



# **Reregistration Eligibility Decision (RED)**

1,3,5-Triethylhexahydro-s-triazine





# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

## CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case 3147 which contains the active ingredient 1,3,5-Triethylhexahydro-s-triazine. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Jane Mitchell (703) 308-8061.

Sincerely yours,

Lois A. Rossi, Director  
Special Review and  
Reregistration Division

Enclosures



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

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

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

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

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

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

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

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

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

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

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

**By U.S. Mail:**

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

**By express:**

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

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

**REREGISTRATION ELIGIBILITY DECISION**

**1,3,5-Triethylhexahydro-s-triazine**

**LIST C**

**CASE 3147**





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# **1,3,5-TRIETHYLHEXAHYDRO-S-TRIAZINE REREGISTRATION ELIGIBILITY DECISION TEAM**

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## GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC <sub>50</sub>	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD <sub>50</sub>	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD <sub>10</sub>	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable

## **GLOSSARY OF TERMS AND ABBREVIATIONS**

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



## ABSTRACT

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision for the pesticide 1,3,5-triethylhexahydro-s-triazine (Case 3147). This decision includes a comprehensive reassessment of the required target data and the use patterns of the two currently registered products. Additionally, the Agency has examined information concerning the exposure and susceptibility of infants and children to 1,3,5-triethylhexahydro-s-triazine and available information concerning aggregate exposure to 1,3,5-triethylhexahydro-s-triazine as well as the potential for cumulative effects from 1,3,5-triethylhexahydro-s-triazine and other substances that have a common mode/mechanism of toxicity.

1,3,5-Triethylhexahydrotriazine, or triethylhexahydrotriazine, is used as a microbiocide/microstat in various rubber products, industrial adhesives, fuels/oil storage tank bottom water, metalworking cutting fluids, wet-end additives/industrial processing chemicals, and latex paints. The Agency has concluded that all uses, as prescribed in this document, will not cause unreasonable risks to humans or the environment and therefore, all products are eligible for reregistration.

Triethylhexahydrotriazine is moderately acutely toxic and corrosive via the oral and inhalation routes. Although in vitro data indicate this pesticide to be mutagenic, in vivo data suggest that triethylhexahydrotriazine lacks in vivo mutagenic potential. EPA is concerned about the corrosivity of triethylhexahydrotriazine and, since studies were waived due to corrosivity, assumes that it is classified as category I for skin irritation and eye irritation potential. The corrosivity to skin of triethylhexahydrotriazine makes dermal penetration likely, since the skin would likely be damaged by contact with the chemical. Triethylhexahydrotriazine is classified as toxicity category II for acute inhalation toxicity.

For short-term (1-7 days) and intermediate-term (1 week-several months) occupational and residential risk assessments, the Agency has chosen the 75 mg/kg/day NOEL, based on both maternal and developmental effects, from the rat developmental toxicity study. In a sub-chronic dermal study in rats, no systemic effects were observed at any dose level. Consistent with current data requirements for non-food use chemicals, no chronic toxicity data have been required for triethylhexahydrotriazine.

Because inhalation exposure data are absent and triethylhexahydrotriazine has a relatively high vapor pressure, EPA will require data for handler and post-application inhalation exposure. The post-application data requirement includes monitoring levels of triethylhexahydrotriazine and its degradates in newly painted rooms where infants and children could be exposed.

Nothing in the available toxicity data base indicates special susceptibility of infants and children to triethylhexahydrotriazine and, therefore, the Agency has concluded that an additional uncertainty factor for estimating risk to young organisms is not warranted at this time.

All products containing triethylhexahydrotriazine have primarily indoor, non-food uses. Based on the available exposure information and current use patterns, EPA does not anticipate exposure to residues of triethylhexahydrotriazine in food or drinking water. Thus, the only non-occupational exposure to triethylhexahydrotriazine would be from uses in the home. Among these, applying paint would yield the greatest potential exposure. Because the dermal MOE for this worst case exposure is high ( $> 1600$ ), EPA believes that aggregate exposures from other sources of triethylhexahydrotriazine in the home are not likely to be of concern.

The Agency has not yet made a determination regarding the common mode/mechanism of toxicity of triethylhexahydrotriazine and whether it is appropriate to consider exposure from triethylhexahydrotriazine with other compounds in order to address potential cumulative effects. However, based on the high dermal MOE for homeowner applicators, the lack of food uses, the unlikelihood of residues in drinking water, and the low concentration in paint, the Agency believes that the contribution of triethylhexahydrotriazine exposure to the risks of other chemicals with a common mode/mechanism of toxicity is likely to be minimal.

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

## **I. INTRODUCTION**

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

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

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA) and FIFRA. The FQPA amendments went into effect immediately. Among other things, FQPA amended the FFDCA by setting a new standard for the establishment of tolerances. Because triethylhexahydrotriazine has no food uses, and therefore no tolerances have been established, the specific determinations outlined in FQPA are not required for the reregistration of this chemical. Nevertheless, EPA believes that consideration of available data relating to the special sensitivity of infants and children, as well as the potential for aggregate exposures and cumulative effects is prudent for triethylhexahydrotriazine because children and other individuals could be exposed to this compound in non-occupational settings.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of triethylhexahydrotriazine. The document consists of six sections. Section I is the introduction. Section II describes triethylhexahydrotriazine, 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 triethylhexahydrotriazine. Section V discusses the reregistration requirements for triethylhexahydrotriazine. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

## II. CASE OVERVIEW

### A. Chemical Overview

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

- **Common Name:** Triethylhexahydrotriazine
- **Chemical Name:** 1,3,5-Triethylhexahydro-s-triazine
- **Chemical Family:** Triazine
- **CAS Registry Number:** 7779-27-3
- **OPP Chemical Code:** 082901
- **Molecular Formula:** C<sub>9</sub>H<sub>21</sub>N<sub>3</sub>
- **Molecular Weight:** 171.29
- **Trade and Other Names:** Vancide TH
- **Basic Manufacturer:** R. T. Vanderbilt Company, Inc.

### B. Use Profile

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

For triethylhexahydrotriazine:

**Type of Pesticide:** Microbiocide/Microbiostat (slime-forming bacteria)  
Microbiocide/Microbiostat (slime-forming fungi)

**Use Sites:** Indoor Non-food  
-Adhesives, Industrial  
-Fuels/Oil Storage Tank Bottom Water Additive  
-Metalworking Cutting Fluids  
-Paints, Latex (In-can) - and aqueous slurries  
-Rubber Products  
-Wet-end Additives/Industrial Processing Chemicals

**Target Pests:** Slime-forming bacteria and fungi

**Types/Formulations Registered:**

End-use product  
-Soluble concentrate/liquid

**Methods of Application:**

Types of Treatment - Additive treatment, Industrial preservative treatment

Equipment - Not specified (registrant must specify on label)

Timing - During manufacture, When needed, Not specified (registrant must specify on label)

Surface Type - Not applicable

**Rates of Application**

Adhesives, Industrial: 95 to 475 ppm a.i. by weight;  
Fuels/oil storage tank bottom water additive: 363 to 1813 ppm a.i. by weight.  
Metalworking cutting fluids: 28500 ppm a.i. by weight.  
Paints, latex (in-can): 475 to 1425 ppm a.i. by weight.  
Rubber products: 190 to 475 ppm a.i. by weight.  
Wet-end additives/industrial processing chemicals: 95 to 1425 ppm a.i. by weight.

**C. Data Requirements**

The Agency required registrants to supply additional data to support reregistration in the Antimicrobial Data Call-In Notice of March 1987 and a Data Call-In Notice issued in November of 1992 that included studies on product chemistry, ecological effects, and toxicity. Appendix B includes all data requirements identified by the Agency for currently registered uses to support reregistration.

**D. Regulatory History**

In 1967, triethylhexahydrotriazine was first registered in the United States as an active ingredient for use as a microbiocide and bacteriostat. There are currently two active products registered for incorporation as a preservative into adhesives, fuels, metal working fluids, paints, slurries and latex rubber. In 1987 the Agency issued the Antimicrobial Data Call-In Notice for toxicity data for this chemical and other antimicrobial chemicals. Another Data Call-In Notice was issued in September 1992 for triethylhexahydrotriazine requiring additional data in support of reregistration.

### III. SCIENCE ASSESSMENT

#### A. Physical Chemistry Assessment

Color:	Colorless to slightly yellow
Physical State:	Liquid
Odor:	Formaldehyde-like odor
Boiling Point:	205-210°C
Specific Gravity:	0.89 gm/cc
Solubility:	Water: 100.000 gm/100ml Hexane: 1.040 gm/100ml Mineral Spirits: 0.129 gm/100ml
Vapor Pressure:	15.7 mm Hg at 25°C
Dissociation Constant:	N/A
K <sub>o/w</sub> :	0.11 (by GC)
pH:	11.0 - 11.1 (5% solution in water)
Stability:	Stable under basic conditions, but decomposition was observed in acid medium.
Flammability:	150°F (Tag closed cup)
Storage Stability:	Stable for more than one year when stored at room temperature in its original container.
Viscosity:	2.80 and 2.82 Centistokes mm <sup>2</sup> /s
Corrosion	
Characteristics:	Triethylhexahydrotriazine was tested in solution of 4.8% for: Brass (corrosion rate = 0.084 g/m <sup>2</sup> /hr), Copper (corrosion rate = 0.011 g/m <sup>2</sup> /hr), Low Carbon steel (corrosion rate = 0), and for Stainless steel (corrosion rate = 0).

#### B. Human Health Assessment

##### 1. Toxicology Assessment

At present, the toxicology data base for triethylhexahydrotriazine meets the Agency's requirements for antimicrobials. The data are adequate and will support a reregistration eligibility determination for currently registered non-food uses.

##### a. Acute Toxicity

Due to the corrosivity of triethylhexahydrotriazine (pH = 11.0-11.1), studies of acute dermal toxicity and primary eye and skin irritation are waived. Triethylhexahydrotriazine has been tested in an acute oral toxicity test (MRID 41773701). In young adult male and female

Crl:CDBR rats, triethylhexahydrotriazine exhibited an acute oral LD<sub>50</sub> value of 291 (193-440) mg/kg for male rats, 135 (79-231) mg/kg for female rats, and 209 (156-280) mg/kg combined. The purity of the test substance was 96.39% a.i..

Triethylhexahydrotriazine has been tested in an acute inhalation toxicity test (MRID 42406101). In Crl:CDBR Sprague-Dawley rats, triethylhexahydrotriazine demonstrated an acute inhalation LC<sub>50</sub> of 251 (249-253) mg/M<sup>3</sup> for male rats, 260 (233-290) mg/M<sup>3</sup> for female rats, and 254 (212-305) mg/M<sup>3</sup> combined. The LC<sub>50</sub> values were calculated using actual chamber concentrations. The purity of the test substance was 96.06% a.i..

Triethylhexahydrotriazine has been tested for its potential to elicit dermal sensitization reactions in guinea pigs (MRID 42293004). Triethylhexahydrotriazine was not a skin sensitizer in this study. The dermal sensitization potential of triethylhexahydrotriazine was evaluated in 10 female Hartley albino guinea pigs using nine occluded dermal induction exposures (clipped back skin; 20 mg dose), one occluded challenge exposure (clipped right flank skin; 4 mg dose), and one occluded rechallenge exposure (clipped left flank skin; 4 mg dose). An irritation control group of five additional females received only the challenge dose, and dermal reactions of the induced animals at challenge and rechallenge were compared to those of this control group. An additional 10 females were induced with nine dermal exposures (clipped back skin; 0.4 mg dose) to 1-chloro-2,4-dinitrobenzene (DNCB), a known skin sensitizer, and then challenged with this same substance (clipped right flank skin; 0.4 mg dose). All animals in all treatment groups survived and gained weight over the test period. After challenge with triethylhexahydrotriazine, one of the 10 animals exhibited well-defined erythema at 24 hours post-challenge. The same animal exhibited very slight erythema at 48 hours post-challenge. After rechallenge, four of the 10 animals exhibited very slight erythema at 24 hours post-treatment, and this slight erythema persisted in one of these animals at 48 hours post-treatment. No edema was observed in any animal at any time period. No dermal reactions were observed in the irritation control group, and 9/10 animals in the positive control group (DNCB-treated) exhibited skin sensitization reactions. The purity of the test substance was 96.39% a.i..

The acute toxicity values, along with their corresponding toxicity categories, are summarized in Table 1.

**Table 1. Acute Toxicity Values for Triethylhexahydrotriazine Technical**

Guideline	Test	MRID	Result	Toxicity Category
81-1	Oral LD <sub>50</sub> - Rat	41773701	LD <sub>50</sub> = 291 mg/kg (M) LD <sub>50</sub> = 135 mg/kg (F) LD <sub>50</sub> = 209 mg/kg (M+ F)	II
81-3	Inhalation LC <sub>50</sub> - Rat	42406101	LC <sub>50</sub> = 251 mg/M <sup>3</sup> (M) LC <sub>50</sub> = 260 mg/M <sup>3</sup> (F) LC <sub>50</sub> = 254 mg/M <sup>3</sup> (M+ F) (LC <sub>50</sub> based on actual chamber concentration)	II
81-6	Dermal Sensitization Guinea Pig	42293004	Triethylhexahydrotriazine was not a sensitizer in this study.	--

The above studies satisfy the acute toxicity data requirements for triethylhexahydrotriazine. Among these requirements, tests for acute dermal toxicity, primary eye irritation in the rabbit, and primary dermal irritation were waived due to the chemical's corrosivity. The test for acute delayed neurotoxicity in the hen was also waived due to lack of acetylcholinesterase inhibition and no structural similarity to compounds known to cause delayed neurotoxicity.

#### **b. Subchronic Toxicity**

In a repeated dose, dermal toxicity study (MRID 41858301), male and female CrI:CDBR Sprague-Dawley rats, 13/sex/group, were exposed (intact skin) to triethylhexahydrotriazine for 13 weeks (6 hours/day, 5 days/week). The purity of the test substance was 96.6% a.i.. The dose levels used were 0, 10, 30, or 100 mg/kg of body weight/day and were based on the results of a preliminary acute dermal toxicity probe study.

Parameters examined for all rats in the study included clinical signs of toxicity, mortality, body weights, food consumption, hematology, clinical chemistry, urinalysis, necropsy, organ weights (liver, lung, kidneys, testes/ovaries, brain, pituitary, and heart), organ/body weight and organ/brain weight ratios and histopathological examination of selected organs/tissues. Severe dermal irritation occurred in both sexes at all doses tested. However, no systemic effects were observed at any dose level.

Based on these findings, the dermal NOEL is < 10 mg triethylhexahydrotriazine/kg body wt./day (the lowest dose tested or LDT) and the dermal LEL is 10 mg/kg/day (LDT), based on the gross observation of dermal irritation which was confirmed histologically. Dermal irritation was characterized by hyperplasia, hyperkeratosis,



inflammation, sebaceous gland hyperplasia, and eschar formation. The systemic NOEL is  $\geq 100$  mg triethylhexahydrotriazine/kg body wt./day and the systemic LEL is  $> 100$  mg/kg/day (the highest dose tested or HDT), based on the lack of systemic effects at any dose level tested.

#### **c. Developmental Toxicity**

A developmental toxicity study (MRID 41865701) was conducted in which pregnant Crl:CDBR Sprague-Dawley rats (25/group) were administered triethylhexahydrotriazine (96.6% a.i.) by gavage during gestation days 6-15, inclusive. The dose levels used were 0, 10, 75, or 150 mg/kg body wt./day and were selected on the basis of a previous range-finding study.

Prior to delivery, animals were sacrificed. The uterus of each animal was examined to determine the numbers of implantation sites, resorption, and live and dead fetuses. The fetuses were examined for external, visceral, and skeletal alterations.

Maternal toxicity was observed only in the high-dose (150 mg/kg/day) group and consisted of a significant (39%) decrease in body weight gain during the dosing period ( $p \leq 0.01$ ). Therefore, the LEL for maternal toxicity was 150 mg triethylhexahydrotriazine/kg of body wt./day and the NOEL for maternal toxicity was 75 mg triethylhexahydrotriazine/kg body wt./day, based on decreased body weight gain. The LEL for developmental toxicity was 150 mg triethylhexahydrotriazine/kg body wt./day (HDT) and the NOEL for developmental toxicity was 75 mg/kg/day, based on the observed significant incidences of bilateral convoluted ureters and dilated renal pelvises in the high-dose (150 mg/kg/day) group.

These effects were statistically significant ( $p \leq 0.05$  for dilated renal pelvises;  $p \leq 0.01$  for bilateral convoluted ureters) for the high-dose (150 mg/kg/day) group, but were within historical control values for the mid- (75 mg/kg/day) and low-dose (10 mg/kg/day) groups. Collectively, MRIDs 42308601, 42366200, and 42366201, and the original study (MRID 41865701), have been upgraded to acceptable.

#### **d. Mutagenicity**

Triethylhexahydrotriazine (98.0% a.i.) was evaluated in a *Salmonella typhimurium*/Ames plate incorporation assay in tester strains TA1535, TA1537, TA1538, TA98, and TA100, with and without metabolic activation (S9), at concentrations up to those inducing

cytotoxicity (MRID 41343401). This study showed that, in repeat trials, triethylhexahydrotriazine demonstrated a dose-related positive for gene reversions in two (TA98 and TA100) of the five strains tested, but only in the presence of metabolic activation (S9) and at elevated concentrations (100-333 µg/plate).

Triethylhexahydrotriazine (98.0% a.i.) was positive for inducing dose-related unscheduled DNA synthesis in primary rat hepatocyte cultures treated at triethylhexahydrotriazine concentrations of 0.03 and 0.06 µL/mL, as determined by radioactive tracer procedures (nuclear silver grain counts). Dose levels used were: 0, 0.001, 0.003, 0.01, 0.03, or 0.06 µL/mL (MRID 41343402).

Triethylhexahydrotriazine (98.0% a.i.) significantly increased the numbers of thioguanine-resistant mutants in cultures of Chinese hamster ovary (CHO) cells at a concentration of 0.02 µL/mL without exogenous (S9) metabolic activation (MRID 41544801). Although less certain, triethylhexahydrotriazine may also increase the numbers of mutants at concentrations of 0.02, 0.025, 0.03, and 0.035 µL/mL with metabolic activation (S9) and at a concentration of 0.03 µL/mL without metabolic activation (S9). The CHO-KiBH4 (Oak Ridge National Laboratory) cell line was used. The concentrations of triethylhexahydrotriazine tested in the non-activated (-S9) studies were: 0, 0.03, 0.02, 0.015, 0.01, 0.007, 0.005, and 0.003 µL/mL. With metabolic activation (+ S9), the concentrations of triethylhexahydrotriazine tested were: 0.035, 0.03, 0.025, 0.02, 0.015, 0.01, 0.007, 0.0035, 0.002, and 0.001 µL/mL. The initial test was complemented by two confirmatory assays.

Triethylhexahydrotriazine (98.0% a.i.) did not induce micronuclei in ICR mice in a mouse micronucleus study (MRID 41321501). Groups of mice (15/sex/dose) were administered single doses of triethylhexahydrotriazine in sterile distilled water orally by gavage at dose levels of 0, 25, 125, or 225 mg/kg body weight. Negative control animals (0 mg/kg) received distilled water only. Five females and five males were administered an intraperitoneal dose of 0.25 mg/kg body weight of the positive control substance, triethylenemelamine. Five per sex of the negative control and test groups were sacrificed at 24, 48, and 72 hours post-dosing. Positive controls were sacrificed at 24 hours post-dosing. Both femurs were dissected out, and smears were made from each femur. Smears were stained with May-Gruenwald-Giemsa stain and examined by light microscopy to determine the number of micronucleated polychromatic erythrocytes. Mortality was increased in the high-dose group (225 mg/kg), in which 4/15 died and were therefore replaced with other mice. The positive control substance caused a significant increase in the number of

micronucleated polychromatic erythrocytes, while negative control animals and all treatment groups exhibited no such increase. Although originally classified as *Unacceptable*, subsequent submission of purity data on the test substance (MRID 41738201) upgrades this study to a classification of *Acceptable*.

In summary, triethylhexahydrotriazine was shown to be mutagenic in three of the four mutagenicity tests conducted. While the three in vitro studies suggest a mutagenic potential for gene mutation and unscheduled DNA synthesis, the negative in vivo micronucleus study indicates that triethylhexahydrotriazine lacks the mutagenic potential for increased incidence of micronucleated polychromatic erythrocytes. Based on the available toxicity data, it is concluded that triethylhexahydrotriazine has intrinsic mutagenicity activity which is only expressed in vitro. No further testing is required at this time.

## **2. Toxicological Endpoints for Risk Assessment**

### **a. Reference Dose (RfD)**

Even though chronic occupational exposure is anticipated with the use of triethylhexahydrotriazine, chronic testing is not required since the NOEL from the 13-week rat dermal toxicity study is greater than 1000 times higher than human dermal exposure (i.e. assuming 100 percent dermal exposure). In addition, since the NOEL from the 13-week rat dermal toxicity study was greater than the highest dose tested, the Agency does not believe that chronic exposure would indicate a risk of concern. Finally, there are no registered food uses for triethylhexahydrotriazine. Therefore, the Agency has decided not to establish an RfD for triethylhexahydrotriazine. This class of chemicals (i.e., disinfectants, microbiocides, microbiostats, sanitizers, etc.) has not been reviewed by the FAO/WHO Joint Meeting on Pesticide Residues.

### **b. Carcinogenicity Classification**

The cancer classification for this chemical has not been established. Since triethylhexahydrotriazine is a non-food use pesticide, carcinogenicity studies have not been required.

### **c. Toxicology Endpoints of Concern**

Based on the review of the toxicology database and information on the general use pattern for triethylhexahydrotriazine, the Agency established toxicity endpoints to be used in the occupational and residential

risk characterization. They are listed in Table 2. The NOEL from the 13-week dermal rat study was not used for short-term or intermediate-term occupational or residential risk assessment since no systemic effects were observed at any dose level tested. In the absence of data on dermal absorption, 100% absorption is assumed.

**Table 2. Summary of Toxicological Endpoints for Triethylhexahydrotriazine**

Type of Exposure (Duration and Route)	Endpoint (And Toxicological Effect)
Acute Dietary: oral	Endpoint is not required for this active ingredient as triethylhexahydrotriazine is a non-food use chemical.
Short-Term Occupational or Residential Exposure (one to seven days): dermal	75 mg/kg/day (maternal oral NOEL for decreased maternal body weight gain during entire gestation period, also developmental NOEL for increased fetal incidences of dilated renal pelvises and bilateral convoluted ureters)
Intermediate-Term Occupational or Residential Exposure (one week to several months): dermal	MRIDs: 41865701; 42366200; and 42308601

### 3. Occupational and Residential Exposure Assessment

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

EPA has determined that an exposure assessment is appropriate for triethylhexahydrotriazine. There is a toxicological concern (i.e., maternal and developmental effects via the oral route) and there is potential for workers and residents to be exposed to triethylhexahydrotriazine during application and post-application.

EPA has also determined that in and near sites where triethylhexahydrotriazine or triethylhexahydrotriazine-containing products are being used, individuals may be exposed to formaldehyde as this pesticide is a possible formaldehyde generator. The registrants report in their Material Safety Data Sheet (MSDS) that: “Simulated routine customer handling suggests that formaldehyde off-gas is unlikely to exceed any of [the Occupational Safety and Health Administration (OSHA) permissible exposure level (PEL) and short-term exposure limit (STEL)] standards. Typical handling of triethylhexahydrotriazine yielded formaldehyde off-gas levels of < 0.005 to 0.01 ppm for an 8-hour exposure (extrapolated). Because off-gas is affected by temperature, pH and plant-specific controls, plant-specific monitoring is recommended to establish compliance with the standard.” In May 1992 OSHA published a comprehensive workplace standard for the protection of workers in the industrial setting due to

formaldehyde-release in the workplace. The standard set a PEL of 0.75 ppm as an 8-hour time-weighted average (TWA), a 15-minute STEL of 2 ppm, and prescribes that certain actions should be taken if monitoring shows levels of 0.50 ppm as an 8-hour TWA. Further, it requires monitoring before workers enter the premises following use of formaldehyde or when potential ambient formaldehyde is generated from other chemicals. The standard also establishes requirements for posting of warning signs, use of personal protective equipment, medical surveillance, hazard communication and training.

### **Use Patterns**

Triethylhexahydrotriazine is a microbiocide/microbiostat used against slime-forming bacteria and fungi. Triethylhexahydrotriazine is formulated as a soluble concentrate/liquid (ranging from 93 to 95 percent active ingredient). Triethylhexahydrotriazine is employed in a variety of industrial uses including:

- Industrial adhesives (95 to 475 ppm a.i. by weight);
- Latex paints (in-can) (475 to 1,425 ppm a.i. by weight);
- Rubber products (190 to 475 ppm a.i. by weight);
- Fuels/oil storage tank bottom water additive (363 to 1,813 ppm a.i. by volume);
- Metalworking cutting fluids (28,500 ppm a.i. by weight);
- Wet-end additives/industrial processing chemicals (95 to 1,425 ppm a.i. by weight).

All triethylhexahydrotriazine products are intended for occupational use when handled directly. Homeowners may be exposed to triethylhexahydrotriazine while using products, such as paints, adhesives, or rubber products, to which triethylhexahydrotriazine has been added. EPA has determined that there is a potential for exposures to mixers, loaders, applicators, or other handlers of triethylhexahydrotriazine, products containing triethylhexahydrotriazine, and its break-down product formaldehyde. There are potential exposures from applications in commercial, industrial, and residential settings. EPA has identified two levels of handler exposures:

- Primary Handlers -- persons handling end-use pesticide products containing triethylhexahydrotriazine as an active ingredient.
- Secondary Handlers -- persons handling products, such as paints, adhesives, and metalworking/cutting fluids to which triethylhexahydrotriazine has been added.

All handler use patterns were only assessed for dermal exposure. They were not assessed for inhalation exposure. Although EPA believes that inhalation exposure may be significant (the vapor pressure of triethylhexahydrotriazine is

15.7 mmHg @ 25°C and it is classified as category II for inhalation toxicity), no data are available to quantitatively assess inhalation exposure.

EPA is also aware of possible handler exposures to formaldehyde in industrial, manufacturing, and residential settings, since formaldehyde is a possible degradate of triethylhexahydrotriazine under certain conditions. However, no data are available at this time upon which to assess the possible exposure and risk.

**a. Occupational Handler Exposure Scenarios**

**Primary Occupational Handlers:** Based on the use patterns, EPA has identified two major triethylhexahydrotriazine exposure scenarios for primary occupational handlers: (1) open-pouring the soluble concentrate liquid formulation and (2) metering-pump applications (automatic dispensing equipment) with the soluble concentrate liquid formulation. Provided in Table 4 are exposure estimates for two Open-Pour Liquid scenarios (Manufacturing of Paint and Metal-Cutting Fluid) and one Pump-Metering System scenario. EPA assumes that mixers and loaders are exposed more than 7 days per year (reasonable worst-case estimate).

EPA has no data for several of the uses listed for triethylhexahydrotriazine. However, EPA has data that may be used as a surrogate for these uses. In this exposure and risk assessment, the following surrogates have been used:

- Data from pulp and paper mill uses is used as a surrogate for the wet-end additives/industrial processing chemicals use, since both use patterns use automatic dispensing equipment rather than open-pour techniques; and
- Data from paint manufacturing uses are used as a surrogate for the rubber, industrial adhesives, and fuels/oil storage tank bottom water uses, since these use patterns use open-pour techniques rather than automatic dispensing equipment.

**Secondary Occupational Handlers:** Based on the use patterns, EPA has identified several major triethylhexahydrotriazine exposure scenarios for secondary occupational handlers of triethylhexahydrotriazine containing products including: (1) paint, (2) adhesives, (3) rubber products, and (4) metalworking/cutting fluids. EPA considers dermal exposures while handling triethylhexahydrotriazine-containing paint to represent a reasonable worst-case dermal exposure scenario for secondary occupational handlers, other than metalworking/cutting fluid uses. Provided in Table 4 (as Paint Application) is the exposure estimate for this scenario.

With respect to secondary occupational exposure to handlers of metalworking/cutting fluids, this exposure assessment addresses only the potential exposures to primary occupational handlers who are adding triethylhexahydrotriazine into metalworking fluids. Although EPA continues to discuss with OSHA and National Institute for Occupational Safety Health (NIOSH) the roles and responsibilities of regulating the uses of metalworking fluids and other products in the industrial setting, OSHA is responsible for regulating machinists' safety and exposure. Therefore, machinists' exposures to triethylhexahydrotriazine or formaldehyde will not be addressed in detail in this document. EPA defers to OSHA for enforcing the formaldehyde air-level standard in industrial and manufacturing settings.

**b. Homeowner Handler Exposure Scenarios**

**Primary Homeowner Handlers:** There are no use patterns identified for primary homeowner handlers, since at this time all triethylhexahydrotriazine end-use pesticide products are intended for occupational use.

**Secondary Homeowner Handlers:** Based on the use patterns, EPA has identified three major triethylhexahydrotriazine exposure scenarios for secondary homeowner handlers of triethylhexahydrotriazine containing products, including: (1) paint, (2) adhesives, and (3) rubber products. (See Table 4.) EPA considers exposures while handling triethylhexahydrotriazine-containing paint to represent a reasonable worst-case dermal exposure scenario for secondary homeowner handlers. Provided in Table 4 (as Paint Application) is the exposure estimate for this scenario.

**c. Post-Application Exposure Scenarios and Assumptions**

EPA believes there are potential exposures following applications of triethylhexahydrotriazine in commercial, industrial, and residential settings. EPA has identified two levels of post-application exposures as described below.

The following post-application use patterns were only assessed for dermal exposure. They were not assessed for inhalation exposure. Although EPA believes that inhalation exposure may be of concern (the vapor pressure of triethylhexahydrotriazine is 15.7 mmHg @ 25°C and it is classified as category II for inhalation acute toxicity), no data are available to quantitatively assess inhalation exposure. EPA also

acknowledges possible post-application exposures to formaldehyde in industrial, manufacturing, and residential settings.

### **Occupational and Homeowner Post-Application Exposure Scenarios**

**Primary Occupational Post-Application Exposures:** Based on the use patterns, EPA has identified two primary post-application exposure scenarios in commercial and industrial settings: (1) potential exposures following applications of triethylhexahydrotriazine to open vats of liquids, such as adhesives, rubbers, fuels/oil storage tank bottom water, and paints, and (2) exposures to persons maintaining equipment, such as water systems, and other industrial equipment, which contain products treated with triethylhexahydrotriazine.

**Secondary Occupational Post-Application Exposures:** Based on the use patterns, EPA has identified several major triethylhexahydrotriazine exposure scenarios for secondary occupational post-application exposures, including: (1) exposures to persons occupying areas recently painted with triethylhexahydrotriazine-containing paint, (2) exposures to persons occupying areas where triethylhexahydrotriazine-containing adhesives have recently been applied, and (3) exposures while handling recently treated rubber.

**Primary Homeowner Post-Application Exposures:** EPA has identified no major triethylhexahydrotriazine exposure scenarios for primary homeowner post-application exposures, since at this time all triethylhexahydrotriazine end-use pesticide products are intended for occupational use.

**Secondary Homeowner Post-Application Exposures:** Based on the use patterns, EPA has identified two major triethylhexahydrotriazine exposure scenarios for secondary homeowner post-application exposures: (1) exposures while occupying areas recently painted with triethylhexahydrotriazine-containing paint, and (2) exposures while occupying areas where triethylhexahydrotriazine-containing adhesives have recently been used.

EPA believes that these primary and secondary post-application dermal exposures in industrial settings and secondary exposures in residential settings would be lower than dermal exposures to primary occupational handlers. Provided in Table 3



is a simple matrix illustrating this narrative description of these primary and secondary exposures.

**Table 3. Description of Primary and Secondary Exposures**

Type of Exposure		Occupational Settings -- Examples	Residential Settings -- Examples
Handler Exposure	Primary	Adding triethylhexahydrotriazine to a vat of paint.	N/A. Triethylhexahydrotriazine is an industrial chemical; homeowners would not handle it directly.
	Secondary	Professional painter using a triethylhexahydrotriazine-containing paint.	A homeowner using a triethylhexahydrotriazine-containing paint.
Post-Application Exposure	Primary	Standing near a vat where triethylhexahydrotriazine was added.	N/A. Triethylhexahydrotriazine is an industrial chemical; homeowners would not receive post-application exposures when triethylhexahydrotriazine is handled directly
	Secondary	Being in a painted room.	Being in a painted room.

N/A = not applicable

#### **d. Exposure Estimations**

The Agency relied on surrogate exposure data from a study submitted by the Chemical Manufacturers Association, the assumption of 100% dermal absorption, the use of chemical resistant gloves (except for paint application), as well as other assumptions which are noted in Table 4 on the next two pages. Short and intermediate-term exposure estimates were calculated for these representative use scenarios using the following formula to estimate actual daily exposure:

$$\frac{\text{unit exposure (ug/lb a.i.)} \times \text{application rate (lb a.i./used)}}{\text{body wt (kg)}}$$

The following exposure and risk characterization addresses both primary and secondary exposure for occupational and residential handlers and post-application scenarios. All of the following exposure scenarios (both handler and post-application) were assessed for dermal exposure only. Although EPA believes that inhalation exposure may be of concern no data are available to assess inhalation exposure quantitatively.

**Table 4. Daily Exposure Estimates for Triethylhexahydrotriazine Handler Scenarios**

OPERATION		SETTING	CALCULATION OF POUNDS A.I. USED PER DAY <sup>1</sup>			CALCULATION OF WORKER EXPOSURE		
			AMOUNT OF PRODUCT USED	VOLUME TREATED/ USED PER DAY	lb a.i. used/day	UE (µg/lb a.i.) <sup>2</sup>	DAILY DOSE (mg/day) <sup>3</sup>	ACTUAL DAILY EXPOSURE (mg/kg/day) <sup>4</sup>
<b>Primary Exposure</b>								
Open-Pour Liquid		Paint Manufacturing (also surrogate for industrial adhesives, rubbers, and fuels/oil storage tank bottom water)	1.5 lb a.i. 100 gallons paint	100 gal	1.5	0.14	0.21	0.0035
Open-Pour Liquid		Metal-Cutting Fluid	28,500 ppm a.i. by weight for the concentrate oil.	10 gal	2.8 (assuming the density of oil is 10 lbs/gal)	0.133	0.37	0.0062
Pump-Metering System		Pulp and Papermill (surrogate for wet-end additives/ industrial processing chemicals)	Final concentration of 1,425 ppm by weight	100 tons	285	0.0075	2.1	0.035
<b>Secondary Exposure</b>								
Paint Application	Occupational	Painting	1.5 lb a.i. 100 gallons paint	5 gal	0.075	182	13.6	0.225
	Residential			1 gal			0.015	2.72

**NOTES:**

<sup>1</sup> Lb a.i./used was derived from the product labels, CMA study, and the LUIS report. Where:

- a.) For paint manufacturing, 1.5 pounds a.i. is used per 100 gallons of paint treated. Assuming that 100 gallons of paint are treated per day, the amount of a.i. handled is 1.5 lb a.i./day.
- b.) For the metal worker, 28,500 ppm a.i. by weight are used for the concentrate oil for further 20-75 times dilution with water to this treated concentrated oil (400-1,500 ppm final a.i. concentration). Since 10 gallons of oil are used per day, the lb a.i. used is 2.8 (assuming the density of oil is 10 lbs/gallon).
- c.) For pulp and paper mills, 1,425 ppm a.i. by weight is used as the final concentration. Assuming 100 tons of the slurry is used per day, the lb a.i. used is 285 (where: [1,425 lbs triethylhexahydrotriazine/1x10<sup>6</sup> lb solution]\*[(100 tons of slurry)\*(2000 lb/ton)]).
- d.) For painting, 1.5 lb a.i. is added per 100 gallons of paint. It will be assumed that a homeowner (H) uses 1 gallon of paint per day, and an occupational (O) worker uses 5 gallon of paint per day. With reference to residential versus occupational daily exposure scenarios, this table is not meant to estimate a typical daily exposure to paint, but is an estimate of short to medium term sub-chronic (several days to several months) exposure broken down into average daily value. This is equal to 0.015 lbs a.i. used by the homeowner and 0.075 lbs a.i. used for the occupational worker. Only dermal exposure is included in this table since there are no adequate inhalation data.

<sup>2</sup> UE = Unit Exposure (UE) data were derived from the Chemical Manufacturers Association study and include dermal and inhalation exposure with workers wearing gloves. Inhalation exposure data are not applicable since the CMA study does not include inhalation data for pesticides having high volatility, as is the case for triethylhexahydrotriazine. For paint application, unit dermal exposures for workers wearing long pants, long-sleeved shirts, and no gloves were derived from the Pesticide Handlers Exposure Database (PHED) V1.1 as amended (15 replicates, grade C, medium confidence in data).

<sup>3</sup> DAILY DOSE (mg/day) = (UE x lb a.i. used/day x % dermal absorption); where dermal absorption = 100%.

<sup>4</sup> ACTUAL DAILY EXPOSURE (mg/kg/day) = POTENTIAL DAILY EXPOSURE (mg/day)/BODY WEIGHT (kg); where BW = 60 kg.

#### 4. Occupational and Residential Risk Characterization

Based on the above exposure estimates and underlying assumptions of the short and intermediate-term toxicological endpoint of 75 mg/kg/day, the Agency estimated the risks with a margin of exposure (MOE). These estimates are calculated by:

$$\text{MOE} = \text{NOEL/Actual Daily Exposure}$$

##### a. Primary Application and Post-Application Scenarios (Occupational Only)

Primary application and post-application exposure scenarios are those involving industrial uses of triethylhexahydrotriazine.

##### Risk Assessment

Based on available toxicity data and exposure scenarios for triethylhexahydrotriazine, the Agency has determined that quantitative risk characterizations for mixer/loader/applicator and handler dermal exposures are appropriate for short- to intermediate-term exposures. Because of the selected toxicity endpoint for this duration of exposure to triethylhexahydrotriazine, the Agency is characterizing the risks by MOEs. Provided in Table 5 are the MOEs for the triethylhexahydrotriazine application scenarios.

**Table 5. Worker Risk Estimates for Triethylhexahydrotriazine Handler Scenarios**

OPERATION		SETTING	ACTUAL DAILY EXPOSURE (mg/kg/day)	MOE <sup>1</sup>
<b>Primary Exposure</b>				
Open-pour Liquid		Paint Manufacturing (also surrogate for industrial adhesives, rubbers, and fuels/oil storage tank bottom water)	0.0035	21,429
Open-pour Liquid		Metal-Cutting Fluid	0.0062	12,088
Pump-Metering System		Pulp and Papermill (surrogate for wet-end additives/industrial processing chemicals)	0.035	2,143
<b>Secondary Exposure</b>				
Paint Application	Occupational	Painting	0.225	333
	Residential		0.046	1643

NOTE: <sup>1</sup>MOE = NOEL/ACTUAL DAILY EXPOSURE, where NOEL = 75 mg/kg/day.

EPA generally is not concerned with occupational and residential risk if MOEs are greater than 100. For triethylhexahydrotriazine, all the primary application exposure dermal MOEs are greater than 100; they range from approximately 2,100 for exposure in wet-end additives/industrial processing chemicals using a pump metering system to approximately 21,000 for open-pour operations during paint, adhesive, and rubber manufacturing and in uses for fuels/oil storage tank bottom water.

As mentioned previously, triethylhexahydrotriazine is so corrosive that the dermal acute toxicity and primary skin and eye irritation studies were waived.

Although no traditional risk assessment is currently available to evaluate risks posed by corrosivity, the Agency has determined that triethylhexahydrotriazine products may pose significant handler risk due to its corrosivity. The Agency is addressing these risks through the establishment of PPE requirements that are to be included on all end-use product labeling that are classified as toxicity category I or II for skin or eye irritation potential.

In addition, the Agency did not conduct a quantitative risk characterization for chronic exposure (several months to one-year) due to the lack of a chronic toxicological endpoint. However, based on the NOEL being greater than the highest dose tested for subchronic toxicity (13-week dermal study), and the high MOE for primary handlers, the Agency does not believe that a chronic exposure MOE would indicate a risk of concern. As previously discussed, the Agency does not have data to assess directly any post-application exposure to triethylhexahydrotriazine. However, EPA believes that dermal exposures incurred during handling tasks are likely to be higher than dermal exposures incurred during post-application. Because all the dermal MOEs for handlers are greater than 100, EPA believes that the post-application dermal MOEs would also be greater than 100.

### **Risk Concerns**

EPA is concerned about potential inhalation exposures to triethylhexahydrotriazine for primary handler and primary post-application situations, since it is classified as category II for acute inhalation toxicity and the vapor pressure is high (i.e., 15.7 mmHg at 25°C). At this time, EPA has no data upon which to conduct an exposure or risk assessment for inhalation concerns. Due to the Agency's concerns about potential inhalation exposure and the lack of inhalation exposure data, the Agency is requiring primary handler and primary post-application inhalation exposure data. Even though the Agency has concerns about these exposure scenarios, the Agency believes that primary handler and primary post-application inhalation exposures are not likely to be a risk of concern based on recommendations noted in the pesticide's MSDS. The MSDS states "Effective exhaust [must be maintained] to draw fumes and vapors away from workers to prevent routine inhalation. If local exhaust ventilation is applied, a capture velocity of 100 to 150 feet per minute should be maintained. Local exhaust is recommended during product mixing." Thus, the Agency is requiring primary handler and post-application dermal and inhalation exposure data to confirm that the risks associated with these exposure scenarios would not indicate a risk of concern.

In addition to inhalation concerns about triethylhexahydrotriazine itself in primary occupational settings, EPA is concerned about potential inhalation exposures to formaldehyde (a potential triethylhexahydrotriazine degradate) in these situations. However, since OSHA has established Permissible Exposure Level (PEL) and Short-Term Exposure Limit (STEL) standards for formaldehyde in industrial and manufacturing settings, EPA defers to OSHA in enforcing formaldehyde air levels in these settings.

#### **b. Secondary Handler and Post-Application Scenarios**

Exposures to products containing triethylhexahydrotriazine as an additive (such as paints, rubber, or adhesives) may occur in industrial, manufacturing, and residential settings.

### **Risk Assessment**

Secondary occupational/residential exposures are expected to be short-term and intermediate-term. Chronic exposure is expected only for occupational workers. Based on available toxicity data and exposure scenarios for triethylhexahydrotriazine, the Agency has determined that a quantitative risk characterization for painters (occupational and residential) is appropriate. Because of the selected toxicity endpoint for short- to intermediate-term exposure to triethylhexahydrotriazine, the Agency is characterizing the risks by MOE. Provided in Table 5 are the MOEs for the triethylhexahydrotriazine dermal secondary handler scenarios. The Agency did not conduct a quantitative risk characterization for chronic exposure (several months to one-year) due to the lack of a chronic toxicological endpoint. However, based on the NOEL being greater than the highest dose tested (13-week dermal study), and the high MOE for painters, the Agency does not believe that a chronic exposure MOE would indicate a risk of concern.

The Agency does not have data to assess directly post-application (occupational or residential) dermal exposure to triethylhexahydrotriazine. However, EPA believes that dermal exposures incurred during application are likely to be higher than exposures incurred during post-application. Because the painter exposure dermal MOEs are greater than 100, EPA believes that the post-application dermal MOEs would also be greater than 100. Thus, a quantitative assessment of the dermal post-application exposure risks is not necessary.

### **Risk Concerns**

EPA is also concerned about potential inhalation exposures to triethylhexahydrotriazine for secondary handler and secondary post-application situations, particularly when triethylhexahydrotriazine-containing paint is used, since triethylhexahydrotriazine is classified as category II for acute inhalation toxicity and the vapor pressure is high (i.e., 15.7 mmHg at 25°C). At this time, EPA has no data upon which to conduct an exposure or risk assessment for inhalation concerns. Thus, the Agency is requiring secondary handler and secondary post-application inhalation, as well as dermal, exposure data. Even though the Agency has concerns about potential inhalation exposures to triethylhexahydrotriazine for these exposure scenarios, the Agency believes that secondary handler and secondary post-application inhalation exposure are not likely to be of concern since triethylhexahydrotriazine concentrations in paint or adhesives would be relatively low (usually less than 1% a.i.). The Agency is requiring these exposure data to confirm that risks associated with these exposure scenarios are acceptable.

In addition to inhalation concerns for triethylhexahydrotriazine in secondary occupational and residential settings, EPA also is concerned about potential inhalation exposures to formaldehyde (a potential triethylhexahydrotriazine

degrade) in these situations. In industrial and manufacturing settings, such as metalworking shops, EPA defers to OSHA enforcement of OSHA's formaldehyde air-level standards. Since potential inhalation exposures may also occur in residential settings where OSHA does not traditionally have jurisdiction, EPA is unable to defer these concerns to OSHA enforcement. Therefore the Agency is requiring secondary applicator and post application inhalation exposure data to confirm that risks associated with these formaldehyde exposure scenarios are acceptable. These inhalation exposure studies will monitor for triethylhexahydrotriazine as well as its degradates (formaldehyde).

## **5. Additional Occupational/Residential Exposure Studies**

### **Handler Studies**

EPA is requiring the following confirmatory data for handler exposures:

- For painting with a brush;
- For painting with a roller;
- For painting with a sprayer.

For each of these handler exposure scenarios, studies should be conducted using guideline numbers: 231, 232, 233, and 234 for the estimation of both inhalation and dermal exposures in indoor and outdoor sites. The air monitoring study must include monitoring for potential degradates (formaldehyde) as well as monitoring for triethylhexahydrotriazine itself.

### **Post-Application Studies**

EPA is requiring confirmatory data for post-application exposures in painted areas where paint is applied by brush, roller, and sprayer. For these exposure scenarios, studies should be conducted using guideline numbers: 133-3 for dermal passive dosimetry exposure and 133-4 for inhalation passive dosimetry exposure. The air monitoring studies for paint uses must include monitoring for the potential degradate (formaldehyde) as well as monitoring for triethylhexahydrotriazine itself.

## **6. Other Considerations**

The Food Quality Protection Act of 1996 amends both FFDCA and FIFRA by setting a new safety standard for the establishment of tolerances. In determining whether or not a tolerance meets the new safety standard, FQPA directs EPA to consider information concerning: the susceptibility of infants and children to residues of the pesticide in food; the potential for aggregate exposures from dietary as well as non-occupational sources, such as pesticides used in and around the home; and the potential for cumulative effects from a pesticide and other substances that have a common mechanism of toxicity.

Because triethylhexahydrotriazine has no food uses, and therefore no tolerances have been established, the specific determinations outlined in FQPA are not required for this

chemical. Nevertheless, EPA believes that consideration of available data relating to the special sensitivity of infants and children, as well as the potential for aggregate exposures and cumulative effects is prudent for triethylhexahydrotriazine because children and other individuals could be exposed to this compound in non-occupational settings.

**a. Potential Risks to Infants and Children**

In determining whether or not an additional uncertainty (safety) factor is appropriate for assessing risks to infants and children, EPA takes into account the completeness and reliability of the toxicity data base, the nature of the effects observed in pre-and post-natal studies, and other information such as epidemiological data.

Based on current data requirements, only one developmental study is usually required, and reproduction studies are not routinely required for non-food use chemicals. A reproduction study has not been required for triethylhexahydrotriazine.

The effects observed in the triethylhexahydrotriazine developmental study can be summarized as follows:

Results from a rat developmental toxicity study (triethylhexahydrotriazine was administered by gavage during gestation days 6-15, inclusive) indicated both developmental and maternal toxicity. Developmental toxicity was observed at 150 mg/kg/day (highest dose tested) and consisted of increased fetal incidences of dilated renal pelvises and bilateral convoluted ureters. Therefore, the LEL was 150 mg/kg/day and the NOEL was 75 mg/kg/day. In terms of maternal toxicity, decreased body weight gains were observed during the entire dosing period at 150 mg/kg/day (highest dose tested). Thus the maternal LEL was 150 mg/kg/day and the NOEL was 75 mg/kg/day.

In the triethylhexahydrotriazine study, developmental effects occurred at the same dose level as maternal effects. The Agency would generally be concerned when developmental effects are seen at doses lower than those which cause maternal effects.

Nothing in the available data suggests special sensitivity of young organisms to triethylhexahydrotriazine. Therefore, the Agency concludes that an additional uncertainty factor need not be applied to the short and intermediate term NOELs selected for the triethylhexahydrotriazine risk assessments at this time.

**b. Aggregate exposure**

In examining aggregate exposures, EPA takes into account available information concerning exposures from pesticide residue in food and other exposures for which there is reliable information. These other sources of exposure can include drinking water, and non-occupational exposures, e.g., to pesticides used in and around the home.

There are no food uses of triethylhexahydrotriazine, therefore exposure to triethylhexahydrotriazine residues in the diet are not expected. Because the uses of triethylhexahydrotriazine are primarily indoors, EPA does not anticipate any significant residues in drinking water. Thus, the only likely non-occupational exposure to triethylhexahydrotriazine would be from uses in the home. These include applying paints and adhesives containing triethylhexahydrotriazine, handling rubber products which contain it as a preservative, and occupying the same room or area where triethylhexahydrotriazine-containing products are being applied or have been used.

Based on available surrogate exposure information, applying triethylhexahydrotriazine-containing paints would result in the reasonable worst case exposure scenario, i.e., the highest exposure, for homeowners. The dermal MOE for this scenario is > 1600. No data are available to estimate inhalation exposure, which could be significant given the volatility of triethylhexahydrotriazine. Therefore, the Agency is requiring inhalation exposure data for both applicators and post-application exposure, including measurements of air concentrations in newly painted rooms where infants and children could be exposed. Pending receipt and review of this inhalation exposure data, EPA believes that it is reasonable to assume that aggregate exposures to triethylhexahydrotriazine in the home are not likely to be of concern based on the high MOE for dermal exposure.

### **c. Cumulative Effects**

The Agency has not yet made a determination regarding the common mode/mechanism of toxicity of triethylhexahydrotriazine and whether it is appropriate to consider exposure to triethylhexahydrotriazine with other compounds in order to address potential cumulative effects. There are significant structural differences between triethylhexahydrotriazine and other more commonly known triazine pesticides such as atrazine, simazine, and propazine. Unlike these other triazines, triethylhexahydrotriazine has no aromatic ring, no double bonds, and is not chlorinated. Because of these structural dissimilarities, the Agency would not expect a common mechanism of toxicity between triethylhexahydrotriazine and the other triazine pesticides.

Furthermore, based on the high dermal MOE for homeowner applicators, the lack of food uses, the unlikelihood of residues in drinking water, and the low concentration in paint, the Agency believes that the contribution of triethylhexahydrotriazine exposure to the risks of any other compounds with a common mode/mechanism of toxicity is likely to be minimal considering the currently registered triethylhexahydrotriazine uses.



## C. Environmental Assessment

### 1. Ecological Toxicity Data

#### a. Toxicity to Terrestrial Animals

**Birds, Acute and Subacute:** An acute oral toxicity study using the technical grade of the active ingredient is required to establish the toxicity of a pesticide to birds. The preferred test species is either mallard duck or bobwhite quail. Results of this test are tabulated below.

**Table 6 : Avian Acute Oral Toxicity**

Species	% A.I.	LD <sub>50</sub> a.i. Mg/Kg/Day	Toxicity Category	MRID No.	Study Classification
Northern Bobwhite Quail ( <i>Colinus virginianus</i> )	96	311	Moderately toxic	42223201	Acceptable
Northern Bobwhite Quail ( <i>Colinus virginianus</i> )	96	394	Moderately toxic	00164390	Supplemental
Mallard duck ( <i>Anas platyrhynchos</i> )	96	595	Slightly toxic	00164390	Supplemental

These results indicate that triethylhexahydrotriazine is slightly to moderately toxic to avian species on an acute oral basis. The guideline requirement (71-1) for a biocide is fulfilled (MRID 42223201).

Two subacute dietary studies using the technical grade of the active ingredient are required to establish the toxicity of a pesticide to birds; however, the Agency has determined that one avian subacute dietary toxicity study is sufficient for a biocide such as triethylhexahydrotriazine that has only indoor use patterns. The tested species is the bobwhite quail (an upland gamebird). Results of this test are tabulated below.

**Table 7: Avian Subacute Dietary Toxicity**

Species	% A.I.	LC <sub>50</sub> (ppm)	Toxicity Category	MRID No.	Study Classification
Northern Bobwhite Quail ( <i>Colinus virginianus</i> )	96	> 5000	Practically non-toxic	42317001	Acceptable

These results indicate that triethylhexahydrotriazine is practically non-toxic to avian species on a subacute dietary basis. The guideline requirement (71-2) is fulfilled (MRID 42317001).

## b. Toxicity to Aquatic Animals

### (1) Freshwater Fish

One freshwater fish toxicity study is typically required for microbiocides; however, tests with two species are available. The tests are conducted with the technical grade of the active ingredient in order to establish the toxicity of a pesticide to fish. The preferred test species are rainbow trout (a cold-water fish) and bluegill sunfish (a warm water fish). Results of these tests are tabulated below.

**Table 8 : Freshwater Fish Acute Toxicity**

Species	% A.I.	LC <sub>50</sub> (ppm)	Toxicity Category	MRID No.	Study Classification
Rainbow trout ( <i>Oncorhynchus mykiss</i> )	96	35	Slightly Toxic	42209701	Acceptable
Rainbow trout ( <i>Oncorhynchus mykiss</i> )	96	23	Slightly Toxic	ACC128718	Acceptable
Bluegill sunfish ( <i>Lepomis macrochirus</i> )	95	31	Slightly Toxic	ACC128718	Acceptable

The results indicate that triethylhexahydrotriazine is slightly toxic to freshwater fish on an acute basis. The guideline requirement (72-1) is fulfilled (MRIDs 42209701, ACC128718).

### (2) Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test using the technical grade of the active ingredient is required to assess its toxicity to invertebrates. The preferred test species is *Daphnia magna*. Results of this test are tabulated below.

**Table 9 : Freshwater Invertebrate Toxicity**

Species	% A.I.	LC <sub>50</sub> / EC <sub>50</sub> (ppm)	Toxicity Category	MRID No.	Study Classification
Waterflea ( <i>Daphnia magna</i> )	96	26	Slightly Toxic	42557301	Acceptable

The results indicate that triethylhexahydrotriazine is slightly toxic to aquatic invertebrates on an acute basis. The guideline requirement (72-2) is fulfilled (MRID 42557301).

## 2. Environmental Fate

### Environmental Fate Assessment

The current policy for microbiocides requires a hydrolysis study. The Agency does not have a hydrolysis study for this active ingredient, but, based on the

behavior of structurally related chemicals, the expected reaction products may be formaldehyde and ethylamine. However, the effect of different pHs on the rate of hydrolytic degradation is not known. The data requirement is not fulfilled. Data are needed on the rate of hydrolysis of triethylhexahydrotriazine at pH 5, 7 and 9, and the reaction products must be identified.

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

#### **a. Exposure and Risk to Nontarget Organisms**

The Agency requires only a limited number of ecotoxicology and environmental fate studies for microbiocides with indoor use patterns. The available data classify triethylhexahydrotriazine as moderately toxic to birds on an acute oral basis, practically non-toxic to birds on a subacute dietary basis, and slightly toxic to freshwater fish and aquatic invertebrates on an acute basis. While the hazard to aquatic organisms from triethylhexahydrotriazine has been characterized, a quantitative risk assessment has not been conducted. The risks to aquatic environments are regulated under the NPDES permitting program of the Agency's Office of Water. Labels for all triethylhexahydrotriazine products must require that discharges to aquatic environments comply with an NPDES permit.

The fuel additive use of triethylhexahydrotriazine may be associated with periodic releases into the environment from the purging of storage tanks. This terrestrial use is expected to result in minimal to no exposure.

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

The Agency does not anticipate any exposure of concern to fish and wildlife, providing that triethylhexahydrotriazine products are discharged into the environment in accordance with all disposal laws or a NPDES permit.

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

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

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing triethylhexahydrotriazine. 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 triethylhexahydrotriazine under the conditions specified in this RED. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of triethylhexahydrotriazine, 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 triethylhexahydrotriazine and to determine that triethylhexahydrotriazine can be used under the conditions specified in this RED without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing triethylhexahydrotriazine as the active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

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

Under section 5 of the Occupational Safety and Health Act, 29 U.S.C. 651 *et sec*, every employer has a general duty to furnish a place of employment which is free from recognized hazards that are causing, or are likely to cause, serious physical harm. Every employer is also required to comply with occupational safety and health standards promulgated by OSHA. Operations such as blending and formulating using 1,3,5-Triethylhexahydrotriazine in general industry (i.e., Standard Industrial Codes 20 - 39) may be subject to other OSHA requirements. There is no OSHA PEL for triethylhexahydrotriazine.

Because triethylhexahydrotriazine currently has no food uses and no tolerances have been established, the specific determinations outlined in the Food Quality Protection Act of 1996 are not required for the reregistration of this chemical. Nevertheless, EPA has considered available data relating to the sensitivity of infants and children, the potential for aggregate exposures and cumulative effects in its risk management decision for triethylhexahydrotriazine because children and other individuals could be exposed to this compound in non-occupational settings.

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

### **1. Eligibility Decision**

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

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

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

## **C. Regulatory Position and Labeling Rationale**

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

### **Labeling Rationale/Risk Mitigation Measures**

#### **1. Potential Risks to Infants and Children/Aggregate Exposure/Cumulative Effects**

In determining whether infants and children are particularly susceptible to the toxic effects of triethylhexahydrotriazine, EPA considered the completeness and reliability of the toxicity data base, the nature of the effects observed in toxicity studies, and other information.

Based on current data requirements, only one developmental study is usually required for non-food use chemicals. In the developmental study for triethylhexahydrotriazine, effects on the fetuses were seen at the same dose as effects on the mothers. Nothing in the available toxicity data base suggests special susceptibility of young organisms to triethylhexahydrotriazine. Therefore, the Agency has concluded that an additional uncertainty factor need not be applied to the short-term and intermediate-term NOELs selected for the triethylhexahydrotriazine risk assessments at this time.

In examining aggregate exposure, EPA takes into account available information concerning exposures from the pesticide residue in food and other exposures for which there is reliable information. These other sources of exposure can include drinking water, and other non-occupational exposures to pesticides used in and around the home.

No dietary exposure is expected since there are no food-uses of triethylhexahydrotriazine. Because there are no outdoor uses, residues in drinking water are unlikely. Thus, residential uses are the only potential sources of exposure that could be aggregated. EPA assumes that applying paint containing triethylhexahydrotriazine would be the reasonable worst case exposure scenario for homeowners. Because the dermal MOE for this scenario is high ( $> 1600$ ), EPA believes that aggregate exposures to other sources of triethylhexahydrotriazine in the home are not likely to be of concern. To confirm this assumption, EPA is requiring dermal and inhalation exposure data for applicators and for post application-exposures including monitoring air concentrations in newly painted rooms where infants and children could be exposed.

The Agency has not yet made a determination regarding the common mode/mechanism of toxicity of triethylhexahydrotriazine and whether it is appropriate to consider exposure from triethylhexahydrotriazine with other compounds in order to address potential cumulative effects.

However, based on the high dermal MOE for homeowner applicators, the lack of food uses, the unlikelihood of residues in drinking water, and the low concentration in paint, the Agency believes that the contribution of triethylhexahydrotriazine exposures to

the risks of other compounds with a common mode/mechanism of toxicity is likely to be minimal considering the currently registered triethylhexahydrotriazine uses.

## **2. Handler Safety Requirements**

During reregistration, the Agency considers handler safety requirements for occupational and residential uses.

### **a. Personal Protective Equipment Requirements for Occupational Handlers**

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

The Agency is developing standardized requirements for occupational handlers of industrial biocides, based on the acute toxicity characteristics of each end-use product. In addition, OSHA has established requirements for hazard communication and use of personal protective equipment for protection of workers potentially exposed to chemical or other types of hazards in the workplace. OSHA's hazard communication standard (29 CFR 1910.1200) establishes requirements for labeling, preparation and dissemination of Material Safety Data Sheets (MSDSs), training, etc., for workers potentially exposed to hazardous chemicals. OSHA requirements for the selection and use of personal protective equipment (29 CFR 1910, Subpart I) include an assessment of the workplace to determine if hazards potentially requiring the use of head, eye, face or foot protection are present or are likely to be present. If hazards are identified, employers must select and have employees use appropriate personal protective equipment (PPE) which has been properly fitted and selected based on the potential hazard present. Employers are required to provide training on the proper use of personal protective equipment, when it is required, what equipment is necessary, how to properly don, doff, adjust, and wear the PPE, the limitations of the equipment, proper care and maintenance, useful life, and disposal of the PPE.

For triethylhexahydrotriazine, the MSDS recommends the use of rubber gloves, goggles, a NIOSH cartridge respirator if respiratory irritation or excessive off-gassing occurs (respiratory protection is typically not required), and effective exhaust or local exhaust ventilation. If these measures are appropriately selected, maintained, and used, worker exposures during operations where triethylhexahydrotriazine is used in paint, adhesives, rubber products, and metalworking/cutting fluids are expected to be reduced.

In general for occupational-use products, the Agency requires that handlers (mixers, loaders, applicators, etc.) of all industrial biocides wear long-sleeve shirts, long pants, shoes, and socks as minimum work attire. For industrial biocide end-use products that are classified as toxicity category I or II for acute dermal or skin irritation potential, handlers are required to wear chemical-resistant gloves and a

chemical-resistant apron in addition to the minimum work attire. For industrial biocide end-use products classified as toxicity category I or II for eye irritation potential, handlers are required to wear protective eyewear. For industrial biocide end-use products classified as toxicity category I or II for acute inhalation toxicity, handlers are required to wear a respirator. The type of respirator must be based on the acute toxicity category and the vapor pressure and must be specified on the end-use product labeling. Table 10 summarizes the personal protective equipment requirements for industrial biocides based on acute toxicity and corresponding toxicity categories. EPA will assist registrants in determining the appropriate type of respirator during the end-use product stage of reregistration.

**Table 10. Personal Protective Equipment Requirements for Industrial Biocides Based on Acute Toxicity and Corresponding Toxicity Categories**

Route of Concern	Toxicity Category I	Toxicity Category II	Toxicity Category III	Toxicity Category IV
Acute Dermal Toxicity or Skin Irritation Potential	Long sleeve shirt, long pants, shoes, socks, & chemical- resistant gloves & apron	Long sleeve shirt, long pants, shoes, socks, & chemical- resistant gloves, & apron	Long sleeve shirt, long pants, shoes, & socks	Long sleeve shirt, long pants, shoes, & socks
Eye Irritant	Protective Eyewear	Protective Eyewear	No minimum	No minimum
Acute Inhalation Toxicity	Respirator	Respirator	No minimum	No minimum

At this time for all handler tasks, safety requirements for products containing triethylhexahydrotriazine must be determined based on the acute toxicity characteristics of the end-use product. It should be noted that in the case of triethylhexahydrotriazine, there are currently no products registered solely as manufacturing use products (MPs).

**b. Engineering Control Requirements for Occupational Handlers**

EPA is prohibiting open pouring and requiring the use of meter pumps or other automatic dispensing equipment for triethylhexahydrotriazine use in wet-end additives and industrial processing chemicals. For use in paint, rubber products, industrial adhesives, or fuel/oil storage tank bottoms, EPA is requiring that the vats to which the triethylhexahydrotriazine is added must be closed and equipped with mechanical vents to the outdoors.

**c. Application and Post Application Exposure Data**

EPA is requiring worker exposure data for triethylhexahydrotriazine containing paint applied by brush, roller, and spray. Additionally, the Agency is requiring post application monitoring data to determine exposure to residents or occupants of areas that have been painted with triethylhexahydrotriazine-containing paints. These post application data will include monitoring for the potential degradate (formaldehyde) as well as for triethylhexahydrotriazine itself.

These data are being required because the Agency currently has no appropriate data available to estimate inhalation exposure to triethylhexahydrotriazine and because this compound is volatile. These data are considered confirmatory because the MOEs for triethylhexahydrotriazine for dermal exposure alone are high, greater than 300 for occupational painters and greater than 1600 for homeowners.

However, if the results of these required studies indicate higher than anticipated exposures to workers or homeowners applying paint or to persons occupying newly painted areas, EPA may require additional inhalation toxicity data and/or further restrictions on use.

#### **d. Additional Labeling Requirements**

The Agency is also requiring specific label language addressing application restrictions, effluent discharge requirements, and user safety requirements and recommendations. Label language is found in Part V.

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

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

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

As noted previously, there are currently no triethylhexahydrotriazine products registered solely as manufacturing use products (MPs). Whenever possible, EPA strongly encourages registrants to separate manufacturing use registrations from end use registrations in order to make clear for the registrants and the Agency which specific data needs and labeling requirements apply to each category of product. However, when one product is used for both manufacturing and end use purposes, as is the case with triethylhexahydrotriazine, that product is subject to both sets of labeling and data requirements.

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

The generic data base supporting the reregistration of triethylhexahydrotriazine for the above eligible uses has been reviewed and determined to be substantially complete. The Agency is requiring confirmatory data for hydrolysis and for post-application dermal and inhalation exposures in painted areas where paint is applied by brush, roller, and sprayer. For these exposure scenarios, studies should be conducted using guideline numbers:

- 161-1 Hydrolysis
- 133-3 Dermal Passive Dosimetry Exposure
- 133-4 Inhalation Passive Dosimetry Exposure
- 231 Estimation of Dermal Exposure (Outdoor)
- 232 Estimation of Inhalation Exposure (Outdoor)
- 233 Estimation of Dermal Exposure (Indoor)
- 234 Estimation of Inhalation Exposure (Indoor)



The air monitoring studies for paint uses must include monitoring for the potential degradate (formaldehyde) as well as monitoring for triethylhexahydrotriazine itself.

The Agency is issuing a DCI concurrent with this RED to triethylhexahydrotriazine registrants for the hydrolysis data. However, because much of the exposure data needed for triethylhexahydrotriazine is generic in nature and will also be required for other antimicrobial chemicals with similar characteristics and uses, EPA is developing a generic exposure DCI. Triethylhexahydrotriazine registrants will receive the generic exposure DCI at the same time as registrants of other antimicrobial chemicals with similar uses.

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

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

“Only for formulation into a [list type of pesticide, i.e. microbicide/microbiostat/bacteriostat] for use as an additive for [list uses that are being supported by MP registrant, i.e., industrial adhesives, metalworking cutting fluid, latex paints and aqueous slurries, synthetic rubber latex, and marine fuels].”

A MP registrant may, at his/her discretion, add one of the following statements to a MP label under “Directions for Use” to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

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

## **B. End-Use Products**

### **1. Additional Product-Specific Data Requirements**

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

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers

should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

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

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

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

#### **(1) PPE Requirements for Occupational Handlers**

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

The minimum handler labeling requirements for occupational uses of triethylhexahydrotriazine end-use products is:

“Mixers, loaders, applicators and other handlers must wear:

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

If the end-use product is classified as toxicity category I or II for eye irritation potential or if data for this route of concern are waived due to corrosivity, add:

- Protective eyewear.

If the end-use product is classified as toxicity category I or II for acute dermal toxicity or skin irritation potential or data for either of these routes of concern are waived due to corrosivity, add:

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

\*For the glove statement, use the statement established for triethylhexahydrotriazine through the instructions in Supplement Three of PR Notice 93-7. In addition, for concentrated triethylhexahydrotriazine products, the corrosiveness and penetration of triethylhexahydrotriazine must be considered. Appropriate chemical-resistant materials must be listed on the product labeling.

If the end-use product is classified as toxicity category I or II for acute inhalation toxicity, a respirator requirement must be added. The type

of respirator must be specified in the statement and is based on the acute toxicity category and the vapor pressure. EPA will assist registrants in determining the appropriate type of respirator during the end-use product phase of reregistration.

In addition to the minimum PPE specified above, the following specific PPE and engineering-control requirements must be added to labels containing the following uses.

When labeling contains uses for wet-end additives/industrial processing chemicals, add the following:

“For use in wet-end additives/industrial processing chemicals, meter pumps or other automatic dispensing equipment is required. Open pouring is prohibited.”

When labeling contains uses for paint, rubber products, or industrial adhesives, or fuels/oil storage tank bottom water, add the following:

“For use in paint, rubber products, industrial adhesives, or fuels/oil storage tank bottom water, the vats to which triethylhexahydrotriazine is being added must be closed and equipped with mechanical vents to the outdoors.”

### **Placement in Labeling**

The personal protective equipment requirements must be placed on the end-use product labeling in the format and language specified above and must be placed in the “Hazards to Humans” section of the pesticide labeling.

### **(2) PPE Requirements for Homeowner Handlers**

EPA's regulatory authority does not encompass requiring label statements for paints or other homeowner products that have had triethylhexahydrotriazine added as part of the manufacturing process. However, based on EPA's assessment of potential homeowner risks, no additional PPE is needed.

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

The Agency is requiring the following labeling statements to be located on all end-use products containing triethylhexahydrotriazine that are intended for occupational use. Additional handler safety requirements will be determined based on the acute toxicity characteristics of each end-use product.

### **Application Restrictions**

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

“Do not apply this product as a spray.”

### **Timing of Applications**

Labels must specify when and how often in the manufacturing process the product is added or applied.

### **Effluent Discharge Restriction**

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

### **User Safety Requirements**

If gloves or protective eyewear are required PPE on the end-use product, add:

“Follow manufacturer’s instructions for cleaning/maintaining PPE. If no such instructions are available for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.”

### **User Safety Recommendations**

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

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

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

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

## **C. Existing Stocks**

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

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



## **VI. APPENDICES**









## **GUIDE TO APPENDIX B**

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 1,3,5-Triethylhexahydro-s-triazine covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 1,3,5-Triethylhexahydro-s-triazine 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 Triethylhexahydrotriazine

REQUIREMENT	USE PATTERN	CITATION(S)
<b>PRODUCT CHEMISTRY</b>		
61-1	Chemical Identity	ALL 41677801
61-2A	Start. Mat. & Mnfg. Process	ALL 41677801
61-2B	Formation of Impurities	ALL 41677801
62-1	Preliminary Analysis	ALL 41677802
62-2	Certification of limits	ALL 41677802
62-3	Analytical Method	ALL 41677802
63-2	Color	ALL 41677803
63-3	Physical State	ALL 41677803
63-4	Odor	ALL 41677803
63-5	Melting Point	ALL 41677803
63-6	Boiling Point	ALL 41677803
63-7	Density	ALL 41677803
63-8	Solubility	ALL 41677803
63-9	Vapor Pressure	ALL 41677803
63-11	Octanol/Water Partition	ALL 41677803
63-12	pH	ALL 41677803, 44139701
63-13	Stability	ALL 41677803

## **Data Supporting Guideline Requirements for the Reregistration of Triethylhexahydrotriazine**

<b>REQUIREMENT</b>	<b>USE PATTERN</b>	<b>CITATION(S)</b>
<b><u>ECOLOGICAL EFFECTS</u></b>		
<b>71-1A</b>	<b>Acute Avian Oral - Quail/Duck</b>	<b>42223201, 164390, 164390</b>
<b>71-2A</b>	<b>Avian Dietary - Quail</b>	<b>42317001</b>
<b>71-2B</b>	<b>Avian Dietary - Duck</b>	<b>42317001</b>
<b>72-1A</b>	<b>Fish Toxicity Bluegill</b>	<b>42209701, ACC128718</b>
<b>72-1C</b>	<b>Fish Toxicity Rainbow Trout</b>	<b>ACC128718</b>
<b>72-2A</b>	<b>Invertebrate Toxicity</b>	<b>42557301</b>
<b><u>TOXICOLOGY</u></b>		
<b>81-1</b>	<b>Acute Oral Toxicity - Rat</b>	<b>41773701</b>
<b>81-2</b>	<b>Acute Dermal Toxicity - Rabbit/Rat</b>	<b>Waived</b>
<b>81-3</b>	<b>Acute Inhalation Toxicity - Rat</b>	<b>4406101</b>
<b>81-4</b>	<b>Primary Eye Irritation - Rabbit</b>	<b>Waived</b>
<b>81-5</b>	<b>Primary Dermal Irritation - Rabbit</b>	<b>Waived</b>
<b>81-6</b>	<b>Dermal Sensitization - Guinea Pig</b>	<b>41620501</b>
<b>82-3</b>	<b>90-Day Dermal - Rodent</b>	<b>41858301</b>
<b>83-3A</b>	<b>Developmental Toxicity - Rat</b>	<b>41865701, 42308601, 42366200, 42366201</b>
<b>83-3B</b>	<b>Developmental Toxicity - Rabbit</b>	<b>Waived</b>
<b>84-2A</b>	<b>Gene Mutation (Ames Test)</b>	<b>41343401, 41343402, 41544801</b>
<b>84-2B</b>	<b>Structural Chromosomal Aberration</b>	<b>41738201, 41321501</b>
<b>84-4</b>	<b>Other Genotoxic Effects</b>	<b>41544801, 41343402</b>

## **Data Supporting Guideline Requirements for the Reregistration of Triethylhexahydrotriazine**

<b>REQUIREMENT</b>	<b>USE PATTERN</b>	<b>CITATION(S)</b>
<b><u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u></b>		
<b>133-3</b>	<b>Dermal Passive Dosimetry Exposure</b>	<b>M,O</b>
		<b>Confirmatory Data Required*</b>
<b>133-4</b>	<b>Inhalation Passive Dosimetry Exposure</b>	<b>M,O</b>
		<b>Confirmatory Data Required*</b>
<b>231</b>	<b>Estimation of Dermal Exposure at Outdoor Sites</b>	<b>K,M,O</b>
		<b>Confirmatory Data Required*</b>
<b>232</b>	<b>Estimation of Inhalation Exposure at Outdoor Sites</b>	<b>K,M,O</b>
		<b>Confirmatory Data Required*</b>
<b>233</b>	<b>Estimation of Dermal Exposure at Indoor Sites</b>	<b>M,O</b>
		<b>Confirmatory Data Required*</b>
<b>234</b>	<b>Estimation of Inhalation Exposure at Indoor Sites</b>	<b>M,O</b>
		<b>Confirmatory Data Required*</b>
<b><u>ENVIRONMENTAL FATE</u></b>		
<b>161-1</b>	<b>Hydrolysis</b>	<b>ALL</b>
		<b>Confirmatory Data Required</b>

\* See page 31





## 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

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### CITATION

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- 00164390 Shellenberger, T. (1971) Letter sent to R. Sawyer dated Sept 17, 1971: Acute toxicological evaluations of Vancide TH with wildlife: GSRI Proj. No. NC-475. Prepared by Gulf South Research Institute. 11 p.
- 41321501 Putman, D.; Melhorn, J. (1989) Structural Chromosome Aberration: Mouse Micronucleus: Vancide TH: Lab Project Number: T8796/ 122010. Unpublished study prepared by Microbiological Associates, Inc. 28 p.
- 41343401 San, R.; Krueel, C. (1989) Mutagenicity Salmonella/Mammalian Microsome Plate Incorporated Assay Ames Test with Confirmation: Lab Project Number: T8796/501014. Unpublished study prepared by Microbiological Associates, Inc. 71 p.
- 41343402 Curren, R. (1989) Other Genotoxic Effects: Unscheduled DNA Synthesis in Rat Primary Hepatocytes: Lab Project Number: T8796/380010. Unpublished study prepared by Microbiological Associates, Inc. 30 p.
- 41620501 Trimmer, G. (1990) Dermal Sensitization Test in the Guinea Pig (Buehler Method): Lab Project Number: 240822. Unpublished study prepared by Exxon Biomedical Sciences, Inc. 44 p.
- 41677801 Flynn, F. (1990) Product Identity and Composition of Hexahydro-1,3,5-triethyl-s-triazine. Unpublished study prepared by R. T. Vanderbilt Co., Inc. 25 p.
- 41677802 Flynn, F. (1990) Analysis and Certification of Product Ingredients of Hexahydro-1,3,5-triethyl-s-triazine. Unpublished study prepared by R. T. Vanderbilt Co., Inc. 10 p.
- 41677803 Flynn, F.; Agahigian, H. (1990) Physical and Chemical Characteristics of Hexahydro-1,3,5-triethyl-s-triazine. Unpublished study prepared by R. T. Vanderbilt Co., Inc. in assoc. with Baron Consulting Co. 5 p.
- 41738201 Flynn, F. (1989) Identification, Assay and Stability of Test Substance Hexahydro-1,3,5-triethyl-s-triazine (VANCIDE TH): Supplement. Unpublished study prepared by R.T. Vanderbilt Co., Inc. 7 p.
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- 41738203 Flynn, F. (1989) Identification, Assay and Stability of Test Substance Hexahydro-1,3,5-triethyl-s-triazine (VANCIDE TH): Supplement. Unpublished study prepared by R. T. Vanderbilt Co., Inc. 7 p.

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- 41773701 Trimmer, G. (1991) Acute Oral Toxicity Test with LD50 Estimation in the Rat with Vancide TH: Lab Project Number: 140802. Unpublished study prepared by Exxon Biomedical Sciences, Inc. 44 p.
- 41858301 Trimmer, G. (1991) Vancide TH: 90 Day Subchronic Dermal Toxicity Study in Rats: Lab Project Number: 240810-MRD-89-408. Unpublished study prepared by Exxon Biomedical Sciences, Inc. 429 p.
- 41865701 Beyer, B. (1991) "Development Toxicity Study in Rats with Vancide TH": Lab Project Number: MRD-89-408: 240834. Unpublished study prepared by Exxon Biomedical Sciences, Inc. 274 p.
- 42209701 Machado, M. (1992) Vancide TH: Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-Through Conditions. Unpublished study prepared by Springborn Labs., Inc. 56 p.
- 42223201 Pederson, C.; Helsten, B. (1992) Hexahydro-1,3,5-triethyl-striazine (VANCIDE TH): 21 Day Acute Oral LD50 Study in Bobwhite Quail: Lab Project Number: 121-003-03. Unpublished study prepared by Bio-Life Associates, Ltd. 66 p.
- 42308601 Beyer, B. (1992) Supplemental Information to MRID 41865701 Developmental Toxicity Study in Rats with Vancide TH: Unpublished study prepared by Exxon Biomedical Sciences, Inc. 6 p.
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- 42366200 R.T. Vanderbilt Co., Inc. (1992) Submission of Data in Response to Antimicrobial Data Call-in for VANCIDE TH: Toxicology Study. Transmittal of 1 study.
- 42366201 Beyer, B. (1992) Supplemental Information to MRID 41865701 and MRID 42308601--Developmental Toxicity Study in Rats with VANCIDE TH: Lab Project Number: 20309. Unpublished study prepared by Exxon Biomedical Sciences, Inc. 7 p.
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- 44139701 R.T. Vanderbilt Co., Inc. (1996) pH of a 5% Aqueous Solution of hexahydro-1,3,5-triethyl-s-triazine: Unpublished study prepared by R.T. Vanderbilt Co., Inc. 9 p.





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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-99).

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

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

The Attachments to this Notice are:

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

## SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

## SECTION II. DATA REQUIRED BY THIS NOTICE

### II-A. DATA REQUIRED

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



## II-B. SCHEDULE FOR SUBMISSION OF DATA

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

## II-C. TESTING PROTOCOL

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

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

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

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

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

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

## SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency

or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

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

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

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

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

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

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

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

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

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

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

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

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

### III-D REQUESTS FOR DATA WAIVERS

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

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

### IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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



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

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

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

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

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

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

#### SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois A. Rossi, Director  
Special Review and  
Reregistration Division

#### Attachments

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

# 1,3,5-TRIETHYLHEXAHYDRO-S-TRIAZINE DATA CALL-IN CHEMICAL STATUS SHEET

## INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing 1,3,5-triethylhexahydro-s-triazine.

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 1,3,5-triethylhexahydro-s-triazine. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria, (6) a list of registrants receiving this DCI (Attachment 5) and (7) the Cost Share and Data Compensation Forms in replying to this 1,3,5-triethylhexahydro-s-triazine Product Specific Data Call-In (Attachment 6). Instructions and guidance accompany each form.

## DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for 1,3,5-triethylhexahydro-s-triazine are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on 1,3,5-triethylhexahydro-s-triazine 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 1,3,5-triethylhexahydro-s-triazine products.

## INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Jane Mitchell at (703) 308-8061.

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

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

**RE: 1,3,5-Triethylhexahydro-s-triazine**

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

- Item 1-4. Already completed by EPA.
- Item 5. If you wish to **voluntarily cancel** your product, answer “**yes.**” If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).
- Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with “**yes**” to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the “Requirements Status and Registrant's Response” form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.
- Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding “**yes.**”
- Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding “**yes.**” If you are requesting a **data waiver**, answer “**yes**” here; in addition, on the “Requirements Status and Registrant's Response” form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.
- Items 8-11. Self-explanatory.
- NOTE:** You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

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

- Item 1-3      Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.
- Item 4.        The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.
- Item 5.        The study title associated with the guideline reference number is identified.
- Item 6.        The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.
- Item 7.        The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.
- Item 8.        The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.
- Item 9.        **Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.
1.            I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (**EPA Form 8570-29**) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
  2.            I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough

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

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed “**Certification of Offer to Cost Share in the Development Data**” form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed “**Certification With Respect To Data Compensation Requirements**” form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed “**Certification With Respect To Data Compensation Requirements**” form (EPA Form 8570-29) to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed “**Certification With Respect To Data Compensation Requirements**” form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this

option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed “**Certification With Respect To Data Compensation Requirements**” form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has “grouped” with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a “Product Specific Data Report” form or in a similar format. By the specified due date, I will also submit: (1) a completed “**Certification With Respect To Data Compensation Requirements**” form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised “Requirements Status and Registrant's Response” Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed “**Certification With Respect To Data Compensation Requirements**” form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

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













**Attachment 4.**

There is no tox batching for this RED because there are only two end use products containing triethylhexahydrotriazine.



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





## **Instructions for Completing the Confidential Statement of Formula**

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

- a. All the blocks on the form must be filled in and answered completely.
- b. If any block is not applicable, mark it N/A.
- c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.
- d. All applicable information which is on the product specific data submission must also be reported on the CSF.
- e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.
- f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.
- g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.
- h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.
- i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.
- j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).
- k. All the items under column 13.b. must total 100 percent.
- l. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.
- m. The upper and lower certified limits for all active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.
- n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.









**United States Environmental Protection Agency**  
 Washington, D.C. 20460  
**Certification of Offer to Cost**  
**Share in the Development of Data**

**Form Approved**  
**OMB No. 2070-0106,**  
**2070-0057**  
**Approval Expires**  
**3-31-99**

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

Please fill in blanks below:

<b>Company Name</b>	<b>Company Number</b>
<b>Product Name</b>	<b>EPA Reg. No.</b>

I Certify that:

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

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

<b>Name of Firm(s)</b>	<b>Date of Offer</b>
------------------------	----------------------

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.

<b>Signature of Company's Authorized Representative</b>	<b>Date</b>
---	-------------

**Name and Title (Please Type or Print)**





**CERTIFICATION WITH RESPECT TO  
DATA COMPENSATION REQUIREMENTS**

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

**Please fill in blanks below.**

Company Name

Company Number

Product Name

EPA Reg. No.

**I Certify that:**

1. For each study cited in support of registration or 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)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)  
  
 The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"
3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature

Date

Name and Title (Please Type or Print)

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

Signature

Date

Name and Title (Please Type or Print)





The following is a list of available documents for 1,3,5-Triethylhexahydro-s-triazine that may further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

**Electronic**

**File format:** Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Nancy Tompkins at (703)-308-8013.

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

The following documents are part of the Administrative Record for 1,3,5-Triethylhexahydro-s-triazine and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

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

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

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