United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA-738-R-96-007
August 1996

Reregistration Eligibility Decision (RED)

4,4-Dimethyloxazolidine

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case 4,4-dimethyloxazolidine. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active 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 is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the receipt of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that this RED was finalized and signed prior to August 3, 1996. On that date, the Food Quality Protection Act of 1996 (FQPA) became effective, amending portions of both the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED does not address any issues raised by FQPA, and any tolerance-related statements in the RED do not take into account any changes in tolerance assessment procedures required under FQPA.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Jean Holmes at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Marie Boucher at (703) 308-8178.

Sincerely yours,

Lois Rossi, Division Director
Special Review
and Reregistration Division

Enclosures

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

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

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

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

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

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

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

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**.

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

4,4 - Dimethyloxazolidine

LIST C

CASE 3095

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

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4,4 - DIMETHYLOXAZOLIDINE REREGISTRATION ELIGIBILITY TEAM

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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

GLOSSARY OF TERMS AND ABBREVIATIONS

NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
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

ABSTRACT

EPA has completed its reregistration eligibility decision regarding the pesticide 4,4-dimethyloxazolidine, case 3095. This decision includes a comprehensive reassessment of the required target data base supporting the use patterns of currently registered products. 4,4-Dimethyloxazolidine is an antimicrobial used in oil recovery drilling muds, packer fluids, secondary oil recovery injection water, adhesives, metalworking cutting fluids, latex paints, resin emulsions, wet-end additives/industrial processing chemicals and specialty industrial products to control bacteria and fungi. The Agency has concluded that all products registered for all uses are eligible for reregistration.

The Agency has identified no toxicological or ecological endpoints of regulatory concern for 4,4-dimethyloxazolidine. No additional data are required by the Agency to confirm its conclusions. Supporting data demonstrate this chemical has low to moderate acute mammalian toxicity (except for eye irritation), and does not cause significant subchronic or developmental effects. Most mutagenicity studies were negative and mutagenicity hazards are expected to be minimal for the currently registered uses. Environmental data show 4,4-dimethyloxazolidine has low to moderate toxicities to wildlife species and it rapidly degrades in water.

The Agency has concluded that all uses, as prescribed in this document, will not cause unreasonable risks to humans or the environment and therefore, all products are eligible for reregistration. For product reregistration, labeling will be upgraded with additional precautions and more explicit directions for use.

I. INTRODUCTION

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

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

This document presents the Agency's decision regarding the reregistration eligibility of the uses of currently registered products containing the active ingredient 4,4-dimethyloxazolidine in the case Methyloxazolidine. This document does not address trimethyloxazolidine or any of its uses in products since all have been voluntarily cancelled. The document consists of six sections. Section I is the introduction. Section II describes 4,4-dimethyloxazolidine, 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 4,4-dimethyloxazolidine. Section V discusses the reregistration requirements for 4,4-dimethyloxazolidine. Finally, Section VI is the Appendices that 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:** Methyloxazolidine
- **Chemical Name:** 4,4 - Dimethyloxazolidine
- **CAS Registry Number:** 51200-87-4
- **OPP Chemical Code:** 114801
- **Empirical Formula:** $C_5H_{11}NO$
- **Molecular Weight:** 101.14
- **Trade and Other Names:** Bioban: CS-1135 Antimicrobial Agent: Angus Chemical Company.
  Cosan 101: Hulls America.
  Troysan 192: Troy Chemical Company.

B. Use Profile

The following is information on currently registered uses with an overview of use sites and application methods. A detailed table of uses of 4,4-dimethyloxazolidine is in Appendix A.

<u>For 4,4 - Dimethyloxazolidine</u>:

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

Use Sites: AQUATIC NON-FOOD INDUSTRIAL
*Oil Recovery Drilling Muds/Packer Fluids
Secondary Oil Recovery Injection Water

TERRESTRIAL NON-FOOD INDUSTRIAL
*Oil Recovery Drilling Muds/Packer Fluids

INDOOR NON-FOOD
Industrial Adhesives
Resin/Latex/Polymer Emulsions

Metalworking Cutting Fluids
Latex Paints (In-Can Preservative)
Specialty Industrial Products
Wet-End Additives/Industrial Processing Chemicals

*Registrants must specify on labels, as per Section V of this document, whether the product is used on off-shore and/or terrestrial sites.

Target Pests: Slime-forming bacteria and fungi, sulfate-reducing bacteria, iron-oxidizing bacteria

Formulation Types Registered:

TYPE: End-use
FORM: Soluble concentrate/liquid

Method and Rates of Application:

Types of Treatment - Industrial preservative treatment, preservative treatment, water treatment (secondary oil recovery injection water)

Equipment - Metering pump (secondary oil recovery injection water), not specified (registrant must specify on labeling; see Section V for labeling requirements)

Use Rate - **Aquatic Non-Food Industrial**
3.7 to 736 ppm active ingredient by weight

Terrestrial Non-Food Industrial
368 to 736 ppm active ingredient by weight

Indoor Non-Food
460 to 3850 ppm active ingredient by weight

Timing - During manufacture (i.e., adhesives, paints), Initial, Subsequent/maintenance, Continuous feed (initial), Feed (subsequent), Shock/slug, Not Specified (registrant must specify on labeling)

Use Practice Limitations: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the appropriate NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority.

C. Data Requirements

The Agency required registrants to supply additional data to support reregistration in a Data Call-In Notice issued in September of 1992 and in the Antimicrobial Data Call-In Notice of March 1987. Appendix B includes all data requirements identified by the Agency to support reregistration of currently registered uses.

D. Regulatory History

In 1982, the Agency first registered 4,4-dimethyloxazolidine in the United States as an active ingredient for use as a microbiocide and bacteriostat. There are currently 6 active products registered as a preservative in adhesives, paints, resin emulsions, and metalworking cutting fluids and as a microbiocide in secondary oil recovery injection water and oil recovery drill muds. In 1987 the Agency issued the Antimicrobial Data Call-In Notice for chronic and subchronic toxicity data requirements for this chemical and other antimicrobial chemicals. Another Data Call-In Notice was issued in September 1992 for 4,4-dimethyloxazolidine requiring additional data in support of reregistration.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Color:	Colorless to slightly yellow
Physical State:	Liquid
Odor:	An amine odor (fishy)
Melting Point:	N/A for liquid
Boiling Point:	100.9°C
Bulk Density:	0.99 gm/ml
Solubility:	Miscible with water in all proportions. It is also miscible with methanol, ethanol, propanol, and acetone.
Vapor Pressure:	100 mm Hg at 70°C
Dissociation Constant:	pKa = 9.35
Octanol/Water Partition Coefficient:	log P = 0.73

pH:	11.0
Stability:	Stable under ambient conditions. It does not react with steel or iron.
Analytical Method:	The technical grade active ingredient can be determined by the use of gas chromatography method using a column packed with 20% carbowax 20M. The method consists of adding measured amounts of 2-amino-2-methyl-1-propanol (AMP) to an aliquot of the sample and determining the excess AMP by gas chromatography. Uncombined formaldehyde in the sample reacts on an equal molar basis with the AMP to form oxazolidine. When uncombined formaldehyde is present, the difference between the amount of AMP added to the sample and the amount found after addition is calculated as uncombined formaldehyde.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base for 4,4-dimethyloxazolidine is based on the requirements for antimicrobial pesticides. The data are adequate and will support a reregistration eligibility determination for the currently registered non-food uses.

a. Acute Toxicity

Results of the acceptable acute toxicity studies conducted with technical 4,4-dimethyloxazolidine are summarized below in Table 1:

Table 1. Acute Toxicity Values of Technical 4,4-Dimethyloxazolidine

Route	Species	Results	Toxicity Category
Oral	Rat	LD_{50}: Males 1308 mg/kg Females 1037 mg/kg	III
Dermal	Rat	LD_{50} = >2000 mg/kg	III
Inhalation	Rat	LC_{50} = 1.1 mg/L	III
Eye Irritation*	Rabbit	Severe irritant	I
Skin Irritation*	Rabbit	Slight dermal irritant	IV
Dermal Sensitization*	Guinea Pig	Non-sensitizer	N/A

* This study is a requirement for manufacturing-use and end-use products (40 CFR Section 158). For 4,4-dimethyloxylzolidine, data have been generated on the TGAI and are presented here for informational purposes.

The acute oral LD_{50} in rats is 1308 mg/kg for males and 1037 mg/kg for females. This places 4,4-dimethyloxazolidine in Toxicity Category III (MRID 41706707). It is also placed in Toxicity Category III for acute dermal LD_{50} in rats at >2000 mg/kg (MRID 41706708) and for acute inhalation LC_{50} in rats at 1.1 mg/L (MRID 41706709).

Placed in Toxicity Category I as a primary eye irritant in rabbits (41706710), 4,4-dimethyloxazolidine is also considered a Toxicity Category IV dermal irritant in rabbits (MRID 41706711), and is not a skin sensitizer in guinea pigs (MRID 41706712).

b. Subchronic Toxicity

The toxicological data requirement (GDLN 82-3) for a 90-day dermal toxicity study in rodents is satisfied by two 13-week dermal toxicity studies in rats. In the first 90-day dermal toxicity study, male and female CD (Sprague-Dawley derived) Crl:CD®BRVAF/Plus® rats, 10/sex/group, were administered dermal doses of aqueous solutions of 4,4-dimethyloxazolidine technical (75.95% a.i.) to yield dosage levels of 0, 1, 30, or 100 mg/kg/day. The test site was occluded, and exposure continued for 6 hours. Animals were treated once daily, five days per week, for a total of 4 or 13 weeks. Due to extreme dermal reactions, all animals in the 100 mg/kg/day dosage group were sacrificed for humane reasons after 4 weeks. The remaining animals were sacrificed after 13 weeks. There were no unscheduled mortalities.

No treatment-related dermal effects were observed in animals in the 1 mg/kg/day treatment group. In the 30 mg/kg/day and 100 mg/kg/day treatment groups, histopathology revealed lymphoid proliferation and plasmacytosis in axillary and/or inguinal lymph nodes in males and females and sinus histiocytosis in males. In addition, microscopic examination of treated skin revealed inflammation, ulceration, and acanthosis in both males and females in these two treatment groups, confirming the clinical observations of scabs on the skin and necrotic patches. Blood neutrophil levels were increased in both males (146% control value; not statistically significant) and females (160% control value; $p < 0.05$) at 30 mg/kg/day; at 100 mg/kg/day, these values were also increased in males (212% control value) and females (338% control value), but no statistical tests were performed for this dosage level. Body weight gain was statistically decreased ($p < 0.01$) only for males in the 100 mg/kg/day group at 4 weeks. The weight of the adrenal glands was increased (112% control value; $p < 0.05$) only in females in the 30 mg/kg/day treatment group; however, the histopathology of this organ was normal. The dermal NOEL is 1 mg/kg/day and the dermal LOEL is 30 mg/kg/day, based on the microscopically observed changes in the skin. The microscopic changes observed in the axillary and/or inguinal lymph nodes and the elevated neutrophil counts are probably secondary effects (e.g., infections) related to the severe dermal effects elicited by this chemical and are not considered to be test substance-related. No systemic effects were apparent after dermal administration of this chemical at the stated doses for 90 days; therefore, the systemic NOEL $\geq$ 100 mg/kg/day (HDT) and the systemic LOEL > 100 mg/kg/day (MRID 43322601).

In the second 90-day dermal toxicity study, male and female Sprague-Dawley rats, 15/sex/group, were administered dermal doses of aqueous-ethanolic solutions of Bioban CS 1135 preservative (4,4-dimethyloxazolidine technical, 78% a.i.) to yield dosage levels of 0 (1:1, water/ethanol vehicle), 1.95, 19.5, or 195 mg/kg/day. Animals were treated once daily, five days per week, for a total of 13 weeks. Animals in the 195 mg/kg/day dosage group showed moderate and severe skin reaction that included thickening and ulcerations. In the 195 mg/kg/day treatment group, histopathology revealed severe ulcerative response in the skin. In addition, these animals had enlarged lung, heart, liver, spleen and adrenals. There were no unscheduled mortalities. No treatment-related dermal effects were observed in animals in the 1.95 and 19.5 mg/kg/day treatment groups. Based on these data, the dermal and systemic NOEL is 19.5 mg/kg/day and the dermal and systemic LOEL is 195 mg/kg/day (MRID 00138227).

c. Chronic toxicity and Carcinogenicity

The Chronic Toxicity Study in Rodents (GDLN 83-1a) and Non-Rodents (GDLN 83-1b), and the Carcinogenicity Study in Mice (GDLN 83-2a) and Rats (GDLN 83-2b) are not required (40 CFR 158.340) because the occupational/residential exposure and the non-food use pattern of 4,4-dimethyloxazolidine will not result in significant chronic human exposure.

d. Developmental Toxicity

In an acceptable dermal developmental toxicity study (GDLN 83-3), New Zealand rabbits were administered dermal doses of 0, 30, 100 or 300 mg/kg/day on days 7 through 19 of gestation. The maternal toxicity NOEL was not determined. The maternal toxicity LOEL was 30 mg/kg/day based on local dermal irritation. Local dermal irritation was demonstrated at all dosage levels and was dose related. The local irritation included erythema, edema, atonia, desquamation, coriaceousness, eschar and bruising. Developmental toxicity was not demonstrated at the doses tested (MRID 00157806).

e. Reproductive Toxicity

The Two-Generation Reproduction study (GDLN 83-4) is not required because the occupational/residential exposure and the non-food use pattern of 4,4-dimethyloxazolidine will not result in significant chronic human exposure.

f. Mutagenicity

Among the available studies, four studies were classified as acceptable and two studies were not classified. The four acceptable studies satisfy the guideline requirements for mutagenicity studies (GDLNs 84-2 and 84-4) for 4,4-dimethyloxazolidine.

<u>The four acceptable studies are as follows</u>:

4,4-dimethyloxazolidine was tested in the L5178Y Mouse lymphoma assay with mutagenic potential up to 0.01 to 0.28 µl/mL with or without activation (MRID 00126353). Another study used 4,4-dimethyloxazolidine in the chromosomal aberration assay in Chinese hamster ovary cells finding mutagenic potential up to 0.16 to 0.28 µl/mL with or without activation (MRID 00126352). Also tested in the micronucleus test in mouse bone marrow, 4,4-dimethyloxazolidine proved no apparent mutagenic potential at 500 mg/kg (only dosage tested). The test substance appears to suppress

hematopoiesis as indicated by a decrease in ratio of polychromatic to normochromatic erythrocytes over a 72 hour time period (MRID 41577003). In a fourth acceptable study, 4,4-dimethyloxazolidine was tested for unscheduled DNA synthesis in rat hepatocytes with no apparent mutagenic potential at 10 to 5000 µg/mL. Also, 4,4-dimethyloxazolidine produced cytotoxicity at 333 µg/mL and above (MRID 41577002).

The two unclassified studies are as follows:

Two studies showed that 4,4-dimethyloxazolidine was tested in the Ames test with no apparent mutagenic potential in *S. typhimurium* strains TA-1535, TA-1537, TA-1538, TA-98 and TA-100 up to 10 µg/plate, both with or without activation (MRIDs 00076976 and 00076977).

One unacceptable study is as follows:

4,4-Dimethyloxazolidine was tested in the chromosome aberration assay in in vivo (metaphase analysis) with no apparent mutagenic potential up to 20, 40, or 80 mg/kg. However, the mutagenic potential of 4,4-dimethyloxazoline in in vivo assay is not confirmed because the dose range tested was insufficient because there was no indication of clinical or bone marrow toxicity at any of the dosages (MRID 41577004).

4,4-Dimethyloxazolidine was negative in most mutagenicity tests. Therefore, the overall results suggest that mutagenicity health hazards from 4,4-dimethyloxazolidine in the expected usage are minimal.

g. Metabolism

A metabolism study is not required to support the non-food uses of 4,4-dimethyloxazolidine because of the expected absence of oral exposure and because the current use pattern scenarios will not result in significant human exposure.

h. Toxicological Endpoints of Concern

The Toxicity Endpoint Selection Committee of the Agency's Office of Pesticide Programs, Health Effects Division, has concluded the following:

Risk assessment is not required because 4,4-dimethyloxazolidine is a non-food use chemical. Based upon review of the toxicology database for 4,4-dimethyloxazolidine, there are no identified toxicological endpoints of concern for short-term (1-7 days) or intermediate-term (7-90 days) occupational or residential exposures. Furthermore, there were no systemic

effects reported at doses of up to 300 mg/kg/day in a dermal developmental toxicity study in rabbits; maternal toxicity effects were limited to local dermal irritation. No systemic effects were apparent in rats following dermal administration for 90-days. While 4,4-dimethyloxazolidine is a Category I eye irritant (rabbits), this effect is more appropriately addressed at the individual product level where formulation and dilution affect the degree of irritation and necessity for eye protection. Therefore, a risk assessment is not warranted.

2. Exposure and Risk Assessment

a. Dietary Exposure

The Agency considers the uses of 4,4-dimethyloxazolidine to be non-food. Therefore, a dietary exposure and risk assessment is not needed.

b. Occupational and Residential Exposure

An occupational and/or residential exposure assessment is required for an active ingredient if: (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators) during use or to persons entering treated sites after application is complete. While there are potential application and post-applications exposures from the use of 4,4-dimethyloxazolidine in commercial, industrial, and residential settings, the Agency has decided that an occupational/residential mixer/loader/applicator exposure analysis is not warranted at this time due to the absence of toxicological endpoints of concern.

Since formaldehyde is a degradate of 4,4-dimethyloxazolidine, the Agency has also looked at potential formaldehyde exposure to products containing 4,4-dimethyloxazolidine. Post-application settings are addressed for formaldehyde by the Occupational Safety and Health Administration. OSHA has a comprehensive workplace standard for formaldehyde for the protection of workers in the industrial setting due to formaldehyde-release in the workplace. The OSHA formaldehyde standard was established as a rule in May 1992, and set a permissable exposure level (PEL) of 0.75 ppm in the workplace. The standard also prescribes that certain actions should be taken if monitoring shows levels of 0.50 ppm. This standard requires monitoring before workers enter the premises following use of formaldehyde, or when potential ambient formaldehyde is generated from other chemicals.

3. Risk Assessment

a. Dietary

Based on the non-food use pattern of 4,4-dimethyloxazolidine, residues in/on food and/or feed are not expected to occur. Therefore, a dietary risk assessment is not needed.

b. Occupational and Residential

A risk assessment was not conducted for the occupational and residential exposures of 4,4-dimethyloxazolidine due to the absence of toxicological endpoints of concern.

C. Environmental Assessment

1. Ecological Toxicity Data

The ecotoxicological data base is adequate to characterize the acute toxicity of 4,4-dimethyloxazolidine to nontarget terrestrial and aquatic organisms when used to control pests in aquatic or terrestrial industrial and indoor nonfood sites.

a. Toxicity to Terrestrial Animals

Birds, Acute and Subacute

In order to establish the toxicity of 4,4-dimethyloxazolidine to birds, the following tests are required using the technical grade of the active ingredient: one avian single-dose oral LD_{50} study on one species (preferably mallard or bobwhite quail); two subacute dietary LC_{50} studies on one species of waterfowl (preferably the mallard duck); and one species of upland game bird (preferably bobwhite quail or ring-necked pheasant) (GDLNs 71-1 and 71-2). The following summaries give the results of these studies.

Table 2: Avian Acute Oral Toxicity Findings

Species tested	% AI	LD_{50}	MRID Author (year)	Conclusion
Bobwhite Quail	76	705 mg/kg	42967201 Pederson (1993)	Slightly toxic
Mallard duck	78	110 mg/kg	0076970 Bodden (1979)	Moderately toxic

The results of the studies, summarized in Table 2, show that 4,4-dimethyloxazolidine displays slight to moderate toxicity to birds. The guideline requirement for the avian acute oral LD_{50} study has been met. (MRIDs 42967201, 0076970).

Table 3: Avian Subacute Dietary Toxicity Findings				
Species tested	**% AI**	**LC_{50}**	**MRID Author (year)**	**Conclusion**
Bobwhite Quail	78%	>3250 ppm	00102975 Bodden (1979)	Slightly toxic
Mallard duck	78%	>4008 ppm	00102976 Bodden (1979)	Slightly toxic

The results of the studies, summarized in Table 3, show that on a subacute dietary basis (GDLN 71-2), 4,4-dimethyloxazolidine is slightly toxic to birds. The two studies, one on the mallard duck and one on the bobwhite quail, produced LC_{50}s >3000 ppm. The guideline requirement has been met. (MRIDs 00102975, 00102976).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies (GDLN 72-1). At least one study should use a coldwater species (preferably the rainbow trout) and the other should use a warmwater species (preferably the bluegill sunfish).

Table 4: Freshwater Fish Acute Toxicity Findings				
Species tested	**% AI**	**LC_{50}**	**MRID Author (year)**	**Conclusion**
Bluegill sunfish	77.2%	59 ppm	00076969 Thompson (1979)	Slightly toxic
Rainbow trout	Technical	95 ppm	00068770 Lee (1974)	Slightly toxic

The results of the 96-hour acute toxicity studies, summarized in Table 4, indicate that 4,4-dimethyloxazolidine displays slight toxicity to both cold and warm water fish. The guideline requirement has been met. (MRIDs 00076969 and 00068770).

(2) Freshwater Invertebrates

The minimum testing required to assess the acute hazard of a pesticide to freshwater invertebrates is an aquatic invertebrate toxicity test (GDLN 72-2), preferably using first instar Daphnia magna or early instar amphipods, stoneflies, mayflies, or midges.

Table 5: Freshwater Invertebrate Toxicity Findings

Species tested	% AI	LC_{50}	MRID Author (year)	Conclusion
Daphnia magna	77%	45 (32-56) ppm	00076968 Thompson (1979)	Slightly toxic

Results of aquatic invertebrate testing, summarized in Table 5, indicate that 4,4-dimethyloxazolidine is slightly toxic to Daphnia magna. The guideline requirement has been met. (MRID 00076968).

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required (GDLN 72-3) when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. The aquatic industrial use patterns of oil recovery for 4,4-dimethyloxazolidine may result in exposure to the estuarine environment.

The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp or mysid, and either a 48-hour embryo-larva study or a 96-hour shell deposition study with an acceptable shellfish species.

Table 6: Estuarine/Marine Acute Toxicity Findings				
Species tested	**% AI**	**LC_{50} (CL's)**	**MRID Author (year)**	**Conclusion**
Sheepshead minnow	82%	218 (171-248) ppm	00102974 Ward (1981)	Practically non-toxic
Pink shrimp	77%	230 (180-300) ppm	00076967 Bionomics (1981)	Practically non-toxic
Eastern oyster	82.5%	9.2 (5.4-10.2) ppm	00102973 Ward (1982)	Moderately toxic

The study results summarized in Table 6 indicate that 4,4-dimethyloxazolidine is practically non-toxic to the tested estuarine fish and shrimp species. Moderate toxicity was observed for eastern oysters exposed to this chemical. The guideline requirements have been met. (MRIDs 00102974, 00076967, and 00102973).

Chronic Aquatic Studies: Chronic testing for 4,4-dimethyloxazolidine is not required based on the criteria presented in title 40 of the Code of Federal Regulations part 158. These criteria cover salient toxicological and/or exposure characteristics that suggest potential for risk from chronic exposure.

c. Toxicity to Terrestrial, Semi-Aquatic and Aquatic Plants

Plant toxicity testing is not required for 4,4-dimethyloxazolidine because of the limited exposure potential of the registered uses.

2. Environmental Fate

Current Agency policy requires only a hydrolysis study to characterize the fate of pesticides for Aquatic non-food industrial, Terrestrial non-food crop, and Indoor non-food.

Environmental Fate Chemistry

4,4-Dimethyloxazolidine apparently hydrolyzed so rapidly in water with pHs of 5, 7, or 9 that no rate or half-life could be determined from the study. Only a small amount of parent 4,4-dimethyloxazolidine (6.3-8.7 ppm, 2.7-3.6 %) was present soon after solution preparation (time=0 samples) and throughout the study. The hydrolysis products were formaldehyde and 2-amino-2-methyl-1-propanol (AMP). AMP was stable for the length of the

studies (30 days for hydrolysis and 6 days for photolysis). AMP was present at time=0 samples in concentrations of 191-207 ppm (96.4-97.3% of dosing rate). Screening level modeling for the determination of expected environmental concentrations (EECs) was performed and is available in documents from the Agency. (MRIDs 41664801, 41960701).

3. Exposure and Risk Characterization

The Agency requires only a limited set of ecotoxicology and environmental fate studies for microbiocides. 4,4-Dimethyloxazolidine is slightly toxic to moderately toxic to birds, slightly toxic to freshwater fish and invertebrates, and practically non-toxic to moderately toxic to estuarine and marine organisms.

The actual component responsible for target organism control is unclear. It is apparent that 4,4-dimethyloxazolidine rapidly degrades to 2-amino-2-methyl-propanol (AMP) and formaldehyde in water. Therefore, it must be assumed that aquatic organisms exposed to the 4,4-dimethyloxazolidine in the acute toxicity tests were exposed to the degradates as well over the 48-96 hour exposure durations. In all cases, except the oyster study, the 4,4-dimethyloxazolidine was introduced statically and the resulting toxicity levels were considered low. The oyster study used a constant flow system to deliver the chemical and the resulting toxicity levels were moderate. Therefore, it appears that both 4,4-dimethyloxazolidine and its degradates display low to moderate toxicity to aquatic organisms.

The oil recovery drilling mud (aquatic and terrestrial) uses are expected to result in minimal to no exposure if proper procedures are employed in the disposal of the contaminated drilling muds.

While the hazard to aquatic organisms from 4,4-dimethyloxazolidine has been characterized, a quantitative risk assessment has not been conducted. The risks to aquatic environments from all uses are regulated under the National Pollution Discharge Elimination System (NPDES) permitting program of EPA's Office of Water. The labels for all 4,4-dimethyloxazolidine products must require that discharges to aquatic environments comply with an NPDES permit.

Endangered Species

The Agency does not anticipate any exposure of concern to fish and wildlife, providing that all 4,4-dimethyloxazolidine products are handled and applied as specified in the product labeling and that discharges to the environment comply with all Federal disposal laws and NPDES.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing 4,4-dimethyloxazolidine. 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 4,4-dimethyloxazolidine. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of 4,4-dimethyloxazolidine, 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 4,4-dimethyloxazolidine and to determine that 4,4-dimethyloxazolidine can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing 4,4-dimethyloxazolidine 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, and the data identified in Appendix B. Although the Agency has found that all uses of 4,4-dimethyloxazolidine 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 4,4-dimethyloxazolidine, 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 ingredient 4,4-dimethyloxazolidine, the Agency has sufficient information on the health effects of 4,4-dimethyloxazolidine and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that 4,4-dimethyloxazolidine 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 products containing 4,4-dimethyloxazolidine for all current uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all current uses of 4,4-dimethyloxazolidine are eligible for reregistration.

C. Labeling Rationale/Risk Mitigation Measures

The Worker Protection Standard (WPS)

At this time all registered uses of 4,4-dimethyloxazolidine are outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The Agency is not establishing any new entry restrictions at this time for occupational uses of 4,4-dimethyloxazolidine end-use products because no toxicological endpoints of concern were identified and no additional risk mitigation measures are warranted. However, the Agency has concluded that it is prudent to require a continuation of current minimal label precautions to afford product users protection from unnecessary exposure. These label requirements are specified below in Section V and must be retained and/or added since there may be potential for application and post application exposure.

Personal Protective Equipment/Engineering Controls for Handlers

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

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

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

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE or engineering-control requirements that pertain to all or most occupational end-use products containing that active ingredient.

- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.

- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if gloves are required to mitigate risk, then a long-sleeve shirt, long pants, socks and shoes are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

At this time there are no engineering control requirements, such as closed systems, currently required on labeling for end-use products containing 4,4-dimethyloxazolidine.

Occupational-Use Products

There are no special toxicological concerns about 4,4-dimethyloxazolidine that warrant the establishment of active-ingredient-based minimum PPE requirements for occupational handlers.

Homeowner-Use Products

There are no homeowner uses of 4,4-dimethyloxazolidine, except as an additive in products, such as paints. There are no special toxicological concerns about 4,4-dimethyloxazolidine that warrant the establishment of active-ingredient-based minimum PPE requirements for homeowner handlers.

Post-Application/Entry Restrictions

EPA is not establishing entry restrictions at this time for 4,4-dimethyloxazolidine end-use products, because the anticipated frequency, duration, and degree of exposure following occupational/residential applications do not warrant specific risk mitigation measures.

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. 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 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.

Method and Rates of Application: the registrant must specify the application and method, equipment, and timing, i.e., labels must specify equipment to be used such as metering pump for secondary oil recovery injection water and at what point should application occur.

2. Labeling Requirements for End-Use Products

PPE/Engineering Control Requirements for Pesticide Handlers

For sole-active-ingredient end-use products that contain 4,4-dimethyloxazolidine, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. For the reason given above, any conflicting PPE requirements on the current labeling must be removed.

For multiple-active-ingredient end-use products that contain 4,4-dimethyloxazolidine, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

<u>Minimum (Baseline) PPE/Engineering Control Requirements</u>

Because of the lack of special toxicity endpoints of concern, EPA is not establishing active-ingredient-based minimum (baseline) PPE/engineering control requirements for 4,4-dimethyloxazolidine end-use products that are intended primarily for occupational use. Any necessary PPE for each 4,4-dimethyloxazolidine occupational end-use product will be established on the basis of the end-use product's acute toxicity category. NOTE: All end-use products will be required to specify a

long-sleeved shirt, long pants, socks and shoes as minimum work attire for all handlers. If the end-use product is classified as toxicity category I or II for eye irritation potential, protective eyewear is also required.

Placement in Labeling

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Other Labeling Requirements

The Agency is requiring the following precautionary labeling statements to be located on all end-use products containing 4,4-dimethyloxazolidine.

Application Restrictions

"Do not use this product in a way that will contact workers or other persons."

User safety requirements

Registrant: add the following statements only if gloves or protective eyewear are required PPE on the end-use product:

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

User Safety Recommendations

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

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

  Add the following statements only if gloves are required PPE on the end-use product:

  "Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible wash thoroughly."

Directions for Use

Registrants must specify on labeling the complete directions for use for each use pattern: site of application, type of application, timing of application, equipment used for application, and the rate of application (dosage).

Effluent Discharge Labeling Statements

To reduce environmental risk from 4,4-dimethyloxazolidine discharge and disposal, product labels must continue to have the statements pertaining to effluent discharge under the National Pollutant Discharge Elimination System (NPDES) permitting system (refer to PR Notice 93-10 or 40 CFR 152.46(a)(1)) and disposal under any applicable federal laws.

B. 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 4,4-dimethyloxazolidine products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A REPORT

Case 3095[Methyloxazolidines] **Chemical 114801[4,4-Dimethyloxazolidine]**

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 Tex. @ unless noted otherwise)	Soil Max. Max. Rate unless noted Max. /crop /year otherwise) Dose cycle	# Apps Max. Dose [(AI /crop /year /A] cycle	Min. Interv (days)	Entry Interv [day(s)]	Restr. Allowed	Geographic Limitations Disallowed Codes	Use Limitations
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 736	W 3667	* NS	NS	NS	NS	NS	NS	A02, C18, C24
	SC/L	W 770	W 3850	* NS	NS	NS	NS	NS	NS	CAH
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 385	W 1540	* NS	NS	NS	NS	NS	NS	CAH
	SC/L	W 736	W 3667	* NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	W 780	W 2340	* NS	NS	NS	NS	NS	NS	
	SC/L	W 950	W 2850	* NS	NS	NS	NS	NS	NS	
METALWORKING CUTTING FLUIDS				Use Group: INDOOR NON-FOOD						
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	SC/L	W 737	W 1474	* NS	NS	NS	NS	NS	NS	A23(6), C18, C24
	SC/L	W 780	W 2340	* NS	NS	NS	NS	NS	NS	
	SC/L	W 950	W 2850	* NS	NS	NS	NS	NS	NS	
Preservative treatment, Initial, Not on label, Not Applicable, Not applicable for this use	SC/L	V 920	V 1838	* NS	NS	NS	NS	NS	NS	C18, C24
Preservative treatment, Subsequent/maintenance, Not on label, Not Applicable, Not applicable for this use	SC/L	V 460	V 460	* NS	NS	NS	NS	NS	NS	C18, C24

APPENDIX A REPORT

Case 3095[Methyloxazolidines] **Chemical 114801[4,4-Dimethyloxazolidine]**

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 Tex. @ unless noted otherwise)	Soil Max. Max. Rate unless noted Dose cycle	# Apps Max. Dose [(AI Max. /crop /year otherwise)/A] cycle	Min. Interv (days) Interv [day(s)]	Entry	Restr. Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION										
NON-FOOD/NON-FEED (con't)										
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS									Use Group: AQUATIC NON-FOOD INDUSTRIAL	
Preservative treatment, Not on label, Not SC/L on label, Not Applicable, Not applicable for this use	V 368		V 736	*	NS	NS	NS	NS	NS	NS	C18, C24
									Use Group: TERRESTRIAL NON-FOOD CROP	
Preservative treatment, Not on label, Not SC/L on label, Not Applicable, Not applicable for this use	V 368		V 736	*	NS	NS	NS	NS	NS	NS	C18, C24
PAINTS (IN-CAN)									Use Group: INDOOR NON-FOOD	
Industrial preservative treatment, During SC/L manufacture, Not on label, Not Applicable, Not applicable for this use	W 736		W 3667	*	NS	NS	NS	NS	NS	NS	C18, C24
SC/L	W 770		W 2310	*	NS	NS	NS	NS	NS	NS	CAH
SC/L	W 780		W 2340	*	NS	NS	NS	NS	NS	NS	
SC/L	W 950		W 2850	*	NS	NS	NS	NS	NS	NS	
SECONDARY OIL RECOVERY INJECTION WATER									Use Group: AQUATIC NON-FOOD INDUSTRIAL	
Water treatment, Continuous feed (initial), Metering pump, Not Applicable, Not applicable for this use	SC/L	V 15	V 112	*	NS	NS	NS	NS	NS	NS	C18, C24
SC/L	W 14		W 109	*	NS	NS	NS	NS	NS	NS	C18, C24
SC/L	W 15		W 110	*	NS	NS	NS	NS	NS	NS	C18, C24
Water treatment, Continuous feed (subsequent), Metering pump, Not Applicable, Not applicable for this use	SC/L	V 3.8	V 112	*	NS	NS	NS	NS	NS	NS	C18, C24
SC/L	W 3.7		W 110	*	NS	NS	NS	NS	NS	NS	C18, C24

APPENDIX A REPORT

Case 3095[Methyloxazolidines] **Chemical 114801[4,4-Dimethyloxazolidine]**

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. Rate unless noted Max. Dose cycle	Max. # Apps /crop cycle	Max. Dose [(AI /crop /year otherwise)/A]	Min. Interv (days)	Entry Interv [day(s)]	Restr. Allowed	Geographic Limitations Disallowed Codes	Use Limitations
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
SECONDARY OIL RECOVERY INJECTION WATER (con't)									Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)		
Water treatment, Shock/slug, Metering pump, Not Applicable, Not applicable for this use	SC/L	V 15	V 112	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	W 14	W 109	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	W 15	W 110	*	NS	NS	NS	NS	NS	NS	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 736	W 3667	*	NS	NS	NS	NS	NS	NS	C18, C24
	SC/L	W 737	W 1474	*	NS	NS	NS	NS	NS	NS	A23(6), C18, C24
	SC/L	W 770	W 2310	*	NS	NS	NS	NS	NS	NS	CAH
Preservative treatment, Initial, Not on label, Not Applicable, Not applicable for this use	SC/L	V 920	V 1838	*	NS	NS	NS	NS	NS	NS	C18, C24
Preservative treatment, Subsequent/maintenance, Not on label, Not Applicable, Not applicable for this use	SC/L	V 460	V 460	*	NS	NS	NS	NS	NS	NS	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 770	W 3850	*	NS	NS	NS	NS	NS	NS	CAH

APPENDIX A REPORT

Case 3095[Methyloxazolidines] Chemical 114801[4,4-Dimethyloxazolidine]

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
A02 : Inedible product area.

APPENDIX A REPORT

Case 3095[Methyloxazolidines] **Chemical 114801[4,4-Dimethyloxazolidine]**

USE LIMITATIONS CODES (Cont.)
A23 : __ pH (minimum)
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)
CAH : Do not discharge into lakes, streams, ponds, or public water unless in accordance with NPDES Permit.
* 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 4,4-dimethyloxazolidine covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 4,4-dimethyloxazolidine 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 4,4-Dimethyloxazolidine

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ALL	42941000, 42941001, 43328100, 43328101
61-2A	Start. Mat. & Mnfg. Process	ALL	42941000, 42941001, 43328100, 43328101
61-2B	Formation of Impurities	ALL	42941000, 42941001, 43328100, 43328101
62-1	Preliminary Analysis	ALL	42941000, 42941001, 43328100, 43328101
62-2	Certification of limits	ALL	42941000, 42941001, 43328100, 43328101
62-3	Analytical Method	ALL	42941000, 42941001, 43328100, 43328101
63-2	Color	ALL	42941000, 42941001, 43328100, 43328101
63-3	Physical State	ALL	42941000, 42941001, 43328100, 43328101
63-4	Odor	ALL	42941000, 42941001, 43328100, 43328101
63-5	Melting Point	ALL	42941000, 42941001, 43328100, 43328101
63-6	Boiling Point	ALL	42941000, 42941001, 43328100, 43328101
63-7	Density	ALL	42941000, 42941001, 43328100, 43328101
63-8	Solubility	ALL	42941000, 42941001, 43328100, 43328101
63-9	Vapor Pressure	ALL	42941000, 42941001, 43328100, 43328101
63-10	Dissociation Constant	ALL	42941000, 42941001, 43328100, 43328101
63-11	Octanol/Water Partition	ALL	42941000, 42941001, 43328100, 43328101
63-12	pH	ALL	42941000, 42941001, 43328100, 43328101
63-13	Stability	ALL	42941000, 42941001, 43328100, 43328101
ECOLOGICAL EFFECTS			

Data Supporting Guideline Requirements for the Reregistration of 4,4-Dimethyloxazolidine

REQUIREMENT		USE PATTERN	CITATION(S)
71-1A	Acute Avian Oral - Quail/Duck	C,F,M	42967201, 0076970
71-2A	Avian Dietary - Quail	C,F,M	00102975
71-2B	Avian Dietary - Duck	C	00102976
72-1A	Fish Toxicity Bluegill	C,F	00076969
72-1C	Fish Toxicity Rainbow Trout	C,F,M	00068770
72-2A	Invertebrate Toxicity	C,F,M	00076968
72-3A	Estuarine/Marine Toxicity - Fish	C,F	00102974
72-3B	Estuarine/Marine Toxicity - Mollusk	C,F	00102973
72-3C	Estuarine/Marine Toxicity - Shrimp	C,F	00076967
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	ALL	41706707
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL	41706708
81-3	Acute Inhalation Toxicity - Rat	ALL	41706709
81-4	Primary Eye Irritation - Rabbit	ALL	41706710
81-5	Primary Dermal Irritation - Rabbit	ALL	41706711
81-6	Dermal Sensitization - Guinea Pig	ALL	41706712
82-3	90-Day Dermal - Rodent	C,F,M	43322601, 00138227
83-3A	Developmental Toxicity - Rat		Waived
83-3B	Developmental Toxicity - Rabbit	C,F,M	00157806
84-2A	Gene Mutation (Ames Test)	ALL	00076976, 00076977

Data Supporting Guideline Requirements for the Reregistration of 4,4-Dimethyloxazolidine

REQUIREMENT		USE PATTERN	CITATION(S)
84-2B	Structural Chromosomal Aberration	ALL	00126352, 41577003, 41577004
84-4	Other Genotoxic Effects	ALL	00126353, 41577002
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
133-3	Dermal Passive Dosimetry Exposure		Waived
133-4	Inhalation Passive Dosimetry Exposure		Waived
ENVIRONMENTAL FATE			
161-1	Hydrolysis	C,F	41664801
161-2	Photodegradation - Water	C,F	41960701

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
00068770	WARF Institute, Incorporated (1977) Report: WARF Institute No. 4041616. (Unpublished study received Mar 16, 1978 under 271-31; submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL:233346-A)
00068771	International Minerals & Chemical Corporation (19??) Product Chemistry--Physical Properties: [Bioban CS-1135]. (Unpublished study received Mar 16, 1978 under 271-31; CDL:233344-A)
00076967	Heitmuller, T. (1979) Acute Toxicity of Amine CS-1135^(R)= to Pink Shrimp (~Penaeus duorarum~): Report No. BP-79-9-147. (Unpublished study, including submitter summary, received Apr 28, 1981 under 271-31; prepared by EG & G, Bionomics, submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL: 245165-A)
00076968	Thompson, C.M.; Forbis, A.D. (1979) Acute Toxicity of Amine CS1135 to~Daphnia magna~: Static Acute Bioassay Report #24668. (Unpublished study, including submitter summary, received Apr 28, 1981 under 271-31; prepared by Analytical Bio Chemistry Laboratories, Inc., submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL:245165-B)
00076969	Thompson, C.M.; Forbis, A.D. (1979) Acute Toxicity of Amine CS1135 to Bluegill Sunfish (~Lepomis macrochirus~): Static Acute Bioassay Report #24667. (Unpublished study, including submitter summary, received Apr 28, 1981 under 271-31; prepared by Analytical Bio Chemistry Laboratories, Inc., submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL:245165-C)
00076970	Bodden, R.M. (1980) Avian Single Dose Oral LD=50^--Mallard Duck. (Unpublished study, including submitter summary, received Apr 28, 1981 under 271-31; prepared by Raltech Scientific Services, Inc., submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL:245165-D)
00076976	Haworth, S.R.; Lawlor, T.E.; Smith, J.K.; et al. (1980) Salmonella/ Mammalian-microsome Plate Incorporation Mutagenesis Assay: Study No. 035-201-430-1. (Unpublished study, including submitter summary, received Apr 28, 1981 under 271-31; prepared by EG & G Mason Research Institute, submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL:245161-H)
00076977	Haworth, S.R.; Lawlor, T.E.; Smith, J.K.; et al. (1980) Salmonella/

MRID	CITATION
	Mammalian-microsome Plate Incorporation Mutagenesis Assay: Study No. 035-201-431-1. (Unpublished study received Apr 28, 1981 under 271-31; prepared by EG & G Mason Research Institute, submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL:245161-I)
00102973	Ward, S.; Parekh, C. (1982) Acute Toxicity of Amine CS-1135 to Eastern Oysters (Crassostrea virginica): Report No. BP-82-3-24. (Unpublished study received May 18, 1982 under 271-31; prepared by EG & G Bionomics, submitted by International Minerals & Chemical Corp., Terre Haute, IN; CDL:247551-A)
00102974	Ward, S.; Parekh, C. (1981) Acute Toxicity of Amine CS-1135 to Sheepshead Minnows (Cyprinodon variegatus): Report No. BP-81-11177. (Unpublished study received May 18, 1982 under 271-31; prepared by EG & G Bionomics, submitted by International Minerals & Chemical Corp., Terre Haute, IN; CDL:247551-B)
00102975	Bodden, R.; Thomson, G. (1979) Avian Dietary LC50--Bobwhite Quail. (Unpublished study received May 18, 1982 under 271-31; submitted by International Minerals and Chemical Corp., Terre Haute, IN; CDL:247551-C)
00102976	Bodden, R.; Thomson, G. (1979) Avian Dietary LC50--Mallard Duck. (Unpublished study received May 18, 1982 under 271-31; submitted by International Minerals and Chemical Corp., Terre Haute, IN; CDL:247551-D)
00126352	Thilagar, A.; Kumaroo, P.; Pant, K.; et al. (1982) Cytogenicity Study--Chinese Hamster Ovary (CHO) Cells in vitro: [Dimethyl Oxazolidine Solution]: Study No. T1840.338. (Unpublished study received Mar 1, 1983 under 48301-8; prepared by Microbiological Assoc., submitted by Angus Chemical Co., Northbrook, IL; CDL: 249687-A)
00126353	Kirby, P.; Pizzarello, R.; Rogers-Back, A.; et al. (1983) L5178Y TK+/Mouse Lymphoma Mutagenesis Assay: [Dimethyl Oxazolidine Solution]: Study No. T1840.701001. (Unpublished study received Mar 1, 1983 under 48301-8; prepared by Microbiological Assoc., submitted by Angus Chemical Co., Northbrook, IL; CDL:249687-B)
00138227	Troy, W.; Pennisi, S.; Felton, K.; et al. (1980) Thirteen Week Subchronic Dermal Toxicity Study in Albino Rats: The Safety Evaluation of an Antimicrobial Raw

MRID	CITATION
	Ingredient: Amine CS-1135: Study Project Code AT0156. Final rept. (Unpublished study received Apr 13, 1984 under 48301-8; prepared by Avon Products, Inc., submitted by Angus Chemical Co., Northbrook, IL; CDL:252955-A)
00157806	Arnold, K. (1986) Dermal Teratology Study in Rabbits: Oxaban: Study No. 509-002. Unpublished study prepared by International Research and Development Corp. 92 p.
41577002	Enninga, I. (1990) Evaluation of the DNA Repair Inducing Ability of Oxaban-A (Bioban CS-1135): Lab Project Number: 020327. Unpublished study prepared by Rcc Notox. 30 p.
41577003	Enninga, I. (1989) Micronucleus Test in Bone Marrow Cells of the Mouse with Oxaban-A (Bioban CS-1135): Lab Project Number: 0112522. Unpublished study prepared by RCC Notox. 21 p.
41577004	Asquith, J. (1984) Cytogenic Analysis of the Bone Marrow of Rats Treated with HP 60/83 (Oxaban-A or Bioban CS-1135): Lab Project Number: SR374. Unpublished study prepared by Toxicol Laboratories, Ltd. 267 p.
41664801	Chang, T. (1990) 4,4-Dimethyloxazolidine and 3,4,4-Trimethyloxazolidine: Hydrolysis Study as a Function of pH at 25 (degree C): Project Number: BR 111:90. Unpublished study prepared by Bolsa Research Associates. 31 p.
41706707	Cuthbert, J.; Carr, S.; Jackson, D. (1986) Compound 192: Acute Oral Toxicity (LD50) Test in Rats: Lab Project Number: 235634: 6401. Unpublished study prepared by Inveresk Research International. 31 p.
41706708	Cuthbert, J.; Carr, S.; Jackson, D. (1986) Compound 192: Acute Dermal Toxicity (LD50) Test in Rats: Lab Project Number: 235634: 6402. Unpublished study prepared by Inveresk Research International. 20 p.
41706709	McDonald, P.; Anderson, B. (1989) Troysan 192: Acute Inhalation Toxicity Study in Rats: Lab Project Number: 641996. Unpublished study prepared by Inveresk Research International. 43 p.
41706710	Cuthbert, J.; Carr, S.; Jackson, D. (1986) Troysan 192: Acute Eye Irritation Study

MRID	CITATION
	in Rabbits: Lab Project Number: 641996. Unpublished study prepared by Inveresk Research International. 21 p.
41706711	Cuthbert, J.; Carr, S.; Jackson, D. (1986) Compound 192: Acute Dermal Irritation Test in Rabbits: Lab Project Number: 235634: 6403. Unpublished study prepared by Inveresk Research International. 19 p.
41706712	Cuthbert, J.; Carr, S.; Jackson, D. (1986) Compound 192: Magnusson -Kligman Maximization Test in Guinea Pigs: Lab Project Number: 135634: 6405. Unpublished study prepared by Inveresk Research International. 26 p.
41960701	Chang, T. (1990) Photolysis Study with 4,4-Dimethyloxazolidine and 3,4,4-Trimethyloxazolidine in Aqueous Solution under Simulated Light Conditions: Lab Project Number: BR 112:90. Unpublished study prepared by Bolsa Research Associates. 34 p.
42864001	Siemann, L. (1993) Supplemental Data to MRID No. 41706706: 4,4-Dimethyloxazolidine Stability: Lab Project Number: 3329-F: TCCREREG 192 93A1: 192 93A1. Unpublished study prepared by Midwest Research Institute. 18 p.
42941001	Wassink, C. (1993) Supplemental Chemistry Data for MRID #'s 41706707, 41706708, 41706710, 41706711, 41706712: Lab Project Number: 192-AC-1: TCCREREG 93 192A1. Unpublished study prepared by Troy Corp. 68 p.
42967201	Pedersen, C.; Kauth, M. (1993) 4,4-Dimethyloxazolidine: 14-Day Acute Oral LD50 Study in Bobwhite Quail: Lab Project Number: 135-001-03: TCCREREG 192B1. Unpublished study prepared by Bio-Life Associates, Ltd. 54 p.
43322601	Allan, S.; Hawkins, A.; Crook, D.; et al. (1994) Thirteen-week Dermal Toxicity Study in Rats with 4,4-Dimethyloxazolidine: Final Report: Lab Project Number: TCC/3/931087: 3/931087: 94/192A1. Unpublished study prepared by Huntingdon Research Centre Ltd. 261 p.
43328100	Troy Chemical Corp. (1994) Submission of Product Chemistry Data in Support of Registration of Troysan 192 Formula II. Transmittal of 1 Study.
43328101	Bollmeier, A. (1990) Product Chemistry for 4,4-Dimethyloxazolidine.

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MRID	CITATION
	Unpublished study prepared by Angus Chemical Co. 27 p.
93150009	Pennisi, S. (1990) Angus Chemical Company Phase 3 Reformat of MRID 00076974 and Related MRIDs 00138227. Thirteen Week Subchronic Dermal Toxicity Study in Rats: AMINE CS-1135: Project AT0156. Prepared by AVON Products, Inc. 180 p.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your

product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-96).

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

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

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

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

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

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

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

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

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

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

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

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in

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

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

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

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 the Confidential Statement of Formula Form

4,4-DIMETHYLOXAZOLIDINE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing 4,4-dimethyloxazolidine.

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 4,4-dimethyloxazolidine. 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 4,4-dimethyloxazolidine 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 4,4-dimethyloxazolidine are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on 4,4-dimethyloxazolidine 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 4,4-dimethyloxazolidine products.

INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

Jean Holmes
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: **4,4-Dimethyloxazolidine**

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

Item 1-4. Already completed by EPA.

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

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

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

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

Items 8-11. Self-explanatory.

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

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

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

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

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

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

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

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

Item 9. **Enter <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.

EPA'S BATCHING OF 4,4-DIMETHYLOXAZOLIDINE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing 4,4-dimethyloxazolidine as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. There are six active products containing 4,4-dimethyloxazolidine as follows: 1100-87, 5383-60, 5383-61, 5383-82, 48301-8, 48301-12. All of these products are expected to have the same acute toxicity profile as the technical material described in the RED and may cite that data for reregistration.

Factors considered in the batching process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she

must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

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

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	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

EPA	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)

The following is a list of available documents for 4,4-dimethyloxazolidine that may further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Jean Holmes at (703)-308-8008.

1. PR Notice 86-5.

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

3. A full copy of this RED document.

4. A copy of the fact sheet for 4,4-dimethyloxazolidine.

The following documents are part of the Administrative Record for 4,4-dimethyloxazolidine and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1.Health and Environmental Effects Science Chapters.

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

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

1. The Label Review Manual.

2. EPA Acceptance Criteria