	**EC_{50} ppm a.i.**	**Conclusions**
Daphnia magna	88.5	> 24.0	not more than slightly toxic

Although the submitted 48-hour acute toxicity study did not define a precise EC_{50} value, the results did demonstrate that dimethoxane is not more than slightly toxic to aquatic invertebrates. The study was scientifically sound, but the test deviated from specified methods in the EPA standard guideline protocol such that in lieu of a calculated EC_{50}, the test indicated the EC_{50} to be greater than 24 ppm of active ingredient. A greater than 100 ppm toxicity category indicates that the pesticide's toxicity is practically nontoxic to aquatic organisms. The No Observed Effect Concentration (NOEC) was determined to be 13 ppm. The guideline requirement is not fulfilled; however, at this time, dimethoxane is registered only for indoor uses. As a result, minimal exposure to wildlife is expected. Therefore, the data are sufficient for the indoor use pattern such that the study does not need to be repeated. (MRID 41962501)

2. Environmental Fate

a. Environmental Fate Assessment

The Agency has waived the requirement for a hydrolysis study. The available data indicate that the major route of degradation is abiotic hydrolysis aided by microbial mediated degradation. Further, the data indicate that dimethoxane is highly unstable in water with over 50% of the compound hydrolyzed in 2 hours. Dimethoxane is purported to react with

water to form acetic acid and a transient intermediate, dioxinol. The dioxinol then breaks down into acetaldehyde and aldol. The breakdown into acetic acid and dioxinol is completed in 14 hours.

3. Exposure and Risk Characterization

Risk assessments are not conducted on nontarget organisms for microbiocides having indoor nonfood uses without effluents. The preservative uses of dimethoxane in emulsion paints, emulsion inks, jet fuels, leather processing liquors, coatings, specialty industrial products, textiles and adhesives are expected to result in minimal to no exposure to the environment. The jet fuel use of dimethoxane, however, is associated with periodic releases into the environment based on purging of jet fuel storage tanks of "water bottoms" (small areas of condensation on the bottom of the tank, which if not removed could cause leakage from rust formation weakening the tank wall). However, the hazard to wildlife and aquatic organisms from these registered indoor nonfood uses is expected to be minimal because dimethoxane is not more than slightly toxic to fish and aquatic invertebrates, and slightly to practically nontoxic to birds. Tank bottom water must be disposed of in accordance with the U.S. Environmental Protection Agency's Resource Conservation and Recovery Act (RCRA).

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

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

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of dimethoxane and to determine that dimethoxane can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing dimethoxane as the active ingredients

are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

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

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients dimethoxane, the Agency has sufficient information on the health effects of dimethoxane and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that dimethoxane products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that all uses for the product containing dimethoxane are eligible for reregistration.

2. Eligible and Ineligible Uses

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

C. Regulatory Position

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

1. Labeling Rationale

Dimethoxane is classified as a strong skin sensitizer. Therefore, the Agency requires a precautionary statement about skin sensitization to be placed on the labeling. The minimum personal protective equipment (PPE) for users of

Giv-Gard DXN is long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves.

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of dimethoxane for the above eligible uses has been reviewed and determined to be substantially complete. However, an hydrolysis study is required as confirmatory data.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

Labeling Requirements

The Agency is requiring the following labeling statements to be located on the product:

"This product has not been cleared under the Federal Food Drug and Cosmetic Act for use in the manufacture of adhesives and coatings that may come in contact with food."

Handler (Mixer, Loader, Applicator, Etc.) Personal Protective Equipment (PPE): The PPE for pesticide handlers will be based on the acute toxicity of the end-use product.

Application Restrictions:
"Do not apply this product in a way that will contact workers or other persons. Only protected handlers amy be in the area during application."

Engineering Controls:
"When handlers use closed metering systems, the handler requirements may be reduced or modified to long-sleeve shirt, long pants, shoes, and socks."

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

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

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

Skin Sensitization Statement: [insert in the "Hazards to Humans (and Domestic Animals)" section of the Precautionary Statements]

"This product may cause skin sensitization reaction in some people."

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell the dimethoxane product bearing old labels/labeling for 26 months from the date of issuance

of this RED. Persons other than the registrant may distribute or sell the product for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A REPORT

Case 3064[Dimethoxane] **Chemical 001001[Dimethoxane]**

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED													
ADHESIVES, INDUSTRIAL				Use Group: INDOOR NON-FOOD									
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	SC/L W 870	W 1740	*	NS	NS	NS	NS	NS	NS				A42, C18, C24
COATINGS, INDUSTRIAL				Use Group: INDOOR NON-FOOD									
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	SC/L W 870	W 1740	*	NS	NS	NS	NS	NS	NS				A42, C18, C24
EMULSIONS, RESIN/LATEX/POLYMER				Use Group: INDOOR NON-FOOD									
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	SC/L W 870	W 1740	*	NS	NS	NS	NS	NS	NS				A42, C18, C24
FUELS/OIL STORAGE TANK BOTTOM WATER ADDITIVE				Use Group: INDOOR NON-FOOD									
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L W 870	W 1740	*	NS	NS	NS	NS	NS	NS				A42, C18, C24
LEATHER PROCESSING LIQUORS				Use Group: INDOOR NON-FOOD									
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	SC/L W 870	W 1740	*	NS	NS	NS	NS	NS	NS				A42, C18, C24
PAINTS (IN-CAN)				Use Group: INDOOR NON-FOOD									
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	SC/L W 870	W 1740	*	NS	NS	NS	NS	NS	NS				A42, C18, C24
PAINTS, LATEX/OIL/VARNISH (APPLIED FILM)				Use Group: INDOOR NON-FOOD									

APPENDIX A REPORT

Case 3064[Dimethoxane] **Chemical 001001[Dimethoxane]**

SITE Application Type, Application Timing, Application Equipment) & Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
PAINTS, LATEX/OIL/VARNISH (APPLIED FILM) (con't)				Use Group: INDOOR NON-FOOD (con't)								
Preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	SC/L	W 870	W 1740	*	NS	NS	NS	NS	NS	NS		A42, C18, C24
SPECIALITY INDUSTRIAL PRODUCTS				Use Group: INDOOR NON-FOOD								
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	SC/L	W 870	W 1740	*	NS	NS	NS	NS	NS	NS		A42, C18, C24
WET-END ADDITIVES/INDUSTRIAL PROCESSING CHEMICALS				Use Group: INDOOR NON-FOOD								
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	SC/L	W 870	W 1740	*	NS	NS	NS	NS	NS	NS		A42, C18, C24

APPENDIX A REPORT

Case 3064[Dimethoxane] **Chemical 001001[Dimethoxane]**

LEGEND

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate, Maximum Number of Applications at Maximum Rate, Maximum Dose per Crop Cycle or per Year, Minimum Interval Between Applications (Days), Restricted Entry Interval (Days), Allowed/Disallowed Geographical Areas, Use Limitations Codes.

HEADER ABBREVIATIONS

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

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

SC/L	: SOLUBLE CONCENTRATE/LIQUID

ABBREVIATIONS

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

APPLICATION RATE

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

USE LIMITATIONS CODES

A42 : This use has not been cleared under the Federal Food, Drug, and Cosmetic Act for use in the manufacture of adhesives and coatings that may come in contact with food.

APPENDIX A REPORT

Case 3064[Dimethoxane] **Chemical 001001[Dimethoxane]**

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USE LIMITATIONS CODES (Cont.)

C18 : Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW).

C24 : Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction)

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

GUIDE TO APPENDIX B

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

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Dimethoxane

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	ALL	42389901, 41678203
61-2A	**Start. Mat. & Mnfg. Process**	ALL	41678206
61-2B	**Formation of Impurities**	ALL	41678207
62-1	**Preliminary Analysis**	ALL	43256301
62-2	**Certification of limits**	ALL	43104601, 41691401, 42389901
62-3	**Analytical Method**	ALL	41691401, 42389901
63-2	**Color**	ALL	93090001
63-3	**Physical State**	ALL	93090001
63-4	**Odor**	ALL	41678202
63-5	**Melting Point**	ALL	Inapplicable
63-6	**Boiling Point**	ALL	93090001
63-7	**Density**	ALL	93090001
63-8	**Solubility**	ALL	41678201
63-9	**Vapor Pressure**	ALL	41678205
63-10	**Dissociation Constant**	ALL	Inapplicable
63-11	**Octanol/Water Partition**	ALL	Inapplicable
63-12	**pH**	ALL	41641106
63-13	**Stability**	ALL	41678204
63-14	**Oxidizing/Reducing Action**	ALL	Inapplicable

Data Supporting Guideline Requirements for the Reregistration of Dimethoxane

REQUIREMENT		USE PATTERN	CITATION(S)
63-15	**Flammability**	ALL	41691402
63-16	**Explodability**	ALL	Inapplicable
63-17	**Storage stability**	ALL	42267501
63-18	**Viscosity**	ALL	41641105
63-19	**Miscibility**	ALL	Inapplicable
63-20	**Corrosion characteristics**	ALL	41678203
63-21	**Dielectric breakdown volt**	ALL	Inapplicable
64-1	**Submittal of Samples**	ALL	Inapplicable
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	M	41962502
71-2A	**Avian Dietary - Quail**	M	41962503
72-1A	**Fish Toxicity Bluegill**	M	WAIVED
72-1C	**Fish Toxicity Rainbow Trout**	M	WAIVED
72-2A	**Invertebrate Toxicity**	M	WAIVED
72-3A	**Estuarine/Marine Toxicity - Fish**	M	WAIVED
72-3B	**Estuarine/Marine Toxicity - Mollusk**	M	WAIVED
72-3C	**Estuarine/Marine Toxicity - Shrimp**	M	WAIVED
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	M	43528501

Data Supporting Guideline Requirements for the Reregistration of Dimethoxane

REQUIREMENT		USE PATTERN	CITATION(S)
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	M	42667701
81-3	**Acute Inhalation Toxicity - Rat**	M	41936702
81-4	**Primary Eye Irritation - Rabbit**	M	41641102
81-5	**Primary Dermal Irritation - Rabbit**	M	41641101
81-6	**Dermal Sensitization - Guinea Pig**	M	41936703
82-3	**90-Day Dermal - Rodent**	M	42952201
83-2A	**Oncogenicity - Rat**	M	WAIVED
83-2B	**Oncogenicity - Mouse**	M	WAIVED
83-3A	**Developmental Toxicity - Rat**	M	41151401
83-3B	**Developmental Toxicity - Rabbit**	M	WAIVED
83-4	**2-Generation Reproduction - Rat**	M	WAIVED
84-2A	**Gene Mutation (Ames Test)**	M	41144101
84-2B	**Structural Chromosomal Aberration**	M	41144102, 41144103
84-4	**Other Genotoxic Effects**	M	41144103
85-1	**General Metabolism**	M	WAIVED
85-2	**Dermal Penetration**	M	WAIVED

Data Supporting Guideline Requirements for the Reregistration of Dimethoxane

REQUIREMENT		USE PATTERN	CITATION(S)
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
133-3	**Dermal Passive Dosimetry Exposure**	M	WAIVED
133-4	**Inhalation Passive Dosimetry Exposure**	M	WAIVED
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**	M	Letter reviewed 9/9/94, 42389901, 41678203
161-1	**Hydrolysis**	M	WAIVED
161-2	**Photodegradation - Water**	M	WAIVED
162-3	**Anaerobic Aquatic Metabolism**	M	WAIVED
162-4	**Aerobic Aquatic Metabolism**	M	WAIVED
163-1	**Leaching/Adsorption/Desorption**	M	WAIVED

GUIDE TO APPENDIX C

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

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

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

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

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

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

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

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

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

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

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

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

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MRID **CITATION**

41040501 Schroeder, R. (1989) A Range-finding Study to Evaluate the Toxicity of Giv 2-0494 in the Pregnant Rat: Proj. No. 88-3321. Unpublished study prepared by 190 p.

41144101 Valentine, D.; Lawlor, T. (1989) Mutagenicity Test on GIV 2-0494 in the Ames Salmonella/Microsome Reverse Mutation Assay: Project ID 10696-0-401. Unpublished study prepared by Hazelton Laboratories of America, Inc. 36 p.

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41144103 Cifone, M. (1989) Mutagenicity Test on GIV 2-0494 in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay: Project ID 10696-0-447. Unpublished study prepared by Hazelton Laboratories America, Inc. 25 p.

41151401 Schroeder, R. (1989) A Teratogenicity Study in Rats with Giv 2-0494: Project No. 88-3322. Unpublished study prepared by Bio/dynamics, Inc. 397 p.

41641101 Blaszcak, D. (1990) Primary Dermal Irritation Study in Rabbits with Giv 3-0494: Final Report: Lab Project Number: 5754-89. Unpublished study prepared by Bio/dynamics, Inc. 17 p.

41641102 Blaszcak, D. (1990) Primary Eye Irritation Study in Rabbits with Giv 2-0494: Final Report: Lab Project Number: 5755-89. Unpublished study prepared by Bio/dynamics, Inc. 21 p.

41641105 Pesselman, R. (1990) Determination of Viscosity of Giv 2-0494: Final Report: Lab Project Number: HLA 6001-563. Unpublished study prepared by Hazleton Laboratories America, Inc. 28 p.

41641106 Pesselman, R. (1990) pH Value Determination of Giv 2-0494: Lab Project Number: HLA 6001-561. Unpublished study prepared by Hazleton Laboratories America, Inc. 26 p.

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41678201 Pesselman, R. (1990) Solubility Determination of Giv 2-0494: Final Report: Lab Project Number: HLA 6001-559. Unpublished study prepared by Hazleton Labs America, Inc. 37 p.

41678202 Pesselman, R. (1990) Odor Determination of Giv 2-0494: Final Report: Lab Project Number: HLA 6001-558. Unpublished study prepared by Hazleton Labs America, Inc. 25 p.

41678203 Pesselman, R. (1990) Determination of Corrosion Characteristics of Givaudan 2-0494: Final Report. Lab Project Number: HLA 6001564. Unpublished study prepared by Hazleton Labs America, Inc. 25 p.

41678204 Pesselman, R. (1990) Stability Determination of Giv 2-0494: Final Report: Lab Project Number: HLA 6001-562. Unpublished study prepared by Hazleton Labs America, Inc. 27 p.

41678205 Pesselman, R. (1990) Vapor Pressure Determination of Giv 2-0494: Final Report: Lab Project Number: HLA 6001-560. Unpublished study prepared by Hazleton Labs America, Inc. 37 p.

41678206 Virgilio, J. (1990) GivGard DXN: Manufacturing Process: Lab Project Number: DXN 10/90A. Unpublished study prepared by Givaudan Corp. 7 p.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

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

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

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

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

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

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

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

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the

request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

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

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

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

you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

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

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

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

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

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

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70

which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

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

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

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

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

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

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

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other

disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

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

III-D REQUESTS FOR DATA WAIVERS

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited

to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

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

DIMETHOXANE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of dimethoxane, please contact C P Moran at (703) 308-8590.

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

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

RE: **dimethoxane**

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

Item 1-4. Already completed by EPA.

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

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

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

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

Items 8-11. Self-explanatory.

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

Insert Part A of the DCI here and remove this page.

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

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

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

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

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

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

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

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

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

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another

product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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

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

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

completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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

Items 10-13. Self-explanatory.

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

Insert Page 1 of Part B here and remove this page.

Insert Page2 of Part B here and remove this page.

Insert Page 3 of Part B here and remove this page.

Insert Page 4 of Part B here and remove this page.

THERE IS NO BATCHING FOR THIS CASE

ATTENTION CRM::: PLEASE NOTE:::
REMOVE THIS PAGE AND INSERT THE LIST OF REGISTRANTS RECEIVING THIS DCI

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
2070-0057
Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	**EPA Reg. No.**

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

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

United States Environmental Protection Agency
Washington, DC 20460

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

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

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date

Name and Title (Please Type or Print)

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

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

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

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

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The following is a list of available documents that may further assist you in responding to this Reregistration Eligibility Decision Document. These documents may be obtained by the following methods listed below:

1. Printed copies of this RED and fact sheet may be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

2. *Health and Environmental Effects Science Chapters*: **You must request copies of these documents by writing to the individual listed on the Chemical Status Sheet.**

3. *Detailed Label Usage Information System (LUIS) Report*: **You must request copies of these documents by writing to the individual listed on the Chemical Status Sheet.**

3. *The Label Review Manual*: **You must request this document by writing to the individual listed on the Chemical Status Sheet.**

The following documents may also be obtained electronically by the following methods:

They can downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

4. *PR Notice 86-5* [Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain providsions of the Federal Food, Drug, and Cosmetic Act (FFDCA)].

5. *PR Notice 91-2* [Accuracy of Stated Percentages for Ingredients Statement].

6. *Fact Sheet* document for this case.

7. The *RED* document for this case.