United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA 738-R-95-017 April 1995

Reregistration Eligibility Decision (RED)

Dowicil®CTAC

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 Dowicil®CTAC which includes the active ingredients Dowicil®75 and Dowicil®150. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this[these] chemical[s], 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.

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Frank Rubis at (703) 308-8184.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

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

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

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

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

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

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

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

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

Dowicil®CTAC

LIST C

CASE 3069

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

TABLE OF CONTENTS

DOWICIL®CTAC REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Frank Hernandez	Economic Analysis Branch
Phyllis Johnson	Biological Analysis Branch
Michele Cottrill	Biological Analysis Branch
Rafael Prieto	Biological Analysis Branch

Environmental Fate and Effects Division

Renee Costello	Science Analysis and Coordination Staff
William R. Effland	Environmental Fate and Groundwater Branch
Renee Costello	Ecological Effects Branch

Health Effects Division

Mary Clock	Risk Characterization Analysis Branch
Pat McLaughlin	Toxicology Branch I
Mike Ioannou	Toxicology Branch I
Winston Dang	Occupational and Residential Exposure Branch

Registration Division

Mary Waller	Registration Support Branch
Wallace Powell	Antimicrobial Program Branch
Sami Malak	Registration Support Branch

Special Review and Reregistration Division

Virginia Dietrich	Accelerated Reregistration Branch
Mark Wilhite	Accelerated Reregistration Branch
Ron Kendall	Accelerated Reregistration Branch

Office of Compliance Assurance and Enforcement:

Beverly Updike

GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
ADI	Acceptable Daily Intake. A now defunct term for refernce dose (RfD).
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA) The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/L, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{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

GLOSSARY OF TERMS AND ABBREVIATIONS

MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PPE	Personal Protective Equipment
ppb	Parts Per Billion
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TMRC	Theoretical Maximum Residue Contribution
TLC	Thin Layer Chromatography
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (hereafter referred to as "the Agency") has completed an assessment of the potential human health and environmental risks associated with the pesticide uses of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (Dowicil® CTAC). There are two active ingredients included in this assessment, Dowicil®75 which contains a ratio of both the cis- and trans-isomers of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride, and Dowicil®150 which contains only the cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride.

This Reregistration Eligibility Decision (RED) also addresses the reregistration requirements for products containing both Dowicil®75 and Dowicil®150 for currently registered uses. These products are used as preservatives in oil recovery drilling muds and packer fluids, metal working cutting fluids, latex paints, industrial adhesives and coatings, latex emulsions, detergent floor wax emulsions, floor polishes, inks, laundry starch, spinning emulsions, and pulp and paper coatings, finishes and printing colors as components of paper and paperboard intended for use in contact with aqueous, fatty, dry bulk, and dry foods. They are also applied as microbicides/microbistats to secondary oil injection water as a water treatment.

The Agency has determined that the uses of Dowicil®75 and Dowicil®150 as currently registered will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration. The Agency has concerns about the potential for workers to be exposed to formaldehyde, a degradate, from the industrial and residential uses. However, the Agency believes that the risks of formaldehyde for the industrial uses is low and should be regulated by the Occupational Safety and Health Administration (OSHA) through their formaldehyde monitoring program and the potential for exposure in residential settings is minimal. The Agency also has concerns about possible adverse affects to aquatic organisms from the discharge of effluent from industrial uses. However, the Agency is requiring as part of this RED that product labels be amended to contain appropriate label restrictions for industrial discharge in the National Pollutant Discharge Elimination System.

Accordingly, the Agency has determined that all products containing either active ingredient Dowicil®75 or Dowicil®150 are eligible for reregistration and will be reregistered when acceptable labeling and product-specific data are submitted and/or cited. Before reregistering the products containing Dowicil®75 or Dowicil®150, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

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

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

This document presents the Agency's decision regarding the reregistration eligibility of the chemical case Dowicil®CTAC and its two active ingredients Dowicil®75, a racemic mixture of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride, and Dowicil®150, the cis isomer of this chemical and their registered uses. The document consists of six sections. Section I is the introduction. Section II describes Dowicil®75 and Dowicil®150, their 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 Dowicil®75 and Dowicil®150. Section V discusses the reregistration requirements for Dowicil®75 an Dowicil®150. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW-Dowicil®CTAC

The Agency will use the case name Dowicil®CTAC for the case containing the two active ingredients Dowicil®75 and Dowicil®150. The active ingredient Dowicil®75 contains both the cis-(.53%) and the trans-(.44%) isomers of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride. The active ingredient Dowicil®150 contains only the cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride. The Agency will use the case name Dowicil®CTAC in this document when referring to both active ingredients together. There are sections in the assessment were it will be necessary to reference each active ingredient separately. In those instances the Agency will use the trade names Dowicil®75 and Dowicil®150 for the specific chemical characteristics or to represent the percentage of active ingredient being referenced.

A. Chemical Overview-Dowicil®75

Common Name: Dowicil®75

Chemical Name: 1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride

CAS Registry Number: 4080-31-3

OPP Chemical Code: 17901

Empirical Formula: $C_9H_{16}N_4Cl_2$

Molecular weight: 251.2

Trade and Other Names:
Dowicil® 75
Dowicil® 100
Cinartc 200
XD-1840
Dowicide Q
Quaternium 15
Dowco 184
Hexamethylenetetramine chloroallyl chloride

Basic Manufacturer: Dow Chemical Company

B. Chemical Overview-Dowicil®150

Common Name: Dowicil®150

Chemical Name: cis-1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride

CAS Registry Number: 51229-78-8

OPP Chemical Code: 17902

Empirical Formula: $C_9H_{16}N_4Cl_2$

Trade and Other Names: Dowicil® 150
Dowicil® 200
Hexamethylenetetramine cis-chloroallyl chloride

Basic Manufacturer: Dow Chemical Company

C. Use Profile

The following is information on the current registered uses with an overview of use sites and application methods. A detailed table of the uses of Dowicil®CTAC is in Appendix A.

Chemical: Dowicil®75

Chemical Number: 17901

1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride

Type of Pesticide: Microbicide/microbistat (slime forming bacteria and fungi)

Use Sites:

Aquatic non-food industrial:

Secondary oil recovery injection water

Indoor non-food:

Industrial adhesives and coatings; resin/latex/polymer emulsions; metalworking cutting fluids; oil recovery drilling muds/packer fluids; latex(in-can) paints; specialty industrial products; textiles/textile fibers/cordage; and wet-end additives/industrial processing chemicals.

Target Pests: Slime-forming bacteria and fungi, spoilage microorganisms.

Formulation Types Registered:

Type: End Use
Form: Solid

Method and Rates of Application:

Types of Treatment:

Microbicide/microbistat for secondary oil injection water-water treatment-17 to 34 ppm.

Preservative for industrial adhesives, industrial coatings, latex emulsions, metalworking fluids, latex paints, oil recovery drilling muds and packer fluids, detergents floor wax emulsions, floor polishes, inks, laundry starch, spinning emulsions, and pulp and paper coatings, finishes and printing colors - preservative treatment - 68 to 4455 ppm active ingredient.

Rate of Application - (See Types of Treatment)

Timing - During manufacture

Use Practice Limitations:

Incompatible with casein in both liquid and dry systems and with some types of amine-modified clays. For preservation of components of paper and paperboard intended for use in contact with aqueous, fatty dry bulk, and dry foods.

Chemical: Dowicil®150

Chemical Number: 17902

cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride

Type of Pesticide: Microbicide/microbistat(slime forming bacteria and fungi)

Use Sites:

Indoor non-food:

Industrial adhesives and coatings; resin/latex/polymer emulsions; metalworking cutting fluids; latex in-can paints; specialty industrial products; textiles/textile fibers/cordage; and wet-end additives/industrial processing chemicals.

Target Pests: Slime-forming bacteria and fungi, spoilage microorganisms.

Formulation Types Registered:

Type: End Use
Form: Solid

Method and Rates of Application:

Types of Treatment:

Preservative for industrial adhesives, industrial coatings, latex emulsions, metalworking fluids, latex paints, detergents floor wax emulsions, floor polishes, inks, laundry starch, spinning emulsions, and pulp and paper coatings, finishes and printing colors - preservative treatment - 282 to 4700 ppm active ingredient.

Method and Rate - (See Types of Treatment)

Timing - During manufacture

Use Practice Limitations:

Incompatible with casein in both liquid and dry systems and with some types of amine-modified clays. For preservation of components of paper and paperboard intended for use in contact with aqueous, fatty dry bulk, and dry foods.

D. Regulatory History

A pesticide product containing Dowicil®150 was first registered in the United States in 1964 as a microbicide/microbistat. A second registration for Dowicil®75 was granted in 1972 for use as a preservative for paints, latexes, metalworking lubricants and to other industrial formulations to prevent deterioration from bacteria and fungi.

Dowicil®CTAC meets the requirement of Food Additive regulations under 21 CFR Section 175.105 for use as a preservative in adhesives, 21 CFR 176.1680 as a preservative of polyurethane resins in contact with dry bulk foods, 21 CFR 176.170 for preservation of components of pulp and paperboard intended for use in contact with aqueous and fatty foods, and 21 CFR 176.180 for preservation of paper and paperboard intended for use in contact with dry foods.

In 1987 the Agency issued the Antimicrobial Data Call-In Notice for chronic and subchronic toxicity data requirements for these two active ingredients and other antimicrobials. The Agency issued a second data call-in under reregistration Phase 4 in of March 1992. This required the registrant to provide appropriate chemistry, toxicological and environmental fate data on these active ingredients to support reregistration. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to these data call-ins.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

The physical chemistry assessment for Dowicil®CTAC was done on Dowicil®75. The Agency believes that the physical chemistry characteristics of Dowicil®150 will be similar to Dowicil®75 since they are related isomers. Dowicil®CTAC has the following physical chemistry characteristics:

Physical State: Powder at 20^{o}C

Melting Point: 178-210^{o}C

Odor: Slight Amine like

Bulk Density: 0.4 gm/cm^{3}

Solubilities in g/100g of solvent at 25^{o}C:

Water	127.2
Methanol (anhydrous)	20.8
Propylene glycol, USP	18.7
Glycerine(99.5)	12.6
Ethanol (absolute)	2.04
Isopropanol (anhydrous)	< 0.1
Mineral Oil	< 0.1

Vapor Pressure: $< 1 \times 10^{-7}$ mm Hg at 25°C

pH: 5.57 at 24°C

Octanol/Water Partition Coefficient: Log p = -0.1

Dissociation Constant: Completely ionized in aqueous solution = 97.8%

Stability: Stable under ambient conditions

B. Human Health Assessment

The toxicology data base for Dowicil®CTAC is adequate for reregistration eligibility. Due to the similarities of the two active ingredients the Agency accepted toxicology studies conducted using either Dowicil®75 (sometimes referred to under trademark name Dowicil®100) or Dowicil®150 (sometimes referred to under trademark name Dowicil®200.)

1. Toxicology Assessment

a. Acute Toxicity

An acute oral toxicity study in rats found the LD_{50} for Dowicil®150 was 2664 mg/kg for both sexes (see Table 1). Clinical signs were lethargy, diarrhea, lacrimation, and tremors, placing Dowicil®CTAC in toxicity category III (guideline 81-1; MRID 00093902). An acute dermal toxicity study with rabbits found the LD_{50} for Dowicil®150 was 923 mg/kg, placing Dowicil®CTAC in toxicity category II (guideline 81-2; MRID 00093902). An acute inhalation toxicity study with rats found the LC_{50} was greater than 4.7 mg/L, placing Dowicil®CTAC in toxicity category IV (guideline 81-3; MRID 42420401).

A primary eye irritation study with Dowicil®150 in rabbits produced slight to moderate conjunctival redness and slight discharge, which cleared by 72 hours. There was slight irritation, toxicity category III (guideline 81-4; MRID 00093902). Dowicil®150, in a primary dermal irritation study with rabbits, produced a very slight edematous reaction on intact skin. There was slight irritation placing Dowicil®CTAC into toxicity category IV (guideline 81-5; MRID 00093902). The dermal sensitization potential of Dowicil®150 was tested with guinea pigs and it was not a dermal sensitizer (guideline 81-6; MRID 00093902).

Table 1. Acute Toxicity Data for DOWICIL®CTAC

Test	Results	Category
Oral LD50--rats	2664 mg/kg	III
Dermal LD50--rabbits	923 mg/kg	II
Inhalation LC50--rats	> 4.7 mg/L	IV
Eye irritation--rabbits	slight irritation	III
Dermal irritation--rabbits	slight irritation	IV
Dermal sensitization--guinea pigs	non-sensitizer	--

b. Subchronic Toxicity

New Zealand white rabbits were given daily dermal applications of Dowicil®75 for 13 weeks. The doses were 0, 50, 200, or 1000 mg/kg/day. The only treatment related effect was a dose-dependent increase in ulcerative dermatitis, at the treatment site, that was correlated with the abrasions from clipping. The NOEL for systemic toxicity was 1000 mg/kg/day (guideline 82-4; MRID 40650201).

One study was conducted to determine the level of Dowicil®75 in the diet which would result in complete acceptance of the diet by rats. Ten rats/sex/group were administered the chemical in the diet at dosages of 0, 1, 2 or 4 mg/kg/day for 90 days. The only parameters evaluated were body weight, food consumption and organ weight (absolute and relative). Male rats in the 4 mg/kg/day group had a significant decrease in body weight at approximately 36% of the weighing periods. This group also had a significant decrease in food consumption throughout the study. The absolute weight of the heart in the 4 mg/kg/day group males was significantly decreased. The relative weight of the brain and liver were increased in the 4.0 mg/kg/day group females. This study was classified as supplementary but was not required for reregistration. The study was performed to investigate a specific toxicological endpoint (MRID# 46358).

In another study, Dowicil®75 was administered in the diet to groups of 10 rats/sex/group at dosages of 0, 7.5, 15 , 30 or 60 mg/kg/day for 90 days. Mean body weight was significantly decreased in all the treated males and females throughout the study. Overall mean body weight gain was decreased in all the treated groups. Mean food consumption was significantly decreased in the treated males, especially at the beginning of the study. Although all of the treated female groups had significantly reduced intake at some time during the study, females were not as frequently affected as males. Calculation of food efficiency values for the overall study and for the latter half of the study showed that the major effect of decreased food intake on body weight occurred at the beginning of the study. However, the decrease in food efficiency does indicate that the chemical had a toxic effect on body weight that cannot be accounted for solely by decreased food consumption. The only other possible effect of treatment was an increase in the incidence of minimal hepatocellular swelling in the 60 mg/kg/day group males (0/5 in the control vs. 3/5 in the 60 mg/kg/day group). This study is classified as supplementary due to the absence of clinical observation data and legible summary tables for the organ weight data (MRID# 111075).

In a dog study, Dowicil®75 was administered in gelatin capsules to four beagle dogs/sex/group at dosages of 0, 7.5, 15 or 30 mg/kg/day for 90 days. One female in the 30 mg/kg/day was sacrificed due to general deterioration on the 84th day of the study; necropsy revealed ascites with evidence of liver toxicity. The only other toxicologically significant findings during the study included a significant decrease in the hematocrit, hemoglobin and white blood count measurements in the 30 mg/kg/day group males and histopathological changes, especially in the liver, in the 30 mg/kg/day group males and females. The incidence and/or severity of several findings in the liver were increased in the 30 mg/kg/day group males and females including the following: obliterative vasculitis and perivasculitis of the hepatic blood vessels; perivascular and pericholangiolar infiltration of mononuclear cells; and hyperplasia of the reticuloendothelial cells lining the hepatic sinusoid. This study is classified as supplementary due to the absence of legible summary tables for hematology and organ weight data (MRID#127915).

c. Developmental Toxicity

A dermal developmental toxicity study was conducted with Fischer 344 rats. Doses of 0, 250, or 500 mg/kg/day of Dowicil®75 as a 50% aqueous solution were applied to the dorsal skin daily on gestation days 6 through 15. No significant adverse effects from treatment with the test compound were found but the study was considered adequate because the doses were sufficiently high (guideline 83-3; MRID 40349701).

d. Mutagenicity

Dowicil®75 was mutagenic in the in vitro Chinese hamster ovary cell HGPRT forward mutation assay with activation but nonmutagenic without activation (guideline 84-2(a); MRID 40545101). Dowicil®75 was negative in the rat hepatocyte unscheduled DNA synthesis assay (guideline 84-4; MRID 40545103). It was negative also in the mouse micronucleus test (guideline 84-2(b); MRID 40545102).

2. Exposure Assessment

a. Occupational and Residential

Due to its low toxicity and the lack of a toxicological endpoint of concern, an exposure assessment is not required for Dowicil®CTAC. However, based on the studies submitted by the registrant (GDLN 161-1, MRID# 43192101 and MRID# 43577601), the Agency has determined that formaldehyde is released from the decomposition of Dowicil®CTAC in aqueous solution. The Agency is concerned with formaldehyde since it has significant toxic effects of its own, and has been classified by the Agency as a Group B1/Probable Human Carcinogen (Integrated Risk Assessment System, 5/1/91).

The potential for exposure to Dowicil®CTAC and/or formaldehyde exists for two groups of individuals: 1) Occupational--workers involved in the industrial setting (addition of the biocide during the manufacturing process); and 2) Residential--individuals in the home setting where Dowicil®CTAC products may be used.

For residential uses, the Agency has determined that the potential exposure to Dowicil®CTAC is minimal. A study submitted by the registrant for carpet adhesives containing Dowicil®CTAC indicates that formaldehyde does not pose an exposure hazard (MRID# 43577601).

For industrial uses, the Agency has determined that Dowicil®CTAC exposure for most workers to is low because of the current use patterns and available use information. Therefore, exposure to Dowicil®CTAC not of concern. The Agency believes workers in industrial settings are adequately protected against exposure to 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 permissible exposure level (PEL) of .75 ppm in the workplace. The standard also proscribes that certain actions should be taken if monitoring shows levels of .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.

Two incident cases have been reported to the Agency for Dowicil®CTAC. The first case, reported in June 1993, involved 7 workers and the specific active ingredient is unknown. This incident was caused by a misuse of the product. In the second case, reported in August, 1994, a woman in Texas claimed to have developed chemical sensitivity to Dowicil®75 in housepaint. From its review of this report, the Agency considers the information insufficient to show a causal relationship between Dowicil®75 and the reported chemical sensitivity. Other than these to cases, no other human incidents have been reported to the Agency.

All uses of Dowicil®CTAC are outside the scope of the Worker Protection Standard (WPS) and requirements for personal protective equipment (PPE) for Dowicil®CTAC products are under the jurisdiction of OSHA. The Agency requires that Dowicil®CTAC labels contain a label statement advising workers to wear chemical resistant gloves for the open-pouring of the end-use product.

3. Risk Assessment

a. Occupational and Residential

Based on the use patterns and toxicological information for the active ingredients Dowicil®75 and Dowicil®150, the Agency has determined that products containing the above active ingredients, labeled and used as specified in this RED, will not pose a significant risk to humans. The Agency further believes potential risks in residential settings will be insignificant. The occupational risks for potential exposure to formaldehyde in the work place when Dowicil®CTAC is used are low and formaldehyde is currently monitored and regulated by OSHA.

C. Environmental Assessment

In summary, Dowicil®CTAC dissipates by abiotic hydrolysis with slightly faster rates of hydrolysis under acidic conditions than were observed for neutral to alkaline conditions. Dowicil®75 and Dowicil®150 have both been classified as practically nontoxic to slightly toxic to avian species, fish, aquatic invertebrates and terrestrial animals. These chemicals' environmental fate and ecological effects are described in more detail below.

1. Environmental Fate

A hydrolysis study is required for industrial use pesticides in which effluent is potentially discharged into aquatic environments. This environmental fate guideline requirement is fulfilled for Dowicil®CTAC.

a. Environmental Chemistry, Fate and Transport

(1) Hydrolysis

Uniformly radio-labeled Dowicil([^{14}C]CTAC), at 58 ppm, degraded with a registrant calculated half-life of 1.1 days in a sterile pH 5 buffer solution that was incubated in the dark at 25^{o}C; the hydrolytic half-lives were 2.7 and 2.2 days for pH 7 and 9 solutions, respectively. Uniformly radio-labeled [^{14}C]CTAC, at 1,004 ppm in 0.05 M buffer solutions, degraded more slowly than the 58 ppm test solutions with registrant calculated half-lives of 6.3, 13 and 26 days for pH 5, 7 and 9 solutions, respectively. Similar half-lives were reported for both cis- and trans-isomers within each concentration range test.

The following degradates were identified:

* 1-methyl-3,5,7-triaza-1-azoniaadamantane ([^{14}C]-HMTA-CH_3);

* the hydrochloride salt of hexamethylenetetramine ([^{14}C]-HMTA; maximum concentration of less than 7 percent of the applied for both [^{14}C]-HMTA-CH_3 and [^{14}C]-HMTA at 10 days posttreatment); and

* nonlabeled cis- and trans-3-chloroallylamines.

In the pH 5 solution, [^{14}C]CTAC was a maximum of 59.11 percent (cis-) and 36.46 percent (trans-) of the applied immediately post treatment and a maximum of 27.46 percent (cis-) and 12.97 percent (trans-) of the applied at 1 day posttreatment. At day 5, [^{14}C]CTAC was a maximum of 2.99 percent (cis-) and 1.56 percent (trans-) of the applied.

In the pH 7 solution, [^{14}C]CTAC was a maximum of 59.27 percent (cis-) and 36.12 percent (trans-) of the applied immediately post treatment and a maximum of 32.38 percent (cis-) and 21.69 percent (trans-) of the applied at 1 day post treatment. At day 5, [^{14}C]CTAC was a maximum of 14.54 percent and 7.9 percent of the applied for the cis- and trans-isomers, respectively.

In the pH 9 solution, [^{14}C]CTAC was a maximum of 45.54 percent (cis-) and 27.25 percent (trans-) of the applied immediately post treatment and a maximum of 26.83 percent (cis-) and 16.23 percent (trans-) of the applied at 1 day post treatment. At day 5, [^{14}C]CTAC was a maximum of 7.96 percent (cis-) and 3.59 percent (trans-) of the applied.

Material balances ranged from 95.5 to 102.2 percent of the applied for the 50 ppm [^{14}C]CTAC experiment. Material balances ranged from 94.5 to 104.4 percent of the applied for the 1,000 ppm [^{14}C]CTAC experiment.

Reaction rates for the [^{14}C]-products suggested that an appreciable amount of the [^{14}C]-products may be precursors to [^{14}C]-methylene glycol. Based on an earlier hydrolysis study, formaldehyde forms as a degradation product of CTAC (Gonsior and Dilling, 1984). The current hydrolysis study indicates that formaldehyde, when present in a dilute aqueous solution, reacts with water to form the hydrate, methylene glycol. Earlier research indicates that after the addition of formaldehyde to a pH 7 solution at 25^{o} C, less than 0.01 percent remained as formaldehyde (Allinger et al., 1971). The current hydrolysis study considered formaldehyde as an equilibrium mixture with methylene glycol. This study fulfills the guideline requirement. (guideline 161-1; MRID 43192101)

b. Environmental Fate Assessment

Information from the above hydrolysis study indicates that Dowicil®CTAC is nonpersistent and degrades rapidly under acidic (pH 5) conditions. Under neutral to alkaline conditions (pH 7-to-9), Dowicil®CTAC degraded more slowly.

Aquatic Tier 1c Estimated Environmental Concentrations (EECs):

The fundamental component of an aquatic exposure assessment for the Agency is the Estimated Environmental Concentration or EEC. An aquatic EEC describes the frequency or probability that a chemical will be found at a certain concentration in a specified environment or group of environments as the result of its use pattern.

To aid in the aquatic risk assessment, a screening level calculation called a Tier 1c EEC was developed by the Agency. A Tier 1c EEC determines the maximum concentration occurring immediately downstream from an industrial (point source) discharge site, and is calculated using very conservative assumptions and does not address the environmental fate of the pesticide, and therefore, may overestimate the true exposure of the chemical. However, it provides a clear demarcation such that if a Tier 1c EEC does not exceed the established Level of Concern (LOC), it indicates that a pesticide poses little or no risk to the aquatic environment. In the same respect, if the Tier 1c EEC does exceed the LOC, it may indicate that the pesticide can potentially adversely impact the environment. For risk assessment, these calculated EECs may be compared to **acute exposure** LOCs (based on the fact that these EECs estimate the concentration immediately downstream from a discharge site and that it assumes no degradation of the chemical). However, chronic exposure risk assessments can be conducted using the Tier 1c EECs when a safety factor (1/100 LC_{50}) is employed.

EECs for high exposure and typical exposure are calculated. The EECs for the high exposure case are based on a return frequency of 1-in-10 years. The high exposure case represents a site that would be expected to produce larger EECs than 90% of all the sites with the specified use pattern. A 1-in-10 year EEC has a 10% probability of being equalled or exceeded in any single year at a given site, or could be equalled or exceeded once every 10 years at that site over a long term average. These frequency of occurrence and site assumptions are similar to the assumptions used by the Agency for modeling agricultural pesticides. The EECs calculated for the typical exposure case represents a site that would be expected to produce larger EECs than 50% of all the sites with the specified use pattern.

The Agency may regulate pesticides using the high (maximum) exposure rather than the typical exposure to provide an added measure of environmental protection. Typical exposure is provided for refinement to further characterize the risk. To calculate both EECs, the concentration in the waste stream was assumed to be the same as the application rate (this

assumes that no degradation occurred in the processing stream). The concentration in the waste stream was then used to calculate the concentration in the receiving water body immediately downstream from the discharge site.

Dowicil®CTAC is also used in pulp/paper mills; however it is not used in the whitewater stage of paper making. These waters are reused several times and are treated with a variety of antimicrobial products. Dowicil®CTAC is incorporated into the coating materials which provide the desired aesthetic or strength characteristics of the paper. During the coating process the water is evaporated and the low residual of Dowicil®CTAC is incorporated into the coating. Because the exposure of Dowicil®CTAC from this use pattern is expected to be minimal, Tier 1c EECs were not calculated for pulp/paper mill use.

Dilution factors used to calculate the EECs were taken from an array of dilution factors compiled by the Office of Pesticides and Toxic Substance of EPA (OPTS, 1992). For each use pattern, an appropriate group of industrial sites was selected to represent the use. Table 1 lists the Standard Industrial Code (SIC) for each industrial classification chosen for a particular use pattern. If the use pattern was not specifically listed on the Industrial Categories Summary Table, the Publicly Owned Treatment Works (POTW) which may also be referenced as SIC #4952 were used as the default category.

The application rates of Dowicil®75 and Dowicil®150 and appropriate dilution factors used to calculate the EECs are listed in Table 2. The typical EEC was calculated by dividing the waste stream concentration by the tabulated dilution factor for the mean flow condition at the median site. The high exposure EEC was calculated by using a dilution factor which represents a site that would be expected to produce larger EECs than 90 percent of all sites with the specified use pattern.

TABLE 2. STANDARD INDUSTRIAL CODES, MAXIMUM APPLICATION RATES, AND DILUTION FACTORS FOR DOWICIL®75 AND DOWICIL®150

USE SITE	SIC	MAX. APPL. RATES	DIL. FACTOR	
			TYPICAL	HIGH EXP.
DOWICIL®75				
Secondary Oil Recovery Water	4952	34 ppm	710.43	1.00
Metalworking Cutting Fluids--Soluble cutting oils	3411	101 ppm	4730.86	3.75
Metalworking Cutting Fluids--Recirculating metalworking lubricants	3411	1688 ppm	4730.86	3.75
Wet-End Additives/Industrial Processing Chemicals	4952	1823 ppm	710.43	1.00
Oil Recovery Drilling Muds/Packer Fluids	4952	338 ppm	126.72	1.00
DOWICIL®150				
Metalworking Cutting Fluids--Soluble cutting oils	3411	1880 ppm	4730.86	3.75
Wet-End Additives/Industrial Processing Chemicals	4952	1880 ppm	710.43	1.00

The high and typical exposure aquatic Tier 1c EECs for Dowicil®75 and Dowicil®150 are listed in Table 3.

TABLE 3. AQUATIC TIER 1c EECs for Dowicil®75 and Dowicil®150

USE SITE	TYPICAL EXPOSURE CASE	HIGH EXPOSURE CASE
DOWICIL®75		
Secondary Oil Recovery Water	0.048 ppm	34 ppm
Metalworking Cutting Fluids-- Soluble cutting oils	0.021 ppm	27 ppm
Metalworking Cutting Fluids-- Recirculating metalworking lubricants	0.357 ppm	450 ppm
Wet-End Additives/Industrial Processing Chemicals	3 ppm	1823 ppm
Oil Recovery Drilling Muds/Packer Fluids	3 ppm	338 ppm
DOWICIL®150		
Metalworking Cutting Fluids -- Soluble cutting oils	0.4 ppm	501 ppm
Wet-End Additives/Industrial Processing Chemicals	3 ppm	1880 ppm

2. Ecological Effects

a. Ecological Effects Data

(1) Terrestrial Data

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

Given that the use patterns of the products with these two chemicals are not likely to expose wild mammals or honey bees, the Agency has not required toxicological testing for these two species.

(a) Avian Acute Toxicity

The Agency has reviewed two studies which indicate that Dowicil®CTAC ranges from slightly toxic to practically nontoxic to birds on an acute oral basis (Table 4). The guideline requirement for the avian acute oral LD_{50} study is fulfilled. (guidelines 71-1(a); MRID 00071725 and 42814703)

Table 4. Avian Acute Oral Toxicity Findings for Dowicil®CTAC

Species	% AI	LD_{50}	Conclusion
Mallard Duck	67.5	> 2510 mg/Kg	Practically nontoxic
Mallard Duck	95	= 1440 mg/Kg	Slightly toxic

(b) Avian Subacute Dietary Toxicity

Dowicil®CTAC is slightly toxic to practically nontoxic to birds on a subacute dietary basis (Table 5). The guideline requirement is fulfilled. (guidelines 71-2(a), 71-2(b); MRID 00074305, 00071726, 42814704, and 42814705)

Table 5. Avian Subacute Dietary Toxicity Findings for Dowicil®CTAC

Species	% AI	LC_{50}	Conclusion
Bobwhite quail	67.5	= 3223 ppm	Slightly toxic
Mallard duck	67.5	> 5620 ppm	Practically nontoxic
Bobwhite quail	95	= 2645 ppm	Slightly toxic
Mallard duck	95	= 5627 ppm	Practically nontoxic

(2) Aquatic Data

(a) Freshwater Fish Toxicity

In order to establish the toxicity of a microbicide to freshwater fish, the minimum data required on the technical grade of the active ingredient is one freshwater fish toxicity study.

The results of the aquatic toxicity studies indicate that Dowicil®CTAC is slightly toxic to practically nontoxic to freshwater fish (Table 6). The guideline requirement for acute toxicity testing of the technical on freshwater fish is fulfilled (guidelines 72-1(a), 72-1(c); MRID 00125029, 42814701, 42814702).

Table 6. Freshwater Fish Toxicity Findings for Dowicil®CTAC

Species	% AI	LC_{50}	Conclusion
Bluegill	67.5	59 ppm	Slightly toxic
Rainbow Trout	91	> 144 ppm	Practically nontoxic
Bluegill	91	148 ppm	Practically nontoxic

(b) Freshwater Invertebrate Toxicity

The minimum testing required to assess the hazard of a microbicide to freshwater invertebrates is one freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. At an EC_{50} of 42 ppm, Dowicil®75 is slightly toxic to Daphnia. Data for an acute invertebrate toxicity test was submitted for Dowicil®75 but not for Dowicil®150. However, based on available freshwater fish toxicity data (see Table 6), which indicate Dowicil®150 is less toxic than Dowicil®75 to aquatic organisms, this study would not add any useful scientific information and is, therefore, waived. The guideline requirement for acute toxicity testing on freshwater invertebrates is fulfilled. (guideline 72-2(a); MRID 00125029)

(c) Estuarine/Marine Toxicity

Estuarine/marine acute toxicity studies are required under the current 40 CFR Part 158 to support use in once-through cooling towers, oil recovery drilling muds/packer fluids, secondary oil recovery injection waters, and pulp and paper mills. The requirement for this category includes a 96-hour LC_{50} for an estuarine fish (sheepshead minnow preferred), a 96-hour LC_{50} for

shrimp (mysid preferred), and a 48-hour embryo-larvae study or a 96-hour shell deposition study (eastern oyster preferred). Estuarine toxicity testing reveals that Dowicil®150 is slightly toxic to estuarine organisms. The estuarine data requirements for Dowicil®150 have been fulfilled (Table 7). (guidelines 72-3(a), (b), and (c); MRID 43107201, 43107202, and 43107203)

Table 7. Estuarine Acute Toxicity Findings for Dowicil®CTAC

Species	% AI	LC_{50} or EC_{50}	Conclusion
Fish (Silverside)	89.2	LC_{50} = 59 ppm	Slightly toxic
Oyster	89.2	EC_{50} = 11 ppm	Slightly toxic
Shrimp	89.2	LC_{50} > 52 ppm	Slightly toxic

Estuarine/marine organisms acute toxicity studies, 72-3(a), (b), and (c), have not been submitted for Dowicil®75. If the relationship between Dowicil®75 and Dowicil®150 for estuarine organisms is analogous to that for freshwater organisms, it can be assumed the former is more toxic to estuarine organisms than is the latter. Therefore, the toxicity to these organisms will likely be underestimated using the Dowicil®150 data. The Agency has required this data as confirmatory, in order to establish the toxicity of Dowicil®75 to estuarine organisms for the secondary oil recovery injection waters, metalworking cutting fluids, wet end additives/industrial processing chemicals, and the oil recovery drilling muds/packer fluids uses.

(3) Terrestrial, Semi-Aquatic and Aquatic Plant Data

Plant testing is not required for microbicides/microbistats under 40 CFR Part 158. Because Dowicil®CTAC is a microbicide/microbistat for control of fungi primarily, aquatic plant toxicity requirements have not been required.

b. Ecological Effects Risk Assessment

(1) Risk to Terrestrial Animals

The use patterns of Dowicil®CTAC would result in minimal exposure to terrestrial organisms, therefore terrestrial species are not likely to be impacted by the use of Dowicil®CTAC. Dowicil®75 and Dowicil®150 are practically nontoxic to slightly toxic to upland gamebirds and wild waterfowl.

(2) Risk to Aquatic Animals

Unlike agricultural pesticides in which aquatic organisms can be exposed via runoff and/or drift, exposure to nontarget aquatic organisms could be expected through a point source discharge of industrial microbicides. In the case of Dowicil®CTAC, there are several use sites and environmental conditions where exposure to aquatic organisms is a distinct possibility. Consequently, the previously mentioned Tier 1c EECs (see Table 3) were calculated in accordance with current Agency policy for the following use sites: secondary oil recovery injection waters, metalworking cutting fluids (two scenarios - soluble cutting oils and metal working lubricant), wet-end additives/industrial processing chemicals, and oil recovery drilling muds/packer fluids.

Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget animal groups and one category (acute) for each of two nontarget plant groups.

In order to determine if an LOC has been exceeded, a risk quotient (RQ) must be derived and compared to the respective LOC. A risk quotient is calculated by dividing an appropriate exposure estimate (e.g., the estimated environmental concentration) by an appropriate toxicity test effect level (e.g., the LC_{50}). In the case of microbicides, when only an aquatic risk assessment is performed, the acute effect levels typically are the LC_{50} (fish) and the EC_{50} (invertebrates). The chronic RQ is derived using a safety factor of 1/100 of the acute effect level. This safety factor enables the use of the previously mentioned Tier 1c estimated environmental concentrations.

The criteria for the presumption of risk as well as the relation of risk to LOC exceedances for aquatic organisms are summarized in the following tables. The most sensitive species was selected, regardless of testing on Dowicil®150 or Dowicil®75:

Table 8. Aquatic Risk LOCs Secondary Oil Recovery Injection Waters for Dowicil®CTAC

SPECIES	ACUTE LC_{50} (ppm)	RQ HIGH EXPOSURE (EEC/LC_{50})	RQ TYPICAL EXPOSURE (EEC/LC_{50})	MAGNITUDE OF LOC EXCEEDANCE	
				HIGH ACUTE EXPOSURE (LOC = RQ > 0.5)	HIGH CHRONIC EXPOSURE (LOC = RQ > 0.01)
Bluegill	59	0.58	0.0008	1.2	58
Daphnia	42	0.81	0.001	1.6	81
Minnow (Silverside)	34	1.0	0.001	2	100
Oyster, Shell	11(EC_{50})	3.09	0.004	6.2	309
Shrimp	52	0.65	0.0009	1.3	65

For Table 8 the typical acute and chronic exposures did not exceed the LOC.
Application rate = 34 ppm
High Exposure EEC = 34 ppm
Typical Exposure EEC = 48 ppb

Table 9. Aquatic Risk LOCs Metalworking Cutting Fluids - Soluble Cutting Oils for Dowicil®CTAC

SPECIES	ACUTE LC_{50} (ppm)	RQ HIGH EXPOSURE (EEC/LC_{50})	RQ TYPICAL EXPOSURE (EEC/LC_{50})	MAGNITUDE OF LOC EXCEEDANCE	
				HIGH ACUTE EXPOSURE (LOC = RQ > 0.5)	HIGH CHRONIC EXPOSURE (LOC = RQ > 0.01)
Bluegill	59	0.46	0.0004	No Exceedance	46
Daphnia	42	0.64	0.0005	1.28	64
Minnow (Silverside)	34	0.79	0.0006	1.6	79
Oyster,Shell	11(EC_{50})	2.45	0.002	4.9	245
Shrimp	52	0.52	0.0004	1.04	52

For Table 9 the typical acute and chronic exposures did not exceed the LOC.
Application rate = 101 ppm
High Exposure EEC = 27 ppm
Typical Exposure EEC = 21 ppb

Table 10. Aquatic Risk LOCs Metalworking Cutting Fluids - Metalworking Lubricant for Dowicil®CTAC

SPECIES	ACUTE LC_{50} (ppm)	RQ HIGH EXPOSURE (EEC/LC_{50})	RQ TYPICAL EXPOSURE (EEC/LC_{50})	MAGNITUDE OF LOC EXCEEDANCE	
				HIGH ACUTE EXPOSURE (LOC = RQ > 0.5)	HIGH CHRONIC EXPOSURE (LOC = RQ > 0.01)
Bluegill	59	7.63	0.0061	15.3	763
Daphnia	42	10.7	0.0085	21.4	1070
Minnow (Silverside)	34	13.2	0.0105	26.4	1324
Oyster, Shell	11(EC_{50})	40.9	0.0325	81.8	4090
Shrimp	52	8.65	0.0069	17.3	865

For Table 10 the typical acute and chronic exposures did not exceed the LOC.
Application rate = 1688 ppm
High Exposure EEC = 450 ppm
Typical Exposure EEC = 357 ppb

Table 11. Aquatic Risk LOCs Wet End Additives/Industrial Processing Chemicals

SPECIES	ACUTE LC_{50} (ppm)	RQ HIGH EXPOSURE (EEC/LC_{50})	RQ TYPICAL EXPOSURE (EEC/LC_{50})	MAGNITUDE OF LOC EXCEEDANCE		
				HIGH ACUTE EXPOSURE (LOC = RQ > 0.5)	HIGH CHRONIC EXPOSURE (LOC = RQ > 0.01)	TYPICAL CHRONIC EXPOSURE (LOC = RQ $ 0.01)
Bluegill	59	30.9	0.05	61.8	3090	5
Daphnia	42	43.4	0.07	86.8	4340	7
Minnow (Silverside)	34	53.6	0.09	107	5360	9
Oyster, Shell	11(EC_{50})	165.7	0.27	332	16570	27
Shrimp	52	35.1	0.06	70.2	3510	6

For Table 11 the typical acute exposure did not exceed the LOC.
Application rate = 1823 ppm
High Exposure EEC = 1823 ppm
Typical Exposure EEC = 3 ppm

Table 12. Aquatic Risk LOCs Oil Recovery Drilling Muds/Packer Fluids for Dowicil®CTAC

SPECIES	ACUTE LC_{50} (ppm)	RQ HIGH EXPOSURE (EEC/LC_{50})	RQ TYPICAL EXPOSURE (EEC/LC_{50})	MAGNITUDE OF LOC EXCEEDANCE		
				HIGH ACUTE EXPOSURE (LOC = RQ > 0.5)	HIGH CHRONIC EXPOSURE (LOC = RQ > 0.01)	TYPICAL CHRONIC EXPOSURE (LOC = RQ $ 0.01)
Bluegill	59	5.73	0.05	11.5	573	5
Daphnia	42	8.05	0.07	16.1	805	7
Minnow (Silverside)	34	9.94	0.09	19.9	994	9
Oyster, Shell	11(EC_{50})	30.7	0.27	61.4	3073	7
Shrimp	52	6.5	0.06	13	650	6

For Table 12 the typical acute exposure did not exceed the LOC.
Application rate = 338 ppm
High Exposure EEC = 338 ppm
Typical Exposure EEC = 3 ppm

Based on the above calculations, the chronic LOC is exceeded for both the high and typical exposure scenarios of the Tier 1c exposure model for wet-end additives/industrial processing chemicals and oil recovery drilling muds/packer fluids. The acute LOC is exceeded for the high exposure scenarios for all five of the examined uses.

It is important to note, that the assumption of no degradation in the waste stream is not valid for Dowicil®CTAC because it degrades by abiotic hydrolysis with reported half-lives ranging from approximately 1-to-3 days for 50 ppm concentrations to approximately 6-to-26 days for 1,000 ppm concentrations. These calculated Tier 1c EECs are likely overestimates of the actual environmental concentration which would be found in the environment. A higher tier EEC calculation which considers the environmental fate and transport properties of Dowicil®CTAC would provide a more accurate estimate of the actual environmental concentrations. However, additional environmental fate data would be needed in order to calculate the higher tier EEC. Based on the rapid hydrolysis and the use sites for Dowicil®CTAC, no additional environmental fate date is required. And, discharge levels are governed under a NPDES permit granted by state regulatory agencies and the Agency.

(3) Risk to Endangered Species

The LOC for endangered aquatic species is exceeded when the EEC value of the exposure model equals or exceeds 1/20 the LC_{50} values, that is the risk quotient of the EEC value divided by the LC_{50} equals or exceeds 0.05. For Dowicil®CTAC the LOCs for risk to endangered species are exceeded for the high exposure scenario for all modelled uses and for the typical exposure scenarios for the wet end additives/industrial processing chemicals and the oil recovery drilling muds/packer fluids. This indicates that endangered aquatic species are at risk with both high and typical exposure scenarios. As Dowicil®CTAC will be discharged at a number of different sites, it is reasonable to assume that endangered species are located in some of these aquatic habitats. Effluent containing Dowicil®CTAC should not be discharged into streams or other waterways where endangered aquatic organisms are known to reside. The Agency wants to reiterate that the toxicity levels referenced above are based on the conservative assumption of no degradation and Dowicil®CTAC does degrade rapidly by abiotic hydrolysis.

The Endangered Species Protection Program is expected to become final in 1995. Limitations in the use of Dowicil®CTAC will be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county bulletins.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

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

The data identified in Appendix B are sufficient to allow the Agency to assess the registered uses of Dowicil®CTAC and to determine that Dowicil®CTAC can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing Dowicil®75 and Dowicil®150 as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document. However, the Agency remains concerned, as discussed above, about the potential exposure and risks associated with formaldehyde in the workplace and to endangered species. The Agency has notified OSHA that the potential for exposure to formaldehyde exists from the use of Dowicil®CTAC. OSHA has agreed to add products containing Dowicil®CTAC to its formaldehyde monitoring program. The Agency is relying on OSHA's monitoring program to regulate the potential risks to workers. The Agency is also relying on future implementation of the Endangered Species Act to have positive effects on exposure and risk reduction.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Although the Agency has found that all uses of Dowicil®CTAC 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 Dowicil®CTAC, 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. Eligibility Decision

Based on the reviews of the generic data for the active ingredients Dowicil®75 and Dowicil®150, the Agency has sufficient information on the health effects of Dowicil®CTAC and on their potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that Dowicil®CTAC 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 Dowicil®CTAC for all uses are eligible for reregistration.

C. Regulatory Position

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

1. Risk Mitigation to Handlers

Personal Protective Equipment (PPE) for Handlers (Mixer/Loader/ Applicators)

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

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

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

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

(2) 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.

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

There are no special toxicological concerns about Dowicil®CTAC, per se, that warrant the establishment of active-ingredient-based PPE requirements other than chemical resistant gloves for open pouring of end-use products. This decision is based on the risk assessment which indicates Dowicil®CTAC is category II for acute dermal toxicity. Therefore, the Agency is requiring chemical resistant gloves for handlers engaged in open pouring of end-use products containing Dowicil®75 and Dowicil®150.

2. Potential Formaldehyde Exposure Statement

As described in Section III. B. above, available information indicates that exposure to Dowicil®CTAC and/or formaldehyde exists for occupational workers involved in industrial settings and for individuals in residential settings where Dowicil®CTAC containing products may be used. However, the Agency has also determined that the potential exposure in residential settings are minimal and that the potential exposure for occupational workers is low and formaldehyde levels in the workplace are being regulated by OSHA. The Agency notified OSHA of Dowicil®CTAC's potential formaldehyde release and they have agreed to include products containing Dowicil®CTAC in their program to monitor for potential formaldehyde exposure in the workplace.

3. Aquatic Industrial Use Statement

Based on the above (Section III) calculations, the chronic LOC is exceeded for both high and typical exposure model for wet end additives/industrial processing chemicals and oil recovery drilling muds/packer fluids. The high exposure scenario assumes that 90% of the sites had greater mean stream flows for the low flow condition. This scenario also assumes that no degradation occurred and that the application rate is the same as the receiving body of water. Further, assuming that degradation has occurred, there are no directions on the label that indicate at what intervals replenishment of the product is necessary. A higher tier EEC calculation taking into account the fate of this chemical would likely further reduce the estimated risk. The Agency has determined that the appropriate risk reduction measure is to require NPDES permitting for direct effluent discharges of all end use products.

4. Endangered Species Statement

The Agency has concerns about the exposure of threatened and endangered species to Dowicil®CTAC as discussed above in the science assessment chapter (Section III.). Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use modifications or a generic product label statement, requiring users to consult county-specific bulletins. These bulletins would provide information about specific use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses.

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

available. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

V. ACTIONS REQUIRED BY REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of Dowicil®CTAC for the above eligible uses has been reviewed and determined to be substantially complete. However, the Agency is requiring that the registrant perform the estuarine/marine organisms acute toxicity studies, as confirmatory data, on Dowicil®75 to establish the toxicity of Dowicil®75 to estuarine/marine organisms for the secondary oil recovery injection waters, metalworking cutting fluids, wet end additives/industrial processing chemicals, and the oil recovery drilling muds/packer fluids uses.

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statements under Directions For Use:

> "Only for formulation into an_____(fill blank with Insecticide, Herbicide or the applicable term which describes the type of pesticide uses(s)) for the following uses(s) :_____(fill in the blank only with those uses that are being supported by the MP registrant)."
>
> An MP registrant may, at his/her discretion, add one of the following statements to an MP label under "Directions For Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or use group:

(a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such uses(s)."

(b) "This product may be used to formulate products for any additional uses(s) not listed on the MP label if the formulator, user group or grower has complied with U.S.EPA submission requirements regarding the support of such uses(s)."

Personal Protective Equipment

Handler PPE for Occupational-Use Products

The minimum (baseline) PPE for handlers engaged in open pouring of Dowicil®75 and Dowicil®150 is chemical-resistant gloves.

Note to Registrants: If a product is currently labeled for both Manufacturing Use and End Uses, the registrant must delete one set of uses in order to make it either an MP or EP. If the registrant chooses to delete the end uses, it must follow the requirements in this MP labeling section. If the registrant chooses to delete the MP use (e.g., "For Manufacturing or Formulation Only Into…"), it must follow the requirements of the EP labeling section below. In either case, a registrant must submit an application to register a new product if he wishes to market a product intended for the uses deleted from the current product.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

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

2. Labeling Requirements for End-Use Products

Effluent Discharge Labeling Statements

All Dowicil®75 and Dowicil®150 end-use products that may be contained in an effluent discharged to the waters of the United States or municipal sewer systems must bear the following revised effluent discharge labeling statement.

> "This product is toxic to fish and invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

All affected pesticide products distributed or sold by registrants and distributors (supplemental registrants) must bear the above labeling by October 1, 1995. All products distributed or sold by persons other than registrants or supplemental registrants after October 1, 1997 must bear the correct labeling. Refer to PR Notice 93-10 or 40 CFR 152.46(a)(1) for additional information.

Personal Protective Equipment

Handler PPE for Occupational-Use Products

The minimum (baseline) PPE for handlers engaged in open pouring of Dowicil®75 and Dowicil®150 is chemical-resistant gloves.

C. Existing Stocks

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

The Agency has determined that registrants may distribute and sell Dowicil®CTAC 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 preexisting Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

SITE Application Type, Application Timing, Application Equipment _ Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED											
ADHESIVES, INDUSTRIAL									Use Group: INDOOR NON-FOOD		
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W 473	W 4455	*	NS		NS	NS			
COATINGS, INDUSTRIAL									Use Group: INDOOR NON-FOOD		
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W 878	W 1823	*	NS		NS	NS			
EMULSIONS, RESIN/LATEX/POLYMER									Use Group: INDOOR NON-FOOD		
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W 338	W 2025	*	NS		NS	NS			
METALWORKING CUTTING FLUIDS									Use Group: INDOOR NON-FOOD		
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W 101	W 1688	*	NS		NS	NS			
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS									Use Group: INDOOR NON-FOOD		
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W 203	W 338	*	NS		NS	NS			
PAINTS, LATEX (IN-CAN)									Use Group: INDOOR NON-FOOD		
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W 68	W 1350	*	NS		NS	NS			
SECONDARY OIL RECOVERY INJECTION WATER									Use Group: AQUATIC NON-FOOD INDUSTRIAL		
Water treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	FM/S	W 17	W 34	*	NS		NS	NS			

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 Max. Dose	Tex.	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
SPECIALITY INDUSTRIAL PRODUCTS										Use Group: INDOOR NON-FOOD			
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W	270	W 1823	*		NS		NS	NS		NS	
TEXTILES/TEXTILE FIBERS/CORDAGE										Use Group: INDOOR NON-FOOD			
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W	878	W 1823	*		NS		NS	NS		NS	
WET-END ADDITIVES/INDUSTRIAL PROCESSING CHEMICALS										Use Group: INDOOR NON-FOOD			
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W	878	W 1823	*		NS		NS	NS		NS	

LEGEND

HEADER ABBREVIATIONS
Max. Apps @ Max Rate : Maximum number of Applications at Maximum Dosage Rate
Min. Interv (days) : Minimum Interval between Applications (days)
Restr. Entry Interv (days) : Restricted Entry Interval (days)

SOIL TEXTURE FOR MAX APP. RATE
* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES
FM/S : FORM NOT IDENTIFIED/SOLID

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

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

SITE Application Type, Application Timing, Application Equipment _ Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED											
ADHESIVES, INDUSTRIAL							Use Group: INDOOR NON-FOOD				
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W 470	W 4700	*	NS		NS	NS			
COATINGS, INDUSTRIAL							Use Group: INDOOR NON-FOOD				
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W 940	W 1880	*	NS		NS	NS			
EMULSIONS, RESIN/LATEX/POLYMER							Use Group: INDOOR NON-FOOD				
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W 470	W 1410	*	NS		NS	NS			
METALWORKING CUTTING FLUIDS							Use Group: INDOOR NON-FOOD				
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W 940	W 1880	*	NS		NS	NS			
PAINTS, LATEX (IN-CAN)							Use Group: INDOOR NON-FOOD				
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W 470	W 1880	*	NS		NS	NS			
SPECIALITY INDUSTRIAL PRODUCTS							Use Group: INDOOR NON-FOOD				
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W 282	W 1880	*	NS		NS	NS			
TEXTILES/TEXTILE FIBERS/CORDAGE							Use Group: INDOOR NON-FOOD				
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W 940	W 1880	*	NS		NS	NS			
WET-END ADDITIVES/INDUSTRIAL PROCESSING CHEMICALS							Use Group: INDOOR NON-FOOD				
Preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	FM/S	W 940	W 1880	*	NS		NS	NS			

LEGEND

HEADER ABBREVIATIONS
Max. Apps @ Max Rate : Maximum number of Applications at Maximum Dosage Rate
Min. Interv (days) : Minimum Interval between Applications (days)
Restr. Entry Interv (days) : Restricted Entry Interval (days)

SOIL TEXTURE FOR MAX APP. RATE
* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES
FM/S : FORM NOT IDENTIFIED/SOLID

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

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

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

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Dowicil®CTAC covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Dowicil®CTAC 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 Dowicil®75

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ALL	MRID# 41679901
61-2A	Start. Mat. & Mnfg. Process	ALL	MRID# 41679901
61-2B	Formation of Impurities	ALL	MRID# 41679901
62-1	Preliminary Analysis	ALL	MRID# 41679901, 41959501
62-2	Certification of limits	ALL	MRID# 41679901
62-3	Analytical Method	ALL	MRID# 41959502, 41959503
63-2	Color	ALL	MRID# 41679902
63-3	Physical State	ALL	MRID# 41679902
63-4	Odor	ALL	MRID# 41679902
63-5	Melting Point	ALL	MRID# 41959504
63-7	Density	ALL	MRID# 41679903, 41959505
63-8	Solubility	ALL	MRID# 41679903
63-9	Vapor Pressure	ALL	MRID# 41679904
63-10	Dissociation Constant	ALL	MRID# 41679905
63-11	Octanol/Water Partition	ALL	MRID# 41679903
63-12	pH	ALL	MRID# 41679906
63-13	Stability	ALL	MRID# 41679903
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	F	MRID# 71725

Data Supporting Guideline Requirements for the Reregistration of Dowicil®75

REQUIREMENT		USE PATTERN	CITATION(S)
71-1B	Acute Avian Oral - Quail/Duck TEP	F	MRID# 74305
71-2B	Avian Dietary - Duck	F	MRID# 71726
72-1A	Fish Toxicity Bluegill	F	MRID# 125029
72-1C	Fish Toxicity Rainbow Trout	F	WAIVED
72-2A	Invertebrate Toxicity	F	MRID# 125029
72-3A	Estuarine/Marine Toxicity - Fish	F	CONFIMATORY
72-3B	Estuarine/Marine Toxicity - Mollusk	F	CONFIMATORY
72-3C	Estuarine/Marine Toxicity - Shrimp	F	CONFIMATORY
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	FM	MRID# 93902
81-2	Acute Dermal Toxicity - Rabbit/Rat	FM	MRID# 93902
81-3	Acute Inhalation Toxicity - Rat	FM	MRID# 42420401
81-4	Primary Eye Irritation - Rabbit	FM	MRID# 93902
81-5	Primary Dermal Irritation - Rabbit	FM	MRID# 93902
81-6	Dermal Sensitization - Guinea Pig	FM	MRID# 93902
82-3	90-Day Dermal - Rodent	FM	MRID# 40650201
83-3A	Developmental Toxicity - Rat	FM	MRID# 40349701
84-2A	Gene Mutation (Ames Test)	FM	MRID# 40545101

Data Supporting Guideline Requirements for the Reregistration of Dowicil®75

REQUIREMENT		USE PATTERN	CITATION(S)
84-2B	Structural Chromosomal Aberration	FM	MRID# 40545102
84-4	Other Genotoxic Effects	FM	MRID# 40545103
OCCUPATIONAL RESIDENTIAL EXPOSURE			
Supplemental Information			MRID# 43577601
ENVIRONMENTAL FATE			
161-1	Hydrolysis	F	MRID# 43192101
161-2	Photodegradation - Water	F	Waived
161-3	Photodegradation - Soil	F	Waived
162-1	Aerobic Soil Metabolism	F	Waived
162-2	Anaerobic Soil Metabolism	F	Waived
162-3	Anaerobic Aquatic Metabolism	F	Waived
162-4	Aerobic Aquatic Metabolism	F	Waived
163-1	Leaching/Adsorption/Desorption	F	Waived
164-1	Terrestrial Field Dissipation	F	Waived
164-2	Aquatic Field Dissipation	F	Waived
165-4	Bioaccumulation in Fish	F	Waived
165-5	Bioaccumulation - Aquatic NonTarget	F	waived

Data Supporting Guideline Requirements for the Reregistration of Dowicil®150

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	ALL	MRID# 41679901
61-2A	**Start. Mat. & Mnfg. Process**	ALL	MRID# 41679901
61-2B	**Formation of Impurities**	ALL	MRID# 41679901
62-1	**Preliminary Analysis**	ALL	MRID# 41679901, 41959501
62-2	**Certification of limits**	ALL	MRID# 41679901
62-3	**Analytical Method**	ALL	MRID# 41959502, 41959503
63-2	**Color**	ALL	MRID# 41679902
63-3	**Physical State**	ALL	MRID# 41679902
63-4	**Odor**	ALL	MRID# 41679902
63-5	**Melting Point**	ALL	MRID# 41959504
63-7	**Density**	ALL	MRID# 41679903, 41959505
63-8	**Solubility**	ALL	MRID# 41679903
63-9	**Vapor Pressure**	ALL	MRID# 41679904
63-10	**Dissociation Constant**	ALL	MRID# 41679905
63-11	**Octanol/Water Partition**	ALL	MRID# 41679903
63-12	**pH**	ALL	MRID# 41679906
63-13	**Stability**	ALL	MRID# 41679903
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	F	MRID# 42814703

Data Supporting Guideline Requirements for the Reregistration of Dowicil®150

REQUIREMENT		USE PATTERN	CITATION(S)
71-1B	**Acute Avian Oral - Quail/Duck TEP**	F	MRID# 42814704
71-2B	**Avian Dietary - Duck**	F	MRID# 42814705
72-1A	**Fish Toxicity Bluegill**	F	MRID# 42814701
72-1C	**Fish Toxicity Rainbow Trout**	F	MRID# 42814702
72-2A	**Invertebrate Toxicity**	F	WAIVED
72-3A	**Estuarine/Marine Toxicity - Fish**	F	MRID# 43107201
72-3B	**Estuarine/Marine Toxicity - Mollusk**	F	MRID# 43107202
72-3C	**Estuarine/Marine Toxicity - Shrimp**	F	MRID# 43107203
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	FM	MRID# 93902
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	FM	MRID# 93902
81-3	**Acute Inhalation Toxicity - Rat**	FM	MRID# 42420401
81-4	**Primary Eye Irritation - Rabbit**	FM	MRID# 93902
81-5	**Primary Dermal Irritation - Rabbit**	FM	MRID# 93902
81-6	**Dermal Sensitization - Guinea Pig**	FM	MRID# 93902
82-3	**90-Day Dermal - Rodent**	FM	MRID# 40650201
83-3A	**Developmental Toxicity - Rat**	FM	MRID# 40349701
84-2A	**Gene Mutation (Ames Test)**	FM	MRID# 40545101

Data Supporting Guideline Requirements for the Reregistration of Dowicil®150

REQUIREMENT		USE PATTERN	CITATION(S)
84-2B	**Structural Chromosomal Aberration**	FM	MRID# 40545102
84-4	**Other Genotoxic Effects**	FM	**MRID# 40545103**
OCCUPATIONAL RESIDENTIAL EXPOSURE			
Supplemental Information			MRID# 43577601
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	F	MRID# 43192101
161-2	**Photodegradation - Water**	F	Waived
161-3	**Photodegradation - Soil**	F	Waived
162-1	**Aerobic Soil Metabolism**	F	Waived
162-2	**Anaerobic Soil Metabolism**	F	Waived
162-3	**Anaerobic Aquatic Metabolism**	F	Waived
162-4	**Aerobic Aquatic Metabolism**	F	Waived
163-1	**Leaching/Adsorption/Desorption**	F	Waived
164-1	**Terrestrial Field Dissipation**	F	Waived
164-2	**Aquatic Field Dissipation**	F	Waived
165-4	**Bioaccumulation in Fish**	F	Waived
165-5	**Bioaccumulation - Aquatic NonTarget**	F	waived

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Dowicil®CTAC

GUIDE TO APPENDIX C

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

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

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

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

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

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears

as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

BIBLIOGRAPHY

MRID	CITATION
--------	Federal Register Notice, Volume 57, Number 102, Department of Labor (OSHA), Occupational Exposure to Formaldehyde, May 27, 1992.
--------	Allinger, N.L., M.P. Cava, D.C. De Jongh, C.R. Johnson, N.A. Lebel, and C.L. Stevens. 1971 Organic Chemistry, Worth Publishers, Inc. New York, NY. pp. 473-474
--------	Gonsior, S.J. and W.L. Dilling. 1984. Reaction of 1-(3-chloro-cis-2-propenyl)-3,5,7-triaza-1-azoniatricyclo[3.3.1.1] decane chloride (active ingredient in Dowicil®200 Preservative) with water-Product studies. The Dow Chemical Company Report ES-704.
00071725	Fink, R.; Beavers, J.B.; Joiner, G.; et al. (1981) Final Report: Acute Oral LD50--Mallard Duck: Project No. 103-204. (Unpublished study received Apr 22, 1981 under 464-403; prepared by Wildlife International Ltd. and Washington College, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:244912-B)
00071726	Fink, R.; Beavers, J.B.; Joiner, G.; et al. (1981) Final Report: Thirteen-day Dietary LC50--Mallard Duck: Project No. 103-203. (Unpublished study received Apr 22, 1981 under 464-403; prepared by Wildlife International Ltd. and Washington College, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:244912-C)
00074305	Fink, R.; Beavers, J.B.; Joiner, G.; et al. (1981) Final Report: Eight-day Dietary LC50--Bobwhite Quail: Project No. 103-202. (Unpublished study received May 12, 1981 under 464-403; prepared by Wildlife International, Ltd., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:245114-A)
00093902	Carreon, R.E.; Yano, B.L.; Kociba, R.J.; et al. (1981) Dowcil^(TM)_ 200: Acute Toxicological Properties: HET K-27342-(46). (Unpublished study received Jan 26, 1982 under 464-327; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:246654-A)
00125029	Bailey, R.; Batchelder, T.; Rhinehart, W.; et al. (1977) Toxicity of Dowicil®75 Antimicrobial Agent and Dowicil®200 Antimicrobial Agent to Aquatic Organisms: ES-191. (Unpublished study received Dec 29, 1977 under 464-403; submitted by Dow Chemical U.S.A., Midland, MI; CDL:232599-A)

BIBLIOGRAPHY

MRID	CITATION
40545101	Linscombe, V.; Gollapudi, B. (1988) Evaluation of Cis/Trans-1-(3 Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride in the Chinese Hamster Ovary Cell/Hypoxanthine-guanine-phosphoribosyl Transferase (CHO/HGPRT) Forward Mutation Assay: Laboratory Project Study ID: TXT:K-027342-064. Unpublished study prepared by Dow Chemical Co. 22 p.
40545102	McClintock, M.; Gollapudi, B. (1988) Evaluation of Cis/Trans-1-(3 Chloroallyl)-3,5,7-triaza-1-azoniaadamatane chloride in the Mouse Bone Marrow Micronucleus Test: Laboratory Project Study ID: TXT:K-027342-062. Unpublished study prepared by Dow Chemical Co. 25 p.
40545103	Gollapudi, B.; McClintock, M. (1988) Evaluation of Cis/Trans-1-(3 Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride in the Rat Hepatocyte Unscheduled DNA Synthesis (UDS) Assay: Laboratory Project Study ID: TXT:K-027342-063. Unpublished study prepared by Dow Chemical Co. 31 p.
40650201	Corley, R.; Cieszlak, F.; Jersey, G. (1988) Cis-Trans-CTAC: 13-week Dermal Toxicity Study in New Zealand White Rabbits: Laboratory Project Study ID K-27342-61: K-27342-061. Unpublished study prepared by The Dow Chemical Co. 224 p.
41679901	Schubert, D.; Wood, D. (1990) Product Chemistry Data for Dowicil®150/100, Per 40 CFR 158. 120: Lab Project Number: DOWICIL/150/100. Unpublished study prepared by Dow Chemical U.S.A. 43 p.
41679902	Schubert, D. (1990) Determination of Color, Physical State and Odor of Dowicil®150/100 Preservative: Lab Project Number: DOWICIL/150 100. Unpublished study prepared by Dow Chemical U.S.A. 11 p.
41679903	Schubert, D. (1990) Physical and Chemical Characteristics of Dowcil 150/100 Per 40 CFR 158.120: Lab Project Number: DOWCIL/150/100. Unpublished study prepared by Dow Chemical U.S.A. 4 p.
41679904	Chakrabarti, A. (1990) Vapor Pressure of Dowicil®100 Measured by the Knudsen-Effusion/Weight Loss Method: Lab Project Number: MLAL/90/020396. Unpublished study prepared by Dow Chemical U.S.A. 10 p.

BIBLIOGRAPHY

MRID	CITATION
41679905	Bonadies, J.; Reim, R. (1990) Dissociation of Dowicil®100 Antimicrobial Agent in Water: Lab Project Number: ML/AL/90/041494. Unpublished study prepared by Dow Chemical U.S A. 11 p.
41679906	Heimeri, J. (1990) pH Determination of Dowicil®100 Antimicrobial Agent for Re-Registration: Lab Project Number: ML-AL/90/080692. Unpublished study prepared by Dow Chemical USA. 7 p.
41959501	Winnett, K.; Harvey, K. (1991) Preliminary Analysis of Product Samples for 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride Antimicrobial Active Ingredient: Lab Project Number: GPAR-91-60020: 91006.00. Unpublished study prepared by Dow Chem. Co. 18 p.
41959502	Winnett, K.; Harvey, K. (1991) Validation of an Analytical Method for Hexamethylenetetramine hydrochlide and Active Ingredient in 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamtane chloride Antimicrobial: Lab Project Number: GP-AR-91-60023. Unpublished study prepared by Dow Chem. Co. 22 p.
41959503	Winnett, K. (1991) Validation of an Analytical Method for Water and Volatile Organic Impurities in 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride Antimicrobial Active Ingredient: Lab Project Number: GP-AR-91-60028: 91005.00. Unpublished study prepared by Dow Chem. Co. 36 p.
41959504	Walker, L. (1991) Determination of Melting Point/Melting Range of C CTAC 1-(3-chloroallyl-3,5,7-triaza-1-azoniaadamantane chloride) Lab Project Number: ML-AL 91-020292. Unpublished study prepared by Dow Chem. Co. 8 p.
41959505	Griffin, K. (1991) Determination of Density of CTAC (1-(3-chloroallyl)-3,5,7-Triaza-1-azoniaadamantane chloride): Lab Project Number: ML-AL-91-020231. Unpublished study prepared by Dow Chem Co. 9 p.
42814701	Brown, R.; Kirk, H.; Richardson, C.; et al. (1993) CTAC: Evaluation of the Acute Toxicity to the Bluegill, Lepomis macrochirus Rafinesque: Lab Project Number: ES-2625. Unpublished study prepared by The Dow Chemical Co. 24 p.

BIBLIOGRAPHY

MRID	CITATION
42814702	Brown, R.; Kirk, H.; Richardson, C.; et al. (1993) CTAC: Evaluation of the Acute Toxicity to the Rainbow Trout, Oncorhynchus mykiss Walbaum: Lab Project Number: ES-2624. Unpublished study prepared by The Dow Chemical Co. 24 p.
42814703	Campbell, S.; Beavers, J. (1993) CTAC Technical: An Acute Oral Toxicity Study with the Northern Bobwhite: Lab Project Number: 103-392: DR-0054-34-31: ES-2608. Unpublished study prepared by Wildlife International, Ltd. 24 p.
42814704	Campbell, S.; Beavers, J.(1993) CTAC Technical: A Dietary LC50 Study with the Northern Bobwhite: Lab Project Number: 103-390: DR-0054-34-31: ES-2657. Unpublished study prepared by Wildlife International, Ltd. 21 p.
42814705	Campbell, S.; Beavers, J. (1993) CTAC Technical: A Dietary LC50 Study with the Mallard: Lab Project Number: 103-391: DR-0054-34-31: ES-2640. Unpublished study prepared by Wildlife International, Ltd. 21 p.
43107201	Boeri, R.; Kowalski, P.; Ward, T. (1994) CTAC: Acute Toxicity to the Silverside, Menidia Beryllina: Lab Project Number: 269-DO: ES-2684. Unpublished study prepared by T. W. Wilbury Labs, Inc. 26 p.
43107202	Boeri, R.; Kowalski, P.; Ward, T. (1994) CTAC: Acute Flow-Through Mollusc Shell Deposition Test: Lab Project Number: 268-DO: ES-2682. Unpublished study prepared by T. W. Wilbury Labs, Inc. 24 p.
43107203	Boeri, R.; Kowalski, P.; Ward, T. (1994) CTAC: Acute Toxicity to the Grass Shrimp, Palaemonetes pugio: Lab Project Number: 267-DO: ES-2683. Unpublished study prepared by T. W. Wilbury Labs, Inc. 26 p.
43192100	The Dow Chemical Co. (1994) Submittal of Hydrolysis Data in Support of Reregistration of Dowicil®150 Antimicrobial and Dowicil®75 Preservative, Dowicil®100 Preservative. Transmittal of 1 study.
43192101	Gonsior, S.; West, R.; Gilbert, J. et al. (1994) The Degradation of 1-(3-Chloroallyl)-3,5,7-Triaza-1-Azoniaadamantane Chloride in Buffered Solutions: Lab Project Number: ES-2709. Unpublished study prepared by The Environmental Toxicology & Chemistry Research Laboratory, The Dow Chemical Co. 73 p.

BIBLIOGRAPHY

MRID	CITATION
43388701	Wright, P. (1994) Letter sent to Registration Division dated September 28, 1994 regarding identification of an impurity in Dowicil®75 Preservative. Prepared by Dow Chemical Co. 1 p.
43577601	Dow Chemical Company, Supplemental Data to Reregistration of 1-(chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CTAC), February 27, 1995, Prepared by Dow Chemical Co.

BIBLIOGRAPHY

MRID **CITATION**

APPENDIX D. List of Available Related Documents

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

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Dowicil®CTAC RED Fact Sheet

4. PR Notice 86-5 (included in this appendix)

5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement

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

PR Notice 86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

PR NOTICE 86-5

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

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

I. Purpose

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

II. Applicability

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

III. Effective Date

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

IV. Background

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

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

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

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

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

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

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

VI. Format Requirements

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

- INDEX-

A. Organization of Submittal Package

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

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

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

- If such materials relate to one study, they should be included as an appendix to that study.

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

B. Transmittal Document

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

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

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

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

C. Individual Studies

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

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

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

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

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

C.1 Special Considerations for Identifying Studies

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

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

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

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

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

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

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

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a

single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

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

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

D.1. Title Page

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

a. Study title. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

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

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

D.3. Confidential Attachment

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

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

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

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

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

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

E. Reference to Previously Submitted Data

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

F. Physical Format Requirements

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

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

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

G. Special Requirements for Submitting Data to the Docket

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

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

V. For Further Information

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

/S/

James W. Akerman
Acting Director,
Registration Division

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

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

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

[+]Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

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

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

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

3. Transmittal date

4. List of submitted studies

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

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

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

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

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

Company Official: _____ _____
Signature Name

Company Name _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

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

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date:_____

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

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

Company: _____

Company Agent: _____ Typed Name _____ Date:_____

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

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

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

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

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

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

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

CROSS REFERENCE NUMBER 1 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE	LINES	REASON FOR THE DELETION
6	14	Identity of Inert Ingredient

FIFRA REFERENCE

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

CROSS REFERENCE NUMBER 5 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )

(Reproduce the deleted paragraph(s) here)

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

CROSS REFERENCE NUMBER 7 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PAGES(S): are attached immediately behind this page

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Example 2.

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

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

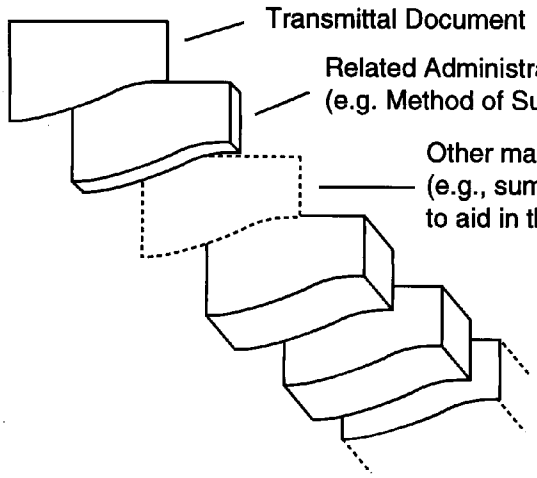
Example 3.

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

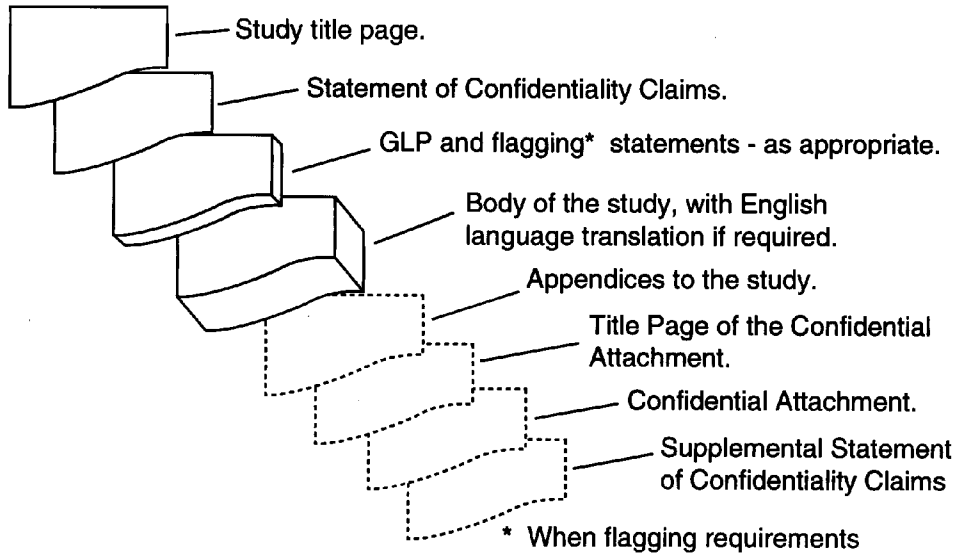
Submitter_____

ATTACHMENT 7.

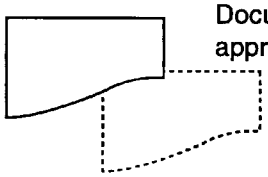
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



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

Documents submitted at submitter's option.

PR Notice 91-2

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

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

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

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

II. BACKGROUND

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

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

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

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

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section l0(b). In this respect the

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

III. REQUIREMENTS

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

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

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

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

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

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

V. COMPLIANCE SCHEDULE

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

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

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

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

VI. FOR FURTHER INFORMATION

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

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

APPENDIX F. Product Specific Data Call-In

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 A through G; or

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

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

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

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

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

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

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

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data

Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

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

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

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

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

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

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

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

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

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

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

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

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

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

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

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA.

You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

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

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

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

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

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

III-D REQUESTS FOR DATA WAIVERS

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines)

regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois A. Rossi, 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 Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

Attachment 1. Chemical Status Sheet

Dowicil®CTAC DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Dowicil®CTAC, please contact Ron Kendall at (703) 308-8068.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Franklin Gee at (703) 308-8008.
(703) 308-8184.

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

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

RE: **Dowicil®CTAC**

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

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 only one of the following response codes for each data requirement 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.

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

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 guidelines 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 patters (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. lt is normally based on 8 months after issuance of the Reregistration Eligibility Documents unless EPA determines that a longer time period is necessary.

Item 9. Enter Only one of the following response codes for each data requirement 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.

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 on 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 my be subject to suspension.

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 require 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.

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.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgrade (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.

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) number (s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registratrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

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 require 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 chosen. I also understand that the deadline for submission of data as specified by the original data cal-in notice will not change.

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 cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

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

No toxicology batching is required for this case.

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

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

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Name of technical material tested (include product name and trade name, if appropriate).

2.____ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.

3.____ Name and upper certified limit for each impurity or each group of impurities present at $\geq$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at $< 0.1\%$.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.
____ EPA Registration Number if registered;
for other beginning materials, the following:
____ Name and address of manufacturer or supplier.
____ Brand name, trade name or commercial designation.
____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____Description of manufacturing process.
____ Statement of whether batch or continuous process.
____ Relative amounts of beginning materials and order in which they are added.
____ Description of equipment.
____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
____ Statement of whether process involves intended chemical reactions.
____ Flow chart with chemical equations for each intended chemical reaction.
____ Duration of each step of process.
____ Description of purification procedures.
____ Description of measures taken to assure quality of final product.

9.____ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

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

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

63-2 Color
____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State
____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25° C

63-4 Odor
____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point
____ Reported in °C
____ Any observed decomposition reported

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

63-7 Density, Bulk Density, Specific Gravity
____ Measured at about 20-25° C
____ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility
____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25° C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure
____ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant
____ Experimental method described
____ Temperature of measurement specified (preferably about 20-25°C)

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

____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
____ Data supporting reported value provided

63-12 pH
____ Measured at about 20-25° C
____ Measured following dilution or dispersion in distilled water

63-13 Stability
____ Sensitivity to metal ions and metal determined
____ Stability at normal and elevated temperatures
____ Sensitivity to sunlight determined

SUBDIVISION F

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

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

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

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

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

21. Date

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

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

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

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

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)

APPENDIX G. FACT SHEET

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-016 April 1995

R.E.D. FACTS

Dowicil®CTAC

Pesticide Reregistration

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

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

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 3069, Dowicil®CTAC.

Use Profile

Dowicil®CTAC is used as a microbicide/microbistat for secondary oil injection water-water treatment and as a preservative for industrial adhesives and coatings; resin/latex/polymer emulsions; metalworking cutting fluids; oil recovery drilling muds/packer fluids; latex(in-can) paints; specialty industrial products; textiles/textile fibers/cordage; and wet-end additives/industrial processing chemicals.

The case Dowicil®CTAC contains the two active ingredients Dowicil®75 and Dowicil®150. The active ingredient Dowicil®75 contains both the cis-(.53%) and the trans-(.44%) isomers of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride. The active ingredient Dowicil®150 contains only the cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride.

Regulatory History

A pesticide product containing Dowicil®150 was first registered in the United States in 1964 as a microbicide/microbistat. A second registration, for Dowicil®75, was granted in 1972 for use as a preservative for paints, latexes, metalworking lubricants, and other industrial formulations to prevent deterioration from bacteria and fungi.

The food additive use of Dowicil®CTAC to preserve adhesives, resins, pulp, and paperboard that contact foods is regulated by the Food and Drug Administration (please see 21 CFR Sections 175.105, 176.1680, 176.170, and 176.180).

In 1987, EPA issued the Antimicrobial Data Call-In (DCI) Notice to obtain chronic and subchronic toxicity data for Dowicil®CTAC and other antimicrobials. The Agency issued a second DCI under reregistration Phase 4 in March 1992, requiring the registrant to provide chemistry, toxicology, and environmental fate data on these active ingredients to support reregistration.

Human Health Assessment

Toxicity

In laboratory animal studies measuring acute toxicity, technical grade Dowicil®CTAC has been shown to cause moderate effects by the dermal route, placing it in Toxicity Category II (the second-highest of four categories) for dermal toxicity. It has been shown to produce slight irritation in eye and dermal irritation studies, placing it in Toxicity Category III for eye irritation and Toxicity Category IV for skin irritation. It is slightly toxic in oral toxicity studies, placing it in Toxicity Category III for oral toxicity. In an acute inhalation study, Dowicil®CTAC was found to be slightly toxic, placing it in Toxicity Category IV. This chemical is not a skin sensitizer based on studies using guinea pigs.

A 90-day dermal toxicity study in rabbits established the NOEL for systemic toxicity as 1000 mg/kg/day.

Dowicil®CTAC was mutagenic in the in vitro Chinese hamster ovary cell HGPRT forward mutation assay with activation, but was nonmutagenic without activation. It was negative in two other mutagenicity studies.

Dietary Exposure

No dietary exposure is expected from the pesticide uses of Dowicil®CTAC since no food or feed uses are registered.

Occupational and Residential Exposure

Due to its low toxicity and the lack of a toxicological endpoint of concern, an exposure assessment was not required for Dowicil®CTAC. However, formaldehyde is released when Dowicil®CTAC decomposes in aqueous solution. EPA is concerned because formaldehyde has been classified as a Group B1 "probable human carcinogen."

The potential for exposure to Dowicil®CTAC and/or formaldehyde exists for occupational workers involved in the industrial setting and for individuals in the home setting. For residential uses, the Agency has determined that potential exposure to Dowicil®CTAC is minimal. For industrial uses, most workers' exposure to Dowicil®CTAC is low because of current use patterns. In addition, workers in industrial settings are protected by the Occupational Safety and Health Administration's (OSHA's) comprehensive workplace standard for formaldehyde, with a permissible

exposure level (PEL) of .75 ppm in the workplace. EPA has notified OSHA of Dowicil®CTAC's potential to release formaldehyde and OSHA has agreed to include these products in their workplace monitoring program.

Since Dowicil®CTAC causes moderate acute dermal toxicity (Toxicity Category II), EPA is requiring that labels contain a statement advising workers to wear chemical resistant gloves for open-pouring of the end-use product.

Human Risk Assessment

Since Dowicil®CTAC has no food or feed uses, dietary risk is not expected. The chemical causes moderate acute dermal toxicity. Therefore, to protect applicators' skin during open pouring of end-use products, EPA is requiring appropriate label precautions regarding use of protective clothing (chemical resistant gloves). Although Dowicil®CTAC releases formaldehyde in aqueous solutions, minimal risk is expected in residential settings. Occupational risks are low due to the chemical's use pattern and because OSHA will monitor workers' exposure to formaldehyde during industrial uses of Dowicil®CTAC. No human health risk of concern is therefore expected.

Environmental Assessment

Environmental Fate

Dowicil®CTAC dissipates by abiotic hydrolysis. It is not persistent and degrades rapidly under acidic conditions. Under neutral to alkaline conditions, it degrades more slowly.

Ecological Effects

Both Dowicil®75 and Dowicil®150 are practically nontoxic to slightly toxic to birds, fish, aquatic invertebrates, and terrestrial animals.

Ecological Effects Risk Assessment

The use patterns of Dowicil®CTAC result in minimal risk to terrestrial organisms. Risk to nontarget aquatic organisms can be expected through point source discharge of industrial microbicides. In the case of Dowicil®CTAC, there are several use sites and environmental conditions where exposure to aquatic organisms is a distinct possibility.

Based on Agency calculations using an exposure model, the chronic level of concern (LOC) for aquatic species is exceeded in both typical and high exposure scenarios for wet-end additives/industrial processing chemicals and oil recovery drilling muds/packer fluids. The acute LOC is exceeded in high exposure scenarios for all five use patterns examined. Endangered aquatic species also are at risk under both typical and high exposure scenarios.

It is important to note, however, that the Agency's calculations likely overestimate the actual concentrations which would be found in the environment. Also, discharge levels are governed by NPDES permits granted by state regulatory agencies and EPA. Based on its rapid hydrolysis

and use sites, no additional environmental fate date are required for Dowicil®CTAC.

Additional Data Required

EPA is requiring product-specific data including product chemistry and efficacy data, revised Confidential Statements of Formula (CSFs), and revised product labeling for reregistration of products containing Dowicil®CTAC.

Product Labeling Changes Required

The labels of all registered pesticide products containing Dowicil®CTAC must comply with EPA's current pesticide labeling requirements. In addition:

Effluent Discharge Statement - All end-use (and manufacturing use) products that may be contained in an effluent discharged to the waters of the U.S. or municipal sewer systems must bear the following statement:

> "This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with requirements of the National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA."

Handler PPE for Occupational-Use Products - The minimum (baseline) personal protective equipment (PPE) for handlers engaged in open pouring of Dowicil®75 and Dowicil®150 is chemical-resistant gloves.

Regulatory Conclusion

The use of currently registered pesticide products containing Dowicil®CTAC in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

These Dowicil®CTAC products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for Dowicil®CTAC during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at

703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

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

Following the comment period, the Dowicil®CTAC RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the Dowicil®CTAC RED, or reregistration of individual products containing Dowicil®CTAC, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 8:00 pm Eastern Standard Time, Monday through Friday.