United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-93-020
September 1993

EPA

Reregistration Eligibility Decision (RED)

Tris(hydroxymethyl) nitromethane

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-93-016 September 1993

EPA R.E.D. FACTS

Tris(hydroxymethyl)-nitromethane

Pesticide Reregistration

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

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

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for the reregistration case Tris(hydroxymethyl) nitromethane, which contains the active ingredient 2-(hydroxymethyl)-2-nitro-1,3-propanediol.

Use Profile

2-(hydroxymethyl)-2-nitro-1,3-propanediol is used as a microbicide and bacteriostat in disinfectants and industrial preservatives. Specifically, it is used as an industrial preservative in metalworking fluids, secondary oil field recovery waters, paper mills and commercial/industrial water cooling systems; as an in-can preservative in latex paints, polishes and detergents; and as a disinfectant to control disease organisms in livestock and poultry areas on farm premises and equipment. It is formulated as a soluble liquid concentrate, powder or pellets, and is applied through use of a metering pump in industrial water systems, by pouring into paints and polishes, and as a spray to farm areas and equipment.

Regulatory History

2-(hydroxymethyl)-2-nitro-1,3-propanediol was first registered in the U.S. in 1955, as an industrial bactericide and slimicide. EPA has issued three relevant Data Call-In (DCI) Notices: the Antimicrobial DCI in March 1987, the comprehensive reregistration Phase 4 DCI in September 1992, and a third DCI in August 1993, the latter for residue data. Currently, nine pesticide products are registered which contain this active ingredient.

Human Health Assessment

Toxicity

Studies using laboratory animals indicate that 2-(hydroxymethyl)-2-nitro-1,3-propanediol is of low to moderate acute toxicity to mammals. It has been placed in Toxicity Category III for acute oral, dermal and inhalation effects (Toxicity Category I indicates the greatest degree of acute toxicity and Category IV the lowest). It has been placed in Category IV for eye and skin irritation effects. Since these studies were not conducted with the technical grade (100%) powder, additional confirmatory acute inhalation and eye irritation studies are required using that formulation.

In a subchronic dermal toxicity study using rats, there were no treatment-related effects observed at any dose level. In developmental toxicity studies using rats and rabbits, treatment-related maternal effects were observed in the high-dose groups. No mutagenic effects were seen in a battery of studies.

2-(hydroxymethyl)-2-nitro-1,3-propanediol decomposes to formaldehyde under alkaline, warm conditions. Formaldehyde has been classified by EPA as a Group B1 "probable" human carcinogen. The toxicity of formaldehyde has been a primary consideration in evaluating the risks of 2-(hydroxymethyl)-2-nitro-1,3-propanediol.

Dietary Exposure

No dietary exposure is expected as a result of the registered uses of 2-(hydroxymethyl)-2-nitro-1,3-propanediol. Its one potential food use, as a disinfectant in or on livestock premises and equipment, has been modified to delete milk house and milking equipment uses, and to add restrictions to poultry house uses which eliminate the means of exposure of edible livestock tissue or eggs. Therefore, no tolerances (maximum residue limits) or exemptions from tolerances are required.

Occupational and Residential Exposure

2-(hydroxymethyl)-2-nitro-1,3-propanediol has many uses that may involve exposure to workers, and exposure monitoring data were required to estimate combined inhalation and dermal exposure of mixers, loaders and applicators in various use sites.

Worker exposure is considered significant for preservative and pulp and paper mill uses, which involve open pouring methods. However, associated risks will be mitigated ten-fold by requiring use of a respirator and personal protective equipment (PPE) including a long-sleeved shirt and long pants, and shoes plus socks.

Worker exposure is considered low for the poultry/livestock disinfectant use, but is of concern since formaldehyde is an active ingredient in the product, and since a spray method of application is involved. Use of PPE and a respirator are required, and will reduce any exposure ten-fold.

Worker exposure during cooling tower and metal working fluid uses is considered very low. Again, PPE is required to reduce possible exposure to formaldehyde.

While post-application worker exposure to formaldehyde is minimal for most uses of 2-(hydroxymethyl)-2-nitro-1,3-propanediol, the disinfectant spray used in livestock/poultry premises, which contains the active ingredient formaldehyde, causes post-application exposure of concern. However, EPA's exposure estimate represents the worst case scenario, and OSHA requires monitoring for formaldehyde before workers may reenter treated premises. Therefore, post-application worker exposure is likely the same or less than exposure during mixing, loading or applying the pesticide.

Similarly, post-application worker exposure to formaldehyde from use of the parent chemical in pulp and paper mills is of some concern. Since the Agency's exposure estimate is very conservative, a post-application inhalation exposure monitoring study is required only as confirmatory data.

Human Risk Assessment

Since 2-(hydroxymethyl)-2-nitro-1,3-propanediol has no food uses, no dietary risk exists. Overall, minimal risk and exposure are associated with the use of this active ingredient. The risks associated are due to its degradation product, formaldehyde.

EPA has examined the cancer risks of formaldehyde extensively. Using the most widely accepted risk assessment methodology, the Agency has estimated the refined upper bound cancer risk to mixers, loaders and applicators from exposure to formaldehyde through use of 2-(hydroxymethyl)-2-nitro-1,3-propanediol. With PPE and respirators, these risks range from 1.1 in 100,000 for preservative uses to 2.5 in 1,000,000 for poultry/livestock disinfectant uses.

Post-application worker exposure to formaldehyde following the livestock/poultry premise spray use is of concern; the upper bound risk to workers is estimated to be 2.5 in 1,000,000. However, the Agency's exposure estimate represents the worst case scenario. Actual risks to workers should be lower considering OSHA's formaldehyde monitoring

requirements. Post-application exposure of pulp and paper mill workers is conservatively estimated to be 2.7 in 100,000. A post-application inhalation exposure monitoring study is required for this use, as confirmatory information.

Environmental Assessment

In evaluating environmental effects, EPA focused on 2-(hydroxymethyl)-2-nitro-1,3-propanediol rather than its degradation product, formaldehyde. In the aquatic environment, the active ingredient is relatively stable. As it breaks down to formaldehyde, the latter chemical is rapidly dissipated. Therefore, the parent compound is of greater interest.

Environmental Fate

Based on the results of an exposure assessment model, the Agency expects that 2-(hydroxymethyl)-2-nitro-1,3-propanediol used according to the label will result in minimal exposure to the environment. Concern would arise only from its discharge into receiving waters from the industrial uses or in the case of spills, accidents or misuse. A hydrolysis study is required to confirm the chemical's degradation in the environment.

Ecological Effects

2-(hydroxymethyl)-2-nitro-1,3-propanediol has a low order of acute oral and dermal toxicity to terrestrial mammals. It may be slightly toxic to upland game birds, but is practically non-toxic to waterfowl. It also is practically non-toxic to freshwater fish species on an acute basis. It is slightly toxic to freshwater aquatic invertebrates and mollusks, and practically non-toxic to crustaceans.

Ecological Effects Risk Assessment

EPA conducted a Tier Ic Estimated Environmental Concentration (EEC) model to assess the residue levels of 2-(hydroxymethyl)-2-nitro-1,3-propanediol in the receiving stream from several use sites. This model provides a reasonable worst case estimate of the maximum concentration that may occur immediately downstream from an industrial point source discharge site. The typical EEC values for all uses of this active ingredient are below the levels of concern for fish and invertebrates. Therefore, the pesticide can be used at typical use sites without producing effluent above levels of concern. Under a high exposure scenario, a high degree of risk would be posed to aquatic organisms. However, discharge of the pesticide is regulated by the National Pollutant Discharge Elimination System (NPDES) permit program administered by EPA. Through this program, the Agency is able to control the discharge of this pesticide and other chemicals so that toxic levels are avoided.

Endangered Species

The high exposure scenarios described above exceed the levels of concern for endangered aquatic organisms. In addition, the typical EEC value for pulp and paper mills exceeds the level of concern for endangered aquatic invertebrates. Effluent containing this active ingredient should not

be discharged into streams or waterways where endangered aquatic organisms are known to reside. EPA is working with the U.S. Fish and Wildlife Service to develop a program to avoid jeopardizing the continued existence of identified species by the use of pesticides. When this program goes into effect, endangered species labeling will be required.

Additional Data Required

The generic data base for 2-(hydroxymethyl)-2-nitro-1,3-propanediol is substantially complete. However, for confirmatory purposes, EPA is requiring acute inhalation and eye irritation studies using the technical grade powder formulation, a post-application inhalation exposure worker monitoring study, and a hydrolysis study. EPA also is requiring product-specific data, including chemistry, acute toxicology and efficacy studies, as well as revised labeling for reregistration.

Product Labeling Changes Required

All end-use products containing 2-(hydroxymethyl)-2-nitro-1,3-propanediol must comply with EPA's current pesticide product labeling requirements. In addition:

- **Effluent Discharge Statement** - All end-use products for indoor non-food uses (industrial uses which discharge effluent), aquatic non-food industrial uses, or terrestrial non-food uses must bear the following effluent discharge statement:

  "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public 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 EPA."

- **Use Site PPE Requirements and Entry Restrictions**

  • In poultry/livestock premises, preservative and pulp and paper mills, the PPE requirement for mixer/loader/applicators is:

  "Pesticide handlers must wear:

  --Long-sleeved shirt and long pants

  --Chemical-resistant gloves

  --Shoes plus socks

  In addition, when engaged in pouring this product,

  --A respirator with either an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)."

• For metal working fluids and cooling tower water uses, the PPE requirement for mixer/loader/applicators is:

"Pesticide handlers must wear:

--Long-sleeved shirt and long pants

--Chemical-resistant gloves

--Shoes plus socks"

• In poultry/livestock premises, post-application workers must observe the following use restriction on the labeling in the directions describing use as a disinfectant spray:

"Entry by any person--other than a correctly equipped handler--is PROHIBITED in the entire enclosed building/structure from the start of application until aeration reduces the air concentration level of formaldehyde in the working area to less than 0.75 ppm. The air level concentration of formaldehyde must be measured before entry is permitted. (OSHA issued a final rule for the PEL for formaldehyde as 0.75 ppm, May 27, 1992, Federal Register, Vol. 57, p. 22290.) Any handler who enters the treated area during this entry-restricted period must wear:

--Long-sleeved shirt and long pants

--Shoes plus socks

--A respirator with either an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)."

Regulatory Conclusion

The currently registered uses of 2-(hydroxymethyl)-2-nitro-1,3-propanediol may pose low level cancer risks to workers from the degradate formaldehyde, and could pose risks to aquatic organisms under certain conditions as industrial effluent containing the parent chemical is released into receiving waters. However, the uses will not cause unreasonable adverse effects to humans or the environment, and are eligible for reregistration.

Products containing 2-(hydroxymethyl)-2-nitro-1,3-propanediol as the sole active ingredient will be reregistered once the required product-specific data and revised labeling are received and accepted by EPA. Products also containing other active ingredients will be reregistered only after the other active ingredients also are determined to be eligible for reregistration.

For More Information

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

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

For more information about EPA's pesticide reregistration program, the Tris(hydroxymethyl)nitromethane RED, or reregistration of individual products containing the active ingredient 2-(hydroxymethyl)-2-nitro-1,3-propanediol, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 6:00 pm Central Time, Monday through Friday.

REREGISTRATION ELIGIBILITY DECISION

TRIS(HYDROXYMETHYL)NITROMETHANE

LIST C

CASE 3149

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

TABLE OF CONTENTS

2-(HYDROXYMETHYL)-2-NITRO-1,3-PROPANEDIOL REREGISTRATION ELIGIBILITY TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Gabe Patrick	Biological Analysis Branch
Michele Pethel	Biological Analysis Branch
Cynthia Szymanski	Biological Analysis Branch

Environmental Fate and Effects Division

Jose Luis Melendez	Environmental Fate and Groundwater Branch
Richard Lee	Ecological Effects Branch
Jean Holmes	Science Analysis and Coordination Staff

Health Effects Division

Winston Dang	Occupational and Residential Exposure Branch
Jane Smith	Chemical Coordination Branch
Flora Chow	Chemical Coordination Branch
Edwin Budd	Toxicology Branch I

Registration Division

Doreen Aviado	Antimicrobial Program Branch
Valdis Goncarovs	Antimicrobial Program Branch
Bipin Gandhi	Registration Support Branch
Mark Perry	Registration Support Branch

Special Review and Reregistration Division

Ernestine Dobbins	Accelerated Reregistration Branch
Kathy Davis	Accelerated Reregistration Branch

Policy and Special Projects Staff

Brian Hirsh

Office of General Counsel:

Debbie Mack

Office of Compliance Monitoring:

Beverly Updike

Office of Research and Development:

Elaine Francis

Office of Water:

Donna Reed

GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
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
GRAS	Generally Recognized As Safe as designated by FDA
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOEL	Lowest Observed Effect Level
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake

GLOSSARY OF TERMS AND ABBREVIATIONS

MOE	Margin Of Exposure (PAD)
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts Per Million
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RED	Reregistration Eligibility Decision
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The dose at which a substance produces a toxic effect.
TMRC	Theoretical Maximum Residue Contribution.

EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (hereafter referred to as "the Agency") has conducted a review of the available scientific data and other relevant information supporting the reregistration of the pesticide active ingredient 2-(hydroxymethyl)-2-nitro-1,3-propanediol.

This Reregistration Eligibility Decision (RED) addresses the reregistration of products containing 2-(hydroxymethyl)-2-nitro-1,3-propanediol for currently registered uses. Pesticide products containing this active ingredient are used as a microbicide and bacteriostat in disinfectants and preservatives. It is formulated as a powder, as pellets and as a soluble liquid concentrate. It is applied to livestock and poultry premises by using a spray application method, and to metalworking cutting fluids, latex paints, drilling muds and packer fluids, pulp/paper mill systems, and evaporative condenser water systems by using metering pump or pouring application methods. The Agency has determined that the uses of 2-(hydroxymethyl)-2-nitro-1,3-propanediol as currently registered may pose low carcinogenic risks to workers from the degradate formaldehyde and could pose risks to aquatic organisms under certain conditions from the release of 2-(hydroxymethyl)-2-nitro-1,3-propanediol in industrial effluent into receiving waters. However, the Agency concludes that the uses will not cause unreasonable risk to human health or the environment and these uses are eligible for reregistration.

Accordingly, the Agency has determined that all products containing the single active ingredient 2-(hydroxymethyl)-2-nitro-1,3-propanediol are eligible for reregistration and will be reregistered when acceptable labeling and product-specific data are submitted and/or cited. Before reregistering each product, the Agency is requiring that product-specific data be submitted by the registrants within eight months of the issuance of this document. Additionally, in order to remain in compliance with FIFRA, it is the Agency's position that revised labeling must be submitted by the registrants within that same time period. After reviewing these data the Agency will determine whether the conditions and requirements of FIFRA section 3(c)5 have been met for the reregistration of these products. Products containing other active ingredients subject to reregistration will be reregistered only after each active ingredient has been reregistered.

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 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 2-(hydroxymethyl)-2-nitro-1,3-propanediol. The document consists of six sections. Section I is the introduction. Section II describes 2-(hydroxymethyl)-2-nitro-1,3-propanediol, 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 2-hydroxymethyl-2-nitro-1,3-propanediol. Section V discusses the reregistration requirements for products containing this active ingredient. 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.[1]

---

[1] EPA's reviews of data on the set of registered uses considered for EPA's analysis may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.

II. CASE OVERVIEW

A. Chemical Overview

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

- Chemical Name: 2-(hydroxymethyl)-2-nitro-1,3-propanediol
- Chemical Family: Tris(HOCH2-)nitromethane
- CAS Registry Number: 126-11-4
- OPP Chemical Code: 083902
- Empirical Formula: $C_4H_9NO_5$
- Structural Formula:

$$HO\text{-}CH_2\text{-}C(NO_2)\text{-}CH_2\text{-}OH$$
$$CH_2\text{-}OH$$

- Trade and Other Names: Tris-Nitro; Cimcool wafers; Tris(hydroxymethyl)nitromethane; Nitroisobutylglycerol;Trimethylolnitromethane; Nitrotris(hydroxymethyl)methane
- Basic Manufacturer: Angus Chemical Company

B. Use Profile

The following is information on the current registered uses with an overview of use sites and application methods. A detailed table of the use of 2-(hydroxymethyl)-2-nitro-1,3-propanediol is in Appendix A.

Type of Pesticide: Disinfectant (general); microbicide/microbiostat (slime-forming bacteria and fungi); fungicide/fungistat; fungicide; industrial preservative/preservative (bacteriostat).

Use Sites: **Terrestrial non-food:**
oil recovery drilling muds/packer fluids (preservatives)

Aquatic non-food industrial:
pulp/papermill water systems; commercial/industrial water cooling systems; evaporative condenser water systems; secondary oil recovery injection water; oil recovery drilling muds/packer fluids (preservatives)

Indoor non-food:
metalworking cutting fluids; oil recovery drilling muds/packing fluids (preservatives); latex paints (in-can preservative); specialty industrial products-packaged; resin/latex/polymer emulsions. (emulsions, solutions, or suspensions such as detergents and polishes containing water); livestock premises and poultry premises.

Target Pests: Disinfectant for disease organisms found on farm premises and equipment. Bacteriostat, microbicide/microbiostat for the following organisms: aerobic slime-forming bacteria (Pseudomonas spp.), anaerobic sulfate-reducing bacteria, such as Desulfovibrio desulfuricans.

Formulation Types Registered:

Technical grade active ingredient, manufacturing use, end use

Soluble concentrate/liquid, soluble concentrate/solid, pelleted/tableted, crystalline

(19.2 - 100% active ingredient)

Method and Rates of Application:

Types of Treatment-

Industrial preservative treatment, water treatment, water recirculating system treatment, premise treatment, transportation vehicle treatment, animal equipment treatment

Equipment - sprayer, metering pump

Method and Rate - Indoor Non-food:

Metalworking cutting fluids: 313-2500 ppm a.i. by volume

Latex paints: 1000-5000 ppm a.i. by weight

Resin/latex/polymer emulsions: 100-5000 ppm a.i. by weight

Specialty industrial products: 500-1000 ppm a.i. by weight

Livestock and poultry premises: 1500 ppm a.i. by volume

Method and Rate - Aquatic non-food industrial:

Commercial/industrial water cooling systems and evaporative condenser water systems: 8-500 ppm a.i. by volume; 10 to 609 ppm by weight

Pulp and paper mill water systems: 570 to 2540 ppm a.i. by weight

Oil recovery drilling muds/packer fluids: 63-500 ppm a.i. by volume

Secondary oil recovery injection water: 476-952 ppm a.i. by volume; 580 ppm to 1159 ppm by weight

Timing - As needed; during manufacture; initial, continuous and intermittent feed

Use Practices Limitations:

The following use practice limitations are currently on labeling for these products:

"Decomposition occurs in the presence of alkaline materials. Protect from vapors of ammonia and amine during handling and storage to prevent deterioration and release of formaldehyde. All treated animal feed appliances must be thoroughly scrubbed with detergent and rinsed with potable water prior to reuse. Ventilate building, vehicles, and other closed spaces. Not for use in California in one, two, or all of the following systems (depending on the label): in industrial recirculating water systems, in pulp and paper mill process water systems, or as a preservative in packaged emulsion, solutions, or suspensions such as detergents and polishes containing water."

"Do not use in milking stalls, milking parlors, or milk houses. Remove all animals, poultry, eggs, or chicks and feeds from buildings, vehicles, coops, crates, and enclosures. Do not house poultry or livestock, introduce eggs or chicks, or employ equipment until treatment has been absorbed, set, or dried. Do not discharge effluent containing this

pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction)."

C. Regulatory History

2-(hydroxymethyl)-2-nitro-1,3-propanediol was first registered in the United States in 1955 as an active ingredient for use in industrial bacteriocide and slimicide products. Currently, nine products are registered for use in metalworking fluids systems, oil field systems, cooling water systems, papermills, and livestock areas as a preservative, as a disinfectant and as a formulating technical material. Three Data Call-In Notices for 2-(hydroxymethyl)-2-nitro-1,3-propanediol have been issued. The Antimicrobial Data Call-In of March 4, 1987, required toxicology data and data on applicator exposure to antimicrobial pesticide active ingredients in a variety of industrial, commercial, consumer, and other applications and settings. An industry consortium generated a single exposure study to cover multiple use patterns for a group of chemicals for consortium members. This applicator exposure study (MRID 41412201) was commissioned by the Chemical Manufacturers Association and the study has fulfilled this data requirement. The second Data Call-In was the comprehensive reregistration Phase 4 Data Call-In of September 30, 1992, in which chemistry, ecotox data, hydrolysis and residue data were required. The third Data Call-In was issued August 9, 1993 for residue data in edible livestock tissues or, in lieu of data, label changes could be made to eliminate all possible means of exposure from this use. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to reregistration.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

2-(hydroxymethyl)-2-nitro-1,3-propanediol is an odorless, white solid which melts at 175-176° C with decomposition. It is soluble in polar solvents such as water, methanol, ethanol, and isopropanol, but insoluble in non-polar solvents like aliphatic and aromatic hydrocarbons. This chemical is stable only under acidic conditions of pH 5.0 and below, and is unstable and decomposes to formaldehyde under alkaline conditions and at temperatures above 49° C.

B. Human Health Assessment

1. Toxicology Assessment

The toxicology data base for 2-(hydroxymethyl)-2-nitro-1,3-propanediol is adequate for reregistration eligibility. Toxicity studies indicate 2-(hydroxymethyl)-2-nitro-1,3-propanediol has low acute toxicity and that there are no toxicological concerns associated with this active ingredient per se that lead to significant concerns. The Agency has also determined, however, that the degradate of the active ingredient, formaldehyde, poses a concern.

Other than the acute inhalation and eye irritation studies using the 100% technical grade powder, the Tier I studies (guidelines 82-3, 90-day dermal; 83-3, developmental toxicity; and 84-2, mutagenicity battery) required for antimicrobial type active ingredients have been satisfied. The acute inhalation (rat) and eye irritation (rabbit) studies using the technical grade powder (100%) are required as confirmatory data for the reasons discussed below.

a. Acute Toxicity

The acute studies were conducted on the 53.1 - 56.8% 2-(hydroxymethyl)-2-nitro-1,3-propanediol aqueous concentrate solution. The table presented below summarizes the results of the acute studies and is intended for general reference only.

TABLE I. Acute Toxicity

Test	Result	Category
Acute Oral LD_{50} (rat)[1]	1890 mg/kg (m) 1860 mg/kg (f)	III
Acute Dermal LD_{50} (rabbit)[2]	> 2000 mg/kg	III
Acute Inhalation LC_{50} (rat)[3]	2.4 mg/liter	III
Eye Irritation (rabbit)[4]	slight irritation	IV
Dermal Irritation (rabbit) [5]	non-irritating	IV
Skin Sensitization (guinea pig) [6]	negative	n/a

1 MRID 094711
2 00043222/00094713
3 00094711
4 00094711
5 00094715/00109228
6 00094715
n/a = not applicable

Acute toxicity studies were not conducted using the technical grade powder (100%). Additional acute inhalation (rat) and the eye irritation (rabbit) studies are required using the 2-(hydroxymethyl)-2-nitro-1,3-propanediol technical grade powder form since this form may present the greater potential exposure, hence risk, as compared with the wafer or pellet forms. The aqueous solution is not an appropriate dosage form for these studies. These two studies, although required by the Agency, are considered to be confirmatory because the acute toxicology data base suggest 2-(hydroxymethyl)-2-nitro-1,3-propanediol has low acute toxicity to mammals.

b. Subchronic Toxicity

In a 90-day subchronic dermal toxicity study, male and female Crl:CD BR rats were treated dermally for 6 hours per day, 5 days per week with a paste of 2-(hydroxymethyl)-2-nitro-1,3-propanediol in deionized water. Dosage levels were 0, 250, 500 and 1000 mg/kg/day. The test material was essentially non-irritating to the skin, although yellowish discoloration was noted at test sites. There were no treatment-related effects observed at any dosage level. The NOEL for systemic toxicity is $\geq$ 1000 mg/kg/day. (MRID 41021101)

c. Developmental Toxicity

A developmental toxicity study was conducted with pregnant Sprague Dawley Crl:CD BR rats which were administered daily doses of 0, 50, 375 or 750 mg/kg/day of 2-(hydroxymethyl)-2-nitro-1,3-propanediol by gavage on days 6 through 15 of gestation. Treatment-related maternal effects were observed only in the high-dose group and included: (1) increased mortality (7/25 or 28% of the group), (2) decreased mean body weight gain, and (3) clinical signs of toxicity (including head bobbing, tremors, and circling motions). A treatment-related developmental effect, observed at 375 mg/kg/day and 750 mg/kg/day, was increased mean number of resorptions per dam. At 750 mg/kg/day, fetal body weights were also reduced. Therefore, the NOEL and LOEL for maternal toxicity are 375 mg/kg//day and 750 mg/kg/day, respectively. The NOEL and LOEL for developmental toxicity are 50 mg/kg/day and 375 mg/kg/day, respectively. A slightly increased incidence of omphalocele in the 750 mg/kg/day fetuses in this study, when compared to historical control data, suggested the possibility of an additional developmental effect. (MRID 41021102/41089301)

In a second developmental toxicity study, pregnant New Zealand white rabbits were administered daily doses of 0, 10, 30 or 75 mg/kg/day of 2-(hydroxymethyl)-2-nitro-1,3-propanediol by gavage on days 7 through 19 of gestation. Treatment-related maternal effects were observed only in the high-dose group and included: (1) decreased mean body weight gain, and (2) decreased mean food consumption. No treatment-related developmental effects were observed in the study. One omphalocele was observed in the control group and one in the 75 mg/kg/day group. This finding was not considered to be treatment-related. Therefore, the NOEL and LOEL for maternal toxicity are 30 mg/kg/day and 75 mg/kg/day respectively. The NOEL for developmental toxicity is $\geq$ 75 mg/kg/day. (MRID 42303501)

d. Mutagenicity

A Salmonella typhimurium reverse mutation assay (Ames assay) was conducted using 2-(hydroxymethyl)-2-nitro-1,3-propanediol as the test material. Strains TA98, TA100, TA1535, TA1537 and TA1538 were tested without and with S9 metabolic activation. No increases in reverse mutations were observed at concentrations up to 1000 ug/plate. (MRID 41058101)

2-(hydroxymethyl)-2-nitro-1,3-propanediol was tested in a chromosomal aberration assay using Chinese Hamster Ovary (CHO) cells

in vitro without and with metabolic activation up to a cytotoxic level of 2000 ug/ml. The study was negative for induction of chromosomal aberrations. (MRID 41944301)

2-(hydroxymethyl)-2-nitro-1,3-propanediol was also tested in an unscheduled DNA damage/repair in vitro study using primary rat hepatocytes at concentrations up to 10,000 ug/ml. The test was negative for inducing unscheduled DNA synthesis. (MRID 41944302)

e. Other Toxicity Considerations

The rat oral developmental toxicity study (MRID 41021102/ 41089301) has not been selected as an endpoint for assessing acute dermal worker exposure to the parent compound 2-(hydroxymethyl)-2-nitro-1,3-propanediol because the NOEL for developmental toxicity via the oral route likely overstates the actual hazard. This conclusion is based on the large gap between the developmental NOEL in the study of 50 mg/kg/day and the LOEL of 375 mg/kg/day for resorptions which were observed at an incidence only slightly higher than that of control values. In addition, the lack of toxicity of 2-(hydroxymethyl)-2-nitro-1,3-propanediol when administered to the rat by the dermal route (the most likely route of worker exposure or human exposure since there are no food uses for this chemical) at a dose of 1000 mg/kg/day (limit dose) for 90 days (MRID 41021101, 932200211) strongly suggests that the dermal absorption of the test material is limited. In contrast, the test material was maternally toxic by the oral route in the developmental toxicity study (NOEL of 375 mg/kg/day and LOEL of 750 mg/kg/day) which incorporated a much shorter dosing period.

The antimicrobial properties of 2-(hydroxymethyl)-2-nitro-1,3-propanediol are due in large part to the slow release over time of formaldehyde (HCHO) from the active ingredient under alkaline conditions. The rate of release is highly dependent on the pH of the solution and on the temperature (the higher the pH of the solution and/or the higher the temperature, the faster the release). Since formaldehyde has significant toxic effects of its own, and has also been classified by the Agency as a Group B1 (probable human) carcinogen, the toxicity of formaldehyde is a primary consideration in evaluating the toxicity of 2-(hydroxymethyl)-2-nitro-1,3-propanediol and performing the risk assessment.

f. Reference Dose

The Agency has not established a Reference Dose (RfD) for 2-

(hydroxymethyl)-2-nitro-1,3-propanediol, because it has no food/feed uses and no subchronic or chronic oral toxicity studies other than developmental toxicity studies in rats and rabbits are available from which to derive an RfD.

2. Exposure Assessment

a. Dietary

No dietary exposure is expected as a result of registered uses. There is one disinfectant use that was identified as a food use during the reregistration process: treatments in/on livestock premises/equipment. No tolerances exist for residues of 2-(hydroxymethyl)-2-nitro-1,3-propanediol in meat, milk, eggs, or poultry. Presently, this disinfectant use has been modified on the label by the registrant deleting the milk house and milking equipment uses. The poultry house uses are maintained with explicit label restrictions reflecting established Agency nonfood use policies eliminating the means of exposure of edible livestock tissues or eggs to 2-(hydroxymethyl)-2-nitro-1,3-propanediol; therefore, no residue data, tolerances or exemptions from tolerances are required.

b. Occupational and Residential

2-(hydroxymethyl)-2-nitro-1,3-propanediol is formulated as a powder, as solid pellets or as a soluble concentrate liquid. It is applied to livestock/poultry equipment by using a spray application method. It is used in metal cutting fluids, drilling muds and packer fluids, pulp/paper mill systems, and evaporative condenser water systems by using metering pump or pouring application methods. The active is used as a preservative in paints, emulsions, and thickeners. Under alkaline conditions, this compound degrades to form formaldehyde which enhances its antimicrobial properties.

2-(hydroxymethyl)-2-nitro-1,3-propanediol has many uses that may involve exposure to workers. This compound meets the Agency's exposure criteria for requiring exposure monitoring data due to the presence of, or degradation to formaldehyde. These data requirements for mixer/loader/applicator can be met by the Chemical Manufacturers Association (CMA) exposure assessment database (MRID 41412201). The exposure to this compound by workers can be represented by five of the uses: paint preservative, pulp and paper mill, cooling tower water, metal cutting fluids and livestock/poultry premises disinfectant. This database was used to *estimate mixer/loader/applicator combined inhalation and dermal exposure* based on the type of application (e.g., pour solids, low

pressure spray) and the uses in pulp and paper mill water, in cooling tower water, in metal cutting fluids, as a preservative in paints and in livestock/poultry premises as a disinfectant. These exposure estimates are provided in Tables II. and III. below.

For the poultry/livestock disinfectant use, the total exposure was determined for formaldehyde as a result of the degradation of 2-(hydroxy methyl)-2-nitro-1,3-propanediol to formaldehyde and from the formaldehyde present as an active ingredient.

Mixers/Loaders/Applicators Exposure Assessment - 2-(hydroxymethyl)-2-nitro-1,3-propanediol

Preservative and pulp and paper mill use - The mixer/loader/applicator exposure is considered significant for these uses (see Table II). The exposure concern associated with using open pouring methods (of this solid material) for pulp and paper systems and paint preservatives can be reduced *ten-fold* by using a respirator and personal protective equipment (PPE).

Poultry/livestock disinfectant - The mixer/loader/applicator exposure is considered low for this low pressure disinfectant spray use (see Table III); however, PPE and a respirator would reduce potential exposure to mixer/loader/applicators from formaldehyde.

Cooling tower and metal cutting fluids - The mixer/loader/applicator exposure is considered very low for these uses (see Table II); however, PPE would reduce potential exposure from formaldehyde.

TABLE II. Average Daily Dose (or Exposure) Using the Pure Solid (100% active ingredient [a.i.]) 2-(hydroxymethyl)-2-nitro-1,3-propanediol

POUR SOLIDS							
Setting	MCS[1] (ug/lb ai)	lb ai used	lb ai/ yr	BW[2] (kg)	Daily Exp.[3]	Annual Exp.[4]	ADD[5]
Preser-vative	14310	2	500	70	408.86	102,214	280.04
P&P Mills	14310	50.8	1321	70	10,385	270,009	739.75
Cooling Tower	630	25.4	660	70	228.6	5,940	16.27
Metal Fluid	14310	7.6	92	70	1,554	18,807	51.53

1 MCS = Maximum Credible Sum was derived from CMA Study.
2 BW = Body Weight
3 Daily Exposure (ug/kg/day) = (MCS X lb ai/used)/BW
4 Annual Exposure (ug/kg/yr) = (MCS X lb ai used/yr)/BW
5 ADD (ug/kg/day) = Annual Exposure / 365 days
= Amortized Average Daily Dose

Assumptions for Table II include the following maximum use rates:

(1). Use as preservative: 0.4 lbs of pure solid is added per 100 gallons of the formulation. Assume a total of 500 gallons per treatment and 250 treatments per year.

(2). Use for pulp and paper mill systems: 5.08 lbs of pure solid per ton of pulp or paper (dry basis). Assume a total of 10 tons of pulp or paper per treatment and 26 treatments per year.

(3). Use for cooling water tower systems: 5.08 lbs of pure solid is added per 1000 gallons of water. Assume a total of 5000 gallons of water per treatment and 26 treatments per year.

(4). Use for metal working fluids: 2.54 lbs of pure solid is added per 100 gallons of oil. Assume a total of 300 gallons of oil per treatment and 12 treatments per year.

TABLE III. Average Daily Dose using the Disinfectant Soluble Concentrate Liquid containing Two Active Ingredients: 19.2% 2-(hydroxymethyl)-2-nitro-1,3-propanediol and 2.28% Formaldehyde

LOW PRESSURE SPRAY							
Setting	MCS[1] (ug/lb ai)	lb ai used	lb ai/ yr	BW[2] (kg)	Daily Exp.[3]	Annual Exp.[4]	ADD[5]
Disinfectant							
2-(hydroxymethyl)-2-nitro-1,3-propanediol	24870	0.67	17.5	70	238.04	6217.5	17.03
Formaldehyde	24870	0.08	2.08	70	28.42	738.99	2.02

1 MCS = Maximum Credible Sum was derived from CMA Study.
2 BW = Body Weight
3 Daily Exposure (ug/kg/day) = (MCS X lb ai used)/BW
4 Annual Exposure (ug/kg/yr) = (MCS X lb ai used/yr)/BW
5 ADD (ug/kg/day) = Annual Exposure / 365 days
= Amortized Average Daily Dose

Assumptions for Table III:
(1) the density is 9 lb/gal for the 19.2 % a.i. solution.

(2) one ounce of this disinfectant solution is diluted by 128 oz (one gallon) of water.

(3) assume 50 gallons of such diluted solution per treatment and 26 treatments per year, the maximum use rate.

Post-Applicator Exposure Assessment - 2-(hydroxymethyl)-2-nitro-1,3-propanediol

Post-application worker exposure to the active ingredient, 2-(hydroxymethyl)-2-nitro-1,3-propanediol, is minimal for <u>all</u> uses. However, given its degradation to formaldehyde this must be considered.

Based on the available information from the literature, at 25°C and pH 7.5, the dissociation rate of 2-(hydroxymethyl)-2-nitro-1,3-propanediol in aqueous phosphate solution is less than 10% in the first 5 days. Higher alkalinity and temperature increase the rate of conversion to and percent of formaldehyde. The release of 2 moles of formaldehyde from one mole of 2-(hydroxymethyl)-2-nitro-1,3-propanediol is shown below:

$(CH_2OH)_3CNO_2 \xrightarrow{OH^-} 2\ CH_2O$ + unidentified products

(unidentified products could be, e.g., nitroethanol is unstable and could decompose to nitroethene and water).

The mixer/loader/applicator exposure to formaldehyde was estimated using the average daily dose (ADD), or exposure, estimated for mixers/loaders/applicators for 2-(hydroxymethyl)-2-nitro-1,3-propanediol and assuming a 10% degradation to formaldehyde (see Table IV).

TABLE IV. The Average Daily Dose of Formaldehyde Based on a 10% Conversion from 2-(hydroxymethyl)-2-nitro-1,3-propanediol and the Exposures from Tables II, and III for All Uses

Setting	ADD 2-(hydroxymethyl)-2-nitro-1,3-propanediol (ug/kg/day)	10% ADD 2-(hydroxymethyl)-2-nitro-1,3-propanediol (ug/kg/day)	ADD Formaldehyde[A] (ug/kg/day)
Preservative	280.04	28.0	12
P & P Mills	739.75	73.97	31.8
Cooling Tower	16.27	1.63	0.69
Metal Fluid	51.53	5.15	2.2
Disinfectant (two actives)	17.03	1.7	0.70 +
	-	-	2.02[B] = 2.72

A As discussed above, 1 mole of 2-(hydroxymethyl)-2-nitro-1,3-propanediol forms 2 moles of formaldehyde. The ADD for formaldehyde is calculated as follows, e.g. (28.0 ug/kg/day / molecular weight of formaldehyde) X 2 moles of formaldehyde = 12 ug/kg/day formaldehyde for the preservative use.

B The ADD for formaldehyde from Table III.

Preservative, pulp and paper mills - The mixer/loader/applicator exposure to formaldehyde for these uses should be brief (e.g., less than one hour for each treatment) since only a small amount, if any, degradation from 2-(hydroxymethyl)-2-nitro-1,3-propanediol to formaldehyde should occur in that short interval. However, the exposure to 2-(hydroxymethyl)-2-nitro-1,3-propanediol is considered significant for these uses. Thus, personal protective equipment is required as well as a respirator. Therefore, what exposure to formaldehyde that might have occurred is reduced *ten-fold* by using personal protective equipment and a respirator.

Cooling towers and metal cutting fluids - Since the time needed for loading 2-(hydroxymethyl)-2-nitro-1,3-propanediol products for these uses should be brief (e.g. less than an hour for each treatment), the potential exposure to the mixer/loader/applicator to 2-(hydroxymethyl)-2-nitro-1,3-propanediol and formaldehyde will be of relatively short duration. Additionally, only a small amount, if any, of degradation from 2-(hydroxymethyl)-2-nitro-1,3-propanediol to formaldehyde should occur in that short interval. For these reasons, the use of a respirator would not

be an advantage.

Poultry/livestock disinfectant - The Agency is concerned about potential exposure of mixer/loader/applicator to formaldehyde for this use since formaldehyde is already present as an active ingredient in the product and the application involves a spray method. These workers are also exposed to the concentrated active ingredients during mixing of the diluted spray solution. Use of a respirator and PPE would result in a *ten-fold* reduction in the exposure.

Post-Application Worker Exposure - Formaldehyde

Preservative use, cooling tower, and metal cutting fluids - Post-application worker exposure to formaldehyde from the degradation of 2-(hydroxymethyl)-2-nitro-1,3-propanediol is minimal for the cooling tower use, the preservative use, and the cutting fluid use because the degradation conditions, i.e. the very alkaline conditions in combination with high temperature, are not likely to occur in these use situations.

Poultry/livestock disinfectant - Post-application worker exposure to formaldehyde can be expected as a result of the use of the disinfectant spray in livestock/poultry premises, because formaldehyde is an active ingredient in this disinfectant spray and the 2-(hydroxymethyl)-2-nitro-1,3-propanediol will slowly degrade to formaldehyde. Therefore, post-application inhalation exposure is of particular concern. Post-application monitoring data requirements for formaldehyde are being addressed for poultry houses under the reregistration data call-in for formaldehyde.

Although the post-application worker exposure is of concern for the poultry/livestock disinfectant use, the mixer/loader/applicator estimate actually represents the worst case scenario of exposure. The post-application worker in the poultry/livestock building is not exposed to the concentrated product (used for mixing) or the spray application of the formaldehyde. In addition, part of the application process is to rinse all treated surfaces with potable water approximately 10 minutes following spray application. Products containing formaldehyde as the active ingredient for this use are also regulated by the Occupational Safety and Health Administration (OSHA) which requires monitoring for formaldehyde before workers enter the premises following treatment. The OSHA Permissible Exposure Limit (PEL) for formaldehyde is 0.75 ppm. Therefore, the post-application worker exposure is the same as (or less than) that of the mixers/loaders/applicators for the disinfectant use. PPE and respirators are required for workers entering the treated areas before air level concentrations for formaldehyde have been measured.

Pulp and paper mills - Post-application worker exposure to formaldehyde can be expected as a result of the use of 2-(hydroxymethyl)-2-nitro-1,3-propanediol products in pulp and paper mills. The post-application worker exposure to formaldehyde can be estimated for a lifetime based on the average daily dose: ADD X work years/years (life expectancy); or, 0.0029 mg/kg/day X 35 work years/70 years (life expectancy) = 0.00145 mg/kg/day = LADD.

In calculating the ADD, the Agency considered converting 10% of the active to formaldehyde; the concentration in pulp mixture; determining the vapor concentration of formaldehyde (if all of the formaldehyde converted to the vapor phase); the inhalation rate for an average worker; the total formaldehyde inhaled during an 8 hour work day; and the lifetime working exposure. These and other assumptions include:

1) the temperature is 25°C and the pH is 7.5,
2) the slow degradation for 2-(hydroxymethyl)-2-nitro-1,3-propanediol, i.e. only 10% in water is converted into the formaldehyde,
3) a total of 50.8 pounds of 2-(hydroxymethyl)-2-nitro-1,3-propanediol is added into the pulp mills,
4) 10 tons of pulp was treated with this compound and approximately 10 million gallons of water (37.8 million liters) are used,
5) the molecular weight of 2-(hydroxymethyl)-2-nitro-1,3-propanediol is 151 and the molecular weight of formaldehyde is 30,
6) an alkaline solution where one mole of 2-(hydroxymethyl)-2-nitro-1,3-propanediol is converted to 2 moles of formaldehyde,
7) the partial vapor pressure of formaldehyde at 760 mmHg, 25°C, and a concentration of 0.02419 mg/L in water can be converted to vapor concentration at 0.0177 mg/m^3,
8) the worker body weight of 70 kg, working at the area for 8 hours/day, 5 days a week, 250 days/year, at an inhalation rate of 16.8 m^3 of air were inhaled/day, and
9) lifetime exposure is 35 years in a lifetime of 70 years.

This determination of post-application exposure is conservative since factors resulting in dilution of the formaldehyde concentration were not considered; e.g., the pulp mixture is generally not stationary and there are ventilation systems in mills. Since this is a very conservative estimate of the post-application worker exposure and the Agency may have overestimated worker exposure, a post-application inhalation exposure monitoring study is required for uses in pulp and paper mill systems. These data are considered confirmatory by the Agency. This study will provide the Agency with a more accurate estimation of potential post-application exposure to workers.

The labeling to protect workers is contained in Section V at the end of this document.

3. Risk Assessment

a. Dietary

There are no food uses associated with the use of 2-(hydroxymethyl)-2-nitro-1,3-propanediol; therefore, no dietary risk assessment was conducted by the Agency.

b. Occupational and Residential

Overall, there is minimal risk associated with the active ingredient, 2-(hydroxymethyl)-2-nitro-1,3-propanediol. The exposure to this active ingredient for mixers/loaders/applicators is minimal and there are no toxicological concerns associated with this chemical that lead to significant risk concerns.

The risk of concern associated with the use of products containing 2-(hydroxymethyl)-2-nitro-1,3-propanediol is due to the degradation product, formaldehyde, which is slowly released from the active ingredient under alkaline conditions and the presence of formaldehyde as an active ingredient in one product.

For details on the effects and risks associated with formaldehyde, the following EPA documents should be consulted:

Assessment of Health Risks to Garment Workers and Certain Home Residents from Exposure to Formaldehyde, Office of Pesticides and Toxic Substances, U.S.E.P.A., April, 1987, pp. 7-1 to 7-11.

Formaldehyde Risk Assessment Update, Final Draft, Office of Toxic Substances, U.S.E.P.A., June 11, 1991.

Guidance for the Registration of Pesticide Products Containing Formaldehyde and Paraformaldehyde as the Active Ingredient, Office of Pesticides and Toxic Substances, Office of Pesticide Programs (OPP), U.S.E.P.A., May 31, 1988.

In the 1987 risk assessment, the administered dose was expressed as ambient air concentration (formaldehyde concentration in ppm) and was used directly as the measure of dose in the risk assessment. In the 1991 risk assessment, the administered dose was expressed as an intracellular

dose, which was derived from a measurement of the amount of DNA-protein crosslinking (DPX) in the nasal target cells themselves. The 1991 document presented scientific evidence derived from studies in rats and monkeys and a rationale which suggested that use of the DPX data would provide a more meaningful measure of dose to the target tissue than the ambient air concentration and, in turn, would lead to a more accurate risk estimate. Also, the 1987 assessment utilized a lifetime average daily exposure adjustment, whereas the 1991 assessment did not.

For the purpose of estimating carcinogenic risks to humans, the 1987 document derived an airborne upper bound incremental unit risk of 1.6×10^{-2} per ppm (lifetime individual risk, based on continuous exposure for 70 years). The 1991 document derived comparable unit risks of 2.8×10^{-3} per ppm and 3.3×10^{-4} per ppm based on the rat and monkey DPX data, respectively (for formaldehyde concentrations below 0.3 ppm). These unit risks are 6 to 50 times lower than those calculated in 1987. The Agency believed the risk for humans most likely was between that for rats and monkeys.

In 1991, the EPA Science Advisory Board (SAB) was asked to comment on the novel 1991 DPX methodology for calculating carcinogenic risks for formaldehyde. The SAB response (in 1992) expressed reservations regarding the use of the 1991 methodology and particularly use of the monkey DPX data for this purpose. Consequently, there is considerable uncertainty at this time regarding the use of the 1991 risk assessment methodology and the 1991 document; a "final draft", has not yet been "finalized." In the interim, prudence dictates that the 1987 methodology should be used for formaldehyde risk assessments.

In 1988, EPA published a Registration Standard for pesticide products containing formaldehyde and paraformaldehyde. In that Registration Standard, carcinogenic risks to agricultural workers were calculated based on the risk assessment methodology presented in the 1987 OPTS document referenced previously in this chapter. In the 1988 Registration Standard, a Q_1^* of 1.87×10^{-2} $(mg/kg/day)^{-1}$ was used to calculate carcinogenic risks for agricultural workers. Using this same Q_1^* and methodology, the estimate of carcinogenic risks associated with the five use patterns for 2-(hydroxymethyl)-2-nitro-1,3-propanediol are calculated as follows:

$$\text{Carcinogenic Risk} = Q_1^* \times \text{LADD}$$

The LADD is determined for the five representative uses by multiplying the Average Daily Dose (ADD) for formaldehyde for each use

times the fraction of lifetime exposed, i.e. 35 work years / 70 years (life expectancy). The LADDs for the five use patterns of 2-(hydroxymethyl)-2-nitro-1,3-propanediol are provided in Table V. below.

TABLE V. Lifetime Average Daily Dose (LADD) of Formaldehyde for Five Representative Use Patterns for Mixers/Loaders/Applicators

Representative Use Pattern	ADD Formaldehyde (mg/kg/day)[1]	LADD Formaldehyde (mg/kg/day)
Preservative	0.012	0.006
Wood P & P	0.032	0.016
Cooling Tower	0.00069	0.00035
Metal Fluid	0.0022	0.0011
Disinfectant (poultry/livestock)	0.0027	0.0014

[1] derived from the 10% conversion of the active ingredient to formaldehyde.

Using these LADD estimates and the Q_1^* cited above, the upper bound increase in carcinogenic risk for each representative use pattern, based on mixer/loader/applicator exposure to formaldehyde, is derived. These estimated excess carcinogenic risks are presented below (Table VI).

TABLE VI. Upper bound Excess Carcinogenic Risk Estimates for Mixers/Loaders/Applicators from Exposure to Formaldehyde without PPE and respirators

Use Pattern	Excess Carcinogenic Risk
Preservative	1.1×10^{-4}
Wood Pulp & Paper	3.0×10^{-4}
Cooling Tower	6.5×10^{-6}
Metal Cutting Fluids	2.1×10^{-5}
Disinfectant (poultry/livestock)	2.5×10^{-5}

The actual exposure to formaldehyde is expected to be less than the values used to calculate the carcinogenic risk estimates presented in Table VI since the conversion rate of the active ingredient to formaldehyde probably would be less than 10%. In addition, mixer/loader/applicator exposure will be further mitigated by the use of personal protective equipment and respirators, which could reduce dermal and primarily inhalation exposure to airborne formaldehyde at least *ten-fold*. With the use of personal protective equipment and respirators for the pulp and paper mill use, the preservative use and the disinfectant use, the refined estimate of the upper bound increase in carcinogenic risk for each of these three representative use patterns, based on mixer/loader/applicator exposure to formaldehyde, is reduced ten-fold. See Table VII below. The metal cutting fluid uses and the cooling tower uses involve minimal exposure of mixer/loader/applicators to formaldehyde as described above in the section on exposure. If PPE, not including respirators, were used, the upperbound excess carcinogenic risk to formaldehyde would be unchanged from the risk estimates in Table VI. Respirators would not be useful in reducing exposure and risk for these two uses because of the short duration of handling the products under these use conditions, resulting in little time available for formaldehyde formation.

TABLE VII. Refined Upper bound Excess Carcinogenic Risk Estimates for Mixers/Loaders/Applicators from Exposure to Formaldehyde with PPE and Respirators

Use Pattern	Excess Carcinogenic Risk
Preservative	1.1×10^{-5}
Wood Pulp & Paper	3.0×10^{-5}
Disinfectant (poultry/livestock)	2.5×10^{-6}

Post-application worker exposure to the active ingredient, 2-(hydroxymethyl)-2-nitro-1,3-propanediol, is minimal for all uses as described above. There are no significant toxicological concerns specifically with this active ingredient or exposure concerns. The toxicological concerns and the post-application worker exposure risks are associated with formaldehyde. The risk associated with formaldehyde for post-application workers as a result of the cooling tower use, the preservative use, and the cutting fluid use is minimal, because the degradation conditions, i.e. the very alkaline conditions in combination with high temperature, are not likely.

Post-application worker exposure to formaldehyde following the livestock/poultry premise use is of some concern; however, the mixer/loader/applicator exposure estimate actually represents the worst case scenario of exposure. The post-application worker is not exposed to the concentrated product or the spray application of the formaldehyde. In addition, part of the application process is to rinse all treated surfaces with potable water approximately 10 minutes following spray application. Products containing

formaldehyde as the active ingredient for this use are also regulated by the Occupational Safety and Health Administration (OSHA) which requires monitoring for formaldehyde before workers enter the premises following treatment. The OSHA Permissible Exposure Limit (PEL) for formaldehyde is 0.75 ppm. Therefore, the post-application worker exposure and risk is the same (or less) than that of the mixers/loaders/applicators for the disinfectant use. The post-application worker upperbound excess carcinogenic risk is $\leq$ 2.5 X 10^{-6}.

Post-application worker exposure to formaldehyde can be expected as a result of the use in pulp and paper mills. The LADD is 0.00145 mg/kg/day; therefore, the upper bound excess carcinogenic risk is estimated to be 0.00145 mg/kg/day X Q^{*1} (1.87 X 10^{-2} mg/kg/day) = 2.7 x 10^{-5}. This carcinogenic risk determination is considered conservative since this exposure (LADD) does not consider dilution of the formaldehyde air concentration, the pulp mixture is generally not stationary, and there are ventilation systems in mills. A post-application inhalation exposure monitoring study is required for uses in pulp and paper mill systems, but these data are considered confirmatory.

C. Environmental Assessment

Above, in subsection B., the Agency discusses the degradation of 2-(hydroxymethyl)-2-nitro-1,3-propanediol to formaldehyde and its concerns for carcinogenic risks to workers. The Agency does not have a similar concern for environmental exposure. Although formaldehyde is slightly more toxic to aquatic organisms than is 2-(hydroxymethyl)-2-nitro-1,3-propanediol (the parent compound), the parent compound is relatively stable in the aquatic environment. As it breaks down to formaldehyde, the latter compound is rapidly dissipated. Therefore, the Agency focused its environmental risk assessment on the parent compound.

1. Environmental Fate

The Agency has assessed a hydrolysis study for 2-(hydroxymethyl)-2-nitro-1,3-propanediol, but it is not adequate to characterize the hydrolysis of this chemical. A new study is being required to confirm the rate of degradation of the active ingredient and products formed during hydrolysis. It is expected, as a result of a model exposure assessment, that this chemical when used according to the label, will pose minimal risk to the environment. The only concerns for environmental exposure, therefore, would be in the case of spills, accidents, misuse or when it may be discharged in industrial effluent under a National Pollution Discharge Effluent System (NPDES) permit. This type of discharge is discussed further below.

2. Ecological Effects

There are sufficient ecotoxicological data to characterize the toxicity of

2-(hydroxymethyl)-2-nitro-1,3-propanediol to nontarget terrestrial and aquatic organisms. The rat and rabbit toxicological data discussed above in subsection B. suggest that 2-(hydroxymethyl)-2-nitro-1,3-propanediol (53.1-56.8%) has a low order of acute oral and dermal toxicity to terrestrial mammals (acute oral LD_{50} = 1860-1890 mg/kg for rats and > 2000 mg/kg for rabbit dermal toxicity test).

The avian toxicity of the technical grade (TGAI) of 2-(hydroxymethyl)-2-nitro-1,3-propanediol, when extrapolated from the results of subacute dietary toxicity data using 50% a.i. formulated product, was found to be slightly toxic to upland game birds (>2,500 ppm) and practically non-toxic to waterfowl (>40,000 ppm). The subacute dietary data using 2-(hydroxymethyl)-2-nitro-1,3-propanediol TEP (50%), indicate that this pesticide is practically non-toxic to upland game bird species (bobwhite quail, LC_{50} greater than 5,000 ppm, (MRID 00094706)) and waterfowl species (mallard duck, LC_{50} greater than 80,000 ppm (MRID 00094707)) on a subacute dietary basis.

The available data indicate that 2-(hydroxymethyl)-2-nitro-1,3-propanediol is practically non-toxic to rainbow trout (TGAI LC_{50} = 414 ppm; TEP LC_{50} > 300 ppm (MRID 00094708)), fathead minnow (TGAI LC_{50} = 280 ppm (MRID 42205203)), and bluegill sunfish (TEP LC_{50} > 300 ppm (MRID 00094709)). Therefore, 2-(hydroxymethyl)-2-nitro-1,3-propanediol can be characterized as practically non-toxic to freshwater fish species based on acute toxicity. Data using Daphnia magna as the test species indicate that 2-(hydroxymethyl)-2-nitro-1,3-propanediol is slightly toxic to freshwater aquatic invertebrates (TGAI LC_{50} = 80 ppm (MRID 42205204)). The results of two studies indicate that 2-(hydroxymethyl)-2-nitro-1,3-propanediol is slightly toxic to molluscs (TGAI LC_{50} 22.8 ppm (MRID 42099001)) and practically non-toxic to crustaceans (TGAI LC_{50} >95.5 ppm (MRID 42099002)). The estuarine/marine fish study was waived based on the low toxicity of 2-(hydroxymethyl)-2-nitro-1,3-propanediol to freshwater fish.

a. Ecological Effects Risk Assessment

A Tier Ic EEC (estimated environmental concentration) model was conducted by the Agency to assess the estimated environmental concentration of residue levels of 2-(hydroxymethyl)-2-nitro-1,3-propanediol in the receiving stream from the pulp/paper mills, cooling towers, oil recovery/drilling muds and metal finishing uses. This model provides an estimate of the maximum concentration that may occur immediately downstream from an industrial (point source) discharge site. The EECs are reasonable worst case, one in ten year EECs. For the high exposure case site, it would be expected that the EEC would be equaled or exceeded once every ten years, i.e., there is a 10% chance in any given year that the EEC will be equaled or exceeded. The difference in the

scenarios is the flow rate of the receiving waters. This is similar to the site and frequency assumptions that are generally being used for agricultural pesticides.

Below, in Table VIII, EEC values are given for high exposure and typical exposure scenarios from the different use patterns of 2-(hydroxymethyl)-2-nitro-1,3-propanediol.

Table VIII. Tier 1c EECs for 2-(hydroxymethyl)-2-nitro-1,3-propanediol

Use Site, Type	High exposure	Typical exposure
Metal Working, Group 1*	68 ppm	0.054 ppm
Metal Working, Group 2**, recovery rate	533 ppm	0.422 ppm
Metal Working, Group 2** maintenance rate	133 ppm	0.105 ppm
Pulp and Paper Mills	2540 ppm	7.100 ppm
Water Cooling Towers, Evaporative Condensers, recovery	609 ppm	0.978 ppm
Water Cooling Towers, Evaporative Condensers, maintenance	152 ppm	0.243 ppm
Secondary Oil Recovery Injection Water, Drilling Muds, recovery	1000 ppm	1.400 ppm
Secondary Oil Recovery Injection Water, Drilling Muds, maintenance	1000 ppm	0.703 ppm

* "OO" Wafers, "OO" Powder, S.S.T. Sump Saver
** "Tris-Nitro 50% Aqueous, Tris-Nitro 25% Aqueous, Tris-Nitro Solid

A level of concern (LOC) is exceeded when the EEC value equals or exceeds 1/2 the LC_{50} values for aquatic organisms. The LOCs for 2-(hydroxymethyl)-2-nitro-1,3-propanediol are 40 ppm for Daphnia and 207 ppm for fish. The typical EEC values are below the LOC values for fish and invertebrates for all uses. Therefore, if the receiving streams never

have a flow rate below their mean flow condition, there is minimal risk to aquatic organisms in these waters under those conditions. However, the following table indicates a high risk to aquatic organisms from the high exposure scenario.

Industrial Appl.	**Type of LOC Exceeded for High Exposure Scenario (Indicates High Risk)**
Metal Finishing	Daphnia for all types, including maintenance and recovery operations Fish only for the recovery operation
Pulp/Paper Mills	Daphnia and fish
Cooling Towers	Daphnia for maintenance and recovery operations Fish for recovery operation
Oil Well Operations	Daphnia and fish for maintenance and recovery operations

b. Endangered Species

The LOC for endangered aquatic species is 1/20 the LC_{50} values, which for 2-(hydroxymethyl)-2-nitro-1,3-propanediol is 4 ppm for invertebrates and 20.7 ppm for fish. The high exposure scenarios for all uses of 2-(hydroxymethyl)-2-nitro-1,3-propanediol exceed the LOC for endangered aquatic organisms. In addition, the typical EEC value for pulp and paper mills exceeds the LOC for endangered aquatic invertebrates. As 2-(hydroxymethyl)-2-nitro-1,3-propanediol will be discharged at a number of different sites, it is reasonable to assume that endangered species are located in some of these aquatic habitats. Therefore, effluent containing 2-(hydroxymethyl)-2-nitro-1,3-propanediol should not be discharged into streams and other waterways where endangered aquatic organisms are known to reside.

Since the discharge of 2-(hydroxymethyl)-2-nitro-1,3-propanediol is limited by the National Pollutant Discharge Elimination System (NPDES) permit program of the Office of Water, the Agency would be able to control the discharge of 2-(hydroxymethyl)-2-nitro-1,3-propanediol so that toxic levels are avoided. Results from modeling indicate that 2-(hydroxymethyl)-2-nitro-1,3-propanediol can be used at use sites without producing effluents above concern levels.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing 2-(hydroxymethyl)-2-nitro-1,3-propanediol as the 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 2-(hydroxymethyl)-2-nitro-1,3-propanediol. However, the Agency is requesting confirmatory data for post-application exposure of the degradate formaldehyde to workers and hydrolysis of 2-(hydroxymethyl)-2-nitro-1,3-propanediol. It is also requiring product specific efficacy, chemistry and acute toxicity data for labeling purposes. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of 2-(hydroxymethyl)-2-nitro-1,3-propanediol, 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 2-(hydroxymethyl)-2-nitro-1,3-propanediol and to determine that 2-(hydroxymethyl)-2-nitro-1,3-propanediol can be used without resulting in unreasonable adverse effects to human health and the environment. The Agency therefore finds that all products containing 2-(hydroxymethyl)-2-nitro-1,3-propanediol 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 and the data identified in Appendix B. Although the Agency has found that all uses of 2-(hydroxymethyl)-2-nitro-1,3-propanediol 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 2-(hydroxymethyl)-2-nitro-1,3-propanediol, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the review of the generic data for the active ingredient 2-(hydroxymethyl)-2-nitro-1,3-propanediol, the Agency has sufficient information on the potential health effects of 2-(hydroxymethyl)-2-nitro-1,3-propanediol, and its degradate formaldehyde, and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that 2-(hydroxymethyl)-2-nitro-1,3-

propanediol products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to human health or the environment as long as label restrictions prescribed in this RED are followed. Therefore, the Agency concludes that products containing 2-(hydroxymethyl)-2-nitro-1,3-propanediol for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of 2-(hydroxymethyl)-2-nitro-1,3-propanediol are eligible for reregistration.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for 2-(hydroxymethyl)-2-nitro-1,3-propanediol. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Labeling Rationale

Because use of 2-(hydroxymethyl)-2-nitro-1,3-propanediol products can result in carcinogenic risk to workers, the Agency is requiring the use of certain protective clothing and equipment while handling and applying end-use products.

Also, because certain uses can result in discharge of 2-(hydroxymethyl)-2-nitro-1,3-propanediol into receiving waters, the Agency is requiring labeling that restricts effluent discharge unless it is under a NPDES permit.

2. Confirmatory Data Rationale

The Agency is requiring, through a Data Call-In Notice as a part of this document, registrants to submit additional data to confirm the acute toxicity and exposure estimated from the current data base. Acute inhalation and eye irritation studies on powdered technical grade 2-(hydroxymethyl)-2-nitro-1,3-propanediol are required. A monitoring study is required to measure post-application inhalation exposure of formaldehyde to workers in pulp and paper mills. Under separate and previous Data Call-In Notice the Agency has required a similar study for the use of formaldehyde products in poultry houses. With these data for these exposure studies, the Agency will either confirm the exposure and upper bound carcinogenic risk estimates or take further regulatory action to mitigate exposure, if necessary.

Additionally, the Agency is requiring a hydrolysis study on 2-(hydroxymethyl)-2-nitro-1,3-propanediol to confirm its degradation in the environment, and especially as it is discharged in effluent into receiving waters from the industrial uses of the products.

Based on its review of these additional confirmatory data, the Agency will determine whether the risk reduction measures required in this document were sufficient or whether further measures are necessary.

V. ACTIONS REQUIRED BY REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

As discussed above the Agency is requiring as confirmatory data additional studies on post-application worker inhalation to formaldehyde from the pulp and paper mill use and the poultry house use (under separate Data Call-In Notice). Acute inhalation and eye irritation data on 2-(hydroxymethyl)-2-nitro-1,3-propanediol are also required as confirmatory data. A new hydrolysis study is also required to confirm the degradation of 2-(hydroxymethyl)-2-nitro-1,3-propanediol. These generic data requirements are listed in Appendix F.

2. Labeling Requirements for Manufacturing-Use Products

"Do not discharge effluent containing this product into lakes, streams,

ponds, estuaries, oceans, or public 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 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 G, the Product Specific Data Call-In Notice. These requirements include efficacy, product chemistry, and acute toxicology studies.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix G; Attachment 5) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

For end-use products labeled for indoor non-food (industrial use with effluent), aquatic non-food industrial and terrestrial non-food uses:

> "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public 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 EPA."

Mixer/loader/applicators

Uses: Poultry/livestock premises, Preservative, and Pulp and paper mills
The personal protective equipment (PPE) requirement for such products is:

> "Pesticide handlers must wear:

--Long-sleeved shirt and long pants
--Chemical-resistant gloves
--Shoes plus socks
--In addition: when engaged in open pouring of this product:
-A respirator with either an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)

Mixer/loader/applicators

Uses: Metal cutting fluids, Cooling tower water
The personal protective equipment (PPE) requirement for such products is:

"Pesticide handlers must wear:
--Long-sleeved shirt and long pants
--Chemical-resistant gloves
--Shoes plus socks

Post-application workers

Uses: Poultry/livestock premises

End-use products that contain 2-(hydroxymethyl)-2-nitro-1,3-propanediol must be revised to adopt the entry restrictions set forth in this section. Place the following use restriction on the labeling in the directions describing use as a disinfectant spray in livestock and/or poultry premises:

"Entry by any person -- other than a correctly equipped handler -- is PROHIBITED in the entire enclosed building/structure from the start of application until aeration reduces the air concentration level of formaldehyde in the working area to less than 0.75 ppm. The air level concentration of formaldehyde must be measured before entry is permitted. (OSHA issued a final rule for the PEL for formaldehyde as 0.75 ppm, May 27, 1992, Federal Register, Vol. 57, p.22290.) Any handler who enters the treated area during this entry-restricted period must wear:

--Long-sleeved shirt and long pants
--Shoes plus socks
--A respirator with either an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval

number prefix TC-14G).

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10. Please follow the instructions in the Pesticide Reregistration Handbook with respect to labels and labeling.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the data of issuance of this RED. Persons other than the registrant may generally distribute or sell such products for 50 months from the data 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"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell 2-(hydroxymethyl)-2-nitro-1,3-propanediol products bearing old labels/labeling for 26 months from the data of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of issuance of this RED.

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

APPENDIX A - CASE 3149, [Tris(HOCH2-)nitromethane] Chemical 083902 [2-(Hydroxymethyl)-2-nitro-1,3-propanediol]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Pattern Limitations
								Allowed	Dis-allowed	
NONFOOD/NONFEED USES										
Commercial/Industrial Water Cooling Systems	Use Group(s): Aquatic Non-Food Industrial									
Water recirculating system treatment, Initial, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	23 ppm by Vol	500 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean claim.
Water recirculating system treatment, Subsequent/maintenance, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	8 ppm by Vol	125 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean claim.
Water recirculating system treatment, Initial, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	23 ppm by Vol	500 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean claim.
Water recirculating system treatment, Subsequent/maintenance, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	8 ppm by Vol	125 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean claim.
Water recirculating system treatment, Initial, Not on label Surface Type: na Efficacy Influencing Factor: na	Cr	30 ppm by Wt	609 ppm by Wt	not spec	not spec	not spec	not spec		CA	Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean for heavily soiled areas.

APPENDIX A - CASE 3149, [Tris(HOCH2-)nitromethane] Chemical 083902 [2-(Hydroxymethyl)-2-nitro-1,3-propanediol]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Pattern Limitations
								Allowed	Dis-allowed	
Water recirculating system treatment, Subsequent/Maintenance, Not on label Surface Type: na Efficacy Influencing Factor: na	Cr	10 ppm by Wt	152 ppm by Wt	not spec	not spec	not spec	not spec		CA	Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean for heavily soiled areas.
Emulsions, Resin/Latex/Polymer Use Group(s): Indoor Non-Food										
Industrial preservative treatment, During manufacture, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	1000 ppm by Wt	5000 ppm by Wt	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Industrial preservative treatment, Not on label, Not on label Surface Type: na Efficacy Influencing Factor: na	Cr	ppm cannot be calculated	ppm cannot be calculated	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Evaporative Condenser Water Systems Use Group(s): Aquatic Non-Food Industrial										
Water recirculating system treatment, Initial, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	23 ppm by Vol	500 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean claim.
Water recirculating system treatment, Subsequent/Maintenance, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	8 ppm by Vol	125 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean claim.
Water recirculating system treatment, Initial, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	23 ppm by Vol	500 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean claim.

APPENDIX A - CASE 3149, [Tris(HOCH2-)nitromethane] Chemical 083902 [2-(Hydroxymethyl)-2-nitro-1,3-propanediol]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Pattern Limitations
								Allowed	Dis-allowed	
Water recirculating system treatment, Subsequent/Maintenance, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	8 ppm by Vol	125 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean claim.
Water recirculating system treatment, Initial, Not on label Surface Type: na Efficacy Influencing Factor: na	Cr	30 ppm by Wt	609 ppm by Wt	not spec	not spec	not spec	not spec		CA	Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean for heavily soiled areas.
Water recirculating system treatment, Subsequent/Maintenance, Not on label Surface Type: na Efficacy Influencing Factor: na	Cr	10 ppm by Wt	152 ppm by Wt	not spec	not spec	not spec	not spec		CA	Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean for heavily soiled areas.
Industrial Processing Water Use Group(s): Aquatic Non-Food Industrial										
Water recirculating system treatment, Initial, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	23 ppm by Vol	500 ppm by Vol	not spec	not spec	not spec	not spec		CA	Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean claim.
Water recirculating system treatment, Subsequent/maintenance, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	8 ppm by Vol	125 ppm by Vol	not spec	not spec	not spec	not spec		CA	Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean claim.
Water recirculating system treatment, Initial, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	23 ppm by Vol	500 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean claim.

APPENDIX A - CASE 3149, [Tris(HOCH2-)nitromethane] Chemical 083902 [2-(Hydroxymethyl)-2-nitro-1,3-propanediol]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Pattern Limitations
								Allowed	Dis-allowed	
Water recirculating system treatment, Subsequent/maintenance, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	8 ppm by Vol	125 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). Preclean claim.
Livestock Use Group(s): Indoor Non-Food										
Animal equipment treatment, Not on label, Sprayer Surface Type: na Efficacy Influencing Factor: na	SC/L	1500 ppm by Vol	1500 ppm by Vol	not spec	not spec	not spec	not spec			Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. 10 minutes contact time. Potable water rinse (non-residual claim).
Animal equipment treatment, Not on label, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	1500 ppm by Vol	1500 ppm by Vol	not spec	not spec	not spec	not spec			Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. 10 minutes contact time. Potable water rinse (non-residual claim).
Equipment treatment, Not on label, Sprayer Surface Type: na Efficacy Influencing Factor: na	SC/L	1500 ppm by Vol	1500 ppm by Vol	not spec	not spec	not spec	not spec			Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. 10 minutes contact time. Potable water rinse (non-residual claim).
Equipment treatment, Not on label, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	1500 ppm by Vol	1500 ppm by Vol	not spec	not spec	not spec	not spec			Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. 10 minutes contact time. Potable water rinse (non-residual claim).
Premise treatment, Not on label, Sprayer Surface Type: hard Efficacy Influencing Factor: na	SC/L	1500 ppm by Vol	1500 ppm by Vol	not spec	not spec	not spec	not spec			Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. 10 minutes contact time. Potable water rinse (non-residual claim).
Transportation vehicle treatment, Not on label, Sprayer Surface Type: hard Efficacy Influencing Factor: na	SC/L	1500 ppm by Vol	1500 ppm by Vol	not spec	not spec	not spec	not spec			Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. 10 minutes contact time. Potable water rinse (non-residual claim).
Metalworking Cutting Fluids Use Group(s): Aquatic Non-Food Industrial										

APPENDIX A - CASE 3149, [Tris(HOCH2-)nitromethane] Chemical 083902 [2-(Hydroxymethyl)-2-nitro-1,3-propanediol]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Pattern Limitations
								Allowed	Dis-allowed	
Preservative treatment, Initial, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/S	ppm cannot be calculated	ppm cannot be calculated	not spec	not spec	not spec	not spec			
Preservative treatment, Subsequent/maintenance, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/S	ppm cannot be calculated	ppm cannot be calculated	not spec	not spec	not spec	not spec			
Preservative treatment, Initial, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/S	ppm cannot be calculated	ppm cannot be calculated	not spec	not spec	not spec	not spec			
Preservative treatment, Subsequent/maintenance, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/S	ppm cannot be calculated	ppm cannot be calculated	not spec	not spec	not spec	not spec			
Preservative treatment, Initial, Not on label Surface Type: na Efficacy Influencing Factor: na	P/T	ppm cannot be calculated	ppm cannot be calculated	not spec	not spec	not spec	not spec			
Industrial preservative treatment, During manufacture, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	1000 ppm (from label)	2000 ppm (from label)	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). 6.0 pH (minimum). 8.0 pH (maximum).
Preservative treatment, Initial, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	1250 ppm by Vol	2500 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Preservative treatment, Subsequent/maintenance, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	313 ppm by Vol	625 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).

APPENDIX A - CASE 3149, [Tris(HOCH2-)nitromethane] Chemical 083902 [2-(Hydroxymethyl)-2-nitro-1,3-propanediol]										
SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Pattern Limitations
								Allowed	Dis-allowed	
Industrial preservative treatment, During manufacture, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	1000 ppm (from label)	2000 ppm (from label)	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). 6.0 pH (minimum). 8.0 pH (maximum).
Preservative treatment, Initial, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	1250 ppm by Vol	2500 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Preservative treatment, Subsequent/maintenance, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	313 ppm by Vol	625 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Industrial preservative treatment, Not on label, Not on label Surface Type: na Efficacy Influencing Factor: na	Cr	1000 ppm (from label)	2000 ppm (from label)	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction). 6.0 pH (minimum). 8.0 pH (maximum).
Preservative treatment, Initial, Not on label Surface Type: na Efficacy Influencing Factor: na	Cr	1000 ppm (from label)	2000 ppm (from label)	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Preservative treatment, Subsequent/maintenance, Not on label Surface Type: na Efficacy Influencing Factor: na	Cr	250 ppm (from label)	500 ppm (from label)	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Oil Recovery Drilling Muds/Packer Fluids Use Group(s): Terrestrial Non-Food Crop, Aquatic Non-Food Industrial, Indoor Non-Food										

APPENDIX A - CASE 3149, [Tris(HOCH2-)nitromethane] Chemical 083902 [2-(Hydroxymethyl)-2-nitro-1,3-propanediol]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Pattern Limitations
								Allowed	Dis-allowed	
Preservative treatment, Not on label, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	63 ppm by Vol	500 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Preservative treatment, Not on label, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	63 ppm by Vol	500 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Preservative treatment, Not on label, Not on label Surface Type: na Efficacy Influencing Factor: na	Cr	ppm cannot be calculated	ppm cannot be calculated	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Paints, Latex (In-Can) Use Group(s): Indoor Non-Food										
Industrial preservative treatment, During manufacture, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	1000 ppm by Wt	5000 ppm by Wt	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Industrial preservative treatment, Not on label, Not on label Surface Type: na Efficacy Influencing Factor: na	Cr	ppm cannot be calculated	ppm cannot be calculated	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Poultry (Egg/Meat) Use Group(s): Indoor Non-Food										
Animal equipment treatment, Not on label, Sprayer Surface Type: na Efficacy Influencing Factor: na	SC/L	1500 ppm by Vol	1500 ppm by Vol	not spec	not spec	not spec	not spec			Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. 10 minutes contact time. Potable water rinse (non-residual claim).

APPENDIX A - CASE 3149, [Tris(HOCH2-)nitromethane] Chemical 083902 [2-(Hydroxymethyl)-2-nitro-1,3-propanediol]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Pattern Limitations
								Allowed	Dis-allowed	
Animal equipment treatment, Not on label, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	1500 ppm by Vol	1500 ppm by Vol	not spec	not spec	not spec	not spec			Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. 10 minutes contact time. Potable water rinse (non-residual claim).
Equipment treatment, Not on label, Sprayer Surface Type: na Efficacy Influencing Factor: na	SC/L	1500 ppm by Vol	1500 ppm by Vol	not spec	not spec	not spec	not spec			Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. 10 minutes contact time. Potable water rinse (non-residual claim).
Equipment treatment, Not on label, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	1500 ppm by Vol	1500 ppm by Vol	not spec	not spec	not spec	not spec			Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. 10 minutes contact time. Potable water rinse (non-residual claim).
Premise treatment, Not on label, Sprayer Surface Type: hard Efficacy Influencing Factor: na	SC/L	1500 ppm by Vol	1500 ppm by Vol	not spec	not spec	not spec	not spec			Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. 10 minutes contact time. Potable water rinse (non-residual claim).
Transportation vehicle treatment, Not on label, Sprayer Surface Type: hard Efficacy Influencing Factor: na	SC/L	1500 ppm by Vol	1500 ppm by Vol	not spec	not spec	not spec	not spec			Preclean claim. Proper ventilation required. Remove animals prior to treatment. Remove feed and water prior to treatment. 10 minutes contact time. Potable water rinse (non-residual claim).
Pulp/Paper Mill Water Systems Use Group(s): Aquatic Non-Food Industrial										
Water treatment, Continuous feed (initial), Metering pump Surface Type: na Efficacy Influencing Factor: na	SC/L	631 ppm by Wt	2525 ppm by Wt	not spec	not spec	not spec	not spec		CA	Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Water treatment, Intermittent (slug)(initial), Metering pump Surface Type: na Efficacy Influencing Factor: na	SC/L	631 ppm by Wt	2525 ppm by Wt	not spec	not spec	not spec	not spec		CA	Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).

APPENDIX A - CASE 3149, [Tris(HOCH2-)nitromethane] Chemical 083902 [2-(Hydroxymethyl)-2-nitro-1,3-propanediol]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Pattern Limitations
								Allowed	Dis-allowed	
Water treatment, Continuous feed (initial), Metering pump Surface Type: na Efficacy Influencing Factor: na	SC/L	570 ppm by Wt	2280 ppm by Wt	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Water treatment, Intermittent (slug)(initial), Metering pump Surface Type: na Efficacy Influencing Factor: na	SC/L	570 ppm by Wt	2280 ppm by Wt	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Water treatment, Continuous feed (initial), Metering pump Surface Type: na Efficacy Influencing Factor: na	Cr	635 ppm by Wt	2540 ppm by Wt	not spec	not spec	not spec	not spec		CA	Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Water treatment, Intermittent (slug)(initial), Metering pump Surface Type: na Efficacy Influencing Factor: na	Cr	635 ppm by Wt	2540 ppm by Wt	not spec	not spec	not spec	not spec		CA	Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Secondary Oil Recovery Injection Water Use Group(s): Aquatic Non-Food Industrial										
Water treatment, Continuous feed (initial), Metering pump Surface Type: na Efficacy Influencing Factor: na	SC/L	476 ppm by Vol	952 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Water treatment, Continuous feed (subsequent), Metering pump Surface Type: na Efficacy Influencing Factor: na	SC/L	476 ppm by Vol	476 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).

APPENDIX A - CASE 3149, [Tris(HOCH2-)nitromethane] Chemical 083902 [2-(Hydroxymethyl)-2-nitro-1,3-propanediol]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Pattern Limitations
								Allowed	Dis-allowed	
Water treatment, Intermittent (slug)(initial), Metering pump Surface Type: na Efficacy Influencing Factor: na	SC/L	476 ppm by Vol	952 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Water treatment, Continuous feed (initial), Metering pump Surface Type: na Efficacy Influencing Factor: na	SC/L	476 ppm by Vol	952 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Water treatment, Continuous feed (subsequent), Metering Pump Surface Type: na Efficacy Influencing Factor: na	SC/L	476 ppm by Vol	476 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Water treatment, Intermittent (slug)(initial), Metering pump Surface Type: na Efficacy Influencing Factor: na	SC/L	476 ppm by Vol	952 ppm by Vol	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Water treatment, Continuous feed (initial), Metering pump Surface Type: na Efficacy Influencing Factor: na	Cr	580 ppm by Wt	1159 ppm by Wt	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Water treatment, Continuous feed (subsequent), Metering pump Surface Type: na Efficacy Influencing Factor: na	Cr	580 ppm by Wt	580 ppm by Wt	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).

APPENDIX A - CASE 3149, [Tris(HOCH2-)nitromethane] Chemical 083902 [2-(Hydroxymethyl)-2-nitro-1,3-propanediol]										
SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Pattern Limitations
								Allowed	Dis-allowed	
Water treatment, Intermittent (slug)(initial), Metering pump Surface Type: na Efficacy Influencing Factor: na	Cr	580 ppm by Wt	1159 ppm by Wt	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Speciality Industrial Products Use Group(s): Indoor Non-Food										
Preservative treatment, Not on label, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	500 ppm/gal by Vol (from label)	1000 ppm/gal by Vol (from label)	not spec	not spec	not spec	not spec		CA	Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Preservative treatment, Not on label, Not on label Surface Type: na Efficacy Influencing Factor: na	SC/L	500 ppm/gal by Vol (from label)	1000 ppm/gal by Vol (from label)	not spec	not spec	not spec	not spec			Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Preservative treatment, Not on label, Not on label Surface Type: na Efficacy Influencing Factor: na	Cr	500 ppm/gal by Wt (from label)	1000 ppm/gal by Wt (from label)	not spec	not spec	not spec	not spec		CA	Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).

Abbreviations used

Header: max = maximum; min = minimum; apps = applications; not spec = not specified; na = not applicable

Form: SC/L = soluble concentrate/liquid; SC/S = soluble concentrate/solid; Cr = crystalline; P/T = pelleted/tableted

Rate: ai = active ingredient; ppm = parts per million; Vol = volume; Wt = weight; gal = gallon

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

TRIS(HYDROXYMETHYL)NITROMETHANE: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data CallIn Notice because you have product(s) containing TRIS(HYDROXYMETHYL)NITROMETHANE.

This Generic 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 TRIS(HYDROXYMETHYL)NITROMETHANE. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment B), (3) the Requirements Status and Registrant's Form (Attachment C), (4) a list of registrants receiving this DCI (Attachment D), (5) the EPA Acceptance Criteria (Attachment E), and (6) the Cost Share and Data Compensation Forms in replying to this TRIS(HYDROXYMETHYL)NITROMETHANE Generic Data Call-In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for TRIS(HYDROXYMETHYL)NITROMETHANE are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on TRIS(HYDROXYMETHYL)NITROMETHANE are needed. These data are needed to fully complete the reregistration of all eligible TRIS(HYDROXYMETHYL)NITROMETHANE products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact ERNIE DOBBINS at (703) 308-8071.

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

ERNIE DOBBINS, Chemical Review Manager
ACCELERATED REREGISTRATION BRANCH
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: TRIS(HYDROXYMETHYL)NITROMETHANE

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 3149 covered by this Reregistration Eligibility Document. It contains generic data requirements that apply to 3149 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 TRIS(HYDROXYMETHYL)NITROMETHANE

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ALL	42958001
61-2A	Start. Mat. & Mnfg. Process	ALL	42958001
61-2B	Formation of Impurities	ALL	42958001
62-1	Preliminary Analysis	ALL	42958001
62-2	Certification of limits	ALL	42958001
62-3	Analytical Method	ALL	42958001
63-2	Color	ALL	42958001
63-3	Physical State	ALL	42958001
63-4	Odor	ALL	42958001
63-5	Melting Point	ALL	42958001
63-6	Boiling Point	ALL	WAIVED
63-7	Density	ALL	42958001
63-8	Solubility	ALL	42958001
63-9	Vapor Pressure	ALL	42806301
63-10	Dissociation Constant	ALL	42806301
63-11	Octanol/Water Partition	ALL	42958001
63-12	pH	ALL	42958001
63-13	Stability	ALL	42958001

Data Supporting Guideline Requirements for the Reregistration of TRIS(HYDROXYMETHYL)NITROMETHANE

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	ALL	WAIVED
71-2A	Avian Dietary - Quail	ALL	WAIVED
71-2B	Avian Dietary - Duck	ALL	94706, 94707
72-1A	Fish Toxicity Bluegill	ALL	42205203
72-1B	Fish Toxicity Bluegill - TEP	ALL	94709
72-1C	Fish Toxicity Rainbow Trout	ALL	94708
72-1D	Fish Toxicity Rainbow Trout- TEP	ALL	94709
72-2A	Invertebrate Toxicity	ALL	42205204
72-3A	Estuarine/Marine Toxicity - Fish	F	WAIVED
72-3B	Estuarine/Marine Toxicity - Mollusk	F	42099001
72-3C	Estuarine/Marine Toxicity - Shrimp	F	42099002
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	ALL	94711
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL	43222
81-3	Acute Inhalation Toxicity - Rat	ALL	DATA GAP
81-4	Primary Eye Irritation - Rabbit	ALL	DATA GAP
81-5	Primary Dermal Irritation - Rabbit	ALL	94711, 109228

Data Supporting Guideline Requirements for the Reregistration of TRIS(HYDROXYMETHYL)NITROMETHANE

REQUIREMENT		USE PATTERN	CITATION(S)
81-6	**Dermal Sensitization - Guinea Pig**	ALL	N/A
82-3	**90-Day Dermal - Rodent**	ALL	41021101
83-3A	**Developmental Toxicity - Rat**	ALL	41089301
83-3B	**Developmental Toxicity - Rabbit**	ALL	42303501
84-2A	**Gene Mutation (Ames Test)**	ALL	41058101
84-2B	**Structural Chromosomal Aberration**	ALL	41944301
84-4	**Other Genotoxic Effects**	ALL	41944302
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
233	**Estimation of Dermal Exposure at Indoor Sites**	ALL	41412201
234	**Estimation of Inhalation Exposure at Indoor Sites**	ALL	DATA GAP
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	ALL	DATA GAP

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of 3149

GUIDE TO APPENDIX C

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

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

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

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

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

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

the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

BIBLIOGRAPHY

MRID	CITATION

00043222 Wilbur, S.; Parekh, C. (1980) Acute Dermal Toxicity of P-2350 (Tris nitro Concentrate): PLR-109; CKP80/59; SW80/3. (Unpublished study received Sep 15, 1980 under 271-39; submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL:243245-G)

00094706 Ralston Purina Company (1978) ¢Dietary LCæ50¬ Determination in Bobwhite Quail | : RT No. 8032836. (Unpublished study received Feb 1, 1982 under 271-40; submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL:246754-B)

00094707 Ralston Purina Company (1978) ¢Dietary LCæ50¬ Determination in Mallard Ducklings | : RT No. 8032836. (Unpublished study received Feb 1, 1982 under 271-40; submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL:246754-C)

00094708 Lee, T. (1973) Report: WARF No. 3051213. (Unpublished study, including letter dated May 3, 1973 from R.F. Purcell to Terrence Lee, received Feb 1, 1982 under 271-40; prepared by Warf Institute, Inc., submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL:246754-D)

00094709 Ralston Purina Company (1978) Analysis for Fish Acute Toxicity (Rainbow Trout, Bluegill): RT No. 8032836. (Unpublished study received Feb 1, 1982 under 271-40; submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL:246754-E)

00094711 Parekh, C.K. (1979) LDæ50¬ and Eye Irritation of Tris Nitro Concentrate (P-2350): Report No. PLR-77. (Unpublished study received Feb 1, 1982 under 271-40; submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL:246755-B)

00094713 Wilbur, S.; Parekh, C. (1980) Acute Dermal Toxicity of P-2350 (Tris Nitro Concentrate): Report No. PLR-109. (Unpublished study received Feb 1, 1982 under 271-40; submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL:246755-D)

00094715 Parekh, C. (1980) Acute Toxicity of P-2350 (Tris Nitro Concentrate): Report No. PLR-135. (Unpublished study received Feb 1, 1982 under 271-40; submitted by International Minerals & Chemical Corp., Terre Haute, Ind.;

BIBLIOGRAPHY

MRID	CITATION

CDL:246755-F)

00109228 Parekh, C. (1981) Acute Toxicity Profile of Tris Nitro Concentrate (P-2350): Report No. PLR-146. (Unpublished study received May 18, 1982 under 271-40; submitted by International Minerals & Chemical Corp., Terre Haute, IN; CDL:247864-B)

41021101 Naas, D. (1989) Tris Nitro Brand of 2-hydroxymethyl-2-nitro-1,3propanediol: 90-day Dermal Toxicity Study in Rats: Project No. Wil-129005. Unpublished study prepared by Wil Research Laboratories, Inc. 637 p.

41021102 Nemec, M. (1988) Tris Nitro Brand of 2-hydroxymethyl-2-nitro-1,3propanediol: A Range-finding Teratology Study in Rats: Project No. Wil-129001. Unpublished study prepared by Wil Research Laboratories, Inc. 87 p.

41058101 Desai, L. (1988) Tris Nitro Brand of 2-Hydroxymethyl-2-nitro-1,3propanediol: Ames Bacterial/Microsomal Plate Incorporation Assay: Project No. 88G-0017. Unpublished study prepared by Toxikon Corp. 14 p.

41089301 Nemec, M. (1989) Tris Nitro Brand of 2-Hydroxymethyl-2-nitro-1,3propanediol: A Teratology Study in Rats: Project No. WIL-129002. Unpublished study prepared by WIL Research Laboratories, Inc. 220 p.

41412201 Popendorf, W.; Selim, M.; Kross, B. (1990) Chemical Manufacturers Association Antimicrobial Exposure Assessment Study: Lab Project ID: Q626. Unpublished study prepared by Univ. of Iowa, Institute of Agricultural Medicine and Occupational Health. 209 p.

41944301 Paika, I. (1991) Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells: Tris Nitro: Lab Project Number: 90G-0538. Unpublished study prepared by Toxicon Corp. 60 p.

41944302 Paika, I. (1991) Unscheduled DNA Synthesis in Rat Liver Primary Cultures: Tris Nitro: Lab Project Number: 90G-0537. Unpublished study prepared by Toxicon Corp. 64 p.

BIBLIOGRAPHY

MRID	CITATION

42099001 Graves, W.; Peters, G. (1991) Tris Nitro: A 96-Hour Shell Deposition Test with the Eastern Oyster (Crassostrea virginica): Final Report: Lab Project Number: 288A-103. Unpublished study prepared by Wildlife International, Ltd. 41 p.

42099002 Murphy, D.; Peters, G. (1991) Tris Nitro: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysid (Mysidoopsis bahia) : Final Report: Lab Project Number: 288-102A. Unpublished study prepared by Wildlife International. 35 p.

42205203 Bowman, J. (1989) Acute Toxicity of Tris Nitro to Fathead Minnow (Pimephales promelas): Lab Project Number: 38249. Unpublished study prepared by ABC Labs., Inc. 68 p.

42205204 Forbis, A. (1989) Acute Toxicity of Tris Nitro to Daphnia magna: Lab Project Number: 38250. Unpublished study prepared by ABC Labs., Inc. 57 p.

42303501 Nemec, M. (1992) A Developmental Toxicity Study of Tris Nitro in Rabbits: Lab Project Number: 129008. Unpublished study prepared by WIL Research Laboratories, Inc. 286 p.

42806301 Bollmeier, A. (1993) Supplemental Product Chemistry: TRIS NITRO Brand of Tris(Hydroxymethyl) Nitromethane. Unpublished study prepared by ANGUS Chemical Co. 7 p.

42958001 Bollmeier, A. (1993) Supplemental Product Chemistry: TRIS NITRO brand of tris(hydroxymethyl)nitromethane. Unpublished study prepared by ANGUS Chemical Company. 32 p.

APPENDIX D. List of Available Related Documents

The following is a list of available documents related to 3149. It's purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for 3149 and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. 3149 RED Fact Sheet

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

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

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

PR Notice 86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

PR NOTICE 86-5

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

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

I. Purpose

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

II. Applicability

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

III. Effective Date

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

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations

specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

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

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

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

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

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

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

VI. Format Requirements

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

- INDEX-

****

A. Organization of Submittal Package

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

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

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

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

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

B. Transmittal Document

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

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

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

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

C. Individual Studies

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

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

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

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

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

C.1 Special Considerations for Identifying Studies

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

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

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

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

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

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

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

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

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

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

D.1. Title Page

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

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

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

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

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

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

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

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

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

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

D.3. Confidential Attachment

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

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

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

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

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

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

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

D.5. Good Laboratory Practice Compliance Statement

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

E. Reference to Previously Submitted Data

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

F. Physical Format Requirements

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

Please be particularly attentive to the following points:

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

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

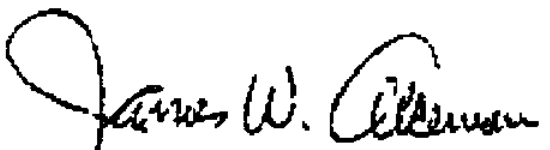
G. Special Requirements for Submitting Data to the Docket

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

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

V. For Further Information

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



James W. Akerman
Acting Director,
Registration Division

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

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

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

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

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

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

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

3. Transmittal date

4. List of submitted studies

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

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

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

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

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

Company Official: _____
Name Signature

Company Name: _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

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

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

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

Company _____

Company Agent: _____ Typed Name _____ Date:_____

_____ Title _____ _____ Signature _____

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

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

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

Company: _____

Company Agent: _____ Typed Name _____ Date:_____

_____ Title _____ _____ Signature _____

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

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

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

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

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

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

CROSS REFERENCE NUMBER 1 This cross reference number is used in the study in place of the following words or phrase at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE	LINE	REASON FOR THE DELETION	FIFRA REFERENCE
6	14	Identity of Inert Ingredient	§10(d)(1)(C)
12	25	"	"
100	19	"	"

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

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

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

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

CROSS REFERENCE NUMBER 7 This cross reference number noted on a place-holder page is used in place of the following whole pages at the indicated volume and page references.

DELETED PAGE(S): are attached immediately behind this page.

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Study Director _____

Example 2.

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

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

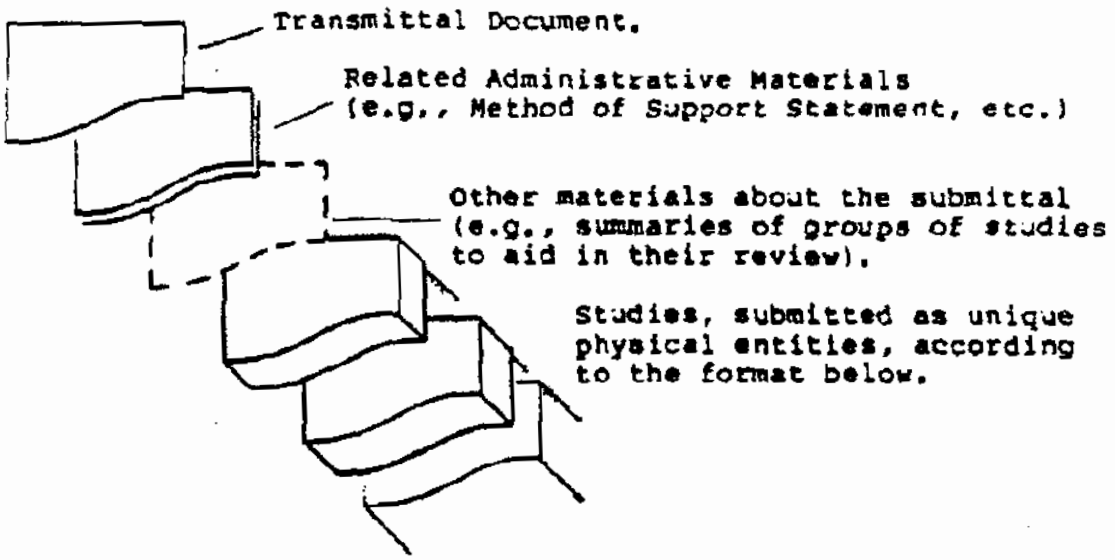
Example 3.

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

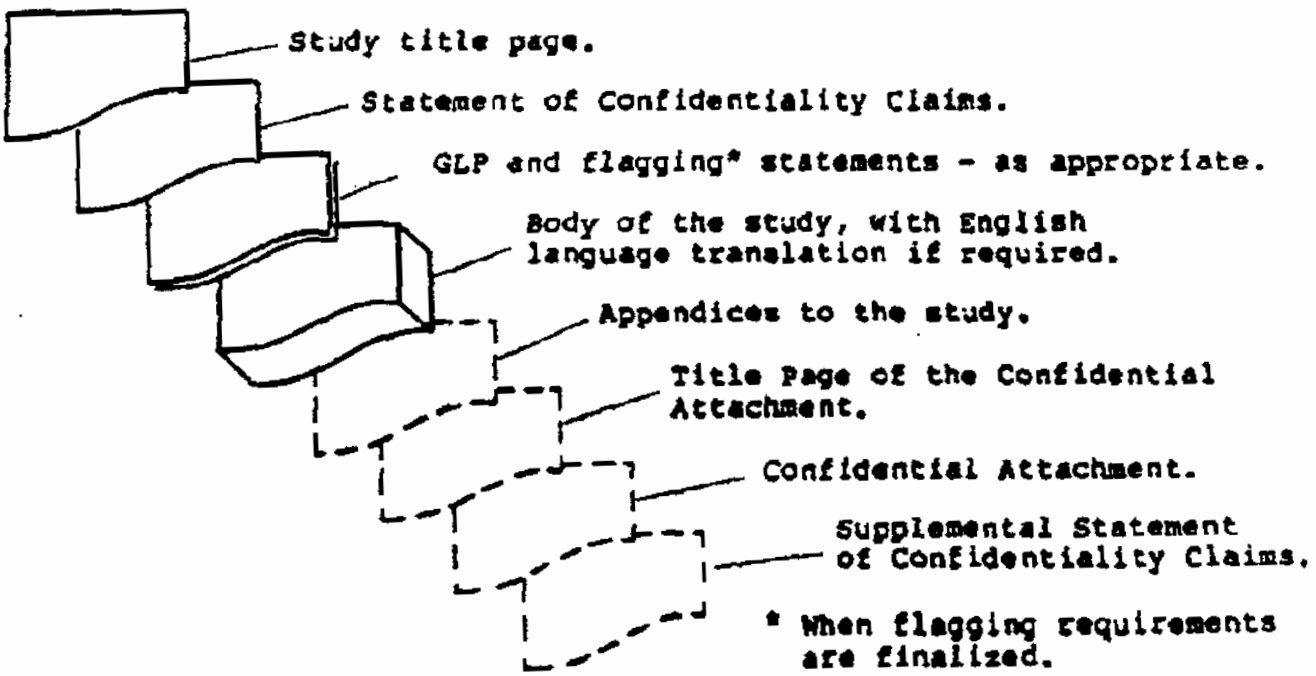
Submitter_____

ATTACHMENT 7.

FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND

PR Notice 91-2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

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

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

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

II. BACKGROUND

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

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

CFR 158.175(c)(3).

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

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

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section 10(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

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

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

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

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

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

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

V. COMPLIANCE SCHEDULE

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

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

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

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

VI. FOR FURTHER INFORMATION

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

Anne E. Lindsay

Anne E. Lindsay, Director
Registration Division (H-7505

APPENDIX F. Generic Data Call-In

GENERIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain 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(s). 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 4; 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 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 4).

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

This Notice is divided into six sections and five 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:

Attachment 1	-	Data Call-In Chemical Status Sheet
Attachment 2	-	Data Call-In Response Form
Attachment 3	-	Requirements Status And Registrant's Response Form
Attachment 4	-	List Of All Registrants Sent This Data Call-In Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

SECTION II. DATA REQUIRED BY THIS NOTICE

A. DATA REQUIRED

The 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.

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.

C. TESTING PROTOCOL

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

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

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

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

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

A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice 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.

B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the 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 (Attachment 2) and the Requirements Status and Registrant's Response Form (Attachment 3). The Data Call-In Response Form must be submitted as part of every response to this Notice. 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 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(s) 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 choose 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. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form, a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Requirements Status and Registrant's Response Form. You must also complete a Data Call-In

Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support and Emergency Response Branch, Registration Division, (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, must bear an amended label.

3. Generic Data Exemption - Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient(s) if the active ingredient(s) in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient(s). EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

a. The active ingredient(s) in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient(s) and is purchased from a source not connected with you; and,

b. every registrant who is the ultimate source of the active ingredient(s) in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

c. you must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for product specific data.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations

of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

4. Satisfying the Data Requirements of this Notice - There are various options available to satisfy the 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 option 6b and 7 on the Data Call-In Response Form. If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

5. Request for Data Waivers. Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 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.

C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), 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. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost-share or agreeing to share in the cost of developing that study. A 90-day progress report must be submitted for all studies. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

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 or protocols. 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 requirement(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 --

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 --

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. 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:

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 ecological effects studies, the classification generally would be a rating of "core." 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.

D. REQUESTS FOR DATA WAIVERS

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are inapplicable and do not apply to your product.

1. Low Volume/Minor Use Waiver -- Option 8 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredient(s) whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient(s) is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient(s) are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient(s) elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified

for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

a. Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

b. Provide an estimate of the sales (pounds and dollars) of the active ingredient(s) for each major use site. Present the above information by year for each of the past five years.

c. Total direct production cost of product(s) containing the active ingredient(s) by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

d. Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient(s) by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient(s), such as costs of initial registration and any data development.

e. A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

f. A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

g. For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient(s), direct production costs of product(s) containing the active ingredient(s) (following the parameters in item c above), indirect production costs of product(s)

containing the active ingredient(s) (following the parameters in item d above), and costs of data development pertaining to the active ingredient(s).

h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

(1) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume minor use waiver will result in denial of the request for a waiver.

2. Request for Waiver of Data --Option 9 on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice do not apply to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

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; or,

   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.

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.

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 Federal Insecticide, Fungicide, and Rodenticide 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(s) for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received <u>after</u> 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 <u>unless</u> 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. <u>REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS</u>

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 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 (Attachment 2) and a completed Requirements Status and Registrant's Response Form (Attachment 3) and any other documents required by this Notice, and should be submitted to the contact person 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,

Daniel M. Barolo, Director
Special Review
and Reregistration Division

Attachment 1. Chemical Status Sheet

3149: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data CallIn Notice because you have product(s) containing 3149.

This Generic 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 3149. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment B), (3) the Requirements Status and Registrant's Form (Attachment C), (4) a list of registrants receiving this DCI (Attachment D), (5) the EPA Acceptance Criteria (Attachment E), and (6) the Cost Share and Data Compensation Forms in replying to this 3149 Generic Data Call-In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for 3149 are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on 3149 are needed. These data are needed to fully complete the reregistration of all eligible 3149 products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Ernie Dobbins at (703) 308-8071.

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

Ernie Dobbins, Chemical Review Manager
Accelerated Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: 3149

Attachment 2. Generic DCI Response Forms Inserts (Form A) plus Instructions

SPECIFIC INSTRUCTIONS FOR THE GENERIC DATA CALL-IN RESPONSE FORM

This Form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1-4 will have been preprinted on the form Items 5 through 7 must be completed by the registrant as appropriate Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

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 suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U S Environmental Protection Agency, 401 M St , S W , Washington, D C 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D C 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the ease number, ease name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this data call-in but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. Cheek this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily cancelled.

Item 6a. Check this item if this data call-in is for generic data as indicated in Item 3 and if you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and-any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 7a. Check this item if this call-in if a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is an end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 8. This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

Attachment 3. Requirements Status and Registrants' Response Forms Inserts (Form B) plus Instructions

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM

Generic Data

This form is designed to be used for registrants to respond to call-in- for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

Public reporting burden for this collection of information is estimated to average 30 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 suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number, and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be

submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:

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 crop
J.	Forestry
K.	Residential
L.	Indoor food
M.	Indoor non-food
N.	Indoor medical
O.	Indoor residential

Item 7. This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows.

EP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP _ *	Typical End-Use Product, Percent Active Ingredient Specified

TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI	Technical Grade Active Ingredient
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
MET	Metabolites
IMP	Impurities
DEGR	Degradates

*See: guideline comment

Item 8. This item identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date **of your** receipt of the Data Call-In Notice.

Item 9. Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

1. (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. 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 and that I will provide the protocol and progress reports required in item 5 above.

2. (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

5. (Upgrading a Study) I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

6. (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. I am providing the Agency's classification of the study.

7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Item 10. This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

Attachment 4. List of Registrant(s) sent this DCI (Insert)

APPENDIX G. Product Specific Data Call-In

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

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

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

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

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

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

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

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

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

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule

including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

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

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

develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

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

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

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

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

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

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the

requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

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

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

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

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

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

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

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

   c. otherwise take appropriate steps to meet the requirements stated in this

Notice, unless you commit to submit and do submit the required data in the specified time frame.

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

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

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

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Attachments

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

Attachment 1. Chemical Status Sheet

3149 DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing 3149.

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 3149. 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 B), (3) the Requirements Status and Registrant's Form (Attachment C), (4) EPA's Grouping of End[-]Use Products for Meeting Acute Toxicology Data Requirement (Attachment D), (5) the EPA Acceptance Criteria (Attachment E), (6) a list of registrants receiving this DCI (Attachment F) and (7) the Cost Share and Data Compensation Forms in replying to this 3149 Product Specific Data Call[-]In (Attachment G). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for 3149 are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional data on 3149 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 3149 products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of 3149, please contact at (703) 308-8071.

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

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

Frank Rubis
Planning and Reregistration Branch (H7508W)
Special Review and Reregistration Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **3149**

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

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

Item 1-4. Already completed by EPA.

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

Item 6. Not applicable since this form calls in product specific data only. However, if your product is identical to another product and you qualify for a data exemption, you must respond with "yes" to Item 7a (MUP) or 7B (EUP) on this form, provide the EPA reregistration 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 that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

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

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

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

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

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

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

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

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

1. I will generate and submit data by the specified due date (Developing Data). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice.

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement. I understand that this option is available on for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this notice that my product is similar. Enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product my be subject to suspension.

3. I have made offers to share in the cost to develop data (Offers to Cost Share)

I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed " Certification of offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the require data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (submitting an Existing Study). I certify that this study will meet all the requirements for submittal of existing data outlined in option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgrade (upgrading a study). I will submit evidence of the Agency's review indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this Option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.

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

7. I request a waiver for this study because it is inappropriate for my product (Waiver Request). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver

request, I will not be require to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status chosen. I also understand that the deadline for submission of data as specified by the original data cal-in notice will not change.

Items 10-13. Self-explanatory.

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

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

EPA'S BATCHING OF 2-(hydroxymethyl)-2-nitro-1,3-propanediol PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of end-use products containing the active ingredient 2-(hydroxymethyl)-2-nitro-1,3-propanediol, 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.

Batching has been accomplished using the readily available information described above, and frequently acute toxicity data on individual end-use products has been found to be incomplete. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual end-use product should the need arise.

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

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.

Only nine products have been found which contain 2-(hydroxymethyl)-2-nitro-1,3-propanediol as an active ingredient. Since some products differ in regard to the active and inert ingredients, formulation type, labeling and acute toxicity, two batches (Table I) and a "no batch" category (Table II) have been formed as follows:

Table I

Batch	EPA Reg. No.	2-(hydroxymethyl)-2-nitro-1,3-propanediol	Formulation Type
1	4808-1	98.5%	Solid
	4808-2	98.5%	Solid
	48301-1	100%	Solid
	48301-33	100%	Solid
2	48301-4	50%	Liquid
	48301-11	50%	Liquid

Table II lists three 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. Registrants of these products are responsible for meeting the acute toxicity data requirements separately for each product.

Table II

EPA Reg. No.	2-(hydroxymethyl)-2-nitro-1,3-propanediol	Formulation Type
134-65	19.2%	Liquid
48301-10	98.5%	Solid
48301-17	25%	Liquid

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

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

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

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

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

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

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

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

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

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

63-2 Color

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

63-3 Physical State

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

63-4 Odor

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

63-5 Melting Point

____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point

____ Reported in °C
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity

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

63-8 Solubility

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

63-9 Vapor Pressure

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

63-10 Dissociation Constant

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

63-11 Octanol/water Partition Coefficient

____ Measured at about 20-25° C
____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
____ Data supporting reported value provided

63-12 pH

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

63-13 Stability

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

SUBDIVISION F

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

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.___ One of the following methods is utilized:
- _____ Freund's complete adjuvant test
- _____ Guinea pig maximization test
- _____ Split adjuvant technique
- _____ Buehler test
- _____ Open epicutaneous test
- _____ Mauer optimization test
- _____ Footpad technique in guinea pig.

4.___ Complete description of test.
5.*__ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

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

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

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

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

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr./Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

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

EPA Form 8570-4 (Rev. 12-98) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA	United States Environmental Protection Agency Washington, DC 20460 CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA	Form Approved OMB No. 2070-0106 2070-0057 Approval Expires 3-31-96

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

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

3. That I have previously complied with section 3(c)(1)(D) 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 sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-95)