

US EPA ARCHIVE DOCUMENT



# 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 1,2-dibromo-2,4-dicyanobutane which includes the active ingredient dibromodicyanobutane. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is 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 Ernest Jones at (703) 308-8069. Address any questions on required generic data to the Special Review and Reregistration Division representative Yvonne Brown at 703-308-8073.

Sincerely yours,

Lois Rossi, Division Director  
Special Review  
and Reregistration Division

Enclosures

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

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

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

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

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

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

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

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

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

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

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

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

**By U.S. Mail:**

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

**By express:**

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

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



**REREGISTRATION ELIGIBILITY DECISION**

**DIBROMODICYANOBTANE**

**LIST B**

**CASE 2780**

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



# TABLE OF CONTENTS

## DIBROMODICYANOBTANE

REREGISTRATION ELIGIBILITY DECISION TEAM . . . . . i

EXECUTIVE SUMMARY . . . . . v

I. INTRODUCTION . . . . . 1

II. CASE OVERVIEW . . . . . 2

A. Chemical Overview . . . . . 2

B. Use Profile . . . . . 2

C. Data Requirements . . . . . 4

D. Estimated Usage of Pesticide . . . . . 4

E. Regulatory History . . . . . 4

III. SCIENCE ASSESSMENT . . . . . 5

A. Physical Chemistry Assessment . . . . . 5

B. Human Health Assessment . . . . . 5

1. Toxicology Assessment . . . . . 5

a. Acute Toxicity . . . . . 5

b. Subchronic Toxicity . . . . . 6

c. Developmental Toxicity . . . . . 9

d. Mutagenicity . . . . . 10

e. Metabolism . . . . . 10

f. Chronic Toxicity/Carcinogenicity . . . . . 11

2. Dose Response Assessment . . . . . 11

a. Reference Dose (RfD) for Chronic Oral Exposure . . . . . 11

3. Exposure and Risk Assessment . . . . . 11

a. Dietary Exposure and Risk Assessment . . . . . 11

b. Occupational and Residential Exposure and Risk Assessment . . . . . 11

C. Environmental Assessment . . . . . 12

1. Ecological Toxicity Data . . . . . 12

a. Toxicity to Birds . . . . . 12

b. Toxicity to Aquatic Animals . . . . . 12

2. Environmental Fate . . . . . 15

a. Environmental Fate Assessment . . . . . 15

b. Environmental Fate and Transport . . . . . 15

3. Exposure and Risk Characterization . . . . . 17

a. Ecological Exposure and Risk Characterization . . . . . 17

b. Endangered Species . . . . . 17



<b>IV.</b>	<b>RISK MANAGEMENT AND REREGISTRATION DECISION</b> .....	18
<b>A.</b>	<b>Determination of Eligibility</b> .....	18
<b>B.</b>	<b>Determination of Eligibility Decision</b> .....	18
<b>1.</b>	<b>Eligibility Decision</b> .....	18
<b>2.</b>	<b>Eligible and Ineligible Uses</b> .....	19
<b>C.</b>	<b>Labeling Rationale/Risk Mitigation Measures</b> .....	19
<b>1.</b>	<b>Handler Safety Requirements</b> .....	19
<b>2.</b>	<b>Engineering Control Requirements for Occupational Handlers</b> .	20
<b>3.</b>	<b>Homeowner-Use Products</b> .....	20
<b>4.</b>	<b>Post-Application Safety Requirements</b> .....	21
<b>5.</b>	<b>Additional Labeling Requirements</b> .....	21
<b>V.</b>	<b>ACTIONS REQUIRED OF REGISTRANTS</b> .....	21
<b>A.</b>	<b>Manufacturing-Use Products</b> .....	21
<b>1.</b>	<b>Additional Generic Data Requirements</b> .....	21
<b>2.</b>	<b>Labeling Requirements for Manufacturing-Use Products</b>	21
<b>B.</b>	<b>End-Use Products</b> .....	22
<b>1.</b>	<b>Additional Product-Specific Data Requirements</b> .....	22
	<b>Labeling Requirements for End-Use Products</b> .....	23
<b>2.</b>	.....	23
<b>C.</b>	<b>Existing Stocks</b> .....	25
<b>VI.</b>	<b>APPENDICES</b> .....	29
<b>APPENDIX A.</b>	<b>Table of Use Patterns Subject to Reregistration</b> .....	31
<b>APPENDIX B.</b>	<b>Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision</b> .....	39
<b>APPENDIX C.</b>	<b>Citations Considered to be Part of the Data Base Supportig the Reregistration of DIBROMODICYANOBTANE</b> ...	45
<b>APPENDIX D.</b>	<b>Product Specific Data Call-In</b> .....	51
<b>Attachment 1.</b>	<b>Chemical Status Sheets</b> .....	63
<b>Attachment 2.</b>	<b>Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions</b> .....	67
<b>Attachment 3.</b>	<b>Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions</b>	69
<b>Attachment 4.</b>	<b>EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration</b> .....	76
<b>Attachment 5.</b>	<b>List of All Registrants Sent This Data Call-In (insert) Notice</b> .....	79
<b>Attachment 6.</b>	<b>Cost Share, Data Compensation Forms, Confidential Statement of Formula Form and Instructions</b> . . . .	80
<b>APPENDIX F.</b>	<b>List of Available Related Documents</b> .....	86

**DIBROMODICYANOBTANE  
REREGISTRATION ELIGIBILITY DECISION TEAM**

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# GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC <sub>50</sub>	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 <sub>50</sub>	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 <sub>10</sub>	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method

## GLOSSARY OF TERMS AND ABBREVIATIONS

PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q <sub>1</sub> *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

## EXECUTIVE SUMMARY

EPA has completed its reregistration eligibility decision regarding the pesticide dibromodicyanobutane, Case 2780. This decision includes a comprehensive reassessment of the required target data base supporting the use patterns of currently registered products. Dibromodicyanobutane is an microbiocide/microbiostat used in commercial/industrial water cooling systems, pulp/paper mill water systems, oil recovery drilling muds and packer fluids, secondary injection water, industrial adhesives and coatings, resin/latex/polymer emulsions, metal working cutting fluids, paints (in-can and applied film), specialty industrial products and wet-end additives/industrial processing chemicals to control slime-forming bacteria and fungi. The Agency has concluded that all products registered for all current uses, with the limitations imposed herein, are eligible for reregistration.

Dibromodicyanobutane is a severe primary eye and dermal irritant classified in toxicity category I. Dibromodicyanobutane is classified in toxicity category III or IV for all other measures of acute toxicity. Subacute studies were conducted in several mammalian species. No unusual compound related effects were observed except for thyroid follicular cell hyperplasia observed in the high dose group in dogs. This finding was further studied in a special thyroid study conducted at the lowest dose tested in the dog study (4.8 mg/kg/day). Several developmental toxicity studies showed no compound-related external, visceral or skeletal abnormalities. Dibromodicyanobutane was positive in one mutagenicity assay, however, this positive finding was not confirmed in multiple other mutagenicity studies.

Indirect food additive tolerances have been established by the Food and Drug Administration for dibromodicyanobutane for use as a preservative in food grade adhesives and as a slimicide in the manufacture of food grade paper and paperboard at a maximum level of 0.005% of dry weight fiber. Any dietary exposure from these uses is expected to be negligible. Therefore, a dietary exposure and risk assessment is not applicable.

The use of dibromodicyanobutane as a microbiocide requires only a limited set of ecotoxicity and environmental fate data. These data indicate moderate toxicity to aquatic invertebrates and estuarine/marine animals, but rapid degradation in aquatic environments is expected. Discharge of industrial effluent containing dibromodicyanobutane residues to aquatic environments must comply with the NPDES permitting requirements of the Office of Water.

A new freshwater fish acute toxicity study on dibromodicyanobutane is required at this time to confirm EPA's risk assessment and conclusions and additional information is required to upgrade the hydrolysis study. Product-specific chemistry, confidential statements of formula, and acute toxicology studies in addition to amended product labels are required for product reregistration.

## I. INTRODUCTION

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

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

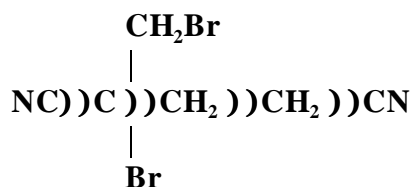
This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of dibromodicyanobutane. The document consists of six sections. Section I is the introduction. Section II describes dibromodicyanobutane, its uses, data requirements and regulatory history. Section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

## II. CASE OVERVIEW

### A. Chemical Overview

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

- **Common Name:** 1,2-dibromo-2,4-dicyanobutane (dibromodicyanobutane)
- **Chemical Name:** 1-bromo-(bromoethyl)-1,3-propanedicarbonitrile
- **CAS Registry Number:** 35691-65-7
- **OPP Chemical Code:** 111001
- **Manufacturer:** Calgon Corp.
- **Empirical Formula:**  $C_6H_6Br_2N_2$
- **Trade and Other Names:** Tektamer 38
- **Molecular Weight:** 265.80
- **Structural Formula:**



### B. Use Profile

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

For dibromodicyanobutane:

**Type of Pesticide:** Microbiocide/microbiostat (slime-forming bacteria and fungi).



**Use Sites:**

**AQUATIC NON-FOOD INDUSTRIAL:**

Commercial/Industrial Water Cooling Systems (recirculating)  
 Oil Recovery Drilling Muds/Packer Fluids\*  
 Pulp/Paper Mill Water Systems  
 Secondary Oil Recovery Injection Water\*

**TERRESTRIAL NON-FOOD:**

Oil Recovery Drilling Muds/Packer Fluids\*

**INDOOR NON-FOOD:**

Adhesives, Industrial  
 Coatings, Industrial  
 Emulsions, Resin/Latex/Polymer  
 Metalworking Cutting Fluids  
 Paints, Latex (In-Can)  
 Paints, Latex/Oil/Varnish (Applied Film)  
 Specialty Industrial Products (includes fiber processing fluids, waxes, polishes, and inks)  
 Wet-End Additives/Industrial Processing Chemicals

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

**Target Pests:**

Slime-forming bacteria and fungi.

**Formulation Types Registered:**

TYPE: End use, Manufacturing use

FORM: Soluble concentrate/liquid, soluble concentrate/solid, pelleted/tableted.

**Method and Rates of Application:**

EQUIPMENT: Metering pump, Chemical pump, Not specified (registrant must specify on labeling).

TYPES OF TREATMENT: Water treatment, Water treatment (recirculating system), Industrial preservative treatment, Preservative treatment, Make-up fluids treatment.

METHOD AND RATE: Aquatic Non-Food Industrial - 5 to 1898 ppm active ingredient.  
 Terrestrial Non-Food -

243 to 585 ppm active ingredient.  
Indoor Non-Food -  
50 to 3060 ppm active ingredient.  
Up to 39200 ppm active ingredient for  
metalworking cutting fluid concentrates.

**TIMING:** Continuous feed (initial), Continuous feed (subsequent), Initial, Subsequent/maintenance, Intermittent (slug)(subsequent), Shock/slug, During manufacture, Not specified (registrant must specify on labeling).

**Use Practice Limitations:** NPDES permit restriction.

### **C. Data Requirements**

In addition to data requirements imposed to obtain the original registration of this active ingredient, the Agency issued an Antimicrobial Data Call-In notice in March, 1987, for toxicity and exposure data for this active ingredient and other antimicrobials. Data were also required in the reregistration Phase IV Data Call-In issued on June 14, 1991. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

### **D. Estimated Usage of Pesticide**

Of all the dibromodicyanobutane sites listed in the use profile, only one in-house source from the late 1980s showed relatively low levels of annual usage. According to that proprietary database, the biocide has a significant share of the adhesive market, while the use in paints or paper is relatively minor.

### **E. Regulatory History**

Pesticide products containing the active ingredient dibromodicyanobutane, (1,2-dibromo-2,4-dicyanobutane), which is sold under its trade name of Tektamer 38, was first registered in the United States in 1980. The primary use for this chemical is as a preservative in various aqueous industrial applications and as a microbiocide in pulp and paper mill systems and industrial cooling tower systems. The various acceptable industrial applications for this chemical as a preservative include adhesives, oil recovery waters and muds, coatings, metalworking cutting fluids, paints, plastic products, and emulsions. There are currently eight Tektamer 38 products registered by the Agency to one registrant.

An indirect food additive tolerance has been established for dibromodicyanobutane in food grade adhesives (see 21 CFR § 175.105). Current labeling allows the adhesive for use only as a preservative. A tolerance also exists for the use of dibromodicyanobutane as a slimicide in the manufacture of food grade paper and paperboard at a maximum level of 0.005% of dry weight fiber (see 21 CFR § 176.300). This area is under the jurisdiction of the U.S. Food and Drug Administration and is not directly regulated by EPA.

### III. SCIENCE ASSESSMENT

#### A. Physical Chemistry Assessment

**TGAI:** 1,2-dibromo-2,4-dicyanobutane

**Color:** Yellowish white

**Physical State:** Granular solid

**Odor:** Slightly sweet

**Melting Point:** 52.2-53.2°C

**Density:** 0.970 g/ml at 20°C

**Solubility:** Water: 0.212 g/100 ml  
Organic solvents: No data provided

**Vapor Pressure:**  $6.70 \times 10^{-3}$  Pascal at 25°C

**Octanol/Water  
Partition  
Coefficient:** 10.52 or  $\log(10.52) = 1.022$

**Stability:** The chemical was found to be stable when subjected to Al, Sn, Ni, Fe, thermal and photosensitivity tests.

**Storage  
stability:** One year storage at room temperature did not produce any significant change regarding purity, color, specific gravity, and refractive index.

#### B. Human Health Assessment

##### 1. Toxicology Assessment

##### a. Acute Toxicity

Acute toxicity values and categories for dibromodicyanobutane are summarized in Table 1.

TABLE 1 - ACUTE TOXICITY VALUES - Dibromodicyanobutane Technical

GUIDELINE	STUDY	TEST RESULT	TOXICITY CATEGORY
81-1	Acute Oral - Rat MRID 41885501 (Technical 99.9%)	LD <sub>50</sub> = 0.77 g/kg (M); 0.515 g/kg (F)	III
81-2	Acute Dermal - Rabbit MRIDs 00027554 (Technical 98%)*	LD <sub>50</sub> > 5 g/kg	IV
81-3	Acute Inhalation - Rat MRID 00025846 (Technical 98%)*	LC <sub>50</sub> > 5.09 mg/L	IV
	Acute Inhalation - Rat MRID 42526401 (Technical 99.9%)	LC <sub>50</sub> > 13.09 mg/L	IV
81-4**	Primary Eye Irritation - Rabbit MRID 00025848 (Technical 98%)*	Severe irritant	I
81-5**	Primary Dermal Irritation - Rabbit MRIDs 00025847, 41885502 (Technical 98%)*	Severe irritant	I
81-6**	Dermal Sensitization - guinea pig MRID 00105188 (Technical 98%)*	Not a skin sensitizer.	N/A
	Dermal Sensitization - Human MRID 43183801 (Technical 98%)*	A skin sensitizer.	N/A

\*XP-38 liquid formulation consisting of technical 98%

\*\*This study is a requirement for manufacturing-use and end-use products (40 CFR 158).

The acute oral LD<sub>50</sub> of dibromodicyanobutane in rats is 0.77 g/kg in males and 0.515 g/kg in females placing it in Toxicity Category III for acute oral toxicity (MRID 41885501). The acute dermal LD<sub>50</sub> in rabbits is > 5 g/kg placing dibromodicyanobutane in Toxicity Category IV for acute dermal toxicity (MRID 00027554). Two acute inhalation studies are available for dibromodicyanobutane. The LC<sub>50</sub> for both studies placed dibromodicyanobutane in Toxicity Category IV for acute inhalation toxicity (MRIDs 00025846 and 42526401). Dibromodicyanobutane is a Toxicity Category I primary eye and dermal irritant in rabbits (MRIDs 00025847 and 41885502). Dibromodicyanobutane is a skin sensitizer in humans, but not in Guinea pigs (MRIDs 00105788 and 43183801). All cited studies satisfy the acute toxicity data requirements for dibromodicyanobutane.

#### b. Subchronic Toxicity

In a subchronic oral toxicity study, dibromodicyanobutane (purity unspecified) was administered to Sprague-Dawley rats exposed *in utero* (10/sex/group) in the diet at dose levels of 0, 83.5, 500 and 3000 ppm (6.3, 37, and 275 mg/kg/day for males and 7.5, 43, and 360 mg/kg/day for females) seven days before mating and throughout the 14-day mating, gestation, and lactation periods.

Forty (20/sex) of the weanling offspring (F<sub>1</sub> rats) receiving each dosage level were randomly selected for use at the corresponding dosage level in the 90-day phase of the study. After 13 weeks the F<sub>1</sub> rats were necropsied and tissues preserved.

There were no compound related effects in mortality, clinical signs, hematology, clinical chemistry, organ weights, ophthalmoscopic findings, urinalysis, and gross pathology. Treatment related changes in the incidence of histopathological findings were observed in the spleen only. There was a dose-related increase in severity of splenic extramedullary hematopoiesis. The severities were elevated (over control values) in the mid-dose group in males and in the high-dose group in both sexes.

The NOEL is 6.3 mg/kg/day for males and 7.5 mg/kg/day for females. The LOEL is 37 mg/kg/day for males and 43 mg/kg/day for females based on increased severity in splenic extramedullary hematopoiesis in F<sub>1</sub> males and increased pituitary weight and pituitary to body weight ratio in F<sub>1</sub> females. Effects were seen at the high-dose group in both sexes of the F<sub>1</sub> animals included significant decrease in body weight, decrease in brain weight, increase in pituitary weight, increase in pituitary to body weight ratio and pituitary to brain weight ratio, increase in spleen to body weight ratio, and splenic hematopoiesis. In addition, males showed a significant increase in liver to body weight ratio and significant decrease in testes with epididymides weight and testes with epididymides to brain weight ratio and females showed an increase in thyroid weight and increase in thyroid to body weight ratio.

The pup weight gains on days 1-21 in both sexes of the low and mid-dose groups were 20-25% and 10% higher than controls, respectively. However, the weight gain in both sexes of the high-dose group were 32-36% lower than controls. This study does not satisfy the current requirements for a 2-generation reproduction study, but does satisfy the guideline requirement for a subchronic oral study (GDLN 82-1) in rats (MRID 00055028).

In another subchronic oral toxicity study, dibromodicyanobutane was administered in the diet to groups of 4-6 beagle dogs/sex at concentrations of 0, 10, 100, or 4000 ppm [males: 0, 0.288, 3.1, or 102 mg/kg/day; females: 0, 0.331, 3.11, or 119 mg/kg/day] for 3 months. A 3-month recovery phase followed using 2 dogs/sex at 0, 100 or 4000 ppm of the test material.

Treatment-related effects of dibromodicyanobutane were seen in the high-dose group in both males and females. One male was euthanized *in extremis* on Day 40. There were decreases in food consumption and body weights. Changes were observed in hematology, clinical chemistry, urological parameters, gross and microscopic pathology. In addition, hypertrophy/hyperplasia was observed in the thyroid gland, axonal degeneration was seen in the brain and spinal cord, anemia triggered bone marrow responses, and seminiferous tubule degeneration was seen in the testis of male dogs. After the 3-month recovery period, a less severe form of axonal degeneration was seen.

The LOEL for females was 3.11 mg/kg/day (100 ppm) based on clinical

signs of diarrhea and emesis and the LOEL for males was 102 mg/kg/day (4000 ppm, the highest dose tested). The NOEL is 0.331 mg/kg/day (10 ppm) for females and 3.1 mg/kg/day (100 ppm) for males. This study satisfies the guidelines for a subchronic oral toxicity study (GDLN 82-1) in dogs (MRIDs 00055027 and 92199020).

In a third subchronic toxicity feeding study, beagle dogs (4/sex/group) were dosed with dibromodicyanobutane in the diet at doses of 0, 167, 1000 and 4000 ppm (males: 0, 4.8, 28.9, and 101.5 mg/kg/day; females: 0, 5.3, 37.7, and 109.8 mg/kg/day] for three months. A NOEL was not attained in the study. In this study the LOEL was considered to be 167 ppm (4.8 mg/kg/day, the lowest dose tested) based on a dose-related increase in absolute and relative thyroid weights in males. The LOEL for females was 167 ppm (5.3 mg/kg/day) based on relative ovary weights. Thyroid follicular cell hyperplasia was observed at the high dose in both sexes. (MRIDs 00055027 and 92199020).

A special study was conducted to determine the effect of the exposure to dibromodicyanobutane on the thyroid hormones triiodothyronine ( $T_3$ ) and thyroxine ( $T_4$ ) in dogs. In this "3-month" subchronic toxicity feeding study, beagle dogs (4/sex/group) were dosed with dibromodicyanobutane in the diet at doses of 0 and 167 ppm (0 and 4.8 mg/kg/day). The dose used in this study (167 ppm) is the low-dose of the 3-month dietary study in dogs described in the preceding paragraph. The NOEL was less than 4.8 mg/kg/day (the only dose tested). Both sexes of animals showed increased levels of thyroid stimulating hormone-stimulated  $T_3$  and  $T_4$  and enlarged thyroids. However, thyroid weights and organ/body weight ratios were significantly increased in females. While this study showed significant thyroid effects via the oral route, dibromodicyanobutane is a non-food use chemical and exposure is not expected by the oral route. This study provided supplemental information and was supportive of the previous two subchronic studies in dogs (MRID 43540501).

In a 21-day dermal toxicity study, Wistar rats (5/sex/dose) received repeated dermal applications of "Tektamer 38" moistened in distilled water at 0 (vehicle control), 1000, 2000 or 4000 mg/kg, 6 hours/day, 5 days/week for 21 consecutive days. Treatment-related dermal reactions were moderate to severe eschar, moderate to severe erythema and edema, necrosis and pale areas and discoloration of the treated site. Dermal reactions were so severe at all dose levels a NOEL for this effect was not determined. Histopathology confirmed the in-life dermal reactions and were characterized as severe necrosis of the epidermis, dermis and cutaneous muscularis. In 4/5 males and 5/5 females necrosis was accompanied by severe leukocytic inflammation beneath the layer of necrotic cutaneous muscularis. In spite of the severe dermal reactions, no systemic toxicity was seen. Treatment had no adverse effect on survival, clinical signs, body weight, body weight gain, or food consumption. There was some evidence that the high dose may have contributed to the slight but consistent decreases seen in hematocrit, hemoglobin, RBC and platelet values and the slight increases in the absolute and relative liver and kidney weights. The hematological and organ weight changes are not considered to be toxicologically significant due to lack of in-life toxicity as well as supportive histopathological lesions in the liver, kidneys,

or the hematopoietic system. The systemic toxicity NOEL is equal to or greater than 4000 mg/kg/day (the highest dose tested). The dermal toxicity NOEL was not established. The dermal toxicity LOEL is equal to or less than 1000 mg/kg/day (lowest dose tested). This study satisfies the data requirement (GDLN 82-2) for a 21-day dermal toxicity study in rats (Cerven, 1990).

### c. Developmental Toxicity

A developmental toxicity study was conducted with Sprague-Dawley rats. Dibromodicyanobutane (98% a.i.) was administered by oral gavage to rats (28-30 rats/group) daily on gestation days (GD) 6 through 15 at 0, 25, 100, or 175 mg/kg/day. Surviving dams were sacrificed on GD 20, necropsied and reproductive status recorded. The maternal NOEL and LOEL are 25 mg/kg/day and 100 mg/kg/day, respectively, based on significant decrease in body weight change corrected for gravid uterine weight. The corrected body weight change was 65% and 53% of the controls at 100 and 175 mg/kg/day, respectively. There were no mortalities among dams. Among dams at high dose, dyspnea (11 vs 0 in controls), hypoactivity (3 vs 0 in controls), and staining of the mouth (4 vs 0 in controls) were reported. There was essentially no change in mean fetal weight with respect to dose.

There were no compound-related external, visceral or skeletal variations or malformations in dibromodicyanobutane treated fetuses in comparison to controls on either a litter or fetal basis. The developmental toxicity NOEL is 175 mg/kg/day (the highest dose tested). Although total number of dams with resorptions was 6, 12, 10, and 14 at 0, 25, 100, and 175 mg/kg/day, respectively, there was no statistically significant decrease in litter size accompanying the increased resorptions. Also, statistical analysis of the number of litters with one or more resorptions in each group indicates a marginally significant pairwise difference at the highest dose tested (175 mg/kg/day; 6/25 vs. 14/28,  $p=0.047$ ). In addition, there was no statistically significant dose-related trend. These reasons plus the presence of significant maternal toxicity (i.e., maternal weight gain decrements) at the two highest doses suggests that the resorption results are not clearly associated with potential developmental toxicity of the test material (MRIDs 0126562 and 92199012). This study satisfies the guideline requirement for a developmental toxicity (GDLN 83-3) in rats.

In another developmental toxicity study, dibromodicyanobutane (100% a.i.) was administered by oral gavage to presumed pregnant New Zealand White (Hra: (NZW)SPF) rabbits (20/dose) at doses of 0, 10, 30, or 60 mg/kg/day on GDs 6 through 18. One doe from the 30 mg/kg/day dose group was found dead on GD 25. From the 60 mg/kg/day dose group, one doe was sacrificed moribund due to intubation error. Two does from the control group aborted on Gds 24 and 28. None of these findings were considered to be treatment-related. None of the clinical and necropsy findings were treatment-related in the above mentioned does or in those sacrificed at termination.

Decreases in maternal body weight gain occurred during Gds 6-9 at 60 mg/kg/day. Decreases in food consumption were seen during Gds 6-9 and Gds

9-12 at 60 mg/kg/day. For both of these parameters, there were no statistically significant decreases when the entire dosing interval (Gds 6-19) for each was compared to those of the controls. Therefore, these effects were not considered to be treatment-related. After cesarean section, no treatment-related findings were seen during external and internal morphological examination. There were no treatment-related skeletal, visceral or external abnormalities. Based on the results of this study, the maternal and developmental toxicity NOEL is 60 mg/kg/day, the highest dose tested. This study satisfies data requirements [GDLN 83-3(b)] for a developmental toxicity study in rabbits (MRID 43540502).

#### **d. Mutagenicity**

Following is a summary of the mutagenic potential of dibromodicyanobutane. These studies were negative for mutagenic effects except in an *in vitro* Chinese Hamster Ovary (CHO) assay. While the *in vitro* CHO assay study was positive, neither the *in vivo* cytogenetics assay in rats nor the UDS study confirmed this finding. The data requirements for mutagenicity testing are fulfilled.

Dibromodicyanobutane was not mutagenic in *S. typhimurium* strains TA100, TA1535, TA1537, TA1538, and TA98 and *E. coli* (WPuvrA) up to viability limits of 100  $\mu\text{g/ml}$  (activated) and 20  $\mu\text{g/ml}$  (non-activated) (MRID 259455). At doses of 12.5, 75.0, and 450 mg/kg/day dibromodicyanobutane did not produce dominant lethal mutations in male mice (MRID 00055029). Dibromodicyanobutane did not produce increases in chromosome aberrations (was not mutagenic) in the *in vivo* cytogenetics assay in the rat at doses up to 50 mg/kg/day (MRID 00125850). In CHL fibroblasts at the HGPRT locus at up to cytotoxicity limits of 50  $\mu\text{g/ml}$  (activated) and up to 1  $\mu\text{g/ml}$  (nonactivated), dibromo-dicyanobutane was not mutagenic (MRID 00144412).

Dibromodicyanobutane did not induce unscheduled DNA synthesis (UDS) up to 100  $\mu\text{g/ml}$  (activated) and 10  $\mu\text{g/ml}$  (non-activated) for IMR-90 human embryonic fibroblasts (MRID 00137288). Lastly, in an *in vitro* Chinese Hamster Ovary cells assay at moderately cytotoxic doses of 11.0  $\mu\text{g/ml}$  (non-activated) and at 190  $\mu\text{g/ml}$  (activated), dibromodicyanobutane produced significant frequencies of chromosome aberrations were produced (MRID 00128134).

#### **e. Metabolism**

The metabolism of  $^{14}\text{C}$ -dibromodicyanobutane was studied in male CD rats following a single oral administration of 50 mg/kg  $^{14}\text{C}$ -dibromo-dicyanobutane (labeled in the butane core of the molecule). Total recovery of radioactivity during the 7 day collection period in the urine, feces, and respired  $^{14}\text{C}$ - $\text{CO}_2$  was 84-91%, 6-10%, and 0.5% of the administered dose, respectively. Tissue assay showed that 7 days after administration organs contained relatively greater concentrations of compound including the lung (2.7 ppm), liver (2.5 ppm), kidneys (2.3 ppm), and spleen (2.3 ppm). Maximum blood concentration (71  $\mu\text{g/ml}$ ) of dibromodicyanobutane equivalent is attained at 5 hours post-administration. On the basis of percent dose per whole organ, each of these



retentions is calculated to be less than 0.1%, except for liver at 0.3%. Although numerous deficiencies were noted, this study provides supplemental information. Since the compound is rapidly absorbed and excreted, most of the radioactivity in the urine was found during the first 24 hours post-administration (MRID 00055031).

**f. Chronic Toxicity/Carcinogenicity**

Chronic data are not required for non-food use chemicals unless the subchronic studies indicate NOELs which trigger endpoints of concern or if exposure to the chemical is chronic in nature. No subchronic endpoints of concern were triggered for dibromodicyanobutane and its use pattern would not be chronic in nature, therefore, no chronic data are required.

**2. Dose Response Assessment**

**a. Reference Dose (RfD) for Chronic Oral Exposure**

At a meeting of the Office of Pesticide Program's RfD/Peer Review Committee, the Committee recommended not to establish a Reference Dose (RfD) because there are no food uses for this chemical.

**3. Exposure and Risk Assessment**

**a. Dietary Exposure and Risk Assessment**

As discussed in the Regulatory History in Section II.E. above, indirect food additive tolerances have been established for dibromodicyanobutane for use as a preservative in food grade adhesives and as a slimicide in the manufacture of food grade paper and paperboard at a maximum level of 0.005% of dry weight fiber. These uses are under the jurisdiction of the U.S. Food and Drug Administration and not directly regulated by the EPA. Any potential dietary exposure to dibromodicyanobutane from these uses is expected to be negligible. Therefore, a dietary exposure and risk assessment is not applicable.

**b. Occupational and Residential Exposure and Risk Assessment**

An occupational and/or residential exposure assessment is appropriate for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers/loaders/ applicators) during use or to persons entering treated sites after application is complete.

Neither a short-term (1 to 7 days) nor an intermediate term (7-90 days) occupational/residential risk assessment is required, since results of the 21-day dermal toxicity study indicate that dibromodicyanobutane is not absorbed via the dermal route because no systemic toxicity was observed following repeated dermal application at doses of 0, 1000, 2000 or 4000 mg/kg/day. For systemic toxicity, the NOEL was greater than 4000 mg/kg/day (the highest dose tested). Since toxicology endpoints of concern, except for skin sensitization and eye

irritation from acute exposures, were not identified for occupational and residential exposures, an occupational and residential mixer/loader/applicator exposure analysis and quantitative risk assessment is not warranted at this time.

Additionally, secondary occupational and residential handler exposure from treated paint, ink and wax products will not pose a significant risk because of the low concentration/dilution factor associated with these products.

**C. Environmental Assessment**

**1. Ecological Toxicity Data**

The ecotoxicological data base is adequate for a limited characterization of toxicity to nontarget terrestrial and aquatic organisms when the chemical is used as an indoor, aquatic industrial, or terrestrial nonfood microbiocide or microbiostat. While the acute toxicity studies in fish are not acceptable to fulfill the required guidelines, they do provide supplemental information. An additional freshwater fish acute toxicity study has been required to complete the target data base. This study is due to the Agency in March of 1997.

**a. Toxicity to Birds**

**(1) Birds, Acute and Subacute**

One single-dose oral (LD<sub>50</sub>) study on one species (preferably mallard or bobwhite quail) and one subacute dietary (LC<sub>50</sub>) study on one species of waterfowl (preferably the mallard duck) or one species of upland game bird (preferably the bobwhite quail or ring-necked pheasant) are required to establish the toxicity of a microbiocide to birds. The results of these studies indicate that dibromodicyanobutane is slightly toxic to avian species on an acute oral and subacute dietary basis. The guideline requirements (71-1 and 71-2) are fulfilled (MRIDs 77315, 77316).

Table 2: Avian Toxicity Findings

Species	% A.I.	Finding	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Avian Acute Oral Toxicity Study - Mallard Duck	98	LD <sub>50</sub> = 1064 mg/kg	77315 R. Fink 1975	Slightly Toxic	Yes
Avian Subacute Dietary Toxicity - Bobwhite Quail	98	LC <sub>50</sub> = 4042 ppm	77316 R. Fink 1975	Slightly Toxic	Yes

**b. Toxicity to Aquatic Animals**

**(1) Freshwater Fish Acute and Chronic**

One freshwater fish toxicity study using the technical grade of the active ingredient is required to establish the toxicity of a microbiocide to freshwater fish. The study should use a cold water species (preferably the rainbow trout) or a warm water species (preferably the bluegill sunfish). The results indicate that dibromodicyanobutane is moderately toxic to fish on an acute basis. These studies, conducted in 1975, were not adequate to fulfill the guideline requirements, but they provide supplemental information (MRID 63850). A new freshwater fish acute toxicity study is required to complete the data base. This study was required in a letter to the registrants dated March 7, 1996 and the data is due to the Agency in March 1997.

Additionally, data from a fish early life-stage test are not required, however, a study has been submitted and reviewed. The no observed effect level (NOEL) is 0.75 ppm and the lowest observed effect level (LOEL) is 1.0 ppm. The maximum allowable toxicant concentration (MATC) level for reproduction impairment and developmental effects is 0.87 ppm. The guideline requirement (72-4) is fulfilled (MRID 41986701).

Table 3: Acute and Chronic Aquatic Toxicity Findings

Species	% A.I.	Findings	MRID No. Author/Year	Toxicity Category/ Endpoints Affected	Fulfills Guideline Requirement?
Freshwater Fish Acute Toxicity - Rainbow Trout	98	LC <sub>50</sub> = 1.75 ppm	63850 Bentley 1975	Moderately Toxic	No
Freshwater Fish Acute Toxicity - Bluegill Sunfish	98	LC <sub>50</sub> = 4.09 ppm	63850 Bentley 1975	Moderately Toxic	No
Fish Early Life-Stage Toxicity - Rainbow Trout	99.85	NOEL = 0.75 ppm LOEL = 1.0 ppm MATC = 0.87 ppm	MRID 41986701	Percent Survival	Yes

**(2) Freshwater Invertebrates Acute and Chronic**

A freshwater aquatic invertebrate toxicity test using the technical grade of the active ingredient is normally required to assess the toxicity of a microbiocide to freshwater invertebrates. Two studies were submitted, reviewed and were found individually to be deficient, but when evaluated together, these studies provided good dose response curves, correlated well when adjusted to the active ingredient, and were sufficient to fulfill the guideline requirement (GDLN 72-2) (MRIDs 63851 and 70890).

Data from an aquatic invertebrate life-cycle test using *Daphnia magna* are not required; however, a study was submitted and reviewed. The NOEL is 1.4 ppm. The MATC level for reproduction impairment and development effects is between 1.4 and 2.6 ppm. The guideline requirement (72-4) is fulfilled (MRID 41885304).

Table 4: Aquatic Invertebrate Acute and Chronic Toxicity Findings

Species	% A.I.	Findings*	MRID No. Author/Year	Endpoints Affected	Fulfills Guideline Requirement?
Daphnid Acute Toxicity - <i>Daphnia magna</i>	98	EC <sub>50</sub> = 2.16 ppm	63851 LeBlanc 1977	Moderate toxicity	Yes
Daphnid Acute Toxicity - <i>Daphnia magna</i>	10	EC <sub>50</sub> = 3.10 ppm	70890 LeBlanc 1978	Moderate toxicity	Yes
Invertebrate Early Life-Stage Chronic Toxicity - Daphnid <i>Daphnia magna</i>	99.85	NOEL = 1.4 ppm MATC >1.4 & <2.6	41885304 Ward & Boeri 1991	Percent survival	Yes

\*Acute toxicity values are adjusted to active ingredient

### (3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms (fish, shrimp, and oyster embryo/larva or oyster shell deposition) using the technical grade of the active ingredient is no longer required for microbiocides; however, data were submitted and reviewed. Preferred test organisms for estuarine/marine acute toxicity testing are the sheepshead minnow, mysid shrimp, and Eastern oyster. The results indicate moderate toxicity to estuarine/marine animals on an acute basis. The guideline requirement (72-3) is fulfilled (MRIDs 41885301, 41885302 and 41885303).

Table 5: Estuarine/Marine Acute Toxicity Findings

Species	% A.I.	LC <sub>50</sub> /EC <sub>50</sub> (ppm)	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Eastern oyster (embryo-larvae)	99.85	2.6	ACC # 41885302 Ward & Boeri 1991	Moderately toxic	Yes
Mysid shrimp	99.85	2.8	ACC # 41885303 Ward & Boeri 1991	Moderately toxic	Yes
Sheepshead minnow	99.85	8.3	ACC # 41885301 Ward & Boeri 1991	Moderately toxic	Yes

## 2. Environmental Fate

## a. Environmental Fate Assessment

A tentative qualitative environmental fate assessment can be made based on available environmental fate and transport data. Studies have been submitted and found to be supplemental, for hydrolysis (GDLN 161-1), aerobic aquatic metabolism (GDLN 162-4), and leaching and absorption/desorption (GDLN 163-1).

Dissipation is expected to be controlled by alkaline-catalyzed hydrolysis and microbially-mediated degradation. The chemical was found to be rapidly degraded in flooded sandy loam soil (half life under 0.864 days). The hydrolytic half-life was 190 days at pH 5, 24.11 days at pH 7, and 12.67 days at pH 9. The degradates *cis* and *trans* isomers of 1-bromo-2,4-dicyano-1-butene and 2-methylene-glutaronitrile were identified in the hydrolysis and aerobic aquatic metabolism studies. These degradates appear to be precursors to more stable unidentified degradates.

The chemical was found to be very mobile ( $K_d < 1$ ) in soil and aquatic environments. No mobility data are available for the degradates. No field studies are required to support the current uses.

The chemical is expected to be very mobile and non-persistent in aquatic and soil environments. However, there is little information on the identity and environmental behavior of degradates. There are no metabolism data on dibromodicyanobutane's rate and route of degradation in neutral and acidic environments. However, rapid degradation was observed in an aerobic aquatic metabolism study, and in soil slurries in a batch equilibrium study.

## b. Environmental Fate and Transport

Hydrolysis (GDLN 161-1) is the only guideline data requirement for reregistration of this chemical (or pesticides in general with aquatic non-food industrial uses and regulated discharge under NPDES permits and indoor uses). The submitted study was not completely acceptable because degradation products making up over 10% of the applied chemical have not been identified. Since this sole data requirement is supported by supplemental data, the study must be upgraded. The identity of hydrolysis degradates is needed because hydrolysis appears to be a major route of degradation. The information is required to be submitted to the Agency by July 31, 1996.

The registrant has submitted studies of aerobic aquatic metabolism and adsorption-desorption. These studies are not required for uses subject to the reregistration decision, but provide supplemental information on metabolism and mobility in aquatic systems.

### (1) Degradation

Hydrolysis (GDLN 161-1) A single study has been submitted. It is not completely acceptable because of inadequate identification of degradates. The registrant has been required to provide the Agency with upgraded information on the identity of degradates at concentrations greater than 10% of the applied dose.

In the study submitted, radiolabeled "Tektamer 38", at concentrations of 10 and 40 µg/ml, was incubated in buffer solutions at 25°C. Half-life measurements were 190 to 198 days at pH 5, 24 to 72.8 days at pH 7, and 12.6 to 14.0 days at pH 9. In similar incubations at 45°C, "Tektamer 38" had hydrolysis half-lives ranging from 96.2 to 123 days at pH 5, 10.7 to 13 days at pH 7, and 0.6 to 0.8 days at pH 9.

The first-order degradation model fit the data poorly, suggesting degradation mechanisms other than hydrolysis. The major hydrolysis degradate of "Tektamer 38" was identified as trans-1-bromo-2,4-dicyanobutene. Hydrolysis degradates were tentatively identified as cis-1-bromo-2,4-dicyanobutene and methylene glutaronitrile. Degradates were detected with  $R_f$  0.00 and 0.42 but were not identified. The information available suggests that degradation is dependent on alkaline catalyzed hydrolysis (MRID 55032).

Aerobic Aquatic Metabolism (GDLN 162-4). A single study has been submitted. The study was not acceptable to fulfill the guideline requirements because of inadequate identification of degradates. The study, while supplemental, may be upgraded with submission of information on identity of degradates at concentrations greater than 10% of the applied dose. These data are not a guideline requirement for dibromodicyanobutane's use pattern, but provide supplemental information.

Radiolabeled "Tektamer 38" at an initial concentration of 10 µg/g had a half-life of 0.874 days in flooded sandy loam soil. Intermediate degradates were identified as 2-methleneglutaronitrile, making up 21.4% of the initial measured dose at 12 hours post-treatment in soil and water extracts, and (E) and (Z) isomers of 1-bromo-2,4-dicyano-1-butene, making up no more than 0.439% of the initial measured dose at 2 days post-treatment in water extracts. Unidentified degradates ( $R_f=0.01$  and  $R_f=0.0$  to 0.05) were also detected (79% of initial measured dose) in soil and water extracts. A volatile degradate making up 10% of the initial measured dose was identified as CO<sub>2</sub>. These results suggest that degradation is rapid in sandy loam soil flooded with alkaline water. The mechanisms of degradation appear to be controlled by alkaline catalyzed hydrolysis and microbially mediated processes (MRID 41883901).

## (2) Mobility

Leaching, Adsorption-Desorption (GDLN 163-1). A single unaged batch equilibrium study was submitted that provides supplemental data

because desorption coefficients were not reported and exaggerated desorption was observed in the study. Aged mobility studies would be needed to fulfill the aged portion of the data requirement. This study is not a data requirement for this chemical's use pattern, but provides supplemental information.

Radiolabeled "Tektamer 38", at 0.1 to 1.0 µg/ml, had Freundlich coefficients of 0.264 ( $K_{oc}=528$ ;  $1/n=1.331$ ) in a sand, 0.351 ( $K_{oc}=87.8$ ;  $1/n=1.046$ ) in a sandy loam soil, 0.474 ( $K_{oc}=72.9$ ;  $1/n=0.9963$ ) in a clay loam soil, and 0.701 ( $K_{oc}=33.4$ ;  $1/n=1.086$ ) in a silt loam soil. "Tektamer 38" degradation was observed during a 2-hour equilibration period. The degradates (E) and (Z) isomers of 1-bromo-2,4-dicyano-1-butene were detected (6.16 to 75% of applied) by HPLC. Desorption coefficients were not reported. However, the mean percent desorption of "Tektamer 38" was 125% for a sand, 107% for a sandy loam soil, 148% for a clay loam soil, and 126% for a silt loam soil. These results suggest that the chemical will be mobile in aquatic and soil environments (MRID 41883902).

### **3. Exposure and Risk Characterization**

#### **a. Ecological Exposure and Risk Characterization**

The Agency requires only a limited set of ecotoxicology and environmental fate studies for microbiocides. The information available indicates that dibromodicyanobutane is slight toxic to birds on an acute oral and subacute dietary basis and moderately toxic to aquatic invertebrates and estuarine/marine animals. Dibromodicyanobutane is expected to degrade rapidly in aquatic environments. A freshwater fish acute toxicity study has been required to complete the data base.

The oil-related aquatic uses (oil recovery drilling muds/packer fluids, secondary oil recovery injection water) are expected to result in minimal to no exposure if proper procedures are employed in the disposal of the contaminated materials.

While the hazard to aquatic organisms from dibromodicyanobutane has been characterized, a quantitative risk assessment has not been conducted. Discharge of industrial effluent containing dibromodicyanobutane residues to aquatic environments must comply with NPDES permitting requirements of the Office of Water..

#### **b. Endangered Species**

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

## **IV. RISK MANAGEMENT AND REREGISTRATION DECISION**

### **A. Determination of Eligibility**

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

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of dibromodicyanobutane and to determine that dibromodicyanobutane can be used, as specified in this document, without resulting in unreasonable adverse effects to humans and the environment. The Agency, therefore, finds that all products containing dibromodicyanobutane as the active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, and the data identified in Appendix B. Although the Agency has found that all uses of dibromodicyanobutane 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 dibromodicyanobutane, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

### **B. Determination of Eligibility Decision**

#### **1. Eligibility Decision**

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

#### **2. Eligible and Ineligible Uses**

The Agency has determined that all uses of dibromodicyanobutane, as specified in this document, are eligible for reregistration.



## C. Labeling Rationale/Risk Mitigation Measures

### 1. Handler Safety Requirements

During reregistration, the Agency is reviewing existing worker protection requirements for all occupational and residential uses.

#### a. Personal Protective Equipment for Occupational Use Products

The Agency establishes handler safety requirements when risk assessments or general concerns suggest such requirements are appropriate. If EPA determines that no specific handler requirements are warranted based on the potential acute or other adverse effects of the active ingredient, the handler safety requirements will be based on the acute toxicity characteristics of the end-use product.

Just as the Agency developed standardized requirements for agricultural workers with the implementation of the Worker Protection Standard (WPS) in 1994, it is now developing standardized requirements for occupational handlers of industrial biocides since the Personal Protective Equipment requirements developed for agricultural workers generally do not reflect the same kind of exposures found in industrial use settings. The handler PPE requirements are based on the acute toxicity characteristics of each end-use product. Comments on these requirements should be addressed during the public comment period for dibromodicyanobutane.

For occupational use products, the Agency has determined that handlers (mixers/loaders/applicators, etc.) of all industrial biocides must wear long-sleeve shirts, long pants and shoes and socks as minimum work attire. For industrial biocide end-use products that are classified as toxicity category I or II for acute dermal or skin irritation/sensitization, the Agency is requiring handlers to wear chemical resistant gloves and an apron in addition to the minimum work attire. For end-use biocide products classified as toxicity category I or II for eye irritation, handlers must wear protective eyewear. For industrial biocide end-use products classified as toxicity category I or II for acute inhalation toxicity, handlers are required to wear a respirator. The type of respirator must be established based on the acute toxicity category and the vapor pressure and must be specified on the end-use product labeling.

Table 6 - Personal Protective Work Attire for Industrial Biocide Handlers (Mixers/Loaders/Handlers)

	Toxicity Category I	Toxicity Category II	Toxicity Category III	Toxicity Category IV
Acute Dermal Toxicity or Skin Irritation Potential	Long Sleeves Long Pants Shoes & Socks Chemical Resistant Gloves & Apron	Long Sleeves Long Pants Shoes & Socks Chemical Resistant Gloves & Apron	Long Sleeves Long Pants Shoes & Socks	Long Sleeves Long Pants Shoes & Socks
Eye Irritant	Protective Eyewear	Protective Eyewear	No minimum	No minimum
Acute Inhalation Toxicity	Respirator	Respirator	No minimum	No minimum

The Agency has determined that no active-ingredient-specific handler safety requirements must be established due to the acute or other adverse effects of dibromodicyanobutane. The handler safety requirements for end-use products containing dibromodicyanobutane must be determined based on the acute toxicity characteristics of the end-use product.

## 2. Engineering Control Requirements for Occupational Handlers

**Primary Occupational Handlers:** At this time, there are no engineering control requirements, such as closed systems, currently required on labeling for end-use products containing dibromodicyanobutane. None are being required as a result of the reregistration evaluation of dibromodicyanobutane uses.

**Secondary Occupational Handlers:** At this time, the Agency believes that risks from skin and eye sensitization would be acceptable without additional handler safety requirements for secondary occupational handlers, since the dibromodicyanobutane in such products as paints, inks and waxes is very diluted, usually far less than one percent.

## 3. Homeowner-Use Products

All dibromodicyanobutane end-use pesticide products are intended only for occupational use. The Agency believes that risks from skin and eye irritation secondary occupational/homeowner handlers to such products as paints, inks and waxes containing dibromodicyanobutane, would be acceptable without additional handler safety requirements as any dibromodicyanobutane in these products is very diluted, usually far less than one percent.

#### **4. Post-Application Safety Requirements**

At this time, the Agency believes that risks from the skin and eye irritation potential of dibromodicyanobutane would be acceptable for primary post-application occupational exposures without additional human safety requirements, since post-application skin and eye contact with the treated substances in commercial and industrial settings is likely to be slight. At this time, EPA also believes that risks from the skin and eye irritation potential of dibromodicyanobutane would be acceptable for secondary post-application occupational and homeowner exposures without additional human safety requirement, since the dibromodicyanobutane in such products as paint, waxes, and ink is very diluted, usually far less than one percent and post-application skin and eye contact with such products is likely to be minimal. Since the dibromodicyanobutane is classified as toxicity category IV for acute inhalation toxicity, the Agency believes, at this time, that risks from post-application inhalation exposure without a respirator requirement would be acceptable.

#### **5. Additional Labeling Requirements**

The Agency is requiring specific label language addressing application restrictions, user safety requirements and recommendations and skin sensitization. The label language can be found in Section V.

### **V. ACTIONS REQUIRED OF REGISTRANTS**

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

#### **A. Manufacturing-Use Products**

##### **1. Additional Generic Data Requirements**

The generic data base supporting the reregistration of dibromodicyanobutane for the above eligible uses has been reviewed and determined to be substantially complete. The hydrolysis study was upgradeable supplemental data. The registrant has been required to provide the identity of the hydrolysis degradates because hydrolysis appears to be the major route of degradation. This information is due to the Agency by July 31, 1996. Also, a freshwater fish acute toxicity study has been required and is due to the Agency by March 31, 1997.

##### **2. Labeling Requirements for Manufacturing-Use Products**

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

"Only for formulation into a microbiocide/microbiostat/bacteriostat for use as an additive for industrial adhesives, emulsions, resin/latex and polymer systems, metalworking cutting fluids, secondary oil recovery injection water, drilling muds, wet-end additives/industrial processing chemicals, specialty industrial products

(includes fiber processing fluids, waxes, polishes, and inks), and latex and oil paints.

A MP registrant may, at his/her discretion, add one of the following statements to a 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 user 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 support of such use(s)."
- (b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

#### Effluent Discharge Labeling Statements

Product labeling must include the statements pertaining to effluent discharge under the NPDES permitting program (refer to PR Notice 93-10):

"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."

## **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 D, the Product Specific Data Call-In Notice.

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

## Labeling Requirements for End-Use Products

### a. Occupational Labeling PPE Requirements for Pesticide Handlers

- Sole-active ingredient
2. ve ingredient end-use products that contain dibromo-dicyanobutane must be revised to adopt the personal protective equipment requirements set forth in this section. Any conflicting PPE requirements on their current labeling must be removed.

Multiple-active-ingredient end-use products that contain dibromo-dicyanobutane must compare the handler personal protective equipment requirements, if any, set forth in this section to the PPE requirements on their current labeling and retain the more protective.

Any necessary PPE for each dibromodicyanobutane occupational end-use product will be established on the basis of the end-use product's acute toxicity category as specified in Section V of this document. All end-use products will be required to specify the minimum work attire for all handlers.

The minimum handler labeling requirement for occupational uses of dibromodicyanobutane end-use products are:

"Mixers/loaders, applicators and other handlers must wear:

- Long-sleeve shirt and long pants,
- Shoes plus socks."

If the end-use product is classified as toxicity category I or II for eye irritation potential, add:

- "Protective eyewear."

If the end-use product is classified as toxicity category I or II for skin irritation potential, add:

- "Chemical-resistant apron, and
- Chemical-resistant gloves\*."

If the end-use product is classified as toxicity category I or II for acute inhalation toxicity, a respirator requirement must be added. The type of respirator must be specified in the statement and is based on the acute toxicity category and the vapor pressure.

\*For the glove statement, use the statement established for dibromodicyanobutane through the instructions in Supplement Three of PR Notice 93-7. However, the corrosiveness and penetration of dibromodicyanobutane must be considered and appropriate chemical-resistant materials must be listed.

### **Placement in Labeling**

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

#### **b. Other Labeling Requirements - Products Intended for Occupational Use**

The agency is requiring the following labeling statements to be located on all end-use products containing dibromodicyanobutane that are intended primarily for occupational use.

#### **Application Restrictions**

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

#### **User Safety Requirements**

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

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

#### **User Safety Recommendations**

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

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

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

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

#### **Skin Sensitizer Statement**

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

### Clarification of Oil Drilling Mud Use

To clarify the intent of the oil recovery drilling muds/packer fluids use (as an aquatic or terrestrial non-food use pattern), the following statement must be added to the labels for terrestrial non-food oil/gas drilling muds and packer fluids:

"For use in terrestrial wells only"

And the following statement must be added to the precautionary labeling:

"Do not apply in marine and/or estuarine oil fields."

The following statement must be added to the labels for aquatic non-food industrial oil/gas drilling muds and packer fluids:

"For use in offshore wells only."

For use in both terrestrial and offshore oil/gas drilling muds and packer fluids, the following statement must be added:

"This product may be used for terrestrial and off-shore oil/gas drilling muds and packer fluids."

### Additional Directions for Use

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

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





## **VI. APPENDICES**



APPENDIX A REPORT

Case 2780[Dibromodicyanobutane] Chemical 111001[1,2-Dibromo-2,4-dicyanobutane]  
))

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. Soil Rate (AI unless noted otherwise)	Max. # Apps @ Max. Rate /crop /year	Max. Dose [(AI unless noted otherwise)/A]	Min. Restr. Entry Interv (days)	Restr. Entry Allowed	Geographic Limitations Disallowed	Use Limitations Codes
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))

USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED  
))

ADHESIVES, INDUSTRIAL

Use Group: INDOOR NON-FOOD

Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	SC/L	W 50		W 250	* NS NS	NS NS	NS NS	NS NS	C18, C24
	SC/L	W 95		W 1520	* NS NS	NS NS	NS NS	NS NS	C18, C24
	SC/L	W 100		W 1000	* NS NS	NS NS	NS NS	NS NS	C12
	SC/L	W 100		W 2500	* NS NS	NS NS	NS NS	NS NS	C12, C18
	SC/L	W 102		W 1530	* NS NS	NS NS	NS NS	NS NS	C18, C24
	SC/L	W 119		W 1898	* NS NS	NS NS	NS NS	NS NS	C18, C24
	SC/S	W 98		W 1960	* NS NS	NS NS	NS NS	NS NS	CAH
	SC/S	W 100		W 2500	* NS NS	NS NS	NS NS	NS NS	C12, C18

COATINGS, INDUSTRIAL

Use Group: INDOOR NON-FOOD

Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	SC/L	W 50		W 250	* NS NS	NS NS	NS NS	NS NS	C18, C24
	SC/L	W 100		W 2500	* NS NS	NS NS	NS NS	NS NS	C12, C18
	SC/L	W 190		W 712	* NS NS	NS NS	NS NS	NS NS	C18, C24
	SC/S	W 100		W 2500	* NS NS	NS NS	NS NS	NS NS	C12, C18

COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS

Use Group: AQUATIC NON-FOOD INDUSTRIAL

Water treatment (recirculating system), Not on label, Not applicable for this use	SC/L	W 119		W 1898	* NS NS	NS NS	NS NS	NS NS	A08, C18, C24
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## **GUIDE TO APPENDIX B**

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

REQUIREMENT	USE PATTERN	CITATION(S)	
<b><u>PRODUCT CHEMISTRY</u></b>			
61-1	Chemical Identity	ALL	42592801
61-2A	Start. Mat. & Mnfg. Process	ALL	42592801
61-2B	Formation of Impurities	ALL	42592801
62-1	Preliminary Analysis	ALL	42592802
62-2	Certification of limits	ALL	42592802
62-3	Analytical Method	ALL	42592802
63-2	Color	ALL	42592803
63-3	Physical State	ALL	42592803
63-4	Odor	ALL	42592803
63-5	Melting Point	ALL	42592803
63-7	Density	ALL	42592803
63-8	Solubility	ALL	42592803
63-9	Vapor Pressure	ALL	42592803
63-10	Dissociation Constant	ALL	42592803
63-11	Octanol/Water Partition	ALL	42592803
63-13	Stability	ALL	42592803
<b><u>ECOLOGICAL EFFECTS</u></b>			
71-1A	Acute Avian Oral - Quail/Duck	ALL	77315
71-2A	Avian Dietary - Quail	ALL	77316

**Data Supporting Guideline Requirements for the Reregistration of Dibromodicyanobutane**

<b>REQUIREMENT</b>		<b>USE PATTERN</b>	<b>CITATION(S)</b>
72-1A	<b>Fish Toxicity Bluegill</b>	ALL	63850
72-1C	<b>Fish Toxicity Rainbow Trout</b>	ALL	63850
72-2A	<b>Invertebrate Toxicity</b>	ALL	63851, 70890
72-3A	<b>Estuarine/Marine Toxicity - Fish</b>	ALL	41885301
72-3B	<b>Estuarine/Marine Toxicity - Mollusk</b>	ALL	41885302
72-3C	<b>Estuarine/Marine Toxicity - Shrimp</b>	ALL	41885303
72-4A	<b>Early Life Stage Fish</b>	ALL	41986701
72-4B	<b>Life Cycle Invertebrate</b>	ALL	41885304
<b><u>TOXICOLOGY</u></b>			
81-1	<b>Acute Oral Toxicity - Rat</b>	ALL	41885501
81-2	<b>Acute Dermal Toxicity - Rabbit/Rat</b>	ALL	27554
81-3	<b>Acute Inhalation Toxicity - Rat</b>	ALL	25846, 42526401
81-4	<b>Primary Eye Irritation - Rabbit</b>	ALL	25848
81-5	<b>Primary Dermal Irritation - Rabbit</b>	ALL	25847, 41885502
81-6	<b>Dermal Sensitization - Guinea Pig</b>	ALL	105188, 43183801
82-1A	<b>90-Day Feeding - Rodent</b>	ALL	55028
82-1B	<b>90-Day Feeding - Non-rodent</b>	ALL	55027, 92199020, 43540501
82-2	<b>21-Day Dermal - Rabbit/Rat</b>	ALL	Cerven, 1990

## Data Supporting Guideline Requirements for the Reregistration of Dibromodicyanobutane

REQUIREMENT		USE PATTERN	CITATION(S)
83-3A	Developmental Toxicity - Rat	ALL	0126562, 92199012
83-3B	Developmental Toxicity - Rabbit	ALL	43540502
84-2A	Gene Mutation (Ames Test)	ALL	25091
84-2B	Structural Chromosomal Aberration	ALL	125850
84-4	Other Genotoxic Effects	ALL	55029, 144412, 137288, 128134
85-1	General Metabolism	ALL	55031
<b><u>ENVIRONMENTAL FATE</u></b>			
160-5	Chemical Identity	ALL	42592803
161-1	Hydrolysis	ALL	55032, Upgrade required
162-4	Aerobic Aquatic Metabolism	ALL	41883901
163-1	Leaching/Adsorption/Desorption	ALL	41883902





## GUIDE TO APPENDIX C

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
  - a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
  - b. **Document date.** The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.
  - c. **Title.** In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
- (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
  - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
  - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
  - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or
2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or
3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

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

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

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

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

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

The Attachments to this Notice are:

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

## SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

## SECTION II. DATA REQUIRED BY THIS NOTICE

### II-A. DATA REQUIRED

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



## II-B. SCHEDULE FOR SUBMISSION OF DATA

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

## II-C. TESTING PROTOCOL

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

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

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

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

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

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

## SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

### III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

### III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

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

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

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

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

### III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

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

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

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

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

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

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

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this

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

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

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

- a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."
- b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.
- c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

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

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

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

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

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

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

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

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

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

### III-D REQUESTS FOR DATA WAIVERS

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

## IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

### IV-A NOTICE OF INTENT TO SUSPEND

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

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.
2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.
3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.
4. Failure to submit on the required schedule acceptable data as required by this Notice.
5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.
7. Withdrawal of an offer to share in the cost of developing required data.
8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:
  - a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;
  - b. fulfill the commitment to develop and submit the data as required by this Notice; or
  - c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.
9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

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

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

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.
2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.
3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.



#### IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois Rossi, Division Director  
Special Review and  
Reregistration Division

#### Attachments

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



## DIBROMODICYANOBTANE DATA CALL-IN CHEMICAL STATUS SHEET

### INTRODUCTION

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

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

### INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Ernest Jones (703) 308-8069.

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

Ernest Jones  
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: DIBROMODICYANOBTANE**



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.









## EPA'S BATCHING OF 1,2-DIBROMO-2,4-DICYANOBUTANE PRODUCTS FOR MEETING REREGISTRATION ACUTE TOXICITY DATA REQUIREMENTS

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing 1,2-dibromo-2,4-dicyanobutane as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a



registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

PRS identified the following products for batching purposes:

- Tektamer 38 = 98% a.i. (10445-33)
- Tektamer 38 O.F. = 98% a.i. (10445-68)
- Tektamer 38 Wet Cake = 85% a.i. (10445-102)
- Tektamer 38 A.D. = 25% a.i. (10445-56)
- Tektamer 38 O.A. = 25% a.i. (10445-67)
- Tektamer 38 Liquid Concentrate = 25% a.i. (10445-22)
- Tektamer 38 O.L. = 10% a.i. (10445-71)
- Metasol CB 225-AD = 25% a.i. (10445-77)
- Metasol CB 225-LC = 25% a.i. (10445-80)
- Metasol CB-220 = 20% a.i. (10445-91)
- Biochek 430 = 23.802% a.i. (10445-89)
- Biochek 410 = 25% a.i. (10445-90)

Twelve products were found which contain 1,2-dibromo-2,4-dicyanobutane (CAS No. 10445-33) as an active ingredient. Eight products have been placed into three "BATCH" categories. Four Products were placed into the "NO BATCH" category.

Table 1

Batch	EPA Reg. No.	% active ingredient	Formulation Type
1	10445-33	98	powder
	10445-68	98	powder

Table 2

Batch	EPA Reg. No.	% active ingredient	Formulation Type
2	10445-56	25.5%	liquid
	10445-67	25.0%	liquid
	10445-77	25.0%	liquid

Table 3

Batch	EPA Reg. No.	% active ingredient	Formulation Type
3	10445-22	25%	liquid
	10445-80	25%	liquid
	10445-91	20%	liquid

The following table lists products that were either considered not to be similar or the Agency lacked sufficient information for decision making and were not placed in any batch. The registrant of these products is responsible for meeting the acute toxicity data requirements separately.

Table 3 (No Batch)

EPA Reg. No.	% active ingredient	Formulation Type
10445-102	85%	solid
10445-71	10%	liquid
10445-89	23.8%	liquid
10445-90	25%	liquid

**PRS Recommendations:**

Only acute toxicity studies supporting **BATCH 1** with Category III and IV classifications may be cited by the registrant to support any **BATCH 2** product.

Acute toxicity data (generated, cited and/or submitted) from **BATCH 1** may be bridged to support 10445-102.

Acute toxicity data (generated, cited and/or submitted) from **BATCH 3** may be bridged to support 10445-71.

PRS was not able to batch or bridge to the following products: 10445-90 or 10445-89.


**Attachment**

- a. List of All Registrants Sent This Data Call-In (insert Notice**

## Instructions for Completing the Confidential Statement of Formula

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

- a. All the blocks on the form must be filled in and answered completely.
- b. If any block is not applicable, mark it N/A.
- c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.
- d. All applicable information which is on the product specific data submission must also be reported on the CSF.
- e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.
- f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.
- g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.
- h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.
- i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.
- j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).
- k. All the items under column 13.b. must total 100 percent.
- l. 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 all 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.

 <p>United States Environmental Protection Agency Office of Pesticide Programs (TS-767) Washington, DC 20460</p>		<p><b>A.</b></p> <input type="checkbox"/> Basic Formulation <input type="checkbox"/> Alternate Formulation		<p><b>B.</b></p> Page _____ of _____ See Instructions on Back	
<p>2. Name and Address of Producer (Include ZIP Code)</p>					
<p>3. Product Name</p>		<p>4. Registration No./File Symbol</p>		<p>5. EPA Product Mgr./Team No.</p>	
<p>7. Pounds/Gal or Bulk Density</p>		<p>8. pH</p>		<p>9. Flash Point/Flame Extension</p>	
<p>10. Components in Formulation (List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)</p>		<p>11. Supplier Name &amp; Address</p>		<p>12. EPA Reg. No.</p>	
<p>EPA USE ONLY</p>		<p>13. Each Component in Formulation</p> <p>a. Amount</p>		<p>14. Certified Limits % by Weight</p> <p>a. Upper Limit b. Lower Limit</p>	
<p>15. Purpose in Formulation</p>		<p>16. TYPED NAME OF APPROVING OFFICIAL</p>		<p>17. Total Weight</p> <p>100%</p>	
<p>18. SIGNATURE OF APPROVING OFFICIAL</p>		<p>19. Title</p>		<p>20. Phone No. (Include Area Code)</p>	
<p>21. Date</p>		<p>22. Date</p>		<p>23. Date</p>	





United States Environmental Protection Agency  
Washington, DC 20460

**CERTIFICATION OF OFFER TO COST  
SHARE IN THE DEVELOPMENT OF DATA**

Form Approved

OMB No. 2070-0106  
2070-0057

Approval Expires 3-31-96

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

**Please fill in blanks below.**

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer
-----------------	---------------

Certification:

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

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

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

US EPA ARCHIVE DOCUMENT







**CERTIFICATION WITH RESPECT TO  
DATA COMPENSATION REQUIREMENTS**

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

**Please fill in blanks below.**

Company Name	Company Number
Product Name	EPA Reg. No.

**I Certify that:**

- 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.
- 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,"
- 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)



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

Electronic

File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Ernest Jones at (703)-308-8069.

1. PR Notice 86-5.
2. PR Notice 91-2 (pertains to the Label Ingredient Statement).
3. A full copy of this RED document.
4. A copy of the fact sheet for DIBROMODICYANOBTANE.

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

1. Health and Environmental Effects Science Chapters.
2. Detailed Label Usage Information System (LUIS) Report.

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

1. The Label Review Manual.
2. EPA Acceptance Criteria

